To: Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0042-NC
Request for Information: Health Technology Ecosystem

Submitted by: Xealth, Inc
Contacts: Mike McSherry, CEO, CoFounder; David Slifka, VP Commercial Operations
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Xealth appreciates and is grateful for the opportunity to respond to CMS' RFI for Health Technology Ecosystem (CMS-0042-NC). We are feel that as an organization with over two dozen health system customers, ranging from large Integrated Delivery Networks (IDNs) and academic medical centers to regional health systems, we have an unique perspective on how patients interact with digital health tools, gain or are restricted of access to tools, and how health systems, vendors, and health plans can work together to drive a healthier America.

Xealth Digital Care enables the automation and streamlining of the ordering, delivery, and monitoring of a health system's digital health apps, content, products, and services across their organization. Xealth is the driving force behind digital health programs at many of the nation's largest health systems, bringing digital health vendors, programs, therapeutics and tools into clinical and patient workflow. When combined with Xealth's custom data and analytics, health systems can track, analyze and evaluate everything through their digital health integration platform. To date, Xealth has sent more than 25 million digital assets and tools to over 6 million patients across many of the largest U.S. health systems.

Xealth's comments are based on its expertise as related to the healthcare technology space, specifically with how digital health apps and tools can benefit patients, clinicians, and health systems. With this perspective, Xealth has addressed a subset of the questions, as follows.

Xealth's Comments:

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

Patients and caregivers often face fragmented access to tools, lack of integration with care plans, and inconsistent usability across platforms. Additionally, caregivers commonly are unaware of digital tools available to them. Xealth addresses this by embedding digital health tools directly into EHR workflows and offering patient-facing experiences that are intuitive, accessible, and linked to their clinical care.

- Frequently, patients are asked to download multiple apps with separate logins, few of which are connected to their provider or plan.
    - Xealth offers a centralized "digital health hub" model integrated into patient portals or EHR-linked apps.
    - This enables caregivers to access patient-facing tools with delegated access when supported.
- CMS can drive adoption through incentive programs that reward prescribing digital health tools aligned with care plans.
- Xealth recommends financial models or grants to support usability testing across underserved populations.

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?

Typically digital apps and tools address a number of usability and accessibility topics - tools should be intuitive, should have easy to read buttons and instructions, and should cater or adapt to the widest populations possible. However, patients often have concerns around privacy, complexity of use, and unclear clinical value when faced with a new digital tool - especially given that there are thousands of apps on the Apple and Google marketplaces. Xealth helps overcome these by delivering tools through trusted provider workflows and ensuring content and apps are clearly tied to the patient's condition or care episode.

- Concern: "Is this safe?" — Xealth only delivers tools that are clinically vetted and EHR-prescribed.
- Concern: "Will this actually help?" — patients use tools when they know their provider will follow-up, improving perceived value.
- Concern: "I don't know how to use this." — Include digital literacy tips, SMS follow-up, and multilingual content.
- CMS opportunity: Endorse digital health navigation support as a covered service (akin to CHWs or care managers).

![xealth]

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

Patients and caregivers benefit most when data is timely, understandable, and directly connected to a current episode of care. While some clinical and visit-related data is accessible through portals, key information like claims, pricing, and clinical notes remains fragmented or inaccessible; or these items are so complex that they're unusable by patients or caregivers. Additionally, many health systems aren't truly on a single EHR system, resulting in partially integrated or connected patient records and data.

a. What data is valuable, but hard for patients and caregivers, or app developers and other technical vendors, to access for appropriate and valuable use?

- Claims data is typically delayed, hard to interpret, and not integrated into a single patient view. This data is likely more valuable for app developers and technical vendors than patients themselves.
- Clinical encounter notes (e.g., specialist consults, discharge summaries) are inconsistently shared or redacted. Additionally, these are potentially too complex for patients to understand directly.
- Operative reports and imaging results are often siloed or not delivered in manners that are easy for patients to understand.
- Appointment schedules are difficult to access in aggregate (especially across systems or for caregivers coordinating care).

