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Congress of the United States
House of Representatives
Washington, DC 20515

January 14, 2014

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave., S.W.
Washington, D.C. 20201

Dear Administrator Tavenner,

I write today concerning the recent proposal by the Centers for Medicare and Medicaid Services (CMS) to reduce coverage of mental health drugs in the Medicare Prescription Drug Benefit, or Part D program, by eliminating designation of those therapeutic categories of medications as so-called "protected classes." Having authored the Helping Families in Mental Health Crisis Act (H.R. 3717), which codifies protected class status for antidepressant and antipsychotic medications, I am particularly interested in this issue and the Agency's proposal.

The protected classes were put into place in 2006 to ensure Medicare beneficiaries in the Part D program had access to life-saving doctor-prescribed medication. At the time, your Agency designated six such classes based upon the correct understanding that medications in each class were chemically distinct and not interchangeable. In fact, the current Part D Manual states that "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."

Given your Agency's extensive history on this issue, and the understanding that access to "all or substantially all" medications in the protected classes were needed by Medicare beneficiaries, I was dismayed to learn that CMS is proposing to remove depression drugs from the protected classes, and is considering the same change for antipsychotic medications in 2015. The seriousness of your proposal, and the unexplained change in the Agency's thinking, is of grave concern to me and millions of senior citizens relying on access to these medications.

The Proposed Rule fails to address the Agency's past acknowledgement that Medicare beneficiaries require access to medications in therapeutic classes where different drugs are not interchangeable. The CMS proposal appears not to be grounded in a concern over beneficiary health. Instead, the proposal seeks to increase profits through increased rebate-negotiating leverage for private Prescription Drug Plans Sponsors or insurers (known as PDPs), which received federal subsidies to participate in the Part D program. To the extent that CMS addresses beneficiary concerns, the Agency asserts that beneficiaries are at-risk from "profitable" drug manufacturers, which have an incentive to promote "off-label" usage. This rationale is made without a factual basis, but even if it were to be true, eliminating Medicare beneficiary access to medications is not the solution to this problem.

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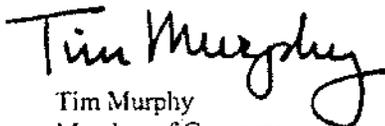
Within days of the Agency's proposed rule, CMS also published a study demonstrating that the very anti-depression drugs CMS proposes removing from protected class status had equivalent, if not higher, generic utilization in Part D than the mean for all drugs in the program.¹ This data undermines the Agency's suggestion that a problem exists in ensuring access to less expensive anti-depression medications, and indicates that notwithstanding their protected class status, these medications are being appropriately prescribed and used in the Part D program. The Agency's own data on generic utilization rates indicates there is no problem to address.

To better understand both the Agency's current thinking about protected classes and the specific proposal to remove mental health drugs from protected class status, I ask that you provide by no later than January 28, 2014, written answers to the follow questions:

1. Please describe the Agency's current medical rationale for designating therapeutic categories of medications as a "protected class." More specifically, please explain whether Medicare beneficiary health and the interchangeability of drugs within a therapeutic class continue to be the Agency's primary considerations for designating medication categories as a "protected class."
2. Please explain the basis upon which CMS concluded clinical concern justifying protected class status arises only "if access to drugs within a category or class for the typical individual who is initiating therapy must be obtained in less than 7 days..." such that "failure to initiate the therapy within that time period would be likely to lead to hospitalization, incapacity, disability or death as a result of the exacerbation of the disease or condition to be treated." In particular, I request that you address the evidence supporting the Agency's view that denial of access to clinically distinct depression medications would not lead to hospitalization, incapacity or disability during a one week period. The Agency should provide me with a detailed explanation of the medical literature it considered in making this important determination on the health and wellbeing of Medicare beneficiaries.
3. Please provide any evidence supporting the Agency's view that "the profitability of products not subject to normal price negotiations as the result of protected class status is a strong incentive for the promotion of overutilization, particularly off-label overutilization, of some of these drugs." In your response, please provide specific examples of the drugs to which you refer, and what factual evidence, as opposed to anecdotal evidence, you have to support this view.

I appreciate your prompt attention to this request. If you have any questions, please contact Brad Grantz in my office at (202) 225-2301.

Sincerely,



Tim Murphy
Member of Congress

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¹ Shiengold, et al., Impacts of Generic Competition and Benefit Management Practices on Spending for Prescription Drugs, Evidence from Medicare's Part D Benefit Medicare and Medicaid Research Review 2014:4(1) at E1 (2014), available at: http://www.cms.gov/mmrr/Downloads/MMRR2014_004_01_a01.pdf