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Secretary Azar:

The American Society of Hematology and the undersigned State Societies, representing practicing oncologists and hematologists, write to you today to provide comments on the Health and Human Services (HHS) Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. Our comments specifically focus on the proposal to move drugs from Medicare Part B to Medicare Part D.

We are particularly concerned about what this move could mean for patients receiving cancer treatment. With the exception of patient-administered chemotherapy medications, which are typically oral and covered under Part D, the majority of chemotherapy is administered in a physician office and covered under Medicare Part B.

Moving these high-cost, yet necessary, anticancer drugs into Part D may increase the costs for the patient or delay care due to instances of improper transport or handling. Medicare beneficiaries' out-of-pocket costs for cancer therapies can vary substantially based on whether a drug is covered by Part B or Part D because of differing benefit designs and the use of supplemental health coverage¹. According to an analysis by Avalere, in 2016, average out-of-pocket costs were about 33 percent higher for Part D-covered new cancer therapies than for those covered in Part B.¹ Even after a patient has reached catastrophic coverage in Part D, they still must pay five percent of the cost of each drug. For example, a patient taking Revlimid, covered under Part D, to treat multiple myeloma could have a copay of several hundred dollars per month. A patient could be on this medication for months or years, creating a devastating financial burden.

Additionally, moving drugs from Part B to Part D will increase the practice of "brown bagging" and "white bagging." "Brown bagging" occurs when a patient picks up a specialty medication from a pharmacy and then carries this medication to their physician's office or hospital for administration. "White bagging" is when a payer purchases drugs through a specialty pharmacy, which then ships the medication directly to the provider for administration.

Both practices are attractive for a payer as they can typically purchase drugs at a lower cost from a specialty pharmacy than they can from a provider. They also both create a shift in reimbursement from a patient's medical benefit (Part B) to a patient's drug benefit (Part D) and because of the difference in payment structures, this usually results in patients taking on a greater portion of the cost burden. In addition, brown and white bagging add concerns about additional costs, as well as quality control and patient safety. For brown bagging, if drugs, specifically chemotherapy, were to be moved from Part B to Part D, patients would then be responsible for collecting these therapies and carrying them to their physician's

office for administration. ASH is very concerned about adverse health effects that would result from improper handling or transport of chemotherapy treatment.

For white bagging, while the provider and institution are not responsible for or reimbursed for the mixing of the specialty pharmacy drug, they do assume responsibility for the handling and administration of the drugs. Furthermore, for specialty drugs covered under Part B, Medicare pays providers the average sales price (ASP) plus 6 percent, which has been reduced to ASP plus 4.3 percent due to sequestration, to cover the added costs of storage, handling, and inventory management. These costs are not covered under Part D reimbursement, yet much of the responsibility remains, placing a greater financial burden on the provider. ASH is concerned that moving chemotherapy drugs from Part B to D will not lower the cost of drugs but rather will shift some of the costs onto patients and providers.

White and brown bagging can also lead to excessive waste in instances in which the medication is billed by the pharmacy but is never administered to the patient. For example, between the time a drug is ordered and the patient arrives at the physicians' office to receive the drug, the required dosage or strength may have changed, or the patient may have been transitioned to a different class of medication. There may also be instances where the provider decided to discontinue therapy, or the patient may experience an adverse event, changing the course of treatment. However, the already ordered medications cannot be reused for a different patient. Lastly, white and brown bagging can cause delayed access to care. Medication delivered through the mail may arrive late or damaged. Patients who require an unexpected dosage change may have to wait to receive treatment until a new order is placed and delivered. We cannot support a policy that would increase the practice of white bagging and brown bagging because of the many potential detrimental impacts this would have on patient care.

Other concerns for this proposal include the fact that not all Medicare beneficiaries have Part D, as this is a voluntary program. Additionally, Part D formularies may change at any time and physicians do not know in advance what is on the formulary. Moving anticancer medications to Part D will make it difficult for cancer patients to know which medications are covered and which are not. Chemotherapy is a very personalized treatment, with regimens potentially changing throughout the year. If a patient picked the wrong plan or is changed to a different form of chemotherapy, which is not covered, this may increase out-of-pocket costs for the patient.

Furthermore, as part of the President's FY2019 Budget request, the Administration proposes to relax the Part D formulary standards by reducing the required number of drugs per class from two to one covered by the formulary, and to allow greater use of restrictive drug utilization management (DUM) policies – quantity limits, step therapy, and prior authorization - for drugs in the protected classes. ASH is concerned that this will sharply reduce patient access to medically necessary drugs, increase delays and administrative hassles for patients and physicians trying to obtain authorization for formulary exceptions and DUM policies, and increase patients' out-of-pocket costs.

Patient access to high-quality, affordable care is a top priority. For the reasons stated above, we oppose moving drugs from Part B to Part D as it will have unintended consequences and limit patient access to care.

Thank you for the opportunity to provide comments on the Health and Human Services (HHS) Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. If you have any questions or require further clarification, please contact Leslie Brady, ASH Policy and Practice Manager at lbrady@hematology.org or 202-292-0264.

Sincerely,

The American Society of Hematology
Denali Oncology Group
The Arizona Clinical Oncology Society

Association of Northern California Oncologists
Medical Oncology Association of Southern California
Rocky Mountain Oncology Society
Delaware Society for Clinical Oncology
Florida Society of Clinical Oncology
Georgia Society of Clinical Oncology
Hawaii Society of Clinical Oncology
Idaho Society of Clinical Oncology
Indiana Oncology Society
Iowa Oncology Society
Kansas Society of Clinical Oncology
Kentucky Association of Medical Oncology
Maryland and District of Columbia Society of Clinical Oncology
Michigan Society of Hematology & Oncology
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Missouri Oncology Society
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