May 5, 2016

Andy Slavitt
Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1670-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Mr. Slavitt:

The American Society of Hematology (ASH) would like to offer comments on the Medicare Program Part B Drug Payment Model as published in the Federal Register on March 11, 2016. ASH represents more than 16,000 physicians, researchers, and medical trainees committed to the study and treatment of blood and blood-related diseases such as leukemia, lymphoma, and myeloma; and non-malignant conditions and disorders, including anemia, hemophilia, sickle cell disease, and thalassemia.

ASH has strong concerns about the overall cost of medical care and in particular the cost of drugs. Every day, hematologists encounter situations in which patients are having difficulty paying for expensive drugs even though they have medical insurance. While the Society is sensitive to and supportive of efforts to reduce the cost of drugs, ASH believes that the proposal offered by the Centers for Medicare and Medicaid Services (CMS) within this proposed rule presents enough opportunity for loss of access that it should not be implemented at this time.

In this model, CMS, using the authority of the Center for Medicare and Medicaid Innovation (CMMI), proposes a two phase process that would offer significant changes in the method by which physician-administered drugs are paid under the Medicare program. Approximately half of the country would have the payment for physician-administered drugs reduced from 106% of average sales price to 102.5% of average sales price with an additional add-on flat fee, currently set at $16.80 but subject to change based on the consumer price index. The second phase adds the opportunity for Medicare to use certain value-based tools that might further adjust the payment rates.

ASH wishes to dispute one of the primary notions that underlies such a demonstration project, which is that physicians select drugs on the basis of profit to themselves. Such an assertion is a serious affront to the duty of a physician to his/her patients. As a practical matter, in the field of hematology, it is unlikely that in most conditions there is even much choice in the selection of chemotherapeutic agents, given continuing advances in the identification and targeted treatment of particular blood cancers. There are more options in supportive care drugs, but those drugs are rarely paid at a high enough rate for such difference to be meaningful. For this reason, changes in the payment rate for individual drugs will not affect individual treatment decisions, but could make it more difficult for some physician practices or hospitals to provide certain drugs.
ASH recommends that CMS withdraw this entire proposed rule. However, if CMS wishes to proceed with the demonstration project, ASH would like to offer a series of comments that should help to limit the chances of patients being denied access to important and life-saving drugs, which is a potential consequence of implementation.

**Geographic Scope of Demonstration**

CMS proposes to divide the country into four roughly equal in size cohorts that would have the following payment mechanisms:

- **Group 1** – 106% of ASP
- **Group 2** – 102.5% ASP plus add-on
- **Group 3** – 106% of ASP and value-based tools
- **Group 4** – 102.5% ASP plus add-on and value-based tools

Such a model throws nearly three quarters of the country into an investigational arm. This is far larger than would be needed to study the effects of such a plan on access and quality. The size of the demonstration also increases the likelihood that adjacent areas with relatively easy travel can have dramatically different payment mechanisms. In some cases, large practices with multiple locations might have different payment rates depending on the geographic location where the patient was treated. ASH believes that an experiment would be much more powerful if the effect of the intervention (in this case a payment reduction for high cost drugs and increase for low cost drugs) can be cleanly measured.

ASH is concerned about access issues for patients that result from this demonstration and believes those access issues would be most likely to be experienced for patients who are treated in rural areas in which there may only be a single option to receive treatment such as chemotherapy. In reducing the number of primary care service areas affected by the demonstration, CMS should endeavor to exclude service areas in which there is limited competition among providers of physician-administered drugs.

The size of the demonstration also raises concerns about the true nature of this proposal. The authority granted to CMMI under the Affordable Care Act is to study innovative payment methods to determine if they can be shown to reduce costs while not reducing quality. Even if one considers a payment reduction to physicians be an innovative payment model, the large size of the demonstration makes it appear more as a workaround for a payment method mandated by statute. While other CMMI programs have been quite large, they were established with voluntary participation rather than assignment.

