ConnectedHealthInitiative

August 29, 2026

The Honorable Dr. Mehmet Oz
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 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program *[CMS-1832-P; 90 FR 32352]*

Dear Administrator Oz:

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 2026. 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. Executive Summary

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. Based on our commitment to the responsible use of digital health innovations, CHI provides a range of views and recommendations on PFS and QPP proposals and policies that impact the digital health community in the proposed CY 2026, including:

- ***Transform the Medicare System Using Wearables and AI:*** we highlight the transformative potential of AI in healthcare to enhance value-based care, improve population health, optimize clinical delivery, reduce administrative burden, and lower overall costs. We urge CMS to establish clear payment and incentive policies that leverage the power of wearables and the use of Patient Generated Health Data (PGHD) by wearable medical devices or general purpose platforms using software and associated AI tools. AI software has only begun to demonstrate its transformational impact in areas such as disease surveillance, fraud prevention, diagnostic applications, and patient care coordination. We encourage CMS to adopt modernized policies that properly classify Software as a Medical Device (SaMD) and medical AI tools as direct practice expenses rather than indirect software costs when practices incur expenses to use a technology in the provision of a given service. We also encourage a move toward national payment rates instead of fragmented contractor pricing. We stress that CMS has a critical opportunity in CY2026 to lead in updating its interpretation of payment methodologies to support safe and efficient integration of AI into Medicare, ensuring beneficiaries access cutting-edge digital medical innovations.
- ***Remote Physiologic Monitoring (RPM) and Remote Therapeutic Monitoring (RTM):*** CMS's 2026 proposed updates to the PFS for RPM and RTM continue positive momentum toward recognizing digital medical technologies and services, which is building experience and infrastructure to support the move towards value-based care models. We are grateful for the addition of new codes representing shorter time and monitoring increments for equipment supply as well as treatment management services, allowing tailored care, especially for patients with acute conditions. CHI recommends that CMS' payment for both RPM and RTM reflect new time increments as opposed to the same payment for lower time threshold supply of equipment codes.

  We also request that CMS permanently allow both new and established patients to access RPM / RTM and refine proposed limits to enhance multi-provider and multi-

device care, while expanding RTM indications beyond current device and diagnostic restrictions and for the adoption of RUC-recommended reimbursement rates for mental health devices. Further, CMS should not use contractor pricing for RTM respiratory nor cognitive behavioral therapy supply of equipment CPT codes. CMS should also provide more clarity on its proposal to use OPPS geometric pricing in recognition of clinical realities needed to fully meet patient and provider needs.

- ***Virtualization of Diabetes Prevention in Medicare:*** CMS is proposing major changes to the Medicare Diabetes Prevention Program (MDPP), expanding coverage for virtual and asynchronous online delivery to increase access for beneficiaries, especially in rural areas, and streamline supplier requirements so virtual-only organizations can enroll and participate through 2029. These positive proposals include aligning MDPP with Center for Disease Control (CDC) standards, removing the necessity for in-person delivery capabilities, updating weight reporting to allow self-reported or digitally captured data, and establishing payment rates for online sessions. However, concerns remain regarding lower reimbursement compared to in-person programs (despite evidence that virtual delivery achieves similar or better outcomes) as well as the need for reimbursement of practice expenses related to home-use medical devices similar to those used for remote monitoring. We encourage CMS to ensure payment parity, expanded eligibility for virtual suppliers, improvements in beneficiary awareness, and removal of barriers that restrict access or provider compensation for asynchronous engagement.
- ***The Proposed Ambulatory Specialty Model:*** We support CMS's proposed Ambulatory Specialty Model (ASM) as a significant move toward specialty-driven value-based care. Especially for chronic conditions like heart failure and lower back pain, emphasizing the importance of digital health tools in improving outcomes and enabling early interventions. We urge for several key modifications, including revising the financial structure to avoid payment cuts for most providers, making participation voluntary rather than mandatory, and setting clear advance performance benchmarks. We highlight the potential of efficacious medical wearables that generate PGHD and AI to enhance disease prevention and care coordination within ASM, and urge CMS to incorporate incentives for wearable use and data integration. Overall, we see ASM as a foundational framework for integrating digital medical innovations into specialty care under Medicare, fostering improved quality and cost control through advanced, technology-enabled chronic disease management.
- ***Medicare Telehealth Services:*** We commend CMS' proposals to expand and streamline Medicare Telehealth Services, including simplifying the process for adding or removing services from the Telehealth Services List, eliminating provisional status, adding new behavioral health services, and lifting frequency limits on certain visits. We support CMS' permanent recognition of real-time audio-

video supervision for most incident-to services which encourages broader access to audio-only telemental health for both new and established patients. We urge CMS to grant Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) maximum flexibility to use digital health tools beyond mental health, including for RPM, RTM, and chronic care services, while avoiding unnecessary in-person requirements. Further, we request that CMS minimize paperwork burdens, and to protect provider safety and privacy by continuing to allow distant practitioners to bill from their enrolled practice location.

- ***Direct Supervision via Virtual Modalities:*** We appreciate CMS' steps to expand the use of virtual supervision by allowing supervising physicians or practitioners to be present via real-time audio-video technology, and request that this policy be made permanent across as many services as possible. We also support CMS' proposal to permanently authorize direct supervision via audio-video beginning January 1, 2026, for most services under 42 C.F.R. § 410.26 and § 410.32.
- ***Digital Mental Health Treatment (DMHT):*** Numerous innovations in digital therapeutics are enabling safe and effective treatments across a wide range of health conditions, and we do not support CMS' proposal to broadly include those technologies under one HCPCS code. CMS should not expand indications currently under G0552 beyond FDA 882.5801. As digital therapeutic medical devices continue to evolve in scope and sophistication, there is an urgent need to create codes that adequately represent these technologies. Accordingly, CMS should adopt RUC recommended valuation and pay for CPT cognitive behavioral therapy remote monitoring codes (98XX6, 98978), and set national rates for DMHT HCPCS codes.

