

# ConnectedHealthInitiative

February 9, 2022

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Washington, District of Columbia 20201

RE: *The Center for Medicare and Medicaid Services' Approach to Artificial Intelligence*

Dear Administrator Brooks-LaSure:

Leveraging the wide range of datasets, including patient-generated health data, with artificial intelligence (AI) tools holds incredible promise for equitably 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 support building infrastructure and preparing and training personnel, as well as developing, validating, and maintaining AI systems to ensure value. Leveraging such AI tools are also critical in meeting the Administration's priorities, such as reducing disparities.

CHI is a not-for-profit multistakeholder policy and legal advocacy coalition driven by a consensus of stakeholders from across the connected health ecosystem which aims to realize an environment where Americans can improve their health using digital and connected health technologies to enhance health outcomes and reduce costs equitably. As part of its commitment to responsibly advance AI in healthcare, CHI has assembled a Health AI Task Force consisting of a range of innovators and thought leaders. CHI's AI Task Force's has developed a range of resources, including a position piece supporting AI's role in healthcare, a set of principles addressing how policy should approach the role of AI in healthcare, and a terminology document targeted at policymakers.<sup>1</sup> Even more recently, CHI's AI Task Force has developed Good Machine Learning Practices, specifically for AI development and risk management of AI meeting the Food and Drug Administration's (FDA's) definition of a medical device,<sup>2</sup> as well as recommendations on

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<sup>1</sup> The CHI Health AI Task Force's deliverables are accessible at <https://actonline.org/2019/02/06/why-does-healthcare-need-ai-connected-health-initiative-aims-to-answer-why/>.

<sup>2</sup> The CHI's Good Machine Learning Practices are available at <https://bit.ly/3gcar1e>.

ways to improve transparency for caregivers, patients, and others necessary for the appropriate uptake of AI tools across the care continuum.<sup>3</sup>

CHI appreciates CMS's efforts to responsibly bring AI to the Medicare system in a way that will advance health equities and benefit all providers and patients. To date, CMS has taken a number of important steps to make AI's benefits available to more caregivers and patients, including updating its Medicare Physician Fee Schedule (PFS) rules to provide national payment rates for AI's responsible use in addressing specific use cases, such as in diabetic retinopathy; and integrating AI into value-based care, specifically in various Quality Payment Program Merit-based Incentive Payment System quality measures.

In its proposed CY 2022 PFS rule, CMS asked a wide range of questions about the use of innovative technologies, including software algorithms and AI in 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.

Since the comment period on the proposed CY 2022 PFS closed, there have been further developments that we strongly encourage CMS to build on. 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.

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<sup>3</sup> The CHI's recommendations on necessary policy changes to enhance transparency for healthcare AI are available at <https://bit.ly/3Gd6cxs>.

2023 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 CY 2023 Medicare rulemakings, we strongly urge CMS to:

- As a baseline for payment policy decisions impacting AI's use in Medicare, rely on the CPT® Editorial Panel's new Appendix S to harmonize CMS's definitions and understanding of health AI and the CHI AI Task Force's released general health AI policy recommendations, recommended 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, software as a medical device (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.

Sincerely,



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