ConnectedHealthInitiative

September 9, 2024

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

RE: ***Connected Health Initiative Comments on the Center for Medicare and Medicaid Services'*** **Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities** ***(CMS-1809-P; 89 FR 59186)***

Dear Administrator Brooks-LaSure:

The Connected Health Initiative (CHI) appreciates the opportunity to provide input and suggestions to the Centers for Medicare and Medicaid Services (CMS) on its proposed changes to the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for Calendar Year 2025.[1]

I. Introduction & 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,

[1] 89 Fed Reg 59186.

and the rising role of artificial/augmented intelligence (AI) in care delivery. For more information, see www.connectedhi.com.

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

Data and clinical evidence from a variety of use cases continue to demonstrate how the connected health technologies available today—whether called 'telehealth," "mHealth," "store and forward," "remote patient monitoring," "remote physiologic monitoring," "communication technology-based services," or other similar terms—improve patient care, prevent hospitalizations, reduce complications, and improve patient engagement, particularly for the chronically ill. Connected health tools, including wireless health products, mobile medical devices, software as a medical device (SaMD), mobile medical apps, and cloud-based portals and dashboards, can fundamentally improve and transform American healthcare.[2] 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, despite the ability to drastically improve beneficiary outcomes as well as to generate immense cost savings.

Further, CMS should seek to enable the use of health data 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, preparing personnel and training, as well as developing, validating, and maintaining AI systems with an eye toward ensuring value. Payment policies must incentivize a pathway for the voluntary adoption and integration of AI systems into clinical practice as well as other applications under existing payment models.

The need for rapid and permanent modernization of Medicare incentives is more imperative considering the impacts of the COVID-19 crisis on the United States. With the public health emergency (PHE) now expired, it is clear that remote monitoring tools have proven effective in preventing hospital admissions and improving recovery from the COVID-19 virus. Building on the PHE experience, and in light of the Congressionally mandated shift from fee-for-service to value-based care in Medicare approaching, CMS' continued efforts to advance the range of connected health innovations that will help American healthcare improve outcomes and cost savings are essential.

CMS' support for remote monitoring capabilities represents a game-changing shift of the Medicare system that recognizes the value of the wide range of asynchronous technologies, and which will contribute to a more connected continuum of care that

[2] This CHI resource is publicly accessible at https://bit.ly/2MblRou.

leverages PGHD in a timely way to mitigate disparities while improving outcomes and reducing Medicare costs. CHI continues to find enthusiasm throughout the healthcare continuum for CMS' leadership in providing support for these critical services. The ability to monitor data enables a wide range of medical specialty use cases that rely on medical device data to monitor physiologic and therapeutic parameters. CHI continues to work with CMS to ensure that all Medicare beneficiaries can leverage remote monitoring tools to improve their care while making the most efficient use of the system's resources. Remote monitoring tools must play a central role in CMS' efforts to make its OPPS more efficient and effective. We strongly encourage CMS to fully support the use of remote monitoring (both physiologic and therapeutic) through its OPPS policies.

And while CMS has, across numerous payment rules, made important pro-digital health updates, 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 that the OPPS and ASC leverage the wide range of connected health tools and services available today, as well as those in development to advance care and lower costs.

III. Connected Health Initiative Views on Various CMS Proposed 2025 OPPS ASC Policies

CHI provides the following specific input on a variety of CMS' proposals impacting digital health interests in its draft CY2025 OPPS rule:

- **Mental Health Services:** 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. We encourage CMS to responsibly expand the availability of critical mental health services already demonstrated to improve patient outcomes while reducing costs. CHI supports CMS' proposed clarifications on remote mental health HCPCS codes and its creation of C79XX, which builds on its finalizing HCPCS codes for mental health services furnished by hospital staff to beneficiaries in their homes through communications technology in the CY2023 OPPS rule.

