

June 16, 2025

Mehmet Oz, MD Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-0042-NC P.O. Box 8013 Baltimore, MD 21244-8013

Thomas Keane, MD, MBA
Assistant Secretary for Technology Policy
National Coordinator for Health Information Technology
Department of Health and Human Services
330 C St., SW
Washington, DC 20201

RE: Request for Information; Health Technology Ecosystem

Dear Administrator Oz and Assistant Secretary Keane:

On behalf of the over 90,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to submit comments to the Request for Information (RFI); Health Technology Ecosystem published in the *Federal Register* on May 16, 2025.

The ACS is a scientific and educational association of surgeons founded in 1913 to improve the quality of care for the surgical patient by setting high standards for surgical education and practice. Health information technology (health IT) and other digital tools continue to be an important part of the healthcare delivery landscape. Given this, the ACS is dedicated to ensuring health IT is being used in ways that offer value and support to surgeons' practices and their patients. With our more than 100-year history leveraging data for optimal surgical care through clinical data registries and developing policy recommendations to optimize the delivery of surgical services, we believe that we can offer key insight into the Centers for Medicare & Medicaid Services (CMS) and Assistant Secretary for Technology Policy's (ASTP) RFI on the Health Technology Ecosystem.

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WASHINGTON OFFICE 20 F Street NW, Suite 1000 Washington, DC 20001 T 202-337-2701 F 202-337-4271 E-mail: ahp@facs.org Throughout this RFI, CMS and ASTP discuss the steps they have taken to support the access, exchange, and use of electronic health information (EHI). The ACS appreciates CMS and ASTP's efforts to gather information on this important topic. This RFI is a good next step in the evolution of the digital era for healthcare. Leveraging the opportunities of the digital environment presents many complexities and will require a multi-pronged effort of all stakeholders, including clinicians. From our perspective, small tweaks are no longer effective in this environment. CMS/ASTP and others should be developing a comprehensive data strategy that continues to advance the modernization of healthcare.

As CMS, ASTP, and others consider ways to remove barriers to technology, it is also important that CMS and ASTP utilize their role as regulators and leaders to develop creative solutions that incentivize the use of open-source data standards and standardized application programming interfaces (APIs) across the healthcare industry. We understand the Agencies are looking to remove regulatory burden, but there is significant risk in removing regulations and incentives that have had a role in increasing the availability and exchange of healthcare data. The implementation of healthcare technology systems requires major investment, and we are concerned that without consistent standards and incentives around data access and exchange important progress could stall.

In addition, while the ACS appreciates CMS and ASTP seeking the public's input, we are concerned that a 30-day comment period does not allow enough time to provide in-depth comments on such a technical and important topic. Below are high-level responses to select questions. However, we request an opportunity to discuss these issues in more depth with ASTP and CMS either through a follow-up meeting or through an extended public comment opportunity.

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?

The primary obstacle that prevents the development, deployment, and effective utilization of the most useful and innovative applications for physician workflows is the lack of nationally adopted open-source data standards. While efforts to increase standardization of healthcare data have been underway, we still see this as a barrier to leveraging digital tools for workflows, clinical decision-making, quality measurement, and optimization of administrative functions. Recent regulations to support more open data access and exchange have helped push the availability of interoperable data forward, but there is still work to be done to achieve full interoperability in healthcare. Therefore, we urge ASTP and CMS to continue to invest in open-source data standards, such as Fast Healthcare Interoperability Resources (FHIR), to ensure that data are available in a consistent manner.

Below is a list of issues that present barriers to development, deployment, and effective utilization of innovative technology in surgical care:

• Lack of framework around advancing technology for value-based care. Strategies to support clinicians and their patients should be cohesive across all CMS and ASTP programs. It is important to keep the intent of all efforts in quality and the digital ecosystem focused on a common goal: advancing patient-centered, goal-oriented, episode-based healthcare. Creating a framework to leverage healthcare data in the digital environment is critical. ASTP and CMS have started to design the infrastructure with its

investment in FHIR, United States Core Data for Interoperability (USCDI), the Certified Electronic Health Record (EHR) Technology (CEHRT) program, and the Trusted Exchange Framework and Common Agreement (TEFCA). The ACS applauds these efforts for their foundational importance. To further advance this work, digital services tools that support research, clinical decision-making, care coordination, and overall improvements in the quality of care should be designed to meet the functional needs of the clinical team, patients, and other stakeholders. With the right digital architecture, it is possible to generate knowledge assets from digital clinical data to tell the story of patients' care experiences beyond one office and one EHR. EHRs by design were business workflow engines best suited for a single office visit or single transaction. But it is through federal efforts that support open standards and interoperability that EHRs and other clinical systems, such as registries, can be extended beyond clinical workflow and enable tracking of conditions and specific outcomes. It is also important to consider developing data systems around conditions/diseases or episodes. This approach allows the use of registries focused on a condition and collaboration with subject matter experts to analyze the data for information and relationships that may prove valuable to the care team.

