Executive Summary

We believe bold ideas and innovation require new and creative collaborations. To that end, we are providing a combined response to the Health Technology Ecosystem Request for Information (RFI) informed by Myant's healthcare market innovations and Deloitte's[1] experience with Federal Health programs, including CMS. We believe well-designed wearables can both save lives and empower Medicare beneficiaries to take control of their health. As CMS shifts its focus to double down on prevention, wellness, and chronic disease management, wearables will play a pivotal role in patient engagement, shared decision-making, and improved health outcomes.

We recommend practical steps to boost innovation and adoption so that life-saving wearables can become a seamless part of everyday healthcare. We recommend that CMS:

- **Collaborate with wearable tech companies and the FDA** to accelerate vetting processes for getting devices into the hands of Medicare beneficiaries.
- **Host focus groups with Medicare beneficiaries, caregivers, and providers** to assess technology needs and leverage existing surveys (e.g., Medicare Current Beneficiary Survey) to collect user experience data.
- Work with payers and providers to **create incentive programs that reward beneficiaries for using select wearables** and share data to improve real-time monitoring, care planning, adherence, and health outcomes.
- **Incentivize the adoption** of wearable health technologies by Medicare beneficiaries and **"prescriptions" from providers**, for example by integrating wearables into CMS Innovation Center models or expanded programs (e.g., Million Hearts) or by providing premium or payment incentives through the Medicare program.
- **Support pilot initiatives to test new digital health solutions,** either through CMS Innovation Center models or private sector partnerships, study and share the results, and refine leading practices for wider adoption.

With these recommendations, CMS can empower patients, caregivers, providers, and payers all with real-time information that can lead to improved wellness and health outcomes. We welcome the opportunity to further discuss any areas of interest with CMS and ASTP/ONC.

CONTACTS	
Kim Dedmon kdedmon@deloitte.com Deloitte Consulting LLP	Milad Alizadeh-Meghrazi miladam@myant.ca Myant Corp.

[1] As used in this document "Deloitte" means Deloitte Consulting LLP. Deloitte Consulting LLP is not a certified public accounting firm. Please see www.deloitte.com/us/about for a detailed description of the legal structure of Deloitte LLP and its subsidiaries. Certain services may not be available to attest clients under the rules and regulations of public accounting.

