



AMERICAN SOCIETY OF HEMATOLOGY

2021 L Street, NW, Suite 900, Washington, DC 20036 **ph** 202.776.0544 **fax** 202.776.0545 **e-mail** ASH@hematology.org

July 16, 2018

Alex M. Azar II
Secretary
Department of Health and Human Services
200 Independence Avenue SW
Room 600E
Washington, DC 20201

Secretary Azar:

I am writing on behalf of the American Society of Hematology to provide the following comments on the Health and Human Services (HHS) Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs.

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 shares the Administration's strong concerns about the overall cost of medical care and, in particular, the cost of drugs, and the Society appreciates that the Administration is taking steps to address this issue. Drugs treating hematologic conditions are often very expensive. Every day, hematologists encounter situations in which patients with medical insurance have difficulty paying for expensive therapies that are necessary to treat the underlying condition and any associated comorbidities. Policy changes must reduce cost and enhance patient access to care, not increase out-of-pocket costs or just shift the cost from the patient to the provider. ASH's overall goal is to protect and improve patient access to drugs. The Society comments on the specific policy proposals within the Administration's Blueprint with this goal in mind.

Moving Drugs from Medicare Part B to D

The President's Budget requested the authority to move some Medicare Part B drugs to Medicare Part D. Drugs are covered by Medicare Part B or Part D, depending on how the drug is administered. As you know, Medicare Part B covers medically necessary services or covered preventative tests received from a physician in a hospital, office setting, or other certified setting. In Part B fee-for-service, beneficiaries pay a 20 percent coinsurance on all medical services, including drugs; however, because most Part B beneficiaries have some type of supplemental medical insurance which covers the cost of the coinsurance, individuals are not likely to pay high out-of-pocket costs, if any. Part D, also called the Medicare prescription drug benefit, requires patients to collect their drugs at a pharmacy. It is important to note that not all Medicare beneficiaries choose to purchase Part D coverage. Due to the more complex benefit design structure under Part D, patients must cover out-of-pocket costs unless they qualify for low-income cost-sharing subsidies (LIS).

2018

President

Alexis Thompson, MD, MPH
Ann & Robert H. Lurie Children's Hospital of Chicago
225 E. Chicago Avenue
Box #30
Chicago, IL 60611
phone 312-227-4834
a-thompson@northwestern.edu

President-Elect

Roy L. Silverstein, MD
Medical College of Wisconsin
Clinical Cancer Center
9200 W. Wosconsin Avenue
Milwaukee, WI 53226
phone 414-805-0518
rsilverstein@mcw.edu

Vice President

Stephanie Lee, MD, MPH
Fred Hutchinson Cancer Research Center
1100 Fairview Avenue N, D5-290
PO Box 19024
Seattle, WA 98109
phone 206-667-5160
sjlee@fhcrc.org

Secretary

Robert A. Brodsky, MD
Johns Hopkins University
Ross Building, Room 1025
720 Rutland Avenue
Baltimore, MD 21205
phone 410-502-2546
brodsro@jhmi.edu

Treasurer

Susan Shurin, MD
222 Quince Street
Unit 2C
San Diego, CA 92103
phone 240-328-8542
shurinsb@mail.nih.gov

Councillors

Steven Allen, MD
John C. Byrd, MD
Mary Dinauer, MD, PhD
Cynthia E. Dunbar, MD
Terry Gernsheimer, MD
Agnes Lee, MD, MSC, FRCPC
Joseph Mikhael, MD, FRCPC, MED
Jane N. Winter, MD

Editors-In-Chief

Laura Mikhael, MD, *The Hematologist*
Bob Lowenberg, MD, PhD, *Blood*
Robert Negrin, MD, *Blood Advances*
Mikhael Sekeres, MD, MS, *ASH Clinical News*

Executive Director

Martha Liggett, Esq.
mliggett@hematology.org

As previously mentioned, many ASH members treat patients with blood cancers, including leukemia, lymphoma, and multiple myeloma, which frequently require treatment with chemotherapeutic agents. 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 co-pay 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 plus 6 percent 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 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

¹ Matt Brown and Richard Kane. Avalere Analysis Highlights Complexities of Transitions Medicare Part B Drugs into Part D. May 21, 2018

a new order is placed and delivered. ASH 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 proposed 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 would 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.

A priority for ASH is patient access to high-quality, affordable care. For the reasons stated above, the Society opposes moving drugs from Part B to Part D as it will have unintended consequences and limit patient access to care.

Reduce patient out-of-pocket spending

ASH has long advocated to help lower out-of-pocket spending for patients. Every patient should have access to the approved evidence-based treatments recommended by his or her physician. Patients should not suffer from cost discrimination based on the type of therapy prescribed or the mechanism of the therapy's delivery. ASH supports efforts at both the state and federal level to provide insurance parity for all approved evidence-based cancer treatments. Patient-administered chemotherapy has become more prevalent and is the standard of care, or frequently the only option for many types of blood cancer. Parity would ensure that patient-administered chemotherapy is covered at the same rate under insurance as intravenous treatment. ASH requests that the Administration work with Congress to require coverage parity for anticancer regimens and supportive therapies regardless of delivery method.

