Ainsley Advisory Group Response to Request for Information (RFI)

Health Technology Ecosystem (CMS-0042-NC)

Centers for Medicare & Medicaid Services (CMS)

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Ainsley Advisory Group (AAG) is a leading physician-led healthcare AI strategy firm located in Washington, D.C. that works with stakeholders across the healthcare and life sciences ecosystem and consists of 20 senior healthcare consultants with 200+ years of combined operator, healthcare, and life sciences experience. We focus on go-to-market (GTM) strategy and AI implementation across the digital health continuum, including advanced diagnostics and biopharma working with start-ups and healthcare systems. We also host a large CxO membership network connecting executives across the healthcare continuum, and we publish weekly market research reports, lead webinars, and produce other thought leadership content and courses, specializing in applications of AI in healthcare.

We welcome the opportunity to comment on the Request for Information (CMS-0042-NC) and commend CMS and ASTP/ONC for taking proactive steps to shape the digital health infrastructure serving Medicare beneficiaries. We have selected those questions most germane to our practice.

AAG appreciates the consideration of these comments and welcomes future opportunities for engagement or collaboration to advance the shared goals of interoperability, innovation, and improved patient outcomes.

TD-1. What short-term and long-term steps can CMS take to stimulate developer interest in building digital health products for Medicare beneficiaries and caregivers?

CMS can support developer engagement by lowering the barriers to piloting and testing digital health tools within the Medicare ecosystem. This includes fostering open collaboration, creating clearer integration pathways, and ensuring start-ups have meaningful access to representative datasets for iteration. Enabling easier access to pilot opportunities within Medicare-aligned organizations will be essential for fostering scalable solutions and broader innovation adoption.

CMS should ensure that digital health tools are incorporated into overall programs, rather than offered as siloed technology solutions. This would help ensure wraparound services, ongoing data review, and clear guidance throughout the user experience. Programs and vendors should also be held accountable for cost efficiencies and health outcomes, with ongoing feedback and iteration.

CMS can stimulate developer interest in the short term by offering sandboxed access to APIs and datasets, fostering innovation challenges, and creating clearer integration and testing pathways for early-stage vendors.

Developers often engage with new APIs and datasets through structured challenges or partnerships. CMS could consider supporting initiatives that increase visibility and hands-on use of its data assets, such as curated developer environments, structured challenges, or API adoption tracks tied to real-world use cases.

Crucially, CMS must address the structural challenge of healthcare data interoperability as a prerequisite for developer participation. Interoperability is not just about data exchange, it involves enabling seamless data aggregation, access, and release across systems, which are foundational for developers building AI/ML tools, digital therapeutics, and care coordination platforms. CMS should support:

- Patient data exchange via open APIs to create unified records and enable total cost-of-care insights
- Bulk data aggregation infrastructure that resolves record fragmentation and deduplication
- Patient-directed data release tools to enable patient control and sharing of records
- Developer toolkits with APIs, testing environments, and access to aggregated clinical data
- Integration with EHRs and remote monitoring apps to support real-world clinical workflows

To ensure continued improvement, CMS should also promote structured program evaluation and feedback loops that allow for rapid iteration and refinement of digital health interventions. These mechanisms are essential to identifying what works, adapting to patient needs, and guiding scalable adoption.

Long-term, CMS could pilot digital product certification aligned with Medicare Advantage networks to facilitate scalable integration.

TD-2. Regarding CMS Data: What additional data would be most valuable if made available through CMS APIs?

Continued expansion of CMS APIs to include broader claims, post-acute, and outcomes data would be welcomed by the developer community.

Better quality contact data, including email, text, and mailing addresses, along with explicit consent to communicate with members, is critical. This is especially important as SMS and text messaging have become increasingly effective communication channels for Medicare and Medicaid populations. Access to pharmacy and lab data would also support integration with digital health tools and enable more robust outcome measurement.

Improving the timeliness, usability, and documentation consistency of available data sources would further support meaningful application development across care settings.

To enable more advanced use cases, CMS should prioritize bulk data interoperability. This includes infrastructure that supports continuous ingestion and harmonization of patient records across systems. Key data types include pharmacy and lab data, de-duplicated patient records spanning multiple institutions, consent-enabled contact data, and de-identified datasets that can be used to train machine learning models.

