September 24, 2019

Ms. Seema Verma, MPH Administrator
Centers for Medicare & Medicaid Services
US Department of Health and Human Services
Attention: CMS-1715-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations

Dear Administrator Verma,

On behalf of the American Society for Clinical Pathology (ASCP), I appreciate the opportunity to provide comments in response to the Centers for Medicare and Medicaid Services' (CMS) CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; and Updates to the Quality Payment Program. This letter will focus on updates to the Quality Payment Program (QPP).

ASCP is a 501(c)(3) nonprofit medical specialty society representing over 100,000 members. Our members are board certified pathologists, other physicians, clinical scientists (PhDs), certified medical laboratory scientists/technologists and technicians, and educators. ASCP is one of the nation's largest medical specialty societies and is the world's largest organization representing the field of laboratory medicine and pathology. As the leading provider of continuing education for pathologists and medical laboratory personnel, ASCP enhances the quality of the profession through comprehensive educational programs, continuous professional development, publications, and self-assessment materials.

ASCP has advocated for increased opportunities for non-patient facing clinicians to participate in payment and delivery reform through the Medicare program. We appreciate the extensive work done by CMS to use the Medicare Access and Children's Health Insurance Program (CHIP) Reauthorization Act of 2015 (MACRA) to streamline quality improvement and value-based care implementation through the QPP. ASCP also appreciates CMS' acknowledgement of the unique variation in clinician practices, and extensive work to further refine program requirements, respond to stakeholder feedback, reduce reporting burden, encourage meaningful participation, and improve patient outcomes.

The practice of pathology is inherently collaborative and impacts the entire spectrum of patient care. Pathologists routinely work closely not only with other healthcare practitioners and facility staff, but also at the institutional or health care system levels, caring for both individual patients and populations. Pathologists are uniquely positioned at the forefront of patient care and are experts in quality improvement, care coordination, and collaboration. However, pathologists have faced

difficulty in participating in CMS' quality improvement incentive programs (e.g., the Physician Quality Reporting System (PQRS), Electronic Health Records (EHR) Incentive program and the Value Modifier (VM) program) in the past. Therefore, ASCP applauds the Agency's efforts to create more flexibility and expand quality reporting programs in the future, but requests that the Agency consider even further expansion of the MIPS program to more effectively capture the efforts of non-patient facing clinicians like pathologists who significantly impact patient care.

The following outlines selected recommendations and concerns with the 2020 proposed rule:

- ASCP remains concerned about the overall applicability and potential for meaningful participation for pathologists in the QPP and would urge CMS to consider the needs of specialists and non-patient facing clinicians when making policy changes. Further, ASCP reiterates our concern that meeting the requirements of the program is overly burdensome and difficult for pathologists, especially for those in small and/or rural practices.

- ASCP is concerned that pathologists and other non-patient facing clinicians would not be able to participate in the MIPS Value Pathways (MVPs) in 2021. We encourage CMS to work with stakeholders to develop a framework that is inclusive of all clinicians.

- ASCP is deeply concerned about the proposed changes to the Qualified Clinical Data Registry (QCDR) program including the proposal to require measures to be fully tested at the time of self-nomination and the requirement for data to be collected on the measures prior to self-nomination. ASCP would urge the agency to consider the challenges of specialists and non-patient facing clinicians (such as pathologists) when making changes to program requirements, particularly the QCDR program.

I. Historical Difficulties Faced by Pathologists in Satisfying CMS Quality Programs

Historically, it has been difficult for non-patient facing clinicians and pathologists to meet the requirements of CMS Quality Programs. ASCP is grateful that CMS has given both patient-facing and non-patient facing clinicians the flexibility to choose activities and measures that are most meaningful to their practices to demonstrate quality performance; specifically, the retention of extremely topped-out pathology performance measures for CY 2020. However, the Society remains concerned that pathologists will continue to experience difficulty in meeting QPP requirements and may, as a result, unfairly attain poor composite performance scores in relation to their patient-facing peers.

