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VIA Electronic Delivery to Regulations.gov
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Ave SW
Washington, DC 20201

Re: Request for Information - Health Technology Ecosystem (CMS-0042-NC)
To: Administrator Oz and Acting Assistant Secretary Posnack

Introduction

Thank you for the opportunity to consider and respond to the Health Technology Ecosystem RFI (CMS-0042-NC).

Aldea Health is an AI platform powering radically more affordable, intelligent, and safe clinical experiences across the patient journey. At the heart of Aldea's platform is **conversational voice AI**, enabling natural, empathetic interactions that make care feel accessible and personal. We partner with providers, payors, and value-based care organizations to deliver these experiences directly to patients. Unlike solutions built on expensive LLMs, Aldea has achieved a technical breakthrough—offering best-in-class performance at substantially lower cost. This unlocks truly scalable, personalized care at a price point that was once impossible given the limits of existing AI infrastructure.

Our mission is to make care radically more accessible, affordable, and intelligent—by building intuitive, holistic tools that support patients from first symptom to end of life.

The Aldea Clinical product suite includes four core applications:

1. **Ask Aldea:** A digital front door that offers on-demand, educational support for one-time health questions, helping patients understand their symptoms and navigate next steps in care.
2. **Care Journeys:** Personalized guidance and behavioral support that focuses on the entire patient rather than a single, siloed condition, acknowledging the complex interplay of conditions and social circumstances. These care management and coordination tools help patients synthesize and prioritize care needs, supporting chronic condition optimization as well as nutrition, weight loss, fertility, prevention, and wellness.
3. **Patient Education Suite:** A patient-facing tool that helps individuals digest new diagnoses or information about their health, and assists patients and families to

participate in shared decision making and prepare for important conversations and care planning discussions with their providers.

4. **Care Assistant:** An administrative helper that supports tasks like finding in-network providers, scheduling appointments, and gathering non-clinical intake information.

The Aldea platform also includes a low-code builder ("Implementation Agent") that allows healthcare organizations to design and deploy custom voice-based AI experiences—trained on their own knowledge bases, workflows, and protocols.

Please find below the Aldea leadership's perspective on important issues solicited in the RFI.

Patient Needs (PC 1-7)

Patients and caregivers need intuitive, voice-friendly digital tools that pull all of their health data into one place, translate that information into clear, personalized guidance, and proactively support everyday tasks—from symptom management and medication reminders to chronic-condition coaching and care-navigation help. To be trusted and widely adopted, these tools must be clinically validated, privacy-secure, interoperable with any EHR, and easy enough for people with limited digital literacy to use; public leadership (e.g., CMS certification, enforcement of open APIs, and reimbursement incentives) is essential to make that unified, patient-centered experience a reality.

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?*

Aldea's platform provides a comprehensive suite of digital health products that directly help patients and caregivers manage their health. Our patient-facing tools support medication adherence, patient education, and chronic condition management to empower individuals to understand their health and take appropriate actions.

PC-1a. *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?*

The most pressing needs for health care management are as follows:

- Accurate and timely guidance: Aldea's tool provides this critical first step, reducing anxiety and guiding patients to appropriate care.
- Personalized, context-aware health education: Our LLM architectures and "tailored brains" allow for patient education that is highly relevant to an individual's specific conditions, medications, and questions. This goes beyond generic information to truly address their unique needs.

- Proactive medication management and adherence support: Our daily support for medication adherence significantly improves outcomes by reminding patients, explaining medications, and addressing ad hoc concerns.
- Continuous, intelligent support for chronic condition management: Aldea's comprehensive tools for chronic conditions provide ongoing guidance, symptom tracking, and proactive intervention suggestions, all delivered through natural, empathetic voice interactions.
- Seamless access to and understanding of personal health information: Additional data integrations, including to EHRs, would enhance our tools to pull and interpret patient-specific data to inform conversations and recommendations.

PC-1b. *If you had a personal assistant to support your health needs, what are the top things you would ask them to help with?*

Many patients and caregivers struggle to absorb confusing and specialized medical information; Aldea provides technology that would help individuals process medical encounters or new diagnoses. Aldea's technology explains medical diagnoses and treatment plans in clear and digestible ways, leveraging the patient's own language or dialect. It can also summarize key health information from various sources (e.g., doctor's notes, lab results) into digestible insights.

Patients and caregivers could also leverage a health assistant to answer specific questions about symptoms, medications, and potential interactions; Aldea's robust platform enables highly accurate and safe responses. The Aldea health assistant helps patients and caregivers manage chronic conditions by providing personalized reminders for appointments, medication, and self-care tasks, providing navigation support through complex healthcare systems (e.g., finding specialists, understanding insurance), and offering emotional support and encouragement for managing chronic conditions. Our conversational design focuses on empathetic and supportive interactions, fostering patient engagement and adherence.

