



# AMERICAN SOCIETY OF HEMATOLOGY

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## 2019

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SUBMITTED ELECTRONICALLY VIA REGULATIONS.GOV

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

Administrator Verma:

The American Society of Hematology (ASH) is pleased to offer comments on the proposed rule, Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses. We appreciate the opportunity to provide these comments to the Centers for Medicare and Medicaid Services (CMS) on how this proposed rule will impact our members and the patients they serve.

ASH represents over 17,000 clinicians and scientists worldwide, who are committed to the study and treatment of blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as non-malignant conditions such as sick cell anemia, thalassemia, bone marrow failure, venous thromboembolism, and hemophilia. In addition, hematologists are pioneers in demonstrating the potential of treating various hematologic diseases and continue to be innovators in the field of stem cell biology, regenerative medicine, transfusion medicine, and gene therapy. ASH membership is comprised of basic, translational, and clinical scientists, as well as physicians providing care to patients in diverse settings including teaching and community hospitals, as well as private practice.

ASH strongly supports the Part D protected class policy and notes that according to the Part D Manual, "Part D sponsor formularies must include all or substantially all drugs in the immunosuppressant (for prophylaxis of organ transplant rejection), antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic classes. 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."<sup>1</sup> It has been critical to ensuring that cancer patients treated by our members have access to appropriate therapies. ASH is very concerned that the proposed changes included in this rule will disrupt therapy for vulnerable populations, and the Society urges CMS to maintain the existing protected class policy without change.

ASH shares the Administration's strong concerns about the overall cost of medical care and, in particular, the cost of drugs. While the Society appreciates that the Administration

is taking steps to address drug costs, the Administration continues to put forth proposals that prioritize reducing expenditures above patient access. Our members treat medically vulnerable patients, many with few treatment options, and ASH cannot support policies to lower the cost of drugs that come at the expense of patient access to high-quality care. ASH provides the following comments with this in mind.

### **Providing Plan Flexibility to Manage Protected Classes**

ASH opposes the three proposed exemptions to the protected class policy. The Society's concerns are outlined below.

1. ASH opposes the proposed exemption, to implement broader use of prior authorization (PA) and step therapy (ST) for protected class drugs, including to determine use for protected class indications, for the following reasons:

First and foremost, this proposal will harm patient access to care. Both PA and ST have the potential to delay patient access to necessary, high-quality medication. For example, chemoimmunotherapy (CIT) has been the standard first-line therapy for chronic lymphocytic leukemia (CLL) for many years and continues to be for most patients. More recently, a better understanding of the biology of CLL has led to significant advances in its treatment, including for patients with specific mutations. It was only recently discovered that patients with a del17p mutation need different therapeutic strategies and targeted treatments. CIT is not appropriate for patients with this mutation and if used, the patient will eventually fail and lose precious time to stabilize their disease. Part D policies must recognize the nuances of treatment for these disease types. If implemented as proposed, a CLL patient with del17p could be first forced to utilize CIT and fail before receiving coverage for ibrutinib. It is especially concerning that this proposal would allow for the use of PA and ST regardless of whether the beneficiary is just starting the treatment or already using the product.

Secondly, allowing for broader use of PA and ST will increase administrative burden even when the Administration's stated priority is to reduce burden as part of the "Patients over Paperwork" initiative. Every other year ASH surveys its membership of practicing US-based hematologists. Survey results from 2013, 2015, and 2017 all include prior authorization as one of the top three issues currently affecting practice.

2. ASH opposes the proposed exemption, to exclude a protected class drug from a formulary if the drug represents only a new formulation of an existing single-source drug or biological product, regardless of whether the older formulation remains on the market, for the following reasons:

Again, this proposed exemption could be detrimental to patient access to clinically appropriate care. ASH understands that this proposal is intended to discourage manufacturers from introducing a more expensive formulation of a protected class drug while discontinuing the original version; however, this could create a scenario in which a patient loses access to an important drug altogether.

3. Lastly, ASH opposes the proposed exemption, to exclude a protected class drug from a formulary if the price of the drug increased beyond a certain threshold over a specified look-back period.

This exemption proposes to exclude drugs based solely on cost, not based on the clinical effectiveness or use of the drug. This exemption, similar to other policies put forth by the Administration, would deny patients access to drugs based on prices set by industry. ASH believes this policy could eliminate our patients' access to needed therapies. There are few treatment options for patients with hematological malignancies and there could be many instances where patients will not have access to an alternative cancer therapy if the drug they are being treated with is removed from the Part D formulary. This demonstrates why the protected class policy as currently applied is so critical for cancer patients or patients recovering from an allogeneic transplant, receiving immunosuppressants.

### **Medicare Advantage and Step Therapy for Part B Drugs**

ASH also opposes allowing Medicare Advantage (MA) plans to apply step therapy as a utilization management tool for Part B drugs. ASH signed onto a [letter](#), led by the American Medical Association (AMA), expressing concern about this policy change when it was originally issued by CMS in August 2018. Step therapy protocols that require patients to try and fail certain treatments before allowing access to other, potentially more appropriate treatments can both harm patients and undercut the physician-patient decision-making process. ASH, the AMA, and the other signees urged CMS to reinstate its 2012 policy prohibiting Medicare Advantage plans from utilizing step therapy protocols for Part B physician administered medications.

### **Prohibition on Gag Clauses in Pharmacy Contracts**

ASH is supportive of the proposal to prohibit gag clauses in pharmacy contracts. This proposal provides that a Part D sponsor may not prohibit a pharmacy from, nor penalize a pharmacy for, informing a Part D beneficiary of the availability of a prescribed medication at a cash price that is below the amount that the enrollee would be charged to obtain the same medication through the enrollee's Part D plan. Prohibiting the gag clauses could allow for a patient to potentially receive his/her medication at a lower out-of-pocket cost than what is being asked for through the Part D plan.

Thank you for the opportunity to provide comments on the proposed rule, Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses. We welcome the opportunity to discuss these comments with you and your team. If you have any questions or require further clarification, please contact Leslie Brady, ASH Policy and Practice Manager at [lbrady@hematology.org](mailto:lbrady@hematology.org) or 202-292-0264.

Sincerely,



Roy L. Silverstein, MD  
President

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<sup>1</sup><https://www.cms.gov/Medicare/Prescription-Drug-coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>