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Washington, D.C. 20515

October 28, 2022

Dear Representatives:

The Association for Clinical Oncology (ASCO) is pleased to provide input on your Request for Information regarding the implementation of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), and associated payment mechanisms.

ASCO is a national organization representing physicians who care for people with cancer. With nearly 45,000 members, our core mission is to ensure that cancer patients have meaningful access to high quality, equitable cancer care.

ASCO supported the passage of the MACRA as a replacement to the flawed Sustainable Growth Rate (SGR) formula for Medicare physician reimbursement. Since its enactment, ASCO provided extensive education to its members as well as significant input to the Centers for Medicare and Medicaid Services (CMS) around necessary refinements to the program to make it work for both their practices and the Medicare beneficiaries they serve. Unfortunately, we still face much of the uncertainty MACRA was intended to address, and there is ongoing financial instability within the Medicare payment system.

We are encouraged by your interest in addressing current challenges and look forward to working with you on ways to stabilize the Medicare payment system. We offer to be an ongoing resource for you as you evaluate MACRA's effectiveness and the transition to a value-based payment system.

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ASCO's History of Quality Improvement

Since its founding, our affiliate organization, the American Society of Clinical Oncology (ASCO), has been dedicated to delivery of high quality, high value care for every patient with cancer—every day, everywhere. The Society has a wide range of resources and programs aimed at improving the standard of cancer care received by patients in the United States and around the world.

Oncology care is entering a time of unprecedented progress in both understanding and treatment of cancer. However, today's practice environment is facing significant disruption, which threatens oncologists' ability to deliver the benefits of that progress. Ongoing consolidation of practices, escalating cost of care, workforce shortages and physician burnout are on the rise and administrative burden has never been greater. As cancer care professionals navigate these challenges, they are looking for models that enable delivery of high quality, high value cancer care—a framework that supports success regardless of payment arrangements and other administrative policies.

In response to this need, in July 2021, the Society launched its ASCO Patient-Centered Cancer Care Certification initiative. This is a two-year pilot promoting the oncology medical home as an effective approach to assuring every patient with cancer achieves the best possible outcome for their disease. It offers oncology group practices and health systems a single set of comprehensive, expert-backed standards for patient-centered care delivery.

The pilot is based on oncology medical home (OMH) standards from the American Society of Clinical Oncology and the Community Oncology Alliance (COA). These standards establish core elements needed to deliver equitable, high-quality cancer care and offer all stakeholders clarity on elements they should expect to see from cancer care teams. The OMH standards focus on seven different domains of cancer care, including patient engagement; availability and access to care; evidence-based medicine; equitable and comprehensive team-based care; quality improvement; goals of care, palliative and end-of-life care discussions; and chemotherapy safety.

The pilot includes 88 cancer care sites and nearly 500 oncologists from 12 participating practice groups and health systems in a variety of settings, including community, hospital, and academic settings. Two commercial insurers are participating in this pilot and others have expressed strong interest. Participating practices use the ASCO Quality Reporting Registry (AQRR) for ongoing measurement of quality, outcomes, and utilization measures. Performance data are derived from electronic health records, insurance claims, patient satisfaction surveys, and clinical pathways systems.

Practices meeting the rigorous ASCO-COA Oncology Medical Home Standards will be certified by the ASCO Certification Program. Certified practices are expected to sustain adherence to the ASCO-COA OMH standards demonstrated through ongoing assessment and improvement activities monitored and evaluated by the ASCO Certification Program.

Additionally, the QOPI Certification Program™ provides a three-year certification recognizing high-quality care for outpatient hematology-oncology practices within the United States and in

certain other countries. Its primary focus is safe delivery of chemotherapy in the outpatient setting. Practices receive QOPI Certification based on their full compliance with QOPI Certification Standards as assessed during an on-site survey.

ASCO members have developed and embraced these quality improvement programs since they were developed. Quality improvement builds on the Society's longstanding and well-regarded programs in education, clinical guidance, and research.

