

June 16, 2025

Thomas Keane, MD, MBA
Assistant Secretary for Technology Policy
Office of the National Coordinator for Health Information Technology
U.S. Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Request for Information; Health Technology Ecosystem

Submitted Electronically: www.regulations.gov

Dear Assistant Secretary Keane:

UnitedHealth Group (UHG) is pleased to submit comments to the Department of Health and Human Services (HHS) in response to a Request for Information (RFI) on private and public efforts to develop and expand our health technology ecosystem. The United States stands at a pivotal moment of health care innovation. Advances in AI, growing adoption of digital health tools, and the unprecedented availability of health care data offer the opportunity to build a system that is not only more efficient, but more personalized and responsive to the needs of every American. Our comments are intended to address how the use of artificial intelligence (AI) strategies can improve health; better engage consumers, health care providers, and caregivers; and expand access to affordable care. Specifically, we will:

- 1) Share our vision to take advantage of this unique moment to build a healthier America through an AI-driven empowerment agenda.
- 2) Offer concrete policy recommendations to help enable our vision by increasing data interoperability and health information technology (IT) adoption while protecting data privacy.

UHG's mission is to help people live healthier lives, and make the health care system work better for everyone. Through UnitedHealthcare, our health benefits business, and Optum, our health services business, we work with employers, providers, and governments to serve people and execute on our vision for a value-based system of care that provides affordable health care, improves outcomes, lessens the burden of disease, and promotes a healthier lifestyle. We have decades of experience partnering with the federal government to help it achieve its policy goals.

We hope HHS considers our recommendations and we look forward to working with all stakeholders to fulfill our shared vision for a healthier America.

Executing an AI-Powered Empowerment Agenda

America has the foundation to lead the world in delivering high quality, affordable care to everyone. No nation competes with America in innovation, AI, medical research, drug discovery, high end care delivery, health data volume or willingness to spend. Despite that, our health statistics are well-documented and sobering, so we will not belabor them here.

What's the problem?

- Health care simply costs too much; the health care system incentivizes sick care over wellness.
- It is too difficult to navigate the health care system, let alone manage one's own care.
- Physicians and clinical care teams are burning out at record rates due to heavy administrative burdens and clinical workforce shortages.
- Wealthy Americans have significantly better access to care and better clinical outcomes than poorer ones.
- Our data systems are broken and fragmented, hindered by regulations and market behavior that has failed to unlock systemic innovation and insights.

The result is a supply-demand mismatch, worsening health outcomes, crippling costs, and rising mistrust of the system. At UHG, we have continued to grow our understanding of the health care system and its pain points. With the humility earned from lessons learned, we share our perspective below on how AI can help us address these vexing, systemic challenges together.

America needs a radical reorientation of how health care is delivered, administered, and experienced through an AI-enabled empowerment agenda that:

- 1) **Empowers and unburdens the American taxpayer** by realizing the promise of value-based care, while dramatically reducing fraud, waste, and abuse and controlling drug prices.
- 2) **Empowers individuals** to easily navigate both well and sick care journeys by building trust, transparency, and choice through personalized support in the palm of their hands.
- 3) **Empowers physicians and all clinical care teams members** to put their full energy and attention into better diagnosis and treatment by reimagining clinical workflows, eliminating most administrative burdens, and augmenting clinical decision-making.
- 4) **Empowers innovators** to address the nation's many health care challenges, by liberating data from entrenched environments (e.g., electronic health record vendors) and cultivating a strong health care developer ecosystem.

1) Empower and Unburden the American Taxpayer

U.S. health spending reached \$4.9 trillion in 2023, or \$14,750 per capita, with spending growth (7.5%) outpacing GDP growth for the first time since the COVID-19 pandemic and is expected to reach 20.1% of GDP and 18.2% of the Federal budget this year.¹⁻² These costs jeopardize America's entire economy and burden the American taxpayer. We envision a future in which consumers determine their path to high value care, either by choosing a provider with fully delegated risk or by directly navigating their own care through AI-enabled transparency-based purchase and payment models. These programs have been shown to improve admissions, readmissions, emergency department visits, and chronic care management.³

What is required: Both shorter and more transformative longer-term levers need to be considered to address this cost burden:

- Higher adoption and more innovation of value-based care models to ensure people lead healthy lives and receive the best care, at the right time, at an affordable price, with increased focus on wellness and prevention.
- Utilization management and payment integrity can be executed faster, more efficiently, and nearly autonomously, with zero “no” determinations made by AI.
- Greater utilization of nationwide health information exchange frameworks such as the Trusted Exchange Framework and Common Agreement (TEFCA), along with adoption of Application Programming Interface (API) based standards to free the data-workflow trap.
- Use of AI to improve our “sources of truth” regarding benefits and coverage, formularies, network participation, and care costs.