We offer the following input on the draft CY 2026 QPP rule for CMS' consideration:

- ***Merit-based Incentive Payment System:*** We encourage CMS to facilitate and reward the flexible and broad use of digital medical technologies, from remote monitoring to AI, throughout the Merit-based Incentive Payment System (MIPS), especially in its Promoting Interoperability (PI) component. CMS should avoid overburdensome MIPS PI program compliance and reporting requirements that contribute to provider confusion and burnout while doing little to improve patient care. The agency should move away from technology-specific mandates that reduce eligible practitioners' ability to adopt and scale their use of digital health tools to best provide value to beneficiaries.
- ***Alternative Payment Models:*** We share CMS' goal of developing a vibrant Alternative Payment Model (APM) ecosystem that will drive value for all beneficiaries. Digital health innovations play a central role in successful APMs by allowing data sharing with their participating physicians. Digital technologies facilitate patient access to the optimal mix of in-person, virtual, and remote

monitoring services that take advantage of the capabilities offered through medical wearables and AI. We urge CMS to utilize every opportunity available to move away from legacy measurement programs and towards a truly connected continuum of care through its implementation of the QPP.

II. 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.

III. 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 digital health technologies available today 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. 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 wearables 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 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 now overdue, it is essential CMS continues efforts to advance the range of connected health innovations that will help American healthcare improve outcomes and cost savings.

Thanks to CMS' expanded support, reliance on digital health technologies has increased over the last decade. Use of these tools continues to allow many underserved populations' access to prevention, diagnosis, and treatment for both acute and chronic conditions. 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.

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. 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.

IV. Connected Health Initiative Recommendations for the Proposed CY2026 Physician Fee Schedule

Building on the above, CHI urges CMS to align its CY2026 PFS with the following recommendations:

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,[1] 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 CY2026 PFS/QPP, CMS makes no proposal to alter this approach, which CHI supports.

During the PHE, CMS chose 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 forward, it is critical that such allowances be made permanent.

b. Remote Physiologic Monitoring and Remote Therapeutic Monitoring

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

CMS' continued support for remote monitoring capabilities, both Remote Physiologic Monitoring (RPM) and Remote Therapeutic Monitoring (RTM), continues to represent a significant and positive 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 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).

In the draft CY2026 PFS, CMS proposed to add new codes for 10-19 minutes of RPM management (CPT 99XX5) and 10-19 minutes of RTM management (CPT 98XX7). CHI supports these proposals because they advance critical updates that make remote care more flexible, accessible, and sustainable, particularly for patients with chronic and complex conditions. By introducing new remote monitoring codes for shorter time increments, CMS recognizes the diverse needs of both patients and providers, allowing more tailored and efficient virtual care delivery. These changes empower clinicians to better engage and manage patients outside traditional clinical settings while aligning payment with modern care practices built around continuous patient monitoring and digital tools. CHI applauds CMS's commitment to evolving Medicare payment to support innovative, technology-enabled care models that improve outcomes and extend access, reinforcing the role of virtual care as an essential part of mainstream health management.

CMS also proposes to add new device supply codes for both RPM and RTM that will also allow for data transmission over a period of 2-15 days per 30-day period (99XX4, Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial: device(s) supply with daily recording(s) or programmed alert(s) transmission, 2-15 days in a 30-day period; 99454, Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, 16-30 days in a 30-day period; 98XX4, Remote therapeutic monitoring (e.g., therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of respiratory system, 2-15 days in a 30-day period; 98976, Remote therapeutic monitoring (e.g., therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of respiratory system, 16-30 days in a 30-day period; 98XX5, Remote therapeutic monitoring (e.g., therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of musculoskeletal system, 2-15 days in a 30-day period; 98977,

Remote therapeutic monitoring (e.g., therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of musculoskeletal system, 16-30 days in a 30-day period; 98XX6, Remote therapeutic monitoring (e.g., therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of cognitive behavioral therapy, 2-15 days in a 30-day period; and 98978, Remote therapeutic monitoring (e.g., therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of cognitive behavioral therapy, 16-30 days in a 30-day period). CHI supports CMS' proposals to update its approach to remote monitoring in alignment with relevant CPT codes. CHI notes that CMS erroneously indicates at 90 FR 32435 that several CPT codes for remote physiologic and remote therapeutic monitoring have "No changes for CY 2026" when the CPT September 2024 Summary of Action makes clear that revisions have been made to codes 99453, 99454, 99457, 99458, 98975, 98976, 98977, 98978, 98980, 98981;[2] CMS should clearly indicate that it its policies are aligning with these significant coding changes (that they have been formally adopted in its regulations and policy).

CMS further proposes the same reimbursement rate for the new codes covering 2-15 days of data as the existing codes that cover 16 days of data. Further, CMS proposes using hospital outpatient data to set payment rates for the equipment supply portion of new and existing RPM (99XX4, 99454) and RTM (98XX5, 98977) codes, arguing that these costs are more representative than the RUC's recommended practice expense inputs, but CMS does not explain its reasoning for this approach. More detail is needed from CMS about how OPPS data will impact reimbursement and why these values are considered more accurate for remote monitoring devices. CHI requests that CMS clarify the specific rationale and effects of this payment methodology change.

Further, CMS should not apply contractor pricing to respiratory monitoring CPT codes 98XX4 and 98976. Since its introduction in 2022, code 98976 has been widely used across multiple specialties for monitoring chronic conditions, and 98XX4 is a new code for 2-15 days of monitoring data, complementing 98976's 16+ days. While the RUC recommends contractor pricing due to insufficient data to establish practice expense inputs, CMS previously approved payment for 98976 by crosswalking it to RPM code 99454's values, a reasonable approach that should continue. Contractor pricing would be a step backward, undermining continuity and predictability in reimbursement.

