

CANCER LEADERSHIP COUNCIL

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

January 31, 2012

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

Re: Essential Health Benefits Bulletin, issued by Center for Consumer Information
and Insurance Oversight on December 16, 2011

Dear Secretary Sebelius:

The Cancer Leadership Council (CLC), representing the undersigned cancer patient, provider, and research organizations, submits the comments below on the Essential Health Benefits Bulletin. These organizations work for access to quality cancer care and improved cancer care treatment through research and development of new therapies and enhanced systems for cancer care delivery.

We urge that the Department of Health and Human Services (HHS) reconsider the approach to defining essential health benefits that is outlined in the bulletin and publish a notice of proposed rulemaking, with a 90-day comment period, that would define a national minimum uniform set of benefits, permit states some flexibility to expand the minimum benefit package, provide clarity about state benefit mandates beyond 2015, and establish a transparent process for updating the minimum benefit package. We also recommend that HHS establish a minimum standard for prescription drug coverage that will assure cancer patients access to necessary medications. Such access cannot be accomplished through coverage of one drug per therapeutic class and instead may require coverage comparable to that of the Medicare Part D “protected classes policy.”

Cancer patients represent a vulnerable population, as they often need complex and intensive health care services when diagnosed and if they have a cancer recurrence. For many people, therapies are targeted according to tumor type and genetics, so drug coverage under the essential health benefits must consider this movement toward targeted cancer treatment. In addition, cancer survivors may have ongoing health care needs related to the late and long-term effects of cancer and cancer treatment. In short, their health care needs are those of patients with serious and life-threatening illnesses and also those of patients with chronic health care issues. Cancer patients are also at increased

financial risk due to the cost-sharing burdens associated with their care, even if they are insured.

Cancer survivors are among those who will benefit from the Affordable Care Act (ACA) and its protections, as they have often found themselves unable to obtain or afford insurance coverage due in large part to pre-existing condition limits. Unfortunately, the promise of the ACA will not become reality for cancer survivors if the essential health benefit (EHB) package leans too heavily toward maximizing state flexibility at the expense of ensuring access to comprehensive and quality cancer care. Cancer patients may find themselves in the position of having insurance that is inadequate for their health care needs and at the same time leaves them with crippling financial responsibility for their care.

Set a Uniform EHB Package

In granting states the authority to choose a benchmark plan from small group plans, state employee health plans, federal employee health plans, or the largest HMO plan offered in the states, HHS is abandoning its statutory responsibility to define essential health benefits. In the bulletin, HHS details the actions it has undertaken, consistent with Section 1302 of the ACA, to inform its efforts to define the EHB bulletin. HHS has received from the Department of Labor (DoL) a survey of employer-sponsored plans, commissioned an Institute of Medicine (IOM) study on the determination of essential benefits, completed research to supplement the DoL plan survey, and convened a series of meetings to receive additional input from stakeholders regarding the EHB package.

The clear intent of the ACA was for the Secretary of HHS to define the EHB package, and in fact the research and consultative work of the Department to date would inform its definition of the EHB package. We urge HHS to fulfill its statutory responsibility and define a national EHB package. HHS will also be better able to oversee the work of the states in administration of Exchanges and application of the EHB package if there is a consistent federal benefit floor applicable to all states.

The undersigned organizations engaged in their own consultative process to define those benefits that are essential for the delivery of quality cancer care. Although the cancer community's internal process included significant discussion regarding those benefits for which evidence is not yet conclusive but which represent the standard of care and therefore should be included in a benefit package, at no time was there any discussion of variation of benefits state-by-state. Instead, there was consensus that those benefits necessary for quality cancer care were consistent nationwide. We strongly recommend that HHS define a package of essential benefits that will apply nationwide, for cancer patients and all others.

If HHS does not reconsider its decision granting flexibility to the states in the choice of a benchmark plan, it must at least eliminate the ability of plan issuers to make substitutions of benefits within the 10 benefit categories defined in the ACA and across those categories. HHS asked in the bulletin if substitution across categories should be scrutinized in order to “mitigate the potential for eliminating important services or benefits in particular categories.” We believe that substitution of benefits has significant potential for elimination of benefits of importance to cancer survivors. Of special concern is the ability of plan issuers to place limits on the scope and structure of prescription drug coverage, so that cancer patients who are heavily dependent on self-administered and physician-administered chemotherapy drugs and supportive therapies will face obstacles to affordable access to critical elements of their treatment regimen.

