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Submitted electronically via www.regulations.gov

May 9, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
200 Independence Ave. S.W.
Washington, DC 20201

Re: CMS-1670-P. Medicare Program; Part B Drug Payment Model.

Dear Acting Administrator Slavitt:

I am writing on behalf of the American Society of Clinical Oncology (ASCO) to express deep concern about the proposed Part B Drug Payment Model published in the Federal Register on March 11, 2016. ASCO is the national organization representing more than 40,000 physicians and other professionals who care for patients with cancer. ASCO members are dedicated to conducting research that leads to improved patient outcomes, and we are also committed to ensuring that evidence-based practices for the prevention, diagnosis and treatment of cancer are available to all Americans, including Medicare beneficiaries.

We share the Administration's concern about the rising cost of care and its impact on Medicare's sustainability. ASCO has invested heavily in developing initiatives to improve quality while lowering cost. Our efforts, taken in combination with steps taken by Medicare and private payers, can have far greater positive impacts on value than anything proposed in the Part B Drug Demonstration – as long as policymakers do not undermine meaningful reform efforts by implementing the Part B Drug Demonstration proposal.

Medicare actions have a profound effect on the care of patients with cancer and, as such, should be very carefully considered with regard to their impact on safety, access and quality of care for individuals facing this life-threatening illness. Sixty percent of new cancer diagnoses in the United States now occur in individuals who are at least 65 years old, and by 2030, estimates indicate that 70 percent of new cancer diagnoses will

2318 Mill Road, Suite 800
Alexandria, VA 22314
T: 571-483-1300
F: 571-366-9530
www.asco.org

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occur in the elderly population.¹ Given the number of Medicare beneficiaries with cancer, the impact of changes to Medicare policy on our delicate cancer care infrastructure, and our shared goals to advance a fairer and more responsible payment system for oncology, ASCO and the Centers for Medicare and Medicaid Services (CMS) should be working together toward a system that achieves CMS' goals and that could be embraced by the oncology community. We believe the foundation for that model already exists today, and we would welcome the opportunity to have an open dialogue with you about how to move forward.

The assumptions and emphasis of the Part B Drug Payment model are misplaced. Providers do not control drug pricing, often lack bargaining power to negotiate lower acquisition prices, and providers should not be required to choose between providing care at a financial loss or sending patients outside of their practice for treatment. If the Administration's goal is to lower drug prices, this demonstration is not designed to achieve that outcome. Rather, the proposed demonstration places doctors and Medicare beneficiaries in the position of making impossible choices without directly addressing the underlying problem of high drug prices. If the goal is to bluntly cut payments for oncologists – and by CMS' own analysis, the proposed demonstration will achieve that goal – then this should be treated as a change in the statutory provision that sets that payment and not presented in the guise of a demonstration project.

ASCO shares your overall goal of making the payment system for oncology more sensible and reflective of modern oncology care. ASCO has been a leader in developing and implementing strategies that improve the quality and value of oncology care and that serve the best interests of individuals with cancer. We are actively engaged with Congress, CMS and other stakeholders to achieve that goal. To that end, ASCO has developed an alternative payment model, the Patient Centered Oncology Program, which would achieve comprehensive reform of the oncology payment system. In contrast, the proposed Part B Drug Payment Model's narrow focus on one aspect of payment is contrary to the many efforts now underway—in oncology and in other specialties—to reform payment in ways that are consistent with your stated national aims to improve health, lower cost and enhance the patient experience.

In view of these serious shortcomings, we ask CMS to withdraw the proposal in its entirety. Instead, the Agency should work with stakeholders to enhance and build on existing efforts that aim to improve quality and access while lowering the cost of care for Medicare beneficiaries who have cancer.

In the spirit of collaboration, ASCO provides constructive proposals meant to help us achieve our shared goal to maintain a robust and efficient infrastructure to deliver cancer care to Medicare beneficiaries while rewarding quality and value-based care. Our comments are summarized below:

¹ Smith BD, Smith GL, Hurria A, Hortobagyi GN, Buchholz TA. Future of cancer incidence in the United States: burdens upon an aging, changing nation. *Journal of Clinical Oncology*. 2009;27:2758-2765.

ASCO agrees that Medicare’s current payment system for oncology is fundamentally flawed, but we strongly oppose any piecemeal reform efforts that fail to address oncology care in a comprehensive manner. We urge CMS to draw on efforts already underway in the oncology community.