Enhancing Oncology Model

This summer, the Center for Medicare and Medicaid Innovation (CMMI) announced a new, 5-year voluntary oncology payment model, the Enhancing Oncology Model (EOM), to begin on July 1, 2023. Participating oncology practices will take on financial and performance accountability for episodes of care surrounding systemic chemotherapy administration to patients with seven common cancer types: breast cancer, chronic leukemia, small intestine/colorectal cancer, lung cancer, lymphoma, multiple myeloma, and prostate cancer. EOM participants will be responsible for the total cost of care during a 6-month episode and will elect to participate in one of two, two-sided financial risk arrangements.

EOM employs specific design elements, including comprehensive, coordinated cancer care; data-driven continuous improvement; payment incentives, including a Monthly Enhanced Oncology Services (MEOS) payment and a performance-based payment (PBP) or a performance-based recoupment (PBR); an aligned multi-payer structure; and focused efforts to identify and address health disparities.
EOM participants will be required to implement participant redesign activities, including 24/7 access to care, patient navigation, care planning, use of evidence-based guidelines, use of electronic Patient Reported Outcomes (ePROs), screening for health-related social needs, use of data for quality improvement, and use of certified electronic health record technology. As part of the data reporting for quality improvement, EOM participants will also submit health equity plans to CMS, where participants will detail evidence-based strategies to mitigate health disparities identified within their beneficiary populations.

ASCO is pleased that CMMI is proposing EOM as a voluntary model and that practices will be able to choose to participate based on their level of readiness and ability to assume financial risk. We also fully support CMMI's focus on equity and coordinated cancer care. The cancer care delivery requirements of the CMMI EOM have many similarities with ASCO-COA Oncology Medical Home Standards and the ASCO certification pilot. Practices achieving ASCO Patient Centered Cancer Care Certification will be well positioned to succeed in the EOM.

We are concerned, however, that CMMI has proposed a sizeable reduction in MEOS payments compared to similar payments in the Oncology Care Model (OCM). This is especially concerning given that there will be a gap of a year between the end of OCM and the start of EOM, during which time practices will receive no additional support for the mechanisms instituted during OCM to enhance patient access and care coordination that will continue under EOM. The reduced MEOS payments may

discourage those groups who did not participate in the OCM from considering the EOM, as the limited MEOS may not cover the practice redesign efforts needed in this model with financial risk.

The EOM and its precursor, the Oncology Care Model (OCM), laid the foundation for practice transformation critical to practices surviving and thriving in the years ahead. We are eager to work with CMS to leverage what worked in OCM, and refining the EOM, so it enables the care patients need and deserve. While OCM prompted practice changes that enhance patient centered care, those changes cannot be sustained—or broadened to other practices—without a regulatory and payment framework that supports them.

Below are areas of improvement we believe are vital to achieving high value, high quality care for all patients with cancer.

1. **The Effectiveness of MACRA**

Congress must address the lack of sufficient payments within the Medicare Physician Fee Schedule.
In repealing the Sustainable Growth Rate (SGR), MACRA specified a 0% update to the Medicare Physician Fee Schedule (MPFS) Conversion Factor (CF) for a period of six years, followed by a 0.25% annual increase for MIPS participants and a 0.75% annual increase for Advanced APM participants thereafter. While Congress provided temporary relief in 2021 and 2022, the CF is expected to decrease by 4.42% in 2023. ASCO strongly supports the *Supporting Medicare Providers Act of 2022* (H.R. 8800), which would address the 4.42% CF cut and urges Congress to pass it before the end of the year.

Failure of the MPFS to keep up with increasing labor, supplies, rent, and other practice expenses influences a growing site-of-service shift from independent physician practices to off-campus outpatient hospital departments paid for by the Outpatient Prospective Payment System (OPPS). Rather than addressing the lack of sufficient payment under the MPFS, Congress directed CMS to reduce payments to new off-campus outpatient hospital departments, thereby encouraging further shifts into on-campus departments. Rather than encouraging value-based care, this consolidation results in reduced beneficiary access to community-based healthcare services. **Congress must ensure that future payment updates within the MPFS are sufficient to sustain beneficiary access to community-based physician care.**

2. **Regulatory, statutory, and implementation barriers that need to be addressed for MACRA to fulfill its purpose of increasing value in the U.S. health care system**

Congress should re-examine the budget neutrality and exceptional performance bonus under MIPS.

