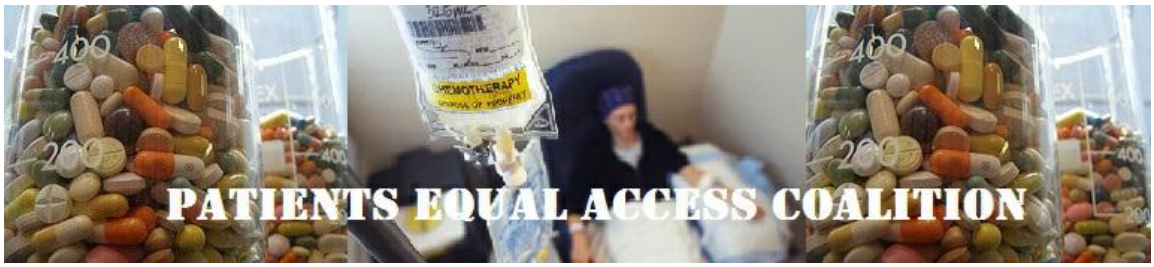

December 21, 2012

The Honorable Kathleen Sebelius
Secretary
Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

Re: CMS-9980-P: Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation

Dear Secretary Sebelius,

The Patients Equal Access Coalition (PEAC) appreciates the opportunity to comment on the proposed rule implementing the Essential Health Benefit (EHB) and Actuarial Value (AV) policies included in the Affordable Care Act (ACA). These policies are critical to ensuring that individuals with cancer can access comprehensive, high-quality health insurance. PEAC is a patient-focused coalition which works to ensure that cancer patients have appropriate access to all approved anti-cancer regimens including, but not limited to, oral and intravenous drugs, intramuscular injections, surgery, radiation, and transplantation. Many of our organizations have formed another coalition, called the State Patients Equal Access Coalition (SPEAC), which advocates for access to comprehensive cancer care on the state level. These comments are from both groups.

PEAC and SPEAC believe that all cancer patients should have access to the anti-cancer regimens recommended by their physicians and should not be forced to choose a less appropriate treatment option, or possibly forego treatment, simply because of inordinate out-of-pocket costs for a more appropriate type of therapy or mechanism of delivery including those that are standard of care. To that end, a well-designed EHB package must provide balanced coverage for all aspects of cancer treatment from preventive care to diagnostic tests to treatment options such as chemotherapy, radiation and surgery to rehabilitation to palliative care. In fact, many cancer patients need essential health services in nine or ten out of the ten categories of benefits. Thus, balanced coverage is central to efforts to ensure that health reform meets its potential to allow Americans to diagnose and treat cancer and other diseases, improve health, and bend the cost curve.

Non-Discrimination Policies

The ACA requires that the Secretary of HHS ensure that the EHB does not discriminate against individuals and takes "into account the health care needs of diverse segments of the population." The proposed rule restates what is in the law but does not detail how the non-discrimination policies will be enforced. Individuals with high-cost chronic and acute conditions like cancer are precisely those who face discriminatory insurance plan designs to limit their treatments and services. As just one example, cancer patients currently face discriminatory plan design, which requires more cost sharing for oral chemotherapy (covered under the pharmacy benefit) than for infused chemotherapy (covered under the medical benefit), simply due to which benefit covers the form of the medication. This is unfair and reduces access to care, since cancer patients who take oral treatments face significant financial burdens. The definition of discrimination included in a final rule should prohibit plans from making coverage decisions, or setting deductible and cost-sharing requirements, that discourage enrollment or

participation, or inhibit access to care needed by particular individuals. Please clarify in the final rule how states and the federal government will monitor and ensure that plans do not discriminate against cancer patients.

Prescription Drug Benefits

Prescription Drug Formularies

We appreciate the expanded prescription drug formulary policy included in the Proposed Rule. The policy included in the Bulletin that would have allowed plans to limit their formularies to one drug per category or class was insufficient for cancer patients, and we are pleased that plans will be required to offer the same number of drugs as the EHB-Benchmark plan, or a minimum of one per category or class. The new policy also satisfies the ACA requirement that the EHB package be modeled after the typical employer-sponsored insurance plan,[1] which generally cover more than one drug per class or category of drugs. [2]

However, we remain concerned that cancer patients may not be able to access all treatments even under the new policy. Cancer patients must have access to the full range of treatments because anti-cancer drugs are not interchangeable and treatment often includes more than one drug or cycling through several regimens during the course of treatment. Also, the emergence of personalized medicine and the increasing use of targeted anti-cancer therapies mean that some treatments are only effective for patients with a particular genetic profile or if their diseases have a particular molecular profile.[3] In addition, many cancer patients must be able to access certain treatments that effectuate chemotherapy or that alleviate side effects of the chemotherapy, such as anti-nausea or anti-emetic drugs.