- The Part B Model targets many strategies embedded in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), but removes critical resources from practices as they are attempting to prepare for this sweeping change.
- The proposal fails to include basic quality protections, monitoring provisions, and other safeguards typically required when treatment of Medicare beneficiaries is being tested.
- There is no consent, informed or otherwise, since participation is mandatory.
- The proposal ignores, undermines and misses the opportunity to leverage existing work by the oncology community to advance high-quality, high-value care.
- CMS is skirting statutory provisions and normal policymaking procedures by labeling this initiative as a “demonstration.”
- Medicare should pursue a comprehensive solution that addresses shortcomings in the current medical oncology reimbursement system.

CMS should not apply this demonstration to oncology because care is too complex and offers limited opportunity to choose between interchangeable, equally efficacious drugs.

- The delivery and treatment of cancer care is too complex to conduct an experiment of this magnitude without understanding the impact on the quality of patient care that may ensue.
- If CMS has specific concerns about areas of practice variation, they should work with ASCO to leverage existing performance measurement, education and clinical guidance to target those issues.
- A national experiment of the kind proposed will not address individual drug prices, will not address clinical variation in care, and could interfere with patient centered care and access to services.

With respect to Phase II, CMS should withdraw its proposal and, through an RFI process, engage with stakeholders in a more collaborative, substantive approach to advancing value in oncology.

* * * * *

Our detailed comments follow:

I. ASCO OPPOSES THE PROPOSED DEMONSTRATION IN THE STRONGEST POSSIBLE TERMS AND URGES CMS TO WITHDRAW IT.

a. Congress has long recognized the ongoing challenge of appropriate reimbursement for anti-cancer drugs and this demonstration would worsen the problem.

Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) in 2003, replacing the average wholesale price (AWP) formula for determining Part B drug reimbursement rates with the average sales price (ASP) formula. 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 include:

- operating practice pharmacies that enable safe storage, mixing, and administration of drugs to patients;
- unusable portions of drug vials that are leftover, spilled or lost due to breakage (although the practice must pay a drug company for the full price of a vial of chemotherapy, the practice can only bill Medicare for the portion of the vial that is used);
- instances when the actual acquisition cost of the drug is higher than the ASP; and
- time spent with patients to obtain financial assistance.

Since MMA, there have been ongoing reductions to this additional payment. Budget sequestration has resulted in a 2 percent reduction in overall Medicare payments since 2012, bringing payment to ASP plus 4.3 percent. Medicare payments for chemotherapy drugs are further eroded because the calculation of ASP includes prompt pay discounts negotiated between the manufacturer and distributor—discounts that are not passed on to the practice. By some estimates, this reduces effective value of the ASP add-on by one-third for community-based oncology practices.

These downward pressures exacerbate longstanding and ongoing financial challenges oncologists face in providing medically appropriate treatment for their patients. Virtually every community-based oncology practice experiences daily situations in which a dozen or more medically necessary drugs are “underwater.” A drug is considered underwater when the Medicare reimbursement rate is insufficient to cover the drug’s acquisition cost. The harsh reality is that oncology providers, especially those who practice in community-based settings, are often unable to acquire all medically necessary anticancer drugs at a price equal to or less than the current ASP-based reimbursement rate.

b. The Part B Model would remove resources from practices as they prepare for changes under MACRA. This could disrupt the site of care for Medicare patients with cancer, work against the goals of MACRA, and increase the costs to the system overall.

Although the current ASP-based reimbursement formula is suboptimal, the Part B Drug Demonstration—especially Phase I—would make an already difficult environment dramatically worse. CMS proposes for the experimental arm a reimbursement rate of ASP plus 2.5 percent with an additional \$16.80 flat fee per drug per day. Because this rate would be subject to sequestration, the effective reimbursement will be ASP plus 0.86 percent and an additional flat fee of \$16.53 per drug per day. These amounts are untenable for many cancer drugs.

