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Medicare Access and CHIP Reauthorization Act of 2015: Examining Implementation of Medicare Payment Reforms

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The American Society of Clinical Oncology (ASCO) is pleased to submit this statement in connection with the hearing titled "*Medicare Access and CHIP Reauthorization Act of 2015: Examining Implementation of Medicare Payment Reforms*" held by the House Energy and Commerce Subcommittee on Health on March 17, 2016. ASCO is thankful to the Committee for its inclusion of the physician community in shaping the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) and looks forward to continued work together with you to see it successfully implemented. ASCO's membership contains nearly 40,000 physicians and other health care professionals dedicated to 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 thanks Chairman Pitts, Ranking Member Green and all members of the House Committee on Energy and Commerce for their attention to the critical role MACRA can play in transitioning Medicare from a volume-based to a value-based payer and the need to guarantee patient access to high-quality, high-value health care for our nation's seniors. We applaud Congress for enacting MACRA and repealing the problematic Sustainable Growth Rate (SGR); however, significant work remains ahead for the Centers for Medicare & Medicaid Services (CMS) and the provider community to implement the Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APMs).

Since the enactment of MACRA, CMS has sought public comments on various aspects of the legislation, including broad comments on MACRA as part of the 2016 Medicare Physician Fee Schedule;

a comprehensive Request for Information that focused on the implementation of MIPS, APMs and physician-focused payment models; two sub-regulatory documents relating to Episode Groups for resource use under MIPS; and the draft Quality Measure Development Plan. ASCO has provided comments on each of these documents, and we will remain actively engaged throughout the MACRA implementation process.

We appreciate the monumental task that CMS has before it, but there are emerging concerns with MACRA implementation that could diminish patient access to cancer care services in the United States and result in arbitrary, unfair and counterproductive reimbursement consequences for oncology specialists. In light of these concerns, we urge Congress and CMS to take steps to ensure that oncologists and other cancer care professionals can provide meaningful access to oncology care for Medicare beneficiaries as well as avoid the pitfalls of the long-troubled SGR formula including the uncertainty of policies and reimbursement rates. We also urge the Committee to direct CMS to continue to work closely with physician specialty societies like ASCO to ensure that new reimbursement methodologies continue to promote quality, community-based patient access to care, and fairness to providers.

I. Merit-Based Incentive Payment System (MIPS)

MACRA requires CMS to implement MIPS, with payment adjustments to providers beginning in 2019 based on their performance across four performance categories: (1) resource use; (2) quality; (3) clinical practice improvement activities; and (4) meaningful use of certified EHR technology. This section discusses ASCO's specific concerns in each of these areas.

(a) Resource Use Measurement

Although we support the transition to value-based payment, we remain concerned that the MIPS methodology for measuring resource utilization could unfairly penalize oncologists that provide medically necessary care with high-costs that are outside of their control. Currently, CMS assesses resource use through the Value-Based Payment Modifier (VBM), which provides too blunt an instrument to protect and promote quality in oncology. To be successful in implementing MACRA, policymakers must learn from and avoid the mistakes made in implementing the VBM.

The treatment of cancer is both clinically complex and highly specialized, creating many factors that must be considered to accurately evaluate medical oncology resource use in a way that protects the interests of patients. There are more than 120 different types of cancer (and through advances in molecular diagnostics, this list is growing), and the most appropriate treatment option for a particular patient often involves the administration of a multi-drug regimen. In many instances, the selection of the most appropriate anticancer drug for an individual patient is based on the fact that there is a single molecular entity without any clinically equivalent substitute that provides a clear clinical advantage for the individual. In these common scenarios, the medical oncologist is left with little flexibility to reduce

drug utilization costs by selecting lower cost alternatives. It is counterproductive to assess a provider's resource use based on Part B or Part D drug expenditures that are outside of their control in this way.

