The leading education and advocacy organization for the cancer team

Association of Community Cancer Centers

June 27, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Ave., SW
Washington, DC 20201

BY ELECTRONIC DELIVERY

Re: Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models (CMS-5517-P)

Dear Administrator Slavitt:

The Association of Community Cancer Centers (ACCC) appreciates this opportunity to comment on the proposed rule regarding the Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule (Proposed Rule), published by the Centers for Medicare & Medicaid Services (CMS) in the Federal Register on May 9, 2016.[1] ACCC is a membership organization whose members include hospitals, physicians, nurses, pharmacists, social workers, and oncology team members who care for millions of patients and families fighting cancer. ACCC represents more than 20,000 cancer care professionals from approximately 2,000 hospitals and private practices nationwide. It is estimated that 65 percent of cancer patients nationwide are treated by a member of ACCC.

ACCC is committed to ensuring that cancer patients have access to the entire continuum of quality cancer care, including access to appropriate cancer therapies in the most appropriate setting. The cancer care delivery infrastructure is a fragile construct of hospital outpatient departments and physician offices working together to provide care to patients in their communities. Physicians and other clinicians face growing numbers of patients requiring cancer care, and their ability to provide care will depend on appropriate Medicare payment rates for cancer care, including drugs and other services.

[1] 81 Fed. Reg. 28,162 (May 9, 2016).

We appreciate CMS's thoughtful proposals to implement the Quality Payment Program as required by the Medicare Access and CHIP Reauthorization Act (MACRA). Cancer care providers understand the challenge of delivering more cost-efficient health care while maintaining a high standard of quality. We understand that the health care payment and delivery paradigm in the United States is increasingly shifting to a value-based care system, and community cancer centers are a part of this reform effort. We fully support the overarching goal of the Quality Payment Program to bend the cost curve by improving care, providing the right care at the right time, reducing over-treatment and under-treatment, and reducing hospital admissions and readmissions. ACCC members have a long history of partnering with CMS on meaningful payment reform including, most recently, the Oncology Care Model (OCM).

One critical factor in this effort is the effect of pharmaceutical pricing on the overall cost of physician care. ACCC and its members generally recognize the need for a broad, national conversation about pharmaceutical pricing and solutions that will rein in drug costs for federal programs and beneficiaries and the health care system as a whole. However, we also believe that new Medicare physician payment policies, including this Proposed Rule and the proposed Part B Drug Payment Model, must acknowledge that drug prices are only one part of the larger effort to provide affordable, quality cancer care, and one over which clinicians have no control.

In addition, we urge CMS to be mindful that cancer care providers already are being challenged to provide care at reduced payment rates because of sequestration. For example, reimbursement rates paid to hospitals for numerous anti-cancer drugs are currently less than the acquisition cost.[2] Cancer care providers are also facing many other complex policy changes that create new uncertainty and potentially drastic reductions in reimbursement, including implementation of the OCM, potential implementation of the Part B Drug Payment Model, and costly and cumbersome safe handling guidelines from the new United States Pharmacopeia (USP) 800 standards. We urge CMS to implement the Quality Payment Program with the awareness that further reductions in reimbursement simply may not be sustainable for a large number of cancer care providers and may result in disruptions to life-saving care.

In our comments on this Proposed Rule, we respectfully request that CMS refine its proposals to ensure that the Quality Payment Program fairly rewards clinicians who deliver high-quality, cost-efficient care and provides an effective incentive for all clinicians to improve their performance. ACCC's specific comments on the Proposed Rule are as follows:

- The Proposed Rule's scope and timeline are too ambitious for clinicians and CMS to implement effectively;
- CMS must ensure that it provides adequate accommodations and protections for small group practices and solo practitioners;
- CMS should refine the definition of "non-patient-facing" eligible clinicians to allow a higher number of patient-facing encounters;

[2] Pharmacy Consulting International, Impact Analysis of Proposed CMS Reimbursement Model (May 2016).

- CMS should modify the resource use methodology to ensure that eligible clinicians are held responsible only for costs that they can control;
- CMS should add all of the OCM quality measures to the final list of MIPS quality measures and consider allowing clinicians to satisfy their MIPS obligations by reporting all OCM measures, and should continue to refine the MIPS quality measures to ensure a meaningful assessment of quality for all clinicians; and
- The APM incentive requirements are drawn too narrowly to offer a meaningful alternative for clinicians and should be revised to make participation in an advanced APM more achievable, and CMS should adopt policies to promote availability of a wide variety of APMs and Physician-Focused Payment Models (PFPMs).