PC-2. *Do you have easy access to your own and all your loved ones' health information in one location (for example, in a single patient portal or another software system)?*

Most patients do not have access to technology that aggregates their information. While Aldea itself is not a "single patient portal," our ability to pull and interpret data from these systems allows our voice experts to act as an intelligent layer on top of existing data silos, bringing relevant information to the patient in a digestible format.

PC-2a. *If so, what are some examples of benefits it has provided?*

When a patient or caregiver is able to directly access important health information, the individual can take an active role in his/her/their healthcare, including communication and coordination of care, independently researching conditions or results and their implications, or mitigating healthcare errors and duplicative testing by providing up to date information.

PC-2b. *If not, in what contexts or for what workflows would it be most valuable to use one portal or system to access all such health information?*

Seamless access to multi-site healthcare information in one setting could decrease duplicative and unnecessary testing and highlight and mitigate adverse drug interactions and errors. It would provide just-in-time insight for emergency situations and facilitate care coordination across multiple providers.

PC-2c. *Were there particular data types, such as x-rays or specific test results, that were unavailable? What are the obstacles to accessing your own or your loved ones' complete health information electronically and using it for managing health conditions or finding the best care?*

While EHRs are improving, complete, standardized, and real-time exchange of all data types (including scanned documents, free text notes, and imaging) remains a significant challenge. Even with structured data, inconsistencies across systems can hinder a unified view.

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?*

Yes, Aldea's suite of products is specifically designed with features that are highly valuable to Medicare beneficiaries and their caregivers. Aldea's conversational AI provides immediate, informed guidance for health concerns, reducing unnecessary ER visits and guiding patients to appropriate care settings. Daily Medication Adherence Support assists Medicare beneficiaries to manage multiple prescriptions, improving outcomes and reducing avoidable hospitalizations. The Patient Education suite addresses the need for clear, understandable health information, empowering beneficiaries to actively participate in their care. The Chronic Condition Management Tools offers continuous support, personalized insights, and proactive management. All of these services are offered using an intuitive Voice-first interface, which promotes empathetic interactions and encourages accessibility, particularly for beneficiaries with visual impairments.

PC-4. *What features are missing from apps you use or that you are aware of today?*

Many apps offer generic information or templated responses. Aldea's 25 proprietary training paradigms and LLM architectures deliver context windows three orders of magnitude better than others, allowing for truly tailored and nuanced interactions. Most apps are transactional. Aldea's voice fidelity and conversational design enable empathetic, proactive support that feels like a true personal health assistant. Many general-purpose AI tools lack the rigor for medical applications. Aldea's 99.99% constitutional compliance with protocols ensures safety and reliability.

Finally, most existing solutions don't meet patients where they are. Aldea's technology enables a patient to converse back and forth with an AI for follow up questions to ensure patient understanding and comprehension.

PC-4a. *What apps should exist but do not yet? Why do you believe they do not exist yet?*

A "Magic Wand" for EHR integration does not yet exist. We must encourage secure, HIPAA compliant bi-directional information transfer and data portability; this has been difficult thus far due in part to the proprietary interests of electronic health record vendors and wide variation in systems in play across the country today.

PC-4b. *What set of workflows do you believe CMS is uniquely positioned to offer?*

CMS is in an excellent position to advance Blue Button 2.0 to the next level, promoting easier access to standardized, accessible, and easily explainable Medicare claims and benefits information. CMS takes a step further and deploys AI to synthesize, interpret and explain this information to beneficiaries in a patient-friendly way, helping them understand costs, coverage, and benefits. CMS should also promote price transparency and high value provider selection, establishing and maintaining a unified provider directory with accurate, real-time availability and specialization details. This would empower patients to find the "right provider" more efficiently. As AI health tools come of age, CMS could also ensure direct, secure channels for patient feedback and outcome reporting on digital health products, informing future policy and product development.

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

CMS should 1) launch public awareness campaigns to improve trust, highlighting the benefits of digital health, especially for managing chronic conditions, medication adherence, and proactive care; and 2) incentivize adoption of evidence based, proven tools for providers and beneficiaries. It would also be helpful for CMS to champion user-friendly design, emphasizing that digital health products must be intuitive, accessible, and address the needs of those with limited digital literacy. Similar to food labeling, a CMS established "Trusted Digital Health" stamp of approval could build trust in quality and efficacy.

