

ConnectedHealthInitiative

June 10, 2024

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: Comments of the Connected Health Initiative to the Centers for Medicare & Medicaid Services Regarding *Medicare and Medicaid Programs and the Children's Health Insurance Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2025 Rates; Quality Programs Requirements; and Other Policy Changes* [CMS-1808-P; 89 FR 35934]

Dear Administrator Brooks-LaSure:

We write on behalf of ACT | The App Association's Connected Health Initiative¹ (CHI) to the Centers for Medicare & Medicaid Services (CMS) regarding proposed revisions to the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals.²

CHI is the leading effort by stakeholders across the connected health ecosystem to clarify outdated health regulations, encourage the use of remote monitoring (RM), and support an environment in which patients and consumers can see improvement in their health. This coalition of leading mobile health companies and stakeholders urges Congress, the Office of the National Coordinator for Health Information Technology (ONC), the Food and Drug Administration (FDA), CMS, and other regulators, policymakers, and researchers to adopt frameworks that encourage mobile health innovation and keep sensitive health data private and secure.

CMS' proposed revisions to the Medicare hospital IPPS for operating and capital-related costs of acute care hospitals come at an important time. 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

¹ <http://connectedhi.com>.

² 89 FR 35934.

(ranging from medical device remote monitoring [RM] products to general wellness products) with open application programming interfaces (APIs) that allow the integration of patient-generated health data (PGHD) into electronic health records (EHRs). Data stored in standardized, interoperable formats facilitated by APIs enhances patient access and 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 barriers to patient engagement.

Interoperability must not only happen between providers, but also between RM products, medical devices, and EHRs. A great example of interoperability between systems, devices, and networks can be seen in the communications technology industry, which has flourished globally. Systems should be widely interoperable in providing useable data from various sources, not just from certified EHR technology (CEHRT) and CEHRT systems. There must be an incentive to communicate and pass information from one party to another. We also note that the Medicare Access and CHIP Reauthorization Act³ (MACRA) provides that incentive in a value-based healthcare environment – one which engages patients, reduces costs, and documents quality metrics.

Remote monitoring of PGHD is integral to the future of the American healthcare system. The demonstrated benefits of RM services include reduced hospitalizations and cost, avoidance of complications, and improved care and satisfaction, particularly for the chronically ill.⁴ To continue supporting true interoperability between all payers while assisting patients in moving their data throughout their medical journey, the Department of Veterans Affairs (VA) provides a compelling use case for the use of virtual chronic care management, which ultimately resulted in a substantial decrease in hospital and emergency room visits.⁵ CHI recommends CMS and the Department of Defense and the VA actively participate in Trusted Exchange Framework and Common Agreement (TEFCA), as well as the soon-to-be revised payer-to-payer data exchange mandate.

Emerging technologies like telemedicine tools, wireless communication systems, portable monitors, and cloud-based patient portals that provide access to health records are revolutionizing RM and asynchronous technologies.⁶ Healthcare providers will also benefit from the potential of RM's cost savings. Remote monitoring has the potential to

³ Pub. L. 114-10 (2015).

⁴ See Hindricks, et al., *The Lancet*, Volume 384, Issue 9943, Pages 583 - 590, 16 August 2014 doi:10.1016/S0140-6736(14)61176-4.

⁵ Darkins, Adam. (2014). *The Growth of Telehealth Services in the Veterans Health Administration Between 1994 and 2014: A Study in the Diffusion of Innovation*. *Telemedicine journal and e-health : the official journal of the American Telemedicine Association*. 20. 761-8. 10.1089/tmj.2014.0143.

⁶ The global wearable medical devices market is expected to progress from US\$2.73 bn in 2014 to US\$10.7 billion by 2023, predicted to progress at a 16.40% CAGR from 2015 to 2023. See <http://www.medgadget.com/2016/05/global-wearable-medical-devices-market-to-reach-us10-7-bn-by-2023-as-increasing-incidence-of-chronic-pain-creates-strong-customer-base.html>.

positively engage patients dealing with chronic and persistent diseases to improve the management of such conditions. Further, the leveraging of health data (including social determinants of health [SDOH] and PGHD) with AI tools 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. 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 but urges for further steps to be taken to responsibly improve beneficiary outcomes using AI.

We believe CMS shares CHI's vision of a seamless and interoperable healthcare ecosystem that leverages the power of PGHD and AI can be realized through the trusted framework, and we strongly encourage CMS to ensure that its efforts prioritize data generated by patients outside of the traditional care setting. CMS has advanced several important changes to MACRA-driven Medicare system, which permits caregivers to incorporate PGHD into how they coordinate care and engage with beneficiaries.⁷ CMS' revisions to the hospital IPPS should build upon these advancements and further augment the ability to bring PGHD into the continuum of care.

Based on the above, CHI offers the following specific comments on CMS' proposed revisions to the hospital IPPS:

- CHI supports efforts to address health data interoperability issues and urges CMS to align and collaborate with sister agencies that are working to address the same issues now. We support incentives to participate in TEFCA under the Health Information Exchange (HIE) objective to advance interoperability, on which CHI has provided detailed input.⁸ Additionally, innovative technologies like blockchain should be endorsed for TEFCA involvement. The goal of safe, cost-effective, and timely data exchange is prime use case for blockchain-based technologies in healthcare, which can balance solutions at large while maintaining data accuracy, timeliness, and appropriate access. In implementing TEFCA, CHI requests CMS, ONC, and related entities to consider the needs of HIEs as it sets goals and pragmatic steps to transition to a Qualified Health Information Network (QHIN)-based approach that will provide a technical infrastructure model and governing approach for different health information networks and their users to securely share clinical information with each other under commonly agreed to and fair terms. CHI reiterates its support for updates to the TEFCA measure under the HIE objective that will encourage greater participation and help realize greater data exchange. We further urge CMS to call on its programs, as well as the Department of Defense and Veterans Administration to participate in the TEFCA and payer-to-payer data exchange

⁷ <https://connectedhi.com/2018-1-2-recognition-reimbursement-results-why-2017-was-a-win-for-connected-health/>.

