ConnectedHealthInitiative

August 29, 2025

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: Comments of the Connected Health Initiative, Medicare and Medicaid Programs; Calendar Year 2026 Home Health Prospective Payment System (HH PPS) Rate Update; Requirements for the HH Quality Reporting Program and the HH Value-Based Purchasing Expanded Model; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program Updates; DMEPOS Accreditation Requirements; Provider Enrollment; and Other Medicare and Medicaid Policies (CMS-1828-P; 90 FR 29108)

Dear Administrator Oz:

The Connected Health Initiative (CHI) appreciates the opportunity to respond to the Centers for Medicare & Medicaid Services (CMS) on its draft calendar year (CY) 2026 rules for Medicare home health agencies (HHAs) as well as updates to its Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP).[1]

I. Introduction & Statement of Interest

CHI is the leading multistakeholder consensus 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

[1] Medicare and Medicaid Programs; Calendar Year 2026 Home Health Prospective Payment System (HH PPS) Rate Update; Requirements for the HH Quality Reporting Program and the HH Value-Based Purchasing Expanded Model; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program Updates; DMEPOS Accreditation Requirements; Provider Enrollment; and Other Medicare and Medicaid Policies, 90 Fed. Reg. 29108 (July 2, 2026).

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. CHI is committed to achieving a Medicare system that serves beneficiaries effectively by leveraging the range of digital health tools available today as well as those in development, to improve outcomes while reducing costs.

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

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, CMS should support the use of wearables and patient-generated health data (PGHD) through AI. There are various applications of AI systems in healthcare 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 and 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.

Notably, the ability of HHAs to adapt to serve those most in need of care is reflected in the patient severity scores of those served by HHAs increasing year-over-year. 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 overdue, CMS' continued efforts to advance the range of connected health innovations that will help American healthcare improve outcomes and cost savings are essential.

Statutory restrictions and certain CMS regulatory-level policy decisions, among other red tape, can inhibit the use of digital health solutions. More broadly, the total number of HHAs is declining, and utilization of digital health innovations that could bring both drastically improved beneficiary outcomes as well as immense cost savings have been excruciatingly low. Rural counties, traditionally suffering from a lack of access to care, would greatly benefit from expansion of HHA access. Unfortunately, without further action from CMS, many rural counties have access to at most one HHA provider. Lack of access to early healthcare visits places an additional burden on the emergency departments of hospitals serving rural and low-access areas driving up overall healthcare costs.

CMS' coverage of remote monitoring began in CY2018, when Current Procedural Terminology (CPT®) Code 99091 was unbundled. In the calendar year 2019 and 2020 Physician Fee Schedules (PFS), CMS took significant steps forward in activating and paying for four remote *physiologic* monitoring codes, with subsequent steps taken in CY2022 to support a new family of remote *therapeutic* monitoring use cases. 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.

In the Home Health Prospective Payment System (HHPPS), CMS took a key step forward in CY2019 by allowing remote patient monitoring costs incurred by an HHA for purposes of augmenting the care planning process to be included in allowable administrative costs that are factored into the costs per visit. Such a change ensured utilization of remote patient monitoring can occur on a cost per visit basis when used by an HHA to augment the care planning process, and a more realistic HHA Medicare margin calculation. CHI agrees with CMS that remote patient monitoring will be helpful in (1) augmenting HHA services in the patient's plan of care; (2) enabling HHAs to identify changes more rapidly 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.

Further, outdated DME coverage rules explicitly exclude many digital health and software solutions because these technologies typically do not meet Medicare's strict criteria. To qualify as DME under Medicare Part B, equipment must be tangible, reusable, primarily and customarily used for a medical purpose, able to withstand repeated use, have an expected lifespan of at least three years, and be appropriate for use in the home. Most digital health products, including software-as-a-service (SaaS) platforms, should meet these requirements, but are excluded by CMS. Consequently, Medicare DME rules generally do not cover many software solutions despite their growing medical utility.

The pace of uptake for digital health innovations in the Medicare system (both in the HHPPS and with respect to DME rules) 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. With the congressionally

mandated shift from fee-for-service to value-based care in Medicare approaches, CMS' efforts in continuing to advance a range of connected health innovations that will help American healthcare the improve outcomes and cost savings. It is essential HHAs leverage the wide range of connected health tools and services available today, as well as those in development to advance care and lower costs.

