



# COLLEGE of AMERICAN PATHOLOGISTS

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October 16, 2018

Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1701-P  
P.O. Box 8013  
Baltimore, MD 21244-8013

*Submitted electronically to: <http://www.regulations.gov>*

Re: Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations--  
Pathways to Success

Dear Administrator Verma:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the proposed rule titled “Medicare Shared Savings Program; Accountable Care Organizations--Pathways to Success” (CMS-1701-P). 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 changes proposed to the Medicare Shared Savings Program will impact “the vast majority of Medicare’s Accountable Care Organizations (ACOs).”<sup>1</sup> With the goal of improving quality of care and restraining spending, ACOs incentivize on the basis of outcomes rather than the number of services. As diagnosticians, pathologists apply their expertise to the diagnosis and management of a wide variety of medical conditions, and thus are integral in any care coordination initiatives. In fact, by virtue of their capabilities and roles, many pathologists already coordinate care and undertake efforts targeted at increasing integration to improve patient care and the patient care experience overall. Recognition of this fact continues to rise – according to CAP’s 2017 Practice Characteristics Survey, more than one-quarter of pathologists said they were either participating in or were actively negotiating participation in an ACO compared to 2014 when approximately 20 percent of the practices were participating or negotiating with an ACO.<sup>2</sup>

Still, pathologists face significant challenges participating in many alternative payment models, including ACOs. For example, despite their unique ability to assist clinicians in meeting their objectives through application of evidence-based approaches to eliminate waste and inefficiencies in laboratory medicine, pathologists have limited control over infrastructure decisions, workflows, and governance structure. Given the appropriate resources and role, pathologists can share clinical and financial data as well as vital education “about the efficacy of new tests and appropriate utilization.”<sup>3</sup>

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<sup>1</sup> <https://www.cms.gov/newsroom/press-releases/cms-proposes-pathways-success-overhaul-medicares-aco-program>

<sup>2</sup> College of American Pathologists, 2017 Practice Characteristics Survey Report, <http://www.cap.org/ShowProperty?nodePath=/UCMCon/Contribution/Folders/WebContent/pdf/2017-practice-characteristics-survey-report.pdf>

<sup>3</sup> <http://info.cap.org/health-care-executives/downloads/executive-dialogue-role-in-value-based-care.pdf>



While certainly there are instances where pathologists are successfully incorporated into value-based care efforts, it is illustrative of the unique role of pathology in ACOs that the CAP's most recent Practice Leader Survey found that approximately 28 percent of practice leaders were unsure about whether their practice participates in an ACO, and 22 percent of those practice leaders who do participate in ACOs were unsure of whether pathologists receive any financial incentives or shared savings for ACO participation.<sup>4</sup>

Further, we understand that with this proposed rule, the agency seeks to encourage the transition to two-sided models where providers assume greater levels of risk. While the CAP supports the voluntary development of innovative health care payment and delivery models, we believe there are a number of considerations that must be taken seriously to ensure pathologists' meaningful participation in these models and their ability to effectively contribute to these models' success. As was stated in the announcement of this proposed rule, ACOs afford an "opportunity to deliver better care in a coordinated fashion, while focusing on patient outcomes instead of processes."<sup>5</sup> To ensure this opportunity is open to pathologists, the CAP urges CMS to address the following issues related to performance-based risk, quality measures, and promoting interoperability.

### **Redesigning Participation Options to Facilitate Transition to Performance-based Risk**

According to the proposed rule, the changes sought by CMS would "provide a new direction for the Shared Savings Program by ... redesigning the participation options available under the program to encourage ACOs to transition to two-sided models (in which they may share in savings and are accountable for repaying shared losses)."<sup>6</sup> Specifically, CMS is proposing two tracks for eligible ACOs: (1) the BASIC track would allow eligible ACOs to begin under a one-sided model and incrementally phase-in higher levels of risk, and (2) the ENHANCED track, which is based on the program's existing Track 3. Importantly, under CMS's proposals, the amount of time an ACO can remain in the program without taking on risk would generally be reduced from 6 years to 2 years. As CMS explains, under the one-sided model years, "an ACO's maximum shared savings rate would be 25 percent based on quality performance," which is down from the maximum sharing rate of 50 percent currently available under Track 1.<sup>7</sup>

