ConnectedHealthInitiative

August 25, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue Southwest
Washington, District of Columbia 20201

RE: *Connected Health Initiative Comments to the Centers for Medicare and Medicaid Services'* Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program *[CMS-1784-P; 88 FR 52262]*

Dear Administrator Brooks-LaSure:

The Connected Health Initiative (CHI) appreciates the opportunity to provide input and suggestions to the Centers for Medicare & Medicaid Services (CMS) on its forthcoming proposed changes to the Medicare Physician Fee Schedule (PFS) and the Quality Payment Program (QPP) for Calendar Year 2024. CHI proposes a variety of changes to the PFS and QPP related to CMS' cross-sectoral consensus views on the use of digital health technologies, particularly in light of the priority to advance innovative value-based care solutions while protecting the integrity of the Medicare program.

CHI's comments are organized as follows:

I. Introduction and Statement of Interest

CHI is the leading multistakeholder policy and legal advocacy effort dedicated to connected health technologies that improve health outcomes and reduce costs. We seek to advance responsible pro-digital health policies and laws in areas including reimbursement/payment, privacy/security, effectiveness/quality assurance, U.S. Food and Drug Administration (FDA) regulation of digital health, health data interoperability, and the rising role of artificial/augmented intelligence (AI) in care delivery. For more information, see www.connectedhi.com.

CHI is a longtime advocate for the increased use of telehealth and remote monitoring across the Department of Health and Human Services (HHS) as well as before other agencies such as the Federal Communications Commission and the U.S. Congress. CHI is also a current appointed member of the American Medical Association's (AMA) Digital Medicine Payment Advisory Group, an initiative bringing together a diverse cross-section of nationally recognized experts that identifies barriers to digital medicine adoption and proposes comprehensive solutions revolving around coding, payment, coverage, and more. A PFS and QPP, and broader Medicare system, that serves beneficiaries effectively must leverage the benefits of the range of digital health tools available today, consistent with other major Medicare programs.

II. Connected and Digital Health's Integral Role in the Future of Medicare

Data and clinical evidence from a variety of use cases continue to demonstrate how the connected health technologies available today—whether called "telehealth," "mHealth," "store and forward," "remote patient monitoring," "remote physiologic monitoring," "communication technology-based services," or other similar terms—improve patient care, prevent hospitalizations, reduce complications, and improve patient engagement. These benefits are particularly impactful for the chronically ill. Connected health tools, including wireless health products, mobile medical devices, software as a medical device, mobile medical apps, and cloud-based portals and dashboards, can fundamentally improve and transform American healthcare.[1] Despite the proven benefits of connected health technology to the American healthcare system, statutory restrictions and CMS regulatory-level policy decisions, among other constraints, inhibit the use of these solutions. As a result, there was low utilization of digital health innovations prior to the COVID-19 public health emergency (PHE), despite the ability to drastically improve beneficiary outcomes and generate immense cost savings.

Further, as discussed below in further detail, CMS should support the use of health data and patient-generated health data (PGHD) through AI. There are various applications of AI systems in health care such as research, health administration and operations, population health, practice delivery improvement, and direct clinical care. Payment and incentive policies must be in place to invest in building infrastructure, preparing personnel and training, as well as developing, validating, and maintaining AI systems with an eye toward ensuring value. Payment policies must incent a pathway for the voluntary adoption and integration of AI systems into clinical practice as well as other applications under existing payment models.

As CMS recognizes, the need for rapid modernization of Medicare incentives is more imperative considering the ongoing COVID-19 PHE in the United States. As a community, we continue to support CMS' efforts to utilize advanced technology to augment care for every patient. With the congressionally mandated shift from fee-for-service to value-based care in Medicare approaching, it is essential CMS continues efforts to advance the range of connected health innovations that will help American healthcare improve outcomes and cost savings.

CHI shares CMS' priority for reducing the inequities in healthcare. Thanks to CMS' expanded support, reliance on digital health technologies increased during the COVID-19 PHE. Use of these tools continues to allow many underserved populations' access to prevention, diagnosis, and treatment for both acute and chronic conditions while also providing routine care to Americans to safely observe public health protocols during the

[1] We urge CMS to leverage CHI's new Digital Health Evidence Resource, which consists of clinician-vetted evidence and studies speaking to the efficacy of digital health tools, which is available at https://connectedhi.com/resources/digital-health-evidence-resource/.

COVID-19 pandemic. CMS should leverage every opportunity for permanent policy changes that will incent responsible deployment and use of innovative digital health technologies that will be vital in ensuring that no American beneficiary is left behind.

Generally, however, despite the proven benefits of connected health technology to the American healthcare system, statutory restrictions and CMS regulatory-level policy decisions, among other constraints, inhibit use of these solutions. As a result, utilization of digital health innovations that could bring both drastically improved beneficiary outcomes as well as immense cost savings remains too low, though it is increasing. CMS' coverage of remote monitoring began in CY2018, when it unbundled Current Procedural Terminology (CPT®) Code 99091. In the calendar year 2019 and 2020 PFS rules, CMS took significant steps forward in activating and paying for four remote physiologic monitoring (RPM) codes, with further steps taken support a new family of remote therapeutic monitoring (RTM) codes, a critical step in supporting key use cases where remote asynchronous technologies will improve outcomes and reduce costs. CMS has also ensured utilization of RPM in existing alternative payment models such as Medicare Advantage, where RPM has been eligible for inclusion as a basic benefit. Even further, CMS has provided coverage for the use of AI in addressing the diabetic retinopathy use case, a commendable step forward towards, ideally, all Medicare providers and beneficiaries being able to realize the benefits of AI in their prevention and treatment activities.

While the policy changes noted above represent important digital health policy changes, the pace of uptake for digital health innovations in the Medicare system continues to lag when compared to the well-established benefits and efficiencies this cutting-edge technology offers. This need became even more obvious with the COVID-19 pandemic, and in light of the Biden Administration's equity priorities. As a community, we continue to support CMS' efforts to utilize advanced technology to augment care for every patient. It is essential Part B providers leverage the wide range of connected health tools and services available today, as well as those in development to advance care and lower costs.

III. Connected Health Initiative Recommendations for the Proposed CY2024 Physician Fee Schedule

Building on the above, CHI urges CMS to include the following in its proposed CY2024 PFS and QPP.

a. Communications Technology-Based Services

CHI continues to agree that "communication technology-based services" (CTBS) do not meet the statutorily provided definition for telehealth services in Section 1834(m) of the Social Security Act,[2] and appreciate CMS continuing to regard CTBS (and the wide range of innovative asynchronous technologies past CTBS that offer much more efficient ways to prevent and treat disease) as falling outside of Section 1834(m)'s restrictions. In the Draft CY2024 PFS/QPP, CMS makes no proposal to alter this approach that was finalized in the CY2019 PFS/QPP rule, which CHI supports.

During the PHE, CMS has chosen to allow use of virtual check-ins (HCPCS code G2012 and HCPCS code G2010) and e-visits (CPT codes 99421-99423 and HCPCS codes G2061-G206) for new and established patients. The benefits of such an allowance are clear in creating flexibility to responsibly offer medically necessary care via CTBS. CHI reiterates its call for CMS to permanently allow use of virtual check-ins and e-visits for new and established patients.

CMS has already provided key support for CTBS through its finalization of HCPCS code G2010 (Remote evaluation of recorded video and/or images) and HCPCS code G2012 (Brief communication technology-based service, e.g., virtual check-in). Both are reportable only by practitioners who can furnish E/M services (physicians, physicians assistants [PAs], nurse practitioners [NPs], clinical nurse specialist [CNSs], and certified nurse-midwife [CNMs]). However, CMS should recognize that there is also value in supporting check-ins with clinical staff, such as nurses, who play an integral role in care, and extend the availability of CTBS to these critical providers. CHI continues to applaud CMS providing further flexibilities to CTBS over the recent years, such as permitting patient consent for CTBS to be documented by auxiliary staff under general supervision and urges for all steps possible to be taken to minimize burdens on caregivers. Moving past the COVID-19 PHE, it is critical that such allowances be made permanent.

b. Remote Physiologic Monitoring and Remote Therapeutic Monitoring

CMS' support for Remote Physiologic Monitoring (RPM) and Remote Therapeutic Monitoring (RTM). CMS' continued support for remote monitoring capabilities

[2] Final CY2019 PFS/QPP at 35722-3.

represents a significant shift of the Medicare system to recognize the value of the wide range of asynchronous technologies, which will contribute to a more connected continuum of care that will mitigate disparities while improving outcomes and reducing Medicare costs. CHI continues to find enthusiasm throughout the healthcare continuum for CMS' leadership in providing support for these critical services. Since its activation and payment, utilization is strong with providers and patients seeing increasing value in the use of remote monitoring. CHI further appreciates CMS's continued efforts to provide guidance on both RPM and RTM CPT codes, which, over the last few years, have provided key clarifications for all stakeholders (e.g., that RPM services may be used for both chronic and acute conditions, among many others).

CHI urges CMS to take the following steps to realize the full potential of RPM and RTM innovations:

- **RPM and RTM services should be available to both new and established patients.** CMS should take steps in its CY2024 PFS rules to extend all PHE allowances for RPM and RTM permanently, including that RPM can be furnished to both new and established patients. CMS' justification for reverting to a requirement that the patient be established once the PHE ends is based on its belief that a provider would likely have had an opportunity to provide a new patient E/M service, which may be true in the case of treating chronic conditions; however, CMS has already clarified that RPM can be used to treat acute conditions as well. In scenarios where acute diseases are being treated, it is unlikely that there will be an opportunity to provide a new patient E/M service. CMS' reversion to RPM only being possible for established patients now that the PHE has ended stands to undercut the ability to use RPM to treat acute diseases. It is not always necessary for a practitioner to have an established relationship, e.g. with a patient exhibiting symptoms of acute disease. Practitioners should be able to leverage RPM as medically necessary to provide the best care possible, including for patients with acute diseases. Therefore, CHI strongly encourages CMS to reconsider its approach and permit RPM services to be used for both new and established patients permanently.

  And while CMS has not yet provided clarity with respect to new and established patient relationships for RTM, we call on CMS to apply the requested allowance for RPM equally to RTM. RTM services were created in the image of RPM services, and should share in the same policy approaches with respect to requirements for an established patient relationship (and other allowances).