PC-5a. *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?*

CMS should review and endorse/certify digital health products based on efficacy, quality, and impact on health outcomes, as well as privacy and security standards. This is critical for building trust and guiding beneficiaries. Criteria for Review: 1) Clinical Efficacy: Demonstrated positive impact on health outcomes (e.g., improved medication adherence, reduced hospitalizations, better chronic disease management); 2) Safety and Privacy (HIPAA Compliance): Rigorous adherence to privacy regulations and robust cybersecurity measures; 3) Usability and Accessibility: Ease of use for diverse populations, including those with limited digital literacy, visual/hearing impairments, and cognitive challenges; 4) Interoperability: Ability to securely exchange data with EHRs and other relevant health information systems; 5) Data Security and Transparency: Clear policies on data collection, use, and sharing; 6) Evidence-Based Design: Products should be grounded in scientific evidence and clinical guidelines (e.g., Aldea's 99.99%

constitutional compliance with protocols); 7) Scalability and Reliability: Ability to serve a large population consistently. In the broader policy environment, CMS should require and enforce robust, standardized APIs for patient and provider access to comprehensive health information. CMS should consider billing codes or reimbursement models that incentivize the use of evidence-based digital health products that demonstrate improved outcomes.

PC-5b. *What changes would enable timely access to high quality CMS and provider generated data on patients?*

CMS should strictly enforce information blocking regulations and aggressively penalize entities that intentionally block access to EHI. CMS should mandate comprehensive FHIR API implementation that requires all EHRs and health systems to support robust, standardized FHIR APIs that cover all USCDI data elements and ideally, full EHI. CMS should also develop a national patient matching strategy to enable a better and more efficient foundation for timely and high-quality data access and exchange.

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?*

As Aldea demonstrates, natural language interaction is far more intuitive for many users than typing or navigating complex menus. A voice-first interface is paramount for beneficiaries with limited digital literacy, visual impairments, or dexterity issues. Like Aldea, technology should avoid medical jargon, use clear, concise language and large, easy-to-read fonts, and minimize the number of steps (clicks) required to complete a task. Technology solutions must also offer personalized onboarding and support; Aldea offers guided tours and readily available conversational AI technical support. Solutions should take pains to enable accessibility, ensuring compatibility with screen readers, adjustable font sizes, and high contrast options. Finally, solutions must offer reliable and consistent performance, avoiding glitches or crashes that can frustrate users and erode trust.

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 should develop clear, standardized metrics and reporting templates for digital health product efficacy based on readily established claims-based metrics (e.g., reduction in ED visits, total cost of care, hospital readmissions) and regularly collected patient satisfaction data. Patient specific Digital Utilization data could then be linked to claims based metrics to study improvement. Beyond readily accessible claims information, CMS could consider leveraging a solution to collect patient reported outcomes, and if EHR integration were possible, track clinical metrics that matter like Diabetes [A1C] control and Blood Pressure Control.

Data Access and Integration (PC 8-12)

To truly empower patients and caregivers, the healthcare ecosystem must unlock access to rich, real-time, and personalized health data—ranging from clinical records to social determinants and device-generated vitals. Solutions like Aldea demonstrate the potential of voice-first, AI-powered platforms to interpret and act on this data, but success hinges on breaking down entrenched data silos, standardizing APIs, supporting patient-mediated access, and enabling scalable interoperability across HIEs, TEFCA, and CMS APIs.

PC-8. *In your experience, what health data is readily available and valuable to patients or their caregivers or both?*

Patients and caregivers often have access to encounter data, medication lists, vaccination records, visit summaries, lab test results and imaging studies through their providers' patient portal, though access can be challenging for individuals without technology expertise or availability, and caregivers require additional permissions to access data on behalf of the patient.

PC-8a. *What data is valuable, but hard for patients and caregivers, or app developers and other technical vendors, to access for appropriate and valuable use (for example, claims data, clinical data, encounter notes, operative reports, appointment schedules, prices)?*

As mentioned, patients and caregivers must petition for access to their own data directly from the office or log on through an electronic portal, which presents access challenges for some individuals. Ease of use varies across portals and health systems. In addition, patients and caregivers have significant difficulty accessing reliable provider data (addresses, phone numbers, appointment availability, scheduling metadata) and accurate, patient-specific cost estimates. Price transparency data is still not standardized, and does not translate well to specific cost estimates that are useful for patients and providers at the visit level.

Vendors seeking to improve health outcomes often face challenges to valuable claims data (data delivery is often delayed and nonstandardized) and clinical data (point of care tests such as Hemoglobin A1Cs, vital signs and other standardized metrics, and important subjective information are often found in free text rather than structured fields, limiting extractibility). Data collected outside of the patient's primary health care site are often siloed in pdf form, attached to the patient's electronic chart and un-mineable; this limits access and useability of data from specialty care, behavioral health consultations, emergency room visits and hospitalizations.

