COLLEGE of AMERICAN PATHOLOGISTS

June 16, 2025

The Honorable Mehmet Oz, MD, MBA
Commissioner
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD
21244-1850

The Honorable Thomas Keane, MD, MBA
Assistant Secretary for Technology Policy and National Coordinator for Health Information Technology
Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C St SW
Floor 7
Washington, DC 20201

Re: File Code CMS-0042-NC; Request for Information; Health Technology Ecosystem (RIN 0938-AV68)

Submitted via Electronic Submission to www.regulations.gov

Dear Commissioner Oz and Assistant Secretary Keane:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) and the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology's (ASTP) Request for Information (RFI) CMS-0042-NC entitled "Health Technology Ecosystem." As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide.

The CAP's specific answers to CMS' and ASTP's questions are below. We have organized our responses by the sections that CMS and ASTP provided. Specifically, we are responding to questions grouped by the use cases corresponding to providers and value-based care organizations.

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PROVIDERS

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?

CAP Response: *Many societies have invested in state-of-the-art data extraction and processing technology, up to and including artificial intelligence and natural language processing to streamline physician workflows and reduce burden for quality measure reporting and quality improvement. However, a major challenge remains accessing the data in the first place. Hospital systems and EHRs often refuse to share data or charge exorbitant fees to providers and clinical data registries to obtain data for quality measure reporting. This prevents deployment of innovative applications and leaves physicians with few options other than manual or swivel-chair data entry. Although standard APIs such as FHIR APIs ease some interoperability burdens, without the willingness to share data, improved technology at the connection point does not fully mitigate the problem. Therefore, we suggest that CMS and ASTP work to increase incentives for hospitals to share data as well as streamlining the information blocking claim system as a last resort for clinicians.*

PR-3. How important is it for healthcare delivery and interoperability in urban and rural areas that all data in an EHR system be accessible for exchange, regardless of storage format (for example, scanned documents, faxed records, lab results, free text notes, structured data fields)? Please address all of the following:

1. Current challenges in accessing different data formats.
2. Impact on patient care quality.
3. Technical barriers to full data accessibility.
4. Cost or privacy implications of making all data formats interoperable.
5. Priority level compared to other interoperability needs

CAP Response: *We defer to our other physician colleagues on this issue. However, because this question mentions lab results as an example of data in an Electronic Health Record (EHR) system, we wish to remind ASTP and CMS that pathologists' control of laboratory data typically ends when the data leave the laboratory HIT systems. Specifically, clinical laboratories have limited control over the patient result data once those results are posted from the laboratory information systems (LIS) to the ordering clinician's EHR. Once the data are transmitted from the laboratory to another institution, the laboratory can no longer influence how its results are displayed or aggregated with results from other laboratories. We wish to remind ASTP and CMS that any promotion of interoperability of data in an EHR system needs to take into account this limitation and that the burden should not fall on clinicians but on EHR vendors to integrate and adapt systems.*

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

CAP Response: *The CAP supports the use of positive incentives rather than penalties on pathologists and laboratories to promote interoperability. Historically, financial investments have proven effective in driving widespread adoption of health technology. For example, in 2009, as part of the Health Information Technology for Economic and Clinical Health (HITECH) Act, the federal government set aside $27 billion to support adoption of EHR systems.[1] As a result, hospital and office-based physician use of EHRs increased dramatically afterwards, demonstrating that well-structured incentives can accelerate technological transformation.[2] A similar investment to the HITECH Act will be necessary to drive transformation in the digital product ecosystem, ensuring that providers have the resources and support needed to adopt and maintain interoperable systems effectively.*

Moreover, with respect to how CMS can help providers to make high-quality, timely, and comprehensive healthcare data available for interoperability in the digital product ecosystem, we would like to note that the benefit of interoperable laboratory data accrues primarily to the users of the data—that is, patients, clinicians, and public health policy makers. However the cost of implementing the changes needed to make laboratory data interoperable is paid by laboratories and LIS vendors. Without positive financial incentives from CMS, these kinds of misalignments between cost and benefit amount to a net financial burden on pathologists and laboratories, thereby slowing down interoperability. Consequently, better aligned, positive incentives for pathologists and laboratories will encourage interoperability.

PR-8. What are ways CMS or partners can help with simplifying clinical quality data responsibilities of providers?

1. What would be the benefits and downsides of using Bulk FHIR data exports from EHRs to CMS to simplify clinical quality data submissions? Can CMS reduce the burden on providers by performing quality metrics calculations leveraging Bulk FHIR data exports?

CAP Response: *Although it may seem appealing to reduce burden via bulk export from an EHR directly to CMS, the complexity of quality measure reporting for pathology, including the unstructured nature of the data and the differences between Laboratory*

[1] https://www.cms.gov/newsroom/fact-sheets/electronic-health-records-glance
[2] https://www.healthit.gov/data/quickstats/national-trends-hospital-and-physician-adoption-electronic-health-records.