High-priority data sets also include post-acute outcomes, social determinants-linked claims data, and denied claims metadata. Today, delays in data access and inconsistencies in documentation create unnecessary barriers for start-ups seeking to prototype and deploy tools that serve Medicare populations.

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

Adoption of open, standards-based APIs will be driven by clear alignment with certification requirements and federal incentive programs. Highlighting best practices and creating visible benchmarks for interoperability performance may also encourage broader uptake across the ecosystem.

CMS should reward adherence to FHIR-based APIs through mechanisms such as grant eligibility, inclusion in national registries, or federal partnership opportunities. A public-facing interoperability index that highlights vendor performance could further drive market alignment and transparency.

In addition, digital health companies can play a role in strengthening the quality infrastructure by contributing data that supports CMS in assessing care quality and evolving performance measures to reflect the capabilities of modern digital tools.

TD-5. How could a nationwide provider directory of FHIR endpoints improve access to health information?

A comprehensive FHIR endpoint directory could simplify integration for developers and reduce the friction involved in provider data exchange. It would be particularly valuable for enabling emerging tools that support care coordination, patient access, and specialty navigation.

A national FHIR endpoint directory, indexed by National Provider Identifier (NPI), would significantly ease integration for digital health companies building provider-facing solutions. It would reduce onboarding time,

support consistent workflows, and make participation in frameworks such as TEFCA (Trusted Exchange Framework and Common Agreement) more accessible for start-ups and smaller vendors.

In addition to improving connectivity, this type of infrastructure could help standardize how value and outcomes are measured across populations. By enabling consistent data exchange, a national directory could support more uniform population health analysis and evaluation of digital health interventions.

TD-13. What new opportunities and advancements could emerge with APIs providing access to the entirety of a patient's electronic health information (EHI)?

Expanded access to the full breadth of electronic health information (EHI) could enable more powerful AI solutions that improve diagnostics, clinical efficiency, and patient outcomes. Greater access to diverse clinical data types would support the development of holistic, interoperable tools and accelerate responsible digital health innovation.

With full EHI access, AI-driven tools would be better positioned to deliver meaningful improvements in diagnosis, workflow optimization, and clinical outcomes across the care continuum. This includes access to unstructured clinical notes, imaging data, and other non-standardized formats, which can significantly enhance model performance, time-to-insight, and overall return on investment. In parallel, greater EHI availability could support multi-modal approaches to care planning and patient engagement, enabling more effective decision-support tools and patient-facing applications.

One persistent challenge is the heterogeneity of data formats across systems, particularly with imaging, narrative documentation, and genomics. Addressing this will require continued alignment on standards and data normalization strategies.

In addition to advancing analytics and AI capabilities, access to comprehensive EHI can also support rules-based eligibility logic. This would allow providers and care teams to identify which patients may qualify for specific digital health tools or programs based on clinical data already available within the record, improving targeting, reducing friction, and supporting more personalized care.

TD-15. How would increased use of bulk FHIR improve use cases and data flow?

Increased use of bulk FHIR APIs can enhance population-level analytics, streamline reporting, and support value-based care. These capabilities enable use cases such as cohort identification, longitudinal analysis, and quality measurement across populations. Expanding access to bulk FHIR, particularly for smaller vendors, could unlock broader innovation while maintaining data governance and security. Key challenges include infrastructure demands and the capacity to manage large-scale data exchange. CMS can support adoption by offering guidance, promoting best practices, and ensuring technical accessibility alongside safeguards.

PR-2. What are obstacles that prevent development, deployment, or effective utilization of the most useful and innovative applications for physician workflows?

There are significant structural obstacles to deploying innovative applications in provider settings. Start-ups often face high integration costs, legacy EHR infrastructure, and inconsistent workflows across care sites. Physicians, already burdened by administrative tasks and documentation demands, frequently lack the time or support to adopt new tools. Many health systems also lack structured pathways to evaluate emerging technologies, particularly in academic or graduate medical education environments where digital literacy and change management support are limited.

