ConnectedHealthInitiative

June 3, 2025

Alec Aramanda
Principal Deputy Director
Center for Medicare
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Dear Principal Deputy Director Aramanda:

The Connected Health Initiative (CHI) appreciates your leadership at the Centers for Medicare & Medicaid Services' (CMS') Center for Medicare. We look forward to supporting your efforts to improve patient outcomes, reduce costs, augment population health, and support the healthcare workforce.

CHI is the leading multistakeholder policy and legal advocacy effort dedicated to improving health outcomes while reducing costs. Our work is driven by the consensus of stakeholders from across the connected health ecosystem. CHI aims to realize an environment in which Americans can see improvements in their health through policies that allow for connected health technologies to advance health outcomes and reduce costs. CHI members develop and use connected health technologies across a wide range of use cases. We actively advocate before Congress, numerous U.S. federal agencies, and state legislatures and agencies, where we seek to promote responsible pro-digital health policies and laws in areas including reimbursement/payment, privacy/security, effectiveness/quality assurance, regulation of digital health, health data interoperability, and the rising role of artificial intelligence (AI) in care delivery. For more information on CHI, please visit https://connectedhi.com/.

Initially, we note our strong support for CMS' exploration of ways to use AI to improve patient outcomes and reduce costs. Across its payment programs and rules, we urge for CMS' alignment with the following, which are also appended:

- CHI's *Health AI Policy Principles*, a comprehensive set of recommendations on the areas that should be addressed by policymakers examining AI's use in healthcare, and how they should be addressed: https://connectedhi.com/wp-content/uploads/2022/02/Policy-Principles-for-AI.pdf;
- CHI's *Advancing Transparency for Artificial Intelligence in the Healthcare Ecosystem*, a proposal on ways to increase the transparency of and trust in health AI tools, particularly for care teams and patients: https://connectedhi.com/wp-content/uploads/2022/02/AdvancingTransparencyforArtificialIntelligenceintheHealthcareEcosystem.pdf;
- CHI's *Health AI Roles & Interdependency Framework*, which proposes clear definitions of stakeholders across the healthcare AI value chain, from development to distribution, deployment, and end use; and suggests roles for supporting safety, ethical use, and

fairness for each of these important stakeholder groups that are intended to illuminate the interdependencies between these actors, thus advancing the shared responsibility concept: https://connectedhi.com/wp-content/uploads/2024/02/CHI-Health-AI-Roles.pdf; and

- CHI's issue paper on the impact of standard-essential patent licensing abuses on digital healthcare: https://connectedhi.com/wp-content/uploads/2025/03/CHI-Issue-Paper-Healthcare-and-Standard-Essential-Patents-Feb-202568.pdf.

Building on leaps forward made during President Trump's previous Administration, CMS has incredible opportunity to leverage the immense value of health innovations that improve healthcare outcomes and secure significant cost savings, including telehealth, remote patient monitoring, and AI. We offer the following payment rule-specific recommendations to you, which will support your goals to modernize and improve the American healthcare system:

Medicare Physician Fee Schedule & Quality Payment Program

Software as a Medical Device (SaMD) as a Direct Practice Expense: We are encouraged that CMS recognizes that its existing practice expense (PE) methodology creates significant barriers to the uptake of digital health innovations through the classification of most SaMD as indirect practice expenses. However, CMS efforts to address this outdated and anti-innovation policy have stagnated, particularly during the previous Administration.

While the existing PE methodology is meant to account for a physician practice's costs, both direct and indirect, the ongoing choice of CMS to categorize SaMD as an indirect practice expense discourages the uptake and use of SaMD, remains one of the largest barriers to meaningful Medicare payment reforms, and is long overdue for a change. CMS' indirect methodology leverages cost bases and uses physician work relative value units (RVUs) but does not account for other factors like device maintenance.

While CMS began considering SaMD an indirect cost in 2019,[1] CMS has more recently indicated an interest in revising its approach to SaMD. CMS has been cross-walking payment rates for SaMD-inclusive codes to what CMS would have paid if the SaMD product had been included as a direct input. CMS has an obligation to steward Medicare beneficiary access to leading SaMD solutions and should seize this opportunity to advance meaningful PE methodology reform. We ask CMS to make these valuable SaMDs more accessible to Medicare beneficiaries by evolving its PE methodology to reflect the value that software provides by incorporating the value of software into Current Procedural Terminology® (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 SaMD 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

[1] *Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; et al*, 83 Fed. Reg. 59452, 59557 (Nov. 23, 2018).

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 SaMD is only used in one service at one time.

CMS should also 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.

