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Via Electronic Submission

September 10, 2018

Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, S.W.
Washington, DC 20201

Re: CMS-1693-P. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program

Dear Administrator Verma:

I am pleased to submit these comments on behalf of the American Society of Clinical Oncology (ASCO) in response to the recent proposed rule for the Medicare Physician Fee Schedule (MPFS) and Quality Payment Program (QPP) for calendar year 2019 published in the Federal Register on July 27, 2018.

ASCO is the national organization representing nearly 45,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. ASCO members are also dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practices for the prevention, diagnosis, and treatment of cancer are available to all Americans, including Medicare beneficiaries. ASCO has significant concerns that the policies proposed by CMS for 2019 will undermine patient access to cancer care for Medicare beneficiaries through a combination of payment reductions under the physician fee schedule and the implementation of the QPP.

If finalized in their entirety, the Agency's proposals would continue a longstanding and troubling trend of reducing the aggregate resources that Medicare devotes to cancer care and would endanger patient access. These consequences are the result of both long-standing deficiencies in the global approach to payment for cancer services and a series of incremental payment reductions. Although we appreciate our ongoing relationship with CMS and hope to continue to collaborate with CMS, we are deeply

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troubled by proposals that would directly or indirectly reduce overall resources devoted to cancer care in an already tenuous reimbursement environment. Instead of enacting policies that produce undesirable consequences for beneficiaries with cancer, Medicare should pursue innovative approaches to payment, including broader access for oncologists to Advanced Alternative Payment Models (APMs) such as ASCO's Patient Centered Oncology Payment (PCOP) model.

This year's proposed rule is especially problematic because it would enshrine permanent and unsustainable reductions in reimbursement for oncology services due to global policy changes. CMS projects a 4% reduction in overall resources for the hematology and oncology specialty. This cut equates to a $76 million in reduced funding for cancer care, which ASCO's independent analysis projects could exceed a 10% reduction for some individual oncology practices. Making matters worse, these reductions are occurring at the same time the payment adjustments from the Merit-Based Incentive Payment System (MIPS) are going into effect. As the potential negative impact of MIPS adjustments grows in future years, oncology practices that are already struggling financially will be unable to survive. This exacerbates the challenges for access to care faced by patients in rural locations and among disadvantaged and underserved populations.

For long term success, Medicare must change course and develop payment policies to support rather than weaken the provision of cancer care in the United States. We urge CMS to refrain from finalizing any proposals that would result in <u>any</u> cuts in payments for cancer services and to work collaboratively with ASCO to implement global payment reforms, including the development and implementation of new APMs that are widely available to all cancer professionals. With broader payment reform reflecting the realities of modern cancer care, Medicare can achieve its goal of greater cost effectiveness while sustaining or enhancing quality of care for the people it serves.

In summary:

I. Physician Fee Schedule

- ASCO opposes any policy changes to the documentation and payment of evaluation and management services that will directly or indirectly result in aggregate reductions in the resources devoted to cancer care.

- Although reducing administrative burdens is a worthwhile goal, it should not be pursued at the expense of reducing the resources dedicated to cancer care. ASCO supports the Agency's proposal to reduce documentation burdens for E&M services but pairing it with reductions in payment will negatively impact patient access and should be avoided.

- CMS should withdraw the proposal to consolidate E&M payments and to create add-on codes for inherent visit complexity because it will reduce the resources that Medicare dedicates to its most complex patient populations. Although we appreciate the Agency's efforts to partially offset these cuts with add-on code payments, the proposal does not appear to fully offset the

direct and indirect cuts to oncology reimbursement, is ambiguous and lacks assurances of long-term durability.

- ASCO opposes any changes to the indirect practice expense methodology to accommodate the flawed E&M payment policies because they would create unsustainable reductions in payment for drug administration and other services routinely delivered in cancer care. Despite the magnitude of these changes, CMS failed to provide adequate explanation for the changes, which deprives stakeholders of the opportunity to fully participate in the policymaking process.

