CANCER LEADERSHIP COUNCIL

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

December 26, 2012

Via Electronic Filing – http://www.regulations.gov

The Honorable Kathleen Sebelius
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-9980-P, Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation

Dear Secretary Sebelius:

The undersigned organizations representing cancer patients, physicians, researchers, and caregivers appreciate the opportunity to comment on the proposed rule setting standards related to essential health benefits, actuarial value, and accreditation. In our comments on the December 2011 bulletin that outlined a state benchmark approach to the establishment of essential health benefits, we urged the Department of Health and Human Services (HHS) to move away from a benchmarking system and instead to provide a national definition of benefits. The proposed rule, although adhering to an approach that gives states great flexibility, is in certain ways more responsive to the needs of all patients, including those with serious and life-threatening illnesses, than the December 2011 bulletin. We applaud those changes. However, the state-based approach to definition of essential health benefits must be further refined to ensure that cancer patients have access to appropriate care.

Our comments are guided by key principles of quality cancer care: 1) patients should participate in decision-making about treatment, based on complete information about all therapeutic options and the benefits and side effects of those treatments and 2) patients should have access to the treatments that are appropriately targeted to their molecular profile, diagnosis, and treatment preferences, including palliative care, as identified through open communication with their cancer care team. We believe these principles will help foster a cancer care system that balances access to comprehensive care and affordability.

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Prescription Drug Benefits

We are pleased that HHS has amended the "one drug per class" standard that was included in the December 2011 bulletin, replacing it with a requirement that health plans providing essential health benefits (EHB) cover the greater of one drug in every category or class or the same number of prescription drugs in each category and class in the EHB-benchmark plan. The standard in the proposed rule, although an improvement over the standard set out in the bulletin, is inadequate to meet the needs of cancer patients. Even if some of the chosen benchmark plans have adequate prescription drug coverage, the imposition of a requirement that plans offer the same number of drugs per class or category as the benchmark will not ensure that plans match the benchmarks in adequacy of prescription drug coverage. Measuring coverage simply by number of drugs on a formulary is not an adequate marker of formulary adequacy or access to quality care.

The treatment of cancer patients requires a robust formulary that will permit appropriate treatment, including combination drug therapies, targeted and personalized therapies, a potentially wide range of drugs in a class over the course of illness and treatment, and drugs for supportive care. The scope of coverage outlined in the proposed rule will not meet those standards of quality cancer care. We recommend that HHS consider incorporating the so-called "protected classes policy" of Medicare Part D, which provides that all or substantially all drugs in certain therapeutic areas be included on Part D formularies.

The protected classes policy has provided important safeguards for cancer patients enrolled in Medicare Part D, and we urge it be considered as an EHB policy. It is a means of assuring that cancer patients have access to the therapies they need over the cancer care continuum and that the movement toward more evidence-based personalization of care is not halted by inadequate formularies. The protected classes policy is especially important in the new era of cancer genomics. Also necessary to ensure the delivery of targeted cancer treatment is access to diagnostic tests that inform treatment decisions. HHS should provide guidance that these tests, which would ensure appropriate targeting of treatment and proper utilization of health care resources, are considered part of the EHB package.

The prescription drug policies in the proposed rule also fall short in the definition of appeals procedures that are provided for patients seeking access to drugs not covered by the health plan. The proposed rule says only that a health plan "must have procedures in place that allow an enrollee to require clinically appropriate drugs not covered by the health plan." We strongly recommend that HHS more specifically define the protections afforded to patients, so that states administering exchanges and health plans have clear guidance about processes for appealing drug coverage decisions. We recommend that the appeals process be an expedited and external appeals process.

Cancer patients and all others must also have access to new drugs that may represent therapeutic breakthroughs for their diseases or essential treatment options when other alternatives have been exhausted. The proposed rule sets no standard for updating formularies to incorporate new drugs. We recommend that the final rule define a process, possibly relying on the plan's independent Pharmacy and Therapeutics (P&T) committee, which would consider incorporation of new drugs into formularies within 90 days of their approval by the Food and Drug Administration (FDA). Moreover, we urge that patients be ensured the right to appeal a denial for a newly approved drug even before the P&T Committee has reviewed the new product.

Drugs Covered by Plans' Medical Benefit

Because physician-administered drugs that are typically covered by plans' medical benefit are critical to cancer treatment, we urge that there be clarity about the standard for coverage for these drugs. We recommend that patients have access to all physician-administered cancer therapies that have been approved by FDA and that would typically be included in the medical benefit. This is the most effective means of ensuring that patients have access to all of the drugs necessary for appropriate cancer treatment as determined through a decision-making process between the patient and physician. We do not believe the United States Pharmacopeia is an adequate system for measuring the adequacy of medical benefit drug coverage, but such adequacy can be encouraged if all FDA-approved therapies are covered.

