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June 16, 2025

The Honorable Mehmet Oz, MD, MBA
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Thomas Keane, MD, MBA
Assistant Secretary for Technology Policy
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
Mary E. Switzer Building
330 C Street, SW
Washington, DC 20201

RE: Request for Information; Health Technology Ecosystem (RIN: 0938-AV68)

Dear Administrator Oz and Assistant Secretary Keane:

Amazon.com Inc. (Amazon) appreciates the opportunity to comment on the Health Technology Ecosystem request for information (RFI) from the Centers for Medicare & Medicaid Services (CMS) and Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC). We support CMS and ASTP/ONC's goals to modernize the nation's digital health ecosystem and empower Medicare beneficiaries through greater access to innovative health technologies.

As a customer-obsessed company, we believe that patients and providers benefit from healthcare that is convenient, accessible, and affordable. Efforts that advance a seamless, secure, and patient-centered digital health infrastructure will improve a beneficiary's longitudinal engagement in their care journey, resulting in improved health outcomes and reduced healthcare expenditures. Across our comments below, we encourage CMS and ASTP/ONC to advance policies that help streamline healthcare access and delivery, allow patients to control their care journey, maximize providers' ability to deliver superior care, and enable public- and private-sector innovation.

1. **Support increased interoperability scenarios, including for payer-related use cases**

Patients are tired of repeating their healthcare story and being surprised by costs at the pharmacy counter. Patients should be able to access care where and when it is most convenient. They deserve to know the cost of their care before they get the bill. And patients and providers deserve access to real-time, comprehensive health information that travels with them, resulting in true interoperability that materially facilitates continuity of care. This includes information unique to a patient's clinical, coverage, and claims history. However, enhanced interoperability cannot rely on outdated, paper-based processes. Digital mechanisms must be standard for connecting care and facilitating true transparency for all healthcare stakeholders, enabling real-time decision-making, empowering patients with choice and selection, and removing the points of friction that perpetuate existing barriers to care.

CMS and ASTP/ONC should identify and implement standards that further improve the ease with which patients and providers can access the true out-of-pocket costs for patients and can see various pricing options, including drug discount programs. Right now, patients lack meaningful agency when seeking to fill a prescription. Costs are opaque and, in many circumstances, the lack of upfront clarity forces patients to walk away empty handed from the pharmacy counter. For example, real-time prescription benefits (RTPBs) checks can help facilitate a better experience for patients and their care team, allowing both parties to be cost-aware when electronically prescribing medications and selecting the most appropriate pharmacy for their needs. This supports utilization, adherence, and improved outcomes. Optimally, patient- and provider-facing RTPBs would display all key coverage-specific details on a medication, such as pricing, prior authorization requirements, or therapeutic equivalents.

However, patients rarely know the cost of a prescription medication at the time of prescribing, and it often remains unknown until they pick up the medication, schedule its delivery, or after administration in an office setting. Patients lack meaningful tools to confirm prescription costs prior to the pharmacy counter. This lack of consumer-facing transparency, in far too many cases, leads to patient abandonment and medication non-adherence at the pharmacy counter, reducing effectiveness and increasing long-term healthcare costs. For example, research published by *Dusetzina et al.* in May 2023 shows approximately 1-in-5 Medicare beneficiaries reported cost-related medication non-adherence while an overwhelming majority expressed interest in using a RTPB. Over half (7.5%) of the nearly 14% of Medicare beneficiaries that were medication non-adherent cited cost as the primary factor (Petroski et al., *Health Affairs,* December 2024). Standards that would mandate consistent, real-time price transparency application programming interfaces (APIs) between payers and pharmacies would meaningfully address this consistent point of friction for beneficiaries.

Additionally, RTPBs are not currently capable of communicating to providers whether a particular medication is carried on a pharmacy's formulary or, if in stock, when the pharmacy can make the medication available to the patient for pickup or delivery. Without this information, providers could unwittingly send a prescription to a pharmacy that is unable to fill the prescription in a timely manner. This can result in treatment delay and significant burden for patients, who often will call alternate pharmacies with urgent need. While an alternative pharmacy may be identified, beneficiaries still experience friction in transferring prescriptions and may experience unexpected cost increases as pricing varies by pharmacy. This may result in further delay given inconsistent use of electronic transfer protocols.

