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## United States Senate

SPECIAL COMMITTEE ON AGING

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July 10, 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

Dear Administrator Tavenner:

We write to you today to express our concern that the policy in the Agency's "Part D Payment for Drugs for Beneficiaries Enrolled in Hospice—Final 2014 Guidance" as drafted could have unintended consequences for hospice patients' access to needed medications.

The guidance, in effect, places mandatory prior authorization (PA) on a benefit, as opposed to specific drugs. This is a notable change from the standard use of PA, and a large departure from prior policy released last year, which simply encouraged Part D plans to place prior authorization on four classes of medications. We are concerned that such a substantial change in policy was made and implemented before the finer points of such a transition were established, resulting in significant confusion for beneficiaries.

We appreciate and recognize the Agency's work with our offices since implementation of the guidance on May 1<sup>st</sup> to clarify a number of inconsistencies with the policy. However, we remain concerned that the guidance does not have the enforcement mechanisms needed to ensure that beneficiaries receive needed medications without delay, and further, that appropriate education and recourse has not been clearly defined for those beneficiaries denied their medications.

Specifically, while the Agency's guidance states that its current authority does not allow for a prescription transition fill period, it does allow for the prior authorization process to begin prior to a beneficiary's pharmacy counter transaction, at the point of hospice election. Unfortunately, in the absence of any requirement to ensure that hospice providers and Part D plans engage in this information exchange, there is no assurance that such proactive communications will occur. Similarly, CMS strongly encourages Part D plans to accept determinations from hospice providers when coverage of a drug is in question, but such a direction is not a requirement. The lack of requirement on both such points leaves beneficiaries in a potentially precarious and vulnerable position.

Furthermore, standardized notification and communication between hospices and beneficiaries, beneficiaries and Part D plans, and indeed, between hospices and Part D plans is inadequate. We ask that the Agency immediately incorporate standardized information notifying and explaining

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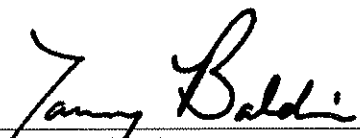
the new policy at the time a beneficiary elects the hospice benefit through the hospice election form, and also incorporate this information into the point-of-sale materials given to beneficiaries at the pharmacy counter, as well as in annual beneficiary coverage documents. There must be, at a minimum, better notification about the new policy to beneficiaries. We would also expect that under the current guidance communications between all involved parties—including Part D plans, hospice providers, and prescribers—would be more easily facilitated with a standardized format, and ask that CMS also ensure the availability of such a format as soon as possible.

Finally, the guidance states that, where necessary, beneficiaries should use the Part D appeals process to challenge coverage decisions for “unrelated” drugs. For “related” drugs, beneficiaries should submit a claim to CMS, and then challenge the determination if necessary. We are concerned that there appears to be no appeals mechanism available to beneficiaries when the issue of “relatedness”—whether the drug is related to the terminal condition or not—is in question. We ask that the agency clarify immediately what appeals process beneficiaries should follow in this instance.

We appreciate CMS’ commitment to program integrity and swift action to correct any double billing that has occurred in this area; however, policy changes should not be implemented so swiftly that beneficiaries are caught in the middle, and left without the care that they need. We ask that you immediately amend the guidance to address the issues that we have raised, and continue to work with stakeholders toward a final rule that better balances program integrity needs while protecting beneficiary access.

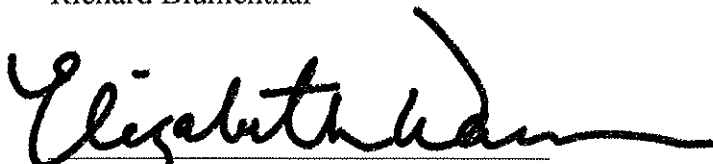
Sincerely,

  
Bill Nelson

  
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Richard Blumenthal

  
Sheldon Whitehouse

  
Elizabeth Warren