There are numerous other use cases that benefit from increased access to digitally available clinical data, such as documentation and administrative functions, predictive risk analysis, patient education and engagement, public health, research, pharmaceutical development and post-market evaluation, and so much more. To realize the full potential of digital services to support the advancement of value-based care, open-source data standards will be necessary to ensure that clinical data found in EHRs and other digital tools are available to enrich clinical decision-making, and track patients throughout their health journey.

• <u>Data ownership and EHR barriers.</u> For many years, technology vendors have positioned themselves as the owner of EHI, which has in some ways slowed innovation such as data silos; eroded trust among patients, providers, researchers, and other clinical experts; and has made it difficult for clinical stakeholders to engage in healthcare technology without enormous investment. Initiatives that ensure patients have ownership over their personal EHI are essential to empowering patients to take ownership and actively participate in healthcare decisions. This will also improve communication with providers, enhancing access and exchange of accurate and complete information to support a learning system that fosters high quality care.

Additionally, as CMS and ASTP develop their strategy to modernize the healthcare technology ecosystem and promote data access, we recommend exploring how to leverage an innovative environment that is not stalled by challenges of working with EHR vendors. In an ideal world:

- Data could flow freely within a platform environment where technology vendors provide aggregation services, but clinical and technical subject matter experts have the freedom to innovate around applications and data inputs and outputs.
- O Clinical teams would be able to carefully extract a patient's EHI to build a clinical story and reveal the underlying illness or problem.
- o Patient clinical documents can be used for improving quality by examining trends.

A patient should be in control of their data and it should not be monetized by everyone who touches it. The monetization of data adds significant costs to healthcare and discourages shared observations across clinical settings. CMS and ASTP have taken steps to remove these barriers with regulations around

information blocking; however, there is more work to be done to ensure data is truly owned and controlled by patients and the burden and cost of leveraging patient data for improved quality of care is not incurred by healthcare providers.

- Unstandardized data unsuitable for registry abstraction. The ACS hosts multiple clinical data registries across various surgical specialties that gather detailed data on surgical care, including data for payerbased quality measures, clinical research, population health tracking for surgical conditions, and key clinical outputs that help inform patients and their surgeons. Due to the lack of broadly adopted clinical data standards (and thus the inability to pull standardized clinical data from EHRs), we have used manual data abstraction to ensure that clinical data are captured with the rigor that is required for accurate and meaningful information on surgical outcomes, despite the high cost and burden. Manual chart abstraction is still the gold standard in healthcare due to the lack of standardization in digital healthcare tools. Continuing to push forward efforts to align data standards across healthcare presents opportunities to advance quality measurement and improvement efforts that are better aligned with patient-centered, value-based care. With widespread adoption of consistent open-source data standards, we would be able to leverage technology to build innovative quality measure mechanisms for surgery that can support not only outcomes measurement, but processes, structures, clinical decision support, and so much more. The burden of manual data abstraction would also be significantly reduced, allowing systems to invest resources in other areas that are needed for the betterment of patient care. For these reasons, regulators should focus on incentivizing standardization across data systems to greatly reduce cost and burden without regulation data standardization will likely not happen or stall.
- Barriers to QHIN participation. The lack of standardization across healthcare technology and the ability to accurately map clinical data is a barrier to participation in Qualified Health Information Networks (QHINs). The ACS is supportive of the intent behind TEFCA and sees efforts to develop a national data exchange network for healthcare as an important step in creating interconnected pathways for clinical data. However, current participation relies on the ability to map data to what is being shared within the QHIN. Currently, data tends to be broad and does not offer the level of detail that is necessary to enrich meaningful digital services, such as clinical data registries. To increase meaningful participation in QHINs, the Agency must continue to incentivize adoption of open-source data standards, such as FHIR, and engage stakeholders to understand operational challenges.

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:

d. Provider Access API.

Overall, the ACS is supportive of the Provider Access API. It is crucial that providers have access to all data that might impact care decisions, including coverage and payer data. As we have stated in the past, the ACS believes that sharing health plan data with a provider's EHR ahead of time could save time during appointments, save resources, reduce costs, and improve the quality of care delivered to patients. We are also supportive of incorporating prior authorization (PA) data into the Provider Access API; giving providers timely access to information about PA decisions will be beneficial in preventing delays in care that are now commonly associated with slow PA processes.

f. Prior Authorization API.