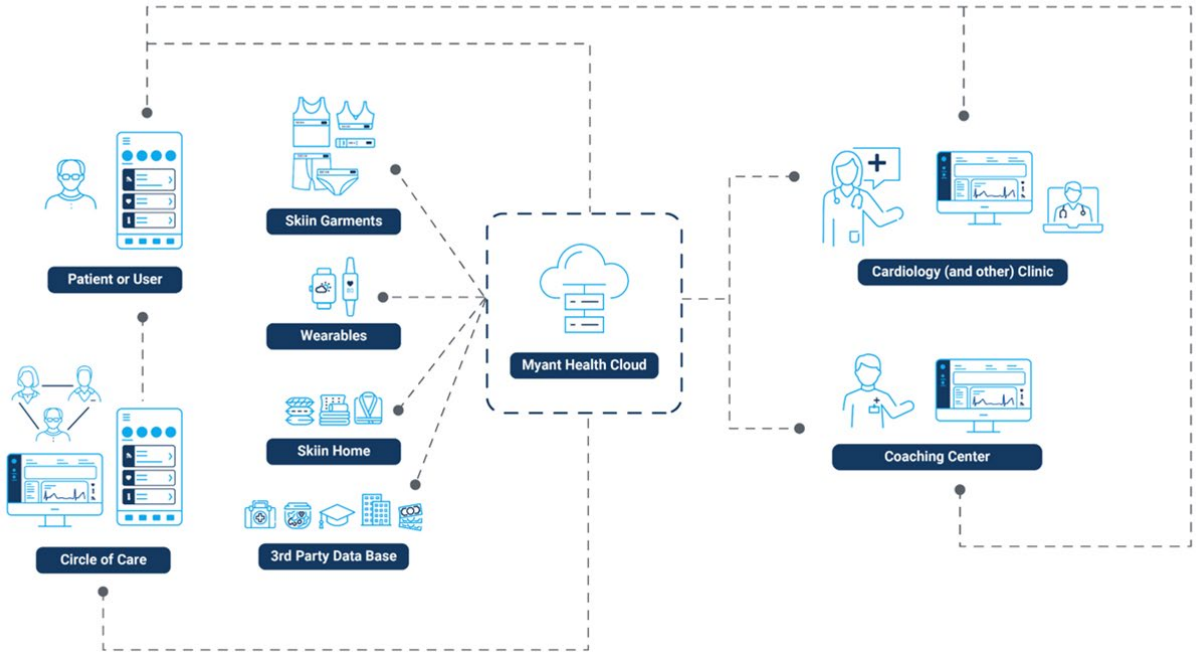
Response to Questions

PC-3. Are you aware of health management, care navigation, or personal health record apps that would be useful to Medicare beneficiaries and their caregivers?

Wearable devices offer significant benefits for Medicare beneficiaries and their caregivers by enabling continuous, real-time monitoring of vital signs (such as heart rate, sleep, and activity) and supporting early detection of health issues— an especially important feature for older adults managing multiple conditions. While wearables collect data instantly, their companion apps create additional value by translating complex health metrics into easy-to-understand visuals, summaries, and recommendations, allowing beneficiaries, caregivers, and providers to make timely health decisions.

One example of an existing and validated wearable used in other countries is Myant's Skiin Holter products (Chestband, Bra, and Tank top), which continuously track real-time ECG (3x leads), temperature, respiration, blood pressure, pulse oximetry, and physical activity. Most cardiac care currently lacks real-time data for patients and doctors, leading to delays in care, increased hospital visits, and higher long-term care costs. The Skiin Holter garments and their companion app can improve health management by securely sharing ECG data and health alerts between patients, caregivers, and providers, reducing the need for in-person visits, and enabling proactive, coordinated care. The products' user-friendly, HIPAA-compliant design makes them accessible and safe for Medicare beneficiaries. Digital health tools like the Myant Skiin Chestband Holter and app can empower Medicare patients with personal health data to manage their heart health more effectively, enhance care coordination, and improve outcomes and quality of life for those living with chronic cardiac conditions.

Example of a Personalized App for Patients and Caregivers



CMS is committed to offering beneficiaries more personalized tools to help them better manage their health and navigate the complexity of our healthcare system. By enabling Medicare beneficiaries to use personalized solutions for chronic conditions such as cardiovascular disease, CMS may see a reduction in costly claims for hospital stays and serious cardiac events. CMS should collaborate with partners who have experience working with health technology vendors/developers and understand CMS's broad stakeholder ecosystem, to **vet wearables and apps most suitable for Medicare beneficiaries.** Additionally, **CMS should conduct focus groups with beneficiaries as well as caregivers and providers, and collect data via existing surveys** (e.g., Medicare Current Beneficiary Survey) to assess needs and preferences, device usage, challenges/barriers, and comfort level with technology.

Information from focus groups can then be shared with wearable companies to tailor apps for the Medicare population. It will be important to understand beneficiaries' readiness for these tools, which features they would find most useful, and the behavioral interventions needed to increase adoption. Ultimately, these efforts can encourage healthier habits, greater engagement, and better health outcomes.

PC-5. What can CMS and its partners do to encourage patient and caregiver interest in these digital health products?

a. ***What role, if any, should CMS have in reviewing or approving digital health products on the basis of their efficacy, quality, or impact or both on health outcomes (not approving in the sense of a coverage determination)? What criteria should be used if there is a review process? What technology solutions, policy changes, or program design changes can increase patient and caregiver adoption of digital health products (for example, enhancements to data access, reimbursement adjustments, or new beneficiary communications)?***
b. ***What changes would enable timely access to high quality CMS and provider generated data on patients?***

CMS should lead the way in making digital health tools accessible, trusted, and easy to use — unlocking better care, lower costs, and improved outcomes for its beneficiaries. By collaborating with wearable tech companies and the FDA, CMS can help **lead efforts to accelerate and automate the pipeline of FDA 510(k) cleared wearables into the national coverage determination process.** CMS can consider codifying improvements in future rulemaking to streamline approvals and adoption. With over half of Medicare beneficiaries using smartphones and more than 40% having tried telehealth since 2020 (KFF, 2023), the opportunities and interest in using digital health products are clear. Yet, many older adults and caregivers still face barriers: confusing apps, privacy concerns, and limited digital skills. A 2022 AARP survey found that 38% of older adults felt uneasy using new health apps without some help.

