CANCER LEADERSHIP COUNCIL

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

May 9, 2016

The Honorable Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-1670-P, Medicare Program, Part B Drug Payment Model

Dear Mr. Slavitt:

The undersigned cancer organizations of the Cancer Leadership Council are pleased to comment on the proposed rule regarding Medicare Part B drug payment models to be tested over the next several years. This proposal has great significance for the cancer patients we represent, and we have included below some comments about the proposal as well as recommendations for alternative approaches to drug payment reform.

Improving Cancer Care Services

Over many years, the Cancer Leadership Council has advocated reforms in Medicare reimbursement for cancer care, to support the delivery of evidence-based care that honors the needs and wishes of cancer patients. As treatment options have expanded to include targeted and even personalized therapies, our policy efforts have focused more intently on encouraging the delivery of the right treatment to the right patient at the right time. We consider cancer care planning and care coordination as critical elements of a patient-centered delivery system and have made them the focus of our payment reform efforts.

We have been engaged in the payment reform debate by commenting on annual updates to the Medicare physician fee schedule, offering recommendations related to alternative payment systems, and offering our own proposals for payment refinement. More specifically, we have proposed the establishment of a cancer care planning service in the Medicare program, which would be appropriately reimbursed and which would foster shared decision-making and care coordination. We have supported the

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establishment of new codes for chronic care management (CCM) services, transition care management (TCM) services, and advance care planning services, as all of these services will advance our goal of delivery of care that is appropriate for the individual patient and honors patient preferences.

We also engaged actively with the Centers for Medicare & Medicaid Services (CMS) to offer our recommendations regarding the design of the Oncology Care Model (OCM), recommendations aimed at ensuring that the OCM fosters practice transformation and patient-centered care. We found our engagement with CMS on the OCM to be positive, we lent our support to the model, and we look forward to its implementation and evaluation.

Buy-and-Bill System for Part B Drugs

The Cancer Leadership Council has not to date made similarly aggressive recommendations regarding reform of the system for reimbursement for Part B drugs. We have supported the position of our colleagues in the cancer provider community that cancer care payment reform must be comprehensive and that drug payment changes must follow, or be concurrent with, the reform of payment for cancer care services. That position assumed that drug payments served to reimburse some amount of cancer care services and that those services are inadequately reimbursed through existing payment codes.

In light of the new care management codes identified above, the design and implementation of the OCM, and growing unease among all providers with the buy and bill system,[1] it is time to consider alternatives to the current drug payment system. A system that relies on an add-on to ASP will continue to raise questions about the impact of "margin" on prescribing decisions. It is time to put those questions to rest by adopting a different means of supplying and reimbursing for Part B drugs.

In the remainder of our comments, we will offer refinements to the CMS proposal on Medicare Part B drug reimbursement.

Reducing the Add-On in the ASP Formula

CMS proposes a two-phase demonstration project in which participation would be required. In the first phase, the ASP add-on would be reduced to 2.5% plus a flat fee of $16.80 for the practices in the experimental arm of the project. In the second phase, several different value-based purchasing tools would be utilized in certain practices, with their impact evaluated over a number of years.

[1] Polite BN, Ward JC, Cox JV, et al. Payment for oncolytics in the United States: a history of buy and bill and proposals for reform. Journal of Oncology Practice, 10:357-362, 2014.

The agency indicates that prior behavioral research following modifications on drug margins "suggests that the modifications we propose to the 6 percent add-on are likely to change prescribing behavior." In describing the current ASP +6 system, the agency said, "expensive drugs receive higher add-on payment amounts than inexpensive drugs while there are no clear incentives for providing high value care, including drug therapy." The proposed rule suggests that the payment methodologies in the demonstration will be evaluated for their ability to create incentives for value and also reduce costs.

In remarks to stakeholders in the cancer community, CMS officials have expressed the view that most cancer providers are delivering appropriate care to their patients without unreasonable attention to the margin in the ASP reimbursement formula. However, those providers are accomplishing this in a system that is not constructed to emphasize or encourage value.

We agree with the agency about the motivations and goals of cancer providers to provide quality care, and we also agree that the system should be refined to create incentives for quality care for every patient.

We have misgivings about a demonstration that will retain a formula that includes an add-on that is a percentage of ASP and suggest instead that CMS move as expeditiously as possible to an entirely different method for drug acquisition. If the goal of the demonstration is to evaluate payment methodologies that incentivize value, we recommend a different first phase test. We address below some potential challenges associated with the proposed first phase of the demonstration project, but our major reservation relates to retaining for testing and evaluation purposes a payment system that includes a margin on ASP.

Identifying the Unintended Consequences of the Medicare Part B Drug Demo

We have heard a great deal about the potential unintended consequences of the first phase of the Part B drug demonstration project, which would reduce the ASP add-on to 2.5% plus a flat fee of $16.80 for certain practices. We are concerned by reports that practices would be unable to purchase drugs and that as a result some practices would no longer be economically viable. If these were the consequences of the demonstration project, patients might face geographic disruptions in their care system. Some have suggested that the "under water" drug problem might also limit drug choice for some patients.

