Addressing Healthcare's Foundational Infrastructure: Kno2's Response to CMS's Health Technology Ecosystem RFI

The Centers for Medicare & Medicaid Services should prioritize solving the foundational infrastructure challenges that have plagued American healthcare for decades before pursuing advanced digital health initiatives. While innovative applications and sophisticated analytics capture attention, the reality is that basic provider-to-provider health information exchange and patient data access remain fundamentally broken at scale across the United States. Without establishing this critical foundation, investments in higher-level digital health solutions will continue to deliver marginal returns and perpetuate the fragmented care delivery that drives both poor outcomes and excessive costs.

Provider-to-provider health information exchange represents the most critical foundational challenge requiring immediate, systematic resolution. Despite billions of dollars invested in electronic health records and interoperability initiatives, most clinical information transfers still occur through fax machines, phone calls, and manual processes that introduce delays, errors, and care gaps. When a Medicare beneficiary transitions from hospital to skilled nursing facility, or when a specialist needs historical records from a primary care provider, the resulting information gaps directly impact patient safety and care quality. CMS should mandate and fund universal TEFCA participation for all Medicare and Medicaid participating providers, establishing clear technical standards, removing financial barriers, and creating enforceable timelines for connectivity. This foundational capability must be solved comprehensively—not through piecemeal approaches that leave gaps in coverage or create additional silos.

Patient access to their complete health information represents the second foundational priority that enables all other digital health innovations. Currently, patients face a bewildering maze of provider portals, each containing fragments of their health story, with no unified mechanism to aggregate, understand, or utilize their complete medical history. The Blue Button 2.0 initiative provides an important foundation, but CMS must expand this to encompass the entire continuum of care data including provider visit notes, diagnostic images, care plans, and real-time updates from all participating providers. Only when patients have seamless, comprehensive access to their health information can truly effective health management applications, care navigation tools, and personalized health services emerge. This foundational capability should include standardized APIs that allow patients to authorize trusted applications to access their complete health record, eliminating the current friction that limits adoption and effectiveness of consumer-facing health technologies.

Once these foundational challenges are systematically addressed, CMS should then pursue the broader digital health ecosystem initiatives outlined in this RFI with significantly greater impact and success. Advanced analytics, artificial intelligence applications, specialized care management tools, and innovative value-based care technologies all depend on reliable, comprehensive health information flow between providers and to patients. By establishing universal provider connectivity and comprehensive patient data access as non-negotiable prerequisites, CMS will create the infrastructure foundation that allows market-driven innovation to flourish while ensuring that all Americans - regardless of their provider network or technical sophistication benefit from improved care coordination and health outcomes. This sequential approach recognizes that sustainable healthcare transformation requires solving fundamental infrastructure problems before optimizing higher-level applications and services.

For over a decade, Kno2 has worked tirelessly to solve the foundational communication challenges that plague our healthcare system. The entry of TEFCA and the opportunity to build one of the nation's Qualified Health Information Networks was a tremendous honor. Kno2, along with our QHIN peers, continue to fund and build the infrastructure that will tackle healthcare's most difficult challenges, changing our current trajectory.

Kno2 recognizes the RFI represents a significant opportunity for stakeholders to influence future CMS policy on digital health technology, informing upcoming regulations and program designs that could reshape how healthcare data is exchanged and how digital health tools are integrated into Medicare and value-based care programs.

As requested, we have provided responses to the pertinent questions asked in each domain in the RFI, however, a narrative response was necessary to paint the appropriate picture of why solving the foundational need of universal participation by every healthcare provider is the ONLY way to move US healthcare forward and solve the more advanced digital health opportunities identified in the RFI.

We appreciate this honor and would like to extend our gratitude for the daily service and commitment of the CMS and ASTP staff in improving healthcare for all Americans.

Warm Regards,

Therasa Bell, President & Cofounder

Kno2

Universal Provider Connectivity

The Centers for Medicare & Medicaid Services faces a foundational infrastructure challenge that must be resolved before advanced digital health applications can achieve their potential. While innovative technologies like bulk FHIR APIs, oAuth authentication, and AI-powered analytics capture attention, the fundamental reality is that **22+ million healthcare workers across 350,000+ facilities cannot reliably exchange basic health information**.