To address these challenges and increase patient and caregiver adoption of wearable products, CMS should **offer reimbursement incentives for providers who demonstrate high patient engagement and digital tool adoption**. Strengthening requirements for data privacy, transparency, and user consent, along with clear communication to beneficiaries about data use and protection, will help build trust.

Program design enhancements can further drive adoption. **Targeted beneficiary communications—using plain language, testimonials, and step-by-step guides**—can demystify digital health products and address common concerns. Meanwhile, similar **provider communications and education** will also ensure clinicians can confidently recommend, teach, and support digital health adoption among their patients.

Supporting pilot initiatives through innovation models will allow CMS to test digital health solutions, experiment with various behavioral prompts or "nudges," gather feedback, and refine for broader rollout. Informed nudging can further enhance the impact on patient and provider responses by making message timing, content, and format more oriented towards action. Example nudges include alerts about significant changes in vitals, appointment reminders, medication alerts, or educational messages. CMS could collaborate with partners to identify which approaches enhance the personalization of digital tools and motivate meaningful steps towards preventative care. This iterative "test and learn" process not only tailors digital experiences to individual needs but also reveals leading practices that can be scaled system-wide, ultimately improving adoption and outcomes for Medicare beneficiaries.

By implementing these solutions, CMS can accelerate digital health adoption and improve care coordination. These steps will also enhance patient satisfaction, lower costs through proactive care, and help CMS deliver on its mission to improve health outcomes for all of its beneficiaries.

PR-7. What strategies can CMS implement to support providers in making high-quality, timely, and comprehensive healthcare data available for interoperability in the digital product ecosystem? How can the burden of increasing data availability and sharing be mitigated for providers? Are there ways that workflows or metrics that providers are already motivated to optimize for that could be reused for, or combined with, efforts needed to support interoperability?

CMS has a unique opportunity to improve how healthcare data is shared and used, especially as digital transformation continues, and more people rely on wearables and other health technologies. Right now, there are still some real challenges: as of 2021, only about 55% of hospitals and 40% of office-based physicians could electronically send, receive, find, and integrate patient information from outside sources (ONC, 2022). This often leads to delays in care, incomplete records, and extra administrative work—issues that are particularly tough to manage for Medicare patients with a chronic condition like cardiovascular disease.

To address these challenges, **CMS should collaborate with electronic health record (EHR) and wearable companies to make it easier for devices to share information directly with EHRs**. Providing technical support and convening industry leaders can help accelerate this digital shift. Once industry standards are established, **CMS should incentivize the integration of data from wearable health technologies.** Providing technical assistance and funding for smaller practices to upgrade their EHR systems is crucial, as resource constraints often limit the ability to integrate wearable-generated data (Adler-Milstein & Jha, 2017, *Health Affairs*). Aligning payment models and quality reporting requirements with the goal of integrating wearable data can further motivate providers to prioritize interoperability without increasing administrative burden.

By leveraging public-private partnerships, there are opportunities to incorporate wearable technology into the implementation of successful models. For example, to build on the CMS Innovation Center's Million Hearts Model's successes and the current expanded initiative, **CMS**

should collaborate with leading wearable tech companies and participating organizations to get devices into the hands of their Medicare patients that are at high-risk for cardiovascular disease.

Wearables can track metrics such as ECG, physical activity, blood pressure, and respiration, and the information they collect can flow right into the systems doctors and nurses already use every day. For example, wearable data could automatically show up in a patient's electronic health record or be included in regular check-ins for chronic disease management. This means providers wouldn't have to change how they work; instead, they would get more complete information to help spot risks and close care gaps, which are areas providers are already measured on for quality and value-based care arrangements.

Additionally, CMS should work with payers to create incentive programs that reward patients for using their wearables and staying engaged. These rewards—like lower premiums or wellness perks—could be tied to goals that providers already care about, such as keeping blood pressure under control or reducing hospital readmissions. By connecting wearable data to the metrics and workflows providers are already focused on, CMS can make it easier for beneficiaries and caregivers to adopt new technology and keep building on what's already working to improve heart health and save costs.

Conclusion

On behalf of Deloitte and Myant, we thank you for the opportunity to respond to this request for information and to share our perspectives on opportunities for innovation in the Health IT Ecosystem. For reference, please find a short video overview of Myant from the 2024 Consumer Electronics Show (CES) here.