Oppose the CMS Medicare Part B Drug Payment Demonstration Proposal

The American Society of Clinical Oncology (ASCO) strongly opposes the mandatory CMS Part B Drug Payment Demonstration Proposal (Part B Demo) and supports enactment of H.R. 5122 or similar legislation that would prevent the Part B Demo from moving forward.

BACKGROUND
Congress has long recognized the ongoing challenge of appropriate reimbursement for anti-cancer drugs. 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;
- Usable 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, in many cases 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.

OVERVIEW
On March 11, 2016, the Centers for Medicare and Medicaid Services (CMS) Center for Medicare and Medicaid Innovation (CMMI) released a proposal to conduct a mandatory demonstration project to test alternative ways to pay for drugs reimbursed though Part B of the Medicare Program. The Part B Demo involves two phases, the first of which would reduce the reimbursement for Part B drugs, including oncology treatments, from 104.3% of Average Sales Price (ASP) to 100.86% with a flat fee add on payment of $16.53 per drug per day for Part B medications. The second phase of the demonstration will add value based purchasing mechanisms to the Phase I adjustments.

Across the board reductions like those proposed in the demonstration remove vital resources from patient care and may force painful decisions, including a reduction in critical staff such as nurses, patient navigators or social workers who provide essential services to Medicare beneficiaries 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 dieticians, and community outreach.

While ASCO shares Congress’ concern about the skyrocketing cost of drugs, the underlying assumptions of the Part B Demo are simply incorrect. Oncologists choose drug treatments based on a core principle: provide the right drug to the right patient at the right time. The Part B Demo rests on the belief that there are ample opportunities to select the lowest cost among several equally effective treatment alternatives. With a very few exceptions, this is not the case. Most high cost cancer drugs do not have a medically appropriate lower cost substitution. Further, providers do not control drug pricing, often lack bargaining power to negotiate lower acquisition prices, and should not be required to choose between providing care at a financial loss or sending patients outside of their practice for treatment. The Part B Demo is not designed to address the problem of high drug prices.

ASCO has modeled the CMS proposal on real practices, and is concerned with the results. Virtually every community-based oncology practice experiences daily situations in which a dozen or more medically necessary drugs are “underwater” – when the Medicare reimbursement rate is insufficient to cover the drug’s acquisition cost -- and the Part B Demo would exacerbate this problem.

The Part B Demo is also likely to cause a shift in site of service that will increase costs to the Medicare program by approximately 30 percent. While oncologists will still prescribe the appropriate treatment, they may have to send patients to the hospital outpatient department to receive that treatment because they cannot purchase the drug at the Medicare payment rate. 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.

The Part B Demo does nothing to ensure patient safety. It has a stunning lack of quality protections, monitoring provisions, and fundamental safeguards typically required in experimental 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 mandatory demonstration.

Further, 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. The Phase II concepts need much further development and stakeholder input before they can be seriously considered. CMS should reissue those ideas in a request for information.

Finally, the Part B Demo ignores work done outside of CMMI that has the potential to yield comprehensive reforms that promote high-quality, high-value oncology care.

RECOMMENDATION
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. 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.

CMS should not proceed with the proposed demonstration and should work with Congress and the administration toward more responsible reform.

REQUEST
We urge Congress to stop the Part B Demo by cosponsoring and passing H.R. 5122 or similar legislation.