ConnectedHealthInitiative

September 13, 2022

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' Proposed CY2023 Medicare Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (CMS-1772-P; 87 FR 44502)***

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 (CY) 2023.[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, and the rising role of artificial/augmented intelligence (AI) in care delivery. For more information, see www.connectedhi.com.

CHI engages with a broad and diverse cross-section of industry stakeholders focused on advancing clinically validated digital medicine solutions. For example, CHI is an

[1] Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating, 87 FR 44502 (Sep. 13, 2022) (Proposed Rule).

appointed member of the American Medical Association's (AMA) Digital Medicine Payment Advisory Group (DMPAG), an initiative bringing together a diverse cross-section of 15 nationally recognized experts who identify barriers to digital medicine adoption and propose comprehensive solutions revolving around coding, payment, coverage, and more.[2]

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.[3] 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.

CMS should actively 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 ongoing COVID-19 crisis in the United States. Already, remote monitoring tools have proven to be effective in preventing hospital admissions and improving recovery from the COVID-19 virus.[4] 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 approaching, CMS' continued efforts to advance the range of connected

[2] https://www.ama-assn.org/delivering-care/digital-medicine-payment-advisory-group
[3] This CHI resource is publicly accessible at https://bit.ly/2MblRou.
[4] https://www.thepermanentejournal.org/issues/2021/summer/7664-description-and-early-results-of-the-kaiser-permanente-southern-california-covid-19-home-monitoring-program.html.

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 will 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.

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. This need became even more obvious with the COVID-19 pandemic. 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 OPPS ASC Policies

CHI provides the following specific input on a variety of CMS' proposals impacting digital health interests in its draft CY2023 OPPS rule:

- **Mental Health Services:** CMS proposes to consider 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.[5] CHI supports this proposal, which will expand the impact of critical mental health services already demonstrated to improve patient outcomes while reducing costs.

  CMS further proposes to require an 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 puts 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.

  CMS also proposes 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.

- **Quality Measures for Various Digital Health Use Cases:** CHI supports CMS' focus on how rural emergency hospitals (REHs) may benefit from digital health services, and its exploration of quality measures across several contexts:[6]
  - CHI appreciates CMS' request for input on REH quality measures in the context of telehealth. CMS is encouraged to adopt measures that advance value and protect against overuse and fraud, while avoiding

[5] Proposed Rule at 44676.

[6] *Id.* at 44762.

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 especially appreciates CMS' consideration of REH quality measures for maternal health, highlighting the benefits of remote monitoring. We agree that maternal health is a key use case for digital health, and should be embraced in the OPPS. CMS' strategy for REHs and maternal health must directly address the need for using advanced technology (telehealth, remote physiological monitoring (RPM), and other communications-based technology services) in improving rural maternal and infant care. These technologies, when deployed responsibly, will greatly further CMS' goals.

- CHI similarly appreciates CMS' request for input 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 or augmented by digital health tools and services. As noted above, CMS should discard its proposed in-person requirements for such services, particularly considering its focus in this rule on rural America. CMS is urged to recognize that digital health tools offer much more efficient means of monitoring claims and quality when deployed responsibly, and to align where possible with quality measures adopted in other key Medicare payment rules.
- CHI also appreciates CMS' request for input 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 (PHE).[7] 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 in the 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

[7] 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.

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 Merit-based Incentive Payment System (MIPs) Value Pathways (MVPs). Health equity measures across Medicare should reflects the need for feasibility and flexibility for providers.

- **Virtual Supervision:** CHI appreciates CMS' discussion of virtual direct supervision in the draft CY2023 OPPS.[8] CMS took important steps to responsibly utilize technology for purposes of medical supervision during the PHE, revising the definition of direct supervision to include virtual presence of the supervising physician or practitioner using interactive audio/video real-time communications technology. CHI 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.

  CHI reiterates that it does not share CMS' concern (expressed in, for example, previous Physician Fee Schedule (PFS) proposed rules) that virtual supervision inherently gives rise to patient safety issues. Numerous clinical staff and auxiliary personnel perform a wide range of tasks easily supervised virtually. Further, such staff categorically do not perform "complex, high-risk, surgical, interventional, or endoscopic procedures, or anesthesia procedures" that CMS has described in the past to explain its concerns with virtual direct supervision. Non-physician practitioners (NPPs), to the extent that they assist with such procedures, are subject to higher standards, certifications, and oversight. Again, CHI strongly encourages CMS to move away from any policies that discriminate against virtual modalities without evidence.

- **Expanded Support for Remote Monitoring:** CMS should 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, including for those receiving treatment for COVID-19. Initially, we request that, for the duration of the COVID-19 PHE, CAHs and REHs enjoy the same fee-for-service carve out that Federally-Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) already enjoy for Chronic Care Management (CCM), Transitional Care Management (TCM), and Behavioral Health Integration (BHI) services.

  Past the PHE, however, CMS must act to support the use of RPM and Remote

[8] Proposed Rule at 44679.

Therapeutic Monitoring (RTM) by CAHs and REHs. Building on important policy changes made FQHCs and RHCs (such as establishing payment for CAHs and REHs for CCM services as well as requirements for general BHI and psychiatric Collaborative Care Management [CoCM] services furnished by the same; and adding Healthcare Common Procedural Coding System (HCPCS) codes G2064 and G2065 to G0511 as a comprehensive care management service for RHCs and FQHCs starting January 1, 2021), CMS should further provide that CAHs and REHs can report RPM/ Transcranial magnetic stimulation (TMS) and RTM/TMS for the development and management of a treatment plan based on patient physiologic data. Because they are included in CMS' CY2021 PFS final rule Table 13 ('Summary of Care Management Codes'), RPM/TMS should meet the requirements for a CAH or REH billable visit and enable them to provide a range of care management services including PCM, CCM, BHI, CoCM. Further, CHI requests that CMS ensure that RPM/TMS are included in the payment calculation of HCPCS Code G0511 for CAHs and REHs. Such steps should be taken with respect to RTM/TMS as well, because it is vital that CAHs and REHs also leverage the steps made for therapeutic data for the reasons discussed above.

- **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.[9] 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.

  In its proposed CY2023 OPPS rule, CMS has posed a range of questions about the use of innovative technologies, including software algorithms and AI in

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

health, to better understand the resource costs for services involving their use. We are encouraged by CMS' leadership in exploring medical AI definitions, present and future AI solutions, how AI is changing the practice of medicine, and 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. For example:

- **The CPT® Editorial Panel accepted the addition of a new Appendix S to provide guidance for classifying various AI applications. The Panel intended the Appendix to be consulted for code change applications to describe work associated with the use of AI-enabled medical services and/or procedures.** This taxonomy provides guidance for classifying various AI applications (e.g., expert systems, machine learning, algorithm-based services) for medical services and procedures into one of three categories: assistive, augmentative, or autonomous, and its adoption represents a significant step forward in the evolution of CPT® coding.
- **CHI's AI Task Force released *Advancing Transparency for Artificial Intelligence in the Healthcare Ecosystem*, the digital health community's consensus recommendations addressing how to create health AI tools and maintain the trust in them of both healthcare professionals and patients.** This new set of recommendations builds on the Task Force's previously released general health AI policy recommendations and recommended good machine learning practices for FDA-regulated AI.

CY2023 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 CY2023 Medicare rulemakings, we strongly urge CMS to:

- 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. We recommend good machine learning practices for FDA-regulated AI, and recommendations addressing how to create and maintain the trust of both healthcare professionals and patients in health AI tools.
- 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 practice expense (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.

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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