NCCS
NATIONAL COALITION FOR CANCER SURVIVORSHIP
The power of survivorship. The promise of quality care.

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 National Coalition for Cancer Survivorship (NCCS) is a national organization representing survivors of all forms of cancer in efforts to improve the quality of cancer care for all. We appreciate the opportunity to comment on the advance notice of proposed rulemaking (ANPRM) for the Medicare Part B drug program.

Drugs that are reimbursed through Medicare Part B represent a significant element of cancer treatment for many Medicare beneficiaries, so the smooth functioning and sustainability of Medicare Part B are of critical importance to people with cancer. Financial toxicity is a serious problem for people with cancer, as they bear significant financial burdens related to the cost-sharing for their care. We understand the effort to consider reforms of the Medicare Part B drug program, if changes in the program can provide financial relief to beneficiaries and address the financial viability of the Part B program for the long term.

The proposal that the Centers for Medicare & Medicaid (CMS) has proposed is a complex one, with three distinct but interrelated elements. The proposal: 1) would "phase down" Medicare Part B prices to align more with international prices, 2) implement a Competitive Acquisition Program (CAP) in which vendors would negotiate prices for drugs, take title to drugs, and compete for physician business, and 3) convert the 6 percent add-on in the ASP formula to a set payment to physicians.

Although we fully understand the desire to address Medicare Part B, the potential to create disruption for Medicare beneficiaries is substantial. The scope of the test – in geographic areas that would include 50 percent of Medicare Part B spending on separately paid Part B drugs – is expansive. We identify below issues that we urge CMS to consider if moves ahead with a proposed rule in 2019 and implementation of the revised Part B program in 2020. However, we offer the general advice that any new Part B program should be tested in a more modest fashion than currently proposed, with aggressive evaluation standards. We also recommend that the new Part B test should be coordinated with the ongoing Oncology Care Model demonstration project.

The Competitive Acquisition Program (CAP)

NCCS has consistently expressed support for another test of CAP, as a follow-up to the generally unsuccessful test from 2006 to 2008. We believe that the previous experience can inform another, successful attempt at CAP implementation. However, there are serious questions to be answered before the test moves forward.

We favor a test of CAP because of persistent suggestions that buy-and-bill is no longer a viable option for some oncology practices. The ability to manage a buy-and-bill system seems to depend on the size of the practice, the mix of patients in the practice, and other factors. CAP may serve as an answer to the burdens associated with buy-and-bill. In addition, there are also criticisms of the ASP formula for reimbursement of Part B drugs because some believe it incentivizes the use of expensive drugs. Although many oncologists dispute the suggestion that the ASP formula influences treatment decisions, we see value in revising a payment system that remains open to criticism.

The ANPRM generally outlines standards for CAP vendors that are more expansive than those of the first CAP pilot. A wider range of entities, including provider organizations and medical practices, would be eligible to become CAP vendors. We think this is a positive change in CAP standards, although the requirement that vendors provide services nationwide may serve as a barrier to participation.

We also support the change in CAP standards that would require providers to collect cost-sharing amounts from patients. In the previous CAP pilot effort, placing responsibility for collecting cost-sharing on the CAP vendor resulted in loss of access for a number of patients. We hope that putting this responsibility on providers will avoid that problem, as providers are better suited to work with patients on payment and ensure patient access to needed treatments.

The ANPRM does not contain specific guidance regarding the standards that CAP vendors must follow in terms of coverage of Part B drugs. The proposal would employ an international reference pricing model – the International Pricing Index, or IPI – to bring prices paid in the CAP more in line with international prices. However, vendors would also have power to negotiate prices. We are concerned about the protection of patient access in this model. We think that obstacles to access – the inability to obtain Part B drugs from manufacturers at the reference price and the application of restrictive coverage standards by vendors – could be addressed in part by employing appropriately developed clinical pathways in the CAP program. We urge that, in developing a proposed rule to implement a CAP pilot program, the agency identify clinical pathways that include consideration of patient quality of life concerns and that are developed through a process with appropriate conflict of interest protections to guide the coverage standards implemented by CAP vendors.