CMS should prioritize **mandatory connectivity for all healthcare providers**, on certified or non-certified EHR technology, through TEFCA before pursuing sophisticated digital health initiatives. This foundational approach will create the infrastructure necessary for all other innovations to succeed, including universal access to consumers, rather than continuing to build advanced applications on fragmented networks.

We would not try to build advanced smartphone features before ensuring universal calling capability. Similarly, healthcare should not pursue sophisticated APIs and AI applications while most providers cannot exchange basic health information. **Foundation first, applications second.**

Key Recommendation: Establish mandatory TEFCA participation as a condition of Medicare and Medicaid participation, implemented through a phased approach beginning in 2026 defined in subsequent pages.

The Foundational Challenge: Universal Connectivity First

The Complete Scope of Healthcare Interoperability

Treatment under TEFCA is defined as the provision, coordination, or management of healthcare by one or more healthcare providers. This includes coordination by third-party providers, consultations between providers treating a common patient, or referrals between providers.

TEFCA's treatment exchange purpose covers the **entire healthcare ecosystem**:

1. **Medical Providers**: 1.1M physicians, 5.2M registered nurses, 385K nurse practitioners, 258K physician assistants
2. **Behavioral Health**: 1.2M+ providers including mental health counselors, psychologists, psychiatrists, social workers
3. **Dental Care**: 202K dentists, 215K dental hygienists, 364K dental assistants across 135K practices
4. **Vision Care**: 48K optometrists, 17K ophthalmologists, plus technicians and support staff
5. **Rehabilitation**: 240K physical therapists, 145K occupational therapists, 162K speech-language pathologists
6. **Support Services**: 5.3M healthcare support workers including home health aides, personal care aides, nursing assistants
7. **Healthcare Facilities**: 350,000+ locations including hospitals, physician offices, dental practices, mental health centers, vision clinics

While TEFCA's Treatment definition covers all 22 million healthcare workers who deliver or support patient care, **voluntary participation means comprehensive provider-to-provider exchange remains fundamentally broken**. This represents the largest interoperability challenge in healthcare history – connecting not just physicians, but the entire ecosystem of nurses, therapists, technicians, support staff and facilities that make healthcare delivery possible.

Care Coordination Imperative: Medicare beneficiaries average 7+ providers across multiple specialties. Effective care coordination requires universal connectivity, not partial connectivity with sophisticated APIs.

Universal Consumer Access: The Foundation for Healthcare Equity

Patient Access Depends on Provider Connectivity

Individual Access Services (IAS) under TEFCA can only succeed with universal provider connectivity. When patients request their complete health information, they need access to data from their **entire care team**, not just their physician providers.

The Patient Access Reality

Current Fragmented State	**Universal Connectivity Foundation**
1. Patient uses Blue Button 2.0 to access Medicare claims data 2. Requests records from primary care and specialist physician provider's patient portal through discrete logins 3. Have access to less than 10% of post-acute data 4. Cannot access mental health counselor records 5. Missing dental history (practice not connected) 6. Vision care records unavailable	7. Patient accesses comprehensive health record from all treating providers 8. Complete medication list including prescriptions from all specialists and current plans of care 9. Full diagnostic history including mental health, dental, and vision care 10. Coordinated care plans visible across entire care team
Result: Incomplete health picture that undermines informed decision-making	**Result**: True patient empowerment with complete health information

Healthcare Equity and Social Determinants

Universal connectivity is essential for addressing healthcare disparities:

Rural and Underserved Communities: Often rely on fragmented provider networks where universal connectivity is even more critical for care coordination. Rural patients frequently travel long distances to specialists who may not be connected to their local providers.

Complex Chronic Conditions: Patients with multiple comorbidities—common among Medicare beneficiaries—require coordinated care across numerous specialties. Fragmented connectivity disproportionately harms these vulnerable populations.