⁸ See <https://bit.ly/2IrvKbl>.

mandate, which would contribute to improved records for patients that experience care across systems.

- CHI urges CMS to work with the Office of Inspector General (as well as other agencies such as ONC) to alleviate confusion and minimize compliance burdens on affected stakeholders by finalizing an information blocking rule that clarifies enforcement.
- CHI encourages CMS' IPPS rule to continue utilizing ongoing work done by standards development organizations like HL7 Davinci and others in the standards development and data interoperability space.
- CHI generally supports changes to the Promoting Interoperability scoring regime and measures proposed that will increase flexibility and lower compliance burdens. Such changes are inherently linked to other important rules CMS is responsible for, including the Physician Fee Schedule which has recently begun to incent the use of asynchronous tools that will bring PGHD into care as well as the MACRA-driven Merit-based Incentive Payment System (MIPS) which provides strong incentives for the use of remote monitoring technology through certain Improvement Activities that CHI strongly supports. CMS' steps to revise the hospital IPPS generally should be made in alignment with key pro-remote monitoring changes to these important programs and others.
 - CHI supports various proposed Promoting Interoperability measures that will, using a light touch, incent the leveraging of RM and telehealth innovations to address pressing public safety needs, namely the opioid crisis in America.
 - CHI also supports efforts to improve care coordination through patient engagement via secure messaging and the use of patient-generated data. CHI urges CMS to take all practicable steps to advance the use of PGHD collected via remote monitoring into the American healthcare system widely including using APIs. We are committed to working with CMS and all other stakeholders to introduce new technology-driven efficiencies into care that will save costs and improve care.
- CHI reiterates our concern with, and lack of confidence that, the 2015 ONC CEHRT standards facilitate seamless interoperability. We also note that the U.S. Core Data for Interoperability (USCDI), on which CHI has provided comments,⁹ continues to be updated, although the updated versions are not yet mandated for use.

⁹ See <https://bit.ly/2KaeXzy>.

- CHI strongly supports incentives to healthcare stakeholders to ensure the secure exchange of information. We do, however, urge that reporting requirements present as low a burden as possible and that the new CMS rules do not have the effect of incenting taxing data dumps that have little practical value.

Further, CHI supports the use of the strongest technical protection mechanisms (TPMs), including end-to-end encryption and multi-step authentication. We urge CMS to include direct endorsement of the strongest TPMs used for securing data integrity, confidentiality, and access. We do, however, highlight that the use of TPMs must also be balanced with the potential financial, staff, or other resource burdens on small, solo, and rural provider offices in a holistic risk management process.

Regarding the Health Insurance Portability and Accountability Act (HIPAA), CHI notes its appreciation for CMS' work with HHS' Office of Civil Rights (OCR) to align the Promoting Interoperability program with HIPAA. CMS' rules should avoid creating uncertainty as to what can be shared, and how patients would be properly notified of their data's use under HIPAA. We strongly discourage creating a scenario where a party making a query must choose between satisfying the Promoting Interoperability program's requirement for disclosing data fields and violating HIPAA's "minimum necessary" requirements. We urge CMS to keenly follow developments underway, both in Congress and at several federal agencies, related to consumer and patient privacy, which will impact measures in the IPPS.

- AI, powered by streams of data and advanced algorithms, has incredible potential to improve healthcare, prevent hospitalizations, reduce complications, and improve patient engagement. CHI recognizes that, as healthcare AI innovations continue to be developed and enter today's regulatory processes, policymakers at the legislative and regulatory levels and industry must collaborate to reach AI's full potential, while prioritizing patient safety. CHI has worked to proactively address health AI governance and policy issues based on consensus views that span the healthcare sector, from technology developers to providers to patients. With respect to its AI-related considerations, we urge CMS to align with several CHI policy and governance recommendations:
 - CHI's *Health AI Policy Principles*, a comprehensive set of recommendations across key areas that should be addressed by any policymaker considering AI's use in healthcare (available at <https://bit.ly/3m9ZBLv>);
 - CHI's *Health AI Roles and Interdependencies Framework*, which describes the health AI value chain, defining actors and describing roles for ensuring safety and efficacy as well as the interdependencies between these actors (<https://connectedhi.com/wp-content/uploads/2024/02/CHI-Health-AI-Roles.pdf>); and
 - CHI's *Advancing Transparency for Artificial Intelligence in the Healthcare Ecosystem*, comprehensive recommendations on ways to increase the

transparency of and trust in health AI tools, particularly for care teams and patients (<https://bit.ly/3n36WO5>).

CHI appreciates CMS' proposal to provide further add-on payment for the use of AI in the IPPS,¹⁰ and encourages CMS to take every opportunity available to advance the responsible deployment of AI tools and services to address chronic and acute disease prevention and treatment.

- CHI urges CMS to take all practicable steps to align Medicaid policies with changes to the Medicare program that are increasingly enabling physicians to flexibly use telehealth and remote monitoring technologies to improve care and reduce costs.

We appreciate the opportunity to submit comments to CMS on this matter and look forward to the opportunity to meet with you and your team to discuss these issues in more depth. Thank you for your consideration.

Sincerely,



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¹⁰ 88 FR 26940-26942.