

May 9, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1670-P
Proposed Rule on Part B Drug Payment Model (81 FR 13230-13261)

Dear Acting Administrator Slavitt:

Thank you for the opportunity to provide comments on the proposal from the Centers for Medicare & Medicaid Services (CMS) to implement a Part B Drug Payment Model in the Medicare program.

There is general agreement that cancer treatment is increasingly unaffordable. There is also general agreement that the primary reason cancer treatment is so expensive is the high and increasing prices manufacturers charge for the drugs cancer patients need. However, instead of finding ways to reduce the high prices of drugs, CMS is proposing to cut the payments it makes to oncology practices that are designed to enable them to buy and use drugs to treat cancer patients. The most likely impact of this will be to make it more difficult for cancer patients to obtain the drugs they need rather than to make any reduction in the prices of the drugs they do receive.

96% of the amount that CMS pays an oncology practice for a cancer drug is based on the price that the drug company charges for that drug. The remaining 4% is not “profit” for the oncology practice. It covers at least five types of costs that are not otherwise reimbursed by Medicare:

- the cost of operating the pharmacy in the oncology practice that enables drugs to be safely stored, mixed, and administered to patients;
- the cost of wastage and breakage for drugs (although the practice must pay a drug company for the full price of a vial of chemotherapy, it can only bill Medicare for the portion of the vial that is used);
- the difference between the “Average Sales Price” (ASP) and the actual acquisition cost of the drug (a more detailed explanation of this point is provided below);

- the time the practice spends in trying to get financial assistance to help patients afford the cost-sharing on expensive drugs; and
- the losses practices incur by not being able to collect the full cost-sharing amount from patients who cannot afford it.

Many of the above costs are higher for more expensive cancer drugs. For example, if an oncology practice cannot use 10% of what is in a drug vial, the practice will not be reimbursed for 10% of what it paid for that drug, and a drug that was five times as expensive as another will cause the practice to lose five times as much. Not surprisingly, practices will need to spend more time trying to help patients obtain financial assistance in paying their cost-sharing on expensive drugs than on lower-cost drugs, and practices will have more bad debt for patients receiving expensive drugs than low-cost drugs.

Covering all of these costs and covering the higher costs associated with more expensive drugs does not create an “incentive” for a practice to use an expensive drug. It merely *avoids* creating a *disincentive* for the practice to use the expensive drug, enabling the oncologist to choose the drug that is best for the patient without worrying (as much) about whether the practice will lose money by using the drug.

Some combination of a flat fee and a percentage markup would probably be a better match for a practice’s costs than a pure percentage-based markup, because the percentage markup under-reimburses pharmacy operations costs when lower-priced drugs are used. However, the specific combination that CMS is proposing would not be a better match for an oncology practice’s costs, because CMS’s own calculations show they would result in a more than \$30 million cut in the payments that oncology practices use to cover their costs of operating their pharmacies and purchasing drugs to administer to patients.

In addition, it is important to understand that Medicare does *not* reimburse a practice for its *actual acquisition cost* associated with an expensive chemotherapy drug. Rather, Medicare pays the practice based on the “average sales price” (ASP) of that drug two calendar quarters earlier. Everyone knows that the prices of most cancer drugs are increasing rapidly. This means that in most cases, the ASP payment from Medicare will be less than what the average oncology practice will have to pay to purchase the drug, because the ASP amount was based on the price of the drug six months earlier, not the price when the practice bought the drug. Moreover, not every practice can acquire drugs at the same price, so at any point in time, some practices are paying more than what will ultimately become the “average sales price.” That means the ASP figure will be even less than the current acquisition cost for those practices.

The result of all this is that many practices lose money on many of the chemotherapy drugs they purchase. Medicare’s 6% add-on payment (4.3% under sequestration) on top of ASP helps to offset this loss in some cases, but not all. The proposal to cut that add-on payment will mean that practices will lose money on even more drugs than they do today.

If CMS does not pay adequately to cover the losses and costs oncology practices incur in buying and administering chemotherapy, oncology practices will not be able to afford to administer the drugs patients need. This will affect the ability to administer the lower-priced drugs CMS wants to encourage use of as well as higher-priced drugs.

As noted earlier, paying adequately for the costs of administering chemotherapy does not give practices an “incentive” to use one drug over another. Rather, it ensures that they are not penalized financially for choosing the most appropriate drug for the patient. Contrary to its stated goal, the CMS proposal would not remove an incentive to use high-priced drugs, it would create a financial penalty for practices to use high-cost drugs even when they are the only appropriate drug option for the patient.

There are really only two types of impacts that would be likely to occur if CMS implements the Part B Drug Payment Model. One is that cancer patients will be unable to receive chemotherapy treatments that they need because their oncologists can no longer afford to purchase and administer them. The second is that community oncology practices will close because they lose money trying to administer treatments their patients need without adequate payment from Medicare, and that in turn will mean that patients will have to travel farther and pay more to obtain cancer treatments. It would be inappropriate for CMS to use the authority provided under the Affordable Care Act to “test” whether this is true or how big the impact would be.

We urge that CMS drop this poorly-designed proposal and instead pursue implementation of oncology payment reforms that will make care more affordable without harming patients. In place of the proposed demonstration, we urge that CMS implement the comprehensive payment reform proposal called Patient-Centered Oncology Payment (PCOP) that was developed by the American Society of Clinical Oncology. PCOP is specifically designed to reduce spending on the kinds of drugs, tests, and treatments that are *avoidable* while giving oncology practices the resources they need to deliver high-quality care to patients and avoid complications and hospitalizations. I would encourage you to read *A Better Way to Pay for Cancer Care*, a report prepared by the Center for Healthcare Quality and Payment Reform, that explains how the PCOP payment model would work and why it is superior to the Oncology Care Model and other approaches to alternative payment models that have been proposed or used by CMS. It is available at <http://www.chqpr.org/cancer-care.html>.

PCOP would be a win-win-win for patients, for CMS, and for oncology practices, whereas the proposed Part B Drug Payment Model would harm both patients and oncology practices in an effort to save money for the Medicare program. If CMS is serious about promoting the three-part aim, you should implement the truly comprehensive payment reform ASCO has developed, not the proposed Part B Drug Payment Model.

Thank you for the opportunity to offer these recommendations. I would be happy to answer any questions you may have about our recommendations or to provide any additional information or assistance that would be helpful to you in implementing them.

Sincerely,



Harold D. Miller
President and CEO

cc: Patrick Conway, MD, Acting Principal Deputy Administrator, CMS