Via Electronic Delivery

August 21, 2017

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
Attention: CMS-5522-P
200 Independence Ave. S.W.
Washington, DC 20201

Re: CMS-5522-P: Medicare Program; CY 2018 Updates to the Quality Payment Program

Dear Administrator Verma:

The American Society of Clinical Oncology (ASCO) is pleased to submit comments on the CMS proposed rule published in the Federal Register on June 30, 2017 to implement Year 2 of the Quality Payment Program (QPP), which arises from the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).

ASCO is the national organization representing over 42,000 physicians and other healthcare 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 partnered closely with Congress and CMS in the development and implementation of MACRA. Moving to a reimbursement system based on value rather than volume is essential to ensuring patient access to cancer services and the long-term sustainability of the Medicare program. We fully appreciate the significant task that CMS faces to implement MACRA in a manner that fairly and predictably evaluates physicians on the value of care they provide.
We look forward to working closely with you and your colleagues as CMS continues the implementation of MACRA. Our recommendations are discussed below.

I. Merit Based Incentive Payment System (MIPS)

A. Issues relating to Patient Access to Drugs used in Anticancer Regimens under MIPS

CMS should not subject Part B drugs administered by medical oncologists to a MIPS adjustment based on a MIPS eligible clinician’s performance during the applicable performance period. While many anticancer drugs are expensive, they represent mainly pass through costs for oncology practices rather than net revenue. Amplifying the penalties or bonuses otherwise applicable under MIPS by the cost of anticancer drugs would dramatically distort the magnitude of the MIPS penalty and bonuses far beyond anything intended by Congress and thereby could create widespread barriers to patient access to lifesaving therapies.

In the preamble of the proposed rule, CMS makes passing reference to the possibility of making Part B drug reimbursement subject to MIPS adjustments. This would seriously distort the magnitude of the MIPS penalty and bonuses beyond the 4% (for 2019) clearly intended by Congress. Applying this adjustment to the large dollar amounts associated with the cost of drugs—the huge majority of which is just a “pass through” for practices—results in penalties and bonuses far beyond anything ever intended with the creation of this program. An ASCO analysis based on collected practice data and Medicare 2015 Public Use Files shows that the actual median penalty as a percent of total collected revenue would actually range between 13.7% - 22.9% -- clearly an impact well beyond the envisioned 4%, and one that could leave some oncology practices with no choice but to close their doors.

We therefore urge CMS to refrain from implementing such a policy at any point in time. Amplifying the cost of drugs needed to fight cancer by downward or upward percentages would create perverse results, undermining the interests of Medicare beneficiaries and the fundamental goals of the Medicare program. In fact, the goals of MACRA as enacted by Congress can only be realized by excluding drug reimbursement from the downward or upward MIPS adjustments, and the Secretary has clear authority to delay or exclude Part B drugs from MIPS adjustments.

Oncology providers play a critical role in providing patients with access to drugs used in anticancer regimens, especially drugs that are delivered via infusion or injection. In 2003, Congress replaced the average wholesale price (AWP) formula for determining Part B drug reimbursement rates with the average sales price (ASP) formula as part of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA). A key goal was to help control the costs of single source drugs while facilitating price competition for multi-source generics.
As part of this change, Congress included a 6 percent add-on to the underlying ASP-based payment to address a number of costs that are not otherwise reimbursed by Medicare. These otherwise unreimbursed costs include:

- Operating practice pharmacies that enable safe storage, mixing, and administration of increasingly complex drugs and biologics to patients;
- Uncovered wastage and breakage for drugs;
- Differences between ASP and the actual acquisition cost of the drug; and
- Time spent with patients to obtain financial assistance.

The potential adverse impacts of applying the MIPS adjustment to oncology drugs are evident from the experience under sequestration. Since the MMA, budget sequestration has resulted in a 2 percent reduction in overall Medicare payments since 2012, bringing payment for Part B drugs to ASP plus 4.3 percent. Medicare payments for drugs used in anticancer regimens are further eroded because the calculation of ASP includes prompt pay discounts negotiated between the manufacturer and distributor, but these discounts are not passed on to the individual oncology practices. By some estimates, this reduces the effective value of the ASP add-on by one-third for community-based oncology practices.