Potential policy actions:

- Launch a national AI-enabled value-based care innovation waiver program within the Centers for Medicare & Medicaid Services (CMS) that functions as a public-private innovation sandbox, empowering Medicare Advantage plans and value-based providers to pilot and scale AI-powered models with fast-track agency review and approvals (e.g., address the need for retrospective chart review vs. real-time risk adjustment).

How UHG can help:

- Design care delivery and payment models for a new value-based innovation waiver in partnership with CMS, initially targeting AI-powered innovation in high-cost populations.
- For those beneficiaries in fee-for-service models, leverage AI to shift payment integrity to pre-payment and reduce fraud, waste, and abuse across the ecosystem.
- Use AI to control drug prices across strategic levers including formulary optimization

¹ <https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet>

² <https://www.healthsystemtracker.org/chart-collection/u-s-spending-healthcare-changed-time/>

³ [JAMA-Network-Open-Article-1.23.25-.pdf](#)

and tiering, underwriting and contracting with manufacturers, and adherence modeling and interventions to ensure drug compliance (thus minimizing waste and maximizing impact).

- Provide population health-level insights to identify hotspots and potential societal and/or regulatory interventions contributing to poor health outcomes (e.g., diet of ultra processed foods, alcohol and tobacco consumption, and sedentary lifestyles).

2) Empower Individuals

Americans are unhappy with their health care. Between 2020-2024, the proportion of U.S. adults that reported trusting the health care system fell from 71.5% to 40.1%.⁴ AI enables us to chart a new path for all Americans, allowing for more choice in both wellness and sickness that meets each individual's unique care needs. AI tools can help:

- Help patients choose and schedule the right health care professional at the right time.
- Leverage medical evidence to develop patient-centric tools to support shared decision making.
- Enable transparency and timely information on price.
- Eliminate burdensome administrative processes.
- Reduce out-of-pocket costs.
- Inform lifestyle choices through a host of third-party applications that can serve as a medical device, digital care manager, meal planning coach or even a personal trainer.

What is required:

- Enhancing individuals' digital ability to access their personal health data.
- A robust developer ecosystem.
- A cooperative regulatory environment.

Potential policy actions:

- Develop voluntary national digital identification standards for individuals (and their caregivers) and providers that are consistent with privacy and security standards.
- Encourage digital transmission of data through APIs and other interoperable tools vs. outmoded transmission models such as faxes.

How UHG can help: UHG can help establish the building blocks for individualized yet seamless navigation of the health care system by enabling true interoperability and creating a lifelong personal digital health experience for all Americans:

- Offer an opportunity for secure digital health ID to every American, providing them with free lifelong access, storage, and secure sharing of medical data, and allowing for easy delegated access for caregivers and providers of their data
- Leverage the above ID technology to enable numerous applications (e.g., secure

⁴ <https://www.ajmc.com/view/erosion-of-trust-in-healthcare-a-public-health-crisis>

communications with physicians, new range of personalized digital health services such as nutrition counseling that integrates with digital health records, wearables, and other tools).

- Transform health care interactions into “real time” retail experiences, with standardized scheduling, true price transparency (e.g., physician service SKU-level pricing vs. post-service claims), personalized guidance on lifestyle and care recommendations, and greater access to well care (vs. sick care only).

3) Empower physicians and all clinical care team members

Primary care providers spend the same or more time on administrative tasks as they do on clinical care today.⁵ Physician burnout is costing the US health care system an estimated \$4.6 billion annually.⁶ In order to unlock the full potential of our clinicians, we must eliminate their administrative burdens, improve clinical workflows, augment clinical decision-making, and create opportunities for shared-decision making and focus on patients to bring back their love and joy for the medical profession while improving quality and outcomes.

UHG is a thought and delivery leader in value-based care providing support to the largest risk-capitated populations in the US. We have AI-driven clinical decision support, predictive analytics in both risk and quality, and AI-powered revenue cycle management. We have the most extensive care delivery system in the country – both in clinical/ambulatory services and our growing In-home care network. Our in-home network and our post-inpatient care is powered by some of the most innovative AI in the world to support nurse scheduling, patient prioritization, and to reduce readmissions.