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

- Patient-reported outcomes and engagement data (e.g., adherence to digital interventions, symptom tracking) give insight into care impact outside clinical settings.
- Care team context (who is involved, roles, responsibilities) helps patients navigate complex treatment landscapes.
- Benefit/coverage data (e.g., real-time formulary, plan details) allows patients and apps to tailor care plans more effectively.
- Digital engagement history—what tools were prescribed, opened, completed—helps caregivers and clinicians align on what support was received.

c. 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:**
  - Broaden adoption of FHIR-based APIs beyond basic patient access—include bulk data, scheduling, care plans, and questionnaire responses. Many EHRs have these data points accessible, but many times are additional fees to the health system, vendor, or even patient to access.
  - Use TEFCA to enforce data liquidity across organizations and vendor types.

- - Leverage platforms like Xealth to normalize and track engagement data, linking digital tool usage with outcomes.
  - Promote patient-controlled data sharing through centralized identity/authentication systems

- **Challenges:**
  - Clinical data is often incomplete or unstructured—especially outside of hospital settings.
  - Clinicians feel responsible and legally liable for data in the EHR, so external patient data should be incentivized to support care
  - Non-FHIR, proprietary APIs still dominate integration workflows for key data types.
  - Lack of unified patient identity across systems hinders longitudinal aggregation.
  - Legal and governance variability across health systems slows innovation.

PR-1: How can health technology tools be better integrated into clinicians' workflows?

CMS can accelerate adoption of digital health products by aligning incentives, funding implementation support, and ensuring that tools are seamlessly integrated into provider workflows. Xealth enables EHR-integrated prescribing and tracking of digital tools—making it easier for providers to use them consistently and confidently, even in resource-constrained settings.

a. What are the current obstacles?

- Lack of reimbursement or credit for using digital tools discourages investment. Health app vendors need a revenue source, either from CMS directly or by the health system. If the revenue source is the health systems, incentives by CMS can drive a desire to try apps and tools out, rather than only deploy things that are revenue generating.
- High cost of acquisition and integration falls on providers, especially problematic for rural and small practices.
- Workflow burden—tools that require separate portals or manual tracking are rarely used.
- Limited technical staff in rural settings makes onboarding new tools difficult without middleware platforms like Xealth.
- Uncertainty about safety, efficacy, or regulatory status leads to clinician hesitancy.

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

- Purpose of the tool and how it relates to their specific diagnosis or treatment plan.
- Instructions on how to access and use the tool (with support for digital literacy or language needs).
- What data will be collected, how it will be used, and who will have access.
- Expected benefit (e.g., symptom monitoring, education, recovery support).
- Contact information for technical or clinical help if questions arise.

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

- Ensure the tool is clinically appropriate and aligned with the patient's care goals.
- Monitor relevant feedback or data returned by the tool, particularly if used to guide clinical decisions.
- Provide alternatives or accommodations for patients who cannot access or use the digital tool.
- Document the recommendation and usage in the patient's health record.
- Stay informed about which tools are approved and meet CMS or health system standards.

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?

Clinicians face cognitive overload, fragmented tools, limited evidence, and lack of EHR integration when thinking about and deploying new digital patient tools. Xealth addresses these by embedding trusted digital tools in clinical workflows with minimal training, while providing feedback loops for usage and impact.

- Siloed EHR ecosystems make it difficult for external tools to access or write back relevant data, stifling innovation in workflow automation.
- Non-standardized data formats and inconsistent FHIR/API implementations limit interoperability across systems and vendors.
- Manual burden for clinicians—even high-value tools are often underused if they require leaving the EHR or add clicks.
- Lack of actionable feedback loops (e.g., engagement or quality performance data) means clinicians can't easily see value from tool usage.
- Vendor approval and procurement processes are slow and expensive, especially in health systems with tight governance controls.
- Limited reimbursement or performance alignment makes it hard to justify operational investments in workflow tools.

Mitigation strategies / CMS opportunities:

- Expand EHR certification requirements to include robust, open, read/write FHIR APIs that support clinical documentation, patient-reported outcomes, and engagement tracking.
- Support middleware platforms (like Xealth) that act as connective tissue between EHRs and innovative third-party apps.
- Include digital tool engagement and data return as valid input into quality measurement reporting (eCQMs).
- Fund innovation accelerators or pilot programs to streamline clinical workflow automation in under-resourced settings.

- Offer VBC-aligned incentives to encourage use of tools that reduce documentation time or improve data capture.

PR-5. Which of the following FHIR APIs and capabilities do you already support or utilize in your provider organization's systems, directly or through an intermediary? For each, describe the transaction model, use case, whether you use individual queries or bulk transactions, and any constraints:

a. Patient Access API.