We encourage the Center for Consumer Information and Insurance Oversight (CCIIO) to implement the protected classes policy included in Medicare Part D. The section of the Social Security Act that describes the category and class requirement for Part D plan sponsors uses anti-cancer drugs as an example of a class where access should be given to multiple drugs: "There is significant clinical need for such individuals to have access to multiple drugs within a category or class due to unique chemical actions and pharmacological effects of the drugs within the category or class, such as drugs used in the treatment of cancer."

We also urge that oral anticancer and anti-emetic therapies covered under Medicare Part B are also covered under the EHB-Benchmark plans.

Access to Drugs Not on the Formulary

We appreciate that plans "must have procedures in place that allow an enrollee to request clinically appropriate drugs not covered by the health plan." However, there are insufficient details for what this process entails. We appreciate HHS's desire to give states and issuers flexibility to comply with these new policies, but we respectfully request that HHS provide standards or guidelines for the appeals process so that there are not delays or disruptions that impact patient care.[4]

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[1] ACA § 1302(b)(2).

[2] A study by Avalere Health, LLC examined the number of covered drugs in nine clinical classes by selected benchmark plans in eight states. Avalere found, "on average, plans covered approximately 62 percent of the drugs available in the studied classes. For most of the classes in the study, most plans covered at least half of the brand-name products and half of the generic drugs available in each class." (Source: Avalere Health LLC study, entitled "Drug Coverage in Essential Health Benefits Benchmark Plans: Formulary Analysis," is available at http://www.avalerehealth.net/news/2012-10-01_EHB_Formulary_Analysis/EHB_Formulary_Analysis.pdf, accessed on December 19, 2012.)

[3] See for example, Dawood S, Broglio K, Esteva FJ, Ibrahim NK, Kau SW, Islam R, Aldape KD, Yu TK, Hortobagyi GN, Gonzalez-Angulo AM. Defining prognosis for women with breast cancer and CNS metastases by HER2 status. *Annals of Oncology.* 2008 Jan; doi:10.1093/annonc/mdn036.

[4] Such criteria would include processes for appeals and grievances, which could mirror requirements of Medicare Part D plans, where CMS requires Part D plans to "accommodate national guidelines and offer treatment options for a variety of medical conditions." (Source: 70. Fed. Reg. 4260, published January 28, 2005, available at http://edocket.access.gpo.gov/2005/05-1321.htm, accessed December 19, 2012.)

Please also address how off-label use for treatments will be addressed in the EHB package. Commonly prescribed off-label uses for cancer treatment must be included in the EHB package. Off-label anti-cancer drugs are currently covered under Medicare Part D, if the use is supported in designated compendia. However, coverage under Medicare Part D should not be the pre-requisite for coverage of off-label therapies. Again we urge that all relevant compendia and cancer guidelines be consulted in determining coverage of off-label anti-cancer therapies.

Finally, please address whether a drug that a patient accesses that's not on the formulary counts as an EHB for purposes of the out-of-pocket maximum. Chemotherapy of all types can be very expensive for patients, and it is critical that any spending on drugs, whether on or off the formulary, covered under the medical or pharmacy benefit, count towards an enrollee's out-of-pocket maximum.

Physician-Administered Drugs

The proposed rule does not address physician-administered drugs, which are covered under the medical rather than pharmacy benefit. Many therapies are delivered in the physician's office, such as anti-cancer treatments and blood products. We respectfully request that the final rule be explicit about any minimum coverage requirements for drugs covered under the medical benefit.

Also, the information on benchmark drugs CCIIO released coincident to the proposed rule does not include sufficient information on how drugs are covered under benchmark plans today. There is information on whether classes of physician-administered drugs are covered, but not how many products in the classes. Please release more information on how many drugs are covered under the medical benefit, as you have for the prescription drug formulary.