- ASCO appreciates that the Agency does not intend to apply the proposed Multiple Procedure Payment Reduction (MPPR) to drug administration services and opposes any potential expansion of the MPPR that could apply to drug administration services delivered on the same date of service as an E&M visit.
- CMS should not finalize the proposed reduction in the add-on rate for Part B drugs subject to payment through the Wholesale Acquisition Cost (WAC) methodology and should instead focus on pursuing comprehensive solutions that drive value-based cancer care.

- ASCO supports expanding coverage and reimbursement for services that do not require face-to-face interactions and urges CMS to finalize its proposal to pay for Virtual Check-Ins, Remote Evaluation of Pre-Recorded Patient Information, and Interprofessional Internet Consultations.

II. Additional Changes in Part B Payment Policy

- ASCO urges CMS to continue implementation of the appropriate use program for diagnostic imaging in an incremental manner. ASCO supports gradual expansion of the Appropriate Use Criteria (AUC) program implementation, including educational and operational testing period in 2020. Additionally, ASCO agrees that using evidence-based criteria to make treatment decisions is necessary to improving the quality of care delivered to patients.

III. Quality Payment Program (QPP)

- ASCO appreciates the Agency's prompt implementation of the exclusion of Part B drug payments from the MIPS payment adjustment and the eligibility calculation for the low-volume threshold pursuant to the technical amendments to the QPP included in the Bipartisan Budget Act of 2018.

- Until CMS implements a cost measurement methodology that fairly and accurately assesses resource use in cancer care, the Agency should exclude all drug costs from the assessment of cost performance and refrain from increasing the weight of cost performance category in the MIPS scoring methodology. CMS can improve the accuracy and fairness of the cost-

performance category as applied to oncology by excluding Part B and Part D drug costs from cost assessments when a provider demonstrates adherence to a high-quality clinical pathway.

- CMS should prioritize the development of episodes of care that are capable of fairly and accurately evaluating the cost of medical oncology services. ASCO would welcome the opportunity to collaborate with CMS to develop appropriate risk-adjusted medical oncology episodes.

- ASCO encourages CMS to provide more complete feedback in response to improvement activity nominations to ensure nominating parties receive a clear justification of the Agency's rationale for including or excluding nominated activities in the improvement activity inventory.

- ASCO commends CMS for reforming the Promoting Interoperability (PI) performance category measures to emphasize the exchange of health information.

- ASCO supports the removal of the Base Score and encourages the Agency to complete its transition away from "all-or-nothing" scoring in the PI performance category by removing the requirement for MIPS participants to report data on each PI measure.

- ASCO encourages CMS to reconsider including the Verify Opioid Treatment Agreement measure as either a bonus or mandatory measure in the PI performance category and recommends the Agency reassign this activity to the Practice Improvement category of MIPS.

- CMS should withdraw its proposal that would require Qualified Clinical Data Registries (QCDRs) to enter a licensing agreement with CMS as a condition for approving QCDR quality measures.

- CMS should standardize the timeline for removing topped-out QCDR measures and MIPS measures to reporting in the MIPS Quality Reporting category.

- ASCO urges CMS to adopt the Patient Centered Oncology Payment (PCOP) Model as an Advanced Alternative Payment Model. Additional Advanced APMs are needed to promote ongoing patient access to cancer care and foster new value-based approaches to cancer care.

- ASCO supports the implementation of the Medicare Advantage Quality Improvement (MAQI) Demonstration Program to exclude professionals that participate in value-based arrangements with Medicare Advantage Organizations from MIPS reporting and the MIPS payment adjustments.

ASCO's specific concerns and recommendations are discussed below:

I. Physician Fee Schedule

A. Changes to Reimbursement and Documentation Policies for Evaluation and Management Services

ASCO opposes any policy changes to the documentation and payment of evaluation and management services that will directly or indirectly result in aggregate reductions in the resources devoted to cancer care.

Cancer patients are among the Medicare program's most medically complex beneficiaries and their care requires significant face-to-face interactions with their treating physician and extensive non-face-to-face care management and cognitive work. Today, despite efforts to reform oncology payment on a global level, the major sources of Medicare revenue in cancer care continue to be evaluation and management (E&M) visits and drug administration services. Significant reimbursement declines for either of these services, like those included in the proposed rule, will have the unintended consequence of creating new barriers to patient access to cancer services for Medicare beneficiaries. They also signal a reduced prioritization on cancer care.