As a result of these pre-existing downward pressures, virtually every community-based oncology practice currently experiences daily situations in which a dozen or more medically necessary drugs that play vital roles in anticancer regimens are “underwater.” A drug is considered underwater when the Medicare reimbursement rate is insufficient to cover its acquisition cost. Oncology providers do not control drug prices, and the harsh reality is that those who practice in community-based settings are unable to acquire all medically necessary anticancer drugs at a price equal to or less than the current ASP-based reimbursement rate.

This experience helps highlight why it would be untenable for CMS to apply the percentage-based penalties arising under MIPS to Part B drugs administered by medical oncology providers. The potential reductions or penalties envisioned under MIPS could quickly render the provision of anticancer drugs financially impossible in virtually any community-based oncology practice subject to a reduction under MIPS. For many oncology practices subject to MIPS penalties, the entire range of oncology drugs could be financially underwater. These practices could be unable to administer cancer drugs to their patients.

Exacerbating patient access barriers to anticancer drugs is not a trivial matter because Medicare beneficiaries with cancer are often frail and unable to travel to alternative facilities outside of their community to receive drug infusions as part of an ongoing treatment regimen. These challenges are most extreme in rural and underserved areas. Further, community-based physician practices often provide the most cost-effective alternative for oncology care. Diverting more patients to more expensive care settings—such as hospitals—is inconsistent with the goals of MACRA. We also question whether CMS or Congress ever intended to
magnify the most generous bonuses available under MIPS by the annual cost of medically necessary anticancer drugs.

There are viable alternatives for incorporating value and financial considerations into the assessment of oncology care, but the use of raw, unadjusted cost data for oncology drugs would create perverse incentives and impose counterproductive penalties on providers serving vulnerable groups of Medicare beneficiaries with cancer.

We commend CMS for proposing to place zero weight on the cost performance category during the 2018 reporting year, and we urge CMS to finalize this proposal. However, CMS should go further and exempt cancer drugs from the cost performance category of MIPS—unless or until CMS produces one or more methodologies that fairly and accurately assess oncology resource use. This is critically important for cancer care providers because the existing cost measurement methodologies are inadequate for oncology-focused practices. CMS currently has an active and well subscribed pilot in the field, the Oncology Care Model. We encourage CMS to exempt cancer drug costs from the cost performance category of MIPS until the results from this important pilot our available.

Cancer is not a single disease. Rather, the word “cancer” refers to many different diseases that are often complex to treat, requiring highly individualized treatments that are selected on the basis of the patient’s cancer morphology, cancer stage, genetic characteristics, mutation status, comorbidities, and patient preferences. Individual physicians or oncology practices may specialize in treating patients with particular oncology diseases—comprised of cancer morphology, stages, and genetic mutations—that are especially complex and expensive to treat. To protect the most vulnerable beneficiaries in the Medicare population, CMS must ensure that any resource use methodology accounts for these considerations without rendering sub-specialization in the treatment of complex forms of cancer financially non-viable.

Clearly, no clinician should be penalized for giving the right treatment to the right patient at the right time—even if the treatment is more expensive than other, less-valuable interventions. The cost measurement in MIPS must be refined to avoid violating this important principle in the area of medical oncology.

CMS should adhere to the following principles to establish and ensure a fair and accurate assessment of cancer costs under MIPS that promotes the interests of Medicare beneficiaries and the Medicare program.

- **Oncology Clinical Pathways:** CMS should measure adherence to high quality oncology clinical pathways as a high stakes quality metric in lieu of using raw, unadjusted oncology cost data for anticancer drugs as a component of the resource category for medical oncology under MIPS.

Private insurers are embracing the use of oncology clinical pathways that incorporate both the evolving scientific evidence and considerations of cost and value. The Medicare
program should adopt the best practices arising from the private sector, subject to the patient safeguards that are well-described in the clinical literature authored by ASCO volunteers.