ASCO’s modeling of this formula using data from 28 practices representing 425 oncologists in 25 states showed an average annual loss of more than \$560,000 for a 15-physician practice. Some practices could face larger cuts. Reductions of this magnitude to a practice’s operating budget may force painful decisions about practice structure, potentially including a reduction in critical staff such as nurses, patient navigators or social workers who provide essential services to patients with cancer. This is especially true because Medicare currently offers little or no payment for *most* of the care cancer patients need: treatment planning, patient education, patient and family counseling, coordination of care, mental health and other emotional support services, quality improvement, patient navigator services, triage nurse services, genetic counseling services, financial counseling services, nutrition counseling and dietitians, and community outreach. The Administration appears to have already acknowledged this longstanding gap in payment for services; CMMI’s Oncology Care Model adds a monthly payment specifically designed to support care transformation—the very services that will be put at risk with the Part B Drug demonstration. Any reform must recognize all of the services required to provide high quality cancer care and fund them adequately.

Oncologists choose drug treatments based on a core principle: provide the right drug to the right patient at the right time. Based on our modeling of the proposal, many practices would face a significant increase in the number of “underwater” drugs. According to data from 27 practices in 19 states, practices would experience an average of 45 drugs or more that are underwater. This is a 39 percent increase over the current situation. Today, some practices are able to accommodate Medicare beneficiaries who experience financial difficulty. However, a 39 percent increase in underwater drugs removes this flexibility and is simply not sustainable for the practice overall. Oncologists will still prescribe the appropriate treatment, but the unfortunate reality is that more patients are likely to receive that treatment at a location other than the office setting or not at all. The likely referral of patients to hospital outpatient departments for chemotherapy administration will serve to disrupt care. Apart from this undesirable fragmentation of care, Medicare will experience an increased cost of approximately 30 percent. Not only does this challenge the notion of overall budget neutrality for the proposal, it raises the possibility of a paradoxical and significant increase in the cost for the program.

In their analysis of the Part B Drug Payment Model, the consulting firm Avalere found that reimbursement would decrease for any drug with a current ASP-based reimbursement of more than

\$480 per day. New drug therapies that can improve the lives of patients with cancer will almost always exceed this threshold. Avalere also noted seven of the ten drugs that would face the largest reductions in reimbursement are used to treat cancer.

In summary, this demonstration will do nothing to further the Administration's goals for health reform: it will not improve health, it will not enhance quality and it will not lower cost.

c. The Part B Model has a stunning lack of quality protections, monitoring provisions, and fundamental safeguards typically required in such situations, the absence of which creates substantial risks for Medicare beneficiaries with cancer, who have no choice as to whether they are part of this demonstration.

We are alarmed at the failure throughout this proposal to articulate patient protections, including mechanisms to avoid adverse consequences of mandating nationwide participation in the demonstration. Other than claims data and patient satisfaction surveys, there is no clear plan to assess impact of this experiment on the quality of care provided. Claims data are widely recognized as insufficient data sources for this kind of evaluation. For example, Medicare cannot determine from claims data whether a patient with HER2+ breast or gastric cancer was not given trastuzumab, which is guideline recommended treatment for a certain population of patients. Data on molecular characteristics of tumors is critical to evaluating performance in modern oncology practice.

CMS hypothesizes that the proposed changes will drive changes in prescribing behavior solely motivated by financial incentives. ASCO does not agree. If this were a prospective randomized trial, the null hypothesis would be that the proposed intervention will not affect physician prescribing practices. As constructed, ruling out the null hypothesis is not possible. Further, we find it unacceptable that CMS would design a payment system that relies on individual financial incentives—instead of evidence and quality—to make treatment decisions.

In order to test CMS's hypothesis, there would need to be ample opportunity for choosing among equally effective drugs with varying cost. However, most high cost cancer drugs do not have a medically appropriate lower cost substitution. For example, pembrolizumab, nivolumab, and ipilimumab have revolutionized the care for melanoma and have no lower cost substitutes. The same is true for rituximab, which is the cornerstone therapy for most multiple lymphoma subtypes—likewise, bortezomib for multiple myeloma and bevacizumab or cetuximab for colon cancer. In these common situations, this demonstration simply represents a reimbursement cut to randomized oncology practices with no hopes of lowering costs or improving care. In fact, if the demonstration causes a shift in prescribing away from the higher priced drugs, patients will surely be receiving inferior care. If physicians do not change practice, then the entire proposal simply reduces the resources available to oncology practices with no change in resource utilization.