These proposed reductions are unacceptable because oncology providers already provide an array of services that are not reimbursed by Medicare and they are reliant on an outdated coding system that fails to recognize or compensate this care. Instead of continuing counterproductive and potentially dangerous reductions in reimbursement for E&M and drug administration services, Medicare should pursue a comprehensive solution that addresses the current shortcomings in the medical oncology reimbursement system and promotes high-value cancer care.

The proposed rule contains several unacceptable policy initiatives related to the documentation and payment of E&M services that could rapidly destabilize the cancer care delivery system. Although we support the Administration's efforts to reduce documentation burdens for E&M services, the proposed policies relating to E&M services will reduce the total resources devoted to cancer care and create patient access barriers and are procedurally deficient. We urge CMS to completely withdraw all E&M proposals that are unrelated to the reducing E&M documentation requirements for the reasons discussed below.

Although reducing administrative burdens is a worthwhile goal, it should not be pursued at the expense of reducing the resources dedicated to cancer care. ASCO supports the Agency's proposal to reduce documentation burdens for E&M services but pairing it with reductions in payment will negatively impact patient access and should be avoided.

The Agency correctly identified E&M documentation as a major source of administrative burden in its "Patients over Paperwork" initiative. Reducing the overall documentation burden that oncologists and other physicians face will continue to promote patient-centered care.

The current framework for E&M coding requires extensive documentation of several elements of care under either the 1995 or 1997 E&M documentation guidelines. Many times, the documentation needed to support an E&M visit duplicates entries that already appear in a patient's medical record that are generated from referring practitioners or a previous interaction with the treating physician. Several elements of the Agency's proposal to reform E&M documentation are designed to decrease the time physicians would need to spend documenting their visits, including a proposal that would permit professionals to document support for E&M visits using only the medical decision-making criteria or the amount of face-to-face time the billing professional spends with the patient. These potential changes recognize that the most valuable documentation a physician produces during a face-to-face interaction is often incremental and based on step-wise changes to the patient's medical history.

Despite the positive effect that reducing E&M documentation will have on medical practice as a whole, the Agency paired this proposal with consolidating E&M payment levels and the introduction of the MPPR proposal, which will each reduce the overall resources Medicare devotes to complex medical services, such as cancer care.

CMS should withdraw the proposal to consolidate E&M payments and to create add-on codes for inherent visit complexity because it will reduce the resources that Medicare dedicates to its most complex patient populations. Although we appreciate the Agency's efforts to partially offset these cuts with add-on code payments, the proposal does not appear to fully offset the direct and indirect cuts to oncology reimbursement, is ambiguous and lacks assurances of long-term durability.

There are currently five levels of E&M services for office-based and outpatient visits that are reimbursed by Medicare. Oncologists treat complex patient populations that require comprehensive face-to-face evaluations to support high-quality and high-value cancer care, which often are coded and paid for at Level 4 or Level 5. The Agency's proposal to eliminate separate payment for Level 2 through Level 5 E&M services and to consolidate all Level 2 through Level 5 services into a single payment level will produce a significant reduction in the overall resources dedicated to Medicare's most clinically complex beneficiaries, including cancer patients.

The result of the proposal is clear: specialties that treat patients requiring more complex E&M services will see declines in payment, while those who treat less complex patients will see increases in payment.

It is counterintuitive that CMS would reduce the resources dedicated to its most complex patients, as their needs are the greatest. The Agency's own projections show that reimbursement for oncology E&M services will decline by 7% if the consolidation policy is finalized. These cuts are unsustainable and may have unintended consequences, including additional patient burdens or shifts in the site-of-service for cancer treatments.

