

RE: Request for Information: Health Technology Ecosystem

We at Kivo Health - a digital health company delivering AI-enhanced, virtual rehabilitation for chronic lung disease (COPD) - would like to commend the authors of this RFI for seeking input from innovators, caregivers, providers, and other stakeholders in pursuit of making America healthy again. As a physician-led company, we share in the mission to build a better system for Medicare beneficiaries by improving the health of seniors with chronic disease.

As a digital health company developing new technology, creating novel models of care, and improving access for Medicare beneficiaries with chronic disease, we have real world experience with the opportunities and challenges affecting digital health companies in today's ecosystem. We are responding to this RFI in hopes that our experience can contribute to creating a flourishing digital health ecosystem that addresses the needs of Medicare beneficiaries. We would welcome the opportunity to continue this dialogue and share our experience or offer concrete recommendations if that would be of value to the team at CMS.

We have distilled our responses to the RFI into four key recommendations below. We also included more comprehensive answers to specific questions posed in the RFI based on our experience and expertise.

Key Recommendations to Drive Innovation in Digital Health for Medicare Beneficiaries

1. Develop alternative payment models for chronic conditions (such as COPD) building upon the learnings from the GUIDE model for dementia.
2. Develop a marketplace for high-quality digital health products - encouraging members and providers to use it by covering 100% of costs (including co-pay) for certain, cost-saving products.
3. Remove barriers to access - such as overly stringent eligibility criteria or lifetime caps - for high-value, cost-saving interventions such as virtual pulmonary rehab for COPD.
4. Better align HEDIS metrics with improved chronic disease management - such as including access to pulmonary rehabilitation for COPD as a HEDIS metric.

Thank you for the consideration.

Sincerely,
The Kivo Health Team

Responses to Specific RFI Questions

Below are responses to specific RFI questions where we believe our experience adds value. We selected the questions we responded to based on relevance to our expertise and experience.

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

- CMS and its partners should curate a vetted marketplace of digital health products for Medicare beneficiaries and publish the marketplace online.
- CMS and its partners should publicize the availability of this marketplace through an omnichannel approach (i.e. email, snail mail, etc.) at specific intervals (i.e. during open enrollment and six months after open enrollment).
- CMS and its partners should also collaborate with medical societies and other organizations (i.e. AARP) to publicize this marketplace to providers, care managers, etc. to inform Medicare beneficiaries of this marketplace.
- CMS and its partners should consider reimbursing part or all of the co-pay associated with digital health products on the marketplace – especially those that have been shown to be cost-saving.

PC-5(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)?

CMS should collaborate with stakeholders and experts to develop criteria for approving digital health products. One suggestion would be to identify themes that are consistent with CMS strategy, and then to collaborate with experts to identify gaps in care, and work with experts to develop a framework for evaluating digital health products that address those gaps based on efficacy, safety, useability, and cost-effectiveness.

For example, themes could include digital health products for common and costly chronic conditions affecting Medicare beneficiaries, such as: chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), chronic kidney disease (CKD), diabetes, etc. CMS could work with experts for each of these conditions to identify the types of digital health products that could address gaps in care for each of these conditions. Digital health products apply to be evaluated and graded based on their efficacy, safety, useability, and cost-effectiveness. Based on their score, they may be a) included in the marketplace, b) included in the marketplace and the member copay could be reimbursed by CMS for products that are cost-saving to CMS, or c) neither.

To be even more specific - here is what this might look like for a specific theme:

- CMS identifies improved care for chronic obstructive pulmonary disease (COPD) as a theme, because COPD is a chronic disease that affects 1 in 8 Medicare members and costs over \$50B annually. It also disproportionately affects people in rural communities that face access barriers.
- CMS works with experts in COPD management (ie pulmonologists, public health experts, etc) to identify gaps in care for COPD that could be addressed by digital health solutions.
- Experts identify that one gap in care is access to pulmonary rehabilitation. Pulmonary rehab is standard of care therapy for COPD and has been shown to reduce costs of care by ~\$5,700 per member, but fewer than 3% of eligible Medicare members complete it due to access barriers.
- CMS works with experts to create a rubric for digital health products that provide virtual pulmonary rehab for COPD, which drastically improves access to pulmonary rehabilitation.
- CMS announces a framework for digital health products that provide virtual pulmonary rehab for COPD.
- CMS reviews applicants based on the rubric and grades the digital health product. Based on the grade, the product is either: a) included in the marketplace, b) included in the marketplace and 100% of fees are covered by CMS (ie no co-pay for the member), or c) neither.

