



AMERICAN SOCIETY OF CLINICAL ONCOLOGY

PRESIDENT

Monica M. Bertagnolli, MD,
FACS, FASCO

IMMEDIATE PAST PRESIDENT

Bruce E. Johnson, MD, FASCO

PRESIDENT-ELECT

Howard A. Burris, III, MD,
FACP, FASCO

TREASURER

Laurie E. Gaspar, MD, MBA,
FASTRO, FACR

DIRECTORS

Peter C. Adamson, MD

A. William Blackstock, MD,
FASCO

Stephen B. Edge, MD,
FACS, FASCO

Lee M. Ellis, MD, FACS, FASCO

Arti Hurria, MD, FASCO

Maha H. A. Hussain, MD,
FACP, FASCO

Reshma Jagsi, MD, DPhil

Michael P. Kosty, MD,
FACP, FASCO

Tony S. K. Mok, MD, FRCP(C),
FRCP, FHKCP, FHKAM, FASCO

J. Chris Nunnink, MD, FASCO

Eric J. Small, MD, FASCO

Jaap Verweij, MD, PhD, FASCO

Jedd D. Wolchok, MD, PhD,
FASCO

Tracey Weisberg, MD

EX-OFFICIO MEMBERS

CHAIR, CONQUER CANCER
FOUNDATION

Thomas G. Roberts, Jr., MD,
FASCO

CHIEF EXECUTIVE OFFICER

Clifford A. Hudis, MD,
FACP, FASCO

2318 Mill Road, Suite 800
Alexandria, VA 22314
T: 571.483.1300
F: 571.366.9530
www.asco.org

Via Electronic Submission

December 31, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-1850

Re: CMS-5528-ANPRM. Medicare Program; International Pricing Index Model for Medicare Part B Drugs

Dear Administrator Verma:

I am pleased to submit comments on behalf of the American Society of Clinical Oncology (ASCO) in response to the recent advanced notice of proposed rulemaking (ANPR) for the Medicare program and International Pricing Index Model (IPI) for Medicare Part B Drugs published in the Federal Register on October 30, 2018.

ASCO is the national organization representing more than 45,000 physicians and other health care 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 shares the Agency's concern regarding the rising cost of drug prices, and we are eager to work with CMS on solutions that address these concerns while promoting patient access to oncology care and supporting the financial sustainability for different models of oncology practices, which include independent community-based practices and hospital outpatient facilities. Because physicians do not set or control the launch price of drugs, we confine our comments to the area where physicians do play an important role: assuring the most appropriate utilization of anti-cancer drugs. Cost containment strategies that attempt to control drug price by placing financial constraints on providers or taking resources from practices will not accomplish this goal, nor will it ensure the best patient outcomes.

Re: CMS-5528-ANPRM
December 31, 2018

We remain concerned about cost-centric utilization management strategies, like step therapy, that will threaten the quality of care for patients with cancer by limiting patient access to the most appropriate treatment. We do believe that there are meaningful initiatives and important changes the Agency should consider that would further the goal of delivering high quality, high value health care. The proposed concept of a revised Competitive Acquisition Program (CAP) lays some of the groundwork for necessary change but has significant flaws in its present form that must be corrected before moving forward in order to avoid jeopardizing access to care.

In October, ASCO responded to the request for information on Price Transparency and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model in the Hospital Outpatient Prospective Payment Systems Proposed rule. We offered suggestions for the structure of a revised CAP program that could address flaws that contributed to Medicare's unsuccessful attempt to introduce CAP several years ago. Our suggestions are aimed at creating a viable alternative for oncology practices, one that enables successful patient outcomes.¹ In summary, ASCO recommended the following:

- **Provider participation in any CAP Demonstration Model must remain entirely voluntary, and CMS should not coerce participation in a CAP Demonstration Model Program by making the traditional buy-and-bill program less effective or less desirable for oncology practices.**
- **A CAP Demonstration Model must avoid any aggregate reduction in payment to oncology practices. A practice management fee is necessary to provide fair and adequate payment to reimburse practices for the costs incurred in handling, preparing, storing, administering and disposing of hazardous drugs and to replace the drug margin in place under the buy-and-bill program.**
- **A CAP Demonstration Model must protect patient access by avoiding interruptions in care when coinsurance issues arise and allowing for common adjustments in prescribed drug regimens that occur on the same date of service as drug administration.**
- **The CAP Demonstration should restrict vendors from engaging in draconian or burdensome utilization management requirements, as described in the above-referenced comment letter.**

