F|42

Public Comment on CMS-2025-0050-0031: Health Technology Ecosystem RFI

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Introduction

More than 100 leaders from across healthcare have come together to build F|42 to define, advocate for and enable a person-centered healthcare system. Based on both research and our collective experience, we believe that person-centeredness can drive better human, clinical and financial performance in healthcare.

Doing so requires taking a holistic approach that is centered on the wants and needs of the individual – something that is beyond the scope, capabilities and experience of individual organizations. Consequently, we are built as a 501(c)3 to serve as an honest broker and to facilitate the ecosystems necessary to holistically support individuals and their needs.

Our response to the RFI is specifically focused on the specific Patients and Caregivers (PC) questions that speak to the need – and opportunity - for greater person-centeredness in healthcare. We identify areas where greater digital solutions can do more to address individual wants and needs, and to account for life context.

Responses

PC-1. What health management or care navigation apps would help you understand and manage your (or your loved ones) health needs, as well as the actions you should take?

The last 15 years have seen an explosion of apps and resources to better help with management of health and disease. Sites like WebMD and the Mayo Clinic provide valuable educational resources. EHR portals such as Epic's MyChart allow for communication with providers and provider systems. Other apps enable the tracking of medical history and provide remote monitoring, such as for cardiac arrhythmias and for blood glucose. Therapeutic apps focus on virtual delivery of behavioral health interventions for treatment of conditions including insomnia, substance use and depression.

These apps are typically not connected with one another, however, extending the fragmentation of the healthcare system. Additionally, there are far fewer products that help people with the life context barriers that get in the way of following treatment plans and accessing care. If you can't travel and the app tells you to see your doctor, that may not be helpful. If you have children to

care for, you may not be able to do the physical therapy you need. We need more apps to fill the gaps that are created by life getting in the way.

We need to build ecosystems that include specific apps alongside traditional players such as health systems and payers, and other components of the life needs of people who become patients. That ability to build and support an ecosystem which is simple from the patient's and caregiver's/family's point of view is critical and is missing. This is the building of the "ecosystem of the individual."

a. ***What are the top things you would like to be able to do for your or your loved ones' health that can be enabled by digital health products?***

   Healthcare today is extremely fragmented and difficult to navigate – and this navigation burden comes on top of everything else a person has in their life, including work, family, finance, and all the other responsibilities and issues they face. People need help to simplify access to care, simplify coordination between different parts of the system, and simplify communication of those needs to their health professionals. Those professionals in turn should be able to adapt their instructions and their treatment modalities to better fit the needs and priorities of the patient.

   This is possible through newer techniques in AI/NLP that allow communication of life issues by a patient. This can enable the healthcare system to better understand and the Social Consequences of Disease as well as the Social Determinants of Health, providing a better window into the emotional needs that come with illness. As a result, digital tools and products can make medicine more personalized and more contextually relevant.

b. ***If you had a personal assistant to support your health needs, what are the top things you would ask them to help with? In your response, please consider tasks that could be supported or facilitated by software solutions in the future.***

   For the most part, the equivalent of personal assistants in healthcare today are care navigators, who are are used for educating patients, helping them anticipate needs, and help them coordinate their appointments. This is insufficient to address the totality of an individual's wants and needs – particularly at a time of vulnerability caused by health concerns.

   Consequently, there is a need for personal assistants to help with life issues that are impacting care. Today, that role is typically played by family and friend caregivers who

are also trying to manage their own life needs. We need to better arm those people and provide backup for them so that they can provide the assistance that their loved ones need. Examples include help with getting to appointments, coordinating between health professionals and other providers, communicating personal wants and desires to the care delivery team so that these wishes can be addressed. The personal assistant must be someone who attempts to understand what is important and what barriers exist to care, and who respects individual priorities.

An assistant should also be able to address the complexity of our healthcare system by proactively identifying the needs of an individual in any given situation and matching them with the appropriate resources. An example could be assessing a beneficiary's desire to age in place, assessing their ability to do so, and proactively connecting them with the necessary medical and non-medical resources, including home modification, mental health, and even financial planning.

One basic illustration of the value of a personal assistant is the mother of one of our team members. She is 78 years old and is deaf in one ear and hard of hearing in the other because of a disease contracted at the age of 5. She needs someone to attend appointments and procedures with her – not only to better communicate with the care team – but to also ensure that she is not positioned with her one good ear on the pillow when having a procedure such as a colonoscopy.

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?***

- *Efficacy* – Does the product do what it claims to do? While some digital health products are subject to FDA review (which does address this), there are many that do not fall under FDA jurisdiction but still have the potential for Medicare reimbursement
- *Usefulness* – Even if the product does what it claims to do, does that matter? Or is the product just creating more healthcare "noise" for users?