CMS proposes to offset reductions in E&M revenue for oncology and other complex medical specialties by creating an add-on code for inherently complex visits. However, the proposed rule does not clearly describe when a visit is inherently complex, and it does not provide any description of the documentation needed to support the use of the add-on code. Although the add-on code is intended to

protect providers that deliver more complex care from severe reimbursement cuts, it is unclear whether resources provided will be adequate to offset the direct and indirect reductions in reimbursement that threaten continued patient access to cancer care. Further, even if the add-codes are finalized there are no assurances that their valuations will remain at the same level in the future.

ASCO opposes any changes to the indirect practice expense methodology to accommodate the flawed E&M payment policies because they would create unsustainable reductions in payment for drug administration and other services routinely delivered in cancer care. Despite the magnitude of these changes, CMS failed to provide adequate explanation for the changes, which deprives stakeholders of the opportunity to fully participate in the policymaking process.

If finalized, the proposed rule would implement significant cuts to services routinely delivered in cancer treatment without any explanation from the Agency on how its global policy changes affect cancer care. ASCO's internal analysis predicts that payment for drug administration services will decline by at least 10% in 2019 as a result of the proposed revisions to the indirect allocation of practice expense for E&M codes.

The Agency's approach to refining indirect expense for E&M services created far-reaching negative consequences on payment for cancer services. Despite the magnitude of the unsustainable declines in payment, the Agency failed to provide any meaningful discussion of the how creating E&M practice expense per hour skewed the valuation of other services across the physician fee schedule. This procedural failure undermines the ability of ASCO and the rest of the public to meaningfully participate in the public comment process. Accordingly, this deficiency cannot be remedied in this rulemaking cycle and we demand the Agency withdraw any proposals to change the indirect allocation of practice expense.

ASCO appreciates that the Agency does not intend to apply the proposed MPPR to drug administration services and opposes any potential expansion of the MPPR that could apply to drug administration services delivered on the same date of service as an E&M visit.

CMS proposed decreasing E&M reimbursement by 50% when a 0-day global or MPPR-indicated code is billed on the same day. We wish to thank the Agency for providing recent clarifications to ASCO that the MPPR would not apply to drug administration services. However, we wish to emphasize that it is never appropriate to apply the MPPR to drug administration services because drug administration services require significant resources for oncology practices to provide that are unrelated to evaluation and management services. Additionally, the MPPR proposal appears to be at odds with the efforts of the American Medical Association's RUC to address overlaps in resources between E&M services and other procedures provided on the same date of service.

B. Other Medicare Physician Fee Schedule Policies

CMS should not finalize the proposed reduction in the add-on rate for Part B drugs subject to payment through the Wholesale Acquisition Cost (WAC) methodology and should instead focus on pursuing comprehensive solutions that drive value-based cancer care.

ASCO shares the Administration's concerns regarding the rising cost of prescription drugs but urges the Agency to forgo finalizing the proposal to reduce the add-on percentage for Part B drugs paid according to WAC from 6% to 3%. The Agency understates the aggregate reduction in reimbursement resulting from the proposal due to the application in sequestration. Further, reducing the add-on percentage for drugs paid through the WAC methodology will not meaningfully reduce drug costs since most drugs are paid through a WAC based methodology on a temporary basis only.

Instead of focusing its efforts on additional incremental cuts that are unlikely to produce significant savings, Medicare should pursue a comprehensive solution that addresses shortcomings in the current medical oncology reimbursement system and that drives value-based cancer care.

ASCO supports expanding coverage and reimbursement for services that do not require face-to-face interactions and urges CMS to finalize its proposal to pay for Virtual Check-Ins, Remote Evaluation of Pre-Recorded Patient Information, and Interprofessional Internet Consultations.

The reimbursement system for cancer care is overly reliant on face-to-face visits and drug administration services. Modernizing the delivery of cancer care will require Medicare to adopt new strategies to support and manage cancer care outside of the traditional face-to-face physician-patient interaction. ASCO is pleased that CMS is continuing to take steps to expand the reach of Medicare services by providing reimbursement for three new services that would not require the patient's physical presence. For example, new models that emphasize remote services would not only expand the availability of services, and improve response time for rural and underserved populations, but could also serve to avoid increasing costs related to unnecessary use of services and emergency room visits. CMS should also consider expanding non-face-to-face services to separately reimburse tumor board patient case discussions. Tumor board discussions among oncologists are very successful in improving patient care and are another example of a valuable yet labor intensive service that is not reimbursed by the Medicare program.