1. The Proposed Rule's scope and timeline are too ambitious for clinicians and CMS to implement effectively.

CMS proposes to begin applying payment adjustments under the MIPS and the APM incentive beginning with payments on or after January 1, 2019, based on performance in Calendar Year (CY) 2017. ACCC is deeply concerned that this timeline would not allow eligible clinicians the time needed to prepare for a new and extremely complex payment system that will put up to 4% of their payments under the Physician Fee Schedule (PFS) at risk in the first year. We urge CMS to revise the proposed timing for implementation of the Quality Payment Program to account for the significant preparation and investment that clinicians will need to make in order to meet their obligations under the program.

Preparing for the Quality Payment Program will be a significant undertaking for our members and other eligible clinicians. The Proposed Rule was published in late April, and clinicians are only now beginning to read and understand the proposals in a rule that is hundreds of pages long. Eight months would be a very narrow window for clinicians to review and implement such a complex set of rules, and by the time CMS reviews comments and issues a final rule, clinicians will have even less time to finalize their preparations before performance measurement begins.

It is not only clinicians who recognize that they will be unable to complete preparations by January 1 of next year. CMS itself acknowledges that a number of critical aspects of the Quality Payment Program will not be implemented until at least the second year of the program. For example, CMS acknowledges that it will be unable to establish the necessary technical infrastructure to allow clinicians to report through virtual groups in the first year. CMS also acknowledges that it will need additional time to develop more episode-based cost measures and a more robust methodology for measuring clinical practice improvement activities. These are important elements of the Quality Payment Program that promote flexibility and fair assessment of clinicians.

We believe that implementation of the Quality Payment Program should be delayed for six months to one year to allow eligible clinicians and CMS a fuller opportunity to work through the details of the program together and develop the systems and infrastructure necessary to carry

out the program effectively and fairly. At a minimum, we urge CMS to include reasonable accommodations to account for the challenges that clinicians will face in completing preparations for the program by January 1, 2017. One approach would be to phase in application of the Quality Payment Program over time, which we believe would be reasonable and consistent with the purpose of MACRA, as well as consistent with past practice in implementing systems like the Physician Quality Reporting System (PQRS) and Value-Based Payment Modifier (VM). For example, CMS could apply a maximum payment adjustment of 2% in the first year of the program, or apply negative adjustments only to groups of eligible clinicians above a certain size, each of which would be a reasonable accommodation to account for the extremely short timeframe that clinicians would have to prepare for the program.

2. CMS must ensure that it provides adequate accommodations and protections for small group practices and solo practitioners.

We thank CMS for recognizing that it will be particularly challenging for small group practices and solo practitioners to implement systems and activities necessary to earn a high MIPS score and avoid a negative adjustment to their payments under the PFS, and we appreciate the proposal to require only two clinical practice improvement activities (CPIAs) for small practices to earn the full CPIA score. However, we urge CMS to expand its accommodations for small and solo practices and provide maximum flexibility and assistance to such practices so that all eligible clinicians have an equal opportunity to succeed under the Quality Payment Program.

While clinicians in large practices can rely on pooled resources to automate quality reporting, purchase EHR technology, and create new efficiencies in resource use, small and solo practices will be forced to do significant legwork on their own and come up with their own cost-saving measures if they wish to perform well under the MIPS or qualify for the APM incentive. Many physicians, particularly in rural practices, simply lack the infrastructure or experience to meet the most basic reporting requirements. Without further efforts to accommodate small practices, CMS itself estimates that practices with fewer than 10 physicians will account for 70% of MIPS penalties in 2019.[3] This penalty would come on top of the already substantial challenges that small and rural clinicians face in maintaining the financial viability of their practices.

CMS recognizes these challenges in the context of the CPIA performance category by allowing small practices to earn full credit on the CPIA component of the MIPS score by reporting two CPIAs instead of the three that would otherwise be required. CMS explains that its proposed accommodation is "grounded in the resource constraints that these MIPS eligible clinicians face,"[4] and that the accommodation also reflects CMS's consideration of small practices in developing CPIAs, as required by Section 1848(q)(2)(B)(iii) of the Act. We appreciate and support this proposal. We also appreciate CMS's announcement that it plans to devote $20 million to train and educate clinicians in small practices about the Quality Payment Program.