Information Systems (LISs) and EHRs, make the potential of bulk export still unclear. There are both technical concerns as well as conceptual ones with this idea. Technically speaking, no two versions of LISs/EHRs are the same; each institution has customized features, fields, and options. Therefore, the data exported from one system would not be the same as data from another system even if the underlying EHR or vendor is the same. The CAP suggests that the effort involved for the CMS to harmonize the data from each LIS/EHR for every practice reporting every measure would be significant. Specifically related to anatomic pathology data, the necessary data transformations have not been established and will likely prove challenging given the lack of an underlying coding structure for such data. Furthermore, direct submission does not necessarily reduce the burden given the assistance and guidance provided by registry experts. Second, it is important to note that while Qualified Registries and Qualified Clinical Data Registries report data to the CMS for the Merit-Based Incentive Payment System (MIPS), many registries perform several other critical functions beyond just quality reporting including research, patient safety and adverse event tracking, and benchmarking. These activities may not be available via bulk FHIR export. The goal of improvements in this space should not only be faster data transmission but also better-quality data that provides clinicians with more meaningful opportunities to improve patient care and patient safety.

2. In what ways can the interoperability and quality reporting responsibilities of providers be consolidated so investments can be dually purposed?

CAP Response: *The CAP is supportive of the idea of dual-purpose data to reduce the burden on providers. However, it is important to note that MIPS, the CMS' primary quality improvement program, has been designed not to overlap with other programs. We suggest that the CMS consider measures and activities within the program that can earn credit in multiple categories as well as providing credit for interoperability-related activities to clinicians or clinician groups who are reporting via registries.*

Additionally, as noted above, registries provide a number of other important services beyond just quality measure reporting. The CAP suggests that the CMS invests in improved data for quality reporting, which can then be used for other purposes within an institution. As an example, use of the CAP's Cancer Protocols provides dual purposes of reporting to national cancer registries as well as generating data needed for some quality reporting. We commend ASTP for supporting the use of the Cancer Protocols as part of the USCDI+ Cancer Registry data elements use case.

3. Are there requirements CMS should consider for data registries to support digital quality measurement in a more efficient manner? Are there requirements CMS should consider for data registries that would support access to real-time quality data for healthcare providers to inform clinical care in addition to simplifying reporting processes?

***CAP Response**: The CAP understands the CMS' desire to move towards digital quality measurement and has also taken steps to move in that direction. However, before digital quality measures can be required, more specific guidance about what CMS considers to be a digital quality measure is needed. For instance, if a measure can be reported manually and via system integration, is this considered a digital quality measure? Many small practices are forced by circumstances to continue reporting via manual methods due to a lack of IT support and funding needed to achieve system integration. However, even when reporting is done manually, many if not most registries provide near-real-time feedback to clinicians and clinician groups via a practice dashboard. We suggest that this is a critical service that registries provide which allows meaningful quality improvement during the performance year, in contrast to feedback about cost measures, which only comes after the fact.*

As noted in response to PR-7, we support the use of incentives to accelerate adoption of digital technologies that increase interoperability. As the CMS and ASTP consider ways to drive digital measurement, it is important to ensure that the underlying health IT ecosystem will support such measure efforts. This includes financial support for small and rural practices to access and upgrade EHRs and LISs. The return on investment for such a move would extend well beyond the practices directly impacted by such initiatives; the entire system would benefit from more data of higher quality.

PR-12. Should ASTP/ONC consider removing or revising any of the information blocking exceptions or conditions within the exceptions (45 CFR part 171, subparts B through D) to further the access, exchange, and use of electronic health information (EHI) and to promote market competition?

***CAP Response:** The CAP supports patient access to test results but opposes mandatory immediate release without clinician and patient input. Automatic release can hinder care coordination and cause undue confusion and distress. The CAP urges an exception to the Information Blocking Rule to delay release when deemed necessary, ensuring results are shared with appropriate context and support for our patients.*

VALUE-BASED CARE ORGANIZATIONS

VB-2. How can key themes and technologies such as artificial intelligence, population health analytics, risk stratification, care coordination, usability, quality measurement, and patient engagement be better integrated into APM requirements?

***CAP Response:** The CAP believes that robust, reliable quality measures should be the foundation of any APM or value-based care program. We support the use of existing fully tested quality measures as part of APMs to reduce provider burden and harmonize across CMS programs. As data is foundational to value-based care arrangements,*

quality measures designed and tested by experts are critical to the success of such efforts.

VB-7. How can technology requirements for APMs, established through CEHRT or other pathways, reduce complexity while preserving necessary flexibility?

***CAP Response**: The CAP emphasizes the need for flexibility in technology requirements for APMs. We applaud CMS' goal to move Medicare beneficiaries and providers into accountable care relationships. However, in order to maximize participation in such arrangements, we encourage the CMS to reduce barriers by removing the requirement for CEHRT as a baseline for APM qualification.*

VB-9. What technology requirements should be different for APM organizations when comparing to non-APM organizations (for example, quality reporting, and interoperability)?

***CAP Response:** The CAP appreciates that APM and non-APM organizations may have different technology needs for quality reporting in the current system. However, we suggest that a future state may not require such different technologies. Instead of the CMS building a new data intake mechanism for each new APM or model, we recommend working with existing registries to support quality measures and data elements needed for the model. This would not only decrease the time and effort on the CMS' part to roll out a new model; it would also decrease the burden on APM participants by removing the administrative and IT resources needed to connect to a new system. Registries, including QCDRs, have extensive experience supporting physician groups in extracting data and have the most current data integration mechanisms. Given this and their subject matter expertise, registries are best placed to assist physician groups, a fact which CMS recognizes for the MIPS program but not for APMs.*

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Thank you for the opportunity to submit these comments. The CAP looks forward to working with ASTP and the CMS. Please direct questions on these comments to Han Tran at htran@cap.org or Colleen Skau at cskau@cap.org.

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