As we have stated in earlier comments to CMS, the CAP believes it is important to focus on increasing opportunity and incentives for specialty physician involvement in alternative payment models before unnecessarily pursuing increased risk. Though there are certainly some new improvements offered by CMS in this proposed rule, the reduction of the risk-free years and lowered maximum shared savings rate changes do not appear in line with that objective. In fact, CMS estimates that the new policy would lead to a drop of over 100 ACOs in the next ten years because of "the expectation that the program will be less likely to attract new ACO formation in future years as the number of risk-free years available to new ACOs would be reduced from 6 years ... to 2 years in the BASIC track, which also has reduced attractiveness with a lower 25 percent maximum sharing rate during the 2 risk-free years."<sup>8</sup>

CMS believes the changes are necessary because "ACOs that take on greater levels of risk show better results for cost and quality over time," but the CAP is concerned with any changes that could

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<sup>4</sup> College of American Pathologists, 2018 Practice Leaders Survey Report, forthcoming

<sup>5</sup> <https://www.healthaffairs.org/doi/10.1377/hblog20180809.12285/full/>

<sup>6</sup> <https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-17101.pdf>

<sup>7</sup> <https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-17101.pdf>

<sup>8</sup> <https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-17101.pdf>



decrease opportunities for specialists to participate in innovative payment models. Research conducted by the CAP shows that while the Shared Savings Program and ACO arrangements among private payers have existed for several years, many pathologists have not yet undertaken this option though they may still consider it – a recent study found that 30 percent of pathology practices do not contract with an ACO but may consider it in the future or are currently exploring the feasibility of forming/joining an ACO.<sup>9</sup> Changes to the Shared Savings Program that would discourage ACO formation could create unnecessary hurdles for pathologists to pursue this path, which would detract from the value-based care that is a priority for CMS.

### **Quality Measures**

CMS remains focused on efforts to update quality measures, reduce regulatory burden, and promote innovation. Towards this end, as is explained in this proposed rule, CMS is “working towards assessing performance on only those core issues that are most vital to providing high-quality care and improving patient outcomes, with an emphasis on outcome-based measures, reducing unnecessary burden on providers, and putting patients first.”

To aid in this effort, the CAP has engaged with CMS on how to appropriately measure providers who typically do not furnish services that involve face-to-face interaction with patients, including pathologists. Pathologists are key to ensuring the quality of laboratory tests by collecting, surveying, analyzing, and using patient population clinical results to guide therapy, best practices, and safety for individual patients and patient populations. Through the years, the CAP has advocated to increase flexibility for pathologists in a way that recognizes and accounts for the value pathologists play in patient care as non-patient-facing clinicians. The CAP continues to believe considerable accommodations or alternate measures are necessary for non-patient-facing clinicians. Further, as CMS notes, aligning the quality reporting requirements under the Shared Savings Program with the reporting requirements under other Medicare initiatives and those used by other payers will help “minimize the need for Shared Savings Program participants to devote excessive resources to understanding differences in measure specifications or engaging in duplicative reporting.”<sup>10</sup> Valid and less burdensome measurement of the quality of care provided through ACOs is essential to ensure the ACO’s success and that the promotion of higher quality of care and cost savings are not the result of limiting necessary care. With extensive experience as a quality standards-setting organization, the CAP looks forward to continuing our conversation with CMS to establish appropriate measures for pathologists as non-patient-facing clinicians.

CMS is also seeking ways quality measures and data sharing may help combat opioid addiction. As stewards of clinical laboratories, pathologists play a critical role in combating the ongoing opioid crisis. Pathologists provide oversight and direction in the appropriate use of laboratory tests to detect and monitor the use of opioids and their ever-proliferating synthetic knock-offs. Additionally, pathologists advise on clinical test selection to battle the many downstream effects of opioid use, including HIV and Hepatitis C infection, as well as detecting and treating organ damage (e.g. liver, heart, kidney, lung) and other effects such as bleeding (coagulation/transfusions). Finally, pathologists serve in a unique role as medical examiners documenting the increasing spread of these sequelae through society.

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<sup>9</sup> College of American Pathologists, 2018 Practice Leaders Survey Report, forthcoming

<sup>10</sup> <https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-17101.pdf>



Given this role in combating the opioid crisis, the CAP has previously supported policies that would enhance surveillance activities of controlled substance overdoses. Additionally, the CAP has urged steps to encourage improved interoperability of various office data systems and support the sharing data related to controlled substance overdoses. Uniformity in data sharing is critical for tracking trends and responding to public health and safety crisis like the opioids epidemic. The CAP is eager to partner with CMS in any opioid utilization efforts.