For payment year 2021, there were a total of 954,664 Merit Based Incentive Payments System (MIPS) eligible clinicians under the Quality Payment Program MIPS track.[1] Out of them, 951,744 (99.7%) avoided a negative payment adjustment. Almost 84% achieved exceptional performance and earned positive payment adjustments ranging from +0.09% to +1.79%. It is critical to note that only those clinicians scoring high enough to earn an exceptional performance bonus actually received any positive

payment adjustment. Clinicians who received a positive score, but did not reach the exceptional threshold, received a payment adjustment of zero percent. This is due to the budget neutrality requirement of MIPS as established by MACRA. As only 0.31% of clinicians received a score below the threshold (and received a 7% penalty), the only real source for a positive payment adjustment came from the $500 million annual "exceptional performance" bonus. With the sunsetting of the ability to earn this bonus in 2022, it is very likely that high-scoring clinicians participating in MIPS going forward will receive little to no positive adjustment through MIPS; this is compounded by the 0% statutory update to the MIPS track until 2026 and the lack of an inflationary update to the MPFS.

When the MIPS track of the QPP was originally envisioned, it was thought that a budget neutral system would provide rewards to high performers, while penalizing low performers. Experience has shown us that small and rural practices disproportionately bear the burden of growing penalties, which in the aggregate are far too small to result in any meaningful distribution to higher performers. The budget neutral nature of MIPS should be re-examined, as should the exceptional performance bonus.

Congress should provide access to claims data to clinical data registries and provide more timely access to data to practices.

Section 105(b) of MACRA required the Secretary to provide Medicare claims data to qualified clinical data registries (QCDRs) "for purposes of linking such data with clinical outcomes data and performing risk-adjusted, scientifically valid analyses and research to support quality improvement or patient safety." Rather than providing a straightforward pathway for registries to access this data, CMS instead required that QCDRs become "quasi-qualified entities," essentially having to use the ResDAC pathway to access this claims data. The many roadblocks in this process have been detailed in a letter from the Physician Clinical Registry Coalition (PCRC) in response to this RFI; we encourage you to review the recommendations laid out in that letter, as CMS has proved unwilling to consider options that would align with the spirit of the claims data provision and is thus hindering the ability of registries to link claims data to outcome data.

Additionally, as mentioned above, access to data is a problem for practices. In order to engage in continuous self-examination and improvement, practices need access to claims and performance data on frequent and timely basis. Even for those practices participating in value-based payment models, many months may elapse between the time services are provided and when a practice receives claims data or other feedback. Roadblocks to the timely provision of data from CMS to practices should be identified and removed.

3. How to increase provider participation in value-based payment models

Congress should extend and improve access to incentive payments for participation in eligible alternative payment models.

MACRA provided for a payment incentive to qualifying advanced alternative payment model (APM) participants (Qualified Participants, QPs) equal to 5% of estimated aggregate payment amounts for

covered professional services. The incentive payment was intended to encourage participation in advanced APMs and has proven to be critical in assisting physicians to develop the infrastructure necessary for the transition to value-based payment models.

Unfortunately, the combination of a lack of specialty-specific advanced APMs, financial uncertainty amid the COVID-19 pandemic, and delays in rollout of certain APMs (e.g., Oncology Care First, now named Enhancing Oncology Model (EOM)) has resulted in many physicians being unable to qualify for this incentive. The payment incentive ends in 2024; given a two-year lag in payment by CMS, this means that 2022 is the last year under which participants may qualify for the incentive. **Congress should either extend the incentive payment until 2030 and/or extend the incentive payment indefinitely and allow physicians to earn the incentive for up to six years.**

Further, to qualify for the eligible alternative payment model incentive, physicians must meet either the Medicare Payment Threshold Option or Medicare Patient Threshold Option. These thresholds are meant to ensure that physicians meaningfully participate in alternative payment models. Under the currently specified thresholds, many specialty physicians will find it difficult to qualify. For example, oncologists who participate in a Medicare Shared Savings Program (MSSP) Accountable Care Organization (ACO) naturally have lower payment and patient threshold scores due to receiving referrals from primary care physicians outside of the ACO. As a result, many ACOs are considering whether to remove specialists from their participating physician lists so that the remaining physicians may be deemed Qualified Participants.