What is required:

- Continued adoption of new enabling technologies (e.g., ambient transcription technology to facilitate and improve clinical documentation).
- Continued development and integration of clinical decision support tools.
- An AI-powered redesign of administrative processes (e.g., completing prior authorization submissions and receiving approval on prior authorizations, coding and claims submission, and real-time adjudication of claims) and operational needs (e.g., contact centers).
- Reimagined clinical workflows and supports (e.g., agentic care management, 24/7 patient monitoring, dynamic patient intake, pharmacy script and referral support, triaging patients to the right level of care).

Potential policy actions:

- Modernize Food and Drug Administration (FDA) approvals for software as a medical device involving generative AI, including post-market surveillance for generative AI models.

⁵ <https://peoria.medicine.uic.edu/administrative-tasks-take-up-more-time-than-patient-care-for-many-pcps/>

⁶ <https://www.acpjournals.org/doi/10.7326/M18-1422>

- Clearly define necessary processes (e.g., Institutional Review Board and clinical trial-like structures) to test and approve autonomous incorporation of AI into clinical practice.
- Enable the power of AI by rules and legislation that mandates uniform access controls and governance policies for large language model integrations across electronic medical records (EMRs) within the prevention of information blocking vision.

How UHG can help:

- Partner with CMS, the Council for Affordable Quality Healthcare (CAQH) and other public and private sector partners to develop a single authoritative provider directory accessible via APIs to reduce provider and payer burden, help consumers, and lower administrative costs.
- Incorporate and scale best practices in our own operations and in servicing non-UHG providers across America (e.g., scale up of ambient transcription, guideline-directed therapy adoption, and diagnosis prediction for advanced practice clinicians in home visits).
- Offer AI-assisted technology to automate large parts of a clinician's daily administrative workflow and their interactions with payers (e.g., claims adjudication, payment collection), all while lowering administrative denial rates, expediting care delivery, and increasing capacity.

4) Empower innovators

Wholesale U.S. health care innovation is held back by an inability to access and utilize data, a complicated regulatory environment, uncertainty on reimbursements, and incentives that prioritize point of service solutions over systemic innovation. If we want to unleash health care innovation with AI, we need to accelerate ecosystem-wide efforts to share data (e.g., TEFCAs) and encourage the safe liberation of clinical data from closed environments.

What is required:

- Cultivation of the developer ecosystem.
- Modernization of Health IT infrastructure to ensure AI readiness.

Potential policy actions:

- Development of national standards on AI that support risk-based innovation and evaluations along with public-private collaboration.
- Liberate clinical data from electronic health records on open platforms.
- Signal the types of health AI innovation that may be reimbursable in the future to the market.

How UHG can help:

- UHG will offer its expertise, experience, and tools, through Optum, to help organizations modernize their infrastructure and leverage AI.

Policy Recommendations to Increase Interoperability and Health IT Adoption

Much progress has been made in digitalizing health care transactions over the past decade. To quickly and efficiently deploy the most cutting-edge technologies to advance health, reduce costs, and improve the patient experience, we recommend that HHS address existing regulations and processes that hinder progress.

1) Establish a national, standardized technology framework that facilitates secure data sharing

- Facilitate Health Information Exchange Highways by promoting nationwide data sharing frameworks such as TEFCA. These structures adopt rules for the secure and seamless exchange of health information by and between payers, providers, and other participants. We recommend that TEFCA and other frameworks facilitate all appropriate treatment, payment, and health care operations by mandating data exchange for these uses, which aligns with the Information Blocking regulations.
- Create a national digital identity standard that is consistent with privacy and security standards and enabled by government certified Credentialing Service Providers (CSPs) allowing payers, providers, and other participants to securely and accurately identify the same individual or provider used for the purpose of facilitating data exchange – including appropriate individual consent for the data exchange. Participants in the exchange of health information must be able to trust and accept identity and consent data provided by CSPs without requiring additional registration or consent workflows.
 - In practice a token from a certified CSP would contain information to uniquely identify the individual or provider and would be accompanied by a signed consent payload or token if required by applicable law that would authorize specific data exchanges on behalf of the member without each data owner needing to separately prompting the member for consent.
 - This consent mechanism should also enable an individual to grant consent to a caregiver / advocate / proxy to request data on their behalf. The audit events and logs of any consent actions taken should also be immediately electronically available to the individual.
- Leverage a federated Identity Provider (IDP) capability to allow a digital identity meeting TEFCA's identity assurance principles (e.g., National Institute of Standards and Technology Identity Assurance Level 2 (IAL2) via a certified CSP) to log in to any participating provider portal, health app, and/or API/FHIR data point. This identity proofing must be available to either the patient or a supporting entity to which the patient has delegated.
 - Given such identity proofing (i.e., (IAL2), patients should be able to get endpoints for data systems that have their data in the registry directory across all published endpoints.
 - If a participant in the health care digital ecosystem accepts a certified token from a certified IAL2 provider, they must make their endpoints available in the registry.