Social Determinants Integration: Community health workers, social services, and non-traditional healthcare providers must be connected to address social determinants of health effectively. Universal connectivity enables this comprehensive approach to population health.

Patient Safety and Informed Consent

Medication Safety: Patients cannot make informed decisions about new medications without complete prescription histories from all providers, including specialists, mental health providers, and dentists who prescribe medications.

Procedure Planning: Surgical and procedural decisions require complete health context, including behavioral health status, dental infections that could affect procedures, and vision issues that might impact recovery.

Emergency Preparedness: In medical emergencies, universal connectivity ensures first responders and emergency departments have immediate access to complete patient information regardless of where the patient usually receives care.

The Business Case for Universal Connectivity

While precise ROI calculations for universal TEFCA implementation are inherently impossible due to our healthcare system complexity, the fundamental economics strongly support the investment. Healthcare interoperability generates cascading benefits that are difficult to quantify. For instance, a prevented readmission saves direct costs but also improves bed availability and reduces staff burden in ways that ripple throughout the system.

These benefits also cannot capture indirect impacts like improved clinical decisions, reduced medical errors, enhanced public health surveillance, and accelerated research capabilities. The challenge is compounded by the fact that savings occur across multiple stakeholders including providers, payers, patients, and society over different time horizons, making it impossible to attribute specific dollar amounts to connectivity improvements.

However, **the directional evidence is overwhelming**: every major study on healthcare interoperability concludes that benefits far exceed implementation costs. The question is not whether universal connectivity will generate positive returns, **but how quickly those returns will compound to transform the US healthcare system efficiency and effectiveness**.

Based upon various estimates, the TEFCA implementation could directly **save CMS $15-25 billion annually**, not including all the compounding, yet difficult to measure, impacts.

Key Findings:

Current CMS Spending Context: Medicare spending grew 8.1% to $1,029.8 billion in 2023, or 21 percent of total NHE. Medicaid spending grew 7.9% to $871.7 billion in 2023, or 18 percent of total NHE. **Combined, CMS oversees $1.9 trillion in annual healthcare spending or 7% of the US economy.**

Major Savings Categories:

1. **Administrative Cost Reduction** ($8-12 billion annually)
    1. Each year, health care payers and providers in the United States spend about $496 billion on billing and insurance-related (BIR) costs
    2. According to recent studies, it is estimated that 15-30% of total healthcare spend goes towards administrative burdens
2. **Duplicate and Unnecessary Services** ($4-6 billion annually)
    1. As an example: According to the Lown Institute, more than 20% of the stents placed in Medicare patients between 2019 and 2021 were unnecessary, at a cost of US$2.44 billion
    2. One study found that the lack of healthcare data interoperability costs the U.S. health system over $30 billion annually
3. **Enhanced Program Integrity** ($2-4 billion annually)
    1. Both Medicare and Medicaid are susceptible to payment errors over $100 billion worth in 2023
    2. The Journal reported that from 2019 to 2021 which included the COVID-19 pandemic, duplicative payments for an average of about 660,000 patients per year totaled $4.3 billion
4. **Chronic Disease Coordination** ($1-3 billion annually)
    1. Building on the diabetic eye care model showing $1.4 billion in 5-year savings potential for one condition alone

Historical Evidence for Interoperability Savings: The Center for Information Technology Leadership estimates that standardized healthcare information exchange among healthcare systems could save as much as $86.8 billion each year, while interoperability can reduce healthcare costs by an estimated $30 billion.

Return on Investment: Even with implementation costs of $5-15 billion over 5 years, the system would break even **within 8-18 months and generate $60-110 billion in net savings over 5 years**, representing an annual ROI of 150-300%.

The analysis shows that universal TEFCA connectivity is not just a technological upgrade, it's a financial imperative that could fundamentally transform healthcare efficiency while preserving program sustainability for future generations.

Strategic Implementation: Mandatory Universal Connectivity

The following is a multi-part approach to achieving universal provider connectivity across the healthcare ecosystem. The expectation of participation would be the support of required Standard Operating Procedures of TEFCA.

