



# COLLEGE of AMERICAN PATHOLOGISTS

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June 3, 2019

Ms. Seema Verma, MPH  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1694-P  
P.O. Box 8011  
Baltimore, MD 21244-1850

Subject: RIN 0938-AT79 – Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-Facilitated Exchanges and Health Care Providers

*Submitted via Electronic Submission to [www.regulations.gov](http://www.regulations.gov)*

Dear Ms. Verma:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS's) proposed rule to improve interoperability and access to health care data. 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. Pathologists are physicians whose timely and accurate diagnoses drive care decisions made by patients, primary care physicians, and surgeons. When other physicians need more information about a patient's disease, they often turn to pathologists who provide specific diagnoses for each patient. The pathologist's diagnosis and value is recognized throughout the care continuum and many patient encounters.

While the CAP understands that this Proposed Rule focuses largely on patient access to health care data, the CAP as partners with the Physician Clinical Registry Coalition (PCRC) hopes to work with CMS to expand provider access to data in order to promote quality of care and enhance health care decision making. Provider access to data is essential to their ability to report complete and accurate information to clinical data registries and thus for registries to fulfill their mission of improving quality of care through the collection, analysis, and benchmarking of data on health care diagnoses, treatments, and outcomes. The CAP understands that this Proposed Rule is only the first phase of CMS's policymaking on interoperability and access to health care data and the CAP looks forward to working with CMS on these issues in future rulemaking.



*Promoting Interoperability Program: Interoperability Activities*

In the Proposed Rule, CMS seeks comments to inform future rulemaking on potential updates to the Promoting Interoperability Program to encourage eligible providers to engage in certain activities focused on interoperability. Specifically, CMS invites comments on ideas for priority health IT or “interoperability” activities that would serve as alternatives to measures in the Promoting Interoperability (PI) Program.

Pathologists and their laboratories have long relied on Laboratory Information Systems (LISs) to support the work of analyzing patient specimens and generating test results, and it is via an LIS that EHR or enterprise-wide clinical information systems exchange laboratory and pathology data. Since LISs do not currently have a pathway to be considered certified under the Office of National Coordinator (ONC) Health IT Certification Program, LISs not being Certified Electronic Health Record Technology (CEHRT) presents a significant barrier to pathologists’ full participation in CMS’ Quality Payment Program (QPP), including the PI program under the Merit-based Incentive Payment System (MIPS) as well as other federal quality reporting programs. While the CAP **hopes to continue its conversations with ONC and CMS for broader interpretation of the agencies’ EHR criteria so that LISs can be deemed CEHRT under that criteria**, we believe that additional PI alternatives are needed to not penalize pathologists because they are not practicing in CEHRT but instead in LISs.

As such, the CAP urges CMS to consider alignment of PI programs across healthcare settings, including the PI program for hospitals and the QPP. Pathologists can currently participate in only two of the four categories of MIPS. This means that 85% of the MIPS final score for pathologists is based on quality measures which places a disproportionate amount of weight on that category. While we appreciate the recognition of the non-applicability of the PI category to pathologists by CMS, the CAP is continuing to explore alternatives for pathologists to engage and more fully participate in the QPP. As the CAP previously responded in its comment letters to the CMS Request for Information included in the 2019 Inpatient Prospective Payment System (IPPS) and the Outpatient Prospective Payment System (OPPS) proposed rules, **one possible alternative would be to allow hospital-based eligible clinicians such as pathologists to earn points in the PI category of MIPS through their hospital’s participation in the PI program, for example, if a majority of the Medicare Part B payments for that clinician are generated at a particular facility**. This would be similar to eligible clinicians’ use of facility-based measurement in MIPS beginning in CY 2019. This would support hospital-based MIPS eligible pathologists’ efforts in promoting the electronic exchange of health information across LIS and hospital EHRs, while ensuring they are given credit for Promoting Interoperability activities.

In addition, pathologists participating in MIPS need to report performance on quality measures. As CMS eliminates claims-based measures, pathologists become disadvantaged in the program because it is difficult or impossible to access data from hospitals’ electronic health records and LIS. Pathologists need hospital-owned data to



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support their ongoing participation in MIPS. As pathologists working in and supporting hospitals, we should have access to all the patient's data from the hospital's EHR and LIS. However, in many cases, this does not occur or is made extremely difficult. For example, a large number of pathologists that use the CAP's clinical data registry, the Pathologists Quality Registry, to report quality measures do not receive any data from their hospitals.

Data from hospitals could include critical information such as laboratory tests and utilization, turnaround times, blood product utilization, cancer diagnostic workups, etc. Without these data elements, the measures cannot be fully calculated and scored. Hospitals claim that they cannot share the data for privacy and security purposes, but CMS has indicated that there are no regulations that impede hospitals from doing so. In addition, each hospital has its own legal framework for potentially accessing data, so this becomes a significant resource issue for pathologists, registries, and the hospitals themselves (since presumably several specialties approach the hospitals for data). The lack of data availability from hospitals is a significant resource problem for the system as a whole (nobody wins), and a particular problem for pathologists.

Since this is a serious issue for hospital-based clinicians, we encourage both ONC and CMS to come up with potential solutions to help improve the flow of information between hospital EHRs, LISs, and registries.

### *Request for Information (RFI) on Advancing Interoperability Across the Care Continuum*

CMS's RFI seeks input on potential strategies for advancing interoperability across care settings to inform future rulemaking activity in this area. In light of CMS's concern about the lack of agreed-upon measure concepts to gauge how well providers are routinely and effectively engaging in exchange of information across settings, **the CAP continues to encourage CMS to provide full credit under the MIPS Promoting Interoperability category to eligible clinicians and groups who submit quality measures through a Qualified Clinical Data Registry (QCDR) using end-to-end reporting, either via CEHRT or via another health IT system such as an LIS.** This proposal would be particularly helpful due to the potential for increased provider burden in the event that CMS pursues its proposal of expanding the scope of interoperability measurement beyond settings that were eligible for the EHR Incentive Programs. Not only would this encourage the use of QCDRs as intended by CMS, it would also leverage health information technology in a more meaningful way while reducing clinician burden.

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Thank you for the opportunity to submit these comments. The CAP looks forward to working with CMS to identify a path for Laboratory Information Systems to be more fully considered in the implementation of the Cures Act. Please direct questions on these comments to Loveleen Singh at (202) 354-7133 or [lsingh@cap.org](mailto:lsingh@cap.org).