- **CMS should not extend a requirement of 16 days of data collection to RPM and RTM professional work codes.** In the proposed 2024 PFS, CMS proposes to clarify that, from the termination of the COVID-19 PHE onward, its requirement for at least 16 days of data collection is back in place and applies to both RPM and RTM "code families," further stating that it has already clarified in its CY2021 PFS rules that (1) remote monitoring "currently depend[s] on collection of no fewer than 16 days of data in a 30-day period, as defined and specified in the

code descriptions" and references "CPT codes 98976, 98977, 98978, 98980, and 98981;" and that (2) "CPT code descriptor language suggests that, even when multiple medical devices are provided to a patient, the services associated with all the medical devices can be billed only once per patient per 30-day period and only when at least 16 days of data have been collected."

However, CMS' statement appears to be erroneous in making this reference to the CY2021 PFS, and the CY2021 only contains discussion of the application of the requirement for at least 16 days of data collection applying to CPT codes 99453 and 99454. Notably, CPT codes 98976, 98977, 98980, and 98981 had not yet been created in 2021, and therefore could not have been referenced in that rule. The CY2021 rule does, however, state that "CPT prefatory language indicates that monitoring must occur over at least 16 days of a 30-day period in order for CPT codes 99453 and 99454 to be billed," without reference to RPM Professional Work codes 99457 and 99458, or any RTM codes. In subsequent PFS rulemakings, CMS took no further action with respect to the extension of the 16 day requirement to further RPM or RTM codes.

In addition, exposing RPM Professional Work codes 99457 and 99458; and RTM Professional Work codes 98980 and 98981 to the 16 day requirement is inconsistent with the CPT Professional Edition codebook, which very clearly states that the 16 day requirement applies to RPM Practice Expense (PE)-only CPT codes 99453 and 99454 and RTM PE-only codes 98975, 98976, 98977, and 98978, reinforced by parenthetical language.

Aside from the apparent error in CMS' citing past PFS rules on this issue and such an approach being inconsistent with the CPT codes themselves, the application of the 16 day requirement to RPM Professional Work codes 99457 and 99458, and RTM Professional Work codes 98980 and 98981 would be confusing and unnecessary. RPM Professional Work codes 99457 and 99458, and RTM Professional Work codes 98980 and 98981 are valued based on the value of intra-service time of clinical staff in 20-minute increments across a 30 day period, not the collection of data by a remote monitoring device for 16 out of 30 days. Put another way, a requirement for 16 days of monitoring are inapplicable to RPM and RTM treatment management service codes.

CHI therefore requests that CMS alter its approach and clarify that the 16 day requirement applies only to RPM Practice Expense (PE)-only CPT codes 99453 and 99454 and to RTM PE-only codes 98975, 98976, 98977, and 98978; and that the requirement for 16 days of data collection does not apply to the RPM Professional Work codes 99457 and 99458, and RTM Professional Work codes 98980 and 98981.

- **CMS should revise its RPM and RTM limitation that restricts use by one provider to one patient per 30-day period even when there is more than one device provided to the patient to only apply to remote monitoring PE-only CPT codes measured on a 30-day period basis.** While CMS proposes to limit RPM and RTM use to only one provider may report RPM/RTM, per patient, per 30-day period, regardless of devices, when 16 days of data collection are accomplished, CHI requests that CMS refine this policy to clarify that this restriction applies only to RPM PE-only CPT codes 99453 and 99454 and to RTM PE-only codes 98976, 98977, and 98978, as these codes are measured on a 30 day period basis. As proposed, CMS' policy would effectively limit a Medicare beneficiary to a single clinician for their medically necessary care, including vulnerable beneficiaries with multiple illnesses. The CPT codes for RPM and RTM enable RPM and RTM professional work via treatment management services to be performed and billed by any practitioner or specialist who is working with a single patient, per 30-day period.
- **CMS should clarify that RPM and RTM codes may be billed with care management services CCM/TCM/BHI, PCM, and CPM.** CHI supports CMS' proposal to clarify that RPM and RTM codes may be billed with care management services CCM/TCM/BHI, PCM, and CPM. This clarification will support RPM and RTM use alongside, and in complement to, other vital care management services.
- **CMS should provide for the use of RTM in physical therapy when it is related to a diagnosis under surgery global periods.** In its proposed PFS rule, CMS proposes to clarify that remote monitoring is permitted for episodes of care that are "separate and distinct from the episode of care for the global procedure." This clarification would effectively exclude services that are related to the diagnosis for which the global procedure was performed, but which are not typically included under the Global Period because they are not the responsibility of the surgeon – such as physical therapy (e.g., after a joint replacement), a primary use case for RTM. Such a restriction therefore stands to deprive countless beneficiaries of remote monitoring benefits without public benefit. CHI requests that CMS clarify that practitioners be able to receive payment for use of remote monitoring separate from the global service payment when the services are not usually included in the global service payment, even if they are technically related to the global procedure diagnosis; and that CMS specify that physical therapy is a prime example of remote monitoring that will be separately supported outside of the global service payment despite it being related to (but not included in) the episode of care for the global procedure.
- **For both RPM and RTM, "software as a Medical Device (SaMD)" used in medical practice should not be categorized as an indirect PE.** We recommend that CMS' final CY2024 PFS rule reflect that SaMD and SaMD licensing fees are not off-the-shelf computer software. Like medical equipment and medical supplies, SaMD is a device as defined by FDA regardless of

whether it is loaded onto and used on general purpose platforms or as dedicated ancillary medical devices. RTM and RPM services cannot function without the software supporting the monitoring systems and are not indirect PEs. Therefore, just like medical equipment, SaMD are a direct PE and software updates and security patches to SaMD are analogous to medical supplies (which are also direct PEs).

- Further, in the context of RTM:
    - We reiterate that CMS should acknowledge that therapeutics are well-suited for a wide range of treatments past respiratory and muscular/skeletal use cases, and the limitation of RTM services to only those two areas would be a disservice to countless Medicare beneficiaries. Notably, RPM services are paired with a condition agnostic supply code in 99454 (and this RPM code served as a model for RTM supply codes). CMS should take steps now to avoid creating a dynamic similar to the Medicare telehealth services list, in which countless condition-specific codes will need to be created and maintained by CMS.
    - We continue to believe that CMS' requirement for the use of devices that meet the FDA's definition of a medical device under the Food, Drug & Cosmetic Act should resolve any quality control issues related to "self-reported" data as such devices will primarily be used in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease. Further, medical devices whose FDA product code has been formally placed under enforcement discretion should satisfy the requirements of RPM services. CHI supports the inclusion of "self-reported" data in RTM as long as such data points cannot be corrupted by subjective or unreliable inputs from the patient.
- We request that Medicare invest in technical and organizational development to help state Medicaid programs understand RPM and RTM (other digital health-related HCPCS Level II coding and policy changes) to ensure that changes are implemented immediately by state Medicaid programs.

c. External Extended Electrocardiogram Monitoring

CMS' proposed CY2024 rule once again addresses payment for furnishing external extended electrocardiogram (ECG) monitoring. CHI supports CMS' continued exploration of this important area and supports the creation of a uniform national payment that appropriately reflects the PE associated with furnishing external extended ECG monitoring. CHI members have, and are, submitting detailed responses based on their individual experiences which should help CMS address its concerns with respect to ECG supply costs and whether resource costs (as reflected in the contractor-based payments) do not adequately cover costs associated with furnishing these services.

d. Chronic Care Management Services

CHI supports CMS' efforts to enhance its support for CCM. CHI also appreciates CMS' continued consideration of how practitioners obtain beneficiary consent for Chronic Care Management services. Flexibilities permitted during the PHE gave providers the ability to obtain beneficiary consent under general supervision, where in the past consent had to be obtained by or under the direct supervision of the primary care practitioner. An efficient Medicare system requires Chronic Care Management Services to leverage the potential of non-face-to-face modalities, such as EHR systems, patient portals, texting/SMS services, chatbot technologies, interactive mobile medical apps, and direct patient calls. While we understand CMS' concerns, it is long past due that CMS do away with the requirement for a provider to directly obtain consent in person. Virtual modalities more than adequately enable a patient to gain an understanding of what they are consenting to at the same level or better than an in-person consent process, making the direct consent requirement outdated and overburdensome. CHI strongly encourages CMS to permanently allow providers to obtain beneficiary consent under general supervision, and to explore how remote automated technologies can help educate patients on the services they are receiving.

e. RHC and FQHC Use of Remote Physiologic and Therapeutic Monitoring

CHI has, for many years, implored CMS to act to support the use of RPM and RTM by Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) at the front lines of care for America's most underserved populations so that these vital providers can leverage key PGHD metrics for timely interventions and care. We applaud CMS for its recognition of the balue of RPM and RTM to equitably improving care, as well as that the RHC all-inclusive rate and FQHC per visit payments do not adequately support uptake of these vital tools. The status quo for RHCs and FQHCs, relative to the continued advancement of responsible support of RPM and RTM for general Part B beneficiaries, has been contributing to a widening gap between RHC and FQHC

beneficiaries and other Part B beneficiaries, which directly undermines the goal of equitable access to medically necessary care.

Therefore, CHI fully supports CMS' proposal to make much-needed alterations to its policy for RPM and RTM use by RHCs and FQHCs to provide them with the ability to receive payment for RPM and RTM outside of the RHC all-inclusive rate and FQHC per visit payments by including RPM and RTM in general care management services (G0511). We share CMS' perspective that both RPM and RTM offer numerous benefits that would particularly benefit patients that RHCs and FQHCs serve. To provide necessary access to these benefits, we encourage CMS to clarify that RHCs and FQHCs can bill G0511 multiple times for the same patient in a month to enable clinicians to use necessary (and non-overlapping) care management services.

We also urge CMS to finalize this policy, in collaboration with the RHC and FQHC community and considering its perspectives on implementation and valuation.

f. Electronic Prescribing of Controlled Substances

CHI appreciates CMS again raising ways to improve the electronic prescribing of controlled substances (EPCS). Utilizing new and improved technology to ensure the confidentiality, integrity, and appropriate accessibility of data, such digital health tools allow for greatly improved fraud and abuse detection and would be of immense benefit to EPCS. Further, the ongoing COVID-19 PHE has necessitated reducing in-person contact as much as possible, which the EPCS program can assist with for those legally prescribed controlled substances. Untouched for 10 years, the Drug Enforcement Agency's (DEA's) EPCS rules have effectively locked out new entrants (particularly digital health small business innovators) and deprived the EPCS market of much-needed competition and innovation that would provide more innovative and more secure solutions to those prescribing controlled substances at lower costs.

