

ConnectedHealthInitiative

May 29, 2024

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

RE: Connected Health Initiative Comments to the Centers for Medicare & Medicaid Services on Medicare Program; Request for Information on Medicare Advantage Data [CMS-4207-NC; 89 FR 5907]

The Connected Health Initiative (CHI) appreciates the opportunity to provide input and suggestions to the Centers for Medicare & Medicaid Services (CMS) on its request for information (RFI) on how best to meet the shared goals of enhancing data capabilities to have better insight into Medicare Advantage (MA), areas for increased MA data transparency, and the potential for future rulemaking.¹

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 is a longtime advocate for the increased use of telehealth and remote monitoring across the Department of Health and Human Services (HHS) as well as before other agencies such as the Federal Communications Commission and the U.S. Congress. CHI is also a current appointed member of the American Medical Association's (AMA) Digital Medicine Payment Advisory Group, an initiative bringing together a diverse cross-section of nationally recognized experts that identifies barriers to digital medicine adoption and proposes comprehensive solutions revolving around coding, payment, coverage, and more.² A Physician Fee Schedule (PFS) and Quality Payment Program (QPP), and broader Medicare system, that serves beneficiaries effectively must leverage the benefits of the range of digital health tools available today, consistent with other major Medicare programs.

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

¹ 89 FR 5907.

² <https://www.ama-assn.org/delivering-care/digital-medicine-payment-advisory-group>



hospitalizations, reduce complications, and improve patient engagement. These benefits are particularly impactful for the chronically ill. Connected health tools, including wireless health products, mobile medical devices, software as a medical device, 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, CMS regulatory-level policy decisions, among other constraints, inhibit the use of these solutions. To overcome this dynamic, CMS must better track the extent to which digital health innovations are used in key programs such as MA.

Further, as discussed below in further detail, CMS should support the use of health data and patient-generated health data (PGHD) through artificial intelligence (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 incent a pathway for the voluntary adoption and integration of AI systems into clinical practice as well as other applications under existing payment models.

We agree with CMS that the need for rapid modernization of Medicare incentives is even more imperative considering the experience during and since the COVID-19 public health emergency (PHE) in the United States. 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, it is essential CMS continues efforts to advance the range of connected health innovations that will help American healthcare improve outcomes and cost savings.

CHI also shares CMS' priority for reducing the inequities in healthcare. Thanks to CMS' expanded support, reliance on digital health technologies increased during the COVID-19 PHE. Use of these tools continues to allow many underserved populations' access to prevention, diagnosis, and treatment for both acute and chronic conditions while also safely observing public health protocols during the COVID-19 pandemic. CMS should leverage every opportunity for permanent policy changes that will incent responsible deployment and use of innovative digital health technologies that will be vital in ensuring that no American beneficiary is left behind.

CMS has already make notable efforts in MA to support the responsible use of digital health innovations through steps such as ensuring utilization of RPM in existing alternative payment models such as Medicare Advantage, where RPM has been eligible for inclusion as a basic benefit. We further commend CMS for its efforts to advance the uptake of connected health innovations across other programs, including but not limited to:

- In its PFS, CMS has now activated and provided payment for the technical and professional elements of remote physiologic monitoring (RPM) and remote therapeutic monitoring (RTM);

³ This CHI resource is publicly accessible at <https://bit.ly/2MblRou>.

- CMS has put key incentives in place for the future value-based Medicare system, as well as taken steps to promote flexible use of PGHD in care coordination in the QPP Merit-based Incentive Payment System (MIPS). As a community, we continue to support CMS' efforts to utilize advanced technology to augment care for every American patient;
- CMS has allowed home health agencies to include evidence-based remote physiologic monitoring expenses used to augment the care planning process as allowable administrative costs that are factored into the costs per visit under the Home Health Prospective Payment System; and
- To address the PHE, CMS took numerous steps to bring the power of connected health technology into detection and treatment of COVID-19, including issuing information to MA organizations and Part D Sponsors to inform them of the obligations and permissible flexibilities related to the COVID-19 public health emergency.

While the policy changes noted above represent important digital health policy changes, 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, a problem highlighted during the COVID-19 pandemic and in the Administration's equity priorities. As a community, we continue to support CMS' efforts to utilize advanced technology to augment care for every patient. It is essential that Medicare Advantage providers leverage the wide range of connected health tools and services available today, as well as those in development to advance care and lower costs. And the lessons learned, both good and bad, from using digital health tools in MA cannot be fully understood unless CMS adequately tracks and publishes relevant data.