PC-8b. *What are specific sources, other than claims and clinical data, that would be of highest value, and why?*

Beyond claims and clinical data, the following data sources are of highest value:

- Social Determinants of Health: timely information on housing, food security, transportation, economic hardship and social support would be invaluable for addressing root causes of poor health outcomes, tailoring interventions, and connecting patients to available resources.
- Patient Reported Outcomes and Symptom Trackers in between visits: Logging the evolution of symptoms and patient experience over time enables timely escalation of issues.
- Continuous streams of physiological data (blood glucose, blood pressure, heart rate, activity levels) from devices and wearables can aid in proactive chronic condition management.

Aldea's proprietary technology leverages conversational AI and state of the art evidence based protocols to efficiently collect, interpret and act on this data.

PC-8c. *What specific opportunities and challenges exist to improve accessibility, interoperability and integration of clinical data from different sources to enable more meaningful clinical research and generation of actionable evidence?*

Opportunities:

- Standardization through FHIR APIs: Widespread adoption of FHIR-based standards can drive consistent access to granular, structured clinical data across systems.
- Incentivizing bi-directional data exchange: Most current models flow data to EHRs or from them, but not both. Payers, providers, and CMS can push for truly reciprocal flows between health systems and digital tools, unlocking real-time care coordination.

Challenges:

- EHR heterogeneity: Even with common standards, vendor-by-vendor and even implementation-by-implementation differences create brittle integrations and high development overhead.
- Unstructured data and labeling: Clinical notes, images, and external reports often lack metadata, provenance, or timestamps, making them difficult to index, search, or validate for research.
- Consent and access architecture: Current models assume provider-controlled access. There's a gap in infrastructure for patient-mediated data portability, including identity verification, permissioning, and longitudinal control over third-party use.

PC-9c. *Is there non-CMS data that should be included in the API?*

Pharmacy Data (beyond claims), including dispense dates, refills, and pharmacist notes and clinical information abstraction from health information exchange notes would provide helpful and actionable context.

PC-10c. *What use cases could have a significant impact if implemented through TEFCA?*

There are many applications for unified patient health records through TEFCA - if patients and healthcare organizations could pull EHI from all providers within the TEFCA network, we could see the following use cases:

- Seamless care transitions (healthcare data follows the patient when they switch providers or receive care in a new setting)
- Public health reporting and surveillance (faster and more complete data sharing for public health initiatives)
- Clinical Research: Enabling researchers to access broader, de-identified datasets for studies.
- Emergency Medical Services (EMS) Access: Providing first responders with critical patient information in emergencies.
- Population Health Management: Aggregating data for risk stratification and proactive outreach.

PC-11. *How are health information exchanges (HIEs) currently helping to advance patient access to health information in the real world?*

Depending on the quality and reliability of the HIE, exchanges can reduce fragmented care and improve care coordination by enabling providers to access documentation from outside their clinic's walls. Many HIEs have been integral in the promotion of alerts for admissions, discharges and transfers that have promoted better and more efficient post-ER/Hospital/SNF discharge follow up and transitional care management.

PC-11a. *How valuable, available, and accurate do you find the data they share to be?*

Value, availability and accuracy is highly variable depending on the region, penetrance, and governance (Delaware Health Information Network stands out as a particularly well functioning, accurate and complete HIE, for a positive example).

PC-11b. *What changes would you suggest?*

1) Promote seamless data exchange between HIEs, including easier processes for patients to grant and manage consent for data sharing across HIEs; and 2) Encourage HIEs to expose their data via FHIR APIs, making it easier for patient-facing apps to integrate.

PC-11c. *Are there particular examples of high-performing HIE models that you believe should be propagated across markets?*

HIEs with strong public-private partnerships, sustainable funding models, and a focus on broad community participation (including social services) often demonstrate high performance. Those that have successfully implemented FHIR APIs for patient access are also notable.

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?*

- **Provider data access and accuracy:** Key data points such as appointment availability, network participation status, specialties, address, and contact information are still fragmented and often

outdated. Aldea's conversational AI can autonomously call provider offices to verify this information in real-time and even book appointments on behalf of patients, significantly reducing administrative burden and care delays.

- **Clinical and medical record data structuring:** Much of the clinical data that patients and caregivers rely on is still unstructured, siloed, and hard to navigate. With foundational AI, Aldea can rapidly train and deploy models that standardize and extract insights from unstructured medical records at scale, supporting both patient comprehension and improved care coordination.

Providers (PR 1-3,8)

The primary barriers to provider adoption and effective use of digital health products stem from lack of reimbursement, poor EHR integration, excessive administrative burden, and fragmented or inaccessible data formats. Solutions must focus on streamlining workflow integration, mandating standardized APIs for billing and scheduling, reducing regulatory complexity, and supporting AI-driven automation for documentation and reporting. Unlocking clinical and administrative efficiency will depend on improving data interoperability and trust in validated digital tools that enhance care, not complicate it.