III. Input of the Connected Health Initiative on CMS' Proposed CY2026 Home Health Prospective Payment System

We commend CMS' continued support for HHAs to use digital health technologies to date, but urge for much-needed further modernization in HHPPS policy to enable and incentivize HHAs to leverage wearables and the PGHD they collect with cutting-edge AI software. CHI offers its views on several aspects of the HHPPS impacting the use of digital health technologies, particularly remote patient monitoring, considering the priority to advance innovative value-based care solutions while protecting the integrity of the Medicare program:

- CHI agrees that HHAs should continue to report the use of telehealth and remote patient monitoring on home health claims using designated G-codes, which will improve CMS's tracking of such care modalities.
- CHI agrees that HHAs should continue to justify how digital health modalities help achieve the care goals for each patient, as included in the plan of care.
- CHI supports CMS efforts to advance digital quality measures as part of the Home Health QRP, which should utilize digital-first approaches and measures captured directly through digital platforms, instead of traditional paper-based or manual submission.
- We urge CMS to build on HHPPS experiences from the COVID-19 PHE (and since) to:
    - Allow HHAs to provide more services to beneficiaries using telecommunications technology (which CMS has previously clarified "can include remote patient monitoring; telephone calls (audio only and TTY); and 2-way audio-video technology that allows for real-time interaction") between the clinician and patient within the 30-day period of care, so long as it's part of the patient's plan of care and does not replace needed in-person visits as ordered on the plan of care (while acknowledging that the use of such technology may result in changes to the frequency or types of in-person visits outlined on existing or new plans of care).
    - Allow for required face-to-face encounters for home health to be conducted via telehealth (i.e., two-way audio-video telecommunications technology that allows for real-time interaction between the physician/allowed practitioner and the patient), which ensure continued access to video-based telehealth and reduce regulatory barriers for both agencies and patients.
    - Amend regulations to provide HHAs with the flexibility, in addition to remote patient monitoring, to use various types of technologies in conjunction with the provision of in-person visits, specifically:

        - Clarify at § 409.43(a) that the use of technology must be related to the skilled services being furnished by the nurse/therapist/therapy assistant to optimize the services furnished during the home visit or when there is a home visit; and
        - Clarify at § 409.43(a) that the use of technology must be included on the home health plan of care along with a description of how the use of such technology will help to achieve the goals outlined on the plan of care without substituting for an in-person visit as ordered on the plan of care (and giving HHAs flexibility on the timing in which they obtain physician signatures for changes to the plan of care when incorporating the use of technology into the patient's plan of care by only requiring that the plan of care must be signed prior to submitting a final claim to Medicare for payment (§ 409.43(c)(2)).
    - Allow HHAs to provide services based on verbal orders in accordance with the regulations at §§ 484.60(b) and 409.43(d).
    - Allow HHAs to report the costs of telecommunications technology as allowable administrative and general costs by identifying the costs using a subscript between line 5.01 through line 5.19.

  CHI urges CMS to take all possible steps to make permanent the digital health-related allowances for HHAs during the PHE. Such permanent policy changes are essential to providing basic care to the vulnerable populations HHAs serve and would better align the HHPPS with other Medicare programs increasingly supporting the use of synchronous and asynchronous digital modalities such as the PFS.

- We request that CMS ensure that its digital health allowances for HHAs enhance value-based care by taking all steps possible to avoid exposing HHAs to CMS' low utilization payment adjustments that would rise due to an increasing number of visits occurring via telehealth, as only in-person visits count for purposes of an HHA qualifying for payments. Allowing for telehealth visits to also count for HHAs would avoid lowering payments to HHAs for using telehealth when CMS is otherwise seeking to encourage its use. Providing HHAs with certainty that telehealth visits will count to avoid low utilization payment adjustments will also provide economic certainty to potential entrants, encouraging growth in the number of HHAs.
- CHI again strongly urges CMS to align the HHPPS definition of "remote patient monitoring" with the definitions of remote physiologic and therapeutic monitoring captured in CPT codes that CMS has activated and paid for in the Physician Fee Schedule (e.g., CPT codes 99453, 99454, 99457, and 99458; and new codes adopted in the PFS as appropriate). While CMS correctly distinguishes between "remote monitoring" services and "telehealth" in the HHPPS rules, CMS borrows heavily from CPT code 99091 in defining "remote patient monitoring" as the "collection of physiologic data (for example, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the HHA;" and today leverages G0322 ("Collection of physiological data that is stored and transmitted") in its reporting/tracking as discussed above. CPT code 99091 does describe

the collection of physiologic data but, as CMS has acknowledged in the CY2018 PFS, "…activating CPT code 99091 for separate payment under Medicare for 2018 will serve to facilitate appropriate payment for these services in the short term" as this code and its descriptor does not capture all remote patient monitoring elements. CMS then, in years following, activated and paid for appropriate remote physiologic and therapeutic monitoring codes (with physiologic and therapeutic monitoring captured in separate code families) that provide for the supply of devices; set up and instruction; data collection; transmittal; and report preparation of quantitative results.

