March 6, 2014

The Honorable Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-4159-P: Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs

Dear Administrator Tavenner:

On behalf of the Cancer Support Community (CSC) and the patients we represent, thank you for the opportunity to comment on the proposed rule entitled “Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs,” published in the Federal Register on January 10, 2014.

We urge the Centers for Medicare & Medicaid Services (CMS) to reconsider its proposal to change the Medicare Part D policy regarding the traditional classes of clinical concern. Individuals with cancer and other complex medical needs rely upon seamless access to life-saving and life-stabilizing prescription drug therapies and benefit greatly from the coverage assured through the protected class status.

As the largest direct provider of social and emotional support services for people impacted by cancer, and the largest nonprofit employer of psychosocial oncology mental health professionals in the United States, CSC has a unique understanding of the cancer patient experience. Each year, CSC serves more than one million people affected by cancer through its network of over 50 licensed affiliates, more than 100 satellite locations, and a vibrant online community — and delivers more than $40 million in free, personalized services each year. Additionally, CSC is home to the Research and Training Institute—the only entity of its kind focusing solely on the cancer patient experience. The Research and Training Institute has contributed to the evidence base regarding the cancer patient experience through its Cancer Experience RegistrySM, publications and peer-reviewed studies on distress screening, the psychosocial impact of cancer and cancer survivorship, to name a few. This combination of direct services and research uniquely positions CSC to provide you and other policymakers with feedback based on evidence as well as real world impact.
CSC commends CMS for its decision to maintain the long-standing policy ensuring Medicare beneficiaries with cancer have access to all antineoplastic agents as well as its recognition of the potential risk to patient outcomes if this policy were to be changed. Unfettered access to all drugs in this class is critical because cancer drugs are not readily interchangeable. This broad access will become increasingly important as personalized medicine advances, and decisions about appropriate therapy become less flexible when driven by the specific attributes associated with an individual’s cancer. Additionally, many treatment plans require access to combination therapies—combining two or more cancer drugs—thus requiring access to multiple agents over the course of a patient’s treatment. In order to maintain the quality of cancer care for Medicare patients, full access to “all or substantially all” cancer drugs must be assured.

CSC is concerned, however, about the impact the proposed elimination of the protected status for other therapeutic drug classes would have on patient access and health outcomes. As a direct service provider, a research entity and a cancer patient advocacy organization, CSC is keenly aware of the importance of treating both the biology and psychology of the patient in order to improve patient outcomes. Quality comprehensive cancer care must treat the whole patient and has many components; for example, the elimination of antidepressants from protected class status could negatively impact patient outcomes.

Up to one-half of all patients with cancer experience moderate to severe levels of distress and approximately fifteen to twenty-five percent of cancer patients experience the comorbid, disabling syndrome of depression. In some cases patients have a pre-existing mental health diagnosis, but for many their need for antidepressant medication is linked directly to their cancer experience. Of the sixteen percent of cancer patients who are prescribed an antidepressant, the specific antidepressant prescribed depends on a multitude of factors: the patient's symptoms, potential side effects and contraindications of the antidepressant, the patient’s individual medical history and previous response to anti-depressant drugs.

Furthermore, data from CSC’s Research and Training Institute shows that disruption of a patient’s work or family life routine is the leading cause of distress for those living with cancer. If the protected classes are altered, patients will face obstacles accessing the drugs prescribed by their physician and will be forced to pursue a number of options in order to maintain access to care—from requesting an alternative prescription from their medical provider to seeking an exemption or appeal. As a result, patients will experience increased burden, uncertainty and delays in treatment. Not only will this jeopardize timely access to biomedical care, the additional disruption created by clinical disease instability may lead to more pronounced distress, especially if switched from an effective therapy to a less suitable alternative with a less optimal clinical outcome. Medicare patients, many of whom are managing multiple chronic conditions, are particularly vulnerable. Creating additional distress for this population may increase patient risk of depression.

CSC recognizes that in the current fiscal climate CMS is looking to control costs and thus argues that full coverage of these six protected classes limits the ability to negotiate price concessions in exchange for formulary placement of drugs and biologics in these classes. Additionally, CMS raises concerns that some drugs in the protected classes are over utilized. While we appreciate the importance of managing costs, it is critical to look more broadly at rising systemic costs that may result if the proposed rule were to be implemented. Limiting the access to and availability
of medications in the protected classes may, in fact, result in treatment delays, decreased medication adherence, additional medical visits and hospitalizations which ultimately result in higher health care costs. As one example, data presented about patients experiencing depression identified higher health care utilization (33.66 visits vs. 18.8 visits per year for those without depression\textsuperscript{vi}) and higher annual health care costs (an additional $8,400 per individual per year\textsuperscript{vii}).

In closing, I would like to thank you for the opportunity to comment on this proposed rule and share the voice of patients living with cancer. Comprehensive, quality cancer care depends on access to a full range of therapeutic options available to treat a number of disease comorbidities. We strongly recommend that you retain the six protected classes of clinical concern as they exist today.

I would be happy to speak with you further about this issue and can be reached at (202) 659-9709 or by email at kim@cancersupportcommunity.org.

Sincerely,

\begin{flushright}
Kim Thiboldeaux
President and CEO
Cancer Support Community
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\textsuperscript{i} Institute of Medicine: Cancer Care for the Whole Patient: Meeting Psychosocial Health Needs, 2008.
\textsuperscript{ii} National Cancer Institute at the National Institutes of Health, \url{http://www.cancer.gov/cancertopics/pdq/supportivecare/depression/HealthProfessional}, last viewed 2/27/2014.
\textsuperscript{iv} \url{http://www.nextavenue.org/article/2011-12/use-anti-depressants-cancer-patients}, adapted from NIH, last viewed 2/27/2014.
\textsuperscript{vii} Ibid.