- **Supported:** Indirectly, via health system EHR implementations.
- **Use Case:** Patients access prescribed tools via portal (e.g., MyChart) or SMS/email, linked to encounter data.
- **Transaction Model:** Individual patient-level transactions; no bulk needed.
- **Constraint:** Varies by EHR; not all include engagement or care plan linkage.

b. Standardized API for Patient and Population Services.

- **Supported:** Yes, via EHR-integrated FHIR endpoints where available.
- **Use Case:** Delivery of digital content/apps linked to patient problems, demographics, and encounter type.
- **Transaction Model:** Primarily individual queries; some batch processing via internal caching.
- **Constraint:** Depth of data (e.g., care teams, visit context) often insufficient for precision targeting.

c. Provider Directory API.

- **Supported:** Not directly used by Xealth today.
- **Use Case:** Could be used to improve referral workflows or patient-provider matching in future roadmap.
- **Transaction Model:** N/A.
- **Constraint:** Lack of national standardization across systems.

d. Provider Access API.

- **Supported:** Not directly used by Xealth today.
- **Use Case:** Would be useful to push patient data and engagement results back into provider systems outside the originating EHR.
- **Transaction Model:** Not yet used in production.
- **Constraint:** Maturity and standardization lagging.

e. Payer-to-Payer API.

- **Supported:** Not directly used by Xealth.
- **Use Case:** Not applicable to current patient engagement workflows.
- **Constraint:** Outside Xealth's integration layer; relevant for payers but not digital engagement platforms.

f. Prior Authorization API.

- **Supported:** Not currently used.
- **Use Case:** Could support downstream workflows if digital therapeutics require prior auth in future.
- **Constraint:** Limited adoption across EHRs; no standardized use case in digital tool delivery.

g. Bulk FHIR—Do you support Group ID-based access filtering for population-specific queries?

- **Supported:** Xealth supports population-based engagement but most data exchange is still per-patient due to EHR/API constraints.
- **Use Case:** Stratified outreach (e.g., to all maternity patients or uncontrolled diabetics).
- **Transaction Model:** Internal batch logic, not true FHIR bulk.
- **Constraint:** Limited EHR support for population-level FHIR queries.

h. SMART on FHIR—Do you support both EHR-launched and standalone app access? What does the process for application deployment entail?

- **Supported:** Yes—EHR-launched SMART on FHIR are supported across Epic and Oracle Health customers.
- **Use Case:** Launch Xealth engagement workflow from chart.
- **Transaction Model:** Real-time user-context launch; embedded in clinical workflow.
- **Process for deployment:**
  - App registry submission (e.g., Epic App Orchard).
  - IT review + InfoSec + governance approval.
  - Role-based access provisioning.
- **Constraint:** Deployment time and variation by site governance.

i. CDS Hooks (for clinical decision support integrations).

- **Supported:** Currently limited; Xealth does not broadly deploy via CDS Hooks but is architecturally compatible.
- **Use Case:** Future trigger-based recommendations (e.g., show app when ordering insulin).
- **Transaction Model:** Event-driven.
- **Constraint:** Adoption varies by EHR and site; often requires additional clinical review board approval.

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

CMS can drive greater data availability by aligning interoperability with existing provider incentives, leveraging quality and value-based care metrics, and supporting shared infrastructure to reduce duplication of effort. Many health systems lag in adopting or widely deploying digital tools because there is a distinct lack of financial reimbursement to deploy such digital tools. Instead, health systems focus on use cases that drive revenue. Xealth enables

scalable, standards-based data sharing by embedding digital engagement workflows directly within EHRs and returning structured usage data to providers and systems.

- Align interoperability with existing metrics—leverage MIPS, HEDIS, and ACO reporting frameworks to include measures tied to data completeness and timely sharing.
- Repurpose existing documentation and engagement workflows (e.g., care planning, discharge summaries, PROs) to generate FHIR-compliant data that can feed into broader ecosystems.
- Support middleware platforms (e.g., Xealth) that translate EHR-native workflows into standards-based APIs for third-party tools.
- Minimize provider burden by focusing on automation, not manual entry—data sharing should occur passively as part of charting, ordering, or patient engagement tasks.
- CMS could mitigate burden through:
  - Grants for implementation of FHIR and SMART-based tools.
  - Incentives for participation in TEFCA and public HIEs.
  - Conformance testing and public scorecards to drive EHR vendor accountability.
- Examples of reusable workflows:
  - Digital education or app prescribing tied to diagnoses and orders.
  - Remote patient monitoring programs that already collect structured data.
  - Discharge instructions or patient summaries converted to structured FHIR documents.