Requiring medically appropriate adherence to high quality oncology clinical pathways in lieu of measuring Part B or Part D drug costs would better align MIPS with the interests of Medicare beneficiaries and the Medicare program and should be assessed specifically as a quality metric. CMS should exclude Part B and Part D drugs from direct measurement in resource use when medical oncologists follow high-quality clinical pathways developed in accordance with standards for robustness and transparency.

- **Oncology Drugs**: If CMS proceeds with using cost data from Medicare claims as a measure of cost performance in MIPS, the costs of Part B and Part D drugs must be excluded or adequately risk-adjusted.

Medical oncologists do not control the cost of drugs, but the selection of the most appropriate anticancer drug regimen often depends on the unique characteristics of the individual patient, including the cancer morphology, cancer stage, genomic characteristics, mutation status, patient comorbidities, and patient preferences.

There is significant variation in the costs of oncology drugs, but in many instances, an expensive drug may not have a less expensive alternative that is clinically interchangeable—that is, a cheaper drug often does not exist that provides equivalent odds of a desirable outcome. The cost of care associated with an individual oncologist or oncology practice often depends primarily on the characteristics of the patient population they serve, and CMS officials must be cautious to avoid eliminating or undermining medical oncology practices that serve vulnerable patient populations with complex medical conditions.

An appropriate risk adjustment system for oncology must include data beyond the information traditionally captured on Medicare’s administrative claims. Although existing standards (such as the HCC system, discussed in greater detail below under “Additional MIPS Issues”) are woefully inadequate for use under MIPS for oncology-focused practices, ASCO staff and volunteers would be pleased to work with CMS officials to develop an appropriate risk-adjustment system for oncology under MIPS. Also, as mentioned above, CMS currently has a pilot in the field (the Oncology Care Model, OCM) that attempts to answer some of these questions associated with risk adjustment and other complex issues, so we would urge CMS to take into account this additional data before introducing untested models.

- **Oncology Episodes of Care**: We support efforts to develop oncology-specific episodes for evaluating resource use under MIPS.
  Oncology episodes should focus on different phases of oncology care, as individual patients may or may not transition through several different phases of care that have significantly different resource requirements. For example, the applicable phases for medical oncology
resource use could include the following: 1) initial diagnostic phase; 2) primary intensive phase (curative or palliative); 3) secondary or subsequent intensive phase (curative or palliative); 4) post-therapy surveillance phase; 5) long-term survivorship phase; and 6) active end of life care.

Constructing clinical oncology episodes that are verifiable, risk adjusted, and comparable would require CMS to seek information beyond its administrative claims data, including information about a patient’s cancer type, cancer stage and molecular markers. Slight differences in these variables can result in wide variances in the cost of care.

We urge CMS officials to work closely with ASCO’s staff and volunteers to develop solutions that address these primary requirements.

**B. Additional MIPS Issues**

ASCO supports the concept of providing additional points to MIPS scoring based on the complexity of services provided, but the proposal to base these bonuses on the HCC system is fundamentally flawed.

In the proposed rule, CMS proposes to add a “complex patient bonus” to the final score for MIPS eligible clinicians. CMS would calculate the amount of that bonus using an average HCC risk score per clinician or group. The proposed complex patient bonus would be capped at 3 points. The proposal would rely on average HCC scores for specialties. The average HCC score for hematology/oncology would be 1.92 and the average risk score for all specialties would be 1.75 (range: 1.24 to 3.05).

ASCO strongly supports the concept of a bonus based on the complexity of services, but the CMS proposal is fundamentally flawed. ASCO has carefully studied the HCC system over the past year and it is inappropriate for application to oncology. The complexity of treating several common cancers has increased significantly since the creation of the HCC system, and the entirety of all cancer care has been condensed into only five HCCs. Further, while oncology specialties were deemed higher risk than 73% of specialties (49 of 67), it is impossible to predict what functional role an absolute two-tenths of a bonus point over the average would have on standardizing risk according to MIPS. If CMS proceeds with the proposal to use HCC scores as a bonus, CMS should first validate its relevance as an appropriate corrective factor.