The ACS is supportive of the development of a national standard for electronic PA through Medicare and Medicaid— all payers should be required to align their practices with the national standard and underwrite the costs. The ACS urges ASTP and CMS to ensure that the below functionalities are included in the Prior Authorization API:

- Real-time eligibility and requirement checking The API connects with payer systems to instantly
 determine if a specific treatment or medication requires prior authorization for a particular patient's
 insurance plan.
- Automated submission of authorization requests Healthcare providers can submit prior authorization requests directly from the EHR workflow without switching to separate payer portals or filling out paper forms.
- **Status tracking and updates** The API provides real-time status updates on pending authorization requests, showing whether they are approved, denied, or require additional information.
- Decision support integration The API can suggest alternative treatments that do not require prior
 authorization or have a higher likelihood of approval, helping clinicians make informed decisions at the
 point of care.
- Workflow integration Prior authorization checkpoints are integrated into existing clinical workflows, alerting providers when authorization is needed during prescribing, ordering, or scheduling.

Functional testing should also be included as part of the EHR certification process to ensure the intentions of the API are met and the burden of prior authorizations is appropriate. Ultimately, the goal of this API should be to reduce the administrative burden on healthcare staff, minimize delays in patient care, decrease claim denials, and improve the overall efficiency of the prior authorization process. This helps ensure patients can access necessary care quickly while maintaining payer cost control requirements.

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

The growing number of healthcare data platforms that sit atop EHRs has resulted from the cost and burden of having to work with numerous disparate EHR vendors. To resolve this, the ACS supports continued investment in SMART on FHIR. SMART on FHIR should be available through EHRs and stand-alone platform environments that are secure and affordable. With its broad applicability, SMART on FHIR can also be leveraged to build out algorithms that work within health information exchanges (HIEs) or QHINs. In addition, the capabilities of SMART on FHIR applications can create a bridge between current quality measure efforts, such as clinical quality measures (CQMs) and electronic clinical quality measures (eCQMs), and the use of artificial intelligence (AI)-based algorithms in quality assessments. There are many opportunities to house and advance SMART on FHIR capabilities, therefore it should remain part of CEHRT standards.

The ACS has decades of experience developing and implementing quality programs across surgery and has been a pioneer in the use of data for quality improvement as demonstrated across our numerous risk-adjusted clinical data registries, such as ACS National Surgical Quality Improvement Program (NSQIP) and the National Cancer Database (NCDB). Based on our extensive experience, we see potential in using SMART apps to build applications that aggregate data for quality metrics that go beyond traditional outcome and process measures. For example, a SMART application could be developed to align with the standards in a quality program or programmatic measure, such as the Age Friendly Hospital measure recently finalized for the Hospital Inpatient

Quality Reporting (IQR) program. The Age Friendly Hospital measure includes five domains: 1) Eliciting Patient Goals, 2) Responsible Medication Management, 3) Frailty Screening and Intervention, 4) Communal Vulnerability, 5) Age Friendly Care Leadership. Each domain includes activities that hospitals must implement in an effort to build care teams that are equipped to address the specific needs of an older adult patient. SMART on FHIR applications can be used to create quality measures that track the implementation of these domains and highlight areas where improvement is needed. An application could pull structured or unstructured data from clinical notes that track how often frailty and mobility assessments are conducted upon admission and how mobility is managed through the hospital stay. By using the data found in the EHR, the applications could pull the relevant data and use natural language processing (NLP) to identify if screenings took place, how often, and how a mobility plan was implemented, including how often the patient was encouraged to move or provided mobility aids throughout their stay. We envision similar metrics could be developed for every domain or standard within a quality program or programmatic measure.

These applications would create mechanisms that offer consistent tracking and assessment of patient goals of care conversations and goal attainment, screening practices, adherence to clinical processes, etc. that are currently difficult to track consistently across systems. To make this possible, hospitals would need to ensure they are documenting these data in their EHRs, but eventually we foresee the development of digital dashboards to allow for real-time monitoring of these processes and inform feedback loops for improvement. Ultimately, these applications would allow for more patient-centric metrics that could significantly enhance surgical care by looking at outcomes as well as the processes and structures necessary to achieve the optimal outcome. From the ACS perspective, leveraging the increased availability of data and advancements in technology to think outside the box of current quality measurement techniques is essential for driving healthcare and quality programs toward tracking elements of care that are important to patients, their caregivers, and care teams, and for ensuring that measurement is seamlessly integrated into clinical practice and not an unnecessary layer of burden.

The ACS appreciates the opportunity to provide feedback on this RFI and looks forward to continuing dialogue with CMS and ASTP on these important issues. If you have any questions about our comments, please contact Jill Sage, Chief of Quality Affairs, at jsage@facs.org.

Sincerely,

Patricia L. Turner, MD, MBA, FACS

Executive Director and CEO

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