These barriers are further compounded by the limited integration of digital health tools into broader care delivery programs, which makes training, deployment, and oversight more difficult. To address this, CMS should invest in comprehensive provider training and implementation oversight frameworks. EHR systems should be equipped with specific data elements and workflow logic that help clinicians identify eligible patients for digital programs and streamline patient education and enrollment during clinical encounters.

To reduce administrative burden, CMS should also promote the development of new roles focused on care coordination and data review, allowing physicians to concentrate on clinical care and practice at the top of their license. Finally, CMS can help accelerate adoption by incentivizing modular, plug-and-play architecture and supporting vendor-neutral workflow pilots that allow for safe, flexible integration of early-stage technologies across diverse health system environments.

PR-7. What strategies can CMS implement to support providers in making healthcare data available for interoperability in the digital product ecosystem?

CMS can help reduce administrative and technical burden by aligning interoperability efforts with existing provider workflows, such as quality reporting and care documentation. Prioritizing standardization in data extraction and encouraging low-code or no-code integration approaches would make it easier for providers and their technology partners to share information efficiently.

To support scalable interoperability, CMS can continue promoting clear expectations for export capabilities and open API access, while working in partnership with EHR vendors and health systems to advance implementation. Providing practical guidance, spotlighting best practices, and supporting shared learning networks can further accelerate progress across diverse care environments.

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?

To support broader adoption of digital health tools in value-based care arrangements, CMS should recognize the time and clinical effort required to educate patients, particularly those with limited digital literacy. Many of these tools demand hands-on support to build trust, ensure understanding, and sustain engagement between visits.

CMS could consider incorporating bonus points or performance credits into Shared Savings or other APM scoring frameworks for organizations that effectively implement digital health interventions and demonstrate measurable impact on patient adherence, engagement, or risk reduction. In parallel, CMS can strengthen adoption by making it easier for providers to implement patient-facing incentive programs. This approach has shown promise in driving patient engagement and encouraging sustained participation between clinical encounters.

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

Capabilities such as event notification, remote device integration, and AI-driven risk stratification are increasingly essential in value-based care. CMS should define core interoperability and patient engagement functions as part of VBC requirements while preserving flexibility for innovative approaches.

To ensure these tools deliver meaningful impact, CMS should recognize that enrollment and sustained engagement often require consistent outreach from both providers and technology vendors. Reminders, educational prompts, and personalized follow-ups help maintain participation between visits. Concurrently, CMS should encourage engagement strategies that promote digital inclusion, accounting for differences in language, digital access, and health literacy across diverse patient populations.

Additional Comment: Enabling Innovation in EHR Ecosystems

As health systems and policymakers work to modernize care delivery, one emerging frontier is the use of autonomous software agents that support clinicians by streamlining workflows, filing orders, and synthesizing clinical information. For these innovations to take root, developers and care teams need consistent access to interoperable, standards-based interfaces within electronic health records (EHRs).

EHR platforms play a foundational role in clinical care infrastructure. This presents an important opportunity to ensure that interfaces between EHR systems and third-party tools remain open, secure, and aligned with broader innovation goals. A shared policy framework can help facilitate collaborative development across vendors, providers, and innovators.

Current Challenges to Address
- Limited or unclear access to core APIs may inhibit third-party developers from building scalable, EHR-connected tools
- Workflow requirements tied to specific apps or modalities (such as order entry) may limit flexibility for automation
- Inconsistent standards or lack of transparent documentation can slow innovation and increase integration burden
- Contractual terms may unintentionally restrict organizations from testing or deploying emerging technologies, including locally developed agents

Policy and Collaboration Recommendations
- Enable health systems to configure and deploy software agents that act on behalf of clinicians, with appropriate permissions, audit trails, and safety controls in place
- Promote open, standards-based workflows while minimizing dependence on vendor-specific tools when broader access is available
- Support consistent read/write access for key EHR components (such as order sets, preference lists, and results) through clearly defined APIs and governance structures
- Encourage the use of transparent, regularly updated interface documentation to support security validation, external development, and integration testing
- Foster shared development environments where vendors, providers, and regulators can co-design capabilities that ensure safety while advancing automation