Phase 1: Immediate CMS Leverage (2025-2026)

Medicare Advantage Plan Requirements

1. Mandate all MA plans contract only with TEFCA-connected providers by end of 2026
2. Impact: 31 million beneficiaries, immediate market pressure for provider participation
3. Enforcement: MA plan certification depends on provider network TEFCA compliance

Accountable Care Organization Mandates

1. Require all ACO participants to be TEFCA-connected by end of 2026
2. Impact: Covers shared savings programs, directly ties to value-based payments
3. Enforcement: ACO agreement compliance, withhold shared savings for non-compliance

Quality Payment Program Integration

1. Make TEFCA participation required for avoiding MIPS penalties
2. Impact: Covers 200,000+ eligible clinicians
3. Enforcement: MIPS scoring, financial penalties for non-participation

Phase 2: Systematic Expansion (2026-2027)

Medicare Provider Enrollment Requirement

1. Mandate new Medicare provider enrollment requires TEFCA participation
2. Impact: All new Medicare providers must be connected
3. Enforcement: Provider enrollment application, automatic denial for non-compliance

Medicaid Managed Care Requirements

1. Require state Medicaid managed care plans mandate provider TEFCA participation
2. Impact: Covers 70+ million Medicaid beneficiaries
3. Enforcement: State plan approval, federal matching fund conditions

Phase 3: Universal Mandate (2027-2028)

Medicare/Medicaid Condition of Participation

1. Establish TEFCA participation as condition for all providers accepting Medicare/Medicaid
2. Impact: Covers all healthcare providers
3. Enforcement: Provider agreement compliance, payment suspension for non-compliance

Addressing Coverage Gaps Beyond CMS Authority

Federal-State Coordination:

1. Partner with states to integrate TEFCA requirements into professional licensing
2. Covers behavioral health, dental, and vision providers with limited Medicare participation
3. Use state Medicaid leverage for additional provider coverage

Private Market Integration:

1. Encourage large employers to require TEFCA participation in provider networks
2. Support insurance companies mandating connectivity for in-network status
3. Create market incentives for non-Medicare dependent providers

Responses to Specific RFI Questions

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?

Universal Health Record Access: Patients need applications that can access their **complete** health information from all providers—not just those in connected networks. This requires universal provider connectivity as the foundation.

Comprehensive Care Coordination Apps: Applications that help patients coordinate care across their entire healthcare team, including scheduling appointments, managing referrals, and ensuring all providers have current information. These apps cannot function effectively with fragmented provider connectivity.

PC-2: Do you have easy access to your own and all your loved ones' health information in one location?

Current Reality: No patient has easy access to complete health information because universal provider connectivity does not exist. Patients must navigate multiple portals, request records from disconnected providers, and often lack access to mental health, dental, or specialty care information.

Universal Connectivity Solution: Only mandatory provider participation in TEFCA can enable true consolidated patient access to complete health records.

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

Primary Gap: Universal provider connectivity. The most sophisticated health management applications are limited by incomplete data because providers are not universally connected. Patients cannot effectively manage their health when their complete care team cannot communicate.

What apps should exist but do not yet: Comprehensive care coordination applications that work across the complete healthcare ecosystem—medical, behavioral health, dental, vision, and rehabilitation providers—are impossible without universal connectivity foundation.

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

Foundation First: Mandate universal provider connectivity so that digital health products can offer patients access to their **complete** health information. Patients will naturally gravitate toward applications that provide comprehensive, rather than fragmented, health data.

Trust Through Completeness: Patient adoption of digital health tools increases when they trust the information is complete and current. Universal connectivity creates this trust by ensuring no gaps in health information access.

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

Primary Obstacle: Fragmented provider networks. Developers cannot build truly effective clinical applications when they cannot assume universal data availability. The most innovative physician workflow applications require complete patient information, which is impossible with voluntary participation approaches.

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 (2025-2026): Mandate universal connectivity through Medicare Advantage and ACO requirements. This creates a reliable, comprehensive data foundation that makes developer investment worthwhile.