CMS should finalize its proposal to provide coverage and reimbursement for Virtual Check-Ins[1], Remote Evaluation of Pre-Recorded Patient Information[2], and Interprofessional Internet Consultations[3].

Although ASCO supports separate payment for each of these codes, we are concerned that the efforts to ensure the coverage requirements for each service are met could be burdensome for many providers when compared to their payment level. For example, both the Virtual Check-In and Remote Evaluation

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[1] HCPCS Code GVCI1.
[2] HCPCS Code GRAS1.
[3] CPT Codes 994X6, 994X0, 99446, 99447, 99448, and 99449.

of Pre-Recorded Patient Information services require the practitioner to assess whether a face-to-face E&M visit occurred within a defined timeframe either before or after the remote service is provided. CMS should avoid creating counterintuitive burdens that could chill rather than facilitate the adoption of innovative service models.

II. Additional Changes to Part B Payment Policies

ASCO urges CMS to continue implementation of the appropriate use program for diagnostic imaging in an incremental manner. ASCO supports gradual expansion of the Appropriate Use Criteria (AUC) program implementation, including educational and operational testing period in 2020. Additionally, ASCO agrees that using evidence-based criteria to make treatment decisions is necessary to improving the quality of care delivered to patients.

Diagnostic imaging is a critical component in the diagnosis and treatment of cancer. ASCO supports using evidence-based criteria to reduce undesirable variations in care. CMS' gradual implementation of the AUC program allows practices to ready their EHR and other health information technology systems for consultation with appropriate use criteria. By recommending an educational and operational testing period in 2020, CMS is providing additional opportunity for practitioners to optimize these tools to manage patients.

The recognition of the AUC program as a MIPS improvement activity has incentivized the adoption of evidence-based criteria and support tools to drive standardization and improved quality of care. We support mechanisms to further integrate existing policies and programs in a manner that encourages rather than penalizes participation in value improvement activities. To that end, ASCO has done extensive work to promote the use and adoption of high-quality clinical oncology pathways, which incorporate guidelines and provide specific tools and direction for treatment and management of complex cancer patients. Well-designed and effectively implemented clinical pathways can reduce unnecessary variations in care while allowing flexibility in treatment based on patient and disease characteristics. We encourage the Agency to consider using pathways in the Medicare program to support evidence-based cancer care and enhance communication and education between a patient and their physician on the complex details of a treatment plan.

III. Quality Payment Program (QPP):

ASCO appreciates the Agency's prompt implementation of the exclusion of Part B drug payments from the MIPS payment adjustment and the eligibility calculation for the low-volume threshold pursuant to the technical amendments to the QPP included in the Bipartisan Budget Act of 2018.

ASCO applauds CMS' prompt implementation of the directives in the Bipartisan Budget Act of 2018 prohibiting the application of the MIPS payment adjustment to Part B drug payments and exempting Part B drug payments from low-volume threshold eligibility calculations. These amendments are critical to promoting the fair application of MIPS to physicians whose patients require complex drug treatments in day-to-day practice. Oncology providers play a critical role in providing patients with access to drugs

used in anticancer treatment, especially drugs that are delivered via infusion or injection. Prior to the enactment of the Bipartisan Budget Act of 2018, the MIPS payment adjustment would have applied to payments for Part B drugs and created potentially devastating impacts on oncology practices that could have quickly rendered the provision of anticancer drugs financially impossible in almost any community oncology practice. We fully support the Agency's action to implement these policies without delay.

A. Merit-Based Incentive Payment System (MIPS)

Until CMS implements a cost measurement methodology that fairly and accurately assesses resource use in cancer care, the Agency should exclude all drug costs from the assessment of cost performance and refrain from increasing the weight of cost performance category in the MIPS scoring methodology. CMS can improve the accuracy and fairness of the cost-performance category as applied to oncology by excluding Part B and Part D drug costs from cost assessments when a provider demonstrates adherence to a high-quality clinical pathway.