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?

CMS can stimulate developer interest by creating near-term reimbursement and recognition pathways for digital tools and, over the long term, establishing a certification and procurement infrastructure that rewards integration, outcomes, and accessibility.   Xealth supports developers by enabling scalable distribution of digital tools within provider workflows and capturing real-world engagement data.

Short-term (next 2 years):

- Offer reimbursement or incentive pathways tied to usage of approved tools—via chronic care management, RPM, or ACO alignment. Most large employers cover tools for things like behavioral health for their employees, however CMS does not, making these patients have to find care on their own.
- Fund pilot programs to test digital tools that address high-priority use cases (e.g., chronic condition management, heart disease, smoking cessation).
- Promote use of middleware platforms like Xealth to ease onboarding and reduce EHR integration burdens.
- Publish guidelines and data standards (e.g., FHIR conformance, SDOH integration, accessibility) to create clear developer targets.

Longer-term (2+ years):

- Establish a CMS digital health certification program that evaluates tools on safety, equity, clinical alignment, and patient outcomes.
- Link digital tool certification to eligibility for reimbursement, model participation, or public procurement.
- Support standardized identity and access infrastructure
- Incentivize open API environments and TEFCA participation for both EHR vendors and health systems.
- Encourage data-sharing networks to provide anonymized, aggregate engagement and outcomes data to inform developer product design.

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

Expanding CMS data access through modern APIs—especially for coverage, pricing, and longitudinal patient context—would unlock meaningful innovation. Xealth supports better patient and provider experiences by integrating CMS-relevant data with EHR workflows and returning real-world usage and engagement metrics that developers and systems can act on.

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

- Real-time coverage and benefits data, including formularies, digital health tool eligibility, and cost-sharing.
- Prior authorization status and history to streamline navigation and tool deployment.
- Social Determinants of Health (SDOH) data available through CMS screening tools or community programs.
- Provider attribution and ACO alignment data, to support population-level outreach and tool targeting.
- Care management program enrollment (e.g., CCM, BHI) to trigger appropriate tool recommendations.

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

- Clinical data from EHRs, including labs, problems, care plans, vitals, and encounter details.
- Payer and third-party pharmacy data (e.g., Rx fulfillment, copay cards, MTM participation).
- Digital engagement and patient-reported outcomes data, including app usage, surveys, and remote monitoring.
- Care coordination or referral data from HIEs, ACOs, and population health platforms.

c. What obstacles prevent accessing these data sources today?

- Limited FHIR API support across EHR and CMS systems; many fields (e.g., encounter context, care team) are still unavailable.

- Inconsistent patient matching and identity resolution across payers, providers, and platforms.
- Restrictive data use policies, especially for combining CMS and non-CMS data in analytics or digital interventions.
- Lack of write-back capabilities—most APIs are read-only, limiting interaction and closed-loop care delivery.
- Complex and fragmented consent models, particularly for caregiver access and longitudinal data sharing.

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

- Digital tool prescribing and tracking APIs, to support closed-loop engagement (e.g., what was prescribed, used, completed).
- Engagement outcome APIs, allowing vendors and researchers to submit app usage, PROs, and outcomes for program evaluation.

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

Full EHI access through APIs would enable more intelligent, personalized digital health experiences, allow richer care coordination, and unlock advanced analytics and AI-driven decision support. Xealth could further optimize tool targeting, engagement, and feedback by using broader context such as encounter notes, device history, and longitudinal care documentation.

Opportunities:

- Personalized care delivery: Access to full EHI (e.g., problem narratives, device settings, historical therapies) allows digital tools to be tailored to the full clinical picture.
- Improved care coordination: Notes and documents not in USCDI (e.g., operative reports, referrals, care team notes) enable seamless transitions across providers.
- Better patient engagement: Tools can reference real-life clinical context to explain relevance ("this app supports your post-surgery recovery").
- Advanced analytics and research: Broader, unstructured data opens the door to NLP, predictive modeling, and more accurate risk stratification.
- More meaningful AI and decision support: Richer EHI allows for context-aware recommendations, closing gaps missed by structured-only systems.

a. What are the primary obstacles to this?

