



February 21, 2013

Mr. Gary Cohen  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
P.O. Box 8016  
Baltimore, MD 21244-8016

**RE: CMS-2334-P: Medicaid, Children's Health Insurance Programs, and Exchanges**

Dear Director Cohen:

The Leukemia & Lymphoma Society (LLS) appreciates the opportunity to comment on the proposed rule on Medicaid, Children's Health Insurance Programs, and Exchanges. These policies are critical to ensuring that cancer patients have access to appropriate care and treatment. Sufficient specificity is required in the guidance promulgated at the federal level to ensure that individuals with cancer and cancer survivors have access to timely and affordable cancer treatments.

LLS is the world's largest voluntary health agency dedicated to blood cancer. Each year, over 140,000 Americans are newly diagnosed with blood cancers, accounting for nearly 10 percent of all newly diagnosed cancers in the United States. LLS funds lifesaving blood cancer research around the world and provides free information and support services. The mission of LLS is to cure leukemia, lymphoma, Hodgkin's disease and myeloma and improve the quality of life of patients and their families.

LLS is committed to ensuring access to and compliance with the most appropriate, evidence-based treatments for all blood cancer patients. Treating cancer involves accessing a complex and extensive set of health care services including combination drug therapies, targeted and personalized therapies, and supportive care therapies, among others. Unless policymakers provide affordable access to comprehensive care, the promise of the Affordable Care Act will not become a reality for cancer patients or survivors. The success or failure of the reforms enacted under the Affordable Care Act will be judged in large part on whether middle class and low-income families can access safe and effective therapies for life-threatening diseases such as blood cancers. Meaningful safeguards are needed to ensure that the most vulnerable cancer patients receive timely access to the most appropriate life-saving therapies. We urge CMS to promulgate additional guidance and regulations that include the patient safeguards described below.

LLS also incorporates by reference comments made by Regulatory Education and Action for Patients (REAP) and the Cancer Leadership Council (CLC). As an active member of these coalitions, LLS strongly supports the arguments made and positions taken on this proposed rule.

## 1. Cost Sharing

In the proposed rule, Section 447.53, Cost Sharing for Drugs, proposes that for Non-Preferred Drugs, individuals with family income  $\leq 150\%$  FPL would pay \$8 per prescription but that ***individuals with family income  $\geq 150\%$  FPL would pay 20% of the cost the agency pays.*** LLS is concerned that this proposal will negatively impact cancer patients' access to critical, life saving therapies. The use of higher coinsurance levels has been shown to be an important factor affecting patient adherence to prescribed cancer therapy. In a study of more than 20,000 patients with at least one adjudicated pharmacy claim for an oral oncolytic agent, claims with cost sharing over \$500 had more than four times the likelihood of abandonment versus claims with cost sharing of \$100 or less.<sup>1</sup>

By implementing a benefit design with a 20% coinsurance on "Non-Preferred Drugs," cancer patients are inherently discriminated against due to the costs associated with the most novel, innovative cancer therapies. By way of example, Imatinib, originally approved for Chronic Myeloid Leukemia (CML) and now also the standard of care for Gastrointestinal Stromal Tumor, carries a retail price for an average monthly (supply) of 400mg tablets in the \$6,000 to \$7,500 range. Even taking into account certain rebates and discounts, the net monthly price is still well above \$4000. Many CML patients are dependent upon Imatinib to keep them alive, yet if Imatinib was not a preferred drug, then a 20% coinsurance requirement would generate a monthly out-of-pocket expense of at least \$900 until the annual limitation on cost sharing is reached, assuming that such a limitation is in place. For an individual making \$17,235 per year (150% of FPL in 2013), a single prescription coinsurance of \$900 per month would be equivalent to 63% of the individual's monthly income, an overwhelming financial strain that does not even consider the costs of additional prescriptions and other medical costs.

Another concern with this provision is that cancer patients could be financially penalized for using certain branded medications, even when deemed medically necessary by their treating providers. Individuals with cancer must have access to a broad range of drugs within each applicable category and class of drugs that are used in evidence-based anticancer treatment regimens. In this way, the medical needs of individuals with blood cancers and other forms of cancer are fundamentally different than many other areas of medicine.

Our understanding of the molecular drivers of blood cancer is at the cutting edge. With this new understanding, cancer treatments will be tailored to an individual tumor's mutations, with drugs

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<sup>1</sup> "Patient and Plan Characteristics Affecting Abandonment of Oral Oncolytic Prescriptions," Streeter, Sonya Blesser, MPP, MPH, et al, Journal of Oncology Practice, Vol. 7, Issue 3S, p. 49.

that hit several key targets at once. This therapeutic cocktail approach would be analogous to H.I.V. treatment, which has dramatically transformed AIDS into a manageable chronic disease.

A benefit design that limits patient access to a list of preferred drugs, fails to appreciate the innovative therapies and precision medicines that are transforming cancer care and letting cancer patients live longer, better, more productive lives. The lower-cost therapies likely to compose the bulk of the preferred drug lists are often not the most medically appropriate option for certain patients; many patients may experience adverse side effects to certain medications and different patients invariably respond differently to various alternatives.

It is critical that this proposed rule encourage patients to have access to the full spectrum of existing and developing patient-centered treatment pathways. It is imperative that cancer patients have access to all drugs that are chemically or molecularly distinct within the applicable categories and classes of drugs used in anticancer treatment regimens or in caring for patients after bone marrow transplants.

In order to encourage the use of critical cancer therapies and to avoid discrimination against cancer patients, we recommend that CMS limit the use of coinsurance as a cost sharing tool by placing a maximum coinsurance payment per prescription over time. CMS should further adopt a reasonable maximum out-of-pocket ceiling expressed in dollars such that all patient out-of-pocket expenses, including all spending for non-covered drugs and services, count against the annual ceiling.

## **2. Exception Process**

The cost sharing provision provides that “the agency must have a process in place so that cost sharing is limited to the amount imposed for a preferred drug if the individual’s prescribing physician determines that the preferred drug for treatment of the same condition either would be less effective for the individual or would have adverse effects for the individual or both.” LLS applauds CMS for the inclusion of this exception process and recommends that CMS provide additional guidance and clarity around the specific process with a defined period of time no more than 48 hours for completion of the process so that patients have access to needed therapies in a timely manner.

## **3. Transparency in Coverage**

Under the newly proposed rule, state Medicaid programs would be required to publish on their websites schedules outlining the parameters of Medicaid coverage, including current premiums, cost-sharing requirements, hospitals charging cost-sharing for non-emergency use of the emergency department and a list of preferred drugs. It is critical that consumers be able to know what drugs and services are covered, as well as the policies concerning off-label usage, access to specialists for second opinions, out-of-network coverage, dental coverage, fertility coverage, nutritional counseling and therapy, palliative care, survivorship care, travel coverage, etc.

Critical advances are made every day in therapies for blood cancer patients, however, these advances must ultimately reach the patients in order keep them healthier longer.

We encourage CMS to ensure that information published on state Medicaid websites on Medicaid coverage, limitations and parameters be in a simple format, and easy to navigate so that patients will be able to easily view and understand such information.

LLS appreciates your consideration of these points and we hope to continue to be a resource as you consider benefit design issues moving forward.

Sincerely,

A handwritten signature in blue ink, appearing to read "Brian M. Rosen".

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Brian M. Rosen, Esq.  
Vice President, Legislative & Regulatory Affairs  
The Leukemia & Lymphoma Society