Longer-term (2027-2030): Once universal connectivity is established, support advanced API development, AI applications, and innovative digital health solutions that can operate on complete patient data sets.

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?

Primary Incentive: Mandatory TEFCA participation for all APM participants. ACOs and MSSP participants cannot effectively manage population health without complete patient data from all treating providers. Universal connectivity enables the care coordination that makes value-based care successful.

Bridging the EHR Technology Divide: Certified vs. Non-Certified Systems

The Hidden Challenge of Healthcare's Digital Infrastructure

While discussions of healthcare interoperability often assume universal adoption of certified Electronic Health Record (EHR) systems, the reality is far more complex. **Universal provider connectivity cannot be achieved without addressing the significant technology gap between certified EHR products and the diverse array of non-certified systems that serve critical segments of the healthcare ecosystem.**

The Scope of Non-Certified EHR Usage

Behavioral Health Providers: Many mental health counselors, psychologists, and smaller behavioral health practices rely on non-certified practice management systems or basic documentation tools. These providers often serve vulnerable populations who cannot afford to lose connectivity to the broader healthcare system.

Dental and Vision Care: Most dental practices and vision care providers operate on specialized practice management systems that are not ONC-certified for health information exchange. These systems are optimized for their specific clinical workflows but lack standardized interoperability capabilities.

Small Primary Care and Specialty Practices: Many solo practitioners and small group practices, particularly in rural and underserved areas, use basic EHR systems or practice management software that provides core functionality but lacks certified interoperability features.

Post-Acute and Long-Term Care: Skilled nursing facilities, home health agencies, and assisted living facilities often operate on specialized systems designed for their unique regulatory and operational requirements, many of which are not ONC-certified.

Community Health Centers and Safety Net Providers: While federally qualified health centers typically use certified EHRs, many community-based organizations providing healthcare services operate on grant-funded or donated systems with limited interoperability capabilities.

The Technology Gap Challenge

Functional vs. Certified Systems: Many non-certified systems provide excellent clinical functionality for their specific use cases but lack the standardized APIs and interoperability features required for TEFCA participation. This creates a false choice between specialized functionality and connectivity.

Financial Barriers: Requiring immediate migration to certified EHR systems would impose unsustainable costs on smaller providers, potentially forcing practice closures in underserved communities where healthcare access is already limited.

Workflow Disruption: Providers who have optimized their clinical workflows around specialized systems face significant operational disruption and staff retraining costs when forced to migrate to different platforms.

Integration Complexity: The assumption that all providers can simply "upgrade" to certified systems ignores the complex integrations many practices have built with billing systems, imaging equipment, laboratory interfaces, and other clinical tools.

CMS Solution Framework: Technology-Agnostic Connectivity

Principle: Universal connectivity should be achieved through technology-agnostic approaches that enable all providers to participate regardless of their underlying EHR technology.

Tiered Connectivity Approach

Tier 1: Direct TEFCA Connection (Certified EHR Systems)

- Providers with certified EHR systems connect directly through existing TEFCA infrastructure
- Leverages existing ONC certification requirements and standardized APIs
- Represents the "gold standard" for seamless interoperability

Tier 2: QHIN-Mediated Connectivity (Non-Certified Systems)

- Qualified Health Information Networks provide connectivity services for providers with non-certified systems allowing for the USCDI to be presented in all formats, including PDF's.
- Utilize and manage QHIN data standards to ensure no provider system left behind, despite content and data formats. Leverage the power of AI on the edge to flatten the interoperability requirements.
- Develop and over time adherence to structured data formats through the EHR technology or their designated data or QHIN service provider.
- Maintains universal connectivity while accommodating diverse technology environments

Implementation Support Framework

Technical Assistance Program

- CMS should fund dedicated technical assistance to help non-certified system providers achieve connectivity
- Regional support centers providing hands-on implementation guidance
- Standardized integration toolkits that reduce development costs for health IT vendors