While there are components of the CAP program proposed in the IPI that are consistent with ASCO's principles, ASCO cannot support a mandatory demonstration program. We are concerned about losing important access points to oncology care provided by oncology practices, especially in rural, underserved, and low-income areas that are already struggling to deliver care. Additionally, we are concerned about the impact on practices that are outside the demonstration program but that are

¹ American Society of Clinical Oncology Comment 2019 Hospital Outpatient Prospective Payment System (HOPPS) proposed rule, found at: <https://www.asco.org/sites/new-www.asco.org/files/content-files/practice-and-guidelines/Comment-Letter-HOPPS-Proposal-2018.pdf>.

Re: CMS-5528-ANPRM
December 31, 2018

likely to be adversely affected by the new ASP values. Below, we provide detailed concerns with the proposal and provide additional recommendations for improving the proposed CAP.

ASCO strongly opposes a mandatory demonstration program. Because oncology practices vary significantly with respect to patient and payer mix, the proposed model will not be viable for all oncology practices. A voluntary model would be more appropriate for patients and practices that are able to participate in the CAP program.

Provider participation in any CAP Demonstration Model must remain entirely voluntary, and CMS should not coerce participation in a CAP Demonstration Model Program by making the traditional buy-and-bill program less effective or less desirable for oncology practices.

CMS should not, under any circumstance, *require* any physician practice or other entity to participate in a CAP Demonstration Model for either some or all of their patients. Voluntary participation means that an oncology practice retains the discretion to choose whether participation in a CAP is appropriate for their practice. Shifting from participation in traditional buy-and-bill for the acquisition of Part B drugs to a CAP Demonstration Model is a significant undertaking for an oncology practice that requires operational investments, including administrative staff and other resources needed to track and manage patient care. Voluntary participation also means a practice must retain the autonomy to choose the appropriate scope of their participation in any CAP Demonstration Model. This includes having a choice regarding whether to acquire some or all drugs used in their practice through either the CAP Model or the buy-and-bill system. This flexibility is necessary, in part, because switching to a CAP arrangement may jeopardize existing, multi-year contractual relationships already in place between the practice and other third parties. Rapid transition from such contracts may be problematic and costly for many oncology practices. The decision to participate in CAP is multi-factorial and should reside solely with the practice.

Additionally, there is fear among members of the cancer community that policymakers may coerce participation in the CAP Demonstration Model by taking actions to make the current payment system untenable for oncology practices outside the demonstration. As CMS considers implementing a CAP Demonstration Model, there should be no changes – including to the ASP – designed to coerce CAP participation by practices outside the model. In order to understand the full implications of a CAP program, there must continue to be a control group that is left undisturbed.

Rather than requiring practices to participate in a mandatory demonstration project, the Agency should consider additional ways to incentivize participation in a program that would ultimately transform the way care is delivered and reimbursed. Medicare adopted such a strategy several years ago, incentivizing treatment of cancer care in the ambulatory vs. hospital setting. Both Congress and CMS recognized this transition represented convenience to patients, as well as a cost-effective alternative to inpatient delivery of treatment, while allowing patients to seek care in the most appropriate setting. Similar incentives, to cover the cost of meaningful transformation, should be considered to attract participation in a CAP environment.

Re: CMS-5528-ANPRM
December 31, 2018

Finally, under section 1847A of the Social Security Act, oncologists are reimbursed at ASP plus six percent for separately paid Part B drugs. While CMS has flexibility under its demonstration authority, policymakers should avoid embedding payment cuts to medical oncologists outside the demonstration through the CAP policy initiative. Said another way, the negotiated prices in the demonstration program should not be factored into the ASP for practices outside the demonstration. The average sales price formula is the statutory requirement for the Medicare Part B buy-and-bill system in place today and should stay as such until Congress enacts a change.

Any proposal to change the reimbursement methodology for medical oncology must ensure that there is fair and adequate reimbursement for the full range of services and products that are necessary to provide modern oncology care. Many of these services are not currently separately reimbursed. CMS must ensure adequate resources to cover the special handling and other overhead costs related to hazardous drugs used to treat cancer patients, including the resources that are currently in the system. CMS should not erode the value of the 6% add-on by requiring the providers to pay vendor distribution fees, applying sequestration cuts, or requiring physicians to pay other costs.