CHI also notes that Executive Order 13777[3] seeks to identify and eliminate outdated or ineffective regulations, and that the DEA intentionally made the current EPCS rules an interim solution to ensure they have the flexibility to address new developments in EPCS technology. We have consistently urged DEA to, consistent with Executive Order 13777, use this policy development process to revise its EPCS regulations to reduce barriers to entry in this EPCS space.

CHI believes the DEA should reduce the regulatory burdens associated with its biometrics requirements, especially those that ignore advancements in technology and have kept costs unnecessarily high for those who electronically prescribe controlled substances. These regulations currently prevent innovators, and particularly small

[3] https://www.federalregister.gov/documents/2017/03/01/2017-04107/enforcing-the-regulatory-reform-agenda.

business innovators, from participating in the EPCS market. For example, the capability exists today for iPhones to provide a biometric factor (e.g., fingerprint or face scan) as a first authentication, with a software application installed on the same phone providing a separate and distinct authentication (e.g., a soft token). Sadly, such a scenario is prohibited by DEA's interim EPCS rules with no discernable public benefit.

While we continue to work to improve DEA's rules, we appreciate CMS' raising ways in which it can improve ECPS. We support CMS' expansion of electronic prescribing, and defer to CHI members with specific experiences and data they are filing themselves. CHI also notes that the cost of purchasing third-party applications with additional identity and security measures so that EHRs meet DEA requirements would decrease with an ECPS program to enable competition between companies.

g. Medicare Telehealth Services

In part because of allowances during the COVID-19 PHE, more patients than ever before have turned to digital health platforms, tools, and services to consult with caregivers. Past the COVID-19 pandemic, the utilization of live voice/video telehealth is key to handling the ongoing PHE, heightened utilization will be a critical factor in realizing greater value for Medicare. CHI offers the following views on CMS' proposals that impact Medicare telehealth services:

- CHI supports CMS' further proposed improvements to the Medicare Telehealth Services List, including reorganizing its Medicare Telehealth Services Category lists into lists of 'permanent' and 'temporary' services, with the retention of services currently on its 'temporary' list until end of 2024. We request that CMS revise its descriptive language for the new 'temporary' list, however, to permit for the addition of new services that permit responsible experimentation. We are concerned that the current framing proposed by CMS, which states that additions to the 'temporary' list are "expected" to become permanent, may be interpreted as seeking to avoid such experimentation.
- CHI supports CMS' implementation of provisions of the Consolidated Appropriations Act, which preserve a range of PHE Medicare Telehealth waivers and flexibilities through the end of 2024, including its delay of in-person requirements for telehealth services furnished for purposes of diagnosis, evaluation, or treatment of a mental health disorder to January 1, 2025; its expansion of telehealth originating site eligibility to any site in the United States where the beneficiary is located at the time of the telehealth service, including an individual's home, through December 31, 2024; and its continued coverage and payment for telehealth services via an audio-only communications system through December 31, 2024.

  CHI also appreciates CMS' efforts to provide a "glide path" as the PHE expired to

avoid countless beneficiaries facing a flash cut of telehealth services on which they have come to rely. We continue to encourage CMS to gather experiences and data to evaluate the effectiveness of these telehealth services and how they performed under PHE flexibilities, which should support those restrictions being made permanently available (via either CMS action under its existing authority or congressional action).

CHI continues to support CMS taking all steps possible to support the use of audio-only technology by patients in order to be as inclusive as possible of beneficiaries who may face a variety of challenges accessing care, which range from inadequate communications infrastructure, lack of accessibility to end-user technology, and patient comfort/preferences. CMS' support for audio-only telehealth services during the PHE has clearly enabled better care, benefiting the underserved communities that CMS is prioritizing, particularly those who lack access to adequate connectivity to support a live video visit. Reverting audio-only telehealth to pre-PHE bundled treatment would be a disservice to the most underserved Medicare beneficiaries, and we urge CMS to do all that it can, including working with Congress, to enable permanent support for audio-only telehealth.

- CHI urges CMS to fully leverage its authority to support providers' efforts to deliver care via telehealth across scenarios when a different practitioner in the same practice may need to offer services to the eligible telehealth individual. CMS should, for example, allow providers in the same practice to offer services to a patient in the event that the patient's original provider is unavailable or if the patient prefers to change providers in the practice.
- In light of the fact that the PHE has influenced some of the digital health-related progress made in the Center for Medicare & Medicaid Innovation's (CMMI) Emergency Triage, Treat, and Transport (ET3) model (e.g., home as an eligible originating site), CHI supports CMS clarifying that an Emergency Medical Service (EMS) agency is an eligible originating site such that the facility fee can be paid to the EMS agency that is sending paramedics to the home.
- CHI continues to have significant concerns with requiring an in-person visit before an eligible telehealth individual can receive a telemental health service. Such a requirement is a direct contradiction to the concept of telehealth services the bill aims to make more widely available that places America's most vulnerable beneficiaries at risk during a pandemic. Further, the requirement places a special restriction on mental health services versus other telehealth services without any evidence to justify the stricter treatment of telemental health services.
- CHI reiterates that audio-only telemental health services should be available to any patient requiring mental health services (in other words, past level 4 or 5 evaluation and management (E/M) visit codes or psychotherapy with crisis), and

to both established and new patients. Consistent with its steps taken in the context of telemental health, we encourage similar support for treatments across other conditions. CMS is also encouraged to keep paperwork burdens to a minimum to avoid wasted resources and provider burnout.

As frontline providers serving America's most vulnerable populations, Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) should be able to utilize digital health technologies in all ways possible that will help them improve outcomes for their communities in more efficient ways. CHI supports CMS' steps already taken to extend the ability of FQHCs and RHCs to offer mental health services via telehealth and urges CMS to avoid unnecessary in-person requirements for FQHCs and RHCs when they use telehealth services (that is, live voice/video). We further encourage CMS to take any needed further steps to provide FQHCs and RHCs with flexibility to leverage the same capabilities for other conditions past mental health, including both RPM and RTM services, general care management, transitional care management (TCM), chronic care management (CCM), chronic pain management (CPM), general behavioral health integration (GBHI), and psychiatric care models.

h. Direct Supervision via Real-Time Audio-Video Presence

CMS took important steps to responsibly utilize technology for purposes of medical supervision during the PHE, revising the definition of direct supervision to include virtual presence of the supervising physician or practitioner using interactive audio/video real-time communications technology. CHI continues to strongly support CMS permiting remote supervision as widely as practicable on a permanent basis to help Medicare providers and beneficiaries realize the widely-recognized efficiencies of remote work being realized across countless other sectors of the economy. CHI supports CMS' extension the PHE policy allowing a physician/practitioner to be present through real-time audio-video technology through the end of 2024, and urges that this policy be made permanent. Greater use of efficacious virtual presence technology, as appropriate, will support medically necessary care while helping address workforce shortage issues.

CHI reiterates that it does not share CMS' concern (expressed in previous PFS proposed rules) that virtual supervision inherently gives rise to patient safety issues. Numerous clinical staff and auxiliary personnel perform a wide range of tasks while easily and efficiently supervised virtually. Further, such staff categorically do not perform "complex, high-risk, surgical, interventional, or endoscopic procedures, or anesthesia procedures" that CMS has described in the past to explain its concerns with virtual direct supervision. In this context, and generally, CHI strongly encourages CMS to move away from policies that discriminate against virtual modalities without evidence. CMS must enable greater efficiencies in medical workforce and patient safety by permanently allowing the supervision of professionals through real-time audio/video technology

across as many services as possible. In this context, CMS' proposed extension of virtual direct supervision is a commendable step in the right direction.

i. Community Heath Integration Services

In its proposed rule, CMS has proposed new G-codes to support practitioners furnishing community health integration services, which will enable the collection of key SDOH that is increasingly important in identifying trends inequities in healthcare. CHI supports CMS' proposal, which would augment access to care. CHI requests that CMS permit community health integration services to be provided both in-person and via virtual presence to support the most appropriate and efficient delivery of such services. New studies demonstrate that a modality neutral approach to services such as community health integration services is equally effective whether provided in person or virtually.[4]

j. Artificial Intelligence's Use in the Medicare System

Leveraging health data (including social determinants of health [SDOH] and PGHD) with AI tools holds incredible promise for advancing value-based care in research, health administration and operations, population health, practice delivery improvement, and direct clinical care. Payment and incentive policies must be in place to invest in building infrastructure, preparing personnel and training, as well as developing, validating, and maintaining AI systems to ensure value. CHI is immensely appreciative of CMS' efforts to responsibly bring AI to the Medicare system in a way that will benefit all providers and patients.

As part of its commitment to responsibly advance AI in healthcare, CHI has assembled a Health AI Task Force consisting of a range of innovators and thought leaders. CHI's AI Task Force has developed a range of resources, including a position piece supporting AI's role in healthcare, a set of principles addressing how policymakers should approach the role of AI in healthcare, and a terminology document targeted at policymakers.[5] Even more recently, CHI's AI Task Force has developed Good Machine Learning Practices, specifically for AI development and risk management of AI meeting the FDA's definition of a medical device,[6] as well as recommendations on ways to

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[4] Shah MK, Gibbs AC, Ali MK, Narayan KMV, Islam N. Overcoming the Digital Divide in the Post-COVID-19 "Reset": Enhancing Group Virtual Visits with Community Health Workers. J Med Internet Res. 2021 Jul 8;23(7):e27682. doi: 10.2196/27682. PMID: 34152995; PMCID: PMC8274676.

[5] The CHI Health AI Task Force's deliverables are accessible at https://actonline.org/2019/02/06/why-does-healthcare-need-ai-connected-health-initiative-aims-to-answer-why/.

[6] The CHI's Good Machine Learning Practices are available at https://bit.ly/3gcar1e.

improve transparency for caregivers, patients, and others necessary for the appropriate uptake of AI tools across the care continuum.[7]

Although AI has various definitions based on context and sector-specific qualifiers, most individuals in the field would agree that AI includes systems or machines that mimic human intelligence to perform tasks. AI is an evolving constellation of technologies that enables computers to simulate elements of human thinking – learning and reasoning among them. Furthermore, AI is a multidimensional term that encompasses a range of approaches and technologies, such as machine learning (ML) and deep learning, where an algorithm can adapt by "learning" when exposed to new inputs, allowing for independent or assisted decision making. AI-driven algorithmic decision tools and predictive analytics are having, and will continue to have, substantial direct and indirect effects on Americans. Some forms of AI are already in use to improve American consumers' lives today. For example, AI can augment efforts to detect financial and identity theft and to protect the communications networks upon which Americans rely against cybersecurity threats.