Relatedly, although existing RTPB standards support queries to drug discount programs, current standards can only accommodate discount programs with processors that use a BIN(IIN)/PCN combination. This creates a significant workflow limitation for providers seeking drug discount program pricing and for patients who may be cost-aware. The prescriber must work with the patient to identify the right discount program and the discount program processor must then also be capable of receiving the transaction and responding with an indication that the pricing presented is for a drug discount and not a prescription benefit. CMS and ASTP/ONC should develop standards that accommodate patient preference and enable greater utilization of drug discount programs that may not use a BIN(IIN)/PCN combination, particularly where such resources can provide meaningful savings to beneficiaries.

Finally, as part of the adoption of standards, we encourage CMS and ASTP/ONC to enable the use of third-party tools embedded in the electronic health record (EHR) workflow to support these real-time benefit capabilities. The use of third-party tools—e.g., via APIs and clinical decision support (CDS) Hooks—can enable prescribers to integrate solutions that best meet their and their patients' needs.

Similar to RTPB hurdles, electronic prior authorization (ePA) has not yet been broadly adopted and streamlined, leading to further constraints in patient access and delays in treatment. We appreciate the interest of both CMS and ASTP/ONC in accelerating ePA and note the potential contributions of artificial intelligence (AI) to expedite reviews to support more prompt patient access to the medications and services they need. CMS and ASTP/ONC should ensure that both the technology used by providers and health plans have deployed standards-based ePA capabilities that enable rapid decision-making and the electronic submission of additional evidence as required. For RTPBs and ePA alike, greater visibility into utilization constraints enable earlier interventions that promote timely access to care.

2. <u>Enhance patient and provider access to more data to support care</u>

When patients and providers have instant access to health data, it transforms passive recipients into empowered patients while enabling clinicians to make smarter, faster care decisions. Consistent with our customer-obsessed approach to healthcare, we seek to identify and deploy incremental, yet meaningful, improvements to the care delivery experience that promote adherence and continuity of care. Fragmentation across care teams, specialists, pharmacists, and others results in a diminished beneficiary experience and often discourages those patients from building long-term relationships with healthcare providers. A key component associated with patient and provider friction resides in data transportability, interoperability, and timeliness.

While meaningful efforts are underway to optimize that experience, patients and caregivers do not have access to tools that enable a complete picture of their care journey. In an optimal environment for patients, caregivers, and providers, health management and care navigation applications would utilize a common technical standard that facilitates truly seamless movement of health information in real-time across covered applications. Disaggregation of clinical data (including primary care, specialists, and hospital-based care), scheduling tools, pricing for products and services, and other key metrics across care teams exacerbates data silos and limits optimal care coordination.

CMS and ASTP/ONC continue to make significant progress towards a more interoperable and consumer-friendly environment. However, barriers remain that inhibit adoption across the healthcare value chain. Examples include a patchwork of state privacy laws with varying levels of consent requirements and inconsistent levels of participation in health information exchanges (HIEs) by EHR vendors and health systems. Continued policymaking should enable all stakeholders to build and deploy technologies intended to better empower patients and clinicians with actionable data and improve provider efficiencies without financial constraints, additional regulatory burdens, or other unnecessary barriers.

Even with greater control over one's health information, downstream barriers persist and hinder care, particularly price transparency. The lack of truly accessible price information often stymies continuity of care and adherence to treatment regimens. As with practically all other segments of our economy, patients should understand clearly the cost of a product or service before it is received. As previously referenced, medication adherence continues to serve as an excellent barometer for the impact of this opacity. Real-time, consumer-facing access to prescription drug prices will enable patients to address cost concerns at the point of care with their prescriber rather than at the pharmacy counter where alternative pathways are limited. **To help empower patients and provide needed visibility, we encourage CMS and ASTP/ONC to establish standards that would make drug formulary information available through certified Patient Access APIs, enabling patients, caregivers, and providers to compare patient-specific prices for prescribed medications against available alternatives.**

In addition to formulary-level data, we also encourage CMS to ensure patients have actionable information at their fingertips when making healthcare purchasing decisions. For example, CMS could mandate the prescription drug plans it regulates to provide more patient-specific cost data through the Patient Access API, including information about the patient's accumulator progress towards their deductible and out-of-pocket limits, preferred alternative medications, and utilization restrictions like prior authorization requirements (e.g., step therapy requirements). CMS and ASTP/ONC should coordinate in developing and implementing standards that better empower beneficiaries through timely access to their specific, real-time drug pricing information.

Building on the 21st Century Cures Act ("Cures"), ASTP/ONC and CMS have accelerated patient access to critical data from individuals' EHRs. Increased use of the Fast Healthcare Interoperability Resources (FHIR) standard has enabled patients to download key elements of their health records, and equipped clinicians with greater access to digital health tools that support clinical decision-making. While meaningful, the lack of coherent patient and provider digital authentication continues to perpetuate disconnected data silos for patients and providers alike.