CMS' use of disparate remote patient monitoring definitions between the HHPPS and the PFS has resulted in HHAs being unable to include remote physiologic or therapeutic monitoring as administrative costs associated with visits to a beneficiary's home for the sole purpose of supplying, connecting, or training the patient on the remote monitoring equipment. To date, CMS has not offered any explanation as to why this disparity is in the public interest.

CHI strongly encourages CMS to, in the HHPPS, contribute to a common definition of "remote patient monitoring" across its beneficiary programs by ensuring consistency with codes that support remote physiologic and therapeutic monitoring.

- CHI continues to support CMS' continued inclusion of remote patient monitoring expenses incurred by an HHA to augment the care planning process as allowable administrative costs that are factored into the costs per visit. CHI agrees with CMS that remote patient 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.

  Still, CMS needs to provide key clarifications regarding remote patient monitoring's use by HHAs which have left HHAs reluctant to undertake remote patient monitoring for HHPPS beneficiaries. CHI calls on CMS to address these questions and ambiguities in its final CY2026 HHPPS rule by providing more detailed guidance on the use of remote patient monitoring by HHAs. Further, we call on CMS to explain how uses of remote patient monitoring technologies by HHAs and Part B eligible caregivers' use of remote patient monitoring (CPT codes capturing remote physiologic monitoring; as well as codes capturing remote therapeutic monitoring) relate. The home health stakeholder community would also benefit immensely from CMS describing its vision for supporting future use of remote patient monitoring and other digital health technologies for HHPPS beneficiaries.

  And while inclusion of remote patient monitoring expenses incurred by an HHA to augment the care planning process as allowable administrative costs represents an important step forward for the HHPPS, we urge CMS to acknowledge in its final CY2026 HHPPS rule that the policy change is incremental because the HHPPS must do more to encourage the uptake of remote monitoring by HHAs. We recommend CMS to take all steps possible to accomplish further policy changes needed to help HHPPS beneficiaries fully realize

improved health outcomes through the responsible use of digital health technologies, which CMS has already acknowledged as a basis for expanded support for remote patient monitoring for over four years in PFS rulemakings. As noted above, CHI supports CMS' decision to use G-codes that would assist in "identifying when home health services are furnished using synchronous telemedicine rendered via a real-time two-way audio and video telecommunications system; synchronous telemedicine rendered via telephone or other real-time interactive audio-only telecommunications system; and the collection of physiologic data digitally stored and/or transmitted by the patient to the home health agency, that is, remote patient monitoring;" and to phase in HHA reporting of the same. We agree that such reporting helps CMS analyze the characteristics of HHPPS beneficiaries utilizing services furnished remotely and will give CMS a broader understanding of the social determinants that affect who benefits most from these services, including what barriers may potentially exist for certain subsets of beneficiaries. We appreciate CMS providing insights from the data it has collected so far to contribute to its further responsible support of digital health for HHPPS beneficiaries.

- CHI agrees that remotely monitoring patients receiving infusion therapy in their home is integral to providing medical care. CHI continues to support CMS coverage of remote patient monitoring services as part of the home infusion therapy services benefit, as well as CMS requiring qualified home infusion therapy suppliers to provide remote monitoring services for continuous assessment, evaluation, response, and an allowance for suppliers to use all available remote monitoring methods available. Building on this important policy that has now been in place for several years, we call on CMS to clarify that CPT codes for remote physiologic and therapeutic monitoring activated in Part B may be billed by eligible professionals while their patients receive the home infusion therapy services benefit.
- CHI applauds CMS' (and ONC's) efforts to encourage and support the adoption of interoperable health information technology and to promote nationwide health information exchange to improve health care and patient access to their digital health information. Electronic health information and educational resources are critical tools that empower patients to engage in their own care. A truly interoperable connected healthcare system includes patient engagement facilitated by asynchronous (also called "store-and-forward") technologies (ranging from medical device remote monitoring products to general wellness products) with open application programming interfaces (APIs) that allow the integration of PGHD into electronic health records (EHRs). Data stored in standardized formats with interoperability facilitated by APIs provides analytics as well as near real-time alerting capabilities. The use of platforms to manage data streams from multiple and diverse sources will improve the healthcare sector, and help eliminate information silos, data blocking, and deficient patient engagement.