Consistent with CMS' clear authority and its obligation to improve Medicare beneficiary outcomes, we call on CMS (1) to act in its Calendar Year 2026 Physician Fee Schedule rulemaking to effect overdue changes to its PE methodology to accurately categorize and support the use of SaMD in Medicare; and (2) to then launch a standalone consultation to inform broader reforms to its PE methodology. We appreciate your attention to this important issue and look forward to working with you to broaden beneficiary access to SaMD.

Telehealth: In key Medicare payment rules (e.g., the Medicare Physician Fee Schedule) CMS has enabled the expanded use of telehealth, which is restricted to live voice/video calls in Medicare due to statutory restrictions. The previous Administration insisted on a read of the Social Security Act (SSA) that imposes outdated constraints that long ago ceased to have public benefit on where and to whom these services are made available. CHI requests that CMS revisit its read of the SSA to appropriately and permanently avoid the application of SSA Section 1834(m) restrictions on telehealth services, as well as asynchronous remote monitoring and other digital modalities.

Remote Monitoring: In the first Trump Administration, CMS enabled the use of remote physiologic monitoring (RPM) and remote therapeutic monitoring (RTM) services for both acute and chronic conditions in Medicare Part B, representing a monumental step forward in advancing the use of digital health tools in the care of America's most vulnerable populations. CMS' payments for RPM should be increased to provide much-needed support for this critical modality that is vital in preventing and treating the system's most expensive chronic conditions. CMS should step forward in removing outdated barriers to innovation and use of RPM and RTM through such steps as waiving co-pay requirements for these services and providing guidance on remaining questions plaguing the RPM and RTM tech developer and provider communities to support its wider use, which is already demonstrated to improve outcomes while reducing Medicare costs.

Artificial Intelligence: Building on steps the first Trump Administration took to support AI innovation in healthcare, we call on CMS to take much needed action to recognize the value of countless AI tools (over 500 of which have already been approved by the FDA) to improve Medicare beneficiaries' experience and care by:

- Leveraging consensus medical AI terminology[2] and CHI's cross-sectoral consensus understanding of the unique roles and interdependencies/shared responsibilities amongst the healthcare AI value chain[3] as a baseline for CMS' approach to health AI.

[2] E.g., https://www.ama-assn.org/practice-management/cpt/cpt-appendix-s-ai-taxonomy-medical-services-procedures.

[3] https://connectedhi.com/wp-content/uploads/2024/02/CHI-Health-AI-Roles.pdf.

- Building on CHI's AI Policy Principles[4] and the leading efforts of the National Institute of Standards and Technology's voluntary AI Risk Management Framework[5] to ensure that a coordinated approach is taken to health AI that scales risk mitigation requirements to intended uses and known harms.
- Helping build trust amongst providers and beneficiaries by enhancing transparency consistent with CHI's recommendations in *Advancing Transparency for Artificial Intelligence in the Healthcare Ecosystem*.[6]
- Advancing Medicare coverage and payment policy changes that appropriately categorize AI (e.g., recognize that AI software as a medical device is appropriately categorized and paid for as a direct practice expense) and responsibly expanding support for AI's use in the prevention and treatment of beneficiaries' acute and chronic conditions.
- Advancing the an appropriately distributed responsibilities and liabilities in the healthcare AI value chain in alignment with CHI's Health AI Roles & Interdependency Framework,[7] which proposes clear definitions of stakeholders across the healthcare AI value chain, from development to distribution, deployment, and end use; and suggests roles for supporting safety, ethical use, and fairness for each of these important stakeholder groups that are intended to illuminate the interdependencies between these actors, thus advancing the shared responsibility concept.
- Continue engaging 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.

Diabetes Prevention: Another area overdue for action by CMS in its Physician Fee Schedule is diabetes prevention. While there is a significant and growing body of empirical evidence showing the benefits of digital health technology for diabetes prevention and treatment, this condition imposes a significant burden on CMS' Medicare program and its beneficiaries, totaling hundreds of billions of dollars each year. However, diabetes care is well-suited to digital medicine innovations because it requires interpretation of many kinds of data that can be captured through automation and biosensors. CMS can address the burden diabetes places on the Medicare program by:

- Finally including virtual diabetes prevention program providers who are CDC-recognized as part of the Medicare Diabetes Prevention Program (MDPP) under section 1115A(c) of the Social Security Act. CHI supports this proposed expansion, and the classification of the MDPP in Part B, as a timely and necessary step to address the diabetes crisis in the United States. CMS has already acknowledged the use of connected health tech products and services will be vital to the success of the MDPP.[8]
- Supporting virtual diabetes self-management training (DSMT), which would eliminate costly and time-consuming barriers to utilization of DSMT. CMS should also define certified

[4] https://connectedhi.com/wp-content/uploads/2024/02/CHI-Health-AI-Roles.pdf.