CMS should also accept the RUC's recommended $50 monthly fee for CPT code 98978 (RTM equipment supply for cognitive behavioral therapy) and establish a payment rate for the new code 98XX6 (2-15 days of monitoring data). The HCPAC recognized these digital

[2] https://www.ama-assn.org/system/files/sept-2024-summary-of-panel-actions.pdf.

therapeutic devices as FDA-authorized tools for tracking patient progress and supported the $50 fee based on submitted invoices. However, CMS proposes contractor pricing for both codes without addressing this recommendation. Considering the high prevalence and chronic nature of behavioral health conditions, CMS should adopt the RUC's valuation, activate coverage and payment for both codes, and list them for future review after accumulating more data. Contractor pricing would hinder access and consistent reimbursement for these important mental health tools.

Further, CHI urges CMS to take the following further 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 CY2026 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 (or proposed in this draft rule) 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 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, CHI urges CMS to avoid limiting a Medicare beneficiary to a

single clinician for their medically necessary care, including vulnerable beneficiaries with multiple illnesses.

- **For both RPM and RTM, "software as a Medical Device (SaMD)" used in medical practice should be categorized as direct PE.** We recommend that CMS' final CY2026 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.
- Finally, CHI understands that the RUC has submitted comments to CMS that offer several alternative approaches to CMS's proposed "efficiency adjustment" to the

work RVUs and practice expense adjustment to facility-based services.[3] CHI has confidence in the work of the RUC and values the input it obtains from specialty societies and practicing clinicians. We urge CMS to give serious consideration to the alternatives proposed by the RUC. In addition, CMS should work with the AMA to include the updated 2024 PPI Survey data in the physician fee schedule as the data being used currently is sorely in need of an update

c. RHC and FQHC Use of Communications-Based Technology Services & 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 value of RPM and RTM to improving care, and 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 has been, relative to the continued advancement of responsible support of RPM and RTM for general Part B beneficiaries, contributing to a widening gap between RHC and FQHC beneficiaries and other Part B beneficiaries, which directly undermines the goal of access to medically necessary care.

CHI therefore fully supported CMS' 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). More recently, CHI supported CMS' policy changes to require RHCs and FQHCs to bill individual codes (including CPT Codes 99435, 99454, 99457, and 99458) that make up the general care management HCPCS code, G0511, and that G0511 would no longer be payable when billed by RHCs and FQHCs; and to allow RHCs and FQHCs to bill the add-on codes for additional time spent once the minimum threshold of time was met to account for a complete encounter, with payment for these services being the national non-facility PFS payment rate when the individual code is on an RHC or FQHC claim, either alone or with other payable services and the payment rates are updated annually based on the PFS amounts for these codes. We continue to share CMS' perspective that both RPM and RTM offer numerous benefits that would particularly benefit patients that RHCs and FQHCs serve.

In the draft CY2026 rule, CMS is now proposing that FQHCs and RHCs be required to report individual codes that make up G0071 (for CTBS) instead of billing the bundled code alone. Payments for these services would be calculated using the non-facility PFS rate, .

[3] https://www.regulations.gov/comment/CMS-2025-0304-1994.

The relevant HCPCS/CPT codes for CTBS and remote evaluation include G0071 (5-minute CTBS by RHC/FQHC), G2010a (remote image evaluation), and G2012 (brief check-in. CHI supports this proposal and welcomes CMS' efforts to enable frontline providers across the country to use the range of digital health tools available to support beneficiaries and reduce costs.

d. Chronic Care Management Services

CHI supports CMS' efforts to enhance its support for Chronic Care Management Services (CCM) and urges for needed updates regarding how practitioners obtain beneficiary consent for Chronic Care Management services. Past PHE flexibilities 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. With the benefit of the PHE experience, it is now 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. Electronic Prescribing of Controlled Substances

CHI notes its continued support for improvements to electronic prescribing of controlled substances (EPCS) for beneficiaries. 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. To date, 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 supports the Administration's efforts to identify and eliminate outdated or ineffective regulations, and notes 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 the Administration's policy, 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 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 urge CMS to explore ways in which it can improve ECPS. We support CMS' expansion of electronic prescribing to date, 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.

f. Medicare Telehealth Services

More patients than ever before have turned to digital health platforms, tools, and services to consult with caregivers. Heightened utilization of Medicare Telehealth Services will be a critical factor in realizing greater value for Medicare.

In the draft CY2026 PFS, CMS proposes to simplify the process for adding or removing services from the Medicare Telehealth Services List by reducing the review steps from five to three, eliminating the "provisional" status and making qualifying services permanent once they meet the criteria of being separately payable, typically furnished face-to-face, and able to be delivered via interactive telecommunication. CHI supports CMS' proposed new approach to adding or removing services from the Medicare Telehealth Services List.

CMS also proposes to add several new services, including multiple-family group psychotherapy and group behavioral counseling for obesity, while removing some services such as social determinants of health risk assessment from the list. CMS also proposes lifting frequency limits on certain telehealth visits and adopts a permanent definition of "direct supervision" via real-time audio-video for most incident-to services, further expanding access. CHI generally supports CMS' updates and curation to the Medicare Telehealth Services List.

CHI further offers the following recommendations to CMS regarding Medicare Telehealth 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.
- 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.
- CMS is encouraged to keep paperwork burdens to a minimum to avoid wasted resources and provider burnout.
- We strongly encourages CMS to extend the current flexibility allowing distant site practitioners to bill under their currently enrolled practice location instead of their home address when delivering telehealth services from home, a policy that was extended for CY2025. Such a policy is necessary to address provider safety and privacy concerns, as well as administrative burdens.

g. Supervision via Remote Digital Modalities

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 permitting remote supervision as widely as practicable on a permanent basis to help Medicare providers and beneficiaries realize the widely recognized efficiencies of remote work across countless other sectors of the economy. CHI urges CMS to allow a physician/practitioner to be present through real-time audio-video technology

permanently. 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' extension of virtual direct supervision is a commendable step in the right direction.

