October 25, 2017

John R. Graham
Acting Assistant Secretary
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Planning and Evaluation, Strategic Planning Team
Attn: Strategic Plan Comments
200 Independence Ave, SW, Room 415F
Washington, DC 20201

RE: HHS Strategic Plan FY2018-2022

Dear Acting Assistant Secretary Graham:

I am writing on behalf of the American Society of Hematology (ASH) regarding the request for comments on the Health and Human Services (HHS) Strategic Plan FY 2018 – 2022.

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 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 is pleased with many of the proposed goals and objectives in the strategic plan but offers the comments below:

**Strategic Goal 1: Reform, Strengthen, and Modernize the Nation’s Health Care System**

ASH is supportive of many of the objectives under Strategic Goal 1. ASH is a strong advocate for access to affordable, high quality health care for all Americans. The Society is committed to ensuring that all individuals who need the services of a hematologist have access to one, and that patients have affordable and reliable coverage options so that the most appropriate and effective treatment options are available to them.

The Society supports the private insurance reforms implemented under the Affordable Care Act that now prohibit health plans from discriminating against patients with pre-existing conditions or imposing limits on annual and lifetime benefits. The public and private insurance reforms that are currently in place have been especially impactful for individuals with blood diseases and disorders. For example, the patient who has a
blood cancer such as multiple myeloma and relies on a combination of expensive therapies, could reach their annual cap within a few months; meanwhile, the patient living with a blood disorder that has high treatment costs such as hemophilia, could reach their lifetime cap within a few years. Additionally, expanded Medicaid coverage is critical for many individuals with hematologic diseases and disorders. In this instance, access to quality care through Medicaid is vital for patients with diseases such as sickle cell anemia, an inherited chronic disorder affecting nearly 100,000 Americans who often experience lifelong complications including stroke, acute chest syndrome, organ damage, and other disabilities.

Specifically, regarding Objective 1.1, the HHS Strategic Plan notes a goal to improve return on investment of federal and state spending by encouraging development of payment models that reward value over volume. ASH stresses that it is important to remember that the reason that alternative payment models should be created is because they better serve patients, by improving quality and reducing unnecessary cost. ASH recommends that efforts on approving alternative payment models are focused on areas where there is a clear need, including rare diseases, in order to ensure that care is improved for everyone, not just those with more common diseases. Individuals with rare diseases, such as sickle cell disease, often face more and greater complications. As stated previously, sickle cell disease complications include severe pain, stroke, acute chest syndrome, organ damage, and in some cases premature death. It is imperative that these individuals are not left behind.

HHS plans to “develop new payment and service delivery models that speed the adoption of best practices” as part of Objective 1.2: Expand safe, high-quality healthcare options, and encourage innovation and competition. ASH has been engaged in efforts to prepare its members to participate in the new Quality Payment Program (QPP) authorized by the Medicare Access and CHIP Reauthorization Act (MACRA). However, as we take steps to help our members successfully participate in the Merit-Based Incentive Payment System (MIPS) and advanced Alternative Payment Models (APMs), we remain concerned about the risk adjustment and attribution methodologies being employed. Our members treat patients with complex, rare conditions and without accurate risk adjustment and attribution methodologies our members are at a distinct disadvantage. Stakeholders must have the opportunity to comment on these methodologies before they are finalized to ensure that new payment and service delivery models meet the needs of both patients and providers.

Additionally, in regard to Objective 1.4, Strengthen and expand the healthcare workforce to meet American’s diverse needs, HHS highlights a number of strategies to strengthen and expand the healthcare workforce. Along these lines, the Society feels strongly that HHS should review and revise Evaluation & Management (E/M) documentation requirements and re-examine the definitions and valuations of E/M codes. Our members have long advocated that the documentation requirements are outdated and create unnecessary administrative burden. Physicians must be paid for the care they deliver to their patients, and the current documentation requirements force our members to spend time and energy meeting extensive documentation requirements to warrant a higher-level visit, time and energy that would be better used to deliver quality care to the complex patients hematologists treat.

Additionally, despite the vastly expanded therapeutic and diagnostic choices, the increasingly complex interactions among treatments and concurrent conditions, and the conversation requirements of an increasingly health literate public, there has been no adjustment in the definitions of E/M services, and only incremental changes in their valuations, since the development of the Resource-Based Relative Value Scale (RBRVS). Frequently, hematologists 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.

**Strategic Goal 2: Protect the Health of Americans Where They Live, Learn, Work, and Play**

Under Strategic Goal 2, ASH is specifically interested in Objective 2.2, Prevent, treat, and control communicable diseases and chronic conditions. Much of the research that produced cures and treatments for hematologic diseases has been funded by the National Institutes of Health (NIH). The study of blood and its disorders is a trans-NIH issue, involving many institutes at the NIH, including the National Heart, Lung and Blood Institute (NHLBI), the National Cancer Institute (NCI), the National Institute of Diabetes, Digestive and Kidney Diseases (NIDDK), and the National Institute on Aging (NIA).