We also urge, for ease of administration and protection of patients, that HHS clarify that benefit protections of the ACA are incorporated into the EHB package. Of special importance to cancer advocates are the ACA provisions related to: 1) access to certain preventive services without cost-sharing (for plans created after September 23, 2010) and 2) coverage of the routine patient care costs of those with cancer and other serious illnesses who enroll in clinical trials.

Permit State Flexibility Beyond the Federal Floor of Benefits

If HHS abandons the plan to permit states to choose a benchmark from ten possible plans in favor of a national uniform minimum standard, the Department should permit states to adopt variations on the national minimum standard if such variations are equal or greater in comprehensiveness and value to the national standard. Prior to adoption of a variation of the national minimum standard, a state should be required to undertake a process of consultation with the public.

Require Comprehensive Coverage of All Ten Statutory Categories of Services

The bulletin acknowledges that states may choose a benchmark that does not ensure coverage of all 10 categories of benefits that are set forth in the ACA as required elements of the EHB package. In the case of a state benchmark that does not include all the 10 categories, the state must supplement the benchmark to ensure that it incorporates those categories of benefits. The challenge associated with amending an inadequate benchmark to ensure it covers all 10 benefit categories could be more directly and effectively addressed by definition of a uniform national EHB package with appropriate benefits in all the benefit categories.

HHS seeks advice in the bulletin regarding some of the benefit categories, as a number of them are not typically included in the plans from which states will choose a benchmark. One of these categories is “rehabilitative and habilitative services and devices.” HHS asks if the definition of these services should reference creating skills and functions, keeping or maintaining function, or restoring function. We urge a broad and expansive definition of rehabilitative and habilitative services, which are critical for cancer survivors of all ages to ensure that they recuperate fully from cancer and its treatment and

are able to address the late and long-term effects that may influence their ability to attend and flourish in school, succeed in the workplace, and enjoy family life. In some cases, including for young children treated for cancer, the challenge will be creating skills and functions. In older children and adults, the situation may call for the restoration of function or skills.

We further urge that this definition of rehabilitative and habilitative services be incorporated into the uniform national EHB package.

Establish a Clear Process for Determining Status of State Benefit Mandates

The bulletin permits a state to choose a benchmark plan that is subject to state mandates and thereby avoid assuming the costs associated with those mandates. This approach would apply during a transition period of 2014 and 2015. If a state chooses a benchmark plan that does not include some or all mandated benefits, the state would be required to cover the cost of the mandates outside the state's EHB package. In the 2014-2015 transition period, HHS will evaluate state mandates and develop an approach for 2016 that may exclude some state mandates from the state EHB package.

We recommend that HHS develop a policy on state mandates that would apply in 2014 and subsequent years and remove uncertainty about state mandates. The Department indicates that it has already undertaken significant research regarding mandates and the extent to which even those plans that are not subject to mandates nonetheless provide such coverage. For example, the bulletin states that the "FEHBP BCBS Standard Option is not subject to any State mandates, but our analysis indicates that it covers about 95 percent of the benefit and provider mandate categories required under State mandates." It appears that HHS has a significant base of knowledge on which to offer long-term guidance about mandates.

HHS should identify those mandates that are generally covered – for example, those that are covered by FEHBP BCBS Standard Option – and incorporate them in the national EHB package. Moreover, it should promptly evaluate those that are not generally covered and determine whether they will or will not be included in the EHB package. A number of states have implemented advisory groups or other mechanisms for evaluating mandates; such approach may hold promise for HHS to assess mandates and their inclusion in the EHB package.

Many state mandates – including those intended to protect access to prescription drugs – are of critical importance to ensuring cancer patients access to quality care, and HHS should make decisions about their inclusion in the EHB package without delaying a final decision to 2016.

Establish Drug Coverage Standards to Ensure Access to Life-Saving Therapies

In general, the bulletin published by HHS offers considerable flexibility to the states and offers very little specific guidance and few concrete standards. In contrast, the bulletin is specific in the limits that it sets on prescription drug coverage. The bulletin states, “we intend to propose a standard that reflects the flexibility permitted in Medicare Part D in which plans must cover the categories and classes set forth in the benchmark, but may choose that specific drugs that are covered within categories and classes.” The bulletin proceeds to abandon the protections that consumers are offered in the Medicare Part D prescription drug benefit, choosing instead to grant “flexibility” to health plans. Instead of requiring that drug plans offer at least two drugs in each category or class, the bulletin requires only that plans offer a single drug in category or class. By way of a footnote, the bulletin also says that “we do not intend to adopt the protected class of drug policy in Part D.”

