CANCER LEADERSHIP COUNCIL

A PATIENT-CENTERED FORUM OF NATIONAL ADVOCACY ORGANIZATIONS ADDRESSING PUBLIC POLICY ISSUES IN CANCER

December 31, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

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

Dear Administrator Verma:

The undersigned organizations, part of the Cancer Leadership Council, are writing to share concerns about the impact of the proposed Medicare Part B drug pricing proposal on people with cancer.

Financial toxicity is a serious side effect of cancer treatment. The patients we represent often struggle with the cost of their care. We support policy efforts to address the cost burden that faces many people with cancer. We are also concerned about the sustainability of the cancer care system in light of the introduction of expensive new therapies that strain patients' financial resources and also those of the system. However, efforts to address the sustainability of the system must also protect patient access to new therapies that may be life-saving.

In evaluating efforts to address the cost of cancer care, we consider whether the plan will be successful without unreasonable disruptions in care and without creating unanticipated barriers to necessary therapies and without adversely affecting quality of care. Our comments below address the impact of the plan on patients.

The plan that is outlined in the advance notice of proposed rulemaking would bring substantial changes to the Medicare Part B drug program and would be tested in an expansive manner. We urge the Centers for Medicare & Medicaid Services (CMS) to review the Part B plan with care, to assess the impact on people with cancer and others who depend on Medicare Part B drugs, and to heed the advice of patients regarding the day-to-day impact of the plan. If CMS moves the plan forward with revisions, the agency should begin with a more modest test that includes strong evaluation elements.

We understand that the advance notice of proposed rulemaking will be followed by a proposed rule in the spring of 2019, with the potential model to be implemented in spring 2020. We also note that the advance notice of proposed rulemaking asks many questions about the Medicare Part B proposal, intended to solicit advice and opinions about the plan. We have attempted to answer a number of the agency inquiries, but we also note that the advance notice, which outlines the Medicare Part B plan in broad strokes, prompts many questions about the plan. We have shared some of the questions raised by the plan, in addition to sharing answers to CMS questions, where possible.

Summary of Proposal

The CMS plan is described as an International Pricing Index (IPI) model but is in fact a model that includes three major components. The model: 1) would "phase down" the Medicare payment amount for certain Part B drugs to align more closely with international prices, 2) allow private-sector vendors to negotiate prices for drugs, take title to drugs, and compete for physician business, and 3) convert the 6 percent add-on payment in the ASP formula to a set payment made to physicians. The conversion of the 6 percent add-on payment is intended to yield an aggregate amount comparable to what would be paid in the absence of the model and before the effects of sequestration, and that aggregate amount would be distributed to providers of Part B drugs.

The model would be tested in selected geographic areas across the United States and its territories; the agency anticipates that "the selected geographic areas would include 50 percent of Medicare Part B spending on separately paid Part B drugs." This is an ambitious launch for the model, and a launch of this scope raises a number of serious questions. In our comments below, we will address issues related to each of the three elements included in the model. However, even if the issues we identify below are addressed, we would advise the agency to test the model in more limited fashion. As we will discuss below, the possibility for harm to patients exists in the model. Launching the program so aggressively is not advisable.

International Pricing Index

Under the proposed international pricing index system, CMS would establish a model Target Price for each drug by "multiplying the IPI by a factor that achieves the model goal of more closely aligning Medicare payment with international prices, which would be about a 30 percent reduction in Medicare spending for included Part B drugs over time…" There are still uncertainties related to setting a target price, including which countries (and their drug prices) will be included in the international pricing index and which drugs will be subject to the Target Price.

We are aware of criticism of some of the countries that are projected for inclusion in the index, because those countries have very different health care systems from that of the US and much lower average incomes. Some have suggested that countries that are so different from the US should not be included in index calculations.

The May 2018 document, American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, offers cautions about reference pricing of the sort that would be utilized in the Part B plan:

> Every time one country demands a lower price, it leads to a lower reference price used by other countries. Such price controls, combined with the threat of market lockout or intellectual property infringement, prevent drug companies from charging market rates for their products, while delaying the availability of new cures to patients living in countries implementing these policies.

In offering the Part B plan, the Administration has not addressed the misgivings about reference pricing that were articulated in the drug pricing blueprint document. If the Administration moves forward with the IPI system for Medicare Part B through a proposed rule, in that document it should explain how the concerns about the impact of reference pricing have been answered and why an IPI reference pricing model is now advisable, when in May 2018 the Administration cautioned against such a plan.

If the IPI model moves forward, we recommend special consideration to new drugs. We have reservations about applying a target price to new drugs, as such action could affect patient access to those drugs. New drugs have generally been subject to "pass through" payment consideration in Medicare payment systems, including those that establish bundled payments or prospective payments. The "pass through" treatment of new drugs has been seen as necessary to protect patient access to these therapies. Such treatment of new therapies may be necessary in an IPI target pricing system. We look forward to commenting on the proposed rule and its recommendations regarding the countries included in the international pricing index and the treatment of new drugs.

The proposal would give the vendors who will be distributing drugs the authority to negotiate prices for drugs, but of course the proposal would provide for establishment of a target price for most Part B drugs. Our concern relates not to the ability of vendors to negotiate prices but instead to the ability of vendors to guarantee access to all Part B drugs at target prices. Has the agency evaluated the potential that vendors may not be able to contract for drugs at the target price and that patient access will be adversely affected by the program?

The Competitive Acquisition Program

In its proposal to attempt once again to implement a Competitive Acquisition Program, under the authority of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the agency cites the financial burden on medical practices associated with purchasing and assuming title to expensive drugs (under the buy-and-bill system) as well as the need to eliminate any incentive to prescribe more expensive drugs. We understand that buy-and-bill is an untenable system for some providers but not others. We also have heard from providers who dispute that prescribing decisions are influenced by the margin on drugs included in the current Part B drug payment methodology.

