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Association of Community Cancer Centers

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February 24, 2014

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Ave., 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 Association of Community Cancer Centers (ACCC), we appreciate this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule regarding revisions to the Medicare Prescription Drug Benefit Program (Part D), published in the Federal Register on January 10, 2014 (the "Proposed Rule"). ACCC remains concerned about the impact these policy changes will have on Medicare Part D beneficiaries and we encourage CMS to not finalize its proposal.

ACCC represents close to 20,000 cancer care professionals from approximately 1,900 hospitals and private practices nationwide. These include Cancer Program Members, Individual Members, and members from 28 state oncology societies. It is estimated that 60 percent of cancer patients nationwide are treated by a member of ACCC.

ACCC is committed to ensuring that cancer patients have access to the entire continuum of quality cancer care, including access to the most appropriate cancer therapies in the most appropriate settings.

Under the Medicare Modernization Act, CMS was tasked with ensuring that plans offered under Part D offered a robust formulary for patients. In an effort to protect certain vulnerable populations, CMS issued regulations requiring insurance companies offering plans through Medicare Part D to cover all, or substantially all, of the drugs in the following six classes of clinical concern ("protected classes"): immunosuppressants, anticonvulsants, antineoplastics, antidepressants, antipsychotics, and antiretrovirals.

There were many sweeping alterations in CMS's recent proposal for changes to Medicare Part D. Oncology care providers and members of ACCC are particularly concerned about the proposal to eliminate at least two of the six protected drug classes by changing the criteria to qualify as a protected class of drug. Often it is the case that cancer patients require not one, but multiple drugs classified as antineoplastics, one of the six protected classes of drugs under the Medicare Part D Program. CMS interprets the Affordable Care Act (ACA) to limit protected class status for drugs to those for which access to all drugs in a category or class for the average person requiring treatment by the drugs in the class is required within seven days. Upon review of the new criteria, CMS found that drugs in the antidepressant and immunosuppressant categories no longer need to be completely covered by Part D plans.

Now, citing authority given by the Affordable Care Act, CMS states that the former six protected classes rule served its purpose by addressing a learning curve for beneficiaries, and changes should be made to ensure efficiencies in the program. CMS proposes to eliminate protected class status for antidepressants and immunosuppressants in 2015, with discussion of eliminating the antipsychotic class in 2016. For the reasons described below, it is ACCC's position that CMS should not erode patient access to care by eliminating any of the Medicare Part D six classes of clinical concern.

Eliminating protected classes of drugs will not save money across the healthcare system. CMS proposes to eliminate protected class status for antidepressants and immunosuppressants in 2015, with discussion of eliminating the antipsychotic class in 2016. The agency estimates that this proposal, if finalized, will save $1.3 billion between 2015 and 2019.

It is true that if plans are no longer required to cover all or substantially all of the drugs in a class, savings will be realized through Part D. However, this does not ensure costs will go down across the healthcare system since decreased access to drugs could result in increased hospitalizations and emergency room visits. It is widely understood that patients who do not receive the most appropriate care at the time they need it access the health system more frequently and with higher costs associated with their care. This would certainly be a large concern for cancer care providers in the event that the protected classes policy is further eroded to include antineoplastics through future rulemaking.

Eroding patient access to needed therapies is a dangerous precedent. In addition to the elimination of antidepressants and immunosuppressants in 2015, CMS also plans to review the antipsychotic class for elimination in 2016, citing that antipsychotics do not fit within the revised criteria.

ACCC believes this is a dangerous precedent for future erosion of the remaining protected classes of drugs. While Part D plans are still required to cover all or substantially all antineoplastic drugs and oncology providers and their patients are not facing an immediate threat, CMS's proposal certainly creates apprehension about the future of the protected classes policy. In just one rulemaking cycle, the CMS proposal would eliminate or directly threaten patient access to drugs in half of the protected classes the agency once thought so important that it created a specific policy aimed at protecting patient access. For those with cancer, it is imperative that all drugs be available to patients since each patient reacts differently to each of the medications, and changes in treatment regimens may be required as patients experience side effects or as their condition advances.

The Medicare Part D Program is a very successful program and policy changes do not need to be made. At the start of the Part D Program, CMS recognized the importance of protecting vulnerable patients who may lose access to their drugs when transitioning into the Part D Program—that is why the six protected classes policy was developed. Now, CMS indicates in the proposed rule its belief that protection of drugs within the six classes has outlived its necessity; therefore, revision of the policy is warranted.

The Medicare Part D Program is already successful and ACCC believes there is no need to alter the program in a way that reduces patient access to the most appropriate care. Thanks to competition between plans, Part D exceeds expectations by delivering the prescription drugs needed at far below anticipated costs. Eliminating any of the protected classes will not significantly grow Part D savings, but it will leave patients without the ability to receive drugs they need. Therefore, ACCC urges CMS to not implement the proposal.

Listen to your colleagues in Congress. In response to the proposed rule, the Senate Finance Committee submitted a letter to CMS stating in part, "We are very concerned this change will lead to decreased access to medication… Unfortunately, over the course of treatment, certain medications may cause undesired side effects or become ineffective. As a result, certain beneficiaries must have a wide range of treatment options available. By limiting the number and type of medications offered under a Part D plan, a beneficiary may be forced to rely, if only temporarily, on medication that simply does not work or results in adverse side effects."

ACCC agrees with the Committee's letter and urges CMS to not finalize its proposal.

CMS should not make changes to the existing "exceptions" requirement to cover all protected class drugs. CMS also requests comments on a possible regulatory exception allowing plans to impose prior authorization or step therapy requirements on enrollees who are "new starts" on a protected class drug, consistent with a current sub-regulatory exception.

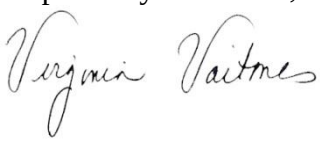
Step edits should not be imposed on patients beginning therapy on a protected class drug. Cancer treatment provides a good example of the problems that the "new start" policy could cause. Cancer treatment options vary by the type, location, extent, and stage of disease. For some patients, cancer can be treated through surgery or radiation, while others may undergo chemotherapy, immunotherapy, or targeted hormonal treatments. The effectiveness of drug therapy varies with each individual patient, as patients' chemical and genetic makeup may affect both their immediate response to different therapies and the duration of response; furthermore, innovations in oncolytic development have led to the emergence of "personalized medicine" agents tailored to the individual characteristics of individual patients and their cancer. Allowing Part D plans to require that cancer patients "fail first" on another therapy before they can try the therapy recommended by their physician—which would usually be the therapy with the best chance of treating a patient's cancer successfully—impedes physicians' efforts to manage the disease effectively and reduces the chance of successful treatment. Part D plans should not be given veto power over these critically important and carefully-considered decisions on the treatment strategy for a cancer patient. And this conclusion also holds true for patients with new prescriptions for drugs in the other protected classes.

Conclusion

ACCC encourages CMS to protect patient access to care by not finalizing the proposed changes to the Medicare Part D Program. The requirement that all drugs be offered is crucial for patients fighting cancer—particularly for antineoplastics—since these drugs may not necessarily be substituted for each other. It is imperative that CMS not implement the proposed changes to the Medicare Part D Program.

ACCC appreciates the opportunity to offer these comments. We look forward to continuing to work with CMS to address these critical issues in the future. Please feel free to contact Sydney Abbott at 301-984-5071, if you have any questions or if ACCC can be of further assistance. Thank you for your attention to these very important matters.

Respectfully submitted,



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