  However, CHI also continues to oppose CMS requirements for in-person service within 6 months prior to the initiation of the remote service and then every 12 months thereafter, with exceptions to the in-person visit requirement allowed to be made based on beneficiary circumstances (with the reason documented in the patient's medical record), and that more frequent visits are also allowed per clinical needs on a case-by-case basis. Requirements for in-person service in order to receive remote mental health services directly undermines the goal of making such services more widely available and places America's most

vulnerable beneficiaries at risk during a pandemic. Further, the requirement would place special restrictions on mental health services without any evidence to justify the stricter treatment of telemental health services. CHI strongly encourages CMS to discard its proposed in-person restrictions from its rules for telemental health entirely. Should CMS elect to retain such restrictions, we support similarly retaining the ability for exceptions to the in-person visit requirement allowed to be made based on beneficiary circumstances. CHI therefore supports CMS' proposal to delay the in-person visit requirements for mental health services furnished remotely by hospital staff to beneficiaries in their homes until January 1, 2025,

Further, CHI encourages CMS to permit audio-only interactive telecommunications systems to be used to furnish mental health services in instances where the beneficiary is not capable of, or does not consent to, the use of two-way, audio/video technology. Such flexibilities are appropriate and reflect allowances made for telemental health in other CMS payment rules.

- **Payment for Outpatient Therapy Services, Diabetes Self-Management Training, and Medical Nutrition Therapy When Furnished by Institutional Staff to Beneficiaries in Their Homes Through Communications Technology:** We appreciate CMS aligned payment policies for outpatient therapy (DSMT and MNT services furnished remotely by hospital staff to beneficiaries in their homes) with policies for Medicare telehealth services and related COVID-19 PHE flexibilities. To the extent that therapists and DSMT and MNT practitioners continue to be distant site practitioners for purposes of Medicare telehealth services, we support CMS aligning its policy for these services with policies under the PFS and continuing to make payment to the hospital for these services when furnished by hospital staff. CHI also supports CMS committing to align with PFS policy delaying in-person visit requirements for professionals billing for mental health services via Medicare telehealth.

  CHI supports separate payment for telemedicine E/M codes and urges CMS to provide for a responsible level of support that will reflect the resource costs associated with these services for hospitals. We also encourage CMS to clarify that its reimbursement is tied to the AMA RUC recommendations.

  In the OPPS proposed 2025 Rule, CMS is seeking comment with regard to hospital resources associated with the 17 telemedicine new codes not covered by facility fee HCPCS G0463; however, it is anticipated that CMS/MPFS will not cover these codes. Further, G0463 is not a covered HCPCS code for any current outpatient telehealth E/M codes for which CMS stands to continue reimbursement for telehealth to a patient's home or to another clinic: behavioral health, SUD, home dialysis, when within a metropolitan statistical area.

  CHI supports coverage of G0463 for telehealth services in the provision of the current and anticipated continued coverage of 99202-99215 E/M encounters to

Medicare beneficiaries. It is not clear in MPFS if facilities will be reimbursed a global payment for all POS 10 eligible home services. As stated in its proposed rule, OPPS typically pays the average of 99202-99215 via HCPCS G0463. We suggest that the same be applied for the equivalent telehealth services which would continue to be reimbursed as a facility-based professional fee. The associated costs are the equivalent of in-person care: registration, scheduling, overhead (audio-video platform costs, transmission costs, etc.) and other costs associated with an HOPD.

- **Virtual Direct Supervision of Cardiac Rehabilitation (CR), Intensive Cardiac Rehabilitation (ICR), Pulmonary Rehabilitation (PR) Services and Diagnostic Services Furnished to Hospital Outpatients:** CHI appreciates CMS' discussion of virtual direct supervision in the draft CY2025 OPPS. We support CMS proposals to (1) revise the definition of direct supervision at § 410.32(b)(3)(ii) to extend the availability of virtual direct supervision of therapeutic and diagnostic services under the PFS through December 31, 2025; and (2) revise § 410.27(a)(1)(iv)(B)(1) and § 410.28(e)(2)(iii) to allow for the direct supervision of CR, ICR, PR services and diagnostic services via audio-video real-time communications technology (excluding audio-only) through December 31, 2025. CHI strongly urges CMS to permit remote supervision as widely as practicable on a permanent basis to help Medicare providers and beneficiaries realize the widely-recognized efficiencies of remote work being realized across countless other sectors of the economy.
- **Needed Support for Remote Monitoring:** CHI renews its call for CMS to 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.