Breakthroughs are expected to create a $126 billion AI marketplace by 2025 with the opportunity for far-reaching benefits.[8] If leading policymakers such as CMS navigate the challenges and opportunities effectively, AI will improve beneficiaries' lives through faster and better-informed decision making enabled by cutting-edge distributed cloud computing. AI will also provide for more effective governance through its ability to enhance infrastructure foresight and support efficient budgeting decisions. AI will beneficially impact every aspect of Americans' lives if we encourage ethical innovation at AI's beginning stages.

Along with these transformative benefits, AI raises a variety of unique considerations for societal concerns that policymakers must address to realize the promise of AI. Policymakers must find a balanced approach to the implementation of AI innovation with necessary safeguards to protect consumers and society. It is important that policymakers consider the variety of stakeholders that AI may influence. This is especially true in the healthcare context when making statutory and regulatory changes impacting AI. Such changes must be based on risk of harm and benefit accounting for a host of factors, including evidence of safety, efficacy and equity including addressing bias, AI system methods, level of automation, transparency, and conditions of deployment. We urge CMS, when considering the value of AI in healthcare, to view the proposition through the lens of the "quadruple aim" framework. Built on the Institute for

[7] The CHI's recommendations on necessary policy changes to enhance transparency for healthcare AI are available at https://bit.ly/3Gd6cxs.

[8] McKinsey Global Institute, *Artificial Intelligence: The Next Digital Frontier?* (June 2017), *available at* https://www.mckinsey.com/~/media/McKinsey/Industries/Advanced%20Electronics/Our%20Insights/How%20artificial%20intelligence%20can%20deliver%20real%20value%20to%20companies/MGI-Artificial-Intelligence-Discussion-paper.ashx.

Healthcare Improvement's "triple aim,"[9] a widely accepted compass to optimize health system performance,[10] the quadruple aim focuses on four key metrics for optimizing health systems to meet the needs a wide range of key stakeholders and communities. The four areas are (1) enhancing population health; (2) improving patient experience, satisfaction, and health outcomes; (3) better clinician and healthcare team experience and satisfaction; and (4) lowered overall costs of healthcare.

AI can dramatically reduce administrative burdens, improve physicians' ability to care for their patients, and permit resource redeployment within Medicare to better serve the most vulnerable populations. Furthermore, AI has also demonstrated an ability to help manage public health emergencies at the state level. In addressing the COVID-19 pandemic, health authorities found that AI greatly assists in population health management (infection trends, resource management, etc.), as well as in diagnosis and treatment of individuals.[11] Additionally, AI played a role in tracking helpful research that contributed to the COVID-19 vaccine.[12]

Further, across the country, disparities in healthcare are sizable and growing, caused by barriers that exist at all levels, exacerbated by the ongoing COVID-19 public health emergency.[13] To address these disparities and achieve health equity, CMS should identify potential bias in data collection and responsibly utilize AI tools. Great strides can be taken to achieve health equity (and aid in a lasting recovery) through, for example, the collection and use of health and/or SDOH data disaggregated by race, ethnicity, gender, disability, and other characteristics.

AI-enabled tools offer great promise in overcoming the challenges faced by clinicians, health systems, health plans, and public health officials working to advance population health management and public health. SDOH—social factors as diverse as income, access to transportation and healthy food, and education—can also provide key indicators of health and well-being, helping providers and health plans manage population health. This can provide public health officials, healthcare systems, and providers near real-time access to essential and actionable data to assist with more timely and accurate population level disease surveillance and assessments of disparities and health care resource distribution. As more systems are created and deployed, the opportunity for AI to help improve healthcare outcomes across

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[9] http://www.ihi.org/engage/initiatives/tripleaim/pages/default.aspx.

[10] Thomas Bodenheimer, MD and Christine Sinsky, MDFrom Triple to Quadruple Aim: Care of the Patient Requires Care of the Provider, Ann Fam Med November/December 2014 vol. 12 no. 6 573-576.

[11] https://hbr.org/2020/04/how-hospitals-are-using-ai-to-battle-covid-19.

[12] https://www.wired.com/story/opinion-ai-can-help-find-scientists-find-a-covid-19-vaccine/.

[13] For example, the Centers for Disease Control and Prevention has noted inadequate reporting on racial disparities in coronavirus patients, which experts believe has hampered the public health response in communities of color. *See* https://appropriations.house.gov/events/hearings/covid-19-response-0.

communities is significant, with estimates suggesting outcomes could be improved by 30-40 percent.[14]

Implementation of AI healthcare tools can not only reduce overall healthcare costs directly, but also contribute to increased efficiencies that address challenges such as lack of care coordination, overtreatment, low value of care, burdensome administrative processes, and identification of fraud and abuse within medical systems. These efficiencies will enable professional medical staff to spend more time with patients by utilizing tools that rely on AI to analyze large datasets, facilitating more informed patient care. Healthcare experts see enormous promise in AI's ability to more accurately capture and leverage the range of health data available. Estimates suggest successful use of AI applications will create $150 billion in annual savings for the U.S. healthcare economy alone by 2026 (note that this savings estimate should be considered conservative, as it only includes a "top 10" of AI scenarios, such as assisted surgery, virtual nursing assistants, and administrative workflow assistance).[15] More efficient and timely use of health data will provide many further benefits across a range of further scenarios and use cases. Because improved patient outcomes for Medicare beneficiaries will entail allotting resources to services other than those addressing acute and chronic illnesses, AI can help bring the right resources to the right areas to support additional services such as therapy, tailored case management, habilitative services, and transport and translation costs.

CHI appreciates CMS's efforts to responsibly bring AI to the Medicare system in a way that will advance health equities and benefit all providers and patients. To date, CMS has taken a number of important steps to make AI's benefits available to more caregivers and patients, including updating its PFS rules to provide national payment rates for AI's responsible use in addressing specific use cases, such as in diabetic retinopathy; and integrating AI into value-based care, specifically in various Quality Payment Program Merit-based Incentive Payment System (MIPS) quality measures.

In its proposed CY2022 PFS rule, CMS asked a wide range of questions about the use of innovative technologies, including software algorithms and AI in health, to better understand the resource costs for services involving their use. We are encouraged by CMS' leadership in exploring medical AI definitions, present and future AI solutions, how AI is changing the practice of medicine, and the future of AI medical coding. We again urge CMS to pose these questions in a standalone Request for Information that is not tied to an annual payment rule.

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[14] Nicole Lewis, Artificial Intelligence to play key role in population health, Medical Economics (2017) (available at http://www.medicaleconomics.com/medical-economics-blog/artificial-intelligence-play-key-role-population-health).

[15] Accenture, Artificial Intelligence: Healthcare's New Nervous System (2017), *available at* https://www.accenture.com/_acnmedia/PDF-49/Accenture-Health-Artificial-Intelligence.pdf#zoom=50.

Since the comment period on the proposed CY2022 PFS closed, there have been further health AI developments on which we strongly encourage CMS to build. For example:

- **The CPT® Editorial Panel accepted the addition of a new Appendix S to provide guidance for classifying various AI applications. The Panel intended the Appendix to be consulted for code change applications to describe work associated with the use of AI-enabled medical services and/or procedures.** This taxonomy provides guidance for classifying various AI applications (e.g., expert systems, machine learning, algorithm-based services) for medical services and procedures into one of three categories: assistive, augmentative, or autonomous, and its adoption represents a significant step forward in the evolution of CPT® coding.
- **CHI's AI Task Force released *Advancing Transparency for Artificial Intelligence in the Healthcare Ecosystem*, the digital health community's consensus recommendations addressing how to create health AI tools and maintain the trust in them of both healthcare professionals and patients.** This new set of recommendations builds on the Task Force's previously released general health AI policy recommendations and recommended good machine learning practices for FDA-regulated AI.

CY2024 offers an excellent opportunity for continued CMS leadership and for timely and impactful policy changes to further support the responsible deployment of AI to benefit all Medicare beneficiaries and to reduce disparities. In its CY2024 Medicare rulemakings, we strongly urge CMS to:

- Rely on the CPT® Editorial Panel's new Appendix S to harmonize CMS' definitions and understanding of health AI and the CHI AI Task Force's released general health AI policy recommendations as a baseline for payment policy decisions impacting AI's use in Medicare. We recommend good machine learning practices for FDA-regulated AI, and recommendations addressing how to create and maintain the trust of both healthcare professionals and patients in health AI tools.
- Continue to support and expand responsible payment (aligning, where possible, with valuation recommendations of the Relative Value Scale Update Committee) for AI tools that will drive greater access to innovative AI mechanisms for Medicare beneficiaries. CMS should adopt national rates for the payment of AI services and shift away from contractor pricing that encourages disparate approaches among Medicare Administrative Contractors.
- Recognize that AI (either standing alone or used in a system) is appropriately paid for as a direct PE. AI software is not simple off-the-shelf software and cannot not be properly categorized as an indirect PE. Like medical equipment and medical supplies, SaMD is a device as defined by FDA regardless of

whether it is loaded onto and used on general purpose platforms or used as dedicated ancillary medical devices.

- Continue to engage in dialogue with the digital health community to inform new steps forward towards an expanded and nationally harmonized approach to AI's use in Medicare.

We commit to continued collaboration with CMS to realize the benefits of AI tools in Medicare equitably and welcome the opportunity to meet with you to discuss the above.

Point-of-Care Diabetic Retinopathy Automated Analysis (CPT code 92229)

While not raised in the proposed CY2024 PFS, CHI reiterates its strong supported CMS' activation of CPT code 92229, which supports point-of-care diabetic retinopathy automated analysis and provides a diagnostic report using AI. 92229's activation and payment in Part B is a precedential development in advancing the system through the responsible uptake of AI. As we noted in our comments on the CY2021 proposed rule, CHI has concern with the low valuation given by CMS to 92229 which disregards the recommendation of the Relative Value Scale Update Committee's (RUC) in proposing a value of $11. At the time, CMS suggested that the analysis fee is simply administrative (indirect), a suggestion that CHI strongly disagrees with as the service provided by the AI is immensely valuable as the RUC recognized. We continue to support the RUC's proposed valuation of $55 ($34 for the augmented intelligence [AI] system, $21 for the technical component).