Congress and CMS must not assume that variations in resource needs among patients and medical oncology providers will “average out” over time. It is common for medical oncologists to specialize in treating particular types or sub-types of cancer. There are some physicians and many oncology practices that specialize in treating the most complex—and often most costly—oncology patients. In some of those instances, there will be significant differences in resource consumption compared with other providers. We are especially concerned that if resource use measurement does not account for these clinical differences, CMS may inadvertently unfairly penalize practices and create access barriers for patients with complex and molecularly unique forms of cancer. Congress and CMS should take this situation into consideration for any process used to measure resource use in oncology and should not implement such a process until there is confidence the methodology will adequately protect quality and access to care for patients with these complex illnesses.

Given the factors described above, and because drug pricing is outside of the control of treating physicians, ASCO recommends that Congress and CMS adopt a more nuanced approach for oncology than simply comparing aggregate drug costs under Medicare Part B and Part D. Congress and CMS should exclude the use of raw drug expenditures in resource use determinations. Instead, CMS should assess drug resource use by evaluating adherence to evidence-based, value-based medical decision-making. ASCO endorses the use of high-quality clinical pathways in oncology as a mechanism to assess the provision of such care.

Appropriately designed clinical oncology pathways are detailed, evidence-based treatment protocols for delivering quality cancer care for specific patient presentations, including type and stage of disease. Clinical oncology pathways are a tool that can be used to appropriately align incentives for cancer patients and providers for resource use assessment in cancer care. Pathways are being used by an increasing number of private payers to ensure evidence-based, value-based care for cancer patients. Used in this way, clinical oncology pathways can enable oncologists, payers, and patients to provide assurances that patients are receiving clinically appropriate therapies without unnecessary costs, including drugs. Oncology pathways balance the considerations of clinical efficacy, safety, toxicities, cost, and scientific advances, including the growing personalization of therapy based on molecular diagnostics.¹ Simply put, clinical pathways help to ensure that the right patient gets the right drug at the right time. Since compliance with appropriately designed oncology pathways define optimal care, medically appropriate concordance with pathway programs that have been developed and peer-reviewed by oncologists should be considered a major quality indicator.

¹ Zon RT, Frame JN, Neuss MN, Page RD, Wollins DS, Stranne SK, Bosserman LD. American Society of Clinical Oncology policy statement on clinical pathways in oncology. *Journal of Oncology Practice*. 2016 [epub ahead of print].

In addition to drug costs, ASCO has serious concerns that CMS is failing to implement adequate risk adjustment to assess resource use in a way that fairly addresses differences in resource use among oncologists. Cancer care is incredibly complex and growing more so with each passing year, and the costs of cancer care are highly variable depending on a patient's diagnosis, cancer stage, molecular markers, geographic access to care, comorbidities and other clinical factors. In light of these complexities, it is imperative that CMS develop a risk adjustment methodology that will be specifically used to address cancer care. Traditional administrative claims data alone are insufficient to provide a desirable risk-adjustment methodology.

We urge Congress to provide oversight in this area to ensure that medical oncologists are not subject to unfair resource use measurement due to the clinical complexity of the patient populations they serve.

(b) Quality Reporting

Ensuring that quality reporting is based on a provider's day-to-day practice is essential for MIPS to become a useful tool for quality improvement. We urge Congress to work with CMS to improve quality reporting in cancer care by promoting the use of quality measures that are important to patients and have meaningful impacts on the day-to-day practice of oncology. Failure to promote clinically relevant quality reporting will continue the "check-the-box" reporting attitude of many providers toward the Physician Quality Reporting System (PQRS) used by Medicare today.

We thank Congress for its continued support of Qualified Clinical Data Registries (QCDRs) by requiring their inclusion in MIPS. For more than a decade, ASCO has offered its members the ability to participate in the Quality Oncology Practice Initiative (QOPI), which is designated as a QCDR and focuses specifically on measuring and assessing the quality of cancer care. Congress should ensure that CMS does not weaken the protections in MACRA that exempt quality measures developed for use in a QCDR from many of the measure development process requirements that other MIPS measures will be required to undergo. This exemption is of critical importance because it will give QCDRs, like QOPI, the flexibility to innovate and develop quality measures that are clinically relevant to specialty practice. One outstanding issue of concern, however, is recent clarification we have received from CMS and ONC related to provider reporting of meaningful use. As currently constructed, reporting rules do not allow providers to use the same registry for both PQRS reporting and to satisfy objective 10 of meaningful use (modified Stage 2). This policy puts providers in the position of having to use two registries for the purposes of satisfying the CMS requirements, even if information provided is different for the two reporting requirements. This is counterproductive, particularly at a time when the federal government and the provider community are trying to streamline these processes—and optimize rational use of HIT. If a provider is reporting information from a certified EHR into a registry and that registry is reporting to CMS, it should be considered that the provider is meaningfully using the EHR for purposes of meeting objective 10. Entities like ASCO, who have spent years building and refining its registry and encouraging