[5] https://www.nist.gov/itl/ai-risk-management-framework.

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

[7] https://connectedhi.com/wp-content/uploads/2024/02/CHI-Health-AI-Roles.pdf.

[8] 85 Fed. Reg. 50074 (Aug. 17, 2020).

diabetes educators (CDEs) as providers of DSMT. A 2014 report by the American Medical Association-convened Physician Consortium for Performance Improvement National Committee for Quality Assurance found an overwhelming majority of DSMT is carried out in primary care offices by non- "qualified diabetes educators."[9] CMS has the regulatory authority in the DSMT authorizing statute,[10] which states a certified DSMT provider is "a physician, *or other entity or individual designated by the Secretary"* [emphasis added] that provides DSMT and other Medicare services, to define a CDE. Recognizing CDEs as providers of DSMT care, including in telehealth, would help to address this gap in diabetes care.

Quality Payment Program (QPP): In the context of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)[11] implementation, we encourage you to prioritize an outcome-based approach, like those identified by Congress in MACRA, as opposed to an approach dependent on quantitative metrics. An outcome-based approach can support the inclusion of digital health tools in providing patient care as part of the Quality Payment Program (QPP).

CMS is still chasing the ideal of a value-based U.S. healthcare system. Unfortunately, utilization of digital health tools in the Merit-based Inventive Payment System (MIPS) and in Alternative Payment Models (APMs) remains unrealized. MACRA's implementation has not even begun to approach realizing congressional goals for the widespread development and uptake of APMs due to significant vulnerabilities in the existing process (e.g., a complete lack of coordination between the Physician-Focused Payment Model Technical Advisory Committee and the Center for Medicare & Medicaid Innovation, neither of which produced successful physician-led models). As a result, APMs that encourage the responsible use of innovative digital health tools are severely lacking.

CHI strongly encourages you to undertake a new effort to identify regulatory changes needed at the federal level to advance value-based care in the American healthcare system by leveraging digital technologies, with a focus on eliminating healthcare disparities. Such an effort should also prioritize new ways to incent innovation by private payers to systemically advance value-based care. CHI commits to work with HHS and any impacted stakeholders to develop a consensus path forward that will bring the vision of value-based care to fruition.

CMS can make major progress in QPP towards this goal through:

- Reducing the reliance on CMS program participation and the use of Certified Electronic Health Record Technology (CEHRT) through the continued evolution of the Promoting Interoperability (PI) Program. The Health Information Technology for Economic and Clinical Health (HITECH) Act incented physicians to purchase and use electronic health records (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

[9] American Medical Association-convened Physician Consortium for Performance Improvement National Committee for Quality Assurance. Adult Diabetes: Performance Measures. January 2014.

[10] 42 U.S.C. 1395x(qq).

[11] Medicare Access and CHIP Reauthorization Act of 2015, Public Law No. 114-10, 129 Stat. 87 (2015).

measure and report on CMS requirements—and are disincentivized 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.

- Permitting a professional to satisfy the demonstration of meaningful use of CEHRT and information exchange through attestation, which is allowed under existing law. HITECH 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.
- Developing, and publicly releasing, a comprehensive vision of a diverse array of connected health products and services, including telehealth, remote monitoring, and AI, playing an integral role in the success of APMs, and providing specific incentives and credits for the responsible use of these digital health tools.
- Using Medicaid waiver authority to permit states to include dual eligibles in their telehealth programs and establish programs for dual eligibles like Diabetes Prevention Programs, as age appropriate.
- Waiving Medicare's telehealth restrictions (under Social Security Act Sec. 1834(m)) for all shared savings programs and APMs, including payment bundles and medical home demonstrations.

Home Health Prospective Payment System (HHPPS)

CMS has included remote monitoring expenses used by a Home Health Agency (HHA) to augment the care planning process as allowable administrative costs that are factored into the costs per visit. Such a change ensures that remote patient monitoring is utilized on a cost per visit basis when it is used by an HHA to augment the care planning process and will result in a more realistic HHA Medicare margin calculation. Remote monitoring will be helpful in: (1) augmenting HHA services in the patient's plan of care; (2) enabling HHAs to more rapidly identify changes in a patient's clinical condition and to monitor patient compliance with treatment plans (further enabling more effective and efficient review and appropriate alteration of plans of care); and (3) augmenting home health visits. However, CHI strongly urges CMS to align its definition of "remote patient monitoring" in the HHPPS with that captured in relevant CPT codes. While CMS correctly and proactively distinguishes between "remote monitoring" services and "telehealth" in this and other rulemakings, CHI suggests that CMS, in the HHPPS, contribute to a common definition of "remote patient monitoring" across its beneficiary programs (e.g., consistency with relevant CPT codes).

