



January 25, 2019

Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
Attention: CMS-4180-P  
7500 Security Boulevard  
Baltimore, MD 21244-18  
Submitted via <https://www.regulations.gov/>

Re: CMS-4180-P: Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses

Dear Administrator Verma,

On behalf of the National Association of Social Workers (NASW), I am writing regarding the proposed rule addressing drug pricing in Medicare Advantage and Medicare Part D (CMS-4180-P). NASW appreciates the opportunity to submit comments on this important issue.

As the largest membership organization of professional social workers in the United States, with 120,000 members, NASW works to enhance the professional growth and development of its members, to create and maintain professional social work standards, and to advance sound social policies. Thus, the association has a dual mission of advocating for the social work profession and advocating for the individuals, families, and communities served by social workers. Integral to that mission is enhancing the health and quality of life of Medicare beneficiaries, many of whom struggle to access the medications they need. Thus, we appreciate CMS's intent to lower out-of-pocket expenses for Medicare beneficiaries, and we concur with CMS that increasing drug costs must be addressed.

At the same time, NASW is concerned that CMS's proposed approach could delay or even jeopardize beneficiaries' access to medications. The proposed rule would enable Medicare Part D plans to limit coverage of the six "protected classes" of drugs—immunosuppressants for transplant rejection, anticonvulsants, antidepressants, antineoplastics, and antiretrovirals—through the use of utilization management strategies such as step therapy or prior authorization. This change undermines the intent of the protected classes policy: to ensure access to medications for which substitutes are not easily made or for which interruptions in drug therapies could significantly damage individual and public health.<sup>1</sup> Similarly, the proposed rule codifies the use of step therapy by Medicare Advantage (MA) plans for Part B medications—a practice supported by CMS in an August 2018 memo to MA plans. Medicare beneficiaries who require Part B treatments often live with life-altering conditions, such as end-stage renal disease (ESRD) or cancer, that require timely and consistent treatment.

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<sup>1</sup> NASW's opposition to this section of the proposed rule notwithstanding, we share CMS's concern about the misuse of antipsychotics in nursing homes, where such medications often function as chemical restraints for residents living with dementia. NASW urges CMS to implement alternate strategies, such as a strengthened consent process, use of independent consultant pharmacists, round-the-clock registered nurse staffing, and enhanced direct care and medical social services staffing, to address this problem.

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The process of step therapy, also known as “fail first,” requires that individuals take the treatment chosen by their insurance companies, rather than the treatment recommended by their health care practitioners. For Medicare beneficiaries using medications covered by Part B or in one of the six protected classes under Part D, step therapy could create a drawn-out process of experimentation and elimination, thereby prolonging or preventing access to the most effective treatment.

NASW is also concerned about CMS’s proposals to allow Part D plans to exclude a protected class drug from their formularies if (1) the drug were a new formulation of an existing product that lacks a unique route of administration and (2) the price of the drug were to increase beyond a certain threshold over a specified look-back period. Again, although we share CMS’s concern about drug costs, NASW urges CMS to avoid actions that would restrict beneficiaries’ access to medications. Moreover, we respectfully disagree that the Part D appeals and exceptions process would be sufficient to mitigate such problems; as noted in the Medicare Payment Advisory Commission’s March 2018 *Report to Congress: Medicare Payment Policy*, “Beneficiary advocates, prescribers, plan sponsors, and CMS have all noted frustrations with Part D coverage determinations, exceptions, and appeals processes” ([http://medpac.gov/docs/default-source/reports/mar18\\_medpac\\_entirereport\\_sec\\_rev\\_0518.pdf?sfvrsn=0](http://medpac.gov/docs/default-source/reports/mar18_medpac_entirereport_sec_rev_0518.pdf?sfvrsn=0), p. xxv).

Were CMS’s proposed changes to Part B and Part D be implemented, therefore, people with cancer, depression, HIV, seizure disorder, and other serious illnesses would face even greater difficulty in obtaining the medications they need. Such barriers would not only increase health and financial burdens for beneficiaries but would also be time-consuming for health care practitioners and costly for CMS. For these reasons, NASW urges CMS to withdraw these proposals.

Thank you for your consideration of NASW’s comments. If you have any questions, please do not hesitate to contact me at [naswceo@socialworkers.org](mailto:naswceo@socialworkers.org) or (202) 336-8200.

Sincerely,



Angelo McClain, PhD, LICSW  
Chief Executive Officer