

CANCER LEADERSHIP COUNCIL

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

August 16, 2010

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
Room N-5653
Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210

RE: RIN 1210-AB42: Interim Final Rules for Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan Under the Patient Protection and Affordable Care Act

The undersigned cancer patient, provider, and research organizations appreciate the opportunity to comment on the interim final rules establishing the standards for status as a grandfathered health plan. We commend the Departments of Health and Human Services, Labor, and Treasury for balancing the needs of plan sponsors and consumers in the interim rules. We recommend some modifications to the rules, as well as the issuance of guidance documents for plan sponsors; our recommendations are aimed at protecting and promoting health care access and quality.

Elimination of benefits

We are pleased that the interim final rules establish that the elimination of “all or substantially all benefits to diagnose or treat particular conditions” would trigger the loss of grandfathered status for a group health plan or health insurance coverage. The language in paragraph (g)(1)(i) also defines the elimination of “benefits for any necessary element to diagnose or treat a condition” as an action that would compel loss of grandfathered status.

This protection of benefits will help ensure that individuals with cancer who remain enrolled in grandfathered plans would have access to the same care that they had access to prior to the enactment of the Patient Protection and Affordable Care Act. We recommend that additional guidance be provided to sponsors and issuers that would clarify that cancer care is multi-disciplinary, possibly requiring patient access to surgery, radiation therapy, and drug treatment, including drugs, biologics, and immunotherapies. For some cancer patients, access to all forms of cancer treatment may be necessary, and at no time in the course of cancer treatment and survivorship would restricting availability to any form or element of cancer treatment be acceptable.

In addition, guidance should clarify that access to cancer drugs and biologics should include access to off-label uses consistent with the standards in the Medicare and Medicaid programs that ensure such off-label uses are evidence-based.

Changes in prescription drug formulary

The interim final rule does not define changes in the prescription drug formulary as actions that would result in loss of grandfathered status. However, the departments do request comment on this issue. We strongly urge that the rule be modified to impose limits on restrictive changes in drug formularies, as such changes could easily result in loss of access to a “necessary benefit” for treatment or diagnosis of cancer.

Changes in the drug formulary -- whether restricting access to particular drugs or to classes or categories of drugs -- could block cancer patient access to necessary drugs for treatment of their specific diagnosis. Such changes would certainly alter the nature of the health care plan on which cancer patients have relied.

The rules should also be amended to place restrictions on the use of formulary management tools, including the utilization of specialty tiers for certain cancer drugs and biologics. Placing cancer drugs on specialty tiers with significant coinsurance requirements might effectively block access to a “necessary element” of cancer treatment.

The provider network

The interim final rules also fail to address the effect of changes in the provider network on a plan’s grandfathered status. We recommend that limits be placed on the scope of changes that could be made to a plan’s provider network, or in the alternative, that health plans or insurance coverage should guarantee continuity of care for those receiving treatment for cancer and other serious and life-threatening illnesses. Such rules would balance the desire of plans to retain grandfathered status and the needs of plan enrollees with serious and life-threatening illnesses for reliable access to high-quality care.

Coverage of routine patient care costs in clinical trials

The Affordable Care Act imposes a requirement, effective in 2014, that health plans cover the routine patient care costs for those enrolled in cancer clinical trials. This provision will ensure that cancer patients can enroll in cancer research studies, which often represent their best treatment option. This benefit will also encourage cancer clinical research that answers fundamental questions about the effectiveness of new cancer treatments and identifies quality cancer care.

We encourage you to take action to make the Affordable Care Act clinical trials provision a meaningful protection for all cancer patients in advance of 2014. We urge the following actions:

- Guidance to grandfathered plans that the option to receive care in a cancer clinical trial, identified by the patient and care team as an appropriate treatment choice, is a necessary element of cancer care and may not be eliminated as a benefit if the plan has included such coverage in the past.

- Encouragement to those plans that have not provided clinical trials coverage to do so voluntarily. Some plans have agreed to such a coverage policy, which they see as advancing the state of knowledge about cancer care and therefore useful not just to those enrolled in trials but to all cancer patients. Others should be encouraged to follow that example.
- Comparison tools, on www.healthcare.gov and in other educational materials, which permit consumers to assess plans for their coverage of clinical trials.

Consumer education regarding grandfathered plans

The departments have to date done an impressive job of posting educational materials online, conducting educational meetings and seminars, and employing other means of providing basic information about the Affordable Care Act. The preamble to the interim rules requests feedback on the materials that grandfathered plans must provide to consumers. We recommend that these documents provide detail about the operation of grandfathered plans and the regulatory requirements that will apply to these plans. It will not be a simple task to create easily accessible consumer materials that explain the rather complicated regulatory structure of the Affordable Care Act. Nonetheless, we recommend that more detail be provided to consumers than seems to be anticipated in the interim rules.

We appreciate the opportunity to comment on the interim final rules on grandfathered plan status. We applaud the work of the departments in developing these rules, which for the most part do an excellent job of balancing the needs of plan sponsors and issuers and the consumers who will rely on coverage through a grandfathered plan.

Sincerely,

Cancer Leadership Council

American Society for Radiation Oncology
American Society of Clinical Oncology
Bladder Cancer Advocacy Network
C3: Colorectal Cancer Coalition
Cancer Support Community
The Children's Cause for Cancer Advocacy
Coalition of Cancer Cooperative Groups
Education Network to Advance Cancer Clinical Trials (ENACCT)
International Myeloma Foundation
Kidney Cancer Association
Lance Armstrong Foundation
The Leukemia & Lymphoma Society
Lymphoma Research Foundation
Multiple Myeloma Research Foundation
National Coalition for Cancer Survivorship
National Lung Cancer Partnership
National Patient Advocate Foundation
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