Further, CHI supports CMS' proposal to, starting January 1, 2026, make permanent the allowance for direct supervision via real-time audio-video technology (excluding audio-only) for all services under 42 C.F.R. § 410.26, except for those with a global surgery indicator of 010 or 090, due to the higher risks involved in these complex procedures. This policy would also extends to applicable services under 42 C.F.R. § 410.32, including cardiac, pulmonary, and intensive cardiac rehabilitation services, enabling supervising practitioners to be virtually present in the office suite while immediately available to assist during the service.

h. Software-as-a-Service and Artificial Intelligence's Use in the Medicare System

Leveraging health data 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.[4] 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;[5] recommendations on ways to improve transparency for caregivers, patients, and others necessary for the appropriate uptake of AI tools across the care continuum;[6] and, most recently, a framework that advances a shared responsibility for efficacy and safety across the healthcare AI value chain.[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.

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

[4] 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/.

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

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

[7] The CHI's Roles and Interdependencies Framework is available at https://connectedhi.com/wp-content/uploads/2024/02/CHI-Health-AI-Roles.pdf.

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 and efficacy 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 Healthcare Improvement's "triple aim,"[8] a widely accepted compass to optimize health system performance,[9] 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.[10] Additionally, AI played a role in tracking helpful research that contributed to the COVID-19 vaccine.[11]

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 health care resource distribution. As more systems are created and deployed, the opportunity for AI to help improve healthcare

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

[9] Thomas Bodenheimer, MD and Christine Sinsky, MD, From 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.

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

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

outcomes across communities is significant, with estimates suggesting outcomes could be improved by 30-40 percent.[12]

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).[13] 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 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 CY2026 PFS rule, CMS asked a wide range of questions about the use of innovative technologies, including software-as-a-service 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 how Medicare can best leverage SaaS and AI innovations.

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[12] 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).

[13] 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.

We generally encourage CMS to monitor health AI developments that it can build on. 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.

1. *The Need for Updates to CMS' Practice Expense Data Collection and Methodology*

Over recent years, CMS has issued multiple requests for comments and information on technology and digital medicine topics, which parallel the topics addressed in this year's SaaS Request for Information. Despite CMS's repeated inquiries about software-based technologies and AI, and concerns about outdated methodologies for supporting clinical decision-making in outpatient and physician office settings, the agency has yet to provide substantive public clarity. CMS can, and should, make overdue modernization to its policies by explicitly incorporating Software as a Medical Device into the current payment methodology as a Direct Practice Expense RVU.

While CMS has traditionally considered SaMD to be an indirect cost (effectively, a refusal to reimburse any costs for SaMD), beginning in 2022, CMS has consistently indicated its interest in revising its approach to SaMD. Until that systemic change is accomplished, CMS has been cross-walking payment rates for SaMD-inclusive codes to different services' whole rates that are similar to what CMS would have paid if the SaMD product had been included as a direct input. CHI appreciates these interim steps taken by CMS, but recognizes that cross-walking is not a long-term solution. Given the rise of digital health solutions, CMS now has an ethical obligation to steward Medicare beneficiary access to leading clinically-validated SaMD treatment solutions. CMS should seize this opportunity to advance meaningful PE methodology reform, taking a leadership role in advancing modernized coverage and payment policies across the U.S. healthcare ecosystem.

In particular, software that is a Medical Device (SaMD) must be classified as a Direct Practice Expense under medical equipment, not as "computer software" that falls under indirect and non-allocable practice expenses. CMS has acknowledged that its current Practice Expense (PE) methodology struggles to account adequately for innovative technologies like software algorithms and AI, as noted in prior rules from 2021 and 2026. PE consists of direct costs (clinical labor, medical supplies, medical equipment) and indirect costs (administrative labor, office expenses, and other costs including computer software); direct costs are estimated per service, while indirect costs are mostly non-

allocable and based on outdated data from the Physician Practice Information Survey last conducted in 2007-2008, before many current digital health technologies existed. Software supporting clinical decisionmaking is simply “other expenses” like administrative labor. Since SaMD qualifies as a medical device, the regulatory and financial responsibilities for SaMD manufacturers are as stringent as those for hardware device makers. Therefore, categorizing SaMD as an indirect expense is inappropriate; it should be recognized and reimbursed as a direct practice expense aligned with medical equipment, whether physical or software-based.

It is inaccurate for CMS to exclude SaMD from its existing payment framework by treating it as indirect "computer software" rather than direct medical equipment PE. Historically, CMS has recognized procedure-specific software as direct PE inputs. SaMD continuously evolves with updates and cybersecurity improvements, which should be accounted for as direct PE costs, similar to disposable medical supplies. Although CMS has acknowledged that its PE methodology struggles to capture costs related to “computer software” properly, it has the authority and ability to integrate SaMD appropriately as direct PE. SaMD services are distinct procedures, as demonstrated by CMS’s coverage of augmentative software codes like Fractional Flow Reserve derived from Computed Tomography, which have defined beginnings and ends akin to new technology classifications in hospital outpatient settings. Additionally, as artificial intelligence increasingly augments or replaces provider work, CMS and the AMA have begun developing taxonomies to classify AI applications in healthcare. With AI automating professional work (e.g., autonomous retinal imaging analysis), CMS should apply existing direct PE payment methodologies to SaaS/SaMD reflective of medical equipment, not reduce it to indirect expense.

CHI strongly encourages CMS to make valuable SaaS/SaMD more accessible to Medicare beneficiaries by evolving its PE methodology to reflect the value that software provides by incorporating the value of software into CPT codes to address PE and/or work intensity for RVUs. Specifically, the value of services delivered by a physician to interpret or act on new digital health technology information should be included in work RVUs, and the value of the software used to address improvements and efficiency in patient care should be factored into practice expense RVUs. As CMS allows for SaaS reimbursement as direct supply inputs, CMS should obtain the most accurate estimate of the per-service cost of the input as possible, particularly by relying on invoices. CMS’ equipment amortization formula should only apply in the case of locally installed computer programs with an upfront payment where a useful life can be estimated and where that SaaS is only used in one service at one time. Further, because a service is represented by a fee does not mean that there are no indirect practice costs associated with using the service.

Relatedly, CHI is aware of CMS’ position (most recently articulated in the finalized TCET rule) that CMS does not have authority to establish new Part B benefit categories, and that benefit categories are statutory and established by Congress. However, the authorizing

statutory language for Medicare does not address digital health technology (with the exception of Medicare Telehealth Services, which are specifically addressed in statute) and also does not limit CMS' ability to provide coverage for digital health technologies within its existing benefit categories. 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. Notably, 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.