### **Promoting Interoperability**

As CMS explains in the proposed rule, ACOs participating in the Shared Savings Program are required to “coordinate care across and among primary care physicians, specialists, and acute and post-acute providers and suppliers and to have a written plan to encourage and promote the use of enabling technologies for improving care coordination, including the use of electronic health records and electronic exchange of health information.”<sup>11</sup> The CAP agrees that the exchange of electronic patient data is the foundation of an ACO’s ability to effectively coordinate care. In fact, pathology was one of the earliest specialties to embrace health information technology, utilizing computerized laboratory information systems (LIS) to support their work of analyzing patient specimens and generating test results. As owners of the laboratory data, pathologists either have taken, or are looking to take on, a leadership role in making data more accessible and more actionable by physicians to improve care management. It is with an LIS that electronic health records (EHR) systems or enterprise-wide clinical information systems exchange laboratory and pathology data. However, most LIS cannot attain Certified EHR Technology (CEHRT) status, and, as non-patient facing clinicians, pathologists face unique challenges in meeting many of the typical EHR and health information technology requirements in both the Quality Payment Program’s Promoting Interoperability performance category and the APM CEHRT use thresholds.

CMS proposes to add a requirement that all ACOs demonstrate a specified level of CEHRT use in order to be eligible to participate in the Shared Savings Program. Specifically, ACOs that are participating in a non-Advanced APM track or payment model would be required to attest that at least 50 percent of their eligible clinicians use CEHRT. ACOs that are participating in a Track or payment model within a Track that is an Advanced APM would be required to attest to the higher of 50 percent or the CEHRT threshold required for Advanced APMs.

Generally, the CAP appreciates CMS’s goal to encourage continued EHR and CEHRT adoption. However, because of the many unique challenges in this area for pathologists, the CAP urges CMS to consider the contributions of diagnostic specialties in the exchange of electronic patient data. For example, while CMS proposes to discontinue the quality measure that incorporates the Promoting Interoperability performance category, we would again highlight that many of the measures under the Promoting Interoperability performance category require face-to-face interaction with patients and therefore are not applicable to pathologists. The CAP is continuing to explore alternatives for pathologists that recognize their efforts in promoting the electronic exchange of health information, while ensuring their participation in the Promoting Interoperability category is not administratively burdensome. Further, the CAP is actively working to find a solution to the current limited CEHRT definition that excludes LISs, which could allow participation in the Promoting Interoperability category, but more importantly, would allow pathologists show their value in alternative payment models. Still, as we expressed in comments on the CY 2019 PFS proposed rule, we have concerns about increasing the CEHRT use criterion for APMs to qualify as Advanced APMs because this

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<sup>11</sup> <https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-17101.pdf>



could create additional barriers for Advanced APM participation. Finally, we have previously supported CMS guidelines for ACOs that encourage bi-directional exchange of data between the laboratory and other patient information, allowing laboratory pathologists easy access to patient data across the patient's EHR and allowing other clinicians easy access to readable and actionable data from the laboratory.

While not directly mentioned in this proposed rule, the CAP would again emphasize that health information technology vendors continue to block information through financial, technical, and contractual means. The CAP believes that EHR vendors continue to create barriers to access patient information. These barriers interfere with and materially discourage physician and patient access to information. The CAP's experience through its Qualified Clinical Data Registry (QCDR), known as the Pathologists Quality Registry (PQR), has been that some EHR vendors make it difficult for the transfer of patient information to clinical data registries. While some EHR vendors have negotiated with physicians and third-party software companies, other EHR vendors tack on large fees to send data from the EHR to clinical data registries or to even connect to a health information exchange. CMS should explore fundamental issues of data blocking that continue to hinder interoperability and identify appropriate methods to address them.

### **Summary**

The CAP is committed to increasing the availability and adoption of innovative payment models, like ACOs, that afford an opportunity for the participation of pathologists. The importance of pathologists comes in their ability, unique among medical specialties, to collect and analyze data related to patient testing and diagnosis. These activities provide the infrastructure and foundation for effective and appropriate care. Still, more changes are needed to appropriately recognize the role of pathologists in successfully achieving the ACO goals of reducing costs and improving quality and safety. Policy changes should be avoided that would unnecessarily lead to a drop in the number of ACOs; appropriate measures must be developed for providers who typically do not furnish services that involve face-to-face interaction with patients; and CMS must consider the contributions of diagnostic specialties in the exchange of electronic patient data. Further, as we have stated previously, more opportunities are needed for specialty providers of all kinds to participate under the Advanced APM track of Medicare's Quality Payment Program. The CAP looks forward to continuing our conversation with CMS to ensure pathologists' ability to participate in ACOs and other alternative payment models and to contribute to effective delivery system reform.

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The College of American Pathologists appreciates your consideration of these comments. Please direct questions on these comments to: Elizabeth Fassbender (202) 354-7125 / [efassbe@cap.org](mailto:efassbe@cap.org).