We are of course concerned about these potential ramifications of the demonstration project. We have reviewed the data in the proposed rule that indicate that the demonstration project is, in the aggregate, budget neutral. We have also reviewed the analyses that show that the practice-by-practice impact may be variable but should not

be significant for any single practice. Many cancer providers do not trust these analyses and believe the impact on practices is understated in the analysis of the proposed rule.

We are not privy to the data that might definitively resolve the debate about the impact of the drug demonstration on practice viability, patient access, and patient choice of drug. If the first phase of the demonstration moves forward as proposed, CMS should provide more information about its ability to monitor any potential problems related to patient access.

Another Option for Incentivizing High Value Care

The proposed rule requests feedback on additional options for incentivizing high value care and asks specifically for responses about the viability of the so-called competitive acquisition program. We are aware of the past history of the competitive acquisition, including its unsuccessful implementation.

Nonetheless, we recommend that some version of the competitive acquisition program – perhaps better described as a centralized acquisition program -- be considered in the Part B drug demonstration project, and we suggest that it be considered as the option for evaluation in the first phase of the project. Despite the previous unsuccessful experience with the program, we think it holds promise going forward. Distribution, tracking, and information technology systems have improved significantly in the last decade, and these improvements might be brought to implementation of a revised centralized acquisition program.

A centralized acquisition program, if it can be implemented successfully, could potentially address the concerns of providers and patients about the current Part B drug payment program. In recent years, cancer care professionals have stressed the difficulties associated with acquiring, storing, and billing for Part B drugs. Physicians have suggested that the number of drugs that are "under water" and which they cannot acquire at current reimbursement rates is increasing. These problems, it has been suggested, are especially severe for small and rural practices that do not have "purchasing power" for chemotherapy drugs. Some have suggested that the sequestration-related adjustments in drug payments contributed to the closure of some community-based oncology practices and the acquisition of others by hospitals. Of course, these trends have been exacerbated by the impact of the 340B drug purchasing program. The centralized acquisition program might answer these concerns by ensuring access to part B drugs for cancer patients in practices of all sizes and structure and in all geographic locations.

For patients, the centralized acquisition program holds attractions because it would address the ability of any provider to obtain all drugs and would ensure there are no economic barriers to prescribing the best drug for any patient. In addition, the competitive acquisition program eliminates the margin that exists in the ASP-based

system and would provide for a clear comparison with the ASP-based payments that would be retained in some practices (the "control" group) in the demonstration. These two options would permit an important evaluation of incentives for high value care.

We recommend that the centralized acquisition program have three parts: 1) a system for shipping drugs to practices for individual patients, 2) a modest fee paid to physician practices for handling and storage of drugs, and 3) a care coordination fee paid to physicians for each patient. The care coordination fee might be a more significant fee paid at the beginning of cycle of chemotherapy or might be a less substantial per-day payment for each day a patient is administered chemotherapy.

The care management fee that we include in the description above may begin to address shortcomings in payment for treatment planning and care coordination by oncologists. We think that additional improvements in payments for physician services – including for the cancer care planning service we described above (and which is reflected in the OCM) – are necessary.

We understand that incorporating a centralized acquisition program in the first phase of the demonstration project would pose an implementation challenge for CMS and for practices. However, we make the recommendation in order to depart from the ASP add-on formula for reimbursement of Part B drugs and at the same time to address the concerns that have been articulated by some about barriers to access to certain drugs under the current first phase proposal.

Protecting and Promoting the Oncology Care Model

As we indicated above, we are strong supporters of the Oncology Care Model, which we think holds real promise of encouraging transformation of practices to deliver patient-centered care. The model acknowledges the need for appropriate payment for physician services associated with patient-centered care as well as payment to improve processes and procedures of care. Upon initial consideration, we thought that those practices that are participating in the OCM should be excluded from the Part B drug demonstration. Our fundamental concern related to the ability of practices to undertake the responsibilities associated with OCM participation and then to be asked to adapt to the Part B demonstration.

However, if the first phase of the Part B drug demonstration is modified, including in the manner we propose above so that a centralized acquisition program is tested, the participation of OCM practices in the Part B drug demonstration should be revisited, as well.

The Second Phase of the Demonstration

We have focused in these comments on the first phase of the proposed demonstration project. We understand that we will have another opportunity to engage with the agency and comment on the second phase of the project. We note the inclusion among the value-based purchasing tools of a plan for discounting or eliminating coinsurance amounts. We think there is promise in eliminating coinsurance responsibilities and determining the extent to which that effort promotes high value care.

We appreciate the opportunity to comment on the proposal for a Medicare Part B drug payment demonstration project.

Sincerely,

Cancer Leadership Council

Cancer*Care*
The Children's Cause for Cancer Advocacy
Fight Colorectal Cancer
International Myeloma Foundation
Kidney Cancer Association
LIVE**STRONG** Foundation
Lymphoma Research Foundation
National Coalition for Cancer Survivorship
National Patient Advocate Foundation
Ovarian Cancer Research Fund Alliance
Prevent Cancer Foundation

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