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Administrator Verma:

On August 17, 2018, the Centers for Medicare and Medicaid Services (CMS) issued a memo ("2018 memo") to Medicare Advantage (MA) Organizations entitled "Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage." The 2018 memo rescinded a memo dated September 17, 2012 ("2012 memo") that prohibited MA plans from using step therapy for Part B drugs.

On behalf of the specialty community and the patients we serve, ***we are extremely concerned about this development and urge the Administration to rescind the 2018 memo.*** While we are encouraged that the Administration has included some patient protections, the memo is a mere guidance that contains few binding requirements for insurers to ensure patients are not harmed. There is little direction from CMS on exactly how to implement this new policy and many questions remain as a result. Yet there is no formal opportunity for comment, nor is there much time remaining before the January 1, 2019 effective date.

Our members' experiences with step therapy and other utilization management in Part D and the commercial market are overwhelmingly negative. In many cases, these requirements are based solely on financial factors such as list prices, rather than any medical considerations. They create administrative burdens for practices and interfere with the physician's treatment plan. These concerns are especially pronounced in the case of physician-administered drugs, which generally treat the sickest and most vulnerable patients. Additionally, certain conditions do not lend themselves to step therapy, and requiring the patient to step through several ineffective options may make it more difficult to control their condition in the long run.

Our concerns related to patient access are not alleviated by the exceptions and appeals process contemplated by the 2018 memo. CMS "recommends" that MA plans follow the rules governing Part D exceptions. Our members cite significant challenges with the Part D exceptions process and are concerned about this process being "exported" into Part B. Additionally, in October 2017, the Medicare Payment Advisory Commission staff presented on the Part D exceptions and appeals process and noted that "CMS has found that several plan sponsors fail to comply with regulations."<sup>1</sup> This is not a system to replicate in Part B.

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<sup>1</sup> <http://medpac.gov/docs/default-source/default-document-library/part-d-e-a-for-oct-2017.pdf?sfvrsn=0>.



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Finally, we are concerned about the cost for patients. In the 2018 memo, CMS states that it “expects” this change not to result in increased out-of-pocket costs for beneficiaries. However, this is not a requirement, nor is there a proposed mechanism for CMS to ensure that insurers meet this expectation. Stating an expectation is insufficient to ensure that patients are protected.

In closing, ***we urge you to withdraw the 2018 memo and keep in place the prohibition on step therapy in Part B.*** The 2018 memo lays out a foundational change to the Part B benefit that could severely harm patient care and that has insufficient detail on key implementation requirements. Stating “expectations” and “recommendations” in a memo with a five-month implementation window in which there is no formal commenting opportunity is insufficient to ensure protection of vulnerable patients who need access to Part B medications.

Thank you for your consideration. Should you have any questions or require additional information, please contact Judith Gorsuch at [jgorsuch@hhs.com](mailto:jgorsuch@hhs.com).

Sincerely,

American Association of Neurological Surgeons  
American College of Osteopathic Surgeons  
American Gastroenterological Association  
American Society of Cataract and Refractive Surgery  
American Society of Plastic Surgeons  
American Society of Retina Specialists  
American Urological Association  
Coalition of State Rheumatology Organizations  
Congress of Neurological Surgeons  
North American Spine Society  
Society for Cardiovascular Angiography and Interventions