Even if buy-and-bill is viable for some and margin does not influence prescribing, we agree that there is value in testing a new drug purchase and distribution system. However, we have a number of questions about the CAP model.

CMS suggests that it has addressed the issues that doomed the CAP when it operated from July 1, 2006, through December 31, 2008. During that period of CAP operation, a single vendor was the CAP vendor, and voluntary participation in CAP was limited. Beneficiaries fared poorly under CAP, because of problems with collection of beneficiary cost-sharing and the denial of services related to cost-sharing payments. There were also reported problems with timely delivery of chemotherapy agents.

CMS proposes that providers will retain the responsibility for collecting cost-sharing payments, to avoid the denials of coverage that previously occurred. The agency also suggests that a wide range of entities, including provider groups, will be eligible to serve as CAP vendors. The goal is to ensure that providers have access to the services of more than one CAP vendor. Although there is flexibility as to the entities that might serve as CAP vendors, the vendors will be required to provide nationwide service. This requirement may serve to limit the number of candidates to serve as CAP vendors.

Although we see promise in CAP conceptually, the promise will only be realized if there are multiple vendors in the program. We have concerns that the requirement to serve as a nationwide vendor may limit participation of vendors. If this plan moves forward, we urge that the agreements with CAP vendors include appropriate patient safeguards. These would include protection against loss of benefits due to confusion about cost-sharing payments but also assurances that drugs will be delivered in timely fashion to support delivery of chemotherapy as recommended by the provider, without delays related to delivery glitches.

Moving from the previous CAP experience, which was not successful, to a vibrant CAP program will require careful design and administration by the agency. Our fundamental concern relates to the proposal to launch this program in a way to encompass roughly half of all Medicare Part B drug spending. Unveiling CAP in such sweeping fashion does not seem warranted, based on previous experience. We recommend instead a more modest test of CAP, a recommendation that is relevant to all elements of the Part B proposal.

The advance notice of proposed rulemaking does not note the impact of the CAP pilot on those providers who are not participants in the program. We anticipate that the impact on providers who are not CAP participants will be significant, as reimbursement is affected through the operation of IPI and subsequent ASP changes. It is also unclear if the existing drug distribution system will remain strong, with so much attention directed to CAP vendor participation. The potential impact on providers not participating in CAP is another reason to proceed with the CAP demonstration in more modest fashion than recommended in the advance notice of proposed rulemaking.

Payments to Providers Administering Part B Drugs

The agency has generally outlined a plan to convert the 6 percent add-on payment that is part of the ASP formula to a set payment to physicians administering Part B drugs. This plan in its general contours reflects a recommendation from oncologists that the ASP add-on payment supports important elements of cancer care and must be retained in cancer care reimbursement. However, the advance notice of proposed rulemaking leaves many questions about how the payments will be designed and administered. In the case of cancer providers, we urge that the payments be structured so that they are patient-centered. By this we mean that the payments should be made in made in connection with the encounters between patient and provider to plan care, initiate drug therapy, or make revisions in care plans. It is also critical that the payment amounts be adequate to support the time and expertise required for drug therapy management, administration, and care coordination.

As we note above, there are questions about how the providers who are not participants in the CAP demonstration will be affected by the changes in the ASP formula. Through the impact of the IPI pricing model and the change in payments to providers in the CAP demonstrations, the providers who are outside the CAP demonstration may experience a reduction in total ASP add-on payments. It is important that CMS evaluate the impact of this possibility on the quality of care provided to cancer patients and others who receive Part B drugs.

Although we have offered comments on the Part B program as if it will be implemented essentially as a new demonstration project, we urge against that course in the case of Part B oncology drugs and oncology practices. Instead, we recommend that the Part B drug plan be informed by the experience of the Oncology Care Model and that the Part B drug program not be implemented alongside the Oncology Care Model. We are concerned that participation in two pilot programs simultaneously will be a management challenge for providers and that management of two pilot programs, with different standards and evaluation criteria for each, may negatively affect patients.

We urge that CMS proceed with ongoing evaluations of the Oncology Care Model, including evaluating the impact of the voluntary participation standard, and use those lessons to guide the implementation of the Part B drug program in oncology practices.

P*rotec*ting Quality of Care

The agency asks for advice about measurement of quality in the Part B program. We recommend that the Part B drug plan incorporate practice guidelines. Adherence to practice guidelines will help to ensure that people with cancer have access to necessary treatments. We have consistently recommended that practice guidelines incorporate critical information about side effects of treatment, financial toxicities, and patient quality of life concerns. Progress has

been made in the development and utilization of guidelines that reflect all of these elements. Utilization of practice guidelines is a core means of protecting cancer patients and should be the baseline of measurement if a Part B program moves forward.

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We appreciate the opportunity to comment on the advance notice of proposed rulemaking related to a Medicare Part B drug program. We urge the agency to carefully evaluate the advice received in response to this notice and to proceed with a proposed rule only if a program can be devised that will protect patient access to quality care now and in the future.

Sincerely,

Cancer Leadership Council

Academy of Oncology Nurse & Patient Navigators
Cancer*Care*
Cancer Support Community
Children's Cause for Cancer Advocacy
Fight Colorectal Cancer
Hematology/Oncology Pharmacy Association
International Myeloma Foundation
LUNGevity
Lymphoma Research Foundation
National Coalition for Cancer Survivorship
Ovarian Cancer Research Alliance
Susan G. Komen

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