CHI therefore calls on CMS to significantly enhance its tracking of the use of digital healthcare tools and services in MA, and for making that data publicly available. Specifically, we urge CMS to track and publish:

- The extent to which Medicare telehealth services (live voice/video) are offered and utilized in MA, and related cost and outcome impacts;
- The extent to which RPM and RTM are offered and utilized in MA, and related cost and outcome impacts;
- The extent to which AI is offered and utilized in MA, and related cost and outcome impacts;
- The extent to which digital health tools and PGHD are used to meet population health management goals, and related cost and outcome impacts; and
- The extent to which digital health tools are used by the healthcare workforce and their impacts on workflow, burnout prevention, etc.

Further, CHI provides the following recommendations for enhancing MA data and improving MA:

- CHI shares CMS' priority for advancing health equity through MA. We urge CMS to leverage the recommendations included in Advancing Health Equity Through

Technology,⁴ a paper jointly released by CHI and the Consumer Technology Association that offers recommendations on ways to responsibly further use of technology to mitigate health disparities. The white paper explores ways in which the increasing use of health technology such as mobile health, wearables, remote monitoring, clinical decision support, AI, and telehealth can be used to improve the country's response to health disparities in diverse geographies, communities, and demographics.

In advancing equity through improvements to MA, CMS should directly address and support the need for using advanced technology (telehealth, RPM, and other communications-based technology services) in improving equitable care. These technologies, when deployed responsibly, are an equalizer that will help accomplish CMS' objectives. CMS should utilize an "upstream" lens to understand the root causes of barriers to optimal use of technologies within historically marginalized communities. CMS should also enable disease prevention through the utilization of the range of technologies available today as well as in development, supporting that functionality, content, user interface, and service access features are designed in an equity-centric fashion, including addressing culture, language, digital literacy ability, and broadband access. Digital health technologies should be leveraged to empower individuals (and individuals making care decisions for those) receiving care, address patients' full range of health needs, promote healthy behaviors, and facilitate the improvement of health for individuals, families, and communities.

- Because the goals of the Medicare Access and CHIP Reauthorization Act of 2015⁵ relating to shifting the Medicare system from quantity-focused to quality-focused remain unrealized until there is a prioritization of the responsible use of digital health technologies in advancing value-based care, we encourage CMS to align with a CHI-developed and healthcare ecosystem-consensus report identifying key challenges to the responsible use of digital health technologies in advancing value-based care and developed corresponding recommendations to policymakers on how to overcome them.⁶
- CMS should provide MA plan sponsors with maximum discretion that enables making the determination that different digital health services are clinically appropriate, and to offer those services to beneficiaries as needed. CMS should make clear that asynchronous services that do not meet the definition of Medicare telehealth services (in other words, all services that are not live voice/video calls) do not face the onerous restrictions of Section 1834(m) of the Social Security Act. Currently, regulations provide that MA plans to cover Part B benefits provided via electronic exchange as "additional telehealth benefits" (including remote monitoring) and as a basic benefit as defined in § 422.101. We strongly encourage CMS to ensure that its implementation of Section 50323 of the Bipartisan Budget Act of 2018 provides for MA plans' alignment with CMS' established approaches to Medicare fee-for-service Telehealth services, as well as to remote monitoring (both RPM and RTM) and other "remote communications technology" that CMS has expressly stated do not fall under 1834(m) and its restrictions.

⁴ http://actonline.org/wp-content/uploads/CTA_HEAL_WhitePaper_Final.pdf.

⁵ Public Law No. 114-10, 129 Stat. 87 (2015).

⁶ <https://www.connectedhi.com/blog/2021/7/14/the-value-based-care-revolution-will-stall-without-health-tech>.

