December 21, 2015

Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC  20201

Re: CMS-9937-P, HHS Notice of Benefit and Payment Parameters for 2017

Dear Mr. Slavitt:

The undersigned organizations representing cancer patients, physicians and other health providers, and researchers appreciate the opportunity to comment on the Proposed Notice of Benefit and Payment Parameters for 2017. We offer advice on some modifications to the standards for qualified health plans and the operations of health insurance exchanges as outlined in the proposed rule. We commend the efforts of the Centers for Medicare & Medicaid Services (CMS) to provide additional tools to Americans to assist them in choosing appropriate health insurance coverage and utilizing that coverage effectively.

The Roles and Responsibilities of Navigators and Assisters (§§155.205, 155.210, and 155.215)

We support the provisions of the proposed rule that would: 1) require Navigators in exchanges to provide targeted assistance to serve underserved and/or vulnerable populations and 2) require Navigators to provide certain post-enrollment assistance.

Navigators are currently required to have expertise in the needs of underserved and vulnerable populations. The proposed rule would expand that responsibility by setting a standard for Navigators to provide targeted assistance to these populations. This assistance is intended to help new insurance consumers find affordable and appropriate health insurance coverage. The proposal does not identify the populations that meet the definition of vulnerable or underserved but suggests that the primary criteria for identifying these populations would be those who are without access to coverage or care or who are at greater risk of poor health outcomes. The Exchanges would be left with the responsibility for defining vulnerable and underserved populations that would receive targeted assistance.
We believe that the targeted assistance anticipated by the proposed rule would be a significant benefit to cancer survivors in choosing health insurance coverage that is adequate to their needs. There is evidence that some young adult cancer survivors may not be fully aware of the surveillance and follow-up care that they may need after active treatment or may not analyze their health insurance choices consistent with those needs. Targeted assistance to this population might yield great benefits in terms of solid plan choices and then utilization of health insurance coverage. We will seek to persuade Exchanges to include cancer survivors among the vulnerable and underserved populations to receive targeted assistance.

We also support the requirement that Navigators provide post-enrollment assistance to consumers. As the proposed rule notes, many of those who are newly insured through the health insurance exchanges need assistance to use their insurance in a meaningful way. The proposed rule attempts to explain the kinds of post-enrollment services that Navigators might provide, and those services relate mostly to providing accurate and reliable information to consumers. However, according to the proposed rule, Navigators should not provide tax advice to consumers and will not have the responsibility for representing consumers, including in eligibility appeals and other actions. We agree with these limits on the roles of Navigators.

Under the terms of the proposed rule, Navigators would have to undergo training in order to provide post-enrollment assistance. Such training is absolutely critical. We also urge CMS to consider guidance to the Exchanges regarding strategies for collaboration between the Navigators, who will be undertaking important and expanded responsibilities, and patient and consumer organizations. These organizations may have special expertise in post-enrollment issues and could serve as a resource and complement to Navigators.

**Standardized Options (§156.20)**

We support the movement toward standardization of plan options, but we have some reservations about the standardized options that are outlined in the proposed rule. We understand that research suggests that an excessive number of plan options may make consumers less likely to make any plan selection and less likely to make plan choices that match their health needs.

By making certain services deductible-exempt in the standardized option designs, CMS has improved the overall quality of the options for individuals with cancer. For example, the exemption of primary care visits, specialty visits, and prescription drugs from the application of deductibles in most circumstances improves the standardized plan options. A major exception to this is the fact that specialty visits are not exempt from deductibles in the standardized bronze plan and neither are drugs, except for generic drugs.
As the agency notes, the bronze standardized option resembles a catastrophic plan, with some exceptions. We are concerned that the bronze plan may be attractive to young adult cancer survivors because of potentially low premiums, despite the fact that the bronze plan may not be appropriate for the survivor with long-term monitoring and follow-up care needs. We urge adjustments to the bronze standardized option, beginning with the exemption of additional services from the application of the deductible. In addition, this possible poor match of the bronze plan with consumer needs underscores the need for Navigators to provide targeted assistance to certain vulnerable populations to ensure solid plan choices. As we argue above, cancer survivors are a vulnerable population.

We are also concerned that the standardized plan options include a specialty drug tier. Although specialty drugs are exempt from deductibles in all standardized options except the bronze plan, coinsurance percentages, instead of copayments, would be applied in the specialty drug tier. These plan design elements may serve to influence the treatment decisions of cancer patients, if they do not slow or block access to specialty drugs. Coinsurance on certain cancer drugs that are in the specialty tier may cause the patient to reach annual cost-sharing limits early in the plan year, but patients may alter their treatment choices in order to better manage these out-of-pocket costs before reaching their maximums.

**Prescription Drug Benefits (§156.122)**

The preamble discusses the current exceptions process that applies to requests for drugs that are not included on a plan’s formulary list. The preamble reiterates the standards of the current exceptions process and distinguishes it from the coverage appeals regulations that apply to drugs on the plan’s formulary drug list. Also in the preamble, CMS indicates that it is considering allowing plans to meet the exceptions process standard if it complies with a state’s “coverage appeals laws or regulations that are more stringent than or in conflict with our exceptions process under §156.122c.” The language of the preamble is not clear, and there is no regulatory language provided at this time that might convey the intent of the agency. It is far from clear that it would be in the best interest of the patient to have access to an exceptions process that adheres to a state standard that is in “conflict” with the exceptions process defined in federal regulations.