Regardless of whether CMS characterizes this proposal as human subjects research, an assumption that different treatment experiences could result because of the imposition of the CMS model should invoke

the same protections afforded other patients who participate in human subjects research—including informed consent and the right to not participate without jeopardizing access to routine clinical care. It is irresponsible for Agency officials to dismiss these risks because the experiment is being conducted in the context of reimbursement policy.

d. The Part B Model ignores work done outside of CMS that has the potential to yield comprehensive reforms that promote high-quality, high-value oncology care.

ASCO has labored for over a decade to support oncology practices in the delivery of high-quality, high-value oncology care. This work includes:

- **The Patient Centered Oncology Payment (PCOP) model** that would fundamentally restructure the delivery of cancer care in the United States. PCOP is designed to better align payments with the services that patients require, simultaneously improving patient care and reducing spending for Medicare and other payers. PCOP would provide sufficient payment to support the full range of services that patients with cancer need and remove the barriers created by the current payment system to deliver high-quality, affordable care.² PCOP is specifically designed to reduce spending on the kinds of drugs, tests, and treatments that are avoidable while giving oncology practices the resources necessary to deliver high-quality care to patients and avoid complications and hospitalizations.

ASCO's PCOP proposes a value-based approach to cancer care and, in fact, could achieve program savings while preserving quality. Participants in PCOP receive additional payments to support medically necessary patient management and care coordination. These payments are subject to a provider's adherence to evidence-based quality measures (embedded within the Quality Oncology Practice Initiative (QOPI), adherence to the Choosing Wisely standards for resource use, and avoidance of unnecessary hospitalizations and emergency department visits.

One commercial payer is already testing this model, and ASCO is in active dialogue with several other interested entities. This kind of constructive engagement will achieve the best results for the system, for providers and—most importantly—patients.

- ASCO has a robust performance measurement system, the **Quality Oncology Practice Initiative (QOPI)** and the **QOPI Certification (QCP) program**. These are the only comprehensive performance measurement and certification programs available for oncology professionals. QOPI's more than 150 performance measures are continuously tested, refined and updated to reflect evolving

² American Society of Clinical Oncology. Patient-centered oncology payment: payment reform to support higher quality, more affordable cancer care. May 21, 2015.

scientific evidence and to ensure the delivery of quality and value in oncology care.^{3,4} Over 1,000 practices are currently registered for QOPI. They receive individualized reports on quality measures relevant to their practice, comparing their results to a national average.

- Building on our 15 years of experience in measure development and quality initiatives with QOPI, ASCO received designation as one of the initial **qualified clinical data registries (QCDRs)** recognized by CMS. QCDRs play an important role in providing meaningful quality measures for use under the Medicare program in highly-specialized areas of medicine, such as oncology. ASCO's QCDR provides an option to fill the significant gaps in oncology measures that exist in Medicare's Physician Quality Reporting System (PQRS).
- ASCO is building a rapid learning system, **CancerLinQ**, which will use "big data" solutions to help practicing physicians distill massive volumes of data into meaningful information that supports the delivery of high-quality, high-value oncology care.⁵ This multi-year initiative will provide real-time feedback to oncologists on performance, allow point of care decision support, and provide rapid insight to patient outcomes. The volume of scientific and clinical information in the field of oncology is growing at an unprecedented rate, especially with the increasing availability of genomic sequencing to help target optimal therapy for appropriate patients. CancerLinQ holds the promise of accelerating our ability to identify clinical interventions that deliver both quality and value to cancer patients and the health care system.
- ASCO has developed a conceptual **Value Framework** for the evaluation of treatment alternatives to help providers and patients analyze the clinical benefit and costs of comparable treatment protocols. ASCO's Value Framework provides a consistent, transparent and evidence-based methodology for balancing clinical effectiveness and value when examining alternative clinical options.⁶
- ASCO's recently released policy statement on **Clinical Pathways in Oncology**, which highlights appropriately developed pathways as an important tool in improving quality for cancer patients and reducing costs in cancer care. The statement outlines concerns related to the current proliferation of clinical pathways, particularly related to their impact on patient access, quality and transparency

³ Gilmore TR, Schulmeister L, Jacobson JO. Quality oncology practice initiative certification program: measuring implementation of chemotherapy administration safety standards in the outpatient oncology setting. *Journal of Oncology Practice*. 2013;9:14s-18s.

⁴ Neuss MN, Malin JL, Chan S, Kadluek PJ, Adams JL, Jacobson JO, Blayney DW, Simone JV. Measuring the improving quality of outpatient care in medical oncology practices in the United States. 2013; 10:1471-1477.

