August 24, 2018

Alex Azar
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Azar,

I am writing on behalf of the American Society of Hematology (ASH) to share the Society’s priorities with respect to a number of recent proposals that have been issued by the Administration.

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 the transplantation of bone marrow stem cells, and we continue to be innovators in the fields 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 who are providing care to patients in diverse settings including teaching and community hospitals, as well as private practices.

ASH is pleased to serve as a resource on hematologic issues. Below we outline the Society’s priorities, many of which align with work being done by the Administration. We look forward to working with you to advance these important matters.

Access to Care

Drug Pricing

ASH is committed to making sure that all patients, especially those with hematologic conditions including both blood cancers and non-malignant diseases and disorders, have access to safe and effective care and treatment. The Society appreciates the Administration’s efforts to take action on the high cost of prescription drugs and was grateful for the opportunity to respond to the “American Patients First: A Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs.” ASH’s comments focused on the proposal to move some drugs from Medicare Part B to Medicare Part D. ASH opposed this proposal as it has the potential to hinder patient access to care and to shift costs onto the provider. Shifting drugs from Part B to D will likely increase the practice of “white bagging,” when a payer purchases drugs through a specialty pharmacy, which then ships the medications directly to the provider for administration. While the provider and institution are not responsible for or reimbursed for the mixing of the specialty pharmacy drug, they do assume the responsibility for the handling and administration of the drugs, thereby, increasing costs for the provider.
While the Society is appreciative of the Administration’s efforts to lower drug prices, ASH is concerned about the recent guidance that allows Medicare Advantage (MA) plans to use step therapy for Part B drugs, beginning January 1, 2019. As you know, step therapy requires a patient to first try and fail on the most cost-effective therapy, even if it is not the therapy recommended by the physician, before moving on to a more expensive, but more effective therapy. Requiring patients with hematologic diseases and disorders, especially those with blood cancers, and many of whom depend on specific and/or cutting-edge therapies, to wait to access the most effective treatment which may include a combination of therapies, is harmful to a patient’s health. Additionally, step therapy has the potential to increase administrative hurdles for both patients and providers.

ASH continues to work to identify ways to combat high drug prices and limit out-of-pocket expenses for patients with hematologic conditions. ASH supports, at both the state and federal level, efforts 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 Members of Congress, urging them to pass legislation to require coverage parity for anticancer regimens and supportive therapies regardless of delivery method. Forty-three states and the District of Columbia have passed such legislation, but federal legislation is needed to protect the millions of Americans whose employer-sponsored health plans are not state-regulated.

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 making this cost unmanageable, 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 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.

**CAR-T Therapy**

The Society is concerned about patient access to chimeric antigen receptor (CAR) T-cell therapy. Unfortunately, our current reimbursement systems and payment rates fall short of covering the costs associated with CAR-T therapy and institutions are forced to make difficult choices on whether to provide the treatment, resulting in long waiting lists for patients to receive the therapy.

It is important for the Administration to recognize the complex nature of this new therapy. Currently, each treatment is customized to the patient whose T-cells are genetically engineered to target a specific tumor-associated antigen. The therapy can have tremendous benefits but requires very close oversight by treating physicians during and following the treatment, as the majority of patients develop manageable, but severe adverse reactions.

ASH submitted comments on the National Coverage Analysis for CAR-T therapy as well as on CAR-T specific proposals in the FY 2019 Inpatient Prospective Payment System (IPPS) proposed rule. ASH thanks the Administration for addressing CAR-T in the IPPS proposed rule but the Society is very concerned that the final
policy, released in early August, may impede access to care to this cutting-edge therapy because hospitals and academic medical centers that provide this personalized treatment will simply not be able to withstand the negative financial impact.

ASH had outlined an alternative reimbursement proposal that was two-pronged: implement the revised MS-DRG 016, as proposed by the agency, and provide a separate CAR-T product payment. This would allow CMS to pay for the cost of care under MS-DRG 016 with its current outlier policy in place and pay for the product cost separately as a pass-through at actual acquisition or invoice cost. Instead, the IPPS proposal assigns CAR-T therapy to the renamed MS-DRG 016 (Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy) and creates a temporary New Technology Add-on Payment (NTAP) for the two currently approved FDA approved products. While this final policy represents an improvement over current CAR-T therapy reimbursement rates, ASH believes patient access to care will be jeopardized as providers and hospitals will not be able to afford to deliver the therapy at this reimbursement rate, particularly as other CAR-T products receive FDA approval. An analysis done by the American Society for Blood and Marrow Transplantation, shows hospitals losing between $62,750 and $304,425 under this proposal. ASH has already followed up with key members of Congress to identify ways to improve this payment.