[3] 81 Fed. Reg. at 28,375.
[4] *Id.* at 28,267.

However, ACCC is concerned that resource constraints faced by small or solo practices will make it similarly difficult to perform well on the remaining three MIPS components. We therefore urge CMS to develop alternative scoring methodologies or other accommodations for small practices in the other performance categories wherever possible. For example, with respect to the quality performance category, CMS should allow small practices to report a smaller number of quality measures, at least for the initial few years. With respect to both the quality and resource use performance categories, CMS should adjust its scoring methodology so that small practices are compared only against each other as opposed to against all other practices (including large, sophisticated practices with greater resources). Finally, with respect to the advancing care information performance category, CMS could allow small practices to report a smaller number of measures to earn the base score, provide more points per measure for the performance score, or both. CMS should also consider other accommodations that would allow small practices more flexibility across the program, such as an increased low-volume threshold for small practices. In the longer term, we ask that CMS continue to develop ways to ensure that small and rural practices can meet the growing number of requirements on providers and remain viable options for cancer care in their communities.

3. CMS should refine the definition of "non-patient-facing" eligible clinicians to allow a higher number of patient-facing encounters.

As authorized by Section 1848(q)(2)(C)(iv) of the Social Security Act, CMS proposes to establish alternative reporting requirements and scoring methodologies for eligible clinicians who are "non-patient-facing." CMS proposes that a "non-patient-facing" eligible clinician would be an individual or group that bills 25 or fewer patient-facing encounters during a performance period, defined by a list of procedure codes that CMS classifies as patient-facing. We thank CMS for flexibility for this group of providers, but also urge CMS to increase the threshold of patient-facing encounters to at least 75 encounters to ensure that the definition of "non-patient-facing" covers eligible clinicians who are likely unable to meet the standard MIPS requirements.

ACCC is concerned that the threshold of 25 patient-facing encounters is too low and will exclude from the definition of "non-patient-facing" a large number of clinicians who "typically furnish services that do not involve face-to-face interaction with a patient."[5] Although the number of clinicians who will exceed the encounter threshold will depend on the list of patient-facing codes that CMS publishes, we believe that many clinicians who do not frequently see patients directly, including radiologists and pathologists, may well perform 25 or more services that CMS designates as patient-facing. At the same time, however, these clinicians would find it difficult or impossible to meet the ordinary MIPS reporting requirements because the nature of their practices does not align with the type of quality measures and clinical improvement activities that CMS has proposed for patient-facing clinicians.

[5] Social Security Act § 1848(q)(2)(C)(iv)(I).

4. CMS should modify the resource use methodology to ensure that eligible clinicians are held responsible only for costs that they can control.

ACCC is deeply concerned that the proposed methodology for calculating the resource use score will hold eligible clinicians accountable for costs that they cannot control, which will not only improperly penalize those clinicians on a key component of their composite MIPS score, but will also fail to create the positive incentive to pursue efficiency in care delivery as Congress intended.

Cancer care providers are leading the way in developing innovative approaches to delivering care more efficiently and reducing unnecessary costs. However, some costs of care are simply beyond the control of clinicians. For example, one of the most significant costs of care for many cancer patients is prescription drugs. Physicians and other health care professionals have a moral and ethical obligation to provide their patients with the best treatment available, regardless of cost. Further, depending on the setting or practice, physicians are often not even aware of the cost of various treatment options – and when physicians are aware of cost, they rarely have the leverage to negotiate with manufacturers. Yet under the Proposed Rule, eligible clinicians would be held accountable for the cost of those drugs.

It is essential that CMS modify its proposed resource use scoring methodology to minimize the effect of costs that are beyond the control of eligible clinicians. One important way to achieve this would be to significantly expand the number and variety of episode-based cost measures or other cost measures that take account of the differences between specialties in terms of the typical cost involved in delivering care. For example, CMS proposes only two oncology-related episode-based cost measures for the 2019 MIPS score. This means that many oncologists will be scored for resource use based solely on the overall cost measures, under which they will be compared not only to other oncologists but also to clinicians in dozens of other specialties, many of which involve therapies with lower overall costs than oncology. As a result, it is likely that many oncologists (and clinicians in other relatively high-cost specialties) will be unfairly penalized because they are not being compared against other clinicians in their specialty on any applicable cost measures.