- To realize an improved care continuum, it is essential that data exchange occurs seamlessly between regular Medicare and MA plans as patients move between the systems (and increasingly migrate to MA). Already, the Office of the National Coordinator for Health IT (ONC) has laid the groundwork for improved information exchange based on HL7® FHIR® Application Programming Interfaces (APIs), and has provided several APIs to encourage data exchange (such as Blue Button, MyHealthEData, the Beneficiary Claims Data API for accountable care organizations [ACOs], the Data at Point of Care API pilot, and the AB2D API that allows stand-alone prescription drug plans to receive Original Medicare data). We encourage CMS to, in coordination with ONC, develop and track markers for capturing how data is exchanged.
- CMS should modify its MA Part D and Accountable Care Organization (ACO) risk adjustment policy to incorporate diagnoses from digital health-enabled remote encounters, including audio-only telehealth services where clinically appropriate.
- MA plans should be encouraged to cover all visits and other services that are on the Medicare Telehealth Services list when provided through telehealth by patients' physicians.
- CHI has long supported CMS' allowing all Medicare-eligible individuals with end-stage renal disease (ESRD) to enroll in MA plans, which will help improve the lives of, and empower, beneficiaries with ESRD by giving them choices in the type of Medicare coverage they receive, including MA plans enabling greater use of digital health technologies supporting hemodialysis and peritoneal home dialysis and remote physiologic monitoring. CMS also should ensure that ESRD patients are properly informed about their potential out-of-pocket costs and the adequacy of plan networks so that they can make good decisions as they consider switching to MA for their health care coverage.
- CHI supports CMS network adequacy methodology and standards that permit MA plans to receive a 10 percent credit towards the percentage of beneficiaries residing within published time and distance standards when they contract with certain telehealth specialty providers (dermatology, psychiatry, cardiology, otolaryngology, and neurology). However, given the demonstrated benefits of digital health technologies in both the prevention and treatment of disease, CHI urges CMS to expand this credit to further specialty provider types.
- CHI supports CMS allowing Special Needs Plans to permit MA organizations' annual face-to-face visits to be conducted via a "visual, real-time, interactive telehealth encounter" within the first 12 months of enrollment within the plan.
- CHI supports CMS policies to improve MA/Part D and Accountable Care Organization risk adjustment policy to incorporate diagnoses from digital health-enabled remote encounters. Providing this clarity would resolve uncertainty as to whether connected health modalities are risk adjustable since they are not face-to-face visits.
- CHI encourages CMS to permit MA plans to use virtual Medicare Diabetes Prevention Program (MDPP) encounters in addition to in-person MDPP encounters, and to permit virtual MDPP to register as Medicare Suppliers to enable uptake by MA plans. Without this allowance, in-person MDPP providers will be unable to service MA plans which will leave numerous beneficiaries without access. CMS can alleviate this issue by affirming that MA plans may use virtual MDPP to meet network adequacy requirements and

satisfy the requirement to provide MDPP services; and by allowing virtual MDPP providers to register as Medicare Suppliers for this purpose. We also note that, whether in the Medicare fee-for-service or MA context, a successful MDPP will require the inclusion of a virtual program the MDPP supplier enrollment, preliminary recognition, and supplier standard provisions of the final rule.

- CMS should consider the inclusion of processing time, approval/denial rates, and denials overturned on appeal in prior authorization metrics in MA plan Star Ratings.
- CMS is encouraged to improve alignment between MA and ACOs by ensuring parity across MA and ACO quality and cost savings goals, including with respect to digital health technologies. Notably, CMS should take all steps possible to reduce burdens on ACOs in value-based care agreements with MA plans, patient eligibility for using digital health tools should be aligned.
- CMS' approach to improving MA should also prioritize the need for the responsible development and uptake of AI tools that will be critical in addressing healthcare worker shortages and in realizing value-based care. The cultural, workforce training and education, data access, and technology-related changes will require strong guidance and coordination across several venues. Given the significant role of the government in the regulation, delivery, and payment of healthcare, it is critical that HHS collaborate with provider organizations, other civil society organizations, and private sector stakeholders to realize the benefits that responsible use of AI tools offers patients and caregivers. CHI has worked with the broader community to develop, and strongly encourage the HHS strategy to align with, healthcare ecosystem-wide consensus recommendations on the use of AI in healthcare:
 - 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>);
 - CHI's Good Machine Learning Practices for FDA-Regulated AI, a risk-based approach to benefit the Food and Drug Administration (FDA) as it addresses both locked and continuously-learning AI systems that meet the definition of a medical device (<https://bit.ly/2YaYljk>); 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 the opportunity to submit comments to CMS and urges its thoughtful consideration of the above input.

Sincerely,

A handwritten signature in black ink, appearing to read 'B. Scarpelli', with a stylized flourish at the end.

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