Opioids

ASH recognizes that the opioid epidemic in the United States is a public health emergency that requires immediate attention. and commends the Administration for appointing Health and Human Services (HHS) Assistant Secretary for Health, ADM Brett P. Giroir, MD, to serve as Senior Advisor to the Secretary for Mental Health and Opioid Policy. Furthermore, the Society applauds the actions taken by the U.S. Surgeon General, VADM Jerome M. Adams, MD, MPH on this important issue. ASH leadership recently met with ADM Brett P. Giroir, MD, and VADM Jerome M. Adams, to discuss ASH’s efforts on sickle cell disease (SCD). During the meeting, ASH leadership identified areas where ASH and the Assistant Secretary’s office can collaborate on this important multi-faceted initiative to improve the lives of people living with SCD.

As our nation continues to address this epidemic, the Society wants to promote cautious, thoughtful, consideration in order to avoid unintended consequences for patients with chronic diseases. ASH recently released a Statement on Opioid Use in Patients with Hematologic Diseases and Disorders. The Society supports a public health approach that improves the way opioids are prescribed and reduces misuse and overdose yet safeguards access to these drugs for acute and chronic pain treatment for individuals with certain clinical conditions. Patients, including those with hematologic diseases such as sickle cell disease (SCD), blood cancers, and bleeding disorders who rely on opioids to treat their debilitating pain, should have opioids prescribed safely with proper follow-up from their physician.

Additionally, ASH would like to thank the Administration for creating the Pain Management Best Practices Inter-Agency Task Force and was pleased to have the opportunity to nominate Dr. Amanda Brandow, who is now an active member of the task force. The Society recently submitted comments to encourage the Task Force to consider implications of pain in special populations, including patients with hematologic conditions, as the group develops recommendations for best practices for pain management. ASH looks forward to continuing to work with Dr. Brandow and the Administration to safely and effectively manage the needs of patients who experience debilitating pain from their disease or disorder.

Drug Shortages

ASH is deeply concerned about the recent surge in drug shortages, especially for hematology-related products. The Society is grateful that these shortages have not gone unnoticed by the FDA and applauds the agency’s creation of a task force on long-term drug shortages. As you can imagine, drug shortages significantly affect patients with hematologic diseases and disorders. For example, there is an ongoing shortage of etoposide, a
chemotherapy drug used to treat common cancers. This shortage is having a major impact on bone marrow transplant (BMT) programs across the country as it is a critical therapy for transplant conditioning chemotherapy regimens – an essential component of regimens for transplant for lymphoma. The therapy is also used for a number of other hematologic indications, including acute myeloid leukemia and acute lymphoblastic leukemia. The shortage has yet to be completely resolved and our members are concerned about how to manage patients in need of this therapy in the meantime, especially in severe and time-sensitive cases when no alternatives are available. In general, drug shortages may force physicians to choose higher cost therapies that are not the standard treatment, or patients may receive less effective or more toxic alternative treatments. The Society encourages you to work with the Food and Drug Administration (FDA) to ensure that the Agency has the resources needed to address these shortages in a timely manner.

Affordable Care Act

ASH strongly supports access to affordable, high quality, health care for all Americans. ASH was supportive of the private insurance reforms that now prohibit health plans from discriminating against patients with pre-existing conditions or imposing limits on lifetime benefits. The Society remains concerned, however, that actions taken by Congress and the Administration threaten patient access to care. ASH opposed the repeal of the individual mandate, which helps to stabilize the health care marketplace and keep premiums down by encouraging more healthy individuals to purchase insurance, thereby, spreading risk more broadly across beneficiaries. The Society also has strong concerns about the recently finalized rule expanding access to association health plans (AHPs). While AHPs are intended to make health insurance more affordable by providing additional flexibility to plans on what benefits they offer, the added flexibility also means that insurers do not have to cover the 10 essential health benefits that are required under the Affordable Care Act for plans in the individual and small-group market. For example, plans could choose not to cover benefits such as prescription drugs or rehabilitation services. The rule also allows plans to charge different rates based on gender, age, and location. As previously mentioned, a top priority for ASH is patient access to affordable, high-quality health care, and the Society believes this final rule threatens that access.

Sickle Cell Disease

ASH is dedicated to addressing the burden of sickle cell disease (SCD) and is undertaking a multifaceted initiative to improve outcomes for individuals with the disease both in the United States and globally. SCD is an inherited, lifelong chronic disorder affecting nearly 100,000 Americans, and is a growing global health problem; by 2050 the number of people with SCD is expected to increase by about 30 percent globally. Over the past century, great advances have been made in the understanding and treatment of SCD. However, many basic scientific processes are still not fully understood, too few treatments have been developed, and most people who have SCD do not have access to the treatments that could improve the duration and quality of their lives. More attention must be paid to SCD at a federal level to ensure that patients have access to high-quality treatments, to assist in the development of more treatments, and to expand the physician workforce caring for this vulnerable population.