Patients who face challenging socioeconomic conditions or other disparities have worse outcomes than patients not facing these challenges; these patients require complex management and extensive practice resources. Practices serving large numbers of such patients should be acknowledged with additional MIPS points. Such practices may be located in rural or underserved areas or in inner cities, and are often the only access point for cancer treatment that is viable for a patient. Providing additional MIPS points to physicians in such practices will help ensure that all patients have access to cancer care that is affordable and convenient.
ASCO urges CMS to promote the use of measures that are clinically relevant to cancer care by eliminating any preapproval requirements for measures that are supported by qualified clinical data registries that are not included in the MIPS measure set.

Qualified Clinical Data Registries (QCDRs) are reporting tools that allow MIPS eligible clinicians to report performance data across the quality, improvement activity and advancing care information performance categories in MIPS. ASCO appreciates the Agency’s recognition of the importance of QCDRs to a value based health care system by allowing their use for data reporting in each MIPS performance category.

ASCO has spent several years developing and implementing a QCDR called the Quality Oncology Practice Initiative (“QOPI”), which successfully self-nominated for participation as a QCDR in MIPS in 2017. By focusing on measures that have the potential to influence day-to-day practice, rather than capturing measures of broad applicability, QCDRs are able to contribute to meaningful quality improvement and realize significant gains for the Medicare program.

Congress has specifically recognized the importance of QCDRs to a value based health care system on multiple occasions. In the American Taxpayer Relief Act of 2012, Congress created a provision allowing QCDRs to be used in lieu of traditional PQRS reporting so that physicians could report and receive performance credit on quality measures that were clinically applicable to their practices. Congress further acknowledged the importance of QCDRs in MACRA by exempting QCDR generated quality measures from many of the requirements that conventional MIPS quality measures must meet for inclusion on the MIPS measure list.

However, in the regulatory implementation of MACRA, CMS imposed burdensome requirements where QCDRs must receive approval from CMS before deploying a QCDR developed quality measure that can be used by a clinician for MIPS credit. ASCO is disappointed that CMS did not take the opportunity to correct its flawed approach from 2017 in its proposal for 2018. In fact, the Agency seems to have moved in the direction of greater control over the development and implementation of QCDR measures by requesting comments about future proposals to require full reliability and validity testing before a measure can be implemented in MIPS. CMS should not risk undermining the potential capabilities of the QCDR program by micro-managing QCDR measures. Instead, the Agency should focus its QCDR oversight on evaluating the QCDR’s measure development methodology during the self-nomination process.

CMS should expand its quality measure validation process to QCDR and EHR based quality reporting to support the adoption and use of new reporting mechanisms by MIPS participants and to avoid unfair applications of the validation process.

The Agency should extend its validation process policies to the QCDR and EHR reporting mechanisms to ensure that MIPS participants that select a QCDR or EHR to report quality data are not unfairly disadvantaged. The validation process allows CMS to assess whether clinicians that report less than six quality measures have done so because there are not sufficient
clinically relevant quality measures available that reflect their practices. If the validation process is applied and CMS finds there are not additional measures that a clinician could have reported, the Agency will adjust the denominator for the quality score to reflect the lack of relevant measures. Under the proposed rule, CMS would only apply the validation process to claims and registry based quality submissions and exclude EHRs and QCDRs from the validation process.

This policy is problematic because it will decrease participation in QCDRs and EHRs when there are not sufficient clinically relevant quality measures available. The urgency of this concern is driven by the difficulties that QCDR stakeholders, including ASCO, have had in getting new MIPS measures approved by CMS for use in MIPS. Further, even among specialty-specific reporting mechanisms such as QCDRs, less than six clinically relevant measures may be available for clinicians that specialize in specific cancers or other subspecialties. These burdens undermine the potential of QCDRs and EHRs offer to facilitate end-to-end electronic reporting. By expanding the validation process to QCDRs and EHRs CMS will help to avoid any potential chilling effects on participation due to concerns that sufficient measures may not be included in either mechanism. If CMS’ validation process cannot, for technical or process reasons, be applied to the QCDR and EHR reporting mechanisms, CMS should consider allowing providers reporting through these mechanisms to attest that they have reported all available and applicable measures and their denominators adjusted accordingly.