ASCP applauds CMS for addressing specialties with a limited number of applicable measures, and the Agency's efforts to modify program requirements to allow greater participation for pathologists – including the addition of episode-based cost measures. Further, ASCP is grateful to be chosen as a recipient of the 3-year MACRA cooperative agreement award to develop pathology-specific QPP measures. We are also appreciative of CMS continuing to encourage/incentivize the use of Qualified Clinical Data Registries (QCDRs) as a means to satisfy QPP requirements as QCDRs allow for flexibility and reduced administrative burden, particularly for non-patient facing clinicians who may otherwise have difficulty meeting program specifications. The Society hopes that CMS will continue

to make non-patient facing clinicians a priority when making policy decisions around program requirements and participation criteria.

II. Quality Payment Program Calendar Year 2020 Updates

A. General Comments

ASCP appreciates the Agency's incremental approach to implementing the Merit-based Incentive Payment System (MIPS), as we believe this approach creates the opportunity for patient facing and non-patient facing clinicians to continue to familiarize themselves with the scoring methodologies and benchmarks, understand the reporting requirements associated with this payment scheme, and better assess and make investments in the most meaningful options for participation. However, we urge CMS to provide clinicians with as much real-time feedback as possible so they, and the Agency, are better equipped to handle changing program requirements and modifications. While we recognize the Agency's efforts to reduce reporting burden and streamline participation for eligible providers, we remain concerned that the complexity of the program still raises challenges, especially for providers practicing in small and rural settings.

Additionally, we are concerned about the ability of non-patient facing clinicians, such as pathologists, to fully participate in the QPP. One barrier pathologists face is the fact that they use Laboratory Information Systems (LIS) in their practice, and thus cannot attain Certified Health Record Technology (CEHRT) status. Therefore, pathologists are unable to meet the requirements for health information technology in both MIPS and Advanced Alternative Payment Models (AAPM). Further, pathologists are not eligible for bonuses offered to other clinicians in the promoting interoperability category simply because they utilize LIS (which pre-date many EHRs) instead of the narrowly-defined CEHRT. ASCP would urge CMS to consider other technologies such as LIS and reward pathologists for the critical work they perform using this technology.

MIPS Value Pathways (MVPs)

CMS is proposing a new conceptual framework beginning in 2021 called the MIPS Value Pathways (MVPs) to move away from siloed activities and connect activities across the Quality, Cost, Promoting Interoperability (PI), and Improvement Activities (IA) categories. We are in support of CMS' vision for the MVPs, and believe that streamlining program requirements and connecting activities across disparate categories will be beneficial to participants and reduce burden. We are concerned however, that the MVPs as currently proposed do not take into account non-patient facing providers such as pathologists. It is unclear where pathologists might fit into this new scheme and we would advocate for flexibility and meaningful participation for them.

Specifically, MVPs as currently proposed include the PI category as a foundation and pathologists are exempted from reporting in this category because they use LIS, not EHRs, as their health information technology. As mentioned above, LISs are not considered CEHRT and current PI measures do not apply to pathologists. ASCP asks CMS to provide clarification on how an MVP could apply to pathologists and others who are exempted from the PI category. We would urge CMS to include non-patient facing clinicians in its vision for MVPs; ASCP reiterates the critical nature of

pathology in maintaining high-quality patient care and hopes that future versions of CMS payment programs are inclusive of all care team members.

ASCP urges CMS to continue special status provisions for non-patient facing clinicians. We believe these provisions are critical to maintain pathologist participation in the program. It would be preferable for pathologists to fully participate in the program by making the performance categories applicable to all clinicians. However, since that is not the case, the exemptions and special status provisions allow for demonstration of the care non-patient facing clinicians provide.

We are also concerned that CMS is moving toward patient reported outcomes and outcomes-based measures in general. While we see the importance and merit in these measures, pathologists do not have these types of measures available to them as pathologists do not directly interact with the patients they serve.

Further, we urge the Agency to consider pathologists when selecting the types of measures included in MVPs. As the stated goal is to standardize reported measures and activities while reducing clinician burden, we are concerned that the measures selected for these pathways will not be feasible or meaningful for pathologists to report. Pathologists practice in the laboratory setting and utilize LIS, so again, we would advocate for meaningful measure types and data collection methods to be inclusive of all clinicians.