Although there has been this initial success from the rollout of the FHIR standard, regulations focused on patient and provider access to data via FHIR-based APIs have not yet included "all data elements" as required by Cures. For example, medical images—including X-rays and MRI scans—offer critical information to inform diagnoses and support patient care. Currently, because the ASTP/ONC certification criteria do not require the inclusion of links to medical images (e.g., accessible through a web-based Digital Imaging and Communications in Medicine (DICOM) application) within the U.S. Core Data for Interoperability (USCDI) or FHIR resources, patients must often request a CD of their images and physically take them to another provider for a second opinion. And, when trying to access their own images at home, patients may not have the necessary hardware in their computer capable of inputting CDs. When patients and clinicians lack access to images, they may unnecessarily repeat imaging procedures—increasing avoidable costs on patients and the healthcare system and unnecessarily exposing patients to repeat procedures.

Therefore, we encourage ASTP/ONC and CMS to accelerate the interoperability of images, such as via the proposed certification requirements in the HTI-2 rule that would enable access to an imaging link with electronic viewing or retrieval capabilities to increase patient and clinician access to this diagnostic information without the need to rely on CD or other physical media. Including links to images in standardized APIs will further increase access to images for care coordination among clinicians and enable patients to incorporate this information in their personal health records. This real-time, electronic access will also obviate the need for patients to shuttle between clinician offices to pick up and drop off their images or redo these expensive procedures.

In another example, the currently required data via FHIR APIs lack cancer care data and genomic data elements. Accelerating FHIR-based access to these data elements could better support the understanding of: cancer severity and progression; details on treatments attempted; toxicity from treatment; and other information with clinical significance. Data elements listed by ASTP/ONC in USCDI staging areas should serve as the roadmap on data elements to accelerate for inclusion in FHIR-based APIs.

Deployment of an API for complete electronic health information (EHI) export in the absence of additional standards could prove exceedingly difficult for receiving organizations to use effectively without significant product development and processing capability. While it would be helpful for HIEs to enable the exchange of unstructured documents and data, a requirement that EHRs offer an API to access such data may prove unmanageable. **As such, CMS and ASTP/ONC should continue to offer certified health IT developers regulatory flexibility to deploy reasonable and appropriate mechanisms for EHI export.**

Opportunities also exist to better enable the access, exchange, and use of EHI among healthcare providers consistent with the information blocking provisions in Cures. ASTP/ONC should consider modifying the manner exception at 45 CFR 171.301 to require that pricing terms offered by the covered actor meet the fees or licensing exceptions. The current process allows covered actors to bypass these exceptions if the manner requested does not solely rely on certified health IT programs or published content and transport standards. Many EHRs require wiring into their unique data models, or use of a proprietary API, to properly integrate an application. By insisting that a custom integration into the proprietary data model is necessary and then exhausting negotiations by offering two less-than-responsive alternatives, these EHRs can continue to require application developers to pay a percentage of application revenue as a price for integration. This unfortunately results in a high cost for technology developers looking to build and deploy meaningful clinical solutions to providers.

   3.   <u>Simplify and expand use of cloud services, call centers for hospitals and beneficiaries</u>
Today's healthcare ecosystem demands unprecedented levels of data integration, security, and digital innovation to improve care for Medicare beneficiaries and reduce costs. Yet many of the critical systems used by healthcare providers, payers, and CMS remain constrained by traditional data center infrastructure that requires significant upfront investment while creating ongoing maintenance and security challenges. Cloud adoption can provide healthcare providers and CMS with the essential building blocks for a modern digital health ecosystem—including access to state-of-the-art security controls and AI-based tools. The first step to leveraging these modern tools is secure migration from legacy data centers to cloud services—an approach that CMS should both accelerate for its own infrastructure and encourage health plans and hospitals to undertake.