⁵ Schilsky RL, Michels DL, Kearbey AH, Yu PP, Hudis CA. Building a rapid learning health care system for oncology: the regulatory framework of CancerLinQ. *Journal of Clinical Oncology*. 2014; 32:2373-2379.

⁶ Schnipper L, Davidson N, Wollins D, Tyne C, Blayney D, Blum D, Dicker A, Ganz P, Hoverman JR, Langdon R, Lyman G, Meropol N, Mulvey T, Newcomer L, Peppercorn J, Polite B, Raghavan D, Rossi G, Saltz L, Schrag D, Smith T, Yu P, Hudis C, Schilsky R. American Society of Clinical Oncology statement: a conceptual framework to assess the value of cancer treatment options. *Journal of Clinical Oncology*. 2015:2563-2577.

in the development process. Nonetheless, the statement emphasizes the utility of properly developed and implemented pathways.⁷ Clinical pathways in medicine in general are designed to reduce variation of care as well as control and improve quality and reduce the cost of care. ASCO's current work focuses on developing recommendations and criteria for managing pathway development to assure these goals are met in oncology care.

- ASCO has identified rising health care costs as a critical barrier to high-quality care for many cancer patients and has identified ten commonly used practices or interventions that do not contribute to quality patient care, as part of the American Board of Internal Medicine Foundation's **Choosing Wisely** Initiative. We are also developing strategies to address these challenges and to measure their impact through the QOPI program. ASCO is committed to providing practical educational tools and resources to assist both oncologists and patients in addressing and discussing the cost of treatment as a component of high-quality care.
- ASCO has evaluated and developed recommendations on a number of additional policy issues that are integrally related to oncology drug payment reform. These recommendations include: the 340B Drug Discount Program,⁸ site neutrality,⁹ and Medicaid reform.¹⁰

Oncology drug payment policy should not be addressed without considering the full range of complex and evolving issues that impact the quality and value of care. The ASCO initiatives described above provide a good checklist for CMS regarding the elements that should be addressed in a comprehensive approach. This proposed rule unfortunately moves us in the opposite direction: piecemeal change that will serve only to set the effort for reform back by draining needed resources from the system. The proposed rule runs counter to the efforts imbedded in MACRA and CMS' own Oncology Care Model (OCM).

e. The scope and breadth of this demonstration exceeds what would typically be considered in testing a new model.

This mandatory demonstration is being implemented in the majority of the country. By its very nature, a demonstration is piloting untested policy changes with unknown impact. Demonstrations should be narrowly focused and voluntary to avoid large scale systemic disruptions in care delivery—and unintended adverse outcomes.

⁷ 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;26:1-266.

⁸ American Society of Clinical Oncology. Policy statement on the 340B drug pricing program by the American Society of Clinical Oncology. *Journal of Oncology Practice*. 2014; 10:259-263.

⁹ American Society of Clinical Oncology. The American Society of Clinical Oncology's statement on site neutrality. *Journal of Clinical Oncology*. 2016;34:277-279.

¹⁰ Polite BN, Griggs JJ, Moy, B, Latham C, duPont NC, Villani G, WongSL, Halpern MT. American Society of Clinical Oncology policy statement on Medicaid reform. *Journal of Clinical Oncology*. 2014;32:4162-4167.

- f. Medicare should pursue a comprehensive solution that addresses shortcomings in the current medical oncology reimbursement system and that drives value-based cancer care.***

Another troubling aspect of the proposed demonstration is the proposed zero sum nature of its impact. As the impact tables in the proposal show, this model would result in a purposeful shift of financial resources away from high cost specialties to those with historically lower costs. This ignores clinical reality and effectively penalizes patients with high cost illnesses such as cancer. Medicare's existing coverage and reimbursement policies already fail to recognize the full scope and cost of services required by cancer patients, and the proposed rule would compound this problem by further reducing resources available to treat their disease. There are far more productive initiatives in cancer—launched by commercial payers and by CMMI—that would move the cancer care delivery system to a more rational payment environment. For example, United HealthCare demonstrated that providing additional support for patient services actually lowered aggregate spending for cancer treatment by one-third, despite increased spending for oncology drugs. CMMI's own COME HOME demonstration showed significant program savings while improving care coordination and disease management. These are ideas that can serve as the foundation for more productive and scalable reforms.