CY2026 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 Medicare beneficiaries. In its CY2026 PFS rulemaking, we strongly urge CMS to:

- Align with CHI's leading detailed health AI recommendations, including:
    - CHI's general principles addressing how policymakers like CMS should approach the role of AI in healthcare: https://connectedhi.com/wp-content/uploads/2022/02/Policy-Principles-for-AI.pdf
    - CHI recommendations on ways to improve transparency for caregivers, patients, and others necessary for the appropriate uptake of AI tools across the care continuum: https://connectedhi.com/wp-content/uploads/2022/02/AdvancingTransparencyforArtificialIntelligenceintheHealthcareEcosystem.pdf
    - CHI's roles and interdependencies framework that advances a shared responsibility for efficacy and safety across the healthcare AI value chain: https://connectedhi.com/wp-content/uploads/2024/02/CHI-Health-AI-Roles.pdf
- Rely on the CPT® Editorial Panel's 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.
- Continue to support and expand responsible payment for augmentative and autonomous AI tools that will drive greater access to innovative and efficacious care 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 SaaS and 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 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 and welcome the opportunity to meet with you to discuss the above.

i. Virtualization of Diabetes Prevention in Medicare

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. Ultimately, permanent changes are needed to finally leverage virtual interaction capabilities in this critical program.

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.

CHI also strongly urges CMS to make the MDPP a permanent Medicare covered benefit. Doing so could entice more potential suppliers to create their own diabetes prevention programs, seek CDC DPRP recognition, and apply to be MDPP suppliers, because such suppliers would know the tremendous efforts involved in establishing a program and becoming an MDPP supplier would be an investment in what could be a long-term MDPP product.

With respect to specific proposals for MDPP in the draft CY2026 rule and consist with our support for an approach to diabetes prevention that fully embraces digital health technology:

- ***Support for CMS Proposal to Expand Delivery Modalities:*** CHI strongly supports, with additional clarifications, CMS' proposal to evaluate inclusion of an asynchronous delivery option and to permit MDPP suppliers to furnish the full suite of MDPP services via online modalities through December 31, 2029. CMS has proposed adding a new paragraph (f) to [45 CFR 410.79] to operationalize this online pilot period. We commend CMS for its leadership in advancing the modernization of MDPP. Thoughtfully designed implementation of asynchronous online MDPP services has the potential to substantially broaden patient access, reduce costs across Medicare, and improve population health outcomes for diabetes and other chronic disease risk factors.
- ***Restricting Eligibility to Suppliers with Strong Recognition Track Records:*** Under the proposed rule, CMS would align MDPP program requirements with the 2024 CDC DPRP standards. Organizations would also be required to apply separately to CDC for each distinct delivery mode, resulting in unique organization codes (ORGCODEs) for every mode used. We support this alignment, and recommend that CMS strengthen the parameters for participation during the test period by limiting asynchronous online MDPP eligibility only to suppliers with current "Full" or "Full Plus" CDC DPRP recognition. Such a requirement ensures that entities with a demonstrated record of effective outcomes—specifically, the ability to help at least 60% of completers reach risk reduction targets—are the ones serving Medicare beneficiaries during this pilot.

  While CMS has previously opened participation to suppliers with "Preliminary" recognition to expand geographic access, the landscape has since shifted. As of August 2025, 24 organizations currently hold "Full" or "Full Plus" recognition for online delivery. Allowing these proven high-quality providers to participate meaningfully balances access with program integrity, while minimizing exposure to substandard performance. Should a supplier lose Full or Full Plus recognition during the test period, it should no longer be permitted to enroll new participants. For beneficiaries already engaged in the program, CMS should create clear

guardrails either to allow a seamless transition to another MDPP supplier or to permit completion of their course with their current provider. These measures protect beneficiaries while directing Medicare resources to organizations most capable of delivering validated outcomes.

- ***Payment Levels for Online Modalities Must Reflect True Costs:*** The proposed rule sets the reimbursement rate for an online MDPP core or core maintenance session at $18, compared to $25 for in-person delivery. This translates to a 28% lower rate per lesson and reduces maximum program payments by 21%. Online MDPP suppliers incur significant upfront fixed costs, such as technology investments and the provision of connected, medical-grade weight scales for participants. These devices are crucial not only for accountability but also for generating continuous data that allow lifestyle coaches to deliver targeted, personalized interventions that would not be captured under infrequent weigh-ins. Given these dynamics, CHI urges CMS to establish, at minimum, payment parity across delivery modalities during the pilot period. CMS's own outcomes data confirm that virtual delivery consistently achieves equal or greater weight loss compared with in-person engagement (5.3% vs. 4.6%). The long-term savings achieved by higher success rates justify payment parity and reduce the financial disincentives facing innovative online providers.

  Further CHI recommendations include:

  - Outcome-based Payments: Restructure payments so compensation is tied directly to weight loss milestones, such as $500 for 5% loss and $268 for 9% loss, rather than frontloading payments around lesson completion.
  - Bundled Upfront Payments: Following models such as Maryland Medicaid's DPP bundled reimbursement, CMS could provide a higher upfront payment at enrollment (to offset costs of device distribution and onboarding) alongside reduced per-session fees, while maintaining outcome-based bonuses.
  - Parity on Lesson Completion Codes: G9871 (asynchronous online delivery) should be reimbursed at the same level as G9886 and G9887 ($25), ensuring that online suppliers are not handicapped compared with in-person or distance-learning providers.

- ***Aligning Weight Collection Requirements with Current Standards:*** CHI agrees with CMS that flexibility in weight reporting should be maintained. However, the current requirement in § 410.79(c)(1)(ii)—mandating in-person weigh-ins—no longer reflects available capabilities for validated digital data capture. We recommend removing this section entirely. CMS should instead adopt the CDC DPRP standard of using participants' first and final recorded weights during Core and Core Maintenance phases. With the availability of connected digital scales transmitting

secure, validated readings, providers can meet recognition requirements and track outcomes without tying weight loss verification solely to synchronous, in-person interactions.