Performance Thresholds

While we understand that the performance threshold must be raised according to statute, we are concerned that increasing point thresholds (from 30 to 45 points in 2020 and to 60 points in 2021) will unfairly place pathologists at a disadvantage. It is difficult for pathologists in particular to meet these thresholds due to lack of available quality measures, being exempt from both the cost and performance categories, and further restrictions to QCDR measure requirements that will limit their availability (see discussion on QCDRs below). The Society has heard from our members that participation in the QPP remains confusing and cumbersome and we feel increasing the threshold while clinicians are still becoming accustomed to the program is too great of an increase. Conversely, we are supportive of allowing flexibility in establishing the performance threshold for three additional years to ensure a gradual transition to the estimated performance threshold for year 6 of the program, which is based on the mean or median of final scores from a prior period. We feel this flexibility will benefit program participants in the transition to value-based payments. Further, many of our members have expressed that the time and resources required to be successful for full participation in MIPS is in contrast to the return on investment. Therefore, we request that CMS consider non-patient facing clinicians when setting performance thresholds and making payment adjustments.

We are supportive of the additional monies to award “exceptional performance” bonuses to those MIPS providers with the highest composite performance scores, but are again concerned that due to the reasons outlined above, pathologists have difficulty meeting the performance thresholds, let alone meeting an exceptional performance threshold.

B. Qualified Clinical Data Registries (QCDRs) and Qualified Registries (QRs)

ASCP appreciates the Agency's efforts in regards to the Qualified Clinical Data Registry (QCDR) reporting option, particularly for specialties who may not have many choices for reporting quality metrics in the current scheme (e.g., the pathology specialty measures set will only have 2 measures remaining, as all others have been extremely topped out for the 2020 program year). However, we believe that the proposed policies will restrict innovation and create difficulties for QCDR vendors seeking to introduce new measures into the program. Further, CMS already has robust policies and procedures in place to ensure that newly developed QCDR measures are fully vetted and high-quality.

Specifically, ASCP is concerned with the following proposed QCDR measure requirements:

a. *Beginning in 2021, QCDRs must identify a linkage between their measures and a cost measure, improvement activity, or CMS-developed MVP during self-nomination*

While we see merit in this proposal as it would further streamline the MIPS program and create more cohesion between disparate program categories, we are concerned about the applicability to pathology and laboratory medicine. Pathologists are not currently included in the cost category, and it is unclear how their participation might be structured in the CMS-developed MVPs. Therefore, we would urge the Agency to build flexibility into QCDR measure requirements with consideration for non-patient facing clinicians.

b. *QCDR measures would be required to be fully developed with completed testing results at the clinician level and must be ready for implementation at the time of self-nomination (beginning in 2021)*

ASCP is deeply concerned about the proposal to require QCDR measures to be fully developed with completed testing and implementation readiness at the time of self-nomination because we feel that this requirement would delay the creation and submission of new measures by a number of months or even years. Full measure testing would require QCDRs to contact practices and ask volunteers to provide data to test the validity of the measures which requires the investment of resources including time and finances. The QCDR space has in the past served as an incubator for measure testing and vetting, which has promoted innovation. We believe this is appropriate and should remain an option for QCDR vendors. While we understand the Agency's desire to only include fully vetted measures in the QCDR program, this proposal will ultimately reduce the very limited number of measures available to pathologists for reporting.

c. *QCDRs would be required to collect data on a QCDR measure, appropriate to the measure type, prior to submitting the QCDR measure for CMS consideration during the self-nomination period.*

The Society is concerned with this proposal as well because it presents a "catch-22" situation in terms of data collection. While we are able to collect data on our measures prior to self-nomination, in the past CMS and its contractors have made significant changes to the measures during the self-nomination process and these changes would need to be reflected in the type of data we collect and how it is collected; therefore, the data collected would be subject to change and would potentially be

rendered moot. We would urge the Agency to continue the current requirements for data collection and testing.