  We further request that CMS allow for the care management services captured in CPT Codes 99457 and 99458 to be billed when provided by a hospital's clinical staff, in alignment with CMS' approach to Chronic Care Management (CCM), Principle Care Management (PCM), Transitional Care Management (TCM), and Behavioral Health Integration (BHI) services, which are billable across sites of care and where remote monitoring is appropriately used as a follow-up to a hospital stay (even when that facility does not have an independent medical group).
- **Artificial Intelligence/Software as a Service (SaaS):** Leveraging 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.

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.

As part of its commitment to responsibly advancing AI in healthcare, CHI assembled a Health AI Task Force, which has produced a number of resources for policymakers considering the role of AI in healthcare.[3] We strongly urge CMS to review these CHI AI Task Force deliverables and consider ways to align with them.

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. Already, CMS' support for the use of AI in the OPPS represents a precedential development in advancing the system through the responsible uptake of AI, which CHI supports. We encourage CMS' expanded support of AI tools in the OPPS, consistent with our views on AI's efficacious deployment. We therefore generally support CMS' further proposed supportive actions of AI, including proposed OPPS New Technology APC and status indicator assignments for CPT codes 0648T and 0649T for CY 2025.

In its proposed CY2025 OPPS rule, CMS has also posed a range of questions related to the potential of patient and workforce safety as a measurement topic area in the Hospital OQR Program. We appreciate CMS' posing of questions that raise the use of innovative technologies, including software algorithms and AI in health, and its efforts to better understand the resource costs for services involving their use. We are encouraged by CMS' leadership in exploring medical AI definitions, present and future AI solutions, how AI is changing the practice of medicine, and the future of AI medical coding. We urge CMS to pose these questions in a standalone Request for Information that is not tied to an annual payment rule.

There have been further health AI developments on which we strongly encourage CMS to build on, and which speak to its questions posed about mitigating AI risks, improving safety, and facilitating quality measurement. For example:

- **CHI's Health AI Policy Principles**, a set of recommendations on the wide range of areas that should be addressed by policymakers examining AI's use in healthcare (available at https://bit.ly/3m9ZBLv);
- **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://bit.ly/3n36WO5); and

[3] The CHI Health AI Task Force's deliverables are accessible at https://connectedhi.com/resources/.

- **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)
- **The CPT® Editorial Panel's Appendix S, which provides guidance for classifying various AI applications and describes 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. This resource is accessible at https://www.ama-assn.org/practice-management/cpt/cpt-appendix-s-ai-taxonomy-medical-services-procedures.

CY2025 offers an excellent opportunity for continued CMS leadership and for timely and impactful policy changes to further support the responsible deployment of AI to benefit all Medicare beneficiaries and to reduce disparities. In its CY2025 Medicare rulemakings, we strongly urge CMS to:

- Consistent with CHI's leading resources noted above, and in coordination with our important Medicare payment rulemakings, broadly advance support for the responsible development and use of AI to support Medicare beneficiaries and to advance value-based care;
- Rely on the CPT® Editorial Panel's new Appendix S to harmonize CMS' definitions and understanding of health AI and the CHI AI Task Force's released general health AI policy recommendations as a baseline for payment policy decisions impacting AI's use in Medicare.
- In its various pending Ambulatory Payment Classification (APC) and writ large, continue to support and expand responsible payment (aligning, where possible, with valuation recommendations of the Relative Value Scale Update Committee) for AI tools that will drive greater access to innovative AI mechanisms for Medicare beneficiaries. CMS should adopt national rates for the payment of AI services and shift away from contractor pricing that encourages disparate approaches among Medicare Administrative Contractors.
- Recognize that AI (either standing alone or used in a system) is appropriately paid for as a direct PE. AI software is not simple off-the-shelf software and cannot not be properly categorized as an indirect PE. Like

medical equipment and medical supplies, SaMD is a device as defined by FDA regardless of whether it is loaded onto and used on general purpose platforms or used as dedicated ancillary medical devices.

