

Centers for Medicare and Medicaid Services
Attn: Diane Gerrits , Director of the Division of State Demonstrations and Waivers
7500 Security Boulevard
Baltimore, MD 21244
Diane.Gerrits@cms.hhs.gov

September 27, 2013

Dear Ms. Gerrits:

On behalf of patients, physicians and nurses we are writing to express our deep concern regarding the approval of the Oregon Prioritized List of Healthcare Services Guideline 12: Treatment of Cancer Near the End of Life, which was adopted by the Health Evidence Review Commission (HERC) on August 8, 2013. The Revised Guideline 12 permits the state to restrict Medicaid patients' access to potentially life-saving medications for cancer patients. Specifically, our concern is that the implementation of this guideline could violate certain provisions of Federal law meant to ensure a critical base line level of access for this vulnerable subset of patients. The guideline states:

Guideline 12 Cancer Care near the end of life:

Cancer is a complex group of diseases with treatments that vary depending on the specific subtype of cancer and the patient's unique medical and social situation. Goals of appropriate cancer therapy can vary from intent to cure, disease burden reduction, disease stabilization and control of symptoms. Cancer care must always take place in the context of the patient's support systems, overall health, and core values. Patients should have access to appropriate peer-reviewed clinical trials of cancer therapies. A comprehensive multidisciplinary approach to treatment should be offered including palliative care services (see Statement of Intent 1, Palliative Care).

Treatment with intent to prolong survival is not a covered service for patients who have progressive metastatic cancer with

1. severe co-morbidities unrelated to the cancer that result in significant impairment in two or more major organ systems which would affect efficacy and/or toxicity of therapy; OR
2. a continued decline in spite of best available therapy with a non reversible Karnofsky Performance Status or Palliative Performance score of <50% with ECOG performance status of 3 or higher which are not due to a pre-existing disability.

Treatment with intent to relieve symptoms or improve quality of life is a covered service as outlined in Statement of Intent 1, Palliative Care. ⁱ

According to the CMS final rule issued on July 15, 2013, coverage offered to the new adult expansion population must comply with section 1302 of the Patient Protection and Affordable Care Act (PPACA), by selecting a Medicaid benchmark plan that offers all Essential Health Benefits (EHB). PPACA states that, "essential health benefits cannot be denied to individuals against their wishes on the basis of the individuals' age or expected length of life or of the individuals' present or predicted disability, degree of medical dependency, or quality of life." ⁱⁱ In addition to concerns regarding a violation of PPACA for the expansion population, we request that CMS consider whether Oregon is in violation of its section 1115 waiver. The waiver requires CMS approval before making changes to existing benefits offered by the program.

The revised Guideline 12 determines coverage based solely on criteria that quantify disease progression and level of physical ability. It fails to take into account other significant endpoints and the likelihood of an individual

patient responding favorably to a particular treatment based on considerations that are unique to a specific individual with a given diagnosis.

As advocates for cancer patients, we are concerned with the manner in which Guideline 12 shifts treatment decisions away from patients and healthcare providers. The revised Guideline 12 is a fundamental shift away from PPACA's intent to provide quality, accessible treatment without discriminating against patients due to their expected length of life and current physical ability.

Cancer is no longer a generic disease that can be treated with regimens based on broad survival rate statistics. The future of cancer treatment is an individualized approach that should center upon evidence based decisions made between a patient and his or her healthcare provider.

As the cancer treatment landscape continues to change and adapt to innovative new research and therapies, it is of the utmost importance that policy guidelines encourage patients with the greatest medical needs to have sustainable, affordable access to the most appropriate therapies. The current policy sets forth arbitrary coverage limitations and fails to account for the unique needs of each patient.

We respectfully request that CMS provide Oregon with guidance to determine if the Guideline is in violation of Federal law.

Sincerely,

The Leukemia & Lymphoma Society
Alliance for Patient Access
Asian & Pacific Islander American Health Forum
Asian & Pacific Islander National Cancer Survivors
Network
Association of Community Cancer Centers
Bladder Cancer Advocacy Network
Blue Ribbon Advocacy Alliance
Caring Ambassadors
Community Oncology Alliance
Desmoid Tumor Research Foundation
Global Colon Cancer Association
International Cancer Advocacy Network
International Myeloma Foundation

Men's Health Network
Molly's Fund Fighting Lupus
National Association of Hispanic Nurses
National Council of Asian Pacific Islander Physicians
The National Grange
National Lung Cancer Partnership
National Organization for Rare Disorders
Northwest Patient Education Network
One in Four Chronic Health
Oncology Nursing Society
The Oregon State Grange
Salud USA
Sarcoma Foundation of America
ZERO - The End of Prostate Cancer

ⁱ Oregon Prioritized List of Health Services Practice Guideline 12

ⁱⁱ Patient Protection and Affordable Care Act Section 1302 (b)(4)(D)