members to participate, will be faced with the choice of encouraging use for PQRS or declaring it a specialized registry for purposes of meaningful use. ASCO, along with many others in the provider community, raised this issue at the agency level and hopes for continued support until a resolution is reached.

Finally, it is essential that Congress continue to support the implementation of group quality reporting in QCDRs. The promotion of group reporting is critical for oncology, since individual oncologists will rarely have enough cases, within any given cancer diagnosis, to report data that is statistically valid and representative of practice patterns and overall performance.

(c) Clinical Practice Improvement Activities

The creation of the clinical practice improvement activities category offers an opportunity for CMS to encourage providers to engage in activities that can meaningfully improve the quality of care they provide. ASCO supports an attestation-based system that allows providers and groups to attest to participation in activities that meaningfully improve the quality of care they deliver to achieve the full clinical practice improvement activity score. Some examples of relevant clinical practice improvement activities that are applicable to oncology practice are participation in a QCDR, achieving ASCO's QOPI Certification and provider participation in clinical trials.

(d) Meaningful Use of Certified Electronic Health Records Technology

MACRA requires CMS to evaluate providers based on their meaningful use of certified EHR technology. We thank the Energy and Commerce Committee for its work on the House-passed *H.R. 6, the 21st Century Cures Act* which included a provision to encourage EHR interoperability. The rest of Congress should take steps to address the lack of widespread interoperability in the current health IT ecosystem and to alleviate administrative burdens of the meaningful use program prior to requiring full compliance with the meaningful use program to avoid adverse reimbursement consequences. Until widespread interoperability is achieved and the regulatory burdens associated with participation in the meaningful use program are lessened, Congress and CMS should not subject providers to penalties based on systemic problems that they had no role in creating.

II. Alternative Payment Models (APMs)

We urge Congress to help ensure that multiple oncology-specific alternative payment models (APMs) are available to oncologists in 2019. This will allow oncologists the ability to select the optimal approach to serve their patients and their community. Currently, the Center for Medicare and Medicaid Innovation (CMMI) is in the process of implementing the Oncology Care Model (OCM), which may provide one pathway for CMMI's designated 100 practices to participate in an APM. However, given

there are over 2,000 oncology practices in the United States and in consideration of the complexities of oncology care, multiple APMs focusing on oncology services are needed by 2019 so that oncologists are able to select the most appropriate payment model to provide high-quality cancer care to their patients. The availability of multiple APMs will allow for these models to be driven by physicians as this Committee intended in drafting the law rather than simply offered top-down from CMMI.

ASCO's Patient-Centered Oncology Payment (PCOP) model provides the ideal framework for an oncology-specific APM. The PCOP framework promotes patient access to the full range of services required by individuals with cancer, supporting high-quality care while reducing overall expenditures and promoting value. Participants in PCOP receive additional payments that support the medically necessary patient management and care coordination. These payments are subject to a provider's adherence to evidence-based, oncology-specific quality measures (embedded within the Quality Oncology Practice Initiative (QOPI), a well-established quality assurance and independent program that is already recognized as a QCDR by CMS), adherence to the Choosing Wisely standards for resource use, and avoidance of unnecessary hospitalizations and emergency department visits.

By supporting the full range of resources necessary for oncology providers to plan, coordinate and manage cancer treatments, the PCOP addresses the fundamental problems with the outdated codes currently used for oncology by Medicare that overemphasize face-to-face visits and drug administration services. It also provides an opportunity to produce savings while enhancing care coordination and overall quality of the patient experience.