While we understand the Agency's desire to only include fully developed, tested measures in the QCDR program, ASCP believes this will unnecessarily delay the creation and submission of new measures; and as pathologists have very few measures on which to report, this will further challenge their participation in the program. Anecdotally, we have heard from other medical specialty societies that the QCDR program requirements are arduous and not worth the investment for their members. It is our belief that the proposals included here would cause further burden on specialty societies and may cause some groups to drop out of the program entirely. The Society urges CMS to continue its current robust policies in regards to QCDRs.

Additionally, we are in support of CMS' clarification in regards to QCDR measure rejection criteria. As there was not any formal policy in place prior to this year's rulemaking, we appreciate the guidelines offered by CMS. We urge the Agency to consider non-patient facing clinicians such as pathologists when evaluating process-based measures as again, there are limited measures available for this specialty. We are in full support of the rejection criteria for topped out measures and those that are "check-box" with no actionable quality action. Through our registry, the National Pathology Quality Registry (NPQR) we have strived to create meaningful measures that directly impact patient care and are not mere "check-box" measures. Further, we would also urge CMS to be considerate of the unique nature of pathology when evaluating attribution. It is difficult to attribute a quality action directly to a pathologist, but we have again strived to highlight the critical role of pathologists in the care continuum through our current QCDR measures. We have enjoyed robust discussions with CMS and their contractors around this topic and hope to continue to engage with the Agency in this regard. Overall, we agree with the criteria that has been outlined.

QCDRs Required to Support Multiple Performance Categories

ASCP would also like to seek clarification on the proposed requirement that QCDRs and QRs be required to submit data for the quality, improvement activities AND the promoting interoperability categories. We are aware of the proposal that certain "third party intermediaries" would be excepted from the requirement of reporting the PI category in instances where the third party intermediary is specialty-specific, but we are unsure whether ASCP's NPQR would fall into this category as pathologists are currently exempt from reporting for the Promoting Interoperability category under the Promoting Interoperability exclusion.

We are in support of the Agency's proposals requiring QCDRs to engage in activities that will foster improvement in quality of care as we have developed our registry for exactly this purpose. Our quality measures seek to close the communication loop with ordering providers, and educate them on test utilization; communicate critical values quickly and accurately; and ensure accuracy in diagnosis – all critically important activities to ensure the highest quality of patient care.

Performance Feedback

We are in agreement with the proposal that beginning in 2021, feedback from QCDRs and Qualified Registries (QRs) must include information on how participants compare to other clinicians within the QCDR or QR cohort who have submitted data on a given measure. ASCP believes that this

feedback and comparison is very beneficial to our participants and helps them identify potential areas for performance improvement as compared to their peers. Further, we are in support of the proposal that QCDRs and QRs be required to attest that they can provide performance feedback at least four times a year. We feel this amount of feedback is appropriate and high-value for our participants as well.

C. Modified Benchmarks to Avoid Potential Patient Risk

ASCP is in support of the proposal to establish flat percentage benchmarks in instances where the otherwise applicable benchmark could incentivize treatment that could be inappropriate for particular patients. The Society is a patient-centric organization and is supportive of proposals that curb inappropriate testing, treatment or care. Specifically, ASCP is the only representative of pathology and laboratory medicine in the Choosing Wisely campaign. The Choosing Wisely campaign was launched in 2012 by the American Board of Internal Medicine (ABIM) Foundation with the goal of creating and advancing a national dialogue on avoiding wasteful or unnecessary medical tests, treatments, and procedures. ASCP volunteers have produced six lists thus far of evidence-based recommendations of "Things Providers and Patients Should Question," with the intent of facilitating wise decisions about the most appropriate care. Pathologists are uniquely positioned to collaborate with patients and fellow practitioners to reduce costs and improve quality and patient safety through appropriate utilization of laboratory testing, and we are thus supportive of this proposal.

III. Merit-Based Incentive Payment System

Quality Performance Category

ASCP supports the proposed reweighting of the Quality category from 45 percent to 40 percent in Year 4 of the QPP. However, ASCP remains concerned that, as non-patient facing clinicians, the Quality category accounts for 85 percent of the total score for pathologists. We encourage CMS to continue identifying proposals to expand participation in the Cost and Promoting Interoperability categories for non-patient facing clinicians, which could help reduce the weight of the Quality performance category.