- ***Clarifying Virtual-Only Supplier Participation:*** CMS proposes clarifying that MDPP organizations participating in the test period are not required to maintain in-person delivery capabilities (§ 410.79(f)(2)). CHI strongly supports this needed clarification, as it lowers barriers for purely virtual providers and expands flexible access for beneficiaries.
- ***Increasing Beneficiary Awareness of Online MDPP Options:*** MDPP uptake has been persistently low, with fewer than 1% of eligible beneficiaries participating over the first six years, despite millions meeting eligibility criteria. Awareness is a central challenge. Beneficiaries looking for MDPP resources today often encounter directories reflecting only in-person delivery, with map-based listings that exclude online options. CMS should promptly update Medicare.gov and related beneficiary-facing resources to include virtual suppliers in provider directories, searchable via zip code. This visibility—and targeted program promotion—will be critical to ensuring that the online pilot fulfills its potential to bring diabetes prevention services to millions of Medicare enrollees.
- ***Live Coach Interaction Should Not be a Condition for Payment:*** CMS's proposal also contemplates withholding payment if asynchronous online participants complete lessons without engaging in real-time lifestyle coach interactions, as codified at § 410.79(f)(2)(i)(A). While lifestyle coach availability is important for participant support, requiring synchronous responses for payment creates undue administrative complexity and risks penalizing providers for circumstances outside their control (e.g., when a participant views and completes lesson content but does not respond to follow-up outreach). MDPP is an outcomes-driven program, and CMS should preserve that focus. Providers should not be denied payment for services rendered if participants fully engage with lesson content. Removing this unnecessary barrier will simplify implementation, mitigate administrative burden, and keep the program centered on measurable health improvement.

j. Advanced Care Primary Management (APCM)

CHI appreciates CMS' establishing payment under the PFS for APCM services described and defined in HCPCS codes GPCM1, GPCM2, and GPCM3. Building on this progress, CMS should allow providers billing APCM services to also furnish Behavioral Health Integration (BHI) and Collaborative Care Model (CoCM) services without requiring time documentation. Aligning these billing requirements would support a holistic, team-based care approach and simplify practice workflows. CMS proposes new optional add-on codes

(GPCM1, GPCM2, GPCM3) for APCM that mirror existing BHI and CoCM codes, facilitating billing for complementary behavioral health services alongside APCM. Additionally, CMS proposes to remove time-based documentation requirements for BHI and CoCM to reduce administrative burden and encourage broader provision of these services. CHI supports these proposals.

CMS should also waive cost-sharing for APCM services to ensure consistency and streamline billing, which will support the practical integration of prevention and treatment within care management and help providers deliver comprehensive care effectively and enhance patient outcomes. CMS should permit providers delivering APCM services to also provide BHI and CoCM services without needing to document time spent. Aligning these billing requirements would promote comprehensive, team-based care and reduce inefficiencies.

CMS also proposes optional add-on codes for APCM that correspond to existing BHI and CoCM codes, allowing simultaneous billing. Additionally, CMS would eliminate time-based documentation for BHI and CoCM services to ease administrative burdens and encourage broader access. CHI supports these proposals, and urges CMS to also waive cost-sharing for APCM services to streamline billing and support integrated prevention and treatment, enabling providers to deliver holistic care more effectively.

k. Digital Mental Health Treatment (DMHT)

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, we again 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.

CHI notes that broader barriers exist that prevent 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.

Building on the above, we offer the following views and recommendations for DMHT:

- In its CY2026 rule, CMS should activate CPT codes 98XX6 and 98978 for RTM of Cognitive Behavioral Therapy (CBT) and establish national coverage and payment for HCPCS code G0552.
    - Though G0552 and 98978 are related, they differ significantly. CPT 98978 is a Category I code widely recognized by private insurers, Medicaid, CMS, and MACs and is billed monthly without including setup or education, which is separately billed under CPT 98975. In contrast, G0552 bundles equipment and onboarding costs into one code billed once per treatment course and received a $0 CMS valuation.
    - Technologically, 98978 focuses on monitoring CBT delivery, whereas G0552 pertains to software devices delivering therapeutic mental health treatment. Devices covered under FDA regulation 21 CFR §882.5801 vary widely in complexity and function, justifying the need for distinct codes to capture this diversity.

- Similarly, CMS should not extend G0552, G0553, and G0554 coverage to devices under §882.5803 for ADHD, which target younger populations less relevant to Medicare beneficiaries. A one-size-fits-all approach risks misvaluation and provider confusion
- CMS should activate CPT 98XX6 and 98978 while setting a national payment for G0552 to reflect the spectrum of digital therapeutic devices. CMS should not broaden G0552 payment policies to cover other digital therapy devices outside §882.5801 (such as devices for gastrointestinal conditions, biofeedback, or fibromyalgia), but instead consider creating new codes as technologies emerge.

l. 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 continues to support CMS' amendment of 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.

CHI further offers the following feedback to CMS on the MSSP:

- ***Program Eligibility:*** Concerning the suggested modifications to the minimum number of beneficiaries, we express our support for CMS's initiatives to relax these minimum beneficiary requirements, which are intended to simplify entry conditions for new participants in the MSSP. Permitting new entrants the flexibility to achieve the 5,000-beneficiary threshold by the third year encourages broader participation, as opposed to obligating them to have a substantial patient population from the outset. Additionally, we propose an extended enrollment period for beneficiaries, allowing entrants more time to meet the threshold while acknowledging that they would assume financial risk during this extended ramp-up phase.
- ***Shortened BASIC Track Duration (Effective January 1, 2027):*** We likewise endorse this proposed adjustment, viewing it as a practical measure to lower the barriers for new entrants and facilitate easier participation in MSSP, thereby contributing to a more accessible and streamlined program structure.