Digital Health Apps:

PR-1a. *What are the current obstacles?*

The most significant barriers to provider adoption of digital health tools are time and money. Providers and staff may lack the technical skills or time for training on new digital tools. The opportunity cost of learning and integrating new technology is high, and many providers find this investment is not worth it unless the digital health tool is meant to be utilized throughout the day, for the majority of their patient panel. It is important to note that providers depend heavily on their EHR systems, and it is often difficult and impractical to consider additional technology applications alongside the EHR (multiple log-ins, screen competition, etc). Products often don't seamlessly integrate into existing clinical workflows, adding burden rather than reducing it. Many digital health products are not directly reimbursed, making adoption difficult for providers (especially when digital technology requires an up front investment, with delayed - if any - financial returns). In addition, some providers may be concerned about HIPAA compliance and security, or may simply be overwhelmed by the sheer number of options available (without any standardized metrics to determine quality and efficacy). In some areas, lack of broadband access and lower digital literacy among some patients may provide additional barriers.

PR-1b. *What information should providers share with patients when using digital products in the provision of their care?*

Providers should clearly explain what the product does (and does not do) and how it will help the patient manage their health. Patients should understand how their data will be collected, used, shared, and protected. Patients may need additional support to understand exactly what they are expected to do (e.g., respond to prompts, track symptoms), and how to get technical support or clinical assistance.

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

It is not practical to expect providers to have in-depth knowledge and understanding of every available digital tool; this makes external validation all the more critical. Ideally, providers will understand how to select patients most likely to benefit from a given digital tool or intervention, and provide specifications and information to the patient about efficacy, appropriate use and validation.

PR-2. *What are obstacles that prevent development, deployment, or effective utilization of the most useful and innovative applications for physician workflows, such as quality measurement reporting, clinical documentation, and billing tasks? How could these obstacles be mitigated?*

Over 500 vendors independently offer some sort of electronic health record system. Proprietary EHR systems often make it difficult for third-party apps to integrate deeply and modify workflows. While clinical data APIs are emerging, APIs for scheduling, billing, and quality reporting are often non-existent or inconsistent. These factors make it complex and expensive to provide integration at scale for common clinical workflows.

Quality measurement is challenging because data needed for reporting is often scattered across different modules or systems, and sometimes hidden in free text rather than structured, standardized data fields.

In order to mitigate these challenges, CMS should require EHR vendors to expose APIs for scheduling, billing, prior authorization, and quality reporting data, streamline and consolidate quality reporting requirements, and provide incentives for adoption of validated workflow tools.

Where possible, providers should leverage AI to automate data extraction and summarization for clinical documentation and quality reporting.

Currently, digital tools are subject to fedRAMP review and approval for national scale across CMS beneficiaries. While regulation is necessary to protect patient health information, privacy and security, CMS should acknowledge that a particularly lengthy process can stymie innovation. An unintended consequence of current fedRAMP processes is that large incumbents are better able to successfully navigate, wait and complete the process; smaller, newer entrants may not be able to compete. If possible, CMS should revisit the process and simplify.

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

Providers still deal with a significant amount of unstructured data. Essential clinical information can be buried in scanned documents like faxes and old paper records, free text notes, and dictation summaries that are largely inaccessible to machines and hard to search or integrate. Even within a single EHR,

different modules or legacy components may store data in incompatible ways. While FHIR is expanding, it doesn't yet cover all legacy or unstructured data types, and EHR vendors often use proprietary formats that are not easily shared or interpreted by outside systems.

PR-3b. *Impact on patient care quality.*

Difficulty accessing complete patient information limits the clinician's understanding of the whole picture, leading to suboptimal diagnoses, redundant tests, and potential medical errors. Many offices spend a disproportionate amount of time searching for important information for care coordination or quality reporting, especially for patients with complex conditions or those seeing multiple specialists.

Data Exchange

PR-8. *What are ways CMS or partners can help with simplifying clinical quality data responsibilities of providers?*

Aldea's foundational AI technology can accurately and efficiently mine, structure, and abstract clinical documentation to support quality reporting.

CMS can support the process by removing interoperability or vendor-specific roadblocks (e.g. incumbent EHR vendor resistance or limited API access), promulgating clear standards and schemas for structured clinical quality data, and aligning incentives (e.g. reducing documentation requirements for providers who successfully leverage digital or AI-based tools like Aldea to report quality metrics).

Overall, the capability of Aldea's technology to drastically reduce the manual burden for clinical quality data responsibilities is already there; but partnership with CMS is needed to realize the value of our technology across the industry.