ASCO continues to believe that CMS should exclude the aggregate costs of Part B and Part D drugs from any measures used to assess the cost performance category in MIPS – unless or until CMS produces one or more methodologies that fairly and accurately assess oncology resource use. This remains critically important because the current cost measurement methodologies are inadequate for measuring cost performance for oncology focused providers and practices.

There are several unique characteristics of cancer care that make the inclusion of aggregate Part B and Part D drug costs in cost performance measures undesirable. Cancer is a complex disease state with multiple forms. Treatment decisions are highly dependent upon a patient's unique medical characteristics, including their cancer morphology, cancer stage, genetic characteristics, mutation status, comorbidities and preferences. Individual physicians often specialize in treating specific types of cancer that may be especially complex or expensive to treat. Protecting the most vulnerable Medicare beneficiaries will require CMS to account for these considerations without threatening the viability of subspecialties that focus on treating certain cancers.

Clearly, no physician should be penalized for providing the right treatment to the right patient at the right time – even when the treatment is more expensive than other, less-valuable interventions. Each of the cost measures that the Agency proposes to use to measure cost in 2019 fails to account for this principle. ASCO again urges CMS to revisit its methodology for measuring cost performance, to remove Part B drug cost—and not include Part D drug cost—in any cost assessment of oncology services.

CMS can improve the accuracy and fairness of the cost-performance category as applied to oncology by excluding Part B and Part D drug costs from cost assessments when a provider demonstrates adherence to a high-value clinical pathway. This strategy would better align the interests of Medicare beneficiaries and the Medicare program by promoting evidence-based and high-value care to assure appropriate utilization of cancer therapies rather than creating incentives based on overall cost.

CMS should prioritize the development of episodes of care that are capable of fairly and accurately evaluating the cost of medical oncology services. ASCO would welcome the opportunity to collaborate with CMS to develop appropriate risk-adjusted medical oncology episodes.

ASCO supports the Agency's continuing efforts to develop episodes of care to measure cost performance under MIPS. The episode-based measures proposed for 2019 are not appropriate for generating meaningful data in oncology because they focus on surgical procedures and other conditions without a meaningful link to non-surgical cancer care.

Developing meaningful medical oncology episodes will require CMS to seek information that goes beyond traditional claims data, including information about a patient's cancer type, stage and molecular markers. Slight differences in these variables can have significant impacts on patient outcomes and the overall cost of care. ASCO also encourages the Agency to focus its oncology episode development on the most common cancer diagnoses and the different phases of cancer care, including the initial diagnostic phase, primary intensive phase (curative or palliative), secondary or subsequent intensive phase (curative or palliative), post-therapy phase, long-term survivorship phase, and active end-of-life care. Phase-based episodes provide an appropriate basis for comparison because each phase may have significantly different resource requirements depending on the unique needs of each patient.

ASCO looks forward to continuing to work with CMS towards the development of appropriate risk-adjusted episodes of care for cancer treatment.

ASCO encourages CMS to provide more complete feedback in response to improvement activity nominations to ensure nominating parties receive a clear justification of the Agency's rationale for including or excluding nominated activities in the improvement activity inventory.

The MIPS Practice Improvement activity performance category provides physicians with an opportunity to engage in activities that are likely to improve the overall quality of care they provide to Medicare beneficiaries. Despite the Agency's establishment of an improvement activity nomination process, ASCO's experience in developing and nominating several programs for inclusion as practice improvement activities has raised questions about the Agency's rationale for deciding if an activity is appropriate for inclusion in the inventory of practice improvement activities.

The nomination process could be vastly improved if the Agency provided more robust feedback to nominating parties. This feedback may take the form of a detailed statement of deficiencies or documentation of the Agency's assessment of the nominated improvement activity against the stated evaluation criteria. Providing this feedback would strengthen the quality of improvement activity nominations and improve the Agency's review process.

ASCO commends CMS for reforming the Promoting Interoperability (PI) performance category measures to emphasize the exchange of health information.