ASCO strongly supports the Agency’s plans to include the ASCO Quality Training Program and QOPI Practice Certification for credit in the MIPS improvement activities performance category. CMS should award the full 40 practice improvement activity points for participation in the ASCO Quality Training program or achieving QOPI Practice Certification.

By providing evidence-based quality improvement programs, ASCO actively assists thousands of clinical oncologists to improve the quality of care they provide to Medicare beneficiaries and other individuals with cancer. We urge CMS to finalize its plans to include ASCO’s Quality Training Program and Quality Oncology Practice Initiative (QOPI) Certification Program to the practice improvement category inventory and to expand its inventory of practice improvement activities to include additional evidence-based quality improvement initiatives in oncology.

CMS should award the full 40 practice improvement activity points for participation in the ASCO Quality Training program or achieving QOPI Practice Certification. The ASCO Quality Training program is a 6-month course designed to measure performance, investigate quality and safety issues and implement change among oncologists. The QOPI Certification Program is an oncology-specific practice improvement program that helps outpatient oncology practices evaluate the quality of care they provide and facilitate continuous quality improvement. Achieving QOPI Certification requires a practice to submit data for core measures across five cancer-specific domains, achieve a minimum overall quality score, comply with 20 certification standards (including chemotherapy preparation and delivery) and adhere to annual QOPI methodological requirements. QOPI Certification also requires an on-site review, ensuring that the accreditation standards have been met. This rigorous review methodology has
demonstrated consistent improvement in adherence to clinical practice standards, and should be recognized by CMS as a mechanism to achieve the full 40 points under the CPIA performance category annually for each 3 year certification period.

We commend CMS for proposing to recognize leadership in clinical trials within the inventory of MIPS improvement activities. We support this proposal, but we urge CMS to broaden the proposal by clarifying that helping patients identify and participate in clinical trials would qualify for recognition as a clinical practice activity.

In the proposed rule, CMS announced its intention to include “leadership in clinical trials, research alliances, or community-based participatory research” within the proposed inventory of clinical practice improvement activities. Beyond the important role that clinical trials play in research, clinical trials often provide individuals with cancer with their best clinical options, and as a result, the vast majority of payers (including Medicare) cover most of the costs associated with an individual’s participation in a clinical trial. In short, access to clinical trials is a critical component of high-quality oncology care.

Nonetheless, helping a patient identify and participate in a clinical trial is often labor-intensive for the physician practice, and clinical trials often result in significant uncompensated or undercompensated costs for oncology providers. CMS should seek to promote patient access to clinical trials, and one tangible way to help overcome barriers to clinical trials is to award points under the performance category for clinical practice improvement activities.

ASCO supports the Agency’s efforts to alleviate the regulatory burdens of electronic health record reporting and to promote opportunities for small and rural practices to achieve success in the Advancing Care Information performance category.

The challenges in creating a robust, standardized and interoperable HIT ecosystem have been well documented. ASCO applauds CMS’ efforts in continuing a phased and gradual implementation of the Advancing Care Information performance category within the MIPS program. Specifically, the Agency’s proposals to delay the deadline for adopting 2015 Edition CEHRT, continuing a 90 day reporting period, and establishing a hardship exception for small practices and practices located in rural areas and health professional shortage areas will enable increased participation and success in MIPS by physicians.