Payers (PA 5)

PA-5. *What are ways payers can help with simplifying clinical quality data responsibilities of providers?*

Payers should refine reportable quality metrics to a consensus set of outcome-oriented "measures that matter;" such as blood pressure control, A1C control and hospitalizations/ER visits per 1000.

Technology Vendors (TD 1,2,4,5)

To unlock the full potential of digital health innovation for Medicare beneficiaries, CMS must create a more open, consistent, and developer-friendly environment. Aldea recommends actionable steps such as expanding access to synthetic data sandboxes, streamlining regulatory pathways, opening API access for non-provider entities, and ensuring real-time availability of key data like prior authorizations, benefits, and care plans. Empowering developers with clearer standards, centralized FHIR endpoint directories, and real-time integration capabilities will enable AI-first platforms like Aldea to deliver personalized, voice-driven care experiences at scale—ultimately improving access, equity, and outcomes across the Medicare ecosystem.

Ecosystem

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 (next 2 years):

- *Reduce friction for developers to access real data:* Establish more CMS-sponsored data sandboxes and synthetic datasets aligned with FHIR standards so developers like Aldea can simulate real-world voice assistant workflows, such as helping patients find care, understand labs, or track chronic condition data without needing direct integration with a provider partner.

- *Offer grants or pilot programs with fast-track evaluation:* Provide lightweight CMS-backed grant mechanisms or pilot opportunities that allow companies like Aldea to rapidly test conversational AI for Medicare populations, especially in low-risk administrative and chronic care use cases.

- *Open channels for early product feedback:* Create structured pathways for innovators like Aldea to receive early feedback on the safety, usability, and policy alignment of AI-driven care experiences. This would help de-risk development while ensuring our work aligns with CMS goals.

- *Promote collaboration with provider groups:* Support matchmaking between digital health startups like Aldea and Medicare-serving provider groups that are eager to pilot novel digital front door experiences, chronic care support tools, or voice-first workflow solutions.

- *Clarify regulatory pathways for AI tools:* Offer clearer guidance on what digital and AI tools qualify as low-risk and don't require extensive pre-clearance, reducing uncertainty for builders. For Aldea, this means enabling our AI to support low-risk diagnostic, treatment, and even prescribing workflows under clear, CMS-aligned guardrails—especially for common, self-limited conditions where conversational AI can safely serve as a first-line resource for Medicare beneficiaries.

- *Streamline fedRAMP and FDA 510(K) approval processes* to encourage new entrants and faster innovation cycles

Longer-term:
- *Create centralized CMS APIs and developer services:* Develop more accessible CMS-facing APIs (e.g., for claims, prior auth, or benefits data) to help developers like Aldea integrate core Medicare services into products. For Aldea, this means enabling our conversational AI to assist patients with benefits navigation, appointment management, and coverage understanding—all within a seamless, voice-based experience. These APIs would allow Aldea to surface real-time, personalized support directly from Medicare data.

- *Champion standards and enforce interoperability:* Mandate API access and standard compliance across all major EHR vendors so startups like Aldea - whose products depend on real-time, structured clinical data - aren't blocked by restrictive practices. Our ability to deploy conversational AI as a digital front door for Medicare beneficiaries depends on full, standards-based interoperability with the systems that hold their health data.

- *Support outcome-based reimbursement pilots:* Enable new reimbursement pathways tied to patient engagement, care adherence, or education outcomes—key areas where Aldea's conversational AI and foundational models can drive measurable improvement through proactive check-ins, reminders, and behaviorally-informed support. This would help align reimbursement models with the tangible outcomes Aldea is designed to improve.

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

Aldea's voice-based AI needs access to a complete and continuous view of each patient's health journey to truly become the digital front door for a patient. The following data would be valuable if made available through CMS APIs:

- Near real-time claims adjudication updates: While Blue Button 2.0 provides valuable historical claims data (Parts A, B, and D), Aldea's AI would benefit from more timely adjudication status updates to give patients real-time clarity on billing, denials, or payment progress. Aldea's technology could even take action on behalf of the patient to inquire about why a claim was denied, immediately.

- **Prior authorization data:** So Aldea can guide patients and providers on where they are in the process and what's needed to move forward.

- **Care plan and chronic care management codes and utilization history:** Enables Aldea to proactively support chronic care goals, adherence, and follow-ups.

- **Prescription and medication data:** Enables Aldea to help patients manage medications, provide refill reminders, and identify potential adherence risks.

- **Social determinants of health (SDOH):** Allows Aldea to tailor support and resource recommendations based on transportation, housing, food insecurity, or other socioeconomic needs.

- **Lab and imaging results:** Equips Aldea's voice assistant to help patients interpret their lab or imaging findings, contextualize them with recent care episodes, and follow up on unresolved clinical questions.