Such successful demonstrations—and ASCO's proposed Patient Centered Oncology Payment model—pursue comprehensive solutions that allow practices the flexibility to organize and deliver care in the way best suited to their practice environment and the needs of their patient population.

II. IF, DESPITE THE MULTITUDE OF LIMITATIONS AND CHALLENGES ALREADY IDENTIFIED, CMS MOVES FORWARD WITH THIS PROPOSAL, CMS SHOULD EXEMPT ONCOLOGY.

- a. The delivery and treatment of cancer care is too complex—and today's system too fragile—to conduct an experiment of this magnitude without understanding the impact on patient care.***

The management of cancer is growing increasingly more complex with the advent of targeted therapies, immunotherapy and other innovative treatment strategies. Cancer itself is many diseases, all of which require timely, individualized treatment in an environment that is best for the patient. Disrupting the delivery system for this care without understanding the implications of the intentional shift in care fails to recognize this complexity and potentially is dangerous for individual patients.

- b. The clinical scenario envisioned by the Part B Model of two equivalent interchangeable treatments is not common in oncology.***

Perhaps the greatest concern for oncology is that CMS, through this proposal, intends to manipulate physician prescribing behavior and therefore undermine patient access to certain drug therapies without regard to whether the higher cost products are clinically superior for an individual patient.

The proposed demonstration rests on the assumption that providers typically have multiple treatment options at widely ranging prices from which they and their patient may choose. As noted in the examples above, typically one treatment is clearly a better choice for the patient based on the evidence, the patient's course of care, comorbidities and potential side effects. If there is unwarranted variation in practice, that should be the focus of education and performance improvement. ASCO has the tools and resources to provide this kind of leadership.

c. As currently constructed, this test has the potential to do significant and irreparable harm to the cancer care delivery system.

The cancer care delivery system is a complex network of independent and hospital-based practices woven together to provide a robust infrastructure to treat cancer patients. The evolution of community-based cancer care in the 1980s reflected a need to deliver quality care closer to the homes of people with cancer at a lower cost to the Medicare program. This demonstration could disrupt this intricate network, driving smaller practices—particularly in rural areas—to close their doors. Larger practices may be forced to close or reduce services in satellite clinics that now support rural or underserved populations. At the end of a five-year demonstration, this infrastructure could be destroyed. Rebuilding will be difficult, if not impossible.

III. CMS HAS NOT PROVIDED SUFFICIENT DETAIL FOR CONSTRUCTIVE COMMENT ON PHASE II OF THE DEMONSTRATION. CMS SHOULD WITHDRAW THIS PROPOSAL AND ENGAGE STAKEHOLDERS THROUGH A REQUEST FOR INFORMATION (RFI) PROCESS.

CMS should pursue value-based solutions that address the oncology system as a whole rather than focusing narrowly on only drug payments. The Medicare reimbursement system for oncology is structurally flawed. Choosing to implement value-based principles into drug payments without addressing other structural deficiencies will not address fundamental problems of today's system—and may cause further damage. CMS should focus on how best to reform oncology policy to support the full scope of oncology services as it seeks to integrate more value-based principles into the Medicare program.

a. CMS did not provide sufficient information to provide notice of the terms or substance of the value-based tools that CMS plans to use in Phase II of the model and has not met the fundamental requirements for rulemaking arising under the Administrative Procedures Act. CMS should withdraw this proposal and release the concepts in a request for information (RFI) for stakeholder input.

It is clear that the Agency has not fully contemplated the specific policy approach it intends to take with respect to Phase II of the model. We appreciate that CMS has acknowledged the weakness of its proposal by including protections that would require CMS to collect future comments from the public before implementation. However, a core procedural requirement of the Administrative Procedure Act is that parties must be given notice of “the terms or substance of the proposed rule or a description of the

subjects and issues involved” when the Agency engages in rulemaking, 5 U.S.C. §553(b)(3), and this demonstration does not meet that requirement.

CMS should withdraw the proposal and release these concepts in the form of a request for information (RFI) to allow for more thorough stakeholder input.

b. CMS did not provide sufficient information to provide notice of the terms or substance of the value-based tools that CMS plans to use in Phase II. As a result, we are unable to comment beyond generalities at this point. There are critical flaws that should be addressed before any of the CMS proposals are considered for implementation under the Medicare program.