Interoperability and the free exchange of health care information are core components to realizing the potential of a value-based health care system. ASCO is pleased that the new measures and objectives proposed under the amended scoring methodology for the PI performance category encourage and incentivize the exchange of health care information with other practitioners and their patients. Under the proposal, 80% of a MIPS participant's PI score will be based on the exchange of health information. This will foster broader exchanges of care information, improve practice efficiencies, and discourage the practice of information blocking—all of which are necessary elements of supporting high-quality and high-value cancer care.

However, the free exchange of health information remains a challenge in some instances. Providers may not always be able to access and exchange treatment information in a timely fashion or may be unable to access information due to blocking or other barriers. We urge CMS to ensure that measures are adequately designed to protect MIPS participants from barriers to successful performance that are out of their control.

ASCO supports the removal of the Base Score and encourages the Agency to complete its transition away from "all-or-nothing" scoring in the PI performance category by removing the requirement for MIPS participants to report data on each PI measure.

In addition to facilitating enhanced information exchange, the proposed rule also proposes to amend the scoring methodology for the PI performance category by eliminating the concept of the Base Score. Under the current policy, if a provider or group fails to demonstrate the minimum criteria to achieve the base score they are precluded from receiving any credit under the PI performance category. However, we remain concerned that failure to report just one measure—or to claim an available exclusion—will result in a score of zero for the entire PI category. Scoring the PI category in this manner undermines CMS' efforts to provide more flexibility to providers and maintains the status quo of undesirable "all or nothing" scoring.

ASCO encourages CMS to reconsider including the Verify Opioid Treatment Agreement measure as either a bonus or mandatory measure in the PI performance category and recommends the Agency reassign this activity to the Practice Improvement category of MIPS.

ASCO supports the overall efforts of the Administration to address the ongoing opioid epidemic. However, the Agency's proposal to include the Verify Opioid Treatment Agreement measure as a bonus measure for 2019 or a mandatory measure in 2020 should not be finalized. Instead, CMS should assign this measure to the MIPS Improvement Activities performance category. As CMS notes in the preamble, there are several fundamental barriers to the implementation and adoption of this measure as a part of the PI performance category. These include disagreement among the medical community regarding the use and effectiveness of Opioid Treatment Agreements, lack of a standardized definition for an Opioid Treatment Agreement, and complexities resulting from differences in state laws. The Agency also notes that practitioners may have significant difficulties locating the appropriate sources to query to identify

the existence of a treatment agreement. These issues are likely to create additional burdens for providers and will not facilitate the Agency's end-goal of promoting interoperability rather than securing additional documentation.

CMS should withdraw its proposal that would require Qualified Clinical Data Registries (QCDRs) to enter a licensing agreement with CMS as a condition for approving QCDR quality measures.

Qualified Clinical Data Registries are powerful tools that support clinically relevant and specialty-specific quality improvement. ASCO has been a pioneer in QCDR development and operates the QOPI Reporting Registry QCDR in partnership with the American Society for Radiation Oncology (ASTRO). The QOPI Reporting Registry has successfully self-nominated for each QPP performance year and supports MIPS reporting in the Quality, Promoting Interoperability (formerly Advancing Care Information), and Improvement Activities domains.

ASCO opposes the Agency's proposal that would require QCDR owners to enter into a licensing agreement with CMS that would permit any approved QCDR to report data using another QCDR's proprietary quality measures. The QOPI Reporting Registry supports five cancer-specific QCDR-measures for QPP performance year 2018, which were developed by experts in the field of oncology quality improvement. This proposal would undermine the incentive for QCDRs to invest in the creation and validation of clinically-relevant and proprietary quality measures. These consequences would stifle innovation in quality measure development and contribute to undermining the overall goals of the QPP. We urge CMS to withdraw this proposal and continue the current policy allowing QCDRs to license their QCDR-measures to each other.

CMS should standardize the timeline for removing topped-out QCDR measures and MIPS measures to reporting in the MIPS Quality Reporting category.