To work toward the goal of providing patients with SCD state-of-the-art care, ASH and other groups issued the State of Sickle Cell Disease: 2016 Report, which evaluated the disease in four priority areas: access to care, training and professional education, research and clinical trials, and global health. ASH has also developed a list of the top research and training priorities in SCD and sickle cell trait, which includes remaining unaddressed questions and specific research topics that could really move the field forward, with the hope of curing SCD in the future. ASH applauds the work of the National Heart, Lung, and Blood Institute (NHLBI) and its Cure Sickle Cell Disease Initiative (CureSGi) and is pleased to partner with NHLBI on this important effort. Furthermore, ASH is also very excited to work in collaboration with the Food and Drug Administration to identify opportunities to bring uniformity and standards to existing SCD endpoints, identify gaps, and propose development of new endpoints as a focus for future research.
ASH encourages the use of multi-disciplinary approaches to support these important areas and urges stakeholder organizations to coordinate their funding in order to produce the greatest impact. Within the Department of Health and Human Services, a multi-agency approach would deliver advances faster, more economically, and more efficiently, to patients suffering from this debilitating disease in the United States. The Society looks forward to working closely with Assistant Secretary for Health, Admiral Brett Giroir, MD as we continue to advance this important initiative and we are appreciative that Captain David Wong, MD from the HHS Office of Minority Health has been asked to facilitate the interagency task force on SCD.

**Physician Payment**

ASH will continue to advocate for appropriate physician reimbursement, adequate payment for cognitive physicians, and guaranteed reimbursement for preventive care.

ASH was supportive of the Medicare Access and CHIP Reauthorization Act (MACRA) in 2015 and believes that this legislation can help the health care system move towards a focus on quality. Since the passage of the legislation and the subsequent rules outlining the implementation of MACRA, ASH has been committed to working with its members to help them understand and comply with the new regulations for the Quality Payment Program (QPP). ASH submitted detailed comments for both the 2016 and 2017 proposed rules and the final rules and looks forward to the opportunity to comment again this year. The Society appreciates the many changes that have been made to the QPP. Specifically, ASH thanks CMS for continuing to work to ensure that small and rural practices are able to meet the requirements of the QPP and for the additional flexibility provided through multiple submission mechanisms. ASH is committed to continuing to work with the Administration, the CMS, and the health care community to make improvements to the law and ensure smooth implementation of the QPP.

Additionally, ASH members have long advocated that HHS should review and revise Evaluation and Management (E/M) documentation requirements and re-examine the definitions and valuations of E/M codes. Our members feel that the E/M documentation requirements are outdated and create unnecessary administrative burden. Hematologists frequently bill with E/M codes as they provide more cognitive care services than procedural treatments. These services include comprehensive evaluation of patients, and the intricate decision-making involved in complex diagnoses and determination of the most appropriate and effective treatment plan. Adequate reimbursement is a factor for young physicians choosing a medical specialty. Without adequate coverage and support for cognitive care services through revised E/M documentation requirements and codes, the field of hematology may have difficulty recruiting and retaining a robust workforce of new, young physicians to treat patients with hematologic conditions.

ASH commends CMS for addressing the issues of E/M documentation and valuation in the Calendar Year (CY) 2019 Physician Fee Schedule. However, despite the agency’s recognition that the existing codes do not accurately represent current cognitive medical practice, the payment proposal does nothing to address the patient access and physician workforce challenges driven by existing compensation gaps facing cognitive physicians as a result of the outdated E/M codes. Hematologists treat medically complex patients and typically bill a Level 4 or 5. Collapsing five levels of E/M codes into two as proposed will severely worsen existing reimbursement problems facing hematologists and other cognitive physicians who rely on these services. ASH is opposed to any proposal that undervalues the work done by cognitive physicians and will submit separate, detailed comments on the proposed rule. The Society strongly supports efforts for CMS to work with stakeholders to develop alternative solutions that can be provided to CMS in time for implementation in the 2020 Medicare Physician Fee Schedule.

ASH looks forward to working with you, and the Administration, along with Congress, to address the challenges and opportunities impacting hematology research and practice, as well as issues impacting hematology patients.
Please feel free to contact either myself or Leslie Brady, ASH’s Policy and Practice Manager (lbrady@hematology.org or 202-292-0264) if you have any questions or would like any additional information about hematology.

Sincerely,

Alexis Thompson, MD
President