Interaction Between State-Required Benefits and EHB

We appreciate the clarification in the proposed rule about the relationship between state insurance laws and costs in the EHB package. The rule differentiates between state laws affecting "care, treatment and services" and those relating to "provider types, cost-sharing or reimbursement methods," and requires states to offset the costs of the former but not the latter. We support this interpretation, because we believe that this policy means that states will not be required to defray the cost of laws relating to oral chemotherapy parity.

In recognition of the prohibitively high costs of many oral anti-cancer medications, many state legislatures around the nation have taken action to ensure access to all anti-cancer therapies for patients. Oregon enacted the first oral cancer drug parity law in 2007, and since then twenty states and the District of Columbia have passed anti-cancer medication parity legislation. Though the statutory language differs slightly between laws, they generally require that state-regulated plans cannot have higher cost sharing for their oral chemotherapy treatment regimen than they would for intravenous chemotherapy treatment.

We are very pleased with your interpretation and believe that it will remove a barrier to enacting further state legislation concerning oral parity in future years. However, in reviewing the documents posted to accompany the proposed rule,[5] we believe CCIIO has inconsistently listed these laws as "state-required benefits" in its analysis of some state benchmark plans, rather than as rules related to cost-sharing. We urge the agency to confirm that state oral chemotherapy parity laws, irrespective of the statutory language used by the state, are considered rules concerning cost-sharing. We are concerned that the CCIIO documents contradict what was stated clearly in the proposed rule's preamble.

[5] See CCIIO "State-Required Benefits" for each state, available at http://cciio.cms.gov/resources/data/ehb.html - review benchmarks, accessed on December 12, 2012.

Treatment of Patient Cost-Sharing for Out-of-Network Care

We are very concerned that the proposed rule would not count an enrollee's expenses for out-of-network care for purposes of the annual out-of-pocket maximum and deductible. This policy would be extremely detrimental for cancer patients, especially those with rare cancers, who must be able to access expertise at specialized centers across the country to effectively treat their disease. It is unlikely that any plan network can include every provider that a cancer patient might need to access during the course of their treatment.

In addition, the proposed rule does not address whether out-of-network providers include pharmacy services, which could further burden patient out-of-pocket costs for lifesaving prescription drugs. Limiting pharmacy choice by requiring beneficiaries to fill prescriptions only at certain locations may make it more difficult for patients to fill their prescriptions. Research has confirmed that medication adherence is associated with lower spending on medical services.[6]

Cancer patients can face high cost-sharing requirements to access out-of-network care, and disallowing this spending for purposes of the out-of-pocket maximum and deductible will severely limit the benefit of this new policy. Please reconsider this policy, so that cancer patients can be sure that they will not face exorbitant out-of-pocket costs when they must access the specialized cancer care they need.

Conclusion

The EHB package will establish standards that will determine the extent to which millions of patients will have access to health care services. Therefore, we appreciate the expanded prescription drug formulary and clarification of state insurance laws policies. However, we urge CCIIO to provide further clarification on the subjects of access to drugs not on the formulary and physician-administered medications to ensure that patients will be able to access the most effective therapies to treat their conditions.

We hope to ensure that cancer patients and others with life-threatening conditions are not discriminated against by plans or denied access to appropriate therapies. PEAC and SPEAC appreciate the opportunity to comment on CCIIO's implementation of the EHB. If you have any questions or would like any additional information, please contact Johanna Gray at jgray@dc-crd.com or 202.484.1100.

Sincerely,

AIM at Melanoma
Aplastic Anemia & MDS International Foundation
Association of Community Cancer Centers
Community Oncology Alliance
Fight Colorectal Cancer
Hematology/Oncology Pharmacy Association
International Myeloma Foundation
Leukemia and Lymphoma Society
National Brain Tumor Society
Oncology Nursing Society
Roswell Park Cancer Institute
Susan G. Komen for the Cure Advocacy Alliance

[6] Roebuck MC, Liberman JN, Gemmill-Toyama M, Brennan TA. Medication adherence leads to lower health care use and costs despite increased drug spending. *Health Affairs.* 2011;30(1):91–9. Available at http://content.healthaffairs.org/content/30/1/91.full, accessed on December 19, 2012.