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January 16, 2018

Seema Verma
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-4182-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Ave, SW
Washington, DC 20201

RE: Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program (CMS-4182-P)

Dear Ms. Verma:

The American Society of Hematology (ASH) is pleased to offer comments on the proposed rule outlining revisions to the Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program.

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 sickle cell anemia, thalassemia, bone marrow failure, venous thromboembolism, and hemophilia. In addition, hematologists were pioneers in demonstrating the potential of treating various hematologic diseases through bone marrow transplantation, and we continue to be innovators in the fields of regenerative medicine, transfusion medicine, and gene therapy. ASH membership is comprised of basic, translational, and clinical scientists, as well as physicians who are providing care to patients in diverse settings including teaching and community hospitals, as well as private practices.

ASH looks forward to working closely with the Centers for Medicare and Medicaid Services (CMS) as the agency implements this proposed rule and offers the following comments which focus on areas of particular importance to our members:

1. Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes
2. Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS Cost Sharing
3. Changes to the Days' Supply Required by the Part D Transition Process
4. Maximum Out-of-Pocket Limit for Medicare Parts A and B Services

Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes (page 285)

The rule proposes to permit Part D plan sponsors to immediately remove brand name drugs (or to makes changes in their preferred or tiered cost-sharing status), when those Part D sponsors replace the brand name drugs with (or add to their formularies) therapeutically equivalent newly approved generics—rather than having to wait until the

direct notice and formulary change request requirements have been met. Currently, Part D Plan sponsors can add a new generic drug to their formularies when it enters the market but cannot remove the brand drug or change the brand drug's formulary status without first obtaining CMS approval and giving beneficiaries 60 days written notice of the pending change and access to a transition fill of the brand drug.

The Society is concerned about the impact of expedited substitutions and/or midyear formulary changes on patients with hematologic diseases and disorders because not all drugs in this space are bioequivalent; furthermore, such changes without notification is also a concern. As patient care becomes more and more complex with the increased use of molecular and genetic diagnostics as well as increased use of more targeted precision medicine therapeutics (i.e. immunotherapies), a high level of expertise is required to understand these new modalities. We urge the agency to ensure that the Part D plan sponsors who review these complex diagnostics and therapies either possess this expertise or consult with organizations and/or experts who do. CMS may consider requiring that the credentials of those making these changes are publicly available. This will ensure that substitutions and/or changes in formularies do not undermine patient care or have any deviation in best practices of care. This is especially important if changes occur during the course of a complex patient's treatment plan, as there could be unintended consequences including the potential for patient harm.

Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS Cost Sharing (page 297)

The rule proposes to revise the definition of "generic drug" to include follow-on biological products solely for purposes of cost-sharing. The intent is that lower cost sharing for lower cost alternatives will improve enrollee incentives to choose follow-on biological products over more expensive reference biological products, and will reduce costs to both Part D enrollees and the Part D program. Currently, follow-on biological products do not meet the definition of multiple source drugs or the definition of generic drug under the Part D rules and consequently, these products are subject to higher cost-sharing limits for low income subsidy eligible (LIS) beneficiaries generally and for all Part D beneficiaries who are in the catastrophic phase of coverage.

Currently, regulations specify lower Part D maximum copayments for low-income subsidy (LIS) eligible individuals for generic drugs and preferred drugs that are multiple source drugs. ASH supports the agency's attempt to lower costs for patients and recommends finalizing this proposal. If finalized, it will only apply to patients receiving low income subsidies and all patients once they reach catastrophic coverage. Patients in the catastrophic phase are required to pay the higher of either a maximum copay or a percentage of a drug's cost. Because of the high cost of biosimilars, patients will most likely have to pay a percentage of the drug's cost; we urge CMS to explore ways to lower costs for those who have catastrophic coverage. Many of the drugs our members prescribe for patients are extremely costly and the maximum copay or percentage of the cost could be extremely high, particularly if this is a lifelong or prolonged therapy.

Changes to the Days' Supply Required by the Part D Transition Process

The rule proposes to shorten the required transition days' supply in the long-term care (LTC) setting to the same supply currently required in the outpatient setting. The rule also proposes a technical change to the current required days' transition supply in the outpatient setting to be a month's supply, rather than the previous 90 days. Consequently, if finalized, the supply for the LTC setting will also be a month's supply. The proposal will require sponsors to honor multiple fills of non-formulary Part D drugs, as necessary during the entire length of the 90-day transition period for a new enrollee in a LTC facility.

The Society feels that the proposed changes to the transition supply required by the Part D transition process is a reasonable approach if it will not incur a higher cost for the patients. If the intent of this policy change is to lower the cost for Part D sponsors, then they should only be allowed to make this change if the patient cost remains at or below what it would have been.

Maximum Out-of-Pocket Limit for Medicare Parts A and B Services

The proposed rule considers changes to the formula used to determine maximum out-of-pocket (MOOP) amounts in an effort to encourage Part D sponsors to voluntarily offer plans with lower MOOP limits, based on local market conditions, rather than actuarial standards set by national Medicare Part A and B cost sharing benchmarks. CMS does not propose changes in this rule, but instead will include them in future rulemaking.

The cost of many of the drugs used to treat rare hematologic diseases and cancers are extremely high, and ASH supports policy to lower patients' MOOP costs. As CMS considers policy to include in future rulemaking, we encourage the agency to ensure that any proposed changes do not narrow the plans' formularies. Part D plans should continue to maintain coverage for the full range of drugs, including those specialized drugs required by patients with hematological and other complex disorders.

Thank you for the opportunity to provide these comments. We welcome the opportunity to discuss these proposals, and others being considered with you and your team. If you have any questions or require further clarification, please contact Suzanne Leous, ASH Chief Policy Officer at sleous@hematology.org or 202-292-0258, or Leslie Brady, ASH Policy and Practice Manager at lbrady@hematology.org or 202-292-0264.

Sincerely,

Alexis Thompson, MD
President