  To fully realize the potential of a value-based care healthcare ecosystem, interoperability must happen between providers, as well as between remote monitoring products, medical devices, and EHRs. A great example of interoperability between systems, devices, and networks is the communications technology industry. In addition to testing and finding consensus on voluntary industry standards, CMS and ONC should prioritize encouraging implementation of those standards to ensure interoperability between EHR systems, medical devices, and healthcare products, and use such standards to measure the

interoperability of EHR products. A system demonstrating "widespread interoperability" will provide useable data from various sources, not just from certified electronic health record technology (CEHRT) and its 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[2] (MACRA) provides that incentive in a value-based healthcare environment, one which engages patients, reduces costs, and documents quality metrics.

We believe CMS (and ONC) shares CHI's vision of a seamless and interoperable healthcare ecosystem that leverages the power of PGHD and can be realized through the trusted framework. We strongly encourage ONC to ensure their efforts prioritize data generated by patients outside the traditional care setting. Providers of federal health plans and the beneficiaries they serve now expect access to seamless and secure patient data across the care continuum, where individuals are able to 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. An interoperability scope that increasingly includes PGHD is also consistent with HHS' health technology policy. CMS has continued to advance important changes to the future MACRA-driven Medicare system, which will permit caregivers to incorporate PGHD into how they coordinate care and engage with beneficiaries. ONC's framework should augment CMS' rules that bring PGHD into the continuum of care (in both the fee-for-service and value-based care context). CMS should act to widely advance digital health quality through Fast Healthcare Interoperability Resources (FHIR) and Trusted Exchange Framework and Common Agreement (TEFCA) uptake, using incentives that enable appropriate flexibilities and population and/or patient-specific deployments while avoiding overburdening providers with compliance and administrative tasks that unfortunately have come to dominate existing APMs.

- CHI supports CMS' continued effort to accelerate the shift from quantity to quality by expanding the Home Health Value-Based Purchasing Model (HHVBPM). A nationwide HHVBPM can only succeed if its providers are able to responsibly use the broad range of digital health tools to enable a fully connected medical home platform which uses both synchronous (Medicare telehealth services) and asynchronous (remote physiologic as well as therapeutic monitoring as well as other wearables that reliably bring tailored PGHD into the care continuum to support timely evaluations and interventions to both prevent and treat disease. We strongly encourage CMS to provide a clear endorsement for HHVBPM providers to flexibly and scalably use the broadest range of medically appropriate digital health tools to serve home health beneficiaries.
- Regarding program integrity, CHI generally supports measures to avoid waste, fraud, and abuse in the HHPPS. The use of various connected and digital health innovation modalities, including remote monitoring technology, does not inherently mean that remote monitoring will translate to greater waste, fraud, and abuse; to the contrary, it is easier to ensure program integrity through real-time or near real-time data analytics provided by digital

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

health technologies. Therefore, we urge CMS to (1) acknowledge the ability of digital health technologies to improve programmatic waste in the HHPPS; and (2) leverage existing and developing program integrity tools and metrics in the HHPPS across its beneficiary programs in a modality-neutral manner, with additional measures being implemented for specific modalities based on demonstrated heightened risks to program integrity specific to modalities.

IV. Input of the Connected Health Initiative on CMS' Proposed CY2026 Durable Medical Equipment Rules

CMS chooses to utilize a DME definition in 42 CFR 414.202 that is narrower in scope than the relevant authorization language provided by Congress. CMS could and 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. Yet under its existing authority, CMS could reconsider and broaden this interpretation to better incorporate digital health innovations and support their responsible and effective use in patient care.

CMS is long overdue to provide a pathway for coverage under DME for software-as-a-service (SaaS) and 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. DME coverage of software should also extend to SaMD therapeutics cleared by the FDA. Further, 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 immediately to improve the DME program under its existing authority. 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 would ignore 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.

CHI also recommends that CMS update its DME rules to:

- Establish a regulatory pathway under DME for software or applications primarily used for medical purposes that can operate on various durable devices (such as laptops, smartphones, or tablets), even if the device isn't exclusively dedicated to the software. The

home device itself would not be covered as DME or a supply. CMS should allow coverage flexibility for software serving a medical function when used on durable home devices meeting CMS durability standards. Non-software components should be separately covered and coded as DME or supplies, without bundling into the software payment. If software qualifies as DME, substantial or clinically significant software updates should be covered as supplies, while routine updates remain part of standard service maintenance.

- Cover as a supply software that is clinically essential and integral to the proper functioning of covered DME, or that introduces new capabilities. This coverage should also extend to clinically significant software upgrades related to the DME, classified as supplies.
- Establish a regulatory framework under DME to cover wearables and linked SaaS/SaMD intended for medically necessary use and prescribed by a physician for use in the patient's home.

V. Conclusion

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

Sincerely,

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