As noted above, SaMD AI (either standing alone or used in a system) is not simply off-the-shelf software and cannot not be properly categorized as an indirect PE. The components of the 92229 code, broken down, include PE (the system's hardware and the AI software that executes an analysis) as well as indirect PE (function of reporting/displaying the AI's analysis). The AI software executing the analysis requires upgrades, improvements, and security updates (supplies). Therefore, AI software cannot be considered similar to a basic operating system and should be treated accordingly by CMS.

We note our appreciation for CMS' support of AI in addressing diabetic retinopathy, and support CMS' proposal to crosswalk CPT code 92229 to CPT code 92325 as an interim measure to more adequately account for the purchase and use of software algorithms in CPT code 92229's PE methodology. Ultimately, it is vital that the reimbursement of this code reflects an appropriate value (as originally recommended by the RUC) to encourage continued AI innovation. CMS approach will move away from contractor pricing to one that provides national coverage and payment.

k. Virtualization of Diabetes Prevention in Medicare

We support the overdue virtualization of key Medicare prevention programs, including the Medicare Diabetes Prevention Program (MDPP), the Diabetes Self-Management Training (DSMT), and Medical Nutrition Therapy (MNT). Notably, we support CMS' proposed extension of the MDPP Expanded Model's Public Health Emergency Flexibilities, which will allow all MDPP suppliers to continue to use specific such PHE flexibilities through December 31, 2027. The proposed flexibilities, which should be finalized and made permanent, include the virtual delivery of MDPP services through distance learning. However, it is important to note that CDC-recognized virtual suppliers are still unable to participate in the program. 39% of all Medicare beneficiaries live more than 25 miles from the nearest MDPP location. Additionally, MDPP supplier locations are clustered in urban areas with significantly fewer locations in rural areas.[16] We encourage further exploration of ways to modernize this critical preventative program in Medicare using digital health innovations and virtual suppliers to solve for the significant lack of in-person MDPP sites.

CMS is long overdue to maximize virtual MDPP services and when applicable, utilize other non-face-to-face services via any available modality that best serves the intended population. CMS acknowledged that the use of connected health tech products and services will be vital to the success of the MDPP, and a virtual MDPP would reap benefits consistent with the experiences and data of the broad community of stakeholders from across the healthcare and technology sectors that CHI represents. Allowances made for the MDPP during the PHE, while modest, do validate that CMS is aware of the outdated requirements of the MDPP that continue to inhibit its effectiveness. CHI supported CMS' past proposed limit on the number of virtual make-up sessions not applying during the remainder of the now-expired COVID-19 PHE, or during any future applicable 1135 waiver events, which enabled MDPP suppliers to provide services virtually so long as the furnishment of virtual services occur in a manner that is consistent with the Centers for Disease Control and Prevention (CDC) Diabetes Prevention Recognition Program (DPRP) standards for virtual sessions, follow the CDC-approved DPP curriculum requirements, and the supplier has an in-person DPRP organizational code.

This said, a lack of comprehensive support for diabetes prevention through permanent policies discards the well-established value of connected health technology to at-risk diabetics, leaving countless Americans in peril, particularly in rural areas of the country as 67 percent of the 65+ population lives farther than five miles away from a face-to-face delivery location. Building on the CDC's recognition of the effectiveness of a virtual MDPP since 2015, and CMS' acknowledgements on the ineffectiveness of the status

[16] RTI International. Evaluation of the Medicare Diabetes Prevention Program, Second Evaluation Report. November 2022. https://protect-us.mimecast.com/s/JtMuCzplnKiMlJML1c4ugDU?domain=innovation.cms.gov.

quo approach in Medicare to diabetes prevention in the proposed CY2024 PFS rule, we encourage a holistic approach to virtualizing MDPP, DMST, and MNT.

Further, we support CMS permitting Medicare Advantage (MA) plans to use virtual MDPP encounters in addition to in-person MDPP encounters, and to permit virtual DPP to register as Medicare Suppliers to enable uptake by MA plans. Without this allowance, in-person MDPP providers will be unable to service MA plans which will leave numerous beneficiaries without access. CMS can alleviate this issue by affirming that MA plans may use virtual MDPP to meet network adequacy requirements and satisfy the requirement to provide MDPP services; and by allowing virtual MDPP providers to register as Medicare Suppliers for this purpose. We also note that, whether in the Medicare fee-for-service or MA context, a successful MDPP will require the inclusion of a virtual program the MDPP supplier enrollment, preliminary recognition, and supplier standard provisions.

I. Response to Request for Information on Digital Therapies

CHI appreciates CMS' embedded request for information (RFI) on digital therapies, including cognitive behavioral therapies, and how technologies like remote monitoring are leveraged in these scenarios. Many CHI members are providing detailed input to CMS that includes responses to specific questions that CMS has posed, which we urge CMS' consideration of. However, to maximize participation by impacted stakeholders and to signal its intent to make needed programmatic changes to support digital therapies, we request that CMS issue a standalone call for input, separate from the annual PFS, to ensure the broadest participation in the comments process.

From the CHI's perspective, consistent with our positions detailed above and below, many new innovations, including digital therapeutics, are supporting safe and efficacious treatments for patients suffering from a wide range of health conditions, and should be accessible to all Medicare beneficiaries. In light if this, in its response to this non-rulemaking embedded RFI, we urge CMS to clearly acknowledge that it is incorrect to categorize all software, particularly SaMD, as general "Computer Software" with an indirect PE that is non-allocable; further we call on CMS to propose steps for collaboration with our community to find ways to leverage opportunities and overcome challenges related to Medicare coverage and payment policies for innovative digital therapy technologies.

Further, in the context of digital therapies and more broadly, we urge CMS to recognize that most cutting-edge medical technologies today include digital and connected characteristics. In particular, SaMD includes Clinical Decision Support, AI, and mobile medical applications that often, but do not always, meet the legal definition of a medical

device under the Food, Drug, and Cosmetic Act. However, because SaMD generally does not fall within an existing benefit category it is accordingly excluded from coverage, precluding countless Medicare beneficiaries from realizing the improved outcomes and reduced costs they bring.

From a coverage standpoint, we agree with CMS' own assessment in this and other rulemakings that illustrate the disjointed and complex pathways to coverage in today's regulatory environment. We are supportive of CMS' goal to realize innovation and value in Medicare using digital therapies, which can and should be accomplished through regulatory changes encouraging the responsible deployment and utilization of digital health technology. In this respect, incremental steps including its separately proposed Transitional Coverage for Emerging Technology pathway should be viewed as an important but incremental step to much-needed modernizations for Medicare coverage, including the harmonization of descriptive terms and the synchronization of associated clinical evidentiary standards for FDA approval, CPT coding, and CMS coverage focused on the clinical meaningfulness of the output from the digital device.

Further, CMS appropriately inquires about barriers to accessing digital therapies for unserved and underserved communities. Major barriers to such innovations, which also impact accessibility to digital health tools more widely, include broadband deployment. CHI is committed to federal subsidies supporting the deployment and maintenance of broadband infrastructure considering health as a key use case, and urges CMS to partner with other federal agencies, including but not limited to the National Telecommunications and Information Administration and the Federal Communications Commission, to ensure that it is.

Accordingly, CMS must take much broader steps at the policy level to enable responsible support for digital health products. Under its existing authority, CMS can and should exercise flexibility when determining whether a potential device or diagnostic falls within a Medicare benefit category by considering how such a solution may already be eligible for inclusion in an existing benefit category even if not explicitly outlined in statute. For instance, CMS should bring eligible digital health innovations into Medicare beneficiaries' care continuum by clarifying whether digital medical devices, such as SaMD, are included in existing benefit categories and if so, which category.

Further, consistent with our views provided above (e.g., with respect to RPM and RTM), CMS should provide flexibility for digital therapies. For example, support for digital therapies should not be restricted to once per billion period per patient per device. Such an approach would deprive some of the beneficiaries most in need, such as those in unserved or underserved areas that suffer from multiple chronic conditions, from getting

the care they need. As a further example, supervision and frequency requirements may need to be tailored to the circumstances to avoid inefficient uses of digital therapies.

m. Response to Request for Information on Strategies for Updates to Practice Expense Data Collection and Methodology

We appreciate CMS' request for input on how to improve its PE methodology. Per CHI's discussion above and below in this comment, CMS must recognize that its existing PE methodology creates significant barriers to the uptake of digital health innovations through the classification of most SaMD as indirect practice expense. We welcome the opportunity to partner with CMS to reform its approach to capturing and appropriately valuating digital health tools and services.

We welcome the opportunity to partner with CMS to reform its approach to capturing and appropriately valuating digital health tools and services.

n. Medicare Shared Savings Program

CHI supports CMS' ongoing efforts to improve the Medicare Shared Savings Program (MSSP) and urges CMS to recognize that digital health tools and services, both synchronous and asynchronous, must play a central role in a successful MSSP.

CHI supports CMS' proposal to amend the definition of primary care services used in the MSSP assignment methodology to include additional codes for the performance year starting on January 1, 2024, and subsequent performance years, in order to remain consistent with billing and coding under the PFS. Specifically, CHI strongly supports CMS' proposal to revise the definition of primary care services used for assignment in the MSSP regulations to include RPM CPT codes 99457 and 99458, which builds on support already provided for digital health in last year's rule changes (e.g., adding G2012 and G2252 codes for virtual check-ins).

CMS can and should enable the MSSP to responsibly leverage such tools in numerous ways, in alignment with the progress made in the fee-for-service PFS context, including but not limited to remote physiologic and therapeutic monitoring, artificial intelligence, and others discussed above. For example, CMS should exercise its statutory authority under 42 U.S.C. 1395jjj(f) to waive MSSP payment and program requirements as appropriate to allow for one-sided and two-sided risk models under a waiver of telehealth restrictions. This would help providers that use APMs to reduce costs and meet statutory requirements. CMS recently exercised relevant waiver authority on several aspects of telehealth for two-sided risk models only and doing so more broadly

would further the success of APMs. Relatedly, CMS should waive Medicare's telehealth restrictions (under Social Security Act Sec. 1834(m)) for all shared savings programs and alternative payment models (APMs)), including payment bundles and medical home demonstrations.