Additionally, ASH advocates against allowing private health insurance plans to require higher cost-sharing for medications in the specialty drug tiers than what is charged for drugs in a non-preferred brand drug tier. Many treatments for blood diseases and disorders are typically placed in specialty tiers, potentially requiring patients to pay in excess of \$10,000 each month for necessary medications. Moreover, these drugs are often used in combination, further increasing the cost, causing patients to choose to forego treatment. Again, the Society requests that the Administration work with Congress to prevent health insurance plans from requiring higher cost-sharing for medications in the specialty drug tier than what is charged for drugs in a nonpreferred brand drug tier.

ASH is also supportive of allowing the Medicare to negotiate Part D drug costs with the pharmaceutical industry. Various congressional bills have been introduced that would allow the Centers for Medicare and Medicaid Services (CMS) to negotiate drug prices directly with pharmaceutical companies. Negotiating prices covered under Medicare Part D allows for drugs to be more affordable for patients.

Site neutrality payment policies

ASH supports the implementation of a site neutral payment policy for drugs. Medical considerations, not those associated with a drug's cost, should drive the determination of whether a patient receives care as a hospital

inpatient, hospital outpatient, or in the physician office. Site neutral payments for drugs will ensure that patient care decisions are not influenced by reimbursement considerations. However, ASH must note this policy, if implemented, will save Medicare money by reducing reimbursement in certain settings, not by reducing drug costs. The Society urges the Administration to primarily implement policies that address drug costs.

It has been reported that some centers will administer treatment as an outpatient to avoid the hospital expense on the DRG even when the physician feels it is more appropriate to administer in the inpatient setting. Specifically, this had been reported for Vyxeos (Daunorubicin and Cytarabine Liposome) used to treat patients with high-risk acute myeloid leukemia (AML).

ASH specifically addressed the issue of site neutrality in the Society's [comments](#) on the 2019 Inpatient Prospective Payment System proposed rule. ASH proposed a payment option for chimeric antigen receptor (CAR) T-cell therapies that would be site neutral, eliminating financial incentives to treat patients in settings that may not be medically appropriate.

Value-Based Purchasing

Part B Competitive Acquisition Program

The Blueprint asks specific questions about bringing back the Part B Competitive Acquisition Program (CAP). However, the original CAP was a failure. The program only attracted a single vendor and lasted for only three years before being terminated in 2008. While ASH is supportive of the concepts underlying the creation of a competitive acquisition program, the Society is unsure if the failures of the previous program can be overcome.

There are a number of potential issues with such a program. The first issue to consider is distribution method. Today, physicians and hospitals are able to work with external vendors to acquire drugs that will be used as needed for patients regardless of their insurance status. This leads to certain efficiencies in managing inventory. A competitive acquisition program, in which each unit or vial of drug is already tied to a patient, will likely require a different inventory system to be implemented.

Another important issue related to the implementation of a competitive acquisition program is the mechanism of delivery. Hematologists have experienced issues in which the design of certain benefits has led to patients purchasing chemotherapeutic agents from a pharmacy and then personally carrying them to their physician's office for infusion or injection. This process is not only cumbersome for patients; it can cause safety issues due to the handling requirements of certain drugs requiring avoiding very hot or very cold temperatures or exposure to sun. ASH would not support any program that required a patient to handle or transport a drug which is administered in a physician office or hospital.

Because ASH believes that the distribution must flow into the physician's office or hospital, the Society would encourage CMS to develop a management or processing fee for the physician to pay for the expensive handling of these drugs. The nature of a competitive acquisition program could result in a great increase in storage needs, potentially in controlled environments such as refrigerators.

Competitive acquisition programs also can hamper the ability to adjust medications on a real-time basis. While most chemotherapy doses are known well in advance, some drugs may require adjustment in dosing or choice of agent on the basis of the patient's condition on that particular day.

Indication-Based Payment

The Blueprint comments on indication-based payment and how this could be implemented. This tool would allow CMS to vary the payment rate for a drug based on the disease which it treats, recognizing that some drugs are used to treat various diseases, but with wide variation in effectiveness. Such incidences are common in medicine. Many drugs developed for indications in hematology are later used for other diseases. This policy has some merit, but for practical reasons cannot go forward as a standalone piece. Hospitals and physician practices

purchase drugs for infusion and injection from suppliers not necessarily knowing for whom they will be used. As such, they would pay a per unit price for a drug. Altering the payment rate based on indication in the current payment system makes the cost of drugs even more central to the economics for a practice. Such a policy could be more practical if implemented as part of a competitive acquisition program that divests physicians from the purchasing of drugs, another strategy that is considered. However, the development of a new competitive acquisition policy would take many years to build to ensure the proper and safe distribution of drugs. ASH does not recommend the inclusion of indication-based pricing outside of that context.

Conclusion

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. ASH looks forward to working with you to address the issue of high drug costs and out-of-pocket costs for patients. 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,

A handwritten signature in black ink that reads "Alexis Thompson" with a long, sweeping underline.

Alexis Thompson, MD, MPH
President