m. Prevention and Management of Chronic Disease Request for Information

Digital health technologies offer tremendous potential to advance Medicare's prevention efforts by improving access, engagement, and early intervention. Most notably, wearable health devices have become widely available as tools to empower patients to proactively engage in their own efforts to combat disease. Wearables that provide timely and actionable patient-generated health data (PGHD) enhance situational awareness for both the patient and their care team, better informing decisions related to preventative measures and treatment plans. Recent advancements in edge computing (processing and storing data closer to the device), cloud computing, and AI/machine learning have enabled the development of numerous personal and population health innovations. Notably, wearables provide health insights through measuring various physiological and therapeutic metrics, including activity levels, sleep patterns, heart rate variability, and oxygen saturation. Such readings are critical to the detection of early warning signs that often signal the onset or further development of disease, providing a critical window to prevent disease. Further, chat-based healthcare services can play a vital role in preventing and managing chronic diseases by providing continuous support, empowering patients with timely information, and enabling early intervention through accessible and personalized communication with care teams. Such functionalities that support disease prevention and improve engagement in care provide CMS with an immense opportunity to reduce costs, and wearables and the data they provide should be the foundation for any modernized healthcare system. CMS can, and should, transform the Medicare system o embrace the preventative tools that wearables and PGHD provide. CMS can do this through, for example, launching new programs in Part B modeled after the Diabetes Prevention Program, which is set to see further virtualization in the CY2026 rule. CMS should consider new incentivizes to promote orchestration amongst devices and apps,

which would encourage the creation of scalable, integrated solutions while helping to reduce the inefficiencies and complexity associated with managing multiple apps and devices.

CHI recommends that CMS broaden Medicare coverage for digital care navigation services beyond the current focus on breast and cervical cancer, in order to provide timely, coordinated care across a wider range of conditions. While recent policy updates appropriately recognize the importance of navigation in cancer screening and follow-up, beneficiaries with other complex or chronic conditions, such as cardiovascular disease, musculoskeletal disorders, and mental health challenges, could also benefit from personalized, technology-enabled support.

Further, CMS could enhance the uptake, accessibility, and effectiveness of the Annual Wellness Visit (AWV) by integrating at-home diagnostic specimen collection solutions. These innovative technologies enable patients to collect samples easily and privately at home, which can then be sent to labs for testing. This approach complements in-person AWVs by making preventive care and chronic disease management more convenient and accessible, especially for patients with limited mobility or those in remote areas. Currently, CMS's practice expense methodology does not fully capture costs related to at-home testing, such as shipping kits to patients, sending specimens to labs, and the cost of the collection devices themselves. For example, CPT code 99001, which addresses specimen handling, is bundled with other services and not separately reimbursed, and there are no codes for many at-home testing kits like those for cervical cancer or HPV. This gap slows adoption of at-home testing, potentially increasing the cost and difficulty of preventive care. Given that many adults miss routine visits due to access barriers and that rural populations face worse health outcomes partly because of limited care access, CMS should advance policies that support at-home diagnostic specimen collection to improve AWV participation and preventive care efficiency.

n. The Proposed Ambulatory Specialty Model (ASM)

CHI generally supports CMS' proposed Ambulatory Specialty Model (ASM) as it represents a transformative step toward specialty-driven value-based care. By supporting effective use of health technology in outpatient specialist activities, ASM will promote a more proactive and integrated approach to chronic disease management, particularly for high-impact conditions like heart failure and low back pain. Further, CHI notes that permitting incentives (directly tied to managing the patient's targeted chronic condition and improving the specialist's performance under the model) worth up to $1,000 per beneficiary each year, and that such incentives will be shielded from liability under the Anti-Kickback Statute as well as the Beneficiary Inducements Civil Monetary Penalty provision, are crucial incentives. CHI views ASM as a key opportunity to embed digital

health tools such as remote monitoring, data analytics, and interoperable electronic health records into daily specialty care, enabling earlier interventions, better patient engagement, and improved outcomes.

We appreciate CMS's effort to design a specialty model and see clear benefits in incorporating wearables and the timely use of PGHD in ASM, yet targeted modifications are needed to ensure providers can succeed. Without these changes, digital health gains may not materialize, depriving patients and model participants of meaningful innovations.

The ASM's current financial structure would guarantee that most participating providers face payment cuts regardless of performance. By redistributing only 85 percent of funds and using a tournament approach with no advance performance benchmark, the model ensures more providers lose than gain, and even universal perfect scores would still result in across-the-board cuts. Instead of achieving Medicare savings by reducing provider payment rates, the model should support providers in reducing avoidable Medicare spending on hospitalizations and other services. Mandated participation for seven specialties in selected geographies is inappropriate and should be redesigned as voluntary. Requiring participation for providers treating as few as 20 patients with heart failure or low back pain risks basing payment adjustments on a small, unrepresentative subset of their overall panels. Tying adjustments to outperforming the median each year introduces uncertainty and undermines fairness and predictability. Although CMS aims to level the playing field for independent practices, the current design could push providers toward larger organizations to maintain financial stability. CMS should revisit the payment-adjustment methodology and set clear, advance performance standards that enable specialists, particularly in independent practices, to succeed without punitive cuts.

We note that wearable health devices have become widely available as tools to empower patients to proactively engage in their own efforts to combat disease. Wearables that provide timely and actionable PGHD enhance situational awareness for both the patient and their care team, better informing decisions related to preventative measures and treatment plans. Recent advancements in edge computing (processing and storing data closer to the device), cloud computing, and AI/machine learning have enabled the development of numerous personal and population health innovations. Notably, wearables provide health insights through measuring various physiological and therapeutic metrics, including activity levels, sleep patterns, heart rate variability, and oxygen saturation. While such readings are indispensable in disease treatment, they also enable the detection of early warning signs that often signal the onset or further development of disease, providing a critical window to prevent disease. These functionalities that support disease prevention and improve engagement in care provide CMS with an immense opportunity to reduce costs in the ASM.