For example, one of the most significant yet overlooked challenges in healthcare is the fragmented and inefficient call center ecosystem that Medicare beneficiaries, providers, and payers must navigate. Currently, CMS operates dozens of separate call centers with hundreds of different phone numbers, creating unnecessary confusion, frustration, and cost. When beneficiaries call the wrong number—which happens frequently—they experience transfers, long wait times, and often must repeat their information multiple times, leading to poor customer experience and reduced access to needed services. The same applies when Medicare beneficiaries call hospitals to refill a medication, schedule an appointment, follow-up on their care, seek their medical records, or the myriad other reasons patients contact their healthcare providers. This fragmentation not only creates a poor experience for Medicare beneficiaries, but it also represents a significant cost

burden for CMS and providers, as each separate call center requires its own infrastructure, training programs, management teams, and technology systems. By implementing a consolidated approach with a single-entry point supported by modern technology, CMS and providers could dramatically reduce operational costs while improving service quality. Using CMS' own operations as an example, rather than consolidating to a single number, CMS could implement an enterprise service call center solution that would allow CMS to: scale resources dynamically to handle fluctuations in call volumes; leverage AI and natural language processing for intelligent call routing; provide omnichannel support across voice, chat, email, and mobile; enable seamless integration with CMS data systems for personalized service; support geographically distributed agents for increased staffing flexibility; and implement advanced analytics. This single solution would optimally be supported through: an improved website and mobile app design to reduce the need for support calls via intuitive self-service options; a robust smartphone application that allows beneficiaries to complete simple tasks without calling; a consolidate entry-point for all call centers behind a unified intelligent routing system; and seamless data sharing among CMS' diverse data systems.

In another example, Medicare Administrative Contractors (MACs) play a vital role in claims processing, program integrity, and beneficiary service delivery—yet they often are not adopting modern technology solutions. Currently, each MAC maintains separate IT systems and infrastructure, which can create redundancies and limit their ability to rapidly implement innovative solutions—including AI. This fragmentation impacts operational efficiency and the ability to consistently deliver high-quality service to providers and beneficiaries. CMS could address these issues by both encouraging cloud migration, and even offering select shared services as an option for MAC adoption. For example, CMS could offer use of a cloud environment with: common security controls and compliance frameworks; shared data services to support program integrity and fraud detection; standardized APIs for simpler system interconnection; advanced analytics platforms that each MAC can leverage for their specific needs; and elastic infrastructure that scales efficiently with workload demands. By offering enterprise cloud services as a foundation, CMS could help MACs realize an estimated $1 billion in annual savings through reduced IT overhead while enhancing their ability to serve providers and beneficiaries. MACs could also benefit from these shared services by having the flexibility to focus their resources on mission-specific innovations rather than maintaining basic infrastructure.

Finally, use of cloud services can also help organizations mitigate security risks and better meet security requirements than if they manage their own data centers. For example, the cloud can help eliminate the risk of orphan or hidden servers, and aid organizations to better monitor, detect, and shut down security breaches—further protecting patient health information. Cloud services also offer redundancies to create data back-ups in the event of ransomware incidents. CMS should examine how to encourage the use of more secure, resilient data systems, such as by offering payment incentives for cloud-based data backups.

4. **Strengthen incentives and resources to accelerate adoption of value-based care practices**

A key component of value-based care is the shift away from volume-based practice and prioritization of an outcomes-based approach rooted in quality. Emphasizing a holistic, beneficiary-centered approach that indexes on enhanced care coordination and data-driven decision-making improves patient satisfaction and health outcomes while reducing the overall cost of care. Alternative payment models (APMs) help achieve this goal by incentivizing quality and efficiency and holding organizations accountable for outcomes that are commensurate with population health needs and associated risk-based benchmarks. This shift also enables, and encourages, value-based care organizations to leverage digital health technologies as a meaningful tool in the care delivery arsenal.

Accountable, value-based care cannot function without a comprehensive, real-time view of the patient to function effectively. To accelerate the adoption and effective use of digital health tools in accountable care organizations (ACOs), we recommend a multi-faceted approach. This includes offering higher shared savings percentages for ACOs demonstrating effective digital tool implementation, providing grants or subsidies to offset initial investment costs, and introducing bonus payments tied to patient engagement metrics via digital platforms. Additionally, allowing digital health investments to count towards risk-bearing requirements can reward further adoption. These measures should support the implementation

of crucial technologies, such as real-time patient event notifications, automated quality reporting, predictive analytics, telehealth services, and integration of diverse data sources including EHRs, claims, and patient-reported outcomes. While challenges such as data quality, complex consent processes, and inconsistent standards must be addressed, the benefits of streamlined quality measurements, improved care coordination, enhanced data exchange efficiency, and earlier fraud detection underscore the importance of these digital initiatives in advancing value-based care.

To help encourage further use of digital health management and care navigation products, CMS should also establish additional benefit enhancements in ACO programs that enables deployment among beneficiaries. Given the focus of these organizations to maintain a high care quality threshold within a capitated payment environment, these enhancements will help incentivize greater adoption and deployment of digital health tools by providers and use among beneficiaries. Similarly, additional benefit enhancements or quality metrics tied to deployment of population health analytics tools, care coordination programs or other interventions further reward uptake. Together, these mechanisms empower ACOs to deploy digital health technologies with the clear focus of improving provider engagement and patient outcomes.