The only other CMMI project that includes mandatory participation is the model focused on comprehensive care for joint replacement. That model was implemented in April 2016 covering approximately 800 hospitals of the more than 5,000 that exist in the country. ASH believes that a demonstration project covering approximately one quarter of the country (as opposed to three quarters) is already quite large and recommends that CMS not make the Part B drug model demonstration any larger in scale.

**Applicability of Demonstration to Particular Drugs and Products**

CMS has proposed to apply the new payment formula in the affected areas to the vast majority of drugs that are priced under Medicare Part B but also proposes to limit the applicability in several categories.
First, CMS proposes to not apply this new formula to blood and blood products. As CMS notes, the distribution channels and production of these elements is fundamentally different from true physician-administered drugs. ASH supports the proposal to exclude these products from the demonstration. While these would clearly be excluded from the changes in payment amount that are part of Phase 1, ASH also believes that the unique nature of these products should make them excluded from Phase 2’s value-based tools as well. ASH is open to consideration and discussion of models from CMMI focusing on blood and blood-based products in the future.

ASH supports the CMS proposal to exclude drugs listed in shortage from such a model. Drug shortages are a very dangerous and scary situation for patients who are in need of certain therapies and it is clear that adding an additional barrier will only make it less likely for a patient to receive the drugs. The list of drugs in shortage is clearly established by the Food and Drug Administration (FDA), so there should be no difficulties in identifying the particular drugs.

Add-on Fee
Rather than merely reducing the payment rates for physician-administered drugs from 106% to 102.5% of ASP, CMS proposes an add-on fee equal to $16.80 in the first year, which would be updated on an annual basis to reflect changes in the Consumer Price Index. This methodology is intended to keep the program budget neutral, meaning that the significant reductions in payments for more expensive drugs are offset by relatively large increases in payments for inexpensive drugs. ASH is concerned with this element of the experiment. If CMS wishes to redistribute funding under this model, it should instead be redistributed towards paying for services that can allow physicians to discuss and recommend appropriate treatment. Hematologists charged with diagnosing a patient and recommending a course of therapy that could cost more than a hundred thousand dollars are limited to the same evaluation and management codes that are used throughout the fee schedule. ASH has worked with CMS to recognize and pay for the unique contribution that they offer to a patient afflicted with a hematologic disease. Some of the other programs created by CMMI, such as the Oncology Care Model, allow a better demonstration of this value.

However, this demonstration merely trades a potential incentive to use more expensive drugs with an incentive to provide less expensive drugs more frequently. The significant specialty redistribution demonstrated by the impact chart demonstrates that inexpensive drugs are much more likely to be provided by primary care and specialties such as orthopedic surgery. For that group, this model would merely be a test of paying more for drugs. There is no underlying hypothesis that IV fluids or similar drugs are under-prescribed within this proposal. Therefore, ASH recommends that any reduction in percentage basis for drugs be redistributed to support the complexities of overseeing difficult infusion therapies.

Value-Based Purchasing Tools
Phase 2 of the proposed rule would allow Medicare to use value-based purchasing tools as alternative pricing mechanisms to the existing statutory formula which is based on the average sales price. This intervention would again be used on half of the country. The implementation of phase 1 is relatively simple in comparison to the reforms proposed in phase 2. ASH will offer specific comments on each of the value-based purchasing tools discussed within the proposed rule, but supports a CMS approach that would include extensive dialogue and opportunity for official public input before the implementation of these new tools. It is clear that no tool will be applicable for all drugs in all areas, so there must be an opportunity for public discourse on the drugs and patients for whom these tools might apply. Such public discourse should also include extensive discussion of the implementation strategy and how it may
affect physicians and patients. Even in cases in which a theoretical policy could increase value for patients, a flawed execution could cause great harm.

Reference Pricing
CMS proposes the option to use a policy commonly referred to as “reference pricing” in the rule. Under this mechanism, if a new drug were to be released and found to be clinically identical to another existing drug, the payment for the new drug would be the same as the existing drug. ASH does not object to this idea in principle, but believes that the applicability would be very limited, particularly in a field such as hematology. ASH cautions against over-ambitious application of such a rule. Some drugs may have the same mechanism of action but could have different side effects or different efficacy in particular patient populations. Determining the appropriate drug is often unclear even at the outset of treatment as patients may respond differently to different regimens. If used in therapies in which there is truly no difference, then such a policy could be considered.