ASCO appreciates the recognition by CMS that the 6% is used by practices to pay for important drug associated costs and that the CAP Demonstration Model must avoid any aggregate reduction in payment to oncology practices. Fair and adequate payment is necessary to account for the costs incurred in handling, preparing, storing, and disposing of hazardous drugs and to enable practices to predictably manage their ongoing financial risk.

The ASP add-on is necessary to help cover a portion of the expenses associated with handling, storage, and preparation requirements that are not otherwise reimbursed by Medicare, including the expenses associated with the procurement, special handling, storage and disposal of cancer drugs. The CAP Demonstration Model must include a fair and adequate payment that replaces the drug margin for oncology practices. Many oncology practices cannot absorb the entirety of costs for the management and handling of cancer drugs.

CMS asked specifically about how the management fee should be calculated. ASCO recommends that the CAP management fee should vary based on the class of drug administered. Basing the fee on the class of drugs allows for the recognition that some drugs – such as the hazardous drugs used in cancer treatment – have more resource intensive handling, storage, preparation and disposal requirements than others. The Agency assumes vendors will compete on the basis of fees, however as currently described in the ANPRM, there are no guidelines for how vendor fees can be structured to drive appropriate competition and avoid a new avenue for “gaming” the system.

The CAP management fee must also be distinct from care management fees for complex chronic condition management, or similar care management payments in other oncology payment reform programs. For example, both the Oncology Care Model (OCM) and ASCO’s Patient Centered Oncology Payment Model (PCOP) use management fees as a mechanism to support care coordination and patient management activities that reduce cost by avoiding unplanned emergency department visits and inpatient hospitalizations. These payments are distinct from

Re: CMS-5528-ANPRM
December 31, 2018

drug management and handling expenses.

The Administration should work with providers to determine the appropriate amount of a fixed fee to compensate practices for these costs.

Physicians should not be responsible for collecting patient coinsurance under the proposed demonstration. A CAP Demonstration Model must protect patient access by avoiding interruptions in care when coinsurance issues arise.

A CAP Demonstration Model must serve the best needs of patients and contain a mechanism for collecting Medicare beneficiary cost-sharing that does not place financial risk on oncology practices. Under a CAP system, the provider no longer “owns” the drug and should not be required to provide this unreimbursed service on behalf of the vendor. Losses associated with coinsurance are not compensated through the ASP formula or otherwise, and saddling physician practices with this administrative burden is not appropriate. Under the previous CAP program, responsibility for collecting Medicare cost-sharing was assigned to the CAP vendor. We received several reports during that time of CAP vendors interrupting or abruptly discontinuing access to oncology drugs when Medicare beneficiaries could not meet their required copayment. CMS must not replicate this model.

ASCO members support robust patient access to cancer care and many practices regularly work with patients to identify resources to support the financial challenges that accompany a cancer diagnosis. Despite these efforts, practices cannot absorb additional administrative burdens and the responsibility for collecting and processing coinsurance should lie solely with CMS in any demonstration.

Oncology practices should be allowed to participate as vendors, with the ability to purchase on behalf of their own practice, and CMS should ensure the availability of both regional and national vendors.

Some small practices could benefit from volume-based purchases and discounts in the CAP program, while some large, multispecialty practices may be more effective at lowering prices through directly purchasing drugs in the current ASP-based system, or in a CAP system allowing for practice-based purchases. The program should also allow practices able to qualify as a vendor to bid on drugs and purchase drugs directly for its own use. If practices choose to participate in the CAP program, they should be able to choose from multiple regional or national vendors to ensure competition exists for both pricing and service. Vendors must deliver high-level service to ensure that patients receive timely access to the most appropriate anticancer regimens. Vendor qualifications should include appropriate safety and quality standards.

Newly calculated ASP rates should only be applied within the demonstration area and not to drugs or providers that are not included in the demonstration.

The ANPRM indicates that outside of the model regions—and the drugs selected for inclusion in

Re: CMS-5528-ANPRM
December 31, 2018

the program—current ASP reimbursement rules would continue to apply. Additionally, the IPI indicates the potential to lower the ASP outside of the model as payments within the model are reduced. One possible result is reducing out of pocket costs for patients, however payments to physicians will also be reduced, removing resources now used to support the complex array of support required for patients with cancer.