As the Agency notes in the preamble, many MIPS eligible physicians, including oncologists, use EHR systems that are designed to support specialty practice, like oncology. This specificity often leads to a difficulty in obtaining market share, and as a result, EHR vendors and practices are left with fewer resources to implement required updates in technology on tight deadlines. The Agency has properly recognized that these constraints should not undermine the viability of specialty-specific products that support care for certain disease states. ASCO supports the Agency’s proposal to delay the deadline for full adoption of a 2015 Edition CEHRT beyond 2018 to allow the maximum number of oncologists to continue to earn positive scores within the ACI performance category.
CMS should finalize the proposal to continue the 90 day reporting period for the ACI performance category. Given the significant administrative burdens that practices have incurred in adjusting to MIPS, a gradual implementation continues to be necessary to guard against an inappropriate diversion of practice resources away from patient care to meet overly ambitious regulatory requirements.

ASCO continues to support efforts to alleviate significant burdens on practices that are small or focus on underserved populations. As noted in past comment letters, community oncology practices are essential components of the overall cancer care infrastructure in the United States. In many instances, a community practice located in a rural or underserved area offers the only access point for cancer treatment that is viable for a patient. Protecting these practices through a hardship exemption will strengthen community practice and ensure that all Americans have access to cancer care that is affordable and convenient.

We applaud CMS for proposing to implement virtual groups in 2018 allowing small and independent oncology practices to benefit from the collaborative and technical aspects of group reporting in MIPS. CMS should also expand this concept to permit groups of oncologists (and other specialists) within large multispecialty practices to form their own virtual groups, enabling such oncologists to focus on measures and activities that are most relevant to the care of their patients.

We are pleased that CMS proposed virtual group reporting in 2018 to allow small and solo oncology practices to collaborate in reporting MIPS data. In oncology, group reporting is critical to permitting adequate assessment of the quality and costs associated with delivering high-quality care. Due to the inherent complexities of cancer disease states, individual providers do not routinely amass enough cases to form valid sample sizes to draw reliable conclusions. This challenge is best addressed by working together through group reporting and related activities.

We urge CMS to finalize its proposal involving virtual groups, and we urge CMS to provide as much flexibility as possible for implementation of this proposal. We also urge CMS to explore and finalize a policy that would enable groups of oncologists within large multispecialty practices to form their own virtual group within that practice. Such flexibility would permit more oncologists to focus their efforts under MIPS on measures and activities that are directly related to the determinations that are under the direct control of the oncology team and would better incentivize high quality cancer care. Through the OCM, CMS has developed the mechanism to create such virtual groups and we would encourage considering that methodology here.

We support the proposal to increase the low-volume threshold to help mitigate the adverse impacts of MIPS on small practices, especially in rural and underserved areas.

Independent community oncology practices are critical elements to the American cancer care delivery system, providing patient access to high quality care at an affordable cost. However,
these practices face significant regulatory and financial challenges to continue operations. These challenges are especially significant for small practices.

We urge CMS to finalize its proposal to extend the low volume threshold exclusion to include practices with up to 200 Medicare Part B beneficiaries under per year. We also urge CMS to exclude Part B and Part D drugs and raise the alternative dollar limit threshold as proposed to $90,000. As stated earlier, including drug costs creates a distortion very particular to oncologist and a few other specialty groups. These costs represent predominantly pass through costs as set by law (94% and sometimes over 100% for underwater drugs) and are not reflective of the actual financial activity of practices. Taken in combination, these changes would help ensure the ongoing viability of community oncology practices in rural and underserved communities by not “penalizing” them for the rising costs of specialty drugs for which they have limited control of from which they see little if any financial benefit.

II. Alternative Payment Models; Physician Focused Payment Models

ASCO strongly urges the Innovation Center to implement additional oncology-focused APMs, such as the Patient-Centered Oncology Payment (PCOP) model, to provide flexibility to oncologists to choose the best option for their patients and their practices. Given the significant morbidity, mortality and financial expenditures arising from cancer in the Medicare population, CMS should avoid a narrow approach that fails to test more than one oncology-focused APM option to meet the needs of the diverse Medicare population.

CMS should embrace oncology-focused Advanced APMs that differ from the Oncology Care Model (OCM), and CMS should remain open to implementing additional oncology-focused models on a timely basis through the Physician Focused Payment Model pathway.