Patient Cost-Sharing for Out-of-Network Care

We are very concerned that proposed rule provides that an enrollee's cost-sharing for out-of-network care will not count toward the enrollee's annual dollar limit on out-of-pocket expenditures or the annual dollar limit on deductibles. This policy gives plans a powerful tool to encourage enrollees to receive their care within the plan's network. We do not think that such a policy can be made acceptable for cancer patients simply by encouraging a broad network with a wide range of providers. It is unlikely that plans will be able to maintain a network of providers that would be sufficient to meet the needs of all enrollees with cancer, especially those with rare or hard-to-treat cancers. Some cancer patients, for example, require sophisticated radiation therapy not widely available or complex surgery available only in certain centers. For these enrollees, the out-of-network cost-sharing standards would effectively undermine the out-of-pocket spending and deductible limits.

We strongly recommend that plans be required to implement an exceptions process through which enrollees could receive treatment from an out-of-network provider and still count the associated cost-sharing toward annual cost-sharing and deductible limits. An expedited exceptions process should be allowed when delay in initiating treatment might affect the patient's outcome.

Definition of Habilitative Services and Rehabilitative Services

We understand that a number of benchmark plans do not include habilitative services as a category of benefits and that there is also some question about the appropriate definition of habilitative services. In light of these questions, the proposed rule gives great deference to plan issuers to provide habilitative services on a par with rehabilitative services or to define the scope of habilitative services they will offer and report those benefits to HHS. We urge HHS to provide more significant guidance to states and plans regarding habilitative services. This category of benefit, if properly defined, holds the promise of providing childhood cancer patients access to services necessary to help them develop critical skills and functions.

Although rehabilitative services may be more clearly defined by many plan issuers than are habilitative services, we recommend that HHS also offer more expansive guidance about rehabilitative services. We believe this category of benefits should be defined in a way that will ensure the coverage of services that will help cancer survivors protect or regain functions and abilities that might be harmed by cancer and cancer treatment. Many cancer survivors experience late and long-term effects of cancer and cancer treatment, and access to survivorship services to help them address these effects may have a positive impact on health status and quality of life.

Preventive and Wellness Services and Chronic Disease Management

We understand that HHS is adhering to a policy that grants discretion to the states in the selection of a benchmark EHB and to plan issuers in the design of plans consistent with the benchmark EHB. We urge the agency to provide additional guidance to the states regarding the benefit category for "preventive and wellness services and chronic disease management." A departure from discretion to the states and plans would be in order for defining chronic disease management, to ensure that enrollees have access to care planning and coordination services. Availability of such services can foster patient-centered care and assist in achieving the balance between comprehensiveness of services and affordability that HHS is pursuing and that is critical for the future of the health care system.

Coverage for Individuals Participating in Approved Clinical Trials

We urge the Department to amend the proposed rule to state that a plan does not provide EHB unless it provides coverage for individuals participating in approved clinical trials, as designated in section 2709 of the Public Health Service Act, as added by section 10103 of the Affordable Care Act (ACA). The Department has taken such action with regard to the provisions of section 2713 of the Public Health Service Act (as added by Section 1001 of the ACA) establishing standards for certain preventive services without cost-sharing. HHS states in the proposed rule that such action is necessary because EHB-benchmark plan benefits are based on 2012 plan designs that are not subject to the preventive services provisions. The same is true for clinical trials coverage protections. Care in a clinical trial often represents the best option for quality care for a cancer patient, and HHS can protect such access by including coverage of clinical trials (according to PHS Act Section 2709) under the definition of EHB.

State-Required Benefits

In the preamble to the rule, HHS proposes that, for plan years 2014 and 2015, state-required benefits that were enacted on or before December 31, 2011 (even if not effective until a later date) will be considered EHB. This determination relieves the states of the responsibility to pay for these benefits. Moreover, the preamble says that "state rules related to provider types, cost-sharing, or reimbursement methods would not fall under our interpretation of state-required benefits." We are gratified by this determination, as it means that states will not be required to defray the costs associated with the cancer drug cost-sharing laws that have been passed in the majority of states. We believe this HHS decision offers important protections to cancer patients.

Although the preamble offers assurances about state responsibilities related to state-required benefits, the language of the proposed rule does not. The proposed rule states only, "A state-required benefit enacted on or before December 31, 2011 is not considered in addition to the essential health benefits." We urge a revision of the proposed rule to reflect the preamble language regarding state rules related to provider types, cost-sharing, or reimbursement methods. Only with such amendment of the regulation can we be assured that the cost-sharing protections so important to cancer patients will be sustained.

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We commend the work of HHS in responding to public comments regarding the December 2011 EHB bulletin. The refinements in the definition of EHB and standards for state selection will

foster a system of care that is more responsive to the needs of cancer patients and others with serious and life-threatening and chronic illnesses than the system defined in the bulletin. We look forward to working with you during the critical implementation period of 2014-2015 and to reporting on the experiences of cancer patients as important health reforms move forward.

Sincerely,

Cancer Leadership Council

American Society for Radiation Oncology
Bladder Cancer Advocacy Network
Cancer Support Community
The Children's Cause for Cancer Advocacy
Fight Colorectal Cancer
International Myeloma Foundation
LIVE**STRONG**
The Leukemia & Lymphoma Society
Lymphoma Research Foundation
National Coalition for Cancer Survivorship
Ovarian Cancer National Alliance
Pancreatic Cancer Action Network
Prevent Cancer Foundation
Sarcoma Foundation of America
Susan G. Komen for the Cure Advocacy Alliance
Us TOO International Prostate Cancer Education and Support Network

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