There are also opportunities from CMS to promote innovation across APMs through clearly articulated technology standards. Refinement to and modernization of the ACO beneficiary outreach requirements can materially reduce barriers to active patient management and needed outreach. CMS should collaborate with ACOs to develop and implement APIs to better support voluntary alignment of beneficiaries. For example, CMS should allow voluntary alignment in the home when there is an established relationship with the beneficiary and the home is the site of care. This would provide parity with the capabilities afforded to brick-and-mortar practices. Additionally, we encourage CMS to enable real-time eligibility checks for beneficiaries compared to the existing quarterly voluntary alignment periods. Enabling more real-time coordination would minimize provider and beneficiary confusion and enable ACOs to proactively engage with these beneficiaries and avoid long wait periods for resubmission. CMS should also allow ACOs to access the MARx system (or similar lookup mechanism) to check beneficiary eligibility and confirm address on file before offering or submitting voluntary alignment. Such transparency will enable ACOs to operate more efficiently and mitigate friction associated with ineligible beneficiaries.

Lastly, the development and deployment of standardized APIs for patient and population health services can meaningfully support a data exchange that enables comprehensive care and resulting healthcare outcomes. For value-based care organizations, in particular, the nature of their global risk arrangement relies in large part on obtaining accurate claims data as quickly as possible. It remains critically important that value-based care organizations receive timely transmissions of claims data to appropriately track and address beneficiary healthcare needs and opportunities for improved outcomes.

5. **Modernize health information data exchanges to optimize care delivery**

Despite advances in technology, clinical studies—for communicable diseases, chronic conditions, and unmet needs—remain constrained by limited scalability, lack of integration with clinical workflows, and insufficient leveraging of routinely collected longitudinal health data. Clinical trials continue to run parallel to routine care, limiting their representativeness and efficiency, especially for pediatric cancer and rare disease populations. Many patients are unable to enroll in studies because they are not located near or otherwise unable to access the site leading the trial.

The Trusted Exchange Framework and Common Agreement (TEFCA)—developed by ASTP/ONC to serve as a single on-ramp to health data sharing nation-wide—or similar efforts can help scale existing clinical interfaces and better use of real-world evidence for research purposes. However, early versions of TEFCA do not authorize or direct the sharing of their data for research purposes. **Therefore, we encourage ASTP/ONC and CMS to collaborate to list research as approved uses in future versions of TEFCA, including via patient-directed data sharing for research purposes.**

Patient and provider access to the full suite of an individual's EHI is also critically important in enabling comprehensive and coordinated care. TEFCA assists provider access by facilitating the growth of private, national HIEs. By developing a unified governance approach, more regional exchanges and health systems have elected to participate with these national

exchanges, making them a rich data source for providers seeking helpful clinical information to assist them in caring for their clinical populations.

CMS and ASTP/ONC should encourage healthcare providers and HIEs to make medication histories and clinical indication information available to pharmacists. Pharmacists play an integral role in ensuring patient safety. To prevent dangerous contraindications or drug interactions, pharmacists must review a patient's entire medication history. Today, pharmacists lack access to information about medications sent to other pharmacies, including whether those prescriptions are ultimately filled and dispensed. Too often, pharmacists cannot access an individual's clinical data from available HIEs and related networks. While this functionality helps facilitate real-time transmission of structured clinical indication information to pharmacists with prescriptions, access to such information is not guaranteed. These gaps often delay access to care unnecessarily due to the need for follow-up.

ASTP/ONC should also leverage qualified health information networks (QHINs) qualification criteria to require QHINs to make clinical data available to pharmacists that have established treatment relationships with patients. Pharmacies want to help patients get access to their own complete medication histories and cannot do so if they are left out of an HIE. To maximize the clinical effectiveness of a drug utilization review, a pharmacist should have access to all medications a patient has been prescribed. This would allow pharmacists to fulfill their responsibility to assess contraindications and provide patients with an easier mechanism to obtain their full medication histories from their pharmacies.

We also support standards development and adoption that would eliminate time lags that occur before medications are updated within HIEs. Medications change quickly and real-time updates to medication lists best ensure patient safety. For example, some QHIN participants still update medications via batch FTP transmissions, thereby increasing the risk of stale medication data.

Thank you for your consideration of our input. We look forward to working with CMS and ASTP/ONC as they take continued steps to empower patients and providers and meaningfully improve health outcomes.