Although we believe that the agency can define with greater precision the standards to be adhered to by CAP vendors and therefore provide some assurances about the quality of the CAP program, it will still be a test of a new program with significant ramifications for cancer providers and patients if it is not a successful model. We strongly urge that the agency reconsider the scope of the test that is outlined in the ANPRM. The agency plans a test that would occur in enough geographic areas to represent half of all Medicare Part B drug spending. A mandatory test of this size and complexity is inadvisable; we urge the agency to test on a more modest scale and through voluntary participation.

We note that the agency asks for advice about the coordination of the Part B demonstration project with the Oncology Care Model. If the Part B demonstration moves forward on the scale that is proposed, we fear that there will be major disruption to the Oncology Care Model. Under the scenario of the ANPRM, it is likely that a number of oncology practices that are voluntarily enrolled in the Oncology Care Model will be assigned by mandate to participate in the Part B demonstration. We think that the choice of these practices could be to discontinue Oncology Care Model participation, just as the model is yielding important data.

The ANPRM does not address the dislocations that will likely occur in the practices that ARE NOT included in the Part B test. Over time, those practices will see changes in the payments for Part B drugs, and the buy-and-bill payment system in which they will continue to operate may cease to be viable.

Payments to Providers Administering Part B Drugs

In the ANPRM, the agency proposes 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. For some time, there has been an acknowledgement that the revenues that are generated as the margin in the ASP formula are used to support patient services that are not otherwise reimbursed by Medicare. The proposal that is generally outlined in the ANPRM seems to support the assumption about how funds from drug margin are utilized and also seems to respond to a policy recommendation from oncologists that the add-on payments in the ASP system be retained as part of the overall payment system so that they continue to support important services to cancer patients. There are still questions about how the payments from the aggregate ASP add-on funds will be distributed. We urge that they payments be distributed in a way that ensures that they support services to patients.

As we note above with regard to the CAP test, the proposed changes in payments to providers who are in the model will ultimately have an impact on those providers who are NOT included in the pilot program. As the prices of Part B drugs likely decline, the add-on payments will decline in the aggregate, with the payments to physicians declining correspondingly. The Part B program as described in the ANPRM does not seem to anticipate the impact on providers outside the pilot program and fails to include a strong evaluation of the divergent treatment of providers in terms of the 6 percent add-on payments.

As noted above, careful attention should be given to the impact of changes in Part B payments to physicians participating in the Oncology Care Model. In fact, a more effective way to implement the changes in Part B payments to cancer care professionals would be to incorporate this change into the Oncology Care Model. A fundamental goal of the Oncology Care model is oncology practice transformation, and practices participating in the voluntary program have demonstrated a commitment to transformation and a willingness to work with the Center for Medicare and Medicaid Innovation (CMMI) to implement payment reforms. Thus, incorporating these payment changes in the model might further foster practice transformation, while also limiting the scope of the demonstration to allow thorough evaluation.

International Pricing Index Pricing Model

We understand concerns about the price of cancer drugs and the increases in prices of those drugs. The patients we represent feel the impact of these prices through their cost-sharing responsibilities. Utilization of the international pricing index, or IPI, pricing system for Part B drugs would, according to the agency, result in a 30 percent reduction in Medicare spending for Part B drugs over time. However, in the drug pricing blueprint document that was released in May 2018, the Administration rejected an international reference pricing model, citing the possibility of "delaying the availability of new cures to patients living in countries implementing these policies."

These concerns about patient access to innovative therapies, so effectively identified in the blueprint document, have not been addressed in the Part B drug plan that relies substantially on the IPI pricing model. We share the reservations about the impact of international reference pricing on patient access to innovative therapies, and we do not think that this pricing model should be implemented until a full evaluation of its effects is completed and offered. We trust that this matter will be addressed in the proposed rule, if the agency moves forward with international reference pricing as an element of the Part B plan.

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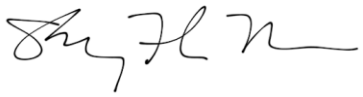
We look forward to participating in the rulemaking process on a Medicare Part B drug plan, if the agency advances, with revisions, the ideas that are outlined in the ANPRM.

Sincerely,



Shelley Fuld Nasso, MPP
Chief Executive Officer