We urge CMS to rapidly and significantly expand the number of episode-based cost measures to include measures across a wide variety of specialties and sub-specialties, including oncology and its sub-specialties such as radiation oncology. ACCC and other stakeholders stand ready to work with CMS to develop such measures. We also urge CMS to consider and develop other ways of minimizing the effect of costs that are beyond clinicians' control, such as a more sophisticated risk adjustment methodology that would take into account the variable costs of care between different specialties and disease areas. In the absence of such revisions, the resource use score will inappropriately penalize certain clinicians and will not serve Congress's intent of incentivizing greater cost-efficiency in the delivery of health care services.

5. **CMS should add all of the OCM quality measures to the final list of MIPS quality measures and consider allowing clinicians to satisfy their MIPS obligations by reporting all OCM measures, and should continue to refine the MIPS quality measures to ensure a meaningful assessment of quality for all clinicians.**

ACCC believes that providing high-quality care is at the heart of the Quality Payment Program, and we appreciate CMS's efforts to implement the quality performance category in a manner that allows all eligible clinicians to report measures that fairly and accurately assess and demonstrate the quality of care that they deliver to their patients. In particular, we appreciate and support CMS's attempt to reduce the reporting burden on clinicians with respect to quality measures, including reducing the number of required measures to six measures, not requiring measures to fall into certain quality domains, and maintaining to the extent possible measures that were available under the PQRS. These proposals will help to make the reporting process as streamlined and familiar to clinicians as possible in the first few years of the program.

However, we are concerned that it will be unreasonably burdensome for some of our members, particularly practices that are participating in the OCM, to identify and report six measures under the MIPS in addition to all of the OCM measures. This is particularly important due to the complexity of the OCM performance-based payment and the difficulty many OCM practices may face moving to two-sided risk when it becomes an option under the OCM. Therefore, we strongly recommend that all of the quality measures from the OCM be available for reporting under the MIPS, both before two-sided risk is an option in the OCM and after, for those practices that still may not be able to make that transition and qualify for the APM track. CMS should also consider aligning the reporting mechanisms between the OCM and the MIPS so that when clinicians report quality data for the OCM, that data would be automatically considered under the MIPS without any additional reporting by those clinicians.

We generally encourage CMS to add quality measures in the final rule to ensure that there is an adequate range and number of quality measures for all cancer care providers, as well as clinicians in other specialties and sub-specialties, to meet their reporting obligations. For example, many cancer care providers would benefit considerably from the availability of a quality measure that assesses whether a clinician appropriately staged a patient for cancer treatment. We look forward to working with CMS to continue adding to and refining the available quality measures and tailoring the quality performance methodology to facilitate clinician reporting and promote fair scoring under the MIPS.

6. **The APM incentive requirements are drawn too narrowly to offer a meaningful alternative for clinicians and should be revised to make participation in an advanced APM more achievable, and CMS should adopt policies to promote availability of a wide variety of APMs and PFPMs.**

APMs represent an important step toward delivery of high-quality, cost-efficient health care, and many cancer care providers have been participating in APMs since their inception. However, the Proposed Rule fails to capitalize on the availability of APMs as a path to cost-

efficient health care and does not effectively implement Congress's intent to recognize the value of APM participation by providing a separate APM incentive and exemption from the MIPS.

Pursuant to Section 1833(z) of the Act, CMS proposes that only "advanced APMs" would qualify for the APM incentive and MIPS exemption, and proposes to define an advanced APM as one that (1) requires use of certified electronic health record technology (CEHRT); (2) pays its participants based on quality measures similar to the MIPS quality measures; and (3) either is an expanded Medical Home Model or requires participants to bear a certain level of risk for financial losses according to criteria specified in the Proposed Rule. However, CMS proposes to implement each of these requirements in a manner that will exclude many well-established APMs, including the Oncology Care Model (OCM), that were created or endorsed by CMS. It is not surprising that CMS estimates fewer than 90,000 clinicians will qualify for the APM incentive, compared to the estimated 687,000 to 746,000 who will be subject to the MIPS adjustment.