Together, these data points would supercharge Aldea's ability to act as a digital front door for Medicare beneficiaries, connecting real-time administrative, clinical, and social context to voice-based, personalized patient experiences. This aligns with the goals and use cases described in earlier sections, including care coordination, symptom support, scheduling, and adherence support.

TD-2b. *What data sources are most valuable alongside the data available through the Blue Button 2.0 API?*

To fully support Medicare beneficiaries through Aldea's voice-based digital front door, it is essential to combine CMS data (via Blue Button 2.0) with additional data from other systems and vendors to know the full context about a patient. Blue Button data provides valuable claims history, but adding EHR, SDOH data allows Aldea to generate more personalized, timely, and context-aware care guidance. This layered approach strengthens Aldea's ability to reinforce care plans and connect users to the right resources at the right time.

TD-2c. *What obstacles prevent accessing these data sources today?*

Aldea faces barriers in accessing the data needed to deliver seamless, voice-based healthcare experiences for Medicare beneficiaries. These include:

- *EHR vendor lock-in and limited access to real-time clinical data,* which restricts Aldea's ability to deliver timely, personalized responses based on the most current health information.
- *Fragmentation across federal and state-level data silos:* State Medicaid agencies hold separate data (for dual-eligible patients). Community programs (like food assistance or housing resources) exist on totally different platforms. This makes it difficult to integrate Medicaid, community resources, and social needs data into a unified user experience.
- *Lack of patient-friendly authorization flows that are compatible with voice-first interactions:* Today, most data access requires clicking through complex login flows and navigating portals (like MyMedicare.gov) not designed for voice or low-friction mobile access. Aldea's assistant is voice-based. We need simple, intuitive, low-friction consent flows that patients can use verbally or on mobile to securely authorize data access.
- *Inconsistent or unclear policies around API access for non-provider entities like Aldea,* preventing innovative, consumer-facing tools from fully participating in CMS-driven data ecosystems. CMS and ONC sometimes do not clearly define whether non-clinical, patient-facing companies like Aldea are eligible to access critical data via APIs such as Blue Button or FHIR endpoints. Additionally, there is ambiguity around what constitutes a 'covered entity' versus a 'third-party app' under HIPAA or CMS rules. This uncertainty creates risk and slows down innovation—especially for companies like Aldea that are not traditional providers or payers but still play a direct role in supporting patient outcomes through responsible, AI-enabled care navigation.

TD-2 d. *What other APIs should CMS and ASTP/ONC consider including in program policies to unleash innovation and support patients and providers?*

- Real-time eligibility and benefits APIs: These would allow Aldea's AI assistant to instantly confirm a patient's coverage status, reducing confusion and delays in care access. This capability is especially

important for helping patients understand what services are covered, when prior authorization is needed, and what their financial responsibility might be.
- Prior authorization status APIs: Real-time visibility into the status of prior auth requests would let Aldea update patients via voice about whether their procedures or medications are approved, pending, or denied, dramatically improving transparency and easing the burden on providers to handle status checks.
- **Community-based resource locator APIs** (e.g., food, housing, transportation): Access to curated, localized SDoH services would enable Aldea to refer patients to programs that support whole-person health, like connecting someone recently discharged with meal delivery, housing help, or transport to follow-up appointments.

Technical Standards and Certification

TD-4. *How can CMS better encourage use of open, standards-based, publicly available APIs over proprietary APIs?*

CMS should reduce fragmentation and expand access for innovators like Aldea by:

- Mandating FHIR APIs across all CMS-contracted orgs (e.g., MA plans, ACOs)
- Incentivizing adoption through payment bonuses or reduced reporting for standards-compliant entities
- Enforcing compliance with existing API mandates
- Ensuring third-party developer access, including non-provider patient-facing tools like Aldea
- Improving developer support with clear documentation, test data, and accessible sandboxes

These steps would shift the ecosystem toward openness, enabling scalable, AI-powered solutions like Aldea to better serve Medicare patients.

TD-5. *How could a nationwide provider directory of FHIR endpoints improve access to health information for patients, providers, and payers? Who should publish such a directory, and should users bear a cost?*

A nationwide FHIR endpoint directory would dramatically streamline how tools like Aldea access health data across providers. Today, connecting to the right API is inconsistent and inefficient. A centralized, open-access directory, maintained by CMS or ONC, would make it easier to locate the correct integration points, improving data flow, care coordination, and administrative efficiency. This would directly enable Aldea's voice-based AI to deliver more timely, personalized, and equitable support to Medicare beneficiaries across clinical and non-clinical needs.