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

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

- **Quality Measures for Various Digital Health Use Cases:** CHI supports CMS' support of digital health services in quality measures across several contexts:
  - CHI encourages CMS to adopt measures that advance value and protect against overuse and fraud, while avoiding overburdensome requirements to alleviate provider burnout. CMS is also encouraged to avoid technology-specific mandates that reduce providers' ability to adopt and scale their use of digital health tools to best provide value to beneficiaries. CMS should acknowledge that the use of digital health tools and a more connected care continuum lends to the easier tracking of quality and efficacy, and makes detection of overuse and fraud easier.
  - CHI urges CMS to continue to prioritize maternal health, a key use case for digital health,[4] in the OPPS. CMS' strategy for rural emergency hospitals (REHs) and maternal health must directly address the need for using advanced technology (telehealth, RPM, and other communications-based technology services) as well as efficacious SaMD, in improving rural maternal and infant care. These technologies, when deployed responsibly, will greatly further CMS' goals. CMS should acknowledge that the use of digital health tools and a more connected care continuum lends to the easier tracking of quality and efficacy, and makes detection of overuse and fraud easier.
  - CHI appreciates CMS' continued focus on quality measures for mental health, including in the context of telehealth and telemedicine. We share CMS' views on the many benefits of mental health services offered via or augmented by digital health tools and services. As noted above, CMS should discard its in-person requirements for such services. CMS should recognize that digital health tools offer much more efficient means of monitoring claims and quality when deployed responsibly, and align where possible with quality measures adopted in other key Medicare payment rules (e.g., the Quality Payment Program). CMS is also encouraged to avoid technology-specific mandates that reduce providers' ability to adopt

[4] https://www.himss.org/resources/developing-digital-tech-enabled-maternal-health-roundtable-report.

and scale their use of digital health tools to best provide value to beneficiaries. CMS should further acknowledge that the use of digital health tools and a more connected care continuum lends to the easier tracking of quality and efficacy, and makes detection of overuse and fraud easier.

- CHI similarly appreciates CMS' continued focus on quality measures for equity. Across the country, disparities in healthcare are sizable and growing, caused by barriers that exist at all levels, exacerbated by the ongoing COVID-19 public health emergency.[5] We strongly encourage CMS to provide support for digital health tools' crucial role in mitigating and eliminating disparities across the American healthcare system and within the home health context. Thanks to CMS' expanded support, reliance on digital health tools increased during the now-expired COVID-19 PHE. Use of these tools allowed many underserved populations' access to prevention, diagnosis, and treatment for both acute and chronic conditions while also providing routine care to Americans to safely observe public health protocols during the COVID-19 pandemic. CMS should leverage every opportunity for permanent policy changes that will incent the responsible deployment and use of innovative digital health technologies that will be vital in ensuring that no American beneficiary is left behind.

  CHI generally supports the development of health equity measures, and suggests that the OPPS may benefit from aligning with the health equity measures created for MIPS Value Pathways (MVPs). Health equity measures across Medicare should reflects the need for feasibility and flexibility for providers. CMS is encouraged to adopt measures that advance value and protect against overuse and fraud, while avoiding overburdensome requirements to alleviate provider burnout. CMS is also encouraged to avoid technology-specific mandates that reduce providers' ability to adopt and scale their use of digital health tools to best provide value to beneficiaries. CMS should acknowledge that the use of digital health tools and a more connected care continuum lends to the easier tracking of quality and efficacy, and makes detection of overuse and fraud easier.

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

IV. 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 OPPS and ASC possible.

Sincerely,

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