We urge CMS to revise its definition of an advanced APM to make the APM incentive a meaningful and achievable alternative to the MIPS, as Congress intended. In particular, we urge CMS to consider a broader definition of bearing financial risk for monetary losses in excess of a nominal amount. Under the Proposed Rule, financial risk for monetary losses would include only monetary losses for which clinicians bear responsibility through the APM's formal scheme for distributing monetary gains or losses. We believe this limited definition ignores the significant monetary risks that health care professionals have already taken in investing the resources necessary to comply with APM requirements. Clinicians who have opted to participate in APMs make these investments as a calculated risk, which may pay off if the APM generates savings that are paid out, in part, to the participating clinician. However, clinicians may never recoup their investment in the APM if they fail to improve quality of care or generate cost savings. CMS should recognize these investments as bearing financial risk for monetary loss in excess of a nominal amount.

We recognize that a broader definition of bearing financial risk would require CMS to adopt workable standards to apply the requirements of the statute to APMs that do not formally distribute monetary losses to participants. These standards could include estimates by the APM or a third party regarding the monetary investment required to participate in the APM or the amount of savings that would be needed to recoup the participant's investment, or documentation of expenditures actually incurred by APM participants. ACCC would be pleased to work with CMS to develop a solution that is practical and administrable both for CMS and for APM participants.

At a minimum, we would expect the final definition of an advanced APM to include APMs that CMS itself has endorsed through the Center for Medicare & Medicaid Innovation (CMMI), such as the OCM and the Bundled Payments for Care Improvement (BPCI). For example, CMS acknowledges that the OCM is intended to "provide higher quality, more highly coordinated oncology care at a lower cost to Medicare." We strongly believe that CMS should make the APM incentive and MIPS exclusion available to clinicians who participate in these comprehensive, CMS-developed APMs.

More generally, we believe that defining an advanced APM too narrowly will discourage eligible clinicians from participating in APMs altogether. We join CMS in their desire to see participation in APMs grow, with an increasing number and variety of APMs (including new and innovative oncology-related APMs) and an increasing number of clinicians who receive payments through APMs. We believe the proposed definition will have the opposite effect. Some clinicians, including many ACCC members, have sufficient resources and risk tolerance to voluntarily participate in an APM in addition to the ordinary risk of financial losses due to market forces or mandatory payment adjustments such as the Value-Based Payment Modifier or the MIPS. Most clinicians, however, are likely to look at the stringent requirements for participating in an advanced APM and conclude that they will not be able to invest the resources or risk needed to report and perform under the MIPS – which they must do anyway – in addition to the resources and risk they would need to commit to an APM. Likewise, clinicians and others who might otherwise devote resources to developing new APMs may decide to invest those resources elsewhere if they determine that it is unlikely the APM will qualify as an advanced APM under the Proposed Rule's strict criteria. We strongly recommend that CMS open the door to greater participation in APMs by adopting a final definition for advanced APMs that recognizes and credits the significant investment of resources and risk that participation in an APM requires.

We appreciate CMS's proposals with respect to MIPS APMs, which would not qualify as advanced APMs but would reflect the existing obligations of APM participants by reducing reporting burdens and adjusting the weight of certain MIPS performance categories. We support the proposals to reduce burdens on MIPS APM participants, particularly the proposal not to score the resource use category for MIPS APM participants. While we strongly encourage CMS to fully recognize the risk investment of APM participants by expanding the definition of an advanced APM as described above, we believe CMS should finalize the proposed accommodations for clinicians who participate in APMs that do not meet the definition that CMS ultimately adopts.

Finally, as noted above, ACCC strongly supports the continued development and dissemination of APMs, including advanced APMs, MIPS APMs, and PFPMs. ACCC is made up of clinicians and other providers in medical, surgical, and radiation oncology, and we firmly believe that there should be a wide variety of APMs related to each specialty, sub-specialty, or disease area, so that each clinician has the opportunity to participate in an APM that is most appropriate and effective for their practice. To that end, we ask CMS to clarify that the existence of one APM addressing a disease area or condition will not preclude or limit PFPM or other proposals that address the same disease or condition using a different payment model. For example, the availability of the OCM in the oncology space should not preclude CMS's approval of other oncology-related PFPMs or APMs that may be more appropriate for radiation oncologists or other cancer care providers.

* * *

Thank you for this opportunity to comment on the Proposed Rule. We look forward to continuing to work with CMS to refine and improve the Quality Payment Program. Please feel free to contact Leah Ralph, ACCC Director of Health Policy, at (301) 984-5071 if you have any questions or need any additional information. Thank you again for your attention to these very important matters.

Respectfully submitted,

Jennie R. Crews, MD, MMM, FACP
President
Association of Community Cancer Centers