The Agency’s demonstration authority exists “to test and measure the effect of potential program changes... [and] the likely impact of new methods of service delivery, coverage of new types of service, and new payment approaches on beneficiaries, providers, health plans, states, and the Medicare Trust Funds.” The IPI must be conducted in such a way that CMS is able to evaluate demonstration findings against traditional Medicare reimbursement methodologies. Thus, a test group and control group should exist to understand the real impact of programmatic changes associated with the IPI, and the effectiveness of the model to reduce Medicare drug costs and improve the quality of care delivered to Medicare beneficiaries.

CMS should consider the use of oncology pathways to promote high-quality, high-value medical oncology care. Clinical Treatment Pathways select a preferred, evidence-based therapeutic option based upon efficacy and toxicity, and only consider costs if the efficacy and toxicity of two or more drugs are equally acceptable in the clinical situation. This promotes consistent use of treatments with demonstrably high value and avoids costs related to unnecessary or inappropriate care.

Validation of pathways through some form of credentialing or deeming process will be important to ensure that pathways are based on scientific evidence and promote the best interests of patients. Pathways also provide a valuable mechanism to collect comparative data on drugs with similar efficacy and toxicity profiles. Pathways are also an effective way to assure every patient, regardless of setting or geography, can benefit from the most current recommended care. Overall, the use of clinical treatment pathways in lieu of more traditional utilization management techniques will lead to higher quality outcomes for patients while encouraging oncology care providers to make care decisions based on the best evidence available and avoiding drug wastage.

The CAP Demonstration should prohibit vendors from engaging in utilization management requirements like step therapy, which focus on controlling cost and do not consider evidence-based medicine.

Medicare should preserve its long and well-established history of providing robust patient access to cancer therapies without delay through both statutory and regulatory protections.

Many utilization management strategies flow from the assumption that there are lower cost clinically equivalent oncology drugs within each general category or class. However, in oncology, it is most often the case that an equally effective and less expensive drug does not exist and there is often only one drug that is appropriate to treat an individual patient’s condition. There must be protections in place to ensure that oncologists and any potential CAP vendors work together to achieve the primary goal of delivering high-quality, timely care that is most appropriate for the patient.

Re: CMS-5528-ANPRM
December 31, 2018

ASCO is strongly opposed to the use of any step-therapy policies that require a cancer patient to try and fail on a therapy before they are able to access the preferred clinical therapy. Step-therapy policies are often based primarily on considerations of cost rather than the best interest of patients, clinical evidence, or aggregate costs. Any CAP demonstration program must prohibit—and certainly not require—the use of step-therapy policies or other draconian utilization management techniques for oncology.

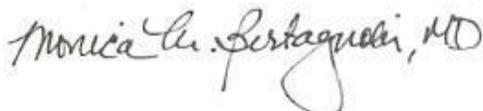
There are a significant number of independent oncology practices that would be interested in participating in a Competitive Acquisition Program (CAP) Demonstration Model—but only if participation is fully voluntary, is designed to avoid reductions in the resources devoted to cancer care, assures timely patient access to oncology treatments, promotes efficiency, and prohibits the use of draconian utilization management policies. We urge CMS to be cautious in its development and implementation of any CAP Demonstration Model and to restrict its initial scope to the Medicare fee-for-service program.

ASCO anticipates that there are also members of the oncology community who will oppose re-introducing a CAP model in any form because of concerns that it would not remain entirely voluntary or would be paired with changes that undermine access to care or otherwise complicate the delivery of cancer care. The flaws from the initial implementation of the CAP program from a decade ago must be avoided to increase the likelihood for CMS to achieve any measure of success if a CAP Demonstration Model is implemented.

* * * * *

Thank you for the opportunity to provide feedback on the Medicare Program; International Pricing Index Model for Medicare Part B Drugs Advanced Notice of Proposed Rulemaking. We look forward to working with you on a solution to maintain affordable access to drugs for Medicare patients. Please contact Sybil Green at Sybil.Green@asco.org with any questions.

Sincerely,



Monica M. Bertagnolli, MD, FACS, FASCO
President, American Society of Clinical Oncology