



*Stop Cancer Before It Starts!*

February 24, 2014

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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, 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 Prevent Cancer Foundation, I am writing today to address the new policy on classes of clinical concern that has been proposed for Medicare Part D beginning in plan year 2015. Removing anti-depressants and immunosuppressants (as well as anti-psychotics at a later date) from protected class status could have devastating effects for the aging, and the most vulnerable individuals, in our country, including many cancer survivors. We strongly urge CMS to continue beneficiary protection through protected classes as they exist today.

As noted in the Medicare Prescription Drug Benefit Manual, "CMS instituted this policy because it was necessary to ensure that Medicare beneficiaries reliant upon these drugs would not be substantially discouraged from enrolling in certain Part D plans, as well as to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations."

The protected classes rule was created so that beneficiaries would have access to the most beneficial, clinically indicated medications. The proposed changes are in direct conflict with this critical concept. This rule could also prohibit beneficiaries from utilizing the newest treatment

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breakthroughs. Further, beneficiaries who need specific drugs that would no longer be considered a protected class would be forced to rely on the Part D appeals process, which is an increased burden on a vulnerable population.

While we applaud the continued protected class status of anticonvulsants, antineoplastics and antiretrovirals, the two criteria under which a decision is made regarding a class of clinical concern are incredibly restrictive and set a dangerous precedent for future decisions.

We understand that this proposed rule has been made in an attempt to cut Medicare costs because protected classes have purportedly reduced the leverage of Part D plans to negotiate discounts for drugs and biologicals. While we support efficiency and the judicious use of limited resources, the potential risk to individuals receiving specific drugs outweighs the possible cost savings. This change poses a burden in terms of cost-sharing and/or health consequences for beneficiaries. Further, as the country shifts towards an overall prevention model to reduce costs and improve outcomes, this proposed rule is simply puzzling.

We applaud the track record of Medicare Part D and recognize the role that it has played in contributing to the health and wellbeing of millions of beneficiaries. For the reasons outlined above, we strongly urge against changes to the protected class status of any of the drugs currently covered. If we can serve as a resource, or provide further information, please do not hesitate to contact me at [Carolyn.aldige@preventcancer.org](mailto:Carolyn.aldige@preventcancer.org) or 703.519.2114.

Sincerely,

*Carolyn Aldigé*

Carolyn Aldigé  
President and Founder