With the advances gained through an increasingly sophisticated understanding of how the blood system functions, hematologists have changed the face of medicine through their dedication to improving the lives of patients. As a result, children are routinely cured of acute lymphoblastic leukemia (ALL); more than 90 percent of patients with acute promyelocytic leukemia (APL) are cured with a drug derived from vitamin A; older patients suffering from previously lethal chronic myeloid leukemia (CML) are now effectively treated with well-tolerated pills; and patients with multiple myeloma are treated with new classes of drugs.

Hematology advances also help patients with other types of cancers, heart disease, and stroke. Even modest investments in hematology research have yielded large dividends for other disciplines. Basic research on blood has aided physicians who treat patients with heart disease, strokes, end-stage renal disease, cancer, and AIDS. Blood thinners effectively treat or prevent blood clots, pulmonary embolism, and strokes. Death rates from heart attacks are reduced by new forms of anticoagulation drugs.

The Society urges HHS to continue to bolster funding and conduct research on opportunities to prevent, treat, and control chronic conditions and communicable diseases so that we can continue to see advances similar to those described above.

**Strategic Goal 4: Foster Sound, Sustained Advances in the Sciences**

Under Strategic Goal 4, ASH is especially interested in Objective 4.2, Expand the capacity of the scientific workforce and infrastructure to support innovative research. ASH strongly supports developing a diverse and sustainable scientific and physician workforce. The future of the biomedical workforce is of paramount importance to ASH and its members. Hematologists with various training backgrounds are currently studying some of the most costly and devastating medical problems that affect health care in the United States. Our members are developing novel treatments for anemia associated with chronic diseases like cancer and chronic kidney disease. Hematologists are also devising alternatives to blood transfusions and enhancements of bone marrow transplantation through the use of umbilical cord blood, stem cells and other technologies. Recent impressive
advances in treating chronic myeloid leukemia, multiple myeloma, sickle cell anemia, thrombosis, and other hematologic disorders have all depended on support from the NIH.

ASH strongly believes that insufficient numbers of PhDs and postdoctoral fellows are being trained domestically to meet the demands of the U.S. research enterprise. ASH feels that there needs to be an increase in the funding of training grants to provide more slots for the training of PhDs, MD-PhDs and MDs interested in biomedical research. This population can be particularly sensitive to fluctuations in funding because the availability of support for pre-doctoral and post-doctoral training can be a decisive factor for choosing whether to pursue a research career.

The early career development of young scientists is also extremely vulnerable to decreases in funding for investigator-initiated research. Making the transition from trainee to independent investigator is challenging under the best of circumstances but has become much more difficult. For example, newly trained investigators must compete for new research grant applications, but since 2003 the number of new R01 awards has declined 18 percent for the Institutes that support most hematology research (NHLBI, NCI, and NIDDK). As a consequence, we are in danger of losing a generation of biomedical investigators.

ASH appreciates NIH’s recognition of this problem and the launch of the Next Generation Researchers Initiative (NGRI) to address it. We are eagerly watching to see if the NGRI significantly improves the young investigators’ ability to transition to independent research. Besides the NGRI, ASH urges HHS to increase funding for training programs and investigator-initiated grants such as R01s, which are crucial for making careers in biomedical research attractive to PhDs, MD-PhDs and MDs who are in pre- or postdoctoral training now or who are considering entering a research-related field. Investigator-initiated research is unparalleled for the return on investment, both with respect to the importance of the research produced and the number of people trained in the biomedical science.

Strategic Goal 5: Promote Effective and Efficient Management and Stewardship

Under Objective 5.2, the HHS Strategic Plan indicates a goal to increase workforce accountability through effective performance measures, enhanced training, and appropriate administrative actions. Throughout the development and implementation of the Medicare Access and CHIP Reauthorization Act (MACRA) and the move to the Quality Payment Program (QPP), the Society has been very vocal about the need for all physicians, regardless of specialty, to be meaningfully measured. In particular, the Society is very concerned that there are an inadequate number of approved quality measures for many specialties, limiting physician participation in the QPP. There currently exists a disconnect between existing quality measures and what hematologists believe adequately measures care delivery for patients with hematologic malignancies and non-malignant blood disorders. This is especially problematic because many of the diseases in hematology are rare and low volume. Currently, there are only four measures for hematology and these are applicable to only some of the specialty. Efforts are needed to strengthen MACRA to assure that it accomplishes its goal for recognizing quality in the Medicare payment system. ASH would like to continue to work with the Administration, the Centers for Medicare and Medicaid Services (CMS) and the health care community as a whole, to make improvements to the law and ensure smooth implementation of the Quality Payment Program.

Thank you for the opportunity to provide feedback. We welcome the opportunity to discuss these comments and others being considered with you and your team. If you have any questions or require further clarification, please contact Suzanne Leous, ASH Director of Government Relations and
Practice 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,

Kenneth C. Anderson, MD
President