IV. CHI Input on the Proposed Quality Payment Program

With respect to QPP, with the passage of the Medicare and CHIP Reauthorization Act of 2015 (MACRA), Congress directed CMS to evolve the Medicare program to emphasize care quality over quantity, requiring enhancements to the healthcare system that connected health technologies may facilitate. Through the CY2020 QPP rulemaking, CMS has an excellent opportunity to advance the American healthcare system by leveraging digital medical technologies, both those available today as well as emerging fields like systems medicine, AI, and enhanced data analytics. We encouraged CMS to incent the use of connected medical technologies throughout MIPS. Furthermore, CMS should avoid overly burdensome MIPS Promoting Interoperability program compliance and reporting requirements. CMS should explicitly endorse the use of digital medical technologies' in APMs.

Today, an estimated 133 million Americans—nearly half the population—suffer from at least one chronic illness, such as hypertension, heart disease, and arthritis, which is 15 million higher than just a decade ago and expected to reach 170 million by 2030. From a cost perspective, chronic illnesses account for 75 percent of the $2.2 trillion we spend on health care each year in the United States. The COVID-19 pandemic has also made disparities and inequities in the American healthcare system even more apparent than ever before. Given these staggering statistics, it's more important than ever that the American healthcare system needs to shift from the traditional approach of paying for discrete services in a fragmented manner, with gaps in payment for many high-value services, to one that supports value and improved health outcomes, but this goal remains far from realized.

Digital healthcare technologies provide an essential major means for advancing value-based care, yet they remain underutilized or completely unused to this end. Seven years out from the passage of MACRA, the time is now to truly incent the use of digital healthcare innovations so that a transition to value-based care happens.

Based on the views and experiences of a diverse range of interests and voices from throughout the healthcare ecosystem, CHI identified key challenges to the responsible use of digital health technologies in advancing value-based care and made recommendations to policymakers on how to overcome them.[17] We urge CMS to align its approach to both MIPS and APMs with the recommendations in this report. Notably, CHI's Value-Based Care Task Force's recommendations include, among others:

- CMS should enable providers to use digital health tools to enhance care quality while the transition to value-based care continues, eliminating barriers to the responsible use of digital health innovations in MIPS as a pathway to Advanced

[17] https://www.connectedhi.com/blog/2021/7/14/the-value-based-care-revolution-will-stall-without-health-tech.

Alternative Payment Models (APMs) and modernizing MIPS components, like Program Integrity (PI) protections, to support the use of digital health tools.

- CMS testing models that leverage digital health innovation tools and support the use of digital health tools and responsible use of technology in APMs should be enhanced and accelerated. HHS should also leverage the work underway in the private sector by partnering with health plans to develop multi-payer models.
- CMS and others should advance the appropriate two-way flow of health information to enhance value throughout the care continuum.

We urge CMS to utilize every opportunity available to move away from legacy technology systems and towards a truly connected continuum of care through its implementation of the QPP.

a. The Use of Digital Health Innovations in the Merit-based Incentive Payment System

We continue to support the overall approach by CMS to the QPP MIPS Improvement Activities (IAs), which take a more goal-oriented and technology-neutral approach to compliance. This shift is important because it will provide needed flexibility to MIPS practitioners to select the most effective approaches for their patients. Further, we appreciate CMS' focus on incenting the use of health IT, telehealth, and the connection of patients to community-based services.

By specifically calling for an inventory that "shall include activities such as…remote monitoring or telehealth" under the Care Coordination performance subcategory,[18] Congress signaled the importance of these technologies to support providers through the transition from volume- to value-based reimbursement. The IA Inventory should provide a robust menu of activities that, through appropriate use of remote monitoring, telehealth, and consumer-oriented information technology, eligible practitioners may use for care improvement. It is crucial that the IA Inventory, from which all MIPS-eligible clinicians or groups must select activities, reflects both congressional intent and the benefits of connected technologies to the Medicare program.

[18] MACRA Section 101(c)(2)(B)(iii)(II).

In the context of MIPS, CMS has already taken important steps to promote flexible use of remote monitoring innovations in the QPP: as part of the QPP's MIPS rules, CMS has already adopted an IA that CHI proposed—IA_BE_14 (Engage Patients and Families to Guide Improvement in the System of Care)—which incents providers to leverage digital tools for patient care and assessment outside of the four walls of the doctor's office. The IA incents providers to ensure that any devices they use to collect PGHD do so as part of an active feedback loop. We encourage CMS to build on IA_BE_14 moving forward.

CHI encourages CMS to remove barriers to, and advance positive incentives for, the responsible use of digital health innovations in MIPS as a pathway to APMs. CMS can accomplish this goal by minimizing unnecessary burdens for MIPS participation and supporting greater digital health use across MIPS Measures. At the same time, CMS should also facilitate those participating in MIPS to shift to Advanced APMs by adopting stakeholder-developed APMs with onramps allowing broad participation. For example, the Medicare program must shift to allow credit for embracing technical solutions and approaches that capture PGHD. Medicare should also provide credit for capturing information using either CEHRT or non-CEHRT (in both Promoting Interoperability measures and Improvement Activities). CMS has already explored this idea using a “yes/no” attestation approach for new measures within the Promoting Interoperability category of MIPS.

The Health Information Technology for Economic and Clinical Health (HITECH) Act incented physicians to purchase and use EHRs. Digitizing medical records helped to reduce issues associated with paper charts and records, including legibility, access, and loss. However, excessive regulation and overly prescriptive federal requirements have created unintended consequences. Program participants are now bound to use poorly functioning CEHRT products, built primarily to measure and report on CMS requirements. The program thus disincents patients from adopting truly useful technology. CMS should identify methods to reduce the overreliance on CEHRT in its programs. Instead, it should allow for physician and patient choice to drive the adoption and use of health IT products by leveraging the value of connected health technology innovations that build on CEHRT.

CMS should also improve the quality data submission criteria to reflect the increased use of digital health tools, and broadly account for the savings achieved by using those tools in MIPS (e.g., in the Cost Performance Category). Medicare must transition from the existing four silos of reporting criteria to facilitate a glide path for MIPS participants to APMs via the voluntary MIPS Value Pathways (MVPs). MVPs have the potential to help CMS capture savings, particularly from preventive care, if CMS allows flexibility to move away from use of a measure template that includes a one-year measurement period. CHI generally supports CMS’ proposals to revise existing, as well as to advance

new, MVPs that are tailored episode-based cost measures, and further supports CMS efforts to capture savings from prevention.

For example, a diabetes prevention MVP would align objectives across all four MIPS categories by helping Medicare patients avoid costly diabetes care, as well as kidney, ophthalmic, and other sequelae of diabetes by promoting screening and participation in the MDPP and other effective prevention care delivery options. Physicians participating in a diabetes prevention MVP would leverage digital health tools, such as virtual tools that track and engage patients toward meeting the goals of MDPP, rather than simply checking the boxes of the Promoting Interoperability (PI) measures.

CMS' previous policy of providing bonus points in the PI category represented CMS' understanding that health IT plays a role in improving outcomes and incented physicians to incorporate health IT into their practice workflows and clinical activities. CMS should reward practices that embrace technical solutions and approaches that capture PGHD and incorporate it into the certified EHR technology (CEHRT) using a standards-based approach for purposes of the Promoting Interoperability performance category. Over the past decade, the FDA listed, cleared, and approved a vast array of technologies which allow for the capture and transmission of PGHD on which providers may act. Pilots to further study the role of PGHD in Medicare at this point are unnecessary, wasteful, and redundant; CHI is more than happy to offer a range of resources and studies which outline the vast evidence on the benefits of remote patient monitoring technologies.[19]

We urge CMS to underscore this understanding by continuing to grant providers with bonus points when using CEHRT to accomplish IAs. Given CMS' proposal to remove the bonus score component of PI, CMS could simply apply bonus points at the composite score level. Doing so would avoid having to "reinvent the wheel" and would provide some consistency to providers who have already adjusted their workflow in the interest of earning the PI bonus. CHI would also support CMS applying high weighting to any improvement activity employing CEHRT.

With regard to how health IT could better support the feedback related to participation in the QPP and quality improvement in general, we believe that CMS' evaluation must reflect the fact that remote communications technologies and telehealth—across patient conditions—offer key "health IT functionalities," including the automatic collection and transmission of important biometrics for timely caregiver review and analysis. A diversity of application program interfaces (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

[19] https://bit.ly/2MblRou.

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.

Many CHI members develop innovative and unique applications that benefit both providers and patients. However, CMS' regulation that includes misplaced 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.

We urge CMS to consider shifting 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. Changes in MIPS are inherently linked to other important rules CMS is responsible for, including the Physician Fee Schedule which has recently begun to incent the use of asynchronous tools that will bring PGHD into care. Efforts to revise MIPS measure 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.

Based on the above, we offer the following further recommendations for CMS' proposed CY2022 MIPS Program:

- Inequities in and around healthcare affect not only those facing the disparities, but significantly decrease the overall medical and public health in the country, resulting in higher costs for health care and poor public health capabilities. The issue is particularly relevant today given the existing and projected diversity of the U.S. population coupled with declining health outcomes compared to other developed nations. For example, preliminary Medicare data shows the rate of hospitalization for Black people with COVID-19 was a rate of 465 per 100,000. Among other racial/ethnic groups, Latinos had 258 hospitalizations per 100,000; Asian American and Pacific Islanders had 187 per 100,000; and Whites had 123 per 100,000.[20] Disparities in access, service use, and health outcomes persist,

[20] CMS, "Preliminary Medicare COVID-19 Data Snapshot" (last visited June 2, 2021), available at https://www.cms.gov/research-statistics-data-systems/preliminary-medicare-covid-19-data-snapshot.

and continue to grow.[21] In a value-based payment world, it can be more challenging to meet quality metrics and spending targets for historically underserved populations. Consistent with our discussion elsewhere in this comment, CHI supports the expansion of the CMS Disparity Methods, including: (1) future potential stratification of quality measure results by race and ethnicity, and (2) improving demographic data collection. Further, CHI agrees that the goal of mitigating healthcare disparities is being appropriately prioritized, and we support the development of health equity measures in MIPS Value Pathways (MVPs). We support health equity measures in the foundational layers of all MVPs, that reflects the need for feasibility and flexibility for providers, is appropriate as a required measure.

- We remind CMS PGHD can take various forms, including SDOH. Healthcare providers should be encouraged and rewarded for collecting information from their patients outside of scheduled appointments and procedures. When CMS and ONC finalized the now-defunct Meaningful Use Stage 3 objectives and measures, as well as the beneficiary engagement Improvement Activities offered under the Merit-Based Incentive Payment System, it did so with the idea of allowing bi-directional availability of data (meaning that both patients and their healthcare providers have real-time access to a patient's EHR).