Cancer patients may require access to combination therapies (combining two or more cancer drugs in a drug regimen) and access to several different chemotherapy agents over the course of their treatment. Drugs in a therapeutic class are not necessarily interchangeable, and patients may respond differently to the drugs in a class. A formulary that includes a limited number of drugs per class is not adequate for effective cancer treatment, will not ensure that cancer patients have access to the drug in the class that is effective for them, and is not in the interests of payers, who will be required to manage frequent coverage appeals related to cancer drug coverage. Even if cancer patients do finally obtain access to the drugs they need by pursuing an appeals process, the delay in access may undermine the quality and effectiveness of their care and may result in extra costs to them and the health care system.

The so-called protected class policy in Medicare Part D provides that “all or substantially all” drugs in six protected drug classes including antineoplastics will be covered. For cancer patients, this coverage policy has been of critical importance to ensuring their access to appropriate drug therapies through Part D. The rejection of the protected classes of Medicare Part D and the lowering of the Part D coverage standard to one drug per class or category may result in prescription drug coverage that will be insufficient for many, including those with cancer.

The policy of covering a single drug per therapeutic class will also be inadequate for classes beyond those that are considered “protected classes” in Medicare. Cancer patients rely on a wide range of supportive medications to address the side effects of cancer and cancer treatment, drugs that are often necessary to assure their completion of therapy. A policy that requires only the inclusion of a single drug per class will not guarantee that cancer patients have access to the best supportive care.

In its bulletin, HHS states that generic and brand prescription drugs were among those benefits that were found to be consistently covered across all insurance markets. We recommend that the Department rely on the typical employer plan, as it has generally

done in its approach to essential benefits, to define the standards of coverage for prescription drugs. Announcing reliance on Medicare Part D standards and then amending them in a way that threatens access to prescription drugs is not good coverage policy.

We also recommend that a clear standard be established for the addition of new therapies to plans' prescription drug coverage. For those with cancer and many other serious and life-threatening illnesses, the standard of care evolves rapidly with introduction of newly approved therapies to the market. Access to those new treatments will not be assured if there is no clear mechanism for their addition to prescription drug coverage in the EHB package.

Set a Clear Standard for Medical Necessity

Although the definition of the EHB package is essential for understanding the scope of benefits that individuals may enjoy, the definition of medical necessity is critical for defining which specific treatments within the EHB package an individual may receive. Medical necessity should be defined clearly, and the process for appealing decisions related to medical necessity should also be straightforward and expeditious.

Medical necessity should be defined as health care services or products that the health care professional would provide to the patient for the prevention, diagnosis, or treatment of an illness, disease, or injury or their symptoms. The care should be evidence-based or in accordance with generally accepted standards of medical practice and should be clinically appropriate in terms of type, frequency, site, and duration of care. In the circumstances where the evidence related to a medical service or product is inconclusive or incomplete, the expertise and judgment of the medical professional should receive deference. This standard is necessary in the case of cancer treatment, where treatment is evolving rapidly and publication of scientific literature may not fully keep pace with evolution of clinical practice.

Insured individuals should have access to an expedited and efficient appeals process to challenge medical necessity decisions of their plans.

Establish a Transparent Process for Updating the EHB Package

The Department states in the bulletin that it will propose a process to evaluate the benchmark approach, and IOM recommended a transparent process for evaluating and updating the EHB package. We recommend that HHS not delay development of a public and transparent process related to definition of the EHB package. In fact, we recommend that the agency promptly initiate a rulemaking process, consistent with the standards of the Administrative Procedure Act and permitting at least 90 days of public comment, to define the EHB package. In the press release announcing the EHB bulletin, the Department stated, "the paper represents only the intended regulatory approach." We urge HHS to articulate its regulatory approach as soon as possible. This rulemaking

process should be initiated as soon as comments on the bulletin, due on January 31, 2012, can be reviewed.

We appreciate the opportunity to comment on the EHB bulletin and look forward to another opportunity to comment on the proposed rule establishing the EHB package.

Sincerely,

Cancer Leadership Council

American Society for Radiation Oncology
American Society of Clinical Oncology
Cancer Support Community
The Children's Cause for Cancer Advocacy
Coalition of Cancer Cooperative Groups
Fight Colorectal Cancer
International Myeloma Foundation
The Leukemia & Lymphoma Society
LIVESTRONG
Lymphoma Research Foundation
Multiple Myeloma Research Foundation
National Coalition for Cancer Survivorship
National Comprehensive Cancer Network
National Lung Cancer Partnership
Ovarian Cancer National Alliance
Pancreatic Cancer Action Network
Prevent Cancer Foundation
Sarcoma Foundation of America
Us TOO International Prostate Cancer Education and Support Network