Financial Incentive Structure

1. Provide enhanced reimbursement rates for providers who achieve TEFCA connectivity regardless of underlying technology
2. Offset implementation costs through value-based care bonuses tied to improved care coordination
3. Support rural and underserved provider connectivity through targeted grant programs

Vendor Engagement Initiative

1. Work with non-certified EHR vendors to develop TEFCA-compatible interfaces
2. Create market incentives for vendors to add interoperability features to existing products
3. Establish certification pathways that don't require complete system overhauls

Standardized Data Quality Requirements

1. Establish minimum data quality standards that apply regardless of underlying technology
2. Require all participating systems to meet baseline security and privacy requirements
3. Implement ongoing monitoring and compliance verification

Patient Safety Protections

1. Ensure that technology-agnostic approaches maintain the same patient safety standards as certified systems
2. Require explicit patient consent for data sharing from non-certified systems
3. Implement audit trails and accountability measures across all connectivity tiers

Clinical Decision Support Integration

1. Enable non-certified systems to receive and act on clinical decision support alerts
2. Ensure that care gaps and quality measures can be tracked across all technology platforms
3. Maintain care coordination benefits regardless of provider technology choices

Economic Impact of Inclusive Connectivity

Avoiding Provider Network Disruption: Forcing immediate migration to certified systems could result in practice closures, particularly in rural and underserved areas where healthcare access is already limited. The cost of losing these providers far exceeds the investment in technology-agnostic connectivity solutions.

Leveraging Existing Infrastructure: Many non-certified systems represent significant investments by healthcare providers. Technology-agnostic approaches preserve these investments while adding connectivity capabilities, maximizing overall system efficiency.

Market Innovation: Creating pathways for non-certified systems to participate in TEFCA encourages innovation in health IT, potentially leading to more cost-effective and user-friendly solutions that benefit the entire ecosystem.

Implementation Timeline and Milestones

2025: Launch technical assistance program and begin QHIN-mediated connectivity pilots **2026**: Establish third-party integration service certification and expand financial incentives **2027**: Achieve 80% connectivity across all provider types regardless of underlying technology **2028**: Full universal connectivity with ongoing support for technology diversity

Conclusion: True Universal Connectivity

Universal provider connectivity cannot be achieved by mandating universal adoption of certified EHR systems. Instead, CMS must create technology-agnostic pathways that enable all providers to participate in TEFCA regardless of their underlying health IT infrastructure.

This inclusive approach recognizes the diversity of the healthcare ecosystem while maintaining the quality, security, and interoperability standards necessary for effective care coordination. By supporting multiple connectivity pathways, CMS can achieve true universal connectivity that strengthens rather than fragments the provider network.

The goal is not EHR uniformity, but universal connectivity that preserves provider choice while enabling seamless information exchange across the entire healthcare ecosystem.

Conclusion and Call to Action

The healthcare industry stands at a critical juncture. CMS can continue the current approach of building sophisticated applications on fragmented infrastructure, or it can solve the foundational connectivity challenge that enables all other innovations to succeed.

The choice is clear: Foundation first, applications second.

Kno2, as a designated QHIN, stands ready to support CMS in implementing mandatory universal connectivity. We have the technical infrastructure, operational experience, and industry relationships necessary to facilitate this transformation.

We urge CMS to:

1. Establish mandatory TEFCA participation as a Medicare/Medicaid condition of participation
2. Implement through the phased approach outlined above
3. Partner with states and private markets to achieve truly universal coverage
4. Then layer advanced digital health applications on this solid foundation

The 22+ million healthcare workers and 350,000+ facilities that comprise America's healthcare ecosystem and the patients they serve deserve nothing less than universal connectivity that enables coordinated, comprehensive care.

Universal connectivity is not just a technical goal, it is a patient safety imperative and the foundation for the innovative, patient-centered healthcare system CMS envisions.

Submitted by:
Kno2, LLC
QHIN Designation: February 12, 2024
Submission Date: June 16, 2025

For questions regarding this response, please contact:
Matt Becker – VP of Interoperability, mbecker@kno2.com

Therasa Bell – President & Cofounder, tbell@kno2.com