  In the past, CMS acknowledged that increasingly affordable wearable devices, sensors, and other technologies capture PGHD, providing new ways to monitor and track a patient's healthcare experience. By capturing health information through devices and other tools between medical visits, care management and patient outcomes will improve, resulting in increased cost savings. Although the use of PGHD in clinical settings continues to steadily increase, integration of patients' health data into EHRs remains uncommon and not widely adopted. CMS correctly points out that in the 2015 Edition Health IT Certification Criteria final rule,[22] ONC finalized "Objective # 6: COORDINATION OF CARE THROUGH PATIENT ENGAGEMENT" measure 3 to allow PGHD or data from "a nonclinical setting" to be incorporated into the CEHRT. Adoption of this functionality would have allowed beneficiaries to identify, record, upload, and access information electronically shared by a patient. Although CMS finalized this measure requiring healthcare providers to incorporate PGHD into CEHRT,[23] it was removed in the CY 2019 PFS final rule (83 FR 59813), for reasons which remain unclear. At the time of the removal, CMS stated concerns that the measure was "not fully health IT-based" and could "include paper-based actions, an approach which did not align with program priorities to advance the use of

[21] Health Affairs, Renée M. Landers, Bruce Vladeck, Bethany K. Cole, "Medicare's Current And Future Role In Reducing Racial And Ethnic Health Disparities" (Mar. 23, 2020), available at https://www.healthaffairs.org/do/10.1377/hblog20200319.932279/full/.

[22] 80 FR 62661; 45 CFR 170.315(e)(3).

[23] 80 FR 62851.

CEHRT"; yet, CMS had the ability to strengthen the measure by requiring only automated digital formats of PGHD to be shared by patients and become part of the CEHRT. Doing so would have eliminated any argument that manual processes to conduct actions would increase healthcare provider reporting burden or confusion over which types of PGHD health data would be applicable and when. Despite having been able to strengthen the measure, CMS rightly has pointed out that "there was ample support from the public for ONC and CMS to continue to advance certified health IT capabilities to capture PGHD."

Considering how the Promoting Interoperability performance category could advance the use of PGHD, CMS has previously discussed that a future element related to PGHD would not necessarily need to be implemented as a traditional measure, and in lieu of a traditional measure, could have providers attest to demonstrating utilization of remote monitoring system predicated on wireless or mobile medical device(s) as defined by FDA that automatically capture PGHD, transmit that data for the physician, qualified healthcare provider, or clinical staff to act upon it. We offer the following specific use cases for capture of PGHD as part of treatment and care coordination across clinical conditions and care settings to improve patient outcomes.

- Clinical examples where remote patient monitoring services can be provided under clinical supervision include, but are not limited to:
  - Emergency department triage or post-discharge follow-up
  - Follow-up services furnished to beneficiaries in hospitals or skilled nursing facilities
  - Nursing facility care services
  - Individual and group kidney, chronic kidney disease, and end-stage renal disease remote monitoring services
  - Individual and group diabetes self-management services
  - Individual and group health and behavior assessment and intervention
  - Individual psychotherapy
  - Telehealth pharmacologic management
  - Psychiatric diagnostic examinations
  - Neurobehavioral status
  - Intervention services
  - Depression screening
  - Cardiovascular disease and heart failure
  - Obesity
  - Psychoanalysis
  - Family psychotherapy
- Other medical uses and use cases for remote monitoring services include, but are not limited to:

- Asynchronous exception management remote monitoring
- COPD
- Sleep apnea and other sleep disorders
- Respiratory care
- Sepsis
- Infection management
- Cardiac (general) ECG monitoring
- Medication adherence
- Medical device data systems for remote monitoring
- Clinical event tagging/patient remote alarm monitoring
- Acoustic gastro-intestinal surveillance
- Remote pulse oximetry
- Psychiatric mental health
- Behavioral medical health
- Mobile monitoring of peritoneal dialysis
- Remote chronic pain relief therapy
- Mental deterioration remote monitoring
- Remote auscultation
- Asthma and environmental scanning analysis
- Respiratory care event detection, compliance, and efficacy
- Pulmonary pressure monitoring
- Smart ingestible pills for monitoring and tracking
- Digital health monitoring for clinical trials
- Family planning fertility monitoring
- Infant development tracking/monitoring
- Remote otolaryngology infection monitoring
- Diabetes monitoring
- Continuous blood glucose monitoring
- Mobile radiology and diagnostic imaging services
- Tinnitus therapy
- Remote neurobehavioral cognitive testing
- Mobile vision degeneration monitoring
- Physical therapy rehabilitation
- Brain trauma evaluation and activity tracking
- Attention deficit hyperactivity disorder assessment tools for long-term development
- Surgical planning
- Spirometry for lung function
- General diagnostic remote monitoring
- Spinal cord stimulation trial system

- CHI supports the leveraging of social determinants of health (SDOH) in advancing value-based care. We support CMS' proposal to provide for a SDOH risk assessment, though a standardized approach to the measurement of SDOH collected by providers is not apparent. We appreciate that CMS points to the ACT REACH program as a model, but this may not apply well to all scenarios. We commit to collaborating with CMS to advance the appropriate collection and use of SDOH.
- CHI notes its support for CMS' acknowledgment that the use of health IT past CEHRT offers the ability to improve care and keep patients safe. We believe that this principle applies across MIPS, and we urge that CMS move away from its reliance on CEHRT (through, for example, permitting health IT that builds on top of CEHRT) in order to provide increased competition in the marketplace as well as greater flexibility and choice to providers and patients. CHI notes its support of 2015 CEHRT requirements in 2019, but we reiterate our concern with, and lack of confidence in, any presumption that the 2015 ONC CEHRT standards will facilitate seamless interoperability.
- To provide CMS with alternative approaches, flexibilities, and methodologies to consider for scoring the PI component of MIPS, CHI urges CMS to align its PI requirements across CMS beneficiary programs to provide simplicity and certainty for connected healthcare stakeholders. Specifically, CHI strongly recommends CMS apply the same 50-point scoring standard enjoyed by facilities to the PI performance category of MIPS to better reduce provider burden and ease concerns with succeeding in PI. In other words, providers who earn 50 points or higher in PI should be deemed to have satisfied the requirements of PI and should receive a 100 for the category, translating to 25 points towards a provider's final composite score.
- We urge CMS to make compliance burdens for PI participants as low as possible to maximize participation and support CMS leveraging the 2018 Bipartisan Budget Act to move away from the Meaningful Use program's "pass/fail" approach.
    - CHI supports scoring measures at the objective level to provide greater flexibility to providers.
    - CHI recommends that CMS move away from numerator/denominator scoring, and instead utilize a yes/no attestation for all measures.
    - CHI recognizes that scoring at the objective level and utilizing a yes/no attestation for all measures may not be practicable for the 2020 reporting year. We, therefore, reiterate our desire for CMS to extend the 50-point scoring standard to the PI performance category in 2020 as a necessary step to align the two PI programs and reduce provider burden. We further recommended CMS establish a plan to transition away from measure-

level and numerator/denominator scoring by the 2021 MIPS reporting year.

- CHI specifically supports various proposed PI measures that will, using a light touch, incent the leveraging of remote monitoring and telehealth innovations to address pressing public safety needs.
- CHI supports CMS' proposals that will align additional Promoting Interoperability performance category objectives with approaches utilizing HL7® FHIR® standard Release 4-based API functionality (or the appropriately evolved standard), specifically targeting the Health Information Exchange as well as the Public Health and Clinical Data Exchange objectives.
- CHI supports efforts to address health data interoperability issues and urges CMS to work in concert with sister agencies that are working to address the same issues now. For example, ONC has developed a Trusted Exchange Framework and Common Agreement (TEFCA) to advance interoperability, on which CHI provided its detailed input; further, an information blocking rulemaking has been completed by ONC, along with a sister rulemaking by CMS. We urge CMS to continue to ensure its approach aligns with ONC's (as well as other agencies) and to meet Congress' goals while minimizing compliance burdens on affected stakeholders. As such, CHI supports CMS' having 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. Furthermore, we recommend that CMS also consider similar trust agreements and not limit potential Health Information Exchange objective options to just the TEFCA.

- 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 incenting data dumps that have little practical value. Further, CHI supports the use of the strongest technical protection mechanisms (TPMs), including end-to-end encryption and multi-step authentication. We urge CMS to include direct endorsement of the strongest TPMs used for securing data integrity, confidentiality, and access. We do, however, highlight that the use of TPMs must also balance with the potential financial, staff, or other resource burdens on small, solo, and rural provider offices in a holistic risk management process. Regarding the Health Insurance Portability and Accountability Act of 1996 (HIPAA), CHI notes its appreciation for CMS' work with HHS' Office of Civil Rights to align the PI program with HIPAA. CMS' rules should avoid creating uncertainty as to what can be shared, and how patients would be properly notified of their data's use under HIPAA. We strongly discourage creating a scenario where a party making a query must choose between satisfying the PI program's requirement for disclosing data fields and violating HIPAA's "minimum necessary" requirements.
- CHI urges for CMS to take all practicable steps to align Medicaid policies with changes to the Medicare program that are increasingly enabling physicians to flexibly use telehealth and remote monitoring technologies to improve care and reduce costs.

b. Advancing Digital Quality Measurement, Fast Healthcare Interoperability Resources and the Trusted Exchange Framework and Common Agreement in Value-Based Care

We appreciate CMS' continued focus on advancing digital quality measurement, including in the context of Fast Healthcare Interoperability Resources (FHIR) and the Trusted Exchange Framework and Common Agreement (TEFCA). ONC's continued efforts to provide health data interoperability are as important as ever. 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 open application programming interfaces (APIs) that allow the integration of PGHD into electronic health records (EHRs). Data stored in standardized formats with interoperability 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 deficient patient engagement.

To fully realize the potential of a value-based care healthcare ecosystem, interoperability must happen between providers, as well as between remote monitoring products, medical devices, and EHRs. A great example of interoperability between systems, devices, and networks is the communications technology industry. In addition to testing and finding consensus on voluntary industry standards, CMS and ONC should prioritize encouraging implementation of those standards to ensure interoperability between EHR systems, medical devices, and healthcare products, and use such standards 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. There must also be an incentive to communicate and pass information from one party to another. We also note that the Medicare Access and CHIP Reauthorization Act[24] (MACRA) provides that incentive in a value-based healthcare environment, one which engages patients, reduces costs, and documents quality metrics.