Multiple oncology-specific APMs are needed to enable oncologists to select the optimal approach for their patients and their practices to survive in a value-based payment environment and to facilitate the oncology community’s transition out of MIPS. The Oncology Care Model (OCM), which is currently in place through the Innovation Center, is certainly one such approach that has drawn participation from a large number of practices. This is a testament to the hunger that oncologists have for moving from the current Fee for Service system. However, as illustrated throughout this proposed rule, there is a deep need for testing multiple creative solutions for defining episodes, and dealing with specialty drug costs in the rapidly changing environment of personalized cancer care. It would be a wasted opportunity if only one model were allowed to be tested.

Therefore, additional approaches to reforming oncology payment are needed and should be tested by the Innovation Center. We strongly support testing ASCO’s Patient-Centered Oncology Payment (PCOP) model that will soon be under consideration by the PTAC alongside the OCM so oncologists are able to participate in an alternative approach to oncology payment reform. Medicare’s need for additional oncology APMs is critical, since cancer is extraordinarily
complex and over half of the new diagnoses of cancer in the United States occur in individuals older than 65.

PCOP differs from the OCM by supporting the full range of resources necessary for oncology providers to plan, coordinate and manage cancer treatments, while focusing on efficient utilization of resources, avoidance of ineffective spending, and reduction in unnecessary hospital visits. We welcome the opportunity to continue to discuss implementation of PCOP with the Innovation Center to provide an alternative pathway for oncology APM participation.

Although we recognize the Agency has limited resources, all ideas and proposals should be welcomed by the PTAC regardless of the existence of other payment models within the CMS portfolio. Failure to provide an open process to new and innovative ideas developed outside of the Agency, even in areas where CMS has implemented an APM, will dramatically undermine the ability of CMS to transform the health care system.

III. Data Transparency

CMS should promote greater transparency and permit private stakeholders access to the 100% version of the Carrier Standard Analytic File (SAF) to permit full analysis and inform comments on the consequences of changes to Medicare reimbursement systems.

As part of its ongoing efforts to improve transparency in the Medicare program, CMS has been seeking to release more data for stakeholders to understand and analyze the impact of changes in Medicare policies. We strongly support these efforts, but we believe that improvements are necessary to aid physicians seeking to project the impact of MIPS, APMs and other provisions of MACRA. In particular, we believe that a 100 percent version of the Standard Analytic File (SAF) containing physician claims should be released as a limited data set to allow private sector researchers to assess the proposals that CMS has advanced in these areas.

Most of the SAFs that CMS releases are available in 5 percent or 100 percent samples of Medicare beneficiaries. However, CMS has thus far declined to release a 100 percent version of the Carrier SAR – the file that contains physician claims. The Agency’s stated reason for this policy is that the size of the 100 percent file would be too large, but today changes in storage and reduction in computing power costs have made size issues less meaningful. Moreover, the ability of stakeholders to analyze the impact of the changes CMS will be implementing under MACRA is significantly limited without access to a 100 percent file. Many of the changes CMS has proposed will have differential effects across physician practices and specialties. This impact cannot be effectively modeled using a 5 percent sample of beneficiaries. A 100 percent Carrier SAF – made available in limited data set form to entities willing to enter Data Use Agreements and abide by CMS policies on data release – is a necessary addition to the Agency’s growing transparency efforts.
We urge CMS to make the 100% Carrier SAF file available to the public to improve the ability of ASCO to interact with CMS about the policies being implemented in this proposed rule, as well as advancing other policies to improve and modernize the Medicare program.

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Thank you for the opportunity to provide comments on this proposed rule. We urge CMS to continue to work closely with ASCO and other stakeholders throughout the implementation process to ensure adoption of a fair, transparent and adequate reimbursement methodology for oncologists and other physicians. Please contact Sybil Green at Sybil.Green@asco.org or 571-483-1620 with any questions.

Sincerely,

Bruce E. Johnson, MD, FASCO
President, American Society of Clinical Oncology