- *Connectivity* – How easy or difficult is it for the user to share information between this product and other healthcare information systems? If the data generated by the product cannot be easily integrated with other healthcare systems, then it limits the usefulness of the product. Information blocking is a concern for all digital health products – not just electronic health records (EHRs).
- *Ease of use (Usability)* – How easy is the product to use, especially for someone with limited health literacy?
- *Family/caregiver access* – Can the end-user provide access to either the product itself or the data output by the product to family members or other designated caregivers if desired? Can family members and caregivers input information if useful and appropriate?
- *Privacy* – Does the product (and the company's policies) appropriately protect personal health information (PHI) and personally identifiable information (PII)?
- *Security* – Does the product and the company's servers use generally accepted best practices for security (e.g., 2-factor authentication, password standards)? Does the company adhere to security best practices internally, such as SOC-2 audits and HI-TRUST certification?
- *Interrogability, error logging and error checking* – If the product produces an unexpected, erroneous or even hazardous result, there should be some ability to assess the operation of that product to 1) determine the cause of the error and 2) fix that error
- *Push updates* – If a significant error is detected and a software solution identified, it should be possible to push updates to the products "over the air" rather than expecting users to manually update the product. Precedent for this exists with software updates for other software-dependent products such as cars.
- *Validation and generalizability* - Most health management and patient-facing digital tools will be built on LLMs and predictive AI to optimize effectiveness, efficiency and scalability. To ensure validity and generalizability of the models, developers should address technical performance, ethical considerations and representational generalizability.

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)?

Greater adoption and utilization of digital tools will occur if individuals feel as though these products are useful to them. That requires accounting for individuals as whole people, rather than just their conditions – so using AI to assess and integrate the non-medical considerations along with medical ones is crucial.

Interoperability and usability are also essential. Individuals should not have to copy or otherwise transfer their information from one app to another (assuming they have permitted such sharing). Additionally, the solution should connect to the larger health ecosystem and allow for personalization of interventions, information and services delivered to the individual. The more users feel that the digital solution is an extension of their care teams, the more likely they are to adopt it.

Finally, usability is critical – as a digital solution will not achieve meaningful impact unless an end-user finds it easy to use, transparent and trustworthy.

PC-6. What features are most important to make digital health products accessible and easy to use for Medicare beneficiaries and caregivers, particularly those with limited prior experience using digital tools and services?

Similar to our answers above, making digital health products accessible includes having a simple user interface and intuitive controls. There should be and a single access point (rather than a multiplicity of logins and applications to manage) and integration between apps, services and payments in a collaborative form. Beneficiaries should be able to provide access to family members and other caregivers, and the products should enable those individuals to also input and access information and resources.

PC-12. What are the most valuable operational health data use cases for patients and caregivers that, if addressed, would create more efficient care navigation or eliminate barriers to competition among providers or both?

a. Examples may include the following:

(1) Binding cost estimates for pre-defined periods.

(2) Viewing provider schedule availability.

(3) Using third-party apps for appointment management.

(4) Accessing patient-facing quality metrics.

(5) Finding the right provider for specific healthcare needs.

All of the capabilities listed above are useful, but they leave out the emotional, social, financial and even cultural barriers that can make it challenging for individuals to access and understand healthcare. Greater use of tools to assess and understand an individual's emotions and life priorities can be accomplished by leveraging AI and sentiment analysis. Nevertheless, while this can create additional complexity and information overload for clinicians, care must be taken to design products for simplicity and interoperability.

b. What use cases are possible today?

- Patient education
- Personal tracking and journaling (found by research to be very helpful)
- Community building among those who have similar medical, social, and/or cultural issues to help with the burden of having an illness
- Mental and behavioral health for conditions such as depression, anxiety, stress, insomnia, SUD, and child and adolescent mental health
- Advanced remote patient monitoring, including Continuous Multi-Vital Monitoring to enable simultaneous measurement of multiple biometrics across a wide range of conditions, with AI-driven predictive algorithms for monitoring, alerting and intervention and reporting functions.

c. What should be possible in the near future?

In the near future, the ability of AI and NLP will only improve, especially if we encourage the use of ecosystems rather than single source solutions. These are learning systems that will gain insights as more data is accumulated.

Ability for apps to access integrated data and analytics to further improve on its AI models, as well as ability to integrated into the EHR/ EMR as barriers of interoperability lessen. In addition, more ability for devises to create robust two-way communications that are reliable, accurate and safe.

d. What would be very valuable but may be very hard to achieve?

As we've indicated in our other answers, capturing information about individual wants and needs and taking those into account is essential to improve both the experience and the outcomes of our healthcare system for all users. Nevertheless, this is challenging for a number of reasons:

- Individual wants and needs evolve over time, and can often be context dependent. The answer captured one day may not be correct on another day.
- Individuals may struggle to express their wants and needs – and to explain their context – in concrete, actionable terms.
- Some wants and needs may go against what may be clinically and socially preferable (for example, an individual may not want to quit smoking).
- It is challenging to elicit and capture this information in a structured way that is usable both by technology and by clinicians. There's a risk of not having enough information or enough clarity, and a risk of having too much information (such as all of the sleep data produced by current health trackers).
- Integrating all of this information into a health plan and an engagement approach requires a lot of work both at the start of the plan and on an ongoing basis for already overworked clinicians. While technology and smart nudges can help with this, it still requires continual oversight to be effective – and it also requires the buy-in and cooperation of the individual and their personal ecosystem of family, caregivers and other relationships.