CANCER LEADERSHIP COUNCIL

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

February 5, 2021

The Honorable Xavier Becerra
Secretary-Designate
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Dear Secretary-Designate Becerra:

The undersigned cancer patient, provider, and research organizations are writing to express opposition to certain new flexibilities that are being provided to Part D sponsors participating in the Medicare Part D Payment Modernization Model for calendar year (CY) 2022. We are concerned about how changes in the protected classes policy and the requirement that only one drug per class be covered will adversely affect cancer patients and the care they receive.

These new flexibilities are outlined in Part D Payment Modernization Model Request for Applications for CY 2022, which was released on January 19, 2021, by the Trump Administration. We urge you to reject these elements of the Request for Applications (RFA) and to release a revised RFA without these provisions.

Protected Classes

The Request for Applications for the Part D Payment Modernization Model would permit Part D sponsors to treat five of the six protected classes – anticonvulsants, immunosuppressants, antidepressants, antipsychotics, and antineoplastics – as any other drug class. The requirement that plans cover all or substantially all drugs in the five protected classes would be eliminated in CY 2022. In CY 2023, this standard would be extended to antiretrovirals.

Our organizations were advocates for the protected classes policy at the time of the initial implementation of Medicare Part D. Cancer patients often require combination therapy with several antineoplastic drugs as well as a range of different drugs over the course of their

treatment. Treatment may be revised if a drug does not provide a benefit to the patient, and patients who have recurrences may require a different treatment regimen from their initial therapy. At the time of launch of Medicare Part D, cancer patients were increasingly receiving "personalized" therapy after undergoing molecular analysis. All these trends in cancer treatment supported formularies for cancer drugs that included "all or substantially all" such drugs. A single patient might have a need for a number of therapies over the course of their cancer treatment, and restrictive formularies would pose a significant challenge to this treatment need.

The trend toward personalized cancer treatment has only accelerated with the development of additional targeted therapies, and cancer patients still require access to "all or substantially all" cancer treatments to prevent obstacles in their access to recommended therapy across the full trajectory of their disease.

The Centers for Medicare & Medicaid Services (CMS) has suggested that terminating the protected classes policy is necessary to provide Part D sponsors enhanced ability to negotiate with pharmaceutical manufacturers regarding inclusion of their drugs on formularies. We understand the desire to restrain the cost of Part D drugs and to reduce cost-sharing and premium responsibilities for Part D enrollees. However, we are concerned that CMS has understated the extent to which Part D plans are managing the protected classes and has also understated the utilization of generics in the protected classes. More importantly, we are concerned that the agency is not adequately considering the impact that eliminating the protected classes policy will have on cancer patients and other enrollees with serious illnesses that require life-saving drug therapies. In the case of cancer patients, the elimination of the protected classes policy may result in serious obstacles to appropriate care.

One Drug Per Class

The Request for Applications would permit Part D plan sponsors to include on formularies only one drug per class, less than the statutory requirement of at least two drugs per class. We believe that this policy would also have an adverse impact on cancer patients and their access to quality care. This policy, if adopted, will have an immediate impact on access to active treatments, but the policy will also adversely affect quality of care by restricting access to supportive care and treatment of comorbidities experienced by cancer patients. Cancer patients need access to supportive therapies throughout the course of their disease, to address the immediate and long-term effects of cancer and cancer treatment. In addition to requiring supportive therapies to address their disease and its effects, cancer patients often have comorbidities that require treatment. Limiting the coverage of drugs in each drug class has the potential to limit patient access to the full range of supportive care and disease treatment that cancer patients require or to impose on patients the need to pursue exceptions to these restrictions.

Part D plan sponsors currently participating in the model have a number of tools to encourage utilization of lower-cost alternatives. These tools include formulary design, drug tiers, and utilization management. We do not support providing sponsors the ability to limit coverage to one drug per class in light of the range of management tools that they already possess and considering the potential adverse effect on cancer patients.

Beneficiary Protections

CMS asserts that, although the Request for Applications would permit waiver of the protected classes policy and the two-drug per class requirement for plans in the model, other beneficiary protections would remain in place. We are not persuaded that these protections will be adequate, especially if plan sponsors take advantage of both flexibilities. If plan sponsors terminate the protected classes policy and take advantage of the flexibility to cover only one drug per class, the implications for cancer patients will be significant. With fewer drugs available on formulary, patients and their care teams will find themselves pursuing appeals from a system that already needs improvement. [1] Without enhancements to the appeals system and resources to address an expected increased number of appeals, patients and providers will experience frustrations that contribute to obstacles to care. Even if patients prevail in the appeals process, they may well experience delays in care that adversely affect the quality of care.

The Request for Applications suggests that the Part D sponsors that are approved to implement the protected classes "flexibility" will be required to implement an enhanced transition process for drugs in the protected classes. This transition process will permit an extended transition supply through temporary refills. There is a lack of clarity in the Request for Applications regarding the implementation of the transition process, but in any event this policy provides inadequate protections to Part D enrollees. The protections they require to ensure access to appropriate treatment are those of the protected classes policy.

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We urge the Department to abandon the so-called flexibilities – elimination of protected drug classes and the implementation of a one-drug per class policy – included in the CY 2022 Request for Applications for the Medicare Part D Payment Modernization models. We would like to see the Part D models move forward, as they are testing policies (including the beneficiary cost-sharing smoothing concept) that are patient-focused and that may improve Part D plans. However, the grant of these two flexibilities will undermine the Part D models. The flexibilities, if embraced by Part D sponsors, may adversely affect access to quality care and may in fact increase – rather than restrain – the financial burden on patients as they deal with the implications of obtaining access to drugs no longer covered by their plans.

[1] Medicare Payment Advisory Commission, Report to Congress: Medicare Payment Policy, March 2017.

Thank you in advance for reviewing the flexibilities identified in the Request for Applications and their potential adverse impact on cancer patients and others with serious health conditions who depend on drug therapies to treat their diseases.

Sincerely,

Cancer Leadership Council

Academy of Oncology Nurse & Patient Navigators
Association for Clinical Oncology
Cancer Support Community
Children's Cancer Cause
Fight Colorectal Cancer
Hematology/Oncology Pharmacy Association
International Myeloma Foundation
LUNGevity Foundation
Lymphoma Research Foundation
National Coalition for Cancer Survivorship
Prevent Cancer Foundation
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CONTACT: 2446 39TH STREET NW · WASHINGTON, D.C. 20007
Phone: 202-333-4041 · www.cancerleadership.org