With the Administration's renewed focus on tackling chronic disease, and especially with Secretary Kennedy's recent statements before Congress in favor of supporting the use of wearables, CHI believes that CMS should seize the opportunity by fully exploring the impacts wearables and timely leveraging of PGHD in the ASM, focusing on impacts on individual patient outcomes, population health management, and cost savings. ASM should explore both the prevention and treatment of disease, and explore how patient data will be protected, how the effectiveness of wearable devices in improving patient care will be evaluated, how data from wearables will be meaningfully integrated into treatment plans, and how the clinical validity and reliability of such data will be demonstrated. CMS should encourage the use of devices and technologies that provide predictive insights, deliver timely alerts, and integrate directly into patient care plans. Wearable device engagement could also be recognized within quality reporting, with bonus payments offered when usage reaches specific levels. Further, the ASM should incentivize the use of chat-based healthcare platforms that support beneficiaries by delivering ongoing guidance and real-time health insights, facilitating tailored interactions between patients and their care teams. These incentives could be built in through a tiered approach, rewarding providers with performance-based payments when a set proportion of their beneficiaries consistently engage with approved wearable technologies. Wearables' role in realizing Medicare reform is long overdue, and CMS has broad authority to design, test, and evaluate innovative payment and service delivery models, including pilot programs, aimed at reducing costs and improving quality within Medicare and Medicaid. Further, CMMI's focus on wearables is critical to realizing Secretary Kennedy's goal of providing every American with access to a wearable within four years.

ASM's design aligns well with the goals of digital health innovation by incentivizing specialists to leverage technology-driven care coordination and performance measurement. Its focus on longitudinal, patient-centered management supported by real-world data creates fertile ground for deploying advanced digital therapeutics and connected devices. As the healthcare system moves beyond fee-for-service models, ASM offers a crucial platform for demonstrating the value of digital health solutions in specialty care, accelerating adoption, and fostering innovation that can improve quality while controlling costs. This alignment makes ASM a foundational initiative for advancing specialty digital health under Medicare.

V. 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, it is estimated that nearly half the population suffers from at least one chronic illness, such as hypertension, heart disease, and arthritis. 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. 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. 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,[14] 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.

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

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

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.[15]

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.

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

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 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 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:

- We remind CMS PGHD can take various forms. Healthcare providers should be encouraged and rewarded for collecting information from their patients outside of scheduled appointments and procedures. When CMS and ASTP 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,[16] ASTP 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,[17] 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 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 ASTP 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

[16] 80 FR 62661; 45 CFR 170.315(e)(3).

[17] 80 FR 62851.

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 appreciates CMS' intent in proposing a new IA, IA_PSPA_XX, titled "Patient Safety Use of Artificial Intelligence," would involve developing a new data-collection field within patient safety reporting systems for AI-attributable events, including where actual harm was caused to a patient because AI technology was used, as well as near misses. However, CMS' proposal is fundamentally flawed because it would unfairly singe out AI instead of adopting a technology-neutral stance that prioritizes addressing patient safety issues regardless of which technology is involved. As an example using medical scribes, safety risks will present themselves whether a physician uses an in-person human assistant, a virtual human assistant, or an AI-powered scribe to document care; the practice should focus on mitigating those risks across all methods, rather than focusing only on one technology. Targeting only AI disproportionately highlights errors from one approach while overlooking similar safety concerns that can occur with other methods. CHI therefore urges CMS to revise its proposed IA to take a technology neutral approach; alternatively, CMS may wish to delete proposed IA_PSPA_XX entirely.
- CHI notes its agreement with CMS 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 ASTP 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.
- CHI supports various proposed PI measures that will, using a light touch, incent the leveraging of digital health innovations to address pressing public health needs. We urge CMS to make compliance burdens for PI participants as low as possible to maximize participation and support CMS moving 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 urges CMS to incentivize the integration of chat-based healthcare services in MIPS by directly rewarding clinicians who deploy secure, patient-centered communication technologies to improve care delivery, promote continuous patient engagement, and enable timely interventions for chronic disease management. CMS should recognize the use of these chat platforms as an activity under the IA category and also tie them to higher scores in PI by encouraging utilization of evidence-based conversational AI, messaging, or virtual care tools that enhance patient understanding, adherence, and health outcomes. By linking participation in

chat-based healthcare with value-driven payment adjustments, CMS can advance its vision for more accessible and proactive care across the nation.

- 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, ASTP 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 ASTP, along with a sister rulemaking by CMS. We urge CMS to continue to ensure its approach aligns with ASTP'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). ASTP'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 ASTP 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[18] (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

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

satisfaction, particularly for the chronically ill.[19] 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.[20] 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. 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 ASTP) 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 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 ASTP) 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 ASTP 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."[21] 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. ASTP'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

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

[20] 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.

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

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.
- 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 CY2026 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.[22]

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

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

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.

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),[23] 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.[24] 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.[25]

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. CHI supports CMS' explicitly endorse the use of digital medical technologies, including wearables and AI leveraging of PGHD for both prevention and treatment, in 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. In the immediate, CMMI should consider testing a digital-first APM that compares AI-enabled approaches with traditional models, using the outcomes framework described above by CHI. The goal is to demonstrate the value these tools bring to both providers and patients, and to show how AI can be successfully integrated into routine care. In this model, CMS should encourage the use of devices and technologies that provide predictive insights, deliver timely alerts, and integrate directly into patient care plans. Wearable device-driven

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

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

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

engagement, as well as the use of efficacious chat-based healthcare services, could also be recognized within quality reporting, with bonus payments offered when usage reaches specific levels. These incentives could be built into Medicare Advantage or broader value-based care models through a tiered approach, rewarding providers with performance-based payments when a set proportion of their beneficiaries consistently engage with approved wearable technologies

Further, to accelerate the adoption and effective use of digital health tools within accountable care organizations (ACOs), CHI recommends a comprehensive strategy that includes offering higher shared savings rates to ACOs that demonstrate successful digital implementation, providing grants or subsidies to offset upfront costs, and introducing bonus payments linked to patient engagement via digital platforms. In addition, permitting digital health investments to qualify toward risk-bearing requirements would encourage wider adoption. These policies would support the deployment of key technologies—such as real-time patient event notifications, automated quality reporting, predictive analytics, telehealth services, and the integration of diverse data sources, including EHRs, claims, and patient-reported outcomes.

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.

VI. 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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