As CMS continues its review of this issue, we urge that the agency consider the federal exceptions process for off-formulary drugs to be a floor and to permit application of state laws if they are more stringent in terms of providing strong procedures for patients to obtain off-formulary drug access.
Network Adequacy Standards (§156.230)

The proposed rule outlines some standards for network adequacy, including a requirement that issuers maintain a network that is sufficient in number and types of providers to assure that all services will be accessible without unreasonable delay, a requirement that issuers supply up-to-date, accurate, and complete provider directories for plan years beginning January 1, 2016, and certain protections against unanticipated out-of-network bills.

The agency proposes a process for the assessment of minimum network adequacy standards that would rely on state review. If the state declines to review network adequacy or does not select a standard that would meet standards that will be outlined in the annual Letter to Issuers, the federally facilitated exchange would conduct a review under Federal default standards. The default standard would be a time and distance standard.

In describing its approach to default standards that would depend on time and distance, CMS said:

> It is not our intent in establishing these default standards to prohibit certification of plans with narrow networks or otherwise impede innovation in plan design. Instead, we intend to establish a minimum floor consistent with the levels generally maintained in the market today, so that generally a very small number of plans would be identified as having networks deemed inadequate.

We appreciate the intent of CMS but are concerned that the articulated network adequacy standards are not adequate. The imposition of time and distance standards represents a modest step toward using quantitative standards for judging network adequacy. However, additional network adequacy standards are necessary to ensure that cancer patients have access to necessary care. We recommend against network tiers and are concerned that the lowest tier in a tiered system would not include the specialists and subspecialists that cancer patients rely on for quality care. We also urge clarity about the timing of review of network adequacy. It is critical that reviews be conducted before plans are marketed in order to provide patients information about their plans’ networks.

CMS notes the ongoing work of the National Association of Insurance Commissioners (NAIC) in developing a model act addressing network adequacy and states that the agency will “take into account the NAIC’s final recommendation as we assess these [network adequacy] policies.” We strongly urge CMS to incorporate into the network adequacy standards for 2017 the provisions of the NAIC Model Act related to patient access to out-of-network care. The NAIC Model Act draft would require insurers to have a process to assure that individuals who require services
from an out-of-network provider may receive those benefits at an in-network level of cost-sharing. The draft Model Act provides that a covered person may receive care from a non-participating provider if the insurer has a sufficient network but not the type of participating provider who can provide the covered benefit to the covered person without unreasonable travel or delay or if the health carrier has an insufficient number or type of provider to care for the insured individual. Those covered persons who are diagnosed with a condition or disease that requires specialized health care services or medical services might receive out-of-network services according to the insurer’s defined process.

A process for ensuring access to out-of-network care at in-network cost-sharing levels is critical for cancer patients. In the case of a patient with a very rare cancer or complex cancer and co-morbidities, or the patient who encounters difficulties in receiving a diagnosis, appropriate care may only be available from providers with special expertise who are not in the insurer’s network. CMS should include among the network adequacy standards a requirement that insurers have a process for reviewing and providing access in such cases. The out-of-network access standards must, of course, include a requirement that out-of-pocket spending for out-of-network care will apply to maximum cost-sharing limits for consumers.

We note that the proposed rule offers modest protections against so-called surprise balance billing for out-of-network care. The proposed rule would permit insured individuals to count their cost-sharing for out-of-network services provided in connection with an in-network service against the annual limitation on cost-sharing, unless the plan has provided the individual a notice in advance of receiving care regarding the additional costs associated with an out-of-network service or provider. Even with advance notice, we are not certain that patients can manage their care to avoid these out-of-network services and charges. We recommend that CMS permit the patient to count cost-sharing for out-of-network services toward annual limits even if the patient has received notice of possible out-of-network services.

We note that the proposed rule acknowledges the challenges that patients may face in maintaining access to their care teams as networks shift and contract. In cases where a provider is terminated from a network without cause, the patient could finish active treatment with that provider until the treatment is complete or for 90 days, whichever is shorter, at in-network rates. There are limits on the definition of active treatment, including that the treatment is for a life-threatening condition or is an ongoing course of treatment for a serious acute condition.

Continued access to a health provider for the shorter of 90 days or until treatment completion will for many cancer patients represent very limited protection and will not prevent disruptions in care. For many adults and children with cancer, treatment regimens are longer than 90 days. For these patients, the only real protections for continuity of care and access to quality cancer care are adequate networks and an efficient process for obtaining out-of-network care at in-network rates.
We are mindful of the need to balance access for the individual to care out-of-network with the cost of such care and the potential effects of these costs on health insurance premiums. Ensuring access to quality care and also guaranteeing affordable premiums require difficult balancing of interests and costs. We make the strong recommendations above regarding out-of-network care with the challenges regarding the overall cost of insurance coverage in mind.

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We appreciate the opportunity to comment on the 2017 Notice of Benefit and Payment Parameters.

Sincerely,

Cancer Leadership Council

CancerCare
Cancer Support Community
The Children's Cause for Cancer Advocacy
Fight Colorectal Cancer
International Myeloma Foundation
Kidney Cancer Association
LIVESTRONG Foundation
Lymphoma Research Foundation
Multiple Myeloma Research Foundation
National Coalition for Cancer Survivorship
National Patient Advocate Foundation
Ovarian Cancer National Alliance
Susan G. Komen
Us TOO International Prostate Cancer Education and Support Network