- Lack of API support: Most EHRs do not expose full EHI via APIs—or if they do, they become extremely expensive at scale.
- Inconsistent documentation standards: Clinical notes vary in structure, language, and completeness, making them hard to interpret without manual review or advanced NLP.

- Privacy and risk concerns: Full EHI may include sensitive or duplicative information not intended for all audiences or downstream uses.
- Performance and scalability: Bulk retrieval of full EHI, especially across institutions, presents significant infrastructure and latency challenges.
- Legal ambiguity: Lack of clarity around "designated record set" vs. EHI can limit release or create provider hesitancy.

b. What are the primary tradeoffs between USCDI and full EHI, especially given more flexible data processing capabilities today?

- **USCDI pros**: Structured, easier to parse, validated for exchange, and supported by most certified APIs. Lower risk of data misinterpretation.
- **USCDI cons**: Narrow scope—omits care team notes, visit context, patient narratives, and referral detail that are critical to personalization and care continuity.
- **Full EHI pros**: Richer, longitudinal view of the patient. Supports innovation in research, engagement, and future use cases.
- **Full EHI cons**: Highly variable, includes redundant or irrelevant data, and presents usability, privacy, and technical challenges.

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?

APMs and MSSP participants need clear financial incentives and implementation support to adopt digital health tools at scale. While digital tools can enhance care navigation, adherence, and population outreach, adoption is limited by cost, workflow complexity, and lack of alignment with quality metrics or shared savings calculations.

Incentives CMS could implement:

- Allow digital tool utilization (e.g., education, RPM, engagement) to count toward quality benchmarks and shared savings scoring.
- Provide per-member/per-month (PMPM) payments or care coordination credits for prescribed digital tools that support risk-based management.
- Include digital engagement data as part of ACO reporting or stratification measures (e.g., rising-risk flagging, PROs, medication adherence).
- Offer start-up grants or infrastructure funding for ACOs adopting platforms that streamline digital tool delivery and tracking (like Xealth).
- Develop a CMS-backed registry of certified digital tools aligned with VBC goals (e.g., chronic disease, transitions of care, behavioral health).

Current obstacles to broader adoption in ACOs:

- Out-of-pocket technology cost—ACO contracts typically don't include funding for third-party tools, making it difficult to justify adoption.
- Lack of EHR integration—many tools require separate logins or manual workflows, limiting clinician and care team uptake.
- Unclear performance attribution—hard to tie digital engagement to specific cost or quality improvements without shared data frameworks.
- Limited awareness and technical capacity in smaller or rural ACOs, particularly those without centralized IT or digital health expertise.
- Inconsistent payer support for digital tools across Medicare Advantage, Medicaid, and MSSP populations, making standardization hard.

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?

CMS should update APM requirements to explicitly include and reward the use of advanced digital tools and technologies that enable smarter, more personalized care at scale. Xealth supports ACOs and risk-bearing entities by integrating patient engagement, care coordination, and real-time feedback into core workflows—helping teams act on analytics, stratification, and quality metrics more effectively.

- Tie digital engagement and care coordination to quality scoring—require or incentivize digital outreach for specific conditions (e.g., diabetes education, depression screening follow-up).
- Allow ACOs to submit digital tool usage data (e.g., app completion, PROs) as supplemental quality evidence.
- Promote AI- and rules-based targeting (e.g., automated referrals, app prescribing, rising-risk alerts) as eligible interventions under APM models.
- Recognize population health analytics platforms as allowable infrastructure costs—especially if used to drive digital tool deployment.
- Require or incentivize integration of risk stratification outputs (e.g., from payer or HIE systems) into digital workflows that act on those insights.
- Include usability and accessibility standards (e.g., multilingual tools, mobile-friendly experiences) in digital engagement measures.
- Define metrics for "meaningful digital engagement"—e.g., percent of patients using condition-specific tools, responding to surveys, or completing educational journeys.
- Enable closed-loop engagement by requiring that tools used in APMs return structured data to the provider or ACO (e.g., via FHIR or custom endpoints).

Thank you for considering Xealth's comments. Xealth is deeply committed to helping all patients get connected to beneficial care through the use of digital tools, and believe that CMS has the ability to further extend these benefits.

Sincerely,

Mike McSherry
David Slifka
Xealth, Inc.
xealth.com

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