The proposed rule also indicates that four of the six pathology quality measures are extremely topped out in the 2019 benchmarking file. However, CMS is proposing to retain these measures to ensure pathologists have a sufficient number of quality measures to report. ASCP is appreciative of this consideration, and seeks clarification on which measures will be included in the Pathology Specialty Measure Set. CMS also noted that they may consider increasing the data completeness requirement for pathologists reporting on the four extremely topped out measures. ASCP is not supportive of increasing the data completeness threshold for pathologists who wish to provide data on the topped out measures due to the resulting reporting burden of an increased data completeness threshold. Instead, CMS should continue to engage with specialty organizations, like ASCP, in the development of pathology performance measures that impact patient care to constitute a robust pathology measure set.

Data Completeness and Scoring

For the second year in a row, CMS is proposing to increase the data completeness threshold. Under the proposed rule, there will be a larger number of clinicians participating in MIPS for the first time in 2020 due to the expanded definition of clinicians who are eligible to participate in MIPS. Because of their newness to the program, scoring them at 0 points for any measure that does not meet data completeness requirements of 70% for the respective performance category will unduly impact providers who are new to the payment system. Furthermore, the increased reporting requirement will also increase the burden on providers currently participating in the program and is contradictory to the Patients Over Paperwork initiative. ASCP understands that CMS is attempting to dissuade providers and vendors from cherry-picking which cases to report on, but feels that CMS should consider other actions such as implementing corrective action plans or requiring randomized sampling of patients instead of increasing the data completeness threshold.

As in previous years, ASCP advocates for data completeness at 50 percent instead of the proposed 70 percent requirement in Year 4. As aforementioned, ASCP also advocates against raising the data completeness threshold for the pathology measures that are indicated as topped out for the 2020 reporting year.

Removal of Measures

ASCP is aware that CMS is proposing the removal of 55 quality measures in Year 4 and is introducing an additional removal factor for 2020: removal of MIPS quality measures that do not meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods. ASCP believes that a 21% decrease in the total number of available MIPS quality measures is unfavorable and that CMS should identify equivalent or better measures to replace those that are being removed.

By removing the 55 measures, the consistency of the MIPS quality category is significantly impacted and does not allow CMS to appropriately measure practices on improvement or the improvement strategies employed by practices submitting those measures. Furthermore, many providers are discouraged from reporting on new measures which do not have predefined benchmarks because they are at risk for receiving only three points on these measures.

As new measures are developed, it would be beneficial for CMS to provide educational resources and materials to encourage the uptake of the new measures, and allow sufficient time for the adoption of those measures. As the program currently exists, it is the measure developers' responsibility to adopt and promote new measures, and it is our belief that having CMS' support in increasing visibility and awareness of new measures may subsequently result in an increase in the number of clinicians reporting on new measures.

As an organization that submits new measure concepts during the QCDR self-nomination period each year, it is discouraging to know that a measure may be eliminated after only two years in the program given the amount of time and effort it takes to develop new measures for consideration. Seven of our QCDR measures are currently being retooled under the MACRA Funding Opportunity: Measure Development for the QPP. The purpose of this 3-year cooperative agreement is to further develop our

registry-based measures to be included in the QPP, thus enhancing the pathology quality measure set. We believe that it would be a grave disservice to prematurely remove measures before there has been a sufficient opportunity to acquire data demonstrating the importance and significance of the measures. We encourage CMS to conduct analysis and engage with measure stewards, like ASCP, to determine the time it takes for measures to achieve acceptable numbers of adoption before removing them from the program.

Cost Performance Category

ASCP supports the proposal to reweight the Cost category to 20 percent in the 2020 MIPS payment year. However, as this category is based on modified Value-based Modifier (VM) cost measures, we reiterate our concern with the lack of applicability to pathologists in this category.

The VM program is primary care-focused and does not capture the value that pathologists provide to their patients. ASCP supports the inclusion of episode-based measures which could allow more clinicians to submit data for the Cost performance category. However, we are concerned that it is unclear which, if any, of the episode-based measures are attributable to pathologists. We believe that CMS should consider developing a fact sheet that provides information for the clinicians who would be eligible to submit data under the episode-based cost measures.