- Create a national endpoint directory and record location services to facilitate the programmatic, accurate exchange of information between payers, providers, and other participants consistent with privacy and security standards. It should be easy for anyone to discover and retrieve the data for any individual regardless of where the data resides. This must be possible without having to explicitly know which systems have data for a patient.
- Maintain the current X12 and NCPDP HIPAA transactions standards while building a bridge to FHIR. HHS should act as a convener for HL7, X12, and NCPDP to work together to develop and implement a coordinated roadmap for moving from legacy transaction standards to real-time APIs facilitated by the FHIR standard.
- Continue to follow a regular and structured rulemaking process that provides the industry the opportunity to comment on proposed rules for technical standards prior to finalizing requirements. Health IT is complex, with many moving parts particularly when it comes to exchanging and using data. Having feedback from all parts of the health care ecosystem prior to finalizing rules ensures that HHS pushes forward innovative technologies that are implementable and do not overly tax health care operations for patients or providers. HHS should also request perspectives on implementation lead times and incorporate such guidance into final rules.
- Advance federal policy leadership while collaborating with state efforts, especially around AI and prior authorization. This approach will help avoid potential fragmentation of data and operational systems due to divergent federal and state policies.

2) Remove Barriers and Risks to Data Sharing

- Facilitate patients' access to request his/her EMR, in an electronic format. Requests must be able to be initiated, tracked, and delivered digitally. Empower individuals to explore and interpret their own health data, gaining personalized, real-time insights through AI models on their own or with a shared access provider.
- Increase EMR bulk data sharing limits to make data sharing more efficient for health plans – especially those plans with significant numbers of members.
 - Emphasize the importance of Bulk FHIR and importance of intermediary networks to support scaling of FHIR.
 - Ensure support for the CARES Act requirements for zero fee endpoints.
 - Public APIs must have sufficient data to meet their intended purpose. Example of issue is provider scheduling in EMR APIs.
 - Expand the definitions or rules under the CARES Act to ensure data providers deliver consumers more meaningful and useful APIs.
- Collaborate with the Office for Civil Rights and other relevant agencies to streamline patient data sharing when needed to help individuals experiencing substance use

disorder, serious mental illness, and in emergency circumstances. HIPAA's Privacy Rule should be updated to consistently promote permissible disclosures of protected health information for care coordination and case management. The Confidentiality of Substance Use Disorder Regulations could be further harmonized with HIPAA to better assist and care for individuals with substance use disorders.

- Establish a safe harbor for any data leaks for data sharing under nationwide data sharing networks such as TEFCA. The safe harbor would address situations where a data breach results from the actions of an entity that is transferring information (such as an HIE) and not the provider or other participant that is sending or receiving the data. This safe harbor should cover all entities that share data that are in compliance with applicable law and the Common Agreement and have the authorized identity token and valid consent as provided by a certified CSP.
- Utilize clearinghouses to scale FHIR for point-to-point connectivity on behalf of entities that are too small to manage these data transfers.
 - We strongly support the proliferation of FHIR APIs to enable real-time connectivity across the health care ecosystem. Scaling nationwide interoperability, even with FHIR, requires intermediaries who can facilitate the many connections, particularly around administrative data. Providers work with multiple payers, while payers work with thousands of providers. Scaling FHIR APIs between these parties requires an intermediary who can enable organizations to connect once to get to all.