ASCO supports Congressional action to direct CMMI to implement and test multiple APMs like PCOP, the COME HOME Project, and the Oncology Medical Home. PCOP would promote care coordination and management while removing barriers under traditional fee-for-service that stifle the delivery of high-quality, affordable oncology care. Testing the PCOP framework alongside the OCM would provide CMMI with comparative data on two separate models and would dramatically increase participation by oncologists in APMs. This would enable stakeholders to evaluate and identify the best approaches to serve the Medicare population and Medicare program over the coming decades.

III. Physician-Focused Payment Models

ASCO supports the development and implementation of physician-focused payment models as APMs. Although Congress created the Physician-Focused Payment Model Technical Advisory Committee (PTAC) when it enacted MACRA, it is still unclear how models evaluated by the PTAC could be approved and implemented for widespread use as APMs. For physicians to have a meaningful voice in the development and implementation of APMs, Congress should enact legislation that would provide a clear pathway for physician-focused payment models recommended by the PTAC to be implemented as APMs beginning in 2019.

IV. Proposed Part B Drug Payment Model

The Center for Medicare and Medicaid Innovation's (CMMI) recent proposal to implement the Part B Drug Payment Model presents a significant, independent threat to community-based oncology care and compounds our concerns with the CMS implementation of MACRA. This new demonstration not only continues to erode practice resources necessary for the care of patients with cancer, it imposes additional administrative burdens by making participation in this experiment mandatory. This requirement—in addition to the practice resources that must be devoted to participate effectively in MACRA's reformed physician payment systems—is simply not sustainable. CMMI plans to implement the first phase of its mandatory two-phase Part B Drug Payment Model in late 2016. If implemented as proposed, Medicare would no longer reimburse the majority of Medicare providers for Part B drugs under the statutory methodology of average sales price plus six percent (ASP + 6%, now ASP + 4.3% under sequestration). The model is proposed to run for five years, meaning its implementation will directly overlap with the implementation of MIPS, APMs and other MACRA-created policy initiatives. Additionally, CMS has expressed its intent to test value-based purchasing tools in Phase II of the Model, but the Agency has failed to identify or describe the tools in any meaningful detail.

We are alarmed that the Agency charged with implementing the Medicare program has published a proposal to radically alter the payment methodology for oncology drugs that is virtually devoid of any meaningful provisions to protect patient access to high-quality, evidence-based care. ASCO has long supported the need for transformative changes in the way that oncology care is covered and reimbursed; however, any effort to revise the oncology payment system must ensure that individuals with cancer maintain access to the full scope of medically necessary products and services. Any such initiatives should be tested in meaningful ways before implementation takes place on a wide scale basis, and such testing should be performed in a way that protects the interests of patients in a proactive manner. ASCO has been active in this area, including its longstanding Quality Oncology Practice Initiative, development of a Value Framework to support shared decision making, a comprehensive proposal for payment reform, and participation in the Choosing Wisely program. Oncologists have demonstrated a readiness to engage in reforms that will achieve the national triple aims of better care, better health and lower cost. It is concerning that the proposed Part B Drug Payment Model is narrowly focused on price—something not controlled by oncologists—has not been designed with stakeholder input, and is set to proceed on a mandatory, nationwide basis in the absence of meaningful pre-launch testing or evaluation.

There are too many assumptions and too few safeguards in the recent proposal to alter the payment rules for Part B drugs. The Agency fails to understand that implementing a proposal that is budget neutral in the aggregate can still run the risk of creating perverse and undesirable impacts on community-based oncology care and patient access. Before running a nationwide experiment with the vulnerable population of elderly patients with cancer, more meaningful planning and testing are necessary. Further, it is problematic to place additional strains on the oncology infrastructure at the same time that significant administrative burdens are likely to arise due to MACRA implementation.

We urge Congress to enact legislation directing CMS and CMMI to forgo implementation of the ill-conceived Part B Drug Payment Model.

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Thank you for your leadership on passage and continued oversight to ensure successful implementation of MACRA. We look forward to working with you and your staff's to ensure that Medicare beneficiaries have access to oncology services moving forward. Please contact Amanda Schwartz at Amanda.Schwartz@asco.org with any questions.