Currently, the Cost category is reweighted to zero for pathologists and we agree that pathologists should not be required to submit data in this category. However, if there are measures applicable to pathologists, we would appreciate clarification on which cost measures are attributable to pathologists so ASCP can educate them to ensure fuller compliance with this measures requirement. Additionally, as CMS works toward implementation of MVPs, ASCP would like to be involved in discussions with CMS to develop cost measures that could be used in pathology-specific MVPs.

Improvement Activities

ASCP is appreciative of the continued inclusion of the Improvement Activities performance category. This performance category gives pathologists greater opportunity to participate in the MIPS program by highlighting activities that are meaningful to them or those they are currently practicing. We are aware that CMS proposes to remove 14 IAs for 2020 reporting year; of those 14 measures, IA_CC_6 is applicable to pathologists. We understand that CMS has found this IA to be duplicative and proposes to modify IA_PSPA_7 to be more robust and inclusive of IA_CC_6. We support the Agency's effort to reduce duplicative measures, however, due to the lack of Improvement Activities applicable to pathologists, we feel that if an applicable activity is removed, it should be replaced with an IA in which pathologists can participate. The new IAs proposed for Year 4 are not applicable to pathologists, therefore pathologists would face a reduction in the number of IAs available to them in 2020. This reduction in IAs, coupled with the proposed removal of several measures in the Quality category, poses a significant threat to meaningful participation by pathologists in the MIPS program.

ASCP opposes CMS' proposal to increase the participation threshold for group reporting from a single clinician to 50% of the clinicians in the practice for the same continuous 90 days in the performance period to which the group is attesting. We feel that this proposal is burdensome and nonsensible

given that this stipulation would not be appropriate for all IAs. CMS also proposes requiring QCDRs to provide detailed information on how QCDRs will audit IA data within the data validation plan, in addition to providing the required information on the Quality category. Again, this is burdensome for practices and QCDRs, especially given that CMS has yet to provide information on what documentation is required to prove performance or participation in certain improvement activities.

ASCP maintains our concern that CMS is over-emphasizing the Quality category under its reweighting policy. In Year 4 of the program, we believe CMS should consider adding weight to the Improvement Activities category so that the Quality and Improvement Activities categories share an equal weight. Pathologists and other non-patient facing clinicians are currently performing activities intended to improve quality of care and should be recognized for these efforts. We urge CMS to increase the amount of weight given to the IA category – especially for non-patient facing clinicians who may lack applicable measures in the Quality category – to avoid creating undue emphasis on only one category, help create a more unified program, and demonstrate the value of the IA category while maintaining emphasis on quality.

Moreover, we concur with the Agency on the need to incentivize participation in robust clinical data registries —such as the NPQR – that provide feedback to participating clinicians, drive quality improvement, and share best practices. Registries function as tools for quality and performance improvement, measurement, and reporting. As such, registries support high value clinical practice improvement. The Society reiterates our belief that the Agency should consider reweighting the priority of activities related to registries from “medium” (20 points for non-patient facing providers) to “high” (40 points) to decrease reporting burden.

In the future, CMS should also consider engaging non-patient facing clinicians and specialty organizations in the development and vetting of new improvement activities.

Promoting Interoperability

ASCP supports the Agency’s efforts to overhaul the Promoting Interoperability performance category to support greater electronic health record interoperability and patient access. However, it is still challenging for pathologists to meaningfully participate in this category and we appreciate the re-weighting of this category to zero for non-patient facing clinicians for whom the category is not applicable.

That said, the Society would like to reiterate our concerns that pathologists are not given credit for the substantial contributions they make to data content included in EHRs via alternative tools such as Laboratory Information Systems (LIS). CMS has expressed the intent to regulate these alternative tools in an effort to ensure interoperability necessary to satisfy some of the PI measures that require the transmission and integration of laboratory data across care settings. As the role of laboratory-generated data continues to expand, the Society reiterates our recommendation that CMS adapt program requirements to recognize LIS as the primary reporting tool for pathologists, and incentivize pathologists’ existing and future efforts.