Even within specialty-specific models, specialists may find that that the limited scope of models—the EOM includes only seven cancer types—makes it difficult to meet the specified thresholds. **Congress should extend the current 50% payment threshold and 35% patient threshold. Congress should also direct CMS to remove barriers to participation in multiple APMs, such as allowing a single practice (identified by a Tax Identification Number) to participate in multiple ACOs.**

Congress should direct CMS to expand access to current and planned APMs and provide a transition period for new participants to adjust to APM requirements.

Unlike the Shared Savings Program, which features an annual signing event, many APMs operated by CMS feature only a single opportunity for physicians to elect participation. For example, physicians wishing to participate in the EOM had to apply by October 10, 2022 (originally September 10, 2022, but extended by CMS), or else forego participation for the entire five-year duration of the model. Physicians who felt they were unprepared to meet model requirements or financial risk arrangements, or those who establish new practices after October 10, are now unable to access this important APM. **Congress should direct CMS to expand access to current and planned APMs by allowing for annual signing periods for new participants.**

While early APMs allowed for new participants to elect one-sided risk arrangements, recently debuted APMs have required immediate acceptance of two-sided risk (e.g., EOM, Radiation Oncology Model). Physicians are not provided their own baseline performance data until after agreeing to participate in a

two-sided risk arrangement. Recent APMs also require that physicians comply with practice redesign and administrative requirements as early as 90 days following the start of the model. These requirements place physicians in the unfortunate position of taking on unknowable operational and financial risk, or foregoing participation due to onerous conditions. **Congress should direct CMS to allow for a minimum of one year of one-sided risk arrangements for new APM participants and provide performance information for at least one performance period prior to requiring a two-sided risk arrangement.**

Congress should expand access to physician- and professional society-developed payment models and other quality initiatives.

MACRA encouraged development of physician-focused payment models (PFPMs) for incorporation into the Medicare program. Since that time, the PFPM Technical Advisory Committee (PTAC) has received 39 proposals. Our affiliate, the American Society of Clinical Oncology, submitted its Patient-Centered Oncology Payment Model to PTAC in 2020. Contrary to Congress' intent, none of the proposed PFPMs have been implemented by CMS. CMMI lacks the capacity to operate the number of models necessary to meet its goals of 100% of Medicare payments tied to quality and value through adoption of two-sided risk APMs. Medicare would benefit from partnering with the healthcare community and other payers on multi-payer models not necessarily operated by CMMI. **Congress should provide a pathway for Medicare Administrative Contractors to participate in multi-payer models that are not operated by CMMI.**

Burdensome administrative requirements contained within Medicare APMs have become a barrier to adoption. For example, within the EOM, participants must implement eight practice redesign activities; collect and report on quality measurement data, clinical and staging data, and beneficiary-level sociodemographic data; and be subject to on-site audits and other administrative requirements.

Today, physicians who wish to participate in multiple APMs, including those operated by Medicare Advantage payers, are confronted with duplicative and conflicting quality measures, practice redesign activities, data reporting, and other administrative burdens. CMMI's approach to adding an increasing number of administrative requirements for traditional Medicare alone dissuades physician participation.

There are solutions to this issue. For example, as described above, ASCO is piloting a Patient-Centered Cancer Care Certification that includes comprehensive standards for patient-centered care, a rigorous on-site survey and compliance process, and a core set of quality measures that are required for all patients regardless of payment source. If CMMI and Medicare Advantage plans would recognize industry standard certifications and provide certified practices relief from model-specific requirements, it would significantly reduce the administrative burden associated with adoption of APMs. **Congress should direct CMMI to identify opportunities to reduce the administrative burden of APMs and recognize industry standard certifications.**

4. Recommendations to improve MIPS and APM programs

Several of our recommendations above would go a long way to improve MIPS and APM programs, including addressing the untenable administrative and reporting burdens and reimplementing the 5% APM bonus.