Equal Payment for Therapeutically Similar Drugs (Reference Pricing): CMS has not provided sufficient detail for ASCO to respond to its proposal to include reference pricing in Phase II. However, we have evaluated previous reference pricing approaches in the past for other programs and determined that these approaches are not appropriate for cancer care because they are predicated on the assumption that cancer drugs and biologicals are comparable and interchangeable. The standard of care for many cancers is one drug or one combination of drugs. We oppose efforts by CMS that do not recognize the lack of comparability or interchangeability of cancer therapies in many clinical scenarios.

Indication-Based Pricing: CMS has not provided sufficient detail for ASCO to respond to its proposal to use indication based pricing in Phase II. Based on the limited description included in the preamble we are unable to ascertain how indication based pricing would operate. We are also concerned that indication based pricing improperly compares a drug against itself for different uses. This comparison fails to contemplate the limited number of treatments cancer patients often have and may result in more drugs becoming underwater for more practices.

Outcomes Based Risk-Sharing Agreements: CMS has not provided sufficient detail for ASCO to respond fully to its proposal to enter outcomes based risk-sharing agreements with drug manufacturers. At the conceptual level, it is imperative that CMS does not design an outcomes-based risk sharing system that puts oncologists at financial risk. Any rebates that are required should only involve CMS and the manufacturer. Finally, tracking outcomes in cancer care will take place over a number of years and require practices to allocate resources. CMS should not compel oncologists and other providers to expend additional resources to track outcomes and other clinical data related to outcomes based risk-sharing agreements without compensation. Doing so would magnify ongoing deficiencies related to uncompensated services in the overall reimbursement system for cancer care.

Discounting or Eliminating Patient Copayments: CMS has not provided sufficient detail for ASCO to respond fully to its proposal to decrease or eliminate patient coinsurance for certain drugs that CMS deems as high-value. Such strategies could help patients who cannot afford copayments for potentially curative therapies. They would also reduce the financial risk practices encounter when patients are unable to meet their coinsurance obligations in buy-and-bill reimbursement models. However, as CMS

has noted, the impact of such a policy may be small since many Medicare beneficiaries have “wrap-around” insurance coverage to partially or completely offset their coinsurance obligations. CMS did not propose criteria for identifying drugs subject to lower patient cost sharing, but at a minimum, such decisions should be based on the drug’s clinical benefits and the context of use, not cost alone. Such decisions should be subject to a clear and transparent process.

c. ASCO strongly opposes any effort by CMS to create a government supported clinical decision support (CDS) tool for oncology. Creating a CDS tool would duplicate more mature and ongoing efforts already underway in the private sector, and we are concerned the CMS would be unable to maintain a nimble, evidence-based CDS tool in the rapidly evolving area of oncology.

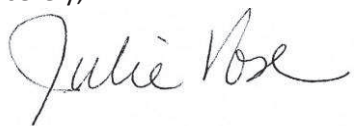
CDS has tremendous potential to impact the practice of oncology and reduce the time and resources devoted to treatment planning. ASCO is supportive of efforts being undertaken in the private sector to improve the quality of cancer care through the use of health information technology (HIT). One example is ASCO’s CancerLinQ program. CancerLinQ is a Rapid Learning System (RLS), which collects and distills massive amounts of clinical information to produce insights supporting development of new treatment regimens and protocols. When fully developed, CancerLinQ will provide point of care decision support and real-time feedback to physicians on their performance. There is also a wide range of CDS tools that HIT vendors and other stakeholders have developed that support oncologists as they work with patients to select treatment best suited to their needs. We do not believe introduction of yet another decision support tool would provide added value to oncology professionals and could undermine highly effective systems already in use.

CMS would be better served by exploring options to integrate ongoing and mature projects into the workflow of oncologists to increase adoption and use of the technology.

* * * * *

Thank you for the opportunity to provide our concerns about the proposed rule. We are confident that after review of our comments and that of other stakeholders, CMS will realize this proposal moves payment policy in the wrong direction and is counter to CMS’ more constructive efforts. With the focus on patients, ASCO has been developing policies and advancing creative solutions to the issues of quality and value in cancer care for over a decade. We would welcome the opportunity to engage with CMS in a meaningful dialogue about these issues.

Sincerely,

A handwritten signature in cursive script that reads "Julie Vose".

Julie M. Vose, MD, MBA, FASCO
President
American Society of Clinical Oncology