QCDR-measures are critical to enhancing the clinical relevancy of quality reporting within the MIPS program. Congress specifically acknowledged the importance of QCDR measures to MACRA when it exempted QCDR measures from many of the requirements that conventional MIPS requirements must meet for inclusion on the MIPS measure list. But like conventional MIPS measures, improvements in performance are the expected outcome of prolonged use of QCDR measures and many QCDR measures will eventually reach topped-out status. CMS created a process to phase-out topped-out MIPS measures over the course of four years, while it proposes to eliminate QCDR measures from the MIPS list in the first year they reach topped-out status. The accelerated timeline for MIPS removal undermines access to clinically relevant measures for many specialists that lack access to clinically relevant measures. Eliminating topped-out QCDR measures at the time CMS determines they are topped-out also imposes a significant burden on QCDR's to develop and validate new measures on an expedited or uncertain timeline. ASCO respectfully requests that the Agency implement a process to phase-out topped-out QCDR measures on the same timeline as MIPS measures.

B. Alternative Payment Models

There is an urgent need to increase the number of Advanced Alternative Payment Models that are available to oncology professionals. The current Medicare fee-for-service policies are over-reliant on an outdated coding system that does not provide reimbursement to support services that are essential for high-quality and high-value cancer care. These services include patient management, care-coordination and other supportive services that are necessary to optimize outcomes for cancer patients.

Although ASCO appreciates the Innovation Center's implementation and operation of the Oncology Care Model (OCM), additional Advanced APM participation options must be developed to avoid exacerbating the challenges presented by traditional fee-for-service Medicare and application of the MIPS payment adjustment.

ASCO urges CMS to adopt the Patient Centered Oncology Payment (PCOP) Model as an Advanced Alternative Payment Model. Additional Advanced APMs are needed to promote ongoing patient access to cancer care and foster new value-based approaches to cancer care.

Additional oncology-specific Advanced APMs are needed to promote patient access to cancer care and to address the ongoing financial challenges that oncology practices face today. Creating additional routes for oncologists to participate in Advanced APMs will enable oncology practices to survive in a value-based payment environment. Although the Oncology Care Model is currently operational, participation is limited to any additional practices. The Agency should seek to promote additional strategies for oncology practices, who care for some of the most complex—and costly—beneficiaries in the Medicare program. Innovation for these individuals would enhance both quality and cost effectiveness.

Many of the health policy challenges facing the cancer community today can be addressed by testing ASCO's Patient Centered Oncology Payment Model[4] (PCOP), which uses adherence to value-based clinical pathways as a key metric to support high-quality and high-value cancer care.

PCOP offers an innovative approach to payment, provides stable and predictable reimbursement and allows each oncology practice to deploy staff and resources in the manner best suited to the community they serve and their patient population. PCOP's design provides practices with the flexibility and resources they need to effectively engage in effective patient care management that promotes quality and controls overall cost of care. PCOP is currently being tested by one commercial payer and other private payers and employer groups have expressed interest.

Adopting PCOP would offer oncologists another opportunity to participate in an oncology-specific APM and strengthen Medicare's commitment to cancer care. ASCO is prepared to collaborate with CMS on implementing PCOP and other approaches to improving oncology care on an expedited basis.

[4] We have attached the current version of the PCOP Model for your review.

ASCO supports the implementation of the Medicare Advantage Quality Improvement (MAQI) Demonstration Program to exclude professionals that participate in value-based arrangements with Medicare Advantage Organizations from MIPS reporting and the MIPS payment adjustments.

The proposed MAQI demonstration allows providers and groups that participate in Medicare Advantage payment arrangements that are similar to Advanced APMs to be rewarded for taking accountability for the cost and value of care they provide. There are many parts of the country with above-average proportions of Medicare Advantage beneficiaries and this demonstration allows physicians in those areas to leverage their participation in value-based care arrangements to avoid burdensome MIPS reporting obligations and payment adjustments.

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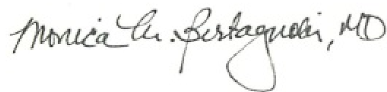
Thank you for the opportunity to provide comment on the 2019 Medicare Physician Fee Schedule and Quality Payment Program proposed rule. Please contact Sybil Green with any questions at Sybil.Green@asco.org.

Sincerely,



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