Given the further weight added to the remaining MIPS performance categories when one or more categories are reweighted to zero, ASCP seeks to maximize pathologists’ applicable performance

categories. As such, the Society encourages CMS to consider broadening its definition of "hospital-based" under the PI category to include hospital-based pathologists. In doing so, the Agency would allow for attribution of hospital-level measures performance to individual pathologists, thereby generating available data for assessment under the PI performance category. Given that hospital-based pathologists historically input structured laboratory data into health IT systems for the fulfillment of the previous MU measures (for which they did not receive credit), ASCP believes that provider-level attribution of hospital-level measures would be an appropriate solution for the pathology specialty.

As CMS looks to transition to MVPs in 2021, ASCP seeks clarification on how pathologists would be able to participate in an MVP when there are currently no PI measures that are attributable to pathologists and other non-patient facing clinicians. Given that PI has been identified as the foundation of MVPs, it is vital that CMS recognizes the importance of the laboratory and LIS and revamp the Promoting Interoperability performance category to include pathologists.

IV. Advanced Alternative Payment Models

ASCP would like to reiterate comments made in the past regarding pathologists' participation in Medicare APMS. In order to incentivize pathologists to participate in APMS, the Agency should create a pathway for participation that rewards them for the important work they currently do to rein in costs and decrease unnecessary utilization of tests through programs like the Choosing Wisely Campaign. Pathologists frequently reach out to fellow providers to educate them on test ordering and utilization and have put in place clinical decision support tools to aid this effort but are not financially incentivized for these important activities that result in cost savings and improved quality of care. Pathologists are typically paid on a fee-for-service basis and are referral-based, and are therefore not necessarily included in discussions of improving patient care, costs, or assumption of risk. As a result, pathologists are also not considered eligible for shared savings or losses.

ASCP appreciates that CMS has recognized the importance of specialists in acknowledging greater participation in future iterations of the QPP and urges CMS to recognize that specialists are limited in their ability to participate in risk contracts because they do not typically have a defined pool of beneficiaries. Additionally, specialists may participate in more than one Accountable Care Organization because of the nature of their practices. The lack of attributable beneficiaries makes participation in APMs particularly challenging for specialists such as pathologists. Accordingly, it is inappropriate for pathologists to be responsible for a defined pool of beneficiaries. However, pathologists are experts in helping advance quality improvement and effective test utilization and could be integral partners in APMs.

ASCP is pleased by the proposal to allow all payer types to be included in the 2019 Payer Initiated Process for the 2020 QP Performance Period. There are many non-Medicare ACOs in which pathologists may participate in to drive quality care. We believe that expanding the payment arrangements to include all payers will further incentivize and increase participation in APMs. Additionally, we support the proposal to allow for QP determinations under the All-Payer Option to be requested at the TIN level in addition to the AAPM Entity and individual eligible clinician levels. This proposal will help reduce confusion, provide more clarity, and streamline participation in APMS.

ASCP strongly supports care coordination and cost-effective, evidence-based, and patient-centered care. Therefore, for quality of care to improve across the healthcare spectrum, CMS must ensure a role for specialists in delivering quality care that is rewarded and recognized. We firmly believe that advanced APMs must be developed in a transparent and collaborative manner that includes specialists if they are to succeed in meeting the goals of the Triple Aim—that is, improved quality of care, reduced cost, and improved patient satisfaction. Pathologists are well-positioned to collaborate with risk-bearing physicians to reduce cost and create efficiency through appropriate ordering and use of anatomic pathology and clinical laboratory services. ASCP would welcome the opportunity to work with CMS and other medical specialties to develop a pathway to participation in advanced APMs for pathologists, provided there is sufficient opportunity for substantive contribution.

ASCP appreciates the opportunity to comment on this proposed rule. Please refer any questions to Matt Schulze, Director, Center for Public Policy at 202-735-2285 or matthew.schulze@ascp.org.

Sincerely,

Gene Siegal, MD, PhD, FASCP
President, ASCP