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January 12, 2015

The Honorable Sylvia Burwell
Secretary
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8010

Submitted electronically to FFEcomments@cms.gov

Re: Draft 2016 Letter to Issuers in the Federally-facilitated Marketplaces

Dear Madam Secretary:

The Prevent Cancer Foundation, the only national nonprofit organization solely devoted to cancer prevention and early detection, appreciates the opportunity to comment on the draft 2016 Letter to Issuers in the Federally-facilitated Marketplaces. We are pleased that HHS has taken this step to ensure adequate patient protection.

Our comments are organized as follows:

Chapter 3

- Section 3: Network Adequacy
- Section 9: Discriminatory Benefit Design
- Section 10: Prescription Drugs
- Section 13: Cost-Sharing Reductions

Network Adequacy

Qualified health plans (QHPs) must “maintain a network that is sufficient in number and types of providers, including providers that specialize in mental health and substance use disorder services, to assure that all services will be accessible to enrollees without unreasonable delay,”

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Issuers will be required to submit a provider list that includes all providers, facilities, and pharmacies in the plan's network. CMS will assess provider networks using a "reasonable access" standard in order to identify networks that fail to provide access without unreasonable delay. We are pleased that CMS will focus most closely on areas which have historically raised network adequacy concerns including oncology providers. However, it would also be helpful for CMS to further define what the "reasonable access" standard entails.

EHB and QHP Discriminatory Benefit Design

The Prevent Cancer Foundation strongly supports the proposed policy for state and health plans ACA requirements to ensure that benefits do not discriminate. It is critical that that CMS expand the proposed policies for 2016 to meet the needs of all patients, particularly those that have chronic illnesses and/or high cost health care needs.

As such, the Prevent Cancer Foundation encourages CMS to:

- Implement more detailed processes for review for plan benefits design to avoid discrimination caused by unfair plan design elements, including utilization management techniques, the structure of the formulary (such as specialty tiers), and cost sharing requirements across all benefits.
 - Perform additional reviews, beyond an outlier test, of QHP Plans and Benefits Templates. Outlier tests are only effective when the predominance of plans is in accordance.
 - Perform additional reviews, beyond an outlier test, of plan cost-sharing. Common practices such as higher cost sharing for certain medications and/or treatments may not be identified in an outlier analysis. Such practices serve equally to discourage individuals with one or more chronic conditions from enrolling and thus are clearly discriminatory. Review of cost sharing should be thorough enough to ensure that such practices do not occur in the Federally Facilitated Marketplaces (FFMs).
 - If outlier tests are implemented in the final letter, the conditions included should not be limited to bipolar disorder, diabetes, HIV, rheumatoid arthritis, and schizophrenia. Other chronic illnesses, such as cancer, are critically important to include.
- Establish final authority at the federal level to approve any state non-discrimination review processes to ensure appropriate measures are in place to guarantee that plans are meeting the requirements of this section.

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- Develop and implement federal monitoring programs to ensure appropriate checks are in place to guarantee that plans are meeting federal requirements.

Prescription Drugs

The Prevent Cancer Foundation appreciates the proposed requirement that formularies be easily accessible. It is critical, however, that all plans should be required to list all of their covered medications on a single formulary rather than multiple formulary documents. Tier placement and utilization management details should also be included in the formulary. Additionally, the data both from plans and on enrollment portals should accurately reflect formulary structure. Currently, healthcare.gov shows only four tiers of drug cost-sharing even for plans with five or more tiers.

The draft letter outlines two net new drug reviews during 2016 QHP certification: a formulary outlier review and a clinical appropriateness review. Outlier reviews are not sufficient, as reviews of plan formularies show a substantial portion of plans designing formularies in ways that discriminate against people living with major chronic conditions. Also, the clinical appropriateness test is limited to bipolar disorder, diabetes, rheumatoid arthritis, and schizophrenia. This, too, is insufficient, as there is clinical concern for adequate formularies for many conditions, including cancer. This is indicated (as one example) by inclusion of antineoplastics in the protected class status of the Medicare Prescription Drug Benefit. As noted in the Medicare Prescription Drug Benefit Manual, "CMS instituted this policy because it was necessary to ensure that Medicare beneficiaries reliant upon these drugs would not be substantially discouraged from enrolling in certain Part D plans, as well as to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations." The protected classes rule was created so that beneficiaries would have access to the most beneficial, clinically indicated medications.

Cost-Sharing Reductions

The Prevent Cancer Foundation is supportive of reviews of cost-sharing reduction (CSR) plans to ensure that people who qualify for lower cost-sharing are accessing plans with reduced costs. It is critical that patients, particularly those most vulnerable and those with high-cost illnesses have predictable health costs and insurance that they can afford.

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Thank you for your consideration of these comments. If the Prevent Cancer Foundation can provide further information, please feel free to contact us as a resource. I can be reached at Carolyn.Aldige@PreventCancer.org or 703-519-2114.

Sincerely,

Carolyn Aldigé

Carolyn Aldigé

President and Founder