Congress Should Ensure Financial Stability and Predictability

Congress should work with CMS to provide financial stability through a baseline positive annual update reflecting inflation in practice costs, and eliminate, replace or revise budget neutrality requirements to allow for appropriate changes in spending growth. The Medicare PFS is the only payment system within Medicare without an annual inflationary update; in fact, data from the American Medical Association shows that, when adjusted for inflation in practice costs, physicians paid under the MPFS have seen decreases in payment of up to 20% over the last two decades.

Under the MIPS track, while a significant portion of providers performed well and will receive positive payment adjustments, the adjustments remain low. The maximum positive adjustment was 2%, as higher positive payment updates have not materialized. Furthermore, this maximum positive adjustment included the $500 million allocated each year for "exceptional performers" and, like the advanced APM bonus, is no longer available after 2022. This rate does not allow providers to keep up with inflation.

The cost to providers continues to increase, particularly in small and rural practices, as the amount of time and money spent on data collection and reporting continues to grow. That often outpaces any increase in MIPS adjustments that they see. It is important for providers to have a clear strategy so that they are not investing in excessive resources. We must reward the value of care provided to patients, rather than administrative activities–such as data entry–that may not be relevant to the service being provided or the patient receiving care. It is clear that under MIPS, the administrative and financial burden of participating outweighs any quality or cost improvements that could be attributed to MIPS participation.

CMS often adjusts requirements and rules with very little time for health information technology (HIT) partners to respond. For example, CMS put forward a new Advancing Cancer Care MVP as part of the 2023 MPFS Proposed Rule released in early July 2022. The final rule will not be released until November 2022; whether this new MVP will be finalized won't be known until then. HIT partners will have only two months to develop the technology to support this new MVP and have it live by January 2023. These unrealistic timelines are costly and put undue pressure on the healthcare system and clinicians. Congress and CMS should seek input from stakeholders to avoid creating additional financial and administrative burdens associated with implementation.

Payment models should invest in and recognize physicians' contributions in providing high-value care and the associated savings and quality improvements across all parts of Medicare and the health care system such as preventing hospitalizations and avoidable emergency department visits.

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Congress Should Offset Cuts to Medicare Part B Reimbursement

The Inflation Reduction Act (IRA), signed into law on August 16, 2022, allows Medicare to negotiate certain prescription drug prices. While ASCO is supportive of the goal of reducing the cost of prescription drug treatments, we are concerned with the unintended consequences of the legislation.

The drug pricing provisions will negatively impact patient access to critical prescription drugs under Medicare Part B. Data from the American Society of Clinical Oncology's PracticeNET show that oncology practices would experience an overall 3% cut to Medicare reimbursement, which would be detrimental to patients and practices, especially in rural and underserved areas. For negotiated drugs, oncology providers can expect a 41.5% decrease in total payments—even accounting for reduced acquisition costs—and by 2027, 38% of all hematology/oncology drugs administered today are expected to be selected for negotiation. The exact impact on a particular practice will depend on the specific services a practice provides.

As with past policies that decreased Medicare Part B reimbursement without full consideration of the ways in which physicians must acquire, store, and provide treatments, the IRA could cause already struggling practices to have to make difficult decisions about the support services they are able to provide or their own viability. This threatens patient access to care and may result in many patients paying more for drugs and medical care—the opposite of what the legislation intended. This is a particularly high risk for Medicare beneficiaries in rural or underserved areas.

Conclusion

Thank you for your commitment to improving the Medicare program. ASCO stands ready to serve as a resource as you continue this much needed dialogue around reforms to the physician reimbursement system. If you have questions on any issue involving the care of individuals with cancer or would like to be directed to ASCO's thoughts on a specific issue noted in this response, please contact Kristine Rufener at Kristine.Rufener@asco.org.

Sincerely,

Lori J. Pierce, MD, FASTRO, FASCO
Chair of the Board