The HHPPS is also overdue for modernization to permit the use of digital health innovations that would benefit both providers and beneficiaries. CHI requests that CMS undertake a new effort, including a public consultation, to address ways the HHPPS can be modernized and improved. We commit to work with CMS and any other impacted stakeholders to develop and advance consensus policy changes.

Medicare Advantage (MA)

CMS should provide MA plan sponsors with the discretion to make the determination that different digital health services are clinically appropriate, and to offer those services to beneficiaries as needed. CMS should make clear that those services that do not meet the definition of Medicare telehealth services (in other words, all services that are not live voice/video calls) do not face the onerous restrictions of Section 1834(m) of the Social Security Act. Currently, regulations provide that MA plans cover Part B benefits provided via electronic exchange as "additional telehealth benefits" (including RPM) and as a basic benefit as defined in § 422.101. We strongly encourage CMS to ensure MA plans' alignment with CMS' established approaches to Medicare fee-for-service telehealth services, including remote patient monitoring and other "remote communications technology" that CMS has expressly stated do not fall under 1834(m) and its restrictions. CMS should also fully leverage the potential of AI in accomplishing MA goals.

In addition, CMS should modify its MA/Part D and Accountable Care Organization risk adjustment policy to incorporate diagnoses from digital health-enabled remote encounters, including audio-only telehealth services where clinically appropriate.

Medicare Shared Savings Program

CMS should exercise its statutory authority under 42 U.S.C. 1395jjj(f) to waive Medicare Shared Savings Program 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. Doing so more broadly would further the success of APMs.

Center for Medicare and Medicaid Innovation (CMMI): Even CMMI's newest models do not adequately focus on exploring innovative technological healthcare delivery mechanisms. A 21st century healthcare system should embrace the array of new technologies available, such as RPM technologies and asynchronous store-and-forward methods, which enable the delivery of healthcare solutions beyond the four walls of a hospital room or doctor's office. We urge you to prioritize a new CMMI path which embraces the use of new technologies in Medicare and Medicaid that will widely benefit beneficiaries.

CMMI should also take new steps to reduce the burdens for potential model applicants. CMMI should articulate consistent requirements that are applicable to all models being tested, rather than developing separate requirements for each. The burden for applicants and participants could be reduced through uniform processes, expectations, principles, and rules that span models like population health and chronic conditions that are being tested. To align payers with the goals of the CMMI models and incent their participation, CMS should build upon the QPP to encourage the development of models that are based on existing structures and payment models and allow existing networks to apply as Advanced APMs to make these entities eligible for Medicare bonuses and programs like MIPS and the QPP. In exploring the benefits of telehealth as defined in 1834(m), CMS should use its established authority to waive the backward-facing and outdated restrictions. CMMI should also focus on exploring new and innovative remote monitoring technologies (which are not telehealth under 1834(m) and therefore do not face its geographic, originating site, etc.,

restrictions). We further urge CMMI to build upon the successes of the Veterans Health Administration in its use of connected health technologies.

CMMI should also recognize and build upon the incredible successes of health systems such as the University of Mississippi Medical Center, the University of Virginia, and Boston Children's Hospital. In these locations (and some others), Medicaid programs have taken steps to support not only telehealth but—more importantly—remote monitoring innovations that bring patient-generated health data (PGHD) into the continuum of care based on demonstrated improvements to patient outcomes and significant cost savings. CMMI can and should play a crucial role in proliferating these successes.

CMS should also continue support beneficiary engagement in accountable care relationships and quickly address the pending expiration of CMMI's Accountable Care Organization (ACO) Realizing Equity, Access, and Community Health (REACH) model on December 31, 2026. Absent timely interventions, beneficiary care may be impacted as model participants will have insufficient time to plan for ongoing care coordination.

Durable Medical Equipment (DME)

CMS should, under its existing authority, discard the arbitrary limitations it places on DME payments to support the responsible uptake and use of digital health technology innovations. CMS' approach today to DME either entirely excludes or insufficiently supports the use of software in medical equipment that is increasingly essential to cutting-edge care. CMS is long overdue to provide a pathway for coverage under DME for software as a medical device (SaMD) that is primarily utilized for a medical purpose even when there are other uses of the software or the product the software is in. For example, if a device is capable of acting as a pulse oximeter and heart rate monitor, then it should be eligible for coverage as DME even if the device has other non-medical capabilities. DME coverage of software should also extend to SaMD therapeutics cleared by the FDA. In addition, support for such software in DME should be unbundled, with needed updates to the software supported as DME supplies when they are integral to the functioning of the underlying DME software.