Value-Based Care Organizations (VB 1-4)

To drive more effective adoption of digital health tools in value-based care models like ACOs and MSSP, CMS should offer upfront funding, validation pathways, and aligned incentives that reward measurable improvements in patient outcomes. APM success depends on robust health IT capabilities that support real-time data integration, proactive outreach, risk stratification, and care coordination across diverse populations. Digital tools like Aldea's AI-powered platform are essential to scaling engagement, tracking quality, and managing patients between visits. However, their effectiveness hinges on access to comprehensive data types—including clinical, claims, SDOH, and behavioral health—which must be made available in standardized, interoperable formats to support population-level analytics and individualized care delivery.

VB-1. *What incentives could encourage APMs such as accountable care organizations (ACOs) or participants in Medicare Shared Savings Program (MSSP) to leverage digital health management and care navigation products more often and more effectively with their patients? What are the current obstacles preventing broader digital product adoption for patients in ACOs?*

Advanced funding to support innovation and independent validation of digital tools would assist ACOs in adopting evidence-based, outcome oriented solutions.

VB-2. *How can key themes and technologies such as artificial intelligence, population health analytics, risk stratification, care coordination, usability, quality measurement, and patient engagement be better integrated into APM requirements?*

Successful APM participants align incentives. Providers and VBC organizations succeed when their patient populations are optimally managed. If CMS is able to provide up front investment dollars for technical innovations AND validation of evidence based platforms, APM participants will be best able to select and implement effective technology for their populations.

VB-3. *What are essential health IT capabilities for value-based care arrangements?*

Participants in value based arrangements must be able to access, ingest and analyze multiple types of data in order to provide usable insights for proactive and reactive patient care, across a diverse population of patients. Providers must have the technology to act on these insights efficiently, and organizations must be able to set key performance targets and track progress on metrics.

VB-3a. *Examples (not comprehensive) may include the following:*

- *Data Extraction/Normalization:* Ability to pull comprehensive data from disparate sources (EHRs, claims, devices) and normalize it for analysis.
- *Analytics for patient segmentation*, identification of high risk patients
- *Proactive outreach and scheduling machinery* (identifying patients in need of a service and scheduling them for necessary visits, procedures or tests)

- *Point of care tools* to maximize the efficacy of each patient visit (e.g. advanced clinical decision support, identifying, documenting and managing important clinical conditions; encouraging evidence-based preventive screenings and immunizations)
- *Tools to manage patients* in between visits (see above for more information on Aldea's care management and support tools, patient education and adherence suite)
- *Patient Event Notification:* Real-time alerts for hospital admissions, discharges, and ED visits (leveraging FHIR).
- *Quality Performance Measurement*: Automated calculation and reporting of quality metrics.

VB-3b. *What other health IT capabilities have proven valuable to succeeding in value-based care arrangements?*

- *Attribution and Patient ID Matching:* Accurate patient matching across all data sources.
- *Referral Management and Tracking:* Digital tools to manage patient referrals and ensure follow-up.
- *Cost Transparency Tools*: Providing patients with estimates for care.

VB-4. *What are the essential data types needed for successful participation in value-based care arrangements?*

Important data sources include:

- Clinical Data: Comprehensive problem lists, diagnoses, medication lists, lab results, vital signs, clinical notes, patient history, procedures, allergies, immunizations
- Claims Data (Medical and Pharmacy): Full history of services rendered, costs, and prescription fills.
- Patient Demographics and Socioeconomic Data: Age, gender, location, race/ethnicity, and relevant SDOH data.
- Patient-Generated Health Data (PGHD): Symptom tracking, biometric data (BP, glucose), activity levels, adherence data (like Aldea's medication adherence tracking).
- Provider Data: NPI, specialty, location, network participation, quality metrics.
- Administrative Data: Appointment schedules, prior authorization status.
- Cost and Utilization Data: Including detailed service line costs and utilization patterns.
- Behavioral Health Data: Assessments, diagnoses, and treatment plans.

Aldea Health is proud to contribute to the national dialogue on improving digital health access, interoperability, and innovation for Medicare beneficiaries and the broader healthcare ecosystem. Our platform is uniquely equipped to address the challenges outlined in this RFI—from delivering empathetic, voice-first support for patients to provide scalable, AI-driven solutions that reduce provider burden and unlock insights from unstructured data.

We believe that a truly patient-centered, digitally enabled healthcare system requires collaboration, trust, and aligned incentives across sectors. Aldea’s technical breakthroughs—including our efficient LLM architecture, clinical safety framework, and

customizable implementation engine—offer practical, scalable solutions to many of the barriers identified.

We appreciate the opportunity to share our perspective and look forward to working with CMS, ONC, and other partners to create a more intelligent, accessible, and equitable healthcare future. Please do not hesitate to reach out for follow-up or collaboration.

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