In the administrative world, clearinghouses have facilitated scaling many-to-many EDI transactions since the 90s, ensuring that transactions conform to standards, meet high data quality standards, and are correctly routed to the intended recipient in a timely manner. FHIR APIs, while real-time, have the same needs: some level of transformation or mapping, high quality data, and routing to the correct recipient. Intermediaries can and do support all of these, and we encourage the administration to ensure that any regulations or policies that mandate the use of FHIR APIs enable intermediaries to facilitate the scalability of those APIs. For example, the current CMS-0057 is written in such a way that it assumes that payers will have a single FHIR endpoint at the company level, rather than what is more likely, which is plan-specific endpoints. As it is written, it may be difficult for a payer or provider to work with an intermediary to support their FHIR connections and still abide by the letter of the law. We strongly recommend that HHS consider how any mandated APIs will scale when drafting regulatory language and ensure that the language does not prohibit or negate intermediaries.

- Enable support for enhanced data liquidity and reduced information blocking by leveraging federated digital identity to enable secure, authorized access to, and the promotion of standardized Bulk FHIR/API for exchanging patient electronic health information through industry certified intermediary networks and/or clearinghouses to

allow scalable, cost-effective data access and sharing for authorized health ecosystem participants and patient/caregiver supporting entities.

- Establish clear legal and regulatory frameworks for data protection and standardized data sharing.
- Enhance standards to further unlock comprehensive scheduling data. Today, provider availability is exposed through EMR APIs, but providers' availability for specific appointment types may not be included, which constitutes a fatal flaw for any third party appointment scheduling tool (e.g., it is necessary to know availability for a new patient vs. existing patient appointment type). Standards that cover these complex needs along with requirements to expose the additional data would open the ecosystem to more innovation.
- If an EMR vendor supports member push notifications within their ecosystem they must provide a service (push) for patient events via an endpoint to allow app developers to react to data updates in a substantially similar way to the vendor's own app. For example, a notification, "new lab results are available."

3) *Create more clarity for participants*

- Modernize FDA approvals for software as a medical device involving generative AI, including post-market surveillance for generative AI models. We also recommend clearly defining necessary processes (e.g., Institutional Review Board and clinical trial-like structures) to test and approve autonomous incorporation of AI into clinical practice.
- Address Information blocking rules and certification burdens. We strongly support ensuring that entities do not gatekeep patient information via information blocking. However, the current information blocking rules have been set up in such a way that may stifle innovation. There are three primary actors identified in the regulations - Health Information Networks, Healthcare Providers, and Developers of Certified Health IT. For Developers, ONC's current regulations specify that an organization that has even a single component certified to any part of its certification criteria makes the entire organization an Information Blocking Actor, regulated by ONC. As a result, every product the organization owns falls under ONC's purview even when it is not the product certified. We believe this makes it difficult for new entrants to come to market with innovative products because of the significant investment and time and resources needed to demonstrate compliance with the regulations, even for products that would not otherwise fall under ONC's purview. We believe that narrowing the definition of a Developer of Certified Health IT to apply only to the products that are actually certified would enable new entrants into the market that could compete with large incumbents and provide innovative, AI-based products that improve patient experiences and decrease provider burden.
- Ensure billing codes evolve in lockstep with efforts to innovate and harness new technology. If billing codes do not allow payers to differentiate services and devices by cost and quality, the US health care system risks inducing waste. Examples include:

- Digital Apps and Remote Patient Monitoring Billing Codes: There is rapid growth of digitally-enabled services and products that are of uncertain value but being promoted and disseminated by third party vendors and some providers, enabled by the publication of billing codes by CMS that are vague and thus open the door to low value service delivery and constrain options for precision management (e.g., behavioral health apps, insomnia apps, and remote patient monitoring technologies). CMS should adopt product-specific codes that enable payers to differentiate the product and manage with precision based on demonstrated clinical effectiveness. This product specific coding approach has enabled similar precision management in the zone of genetic testing (e.g., Palmetto Moldex Z-code effort).
- eConsult Billing Codes: The model (reimbursed by most payers including CMS) involves digital consultation between two clinicians (e.g. primary care provider to specialist) to enable collaborative management by two clinicians without requiring patients to be seen in person by them. This care model exemplifies what has been made possible by the diffusion of EMRs and the alignment of an enormous number of clinicians on a small number of platforms, where they can share rich clinical data. However, the billing codes were written in a way that inhibits billing of this care model by the clinician initiating the service. CMS should rewrite the CPT language to enable rather than inhibit use of this service that has huge potential to drive efficiency by leveraging data and platforms in place of low-value face-to-face visits.

We appreciate the opportunity to provide our perspectives on the technology ecosystem and look forward to further discussions with you.

Sincerely,



Sandeep Dadlani
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UnitedHealth Group