CMS can take modest steps today to improve the DME program. For example, while CMS established that "therapeutic continuous glucose monitors (CGMs)" can be billed to CMS for both the DME component and an all-inclusive supply allowance, in 2018 local Medicare contractors issued a coverage determination that resulted in rejection of the supply allowance if a smart tablet or smartphone-compatible mobile medical app is used in conjunction with the CGM device and biosensors. This interpretation by Medicare contractors was not dictated by law and resulted in a programmatic policy that ignores the many efficiencies of secure connected medical technologies that have the ability to ease the burdens on patients while reducing costs to Medicare in DME payments. CMS has the ability to change their course under existing authority and appears to have intervened to address the decisions of local Medicare contractors in this specific instance; however, due to the continued confusion created by Medicare contractors and CMS' policy correction regarding CGMs, CHI strongly urges CMS to ensure that the use of dual-use connected technology as DME is permitted widely through its DME rules.

DME enabled by internet connectivity and new, innovative features can and should be permitted to meet CMS' requirement for face-to-face encounters. Care providers can leverage connected

health technology to obtain DME PGHD for continual evaluation and treatment of conditions. Such capabilities negate the need for an annual demonstration of medical necessity through their ongoing collection and transmission of PGHD. Therefore, CMS should eliminate this annual certification requirement when RPM can demonstrate medical necessity.

Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems

CHI generally supports CMS' efforts to modernize the OPPS and ASC through the appropriate inclusion and support of digital health technology innovations that will improve patient outcomes and reduce program costs. We urge CMS to take the following steps:

- Responsibly expand the availability of critical mental health services already demonstrated to improve patient outcomes while reducing costs. CHI continues to support CMS permitting mental health services furnished remotely by hospital staff using communications technology to beneficiaries in their homes as covered outpatient department services payable under the OPPS, and to create OPPS-specific coding for these services.
- Take all steps necessary to ensure that critical access hospitals (CAHs) and REHs are able to provide services via the most appropriate and accessible modality, whether live voice/video or asynchronous modalities including remote monitoring. CAHs and REHs, at the front lines of care for America's most underserved populations, need the ability to monitor key PGHD metrics. CAHs and REHs should enjoy support that Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) enjoy for remote monitoring in the PFS.
- Leverage health data, including social determinants of health (SDOH) and PGHD with AI tools (and software as a service [SaaS] AI applications) holds incredible promise for advancing value-based care in research, health administration and operations, population health, practice delivery improvement, and direct clinical care. Building on its incrementally-increasing support for AI in the OPPS over recent years, we urge CMS to provide robust incentives in the OPPS for the use of AI, and to invest in building infrastructure, preparing personnel and training, as well as developing, validating, and maintaining AI systems to ensure value.

Part D

CHI generally supports CMS' work to provide clarity on Medicare Part D plan sponsor requirements but remains concerned that CMS is not enabling the maximum potential of digitally-enabled pharmacies that provide convenient and efficient home delivery that Americans across the country expect. CMS should take clear steps to support digitally-enabled pharmacies by avoiding applying the same requirements to each pharmacy type, as the previous Administration proposed, which will hold back digitally-driven efficiencies from countless beneficiaries without benefit to them.

The agency should further support adoption of digital forward technologies through modernizing Medicare Part D's convenient access standards to reflect the current state of pharmacy access. New policies should support beneficiary choice and convenience by removing the distance-based

geographic constraints and enable plans to meet such standards through non-Pharmacy Benefit Manager-owned mail-order pharmacies.

In alignment with ASTP, CMS should advance policy that allows pharmacies to directly surface real-time pharmacy benefit information for Medicare Part D beneficiaries at the point of sale, supporting choice, convenience and affordability.

Absent congressional action to address the issue, CMS should promulgate rulemaking for standard terms and conditions for pharmacies participating in Medicare Part D that does not disadvantage digital-forward pharmacies unaffiliated with a Pharmacy Benefit Manager (part of the *any willing provider* language).

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We look forward to working with you on behalf of digital health providers, connected device manufacturers, and patients who benefit from the variety of available digital health services.

Sincerely,

Brian Scarpelli
Executive Director

Chapin Gregor
Policy Counsel

Connected Health Initiative
1401 K St NW
Suite 501
Washington, DC 20005