PC-7. If CMS were to collect real-world data on digital health products' impact on health outcomes and related costs once they are released into the market, what would be the best means of doing so?

- CMS has access to all claims data, so CMS should collaborate with digital health companies to identify which claims would be impacted by their solution (ie pulmonary rehab reduces hospital bed days and SNF days for members with COPD).
- CMS should then identify members that are utilizing a specific solution and aggregate the claims data and compare claims data among those members who are engaged in the solution vs those that are not.
- This would provide real-time, real-world measurement of utilization and outcomes using existing claims data infrastructure.

PR-1. What can CMS and its partners do to encourage providers, including those in rural areas, to leverage approved (see description in PC-5) digital health products for their patients?

- CMS can offer bonus payments to providers in rural areas that utilize approved digital health products for their patients.
- CMS could offer education sessions that are either mandatory or that provide continuing education credits for providers that complete them.
- CMS could create a HEDIS metric that measures which providers inform their patients about the approved digital health products.

PR-1(a) What are the current obstacles?

- The biggest obstacles are:
 - Knowledge of available products.
 - Differentiating between high quality and low quality products. Providers can't keep up with all the new products and struggle to know which ones to recommend.

PR-1(c) What responsibilities do providers have when recommending use of a digital product by a patient?

- When recommending use of a digital product to a patient, the provider is responsible for recommending an appropriate product based on the patient's medical needs.
- Ideally, the provider can recommend a product that has been evaluated by CMS for efficacy, safety, useability, and cost-effectiveness.

PR-3. How important is it for healthcare delivery and interoperability in urban and rural areas that all data in an EHR system be accessible for exchange, regardless of storage format (for example, scanned documents, faxed records, lab results, free text notes, structured data fields)? Please address all of the following:

- It's critical that all data, regardless of format, be easily accessible across different organizations to reduce unnecessary duplication of work and other waste.

PR-3(a) Current challenges in accessing different data formats.

- Based on our experience, currently, electronic data exchanges are effective about 70% of the time, and are more effective for certain types of data.
- Data that is captured outside of the EHR and then uploaded into the EHR (especially if in a PDF format) is particularly challenging to access through the data exchange.
 - As a specific example, pulmonary function tests are oftentimes completed using a different system than the EHR and then uploaded as a PDF to the EHR.
 - These types of test results are especially difficult to access through electronic data exchanges.

PR-3(b) Impact on patient care quality.

- Difficult access to data negatively affects patient care quality because either a) care may be delayed or b) tests must be duplicated (creating discomfort for patients and creating waste in the system).

TD-1. What short term (in the next 2 years) and longer-term steps can CMS take to stimulate developer interest in building digital health products for Medicare beneficiaries and caregivers?

- Short term steps -
 - Develop additional novel payment models for high priority populations - building on the learnings for the GUIDE model. Consider high-cost, common chronic conditions that affect Medicare beneficiaries and have been historically underinvested in, yet disproportionately affect rural populations - such as COPD.
 - Create a “digital health hub” or marketplace to spur competition and innovation in digital health for Medicare beneficiaries.
 - Publish key themes that CMS is focusing on to encourage innovation. Create reimbursement mechanisms that create viable business models for novel digital health solutions.

- Tie HEDIS and STARS metrics to providing access to digital health solutions for key themes identified by CMS (such as solutions addressing chronic conditions disproportionately affecting Medicare beneficiaries, including COPD).
- Long term steps -
 - Invest in broadband infrastructure to improve internet connectivity across the entire nation, especially rural areas, to expand the market for digital health solutions.
 - Accelerate move to value-based care reimbursement models, creating incentives for digital health solutions that improve access and reduce costs of care.

TD-2. Regarding CMS Data, to stimulate developer interest—

TD-2(a) What additional data would be most valuable if made available through CMS APIs?

- Claims or utilization data to help organizations track and prove the cost-effectiveness of their solution.
- Information on other treating providers to help organizations coordinate care across the patients care team.