As discussed above, remote monitoring of PGHD is integral to the future of the American healthcare system. The demonstrated benefits of RM services include reduced hospitalizations and cost, avoidance of complications, and improved care and satisfaction, particularly for the chronically ill.[25] The Department of Veterans Affairs provides a compelling use case for the use of virtual chronic care management, which ultimately resulted in a substantial decrease in hospital and emergency room visits.[26] Emerging technologies like telemedicine tools, wireless communication systems, portable monitors, and cloud-based patient portals that provide access to health records are revolutionizing RM and asynchronous technologies.[27] Healthcare providers will also benefit from the potential of RM's cost savings. RM demonstrably improves patient engagement dealing with chronic and persistent diseases to improve the management of such conditions.

Further, CHI urges CMS (and ONC) to support the use of health data and PGHD through AI in research, health administration and operations, population health, practice delivery improvement, and direct clinical care. CMS' policies should contribute to the

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[24] Pub. L. 114-10 (2015).

[25] *See* Hindricks, et al., The Lancet, Volume 384, Issue 9943, Pages 583 - 590, 16 August 2014 doi:10.1016/S0140-6736(14)61176-4.

[26] Darkins, Telehealth Services in the United States Department of Veterans Affairs (VA), *available at* http://c.ymcdn.com/sites/www.hisa.org.au/resource/resmgr/telehealth2014/Adam-Darkins.pdf.

[27] The global wearable medical devices market is expected to progress from US$2.73 bn in 2014 to US$10.7 billion by 2024, predicted to progress at a 16.40% CAGR from 2015 to 2024. See http://www.medgadget.com/2016/05/global-wearable-medical-devices-market-to-reach-us10-7-bn-by-2024-as-increasing-incidence-of-chronic-pain-creates-strong-customer-base.html.

investment in building infrastructure, preparing personnel and training, as well as developing, validating, and maintaining AI systems with an eye toward ensuring value, ultimately offering a pathway for the voluntary adoption and integration of AI systems throughout the care continuum.

We believe CMS (and ONC) shares CHI's vision of a seamless and interoperable healthcare ecosystem that leverages the power of PGHD and can be realized through the trusted framework. We strongly encourage ONC to ensure their efforts prioritize data generated by patients outside the traditional care setting. Providers of federal health plans and the beneficiaries they serve now 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."[28] An interoperability scope that increasingly includes PGHD is also consistent with HHS' health technology policy. CMS has continued to advance important changes to the future MACRA-driven Medicare system, which will permit caregivers to incorporate PGHD into how they coordinate care and engage with beneficiaries. ONC's framework should augment CMS' rules that bring PGHD into the continuum of care (in both the fee-for-service and value-based care context).

CMS should act to widely advance digital health quality through FHIR and TEFCA uptake, using incentives that enable appropriate flexibilities and population and/or patient-specific deployments while avoiding overburdening providers with compliance and administrative tasks that unfortunately have come to dominate existing APMs. As a few examples, CMS can make major progress in QPP towards this goal through:

- The continued evolution of the Prompting Interoperability (PI) Program, CMS should reduce the reliance on CMS program participation and the use of CEHRT. The HITECH Act incented physicians to purchase and use EHRs. Digitizing medical records has helped reduce issues associated with paper charts and records, including legibility, access, and loss. However, excessive regulation and overly prescriptive federal requirements have created unintended consequences. Program participants are now bound to use poorly functioning CEHRT products—built primarily to measure and report on CMS requirements—and are disincented from adopting truly useful technology. CMS should identify methods to reduce the overreliance on CEHRT in its programs and allow for physician and patient choice to drive the adoption and use of health IT products, such as by leveraging the value of connected health technology innovations that build on CEHRT.

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

- HITECH permits a professional to satisfy the demonstration of meaningful use of CEHRT and information exchange through attestation. HITECH also permits reporting via "other means specified by the Secretary," granting the Secretary the authority to allow provider attestation across all EHR reporting programs. CMS should create broad categories of PI objectives allowing physicians to attest "yes/no" to the use of CEHRT itself to achieve those categories. CMS should reevaluate the need for numerator/denominator requirements in its EHR reporting programs.

We look forward to continued collaboration with CMS to advance digital quality and advance value-based care.

c. Digital Health Innovations Use in Alternative Payment Models

Through the CY2024 QPP rulemaking, CMS has an excellent opportunity to advance the American healthcare system by leveraging digital medical technologies, both those available today as well as emerging fields such as AI and enhanced data analytics. We urge CMS to utilize every opportunity available to move away from legacy technology systems and towards a truly connected continuum of care through its implementation of the QPP, consistent with the CHI's Value-Based Care Task Force recommendations.[29]

Despite the best efforts of CMS to increase the number of Advanced APMs, many providers in certain geographies, specialties, and practice settings lack viable options for APM participation over a decade since CMMI's inception, particularly when pro-digital health policies could incent the move to APMs. Moreover, CMMI's existing suite of Advanced APMs do not adequately embrace innovative technological healthcare delivery mechanisms. Value-based care models that are currently in place do not provide the flexibilities needed to incorporate the full range of virtual care modalities (except for voice/video) into digitally enabled care models. And it is becoming increasingly evident that the goal of realizing value-based care is escaping, despite the efforts of public and private healthcare efforts.[30]

Moreover, CMMI models are typically only run for five years since CMMI must pilot test models before making them permanent. CMMI has sole authority to "expand" models for either permanent or wide geographic implementation if the model is expected to decrease spending without decreasing quality of care, or if the model is expected to increase quality without increasing spending. As of February 2021, CMMI tested 54 models; in 2020, CMMI was actively operating 24 payment and delivery models. Seven

[29] https://www.connectedhi.com/blog/2021/7/14/the-value-based-care-revolution-will-stall-without-health-tech.

[30] Gondi et al, "REACHing" for Equity — Moving from Regressive toward Progressive Value-Based Payment, N Engl J Med 2022; 387:97-99, DOI: 10.1056/NEJMp2204749.

of these models received designation as Advanced APMs. Despite testing dozens of models, only four CMMI models have met the criteria for expansion into a nation-wide program, including only one Advanced APM— The Pioneer Accountable Care Organizations (ACO) model—which served as a model for one of the tracks in the MSSP program, the current Enhanced Track. Given the critical need for transformation of the American healthcare sector and the rapid development of new technologies that can contribute to CMS' value-based care mission, this process can be astonishingly slow. For the 2019 Quality Payment Performance Period, 195,564 eligible clinicians earned Qualifying APM Participant (QP) status while another 27,995 eligible clinicians earned partial QP status; in contrast, 954,614 eligible clinicians participated in MIPS in 2019.[31]

While CMS has long stated that its goal is for most providers to participate in APMs, rather than MIPS, this is far from realized and there are insufficient APM options for most specialists. The Physician-Focused Payment Model Technical Advisory Committee (PTAC),[32] charged with recommending new specialty-relevant APM models to CMS for testing under CMMI, has to date received and evaluated 39 proposed APMs and recommended that HHS take action on 28 of them.[33] While PTAC has authority to recommend models to CMMI to pilot test, its authority is merely advisory as CMMI has sole authority to test, implement, and expand APMs. Congress envisioned that the PTAC would help accelerate the development of new Advanced APM options, which could be exploring new digital health-driven efficiencies and ways to bring greater quality into the care continuum while reducing costs. However, HHS has not, to date, adopted a single PTAC-recommended model for testing. CMMI leadership has acknowledge that, after 10 years, not enough progress has been made in successfully shifting to value-based care.[34]

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[31] Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug; Payment for Office/ Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy; Coding and Payment for Virtual Check-in Services Interim Final Rule Policy; Coding and Payment for Personal Protective Equipment (PPE) Interim Final Rule Policy; Regulatory Revisions in Response to the Public Health Emergency (PHE) for COVID–19; and Finalization of Certain Provisions from the March 31st, May 8th and September 2nd Interim Final Rules in Response to the PHE for COVID–19, 85 Fed. Reg. 84472 (Dec. 28, 2020).

[32] https://aspe.hhs.gov/ptac-physician-focused-payment-model-technical-advisory-committee

[33] https://aspe.hhs.gov/proposal-submissions-physician-focused-payment-model-technical-advisory-committee

[34] E.g., https://podcasts.apple.com/us/podcast/health-for-all/id1530836259?i=1000548550683.

CHI again requests that CMS explicitly endorse the use of digital medical technologies in both MIPS and APMs. CHI supports Congress' goal of realizing innovative APMs and continues to work with stakeholders to find eligible alternatives to MIPS. APMs, with their financial and operational incentives, demonstrate the best uses of digital health tools. Because providers who practice in APMs are often judged on their ability to control patients' total spending, they have a natural constraint on fraud, abuse, and overuse that digital health's use might be susceptible to in a pure fee-for-service system.

To date, CMS has not discussed digital health tools' key role in the success of APMs which should have the flexibility to use connected health technologies for patients with specific at-risk chronic conditions. For example, the MSSP, by far Medicare's largest APM, CMS only waives patient location and geographic limitations on accountable care organizations (ACOs) that are at financial risk and use prospective assignment. There also haven't been case studies on ACOs' use of RPM. In order to help providers utilizing APMs meet statutory requirements to reduce total costs, CMS should exercise its statutory authority under 42 U.S.C. 1315a(d)(1) (in the case of CMMI Models) and 42 U.S.C. 1395jjj(f) (in the case of the MSSP) to waive payment and program requirements as appropriate. Specifically, CMS should allow wider use of telehealth in the MSSP by allowing all ACOs access to telehealth waivers and expand what telehealth waivers cover, for example, to include patient cost-sharing, modalities, and covered services.

CMS should also waive payment and program requirements as appropriate to provide flexibility for use of digital health innovations in APMs. Congress has already granted CMS broad authority to implement telehealth use in APMs, but the agency has so far been reluctant to allow its use. For example, Medicare provides telehealth waivers for two-sided ACOs who use prospective attribution. But this limits telehealth's use to a mere 17 percent of ACOs in the MSSP. Instead, all ACOs, regardless of risk selection or use of attribution, should enjoy this flexibility.

V. Conclusion

CHI appreciates the opportunity to submit comments to CMS and urges its thoughtful consideration of the above input. We look forward to the opportunity to further work with CMS and other stakeholders towards realizing the most successful PFS and QPP possible.

Sincerely,

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