ConnectedHealthInitiative

January 28, 2024

Ms. Lindsey Baldwin
Ms. Emily Yoder
Ms. Mikayla Murphy
Division of Practitioner Services,
Hospital and Ambulatory Policy Group
Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8011
Baltimore, Maryland 21244-1850

Dear Ms. Baldwin, Ms. Yoder, and Ms. Murphy:

CHI, the leading multistakeholder policy and legal advocacy effort driven by a consensus of stakeholders from across the U.S. health ecosystem, writes to share recommendations for the Center for Medicare and Medicaid Services' (CMS) future Calendar Year (CY) 2027 Medicare Physician Fee Schedule (PFS) and Quality Payment Program (QPP) rulemaking.

Digital health technologies are essential in improving beneficiary outcomes, reducing costs, and mitigating disparities in healthcare. Thanks to CMS' consistent efforts over recent years, the use of digital health services and related technologies have expanded, demonstrating value across a range of use cases. Notably, CMS' significantly positive steps taken in its final CY 2026 PFS rulemaking that took numerous actions to responsibly advance coverage and support for digital health innovations' use across Part B, including through modernization of the Medicare Diabetes Prevention Program, improvements to asynchronous remote monitoring coverage and payment, and providing permanent support for virtual presence, among many other updates.

With your continued partnership, the digital health tools and services we develop and use have given – and will only continue to increasingly give – Americans across every walk of life, from urban centers to underserved rural geographies, needed access to vital prevention and treatment services for both acute and chronic conditions. Yet, we believe that further policy shifts and updates are needed in this critical annual rulemaking. In its rulemaking for CY 2027, CMS should leverage every opportunity to incentivize the responsible use of innovative digital health technologies and ensure that no American beneficiary is left behind.

<u>Specifically, we recommend you consider the following in the CY 2027 PFS:</u>

- **Modernizing CMS' Practice Expense Methodology:** We appreciate CMS' considering how to improve its PE methodology across recent PFS rulemakings, and for consistently recognizing that its existing PE methodology creates significant barriers to the uptake of digital health innovations through the classification of most software (including Clinical

Decision Support, AI, and mobile medical applications that meet the definition of a medical device under the Food, Drug, and Cosmetic Act – referred to collectively here as software-as-a-medical device [SaMD]) as indirect practice expense. 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. Today, 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 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 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.

- **Remote Physiologic Monitoring:** We appreciate and support CMS' supportive approach to remote physiologic monitoring (RPM). Given the demonstrated role of RPM tools in treating both chronic and acute illnesses, CMS should provide further policy-level clarifications in its CY 2027 PFS rule, including:
  - CMS should permanently permit RPM services to be furnished to both new and established patients, and for consent to be obtained verbally. During the COVID-19 Public Health Emergency (PHE), CMS clarified that RPM services may be applied for patients with acute and chronic conditions on a permanent basis. To require patients who present with acute conditions to have an established relationship with a provider, runs contrary to the notion of reasonable and necessary.
  - Contrary to what has been expressed in past Fee Schedules, CMS should reconsider allowing multiple providers the ability to report RPM codes 99453, 99445, 99454, 99470, 99457, and 99458 for a patient. Under current CMS policy, only one provider, in a 30-day billing period, may bill RPM for a given patient. Doing so undercuts the ability for multiple specialists to remotely monitoring a single patient, even when monitoring and treating separate episodes of care.
  - CMS should permit physicians to perform and separately bill/report RPM during a global surgical period when related to the global surgical event. Such support is necessary to provide medically necessary routine follow-up care for many beneficiaries in the post-surgery stage of their care.

- CMS should consider clarifying whether there are any extraordinary provider documentation requirements when reporting RPM and RPM Treatment Management Services (RPM-TMS) codes.

- **Remote Therapeutic Monitoring:** We also appreciate CMS' supportive approach to Remote Therapeutic Monitoring (RTM) and Remote Therapeutic Monitoring Treatment Management Services (RTM-TMS). While the use of RTM tools is improving beneficiary care already, several areas of need for clarifications remain:
    - CMS should continue to clarify the shared or divergent policy nuances between RTM and RPM services such as whether RTM is allowed for patients with acute and chronic conditions, if RTM requires an established provider patient relationship, and how consent may be obtained.
    - CMS should provide elaborative language clarifying the broad range of use cases allow under the RTM work codes (98979, 98980 and 98981) beyond musculoskeletal and respiratory – common interpretation is that similar to the physiologic codes 99470, 99457, and 99458) that any therapeutic medical condition (acute or chronic, when reasonable and necessary, and when addressed in combination with a digital medical device that automatically – that is digitally – uploads the medical device data to the provider) should be permissible in order to report 98979, 98980, and 98981 – as opposed to the PE only RTM equipment supply codes (98975, 98984, 98976, 98985, 98977, 98986, and 98978) which require devices that address specific medical conditions (i.e., respiratory, musculoskeletal, and cognitive behavioral therapy).
    - CMS should permit multiple providers the ability to concurrently report RTM services, for the same patient, per-30-day period, consistent with our similar recommendation for RPM above.
    - CMS should permit RTM to be billed separately during a global surgical period that it is related to the global surgical event. Such support is necessary to provide medically necessary routine follow up care for many beneficiaries in the post-surgery stage of their care. RTM services should be considered an adjunct service and not covered by the pos-surgical global period.
    - CMS should clarify which providers, including non-physician providers, may bill RTM codes beyond those who can typically bill E/M services – particular in the psychological space.
    - CMS should adopt the 2025 Relative Value Scale Update Committee's HCPAC recommended valuation of $50.00 to cover and pay for CPT cognitive behavioral therapy remote monitoring codes 98986 and 98978 thereby establishing a national rate.

- **Medicare Telehealth Services:** CMS should continue to support telehealth services to the maximum extent possible. We urge for the appropriate expansion of support for Medicare telehealth services in the CY2027 PFS.

- **Artificial Intelligence (AI):** As CMS' continues to explore how to responsibly bring AI to the Medicare system to advance health equity to all patients, consistent with detailed recommendations provided to CMS separately,[1] we encourage the following:
    - 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.
    - Building on the leading efforts of the National Institute of Standards and Technology's voluntary AI Risk Management Framework[4] 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*.[5]
    - 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.
    - 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.
- **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). 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

[1] https://actonline.org/wp-content/uploads/CHI-AI-Ltr-to-CMS-Feb-9-2022.pdf.
[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.
[4] https://www.nist.gov/itl/ai-risk-management-framework.
[5] CHI's recommendations on necessary policy changes to enhance transparency for healthcare AI are available at https://bit.ly/3Gd6cxs.

available to move away from legacy measurement programs and towards a truly connected continuum of care through its implementation of the QPP.

We value CMS' collaboration and appreciate consideration of our input above. We stand ready to assist further in any way that we can.

Sincerely,

Brian Scarpelli
Executive Director

Chapin Gregor
Policy Counsel

Connected Health Initiative
1401 K St NW (Ste 501)
Washington, DC 20005
p: +1 517-507-1446
e: bscarpelli@actonline.org