If CMS were to implement reference pricing, ASH supports the proposal to not allow for balance billing the patient the difference between the reference price and the rate charged by the drug manufacturer. This would merely shift the burden for high cost drugs to Medicare patients, many of limited means. ASH has seen the consequences of high patient cost sharing for oral drugs in Medicare Part D plans and commercial drug plans with high coinsurance, and does not recommend repeating it in this new program.

Indications-Based Pricing
CMS also proposes the use of “indications-based pricing” as a value-based payment tool. 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 of 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 CMS considers in the proposed rule. 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.

Risk-sharing Agreements
CMS proposes to use “risk-sharing agreements” as another value-based payment tool for Part B drugs. Under this policy, CMS would allow for drug manufacturers to negotiate with CMS to price drugs on the basis of outcomes. ASH supports the use of such a policy but wishes to offer comments on implementation. First, paying based on outcomes depends very heavily on the identification of those outcomes. CMS should create a process for drugs intended to be priced in this model. Such a process would require the proposal of outcomes and a summary of evidence supporting the importance of these outcomes to patients. All drugs should have some component of true outcome measures included if they are intended to be priced in this manner.

In addition, since the payment relationship in this case would be directly between the manufacturer and Medicare, CMS should develop a payment mechanism that recognizes the costs of acquiring and
properly storing the drugs paid under this mechanism for the physician office or hospital that administers the drug.

Because this is a strategy that is newly developed even in the commercial insurer world, ASH recommends that CMS proceed slowly and carefully if it chooses to use such a pricing policy, starting with only a couple of drugs.

**Clinical Decision Support Tools**
The increasing number of therapeutic options for diseases such as cancer have made clinical decision support tools helpful in some circumstances. CMS proposes the inclusion of a voluntary clinical decision support tool as a value-based tool that could be used as part of this demonstration. ASH supports CMS creation of a voluntary clinical decision support tool. CMS does not propose mandating the use of a clinical decision support tool. ASH has been troubled by insurers’ inconsistent implementation of clinical decision support tools called “clinical pathways” and would not support the mandatory use of clinical decision support tools at this time. Regardless of whether the tool is mandatory or voluntary, ASH supports the process that CMS proposes in which such tools are based on reviews of clinical evidence and expert opinion. ASH also supports the CMS proposal for a public review of the evidence base of these clinical decision support tools prior to implementation.

CMS also proposes to aggregate physician results from clinical decision support tools and report that information through the existing physician feedback reports used in the physician value-based purchasing program. ASH supports this approach as a method of practice improvement. However, ASH cautions against inclusion of any element of performance on clinical decision support into the new merit-based incentive payment system program. Clinical decision support tools were crafted as aides to physicians and are not intended for accountability.

**Future Value-Based Purchasing Tools**
CMS indicates that it is interested in comments on a number of other potential value-based purchasing tools that could be included in phase 2 of the project, but does not actually propose to include them. This raises some questions about how adjustments to the program during the five-year duration will be handled. ASH recommends that any value-based tools that limit the options of physicians and patients (such as reference pricing described above) be created through rulemaking. Rulemaking requires the creation of an impact statement which will be very important for these kinds of changes. For value-based purchasing tools that create new options (e.g., the establishment of voluntary clinical decision support tools), ASH does not believe that rulemaking would need to be used, but does recommend that some opportunity for public comment be offered. Even if there is not a direct financial impact, the creation of voluntary tools can still affect patients so stakeholders should be given the opportunity to comment. CMS requests comments on some specific future value-based purchasing tools without specifically proposing them. ASH offers comments on these tools below.

**Value-Based Purchasing Arrangements with Manufacturers**
ASH supports the exploration of value-based purchasing relationships between manufacturers and CMS. The direct relationships that CMS envisions could involve so-called “try before you buy” in which the manufacturer must provide a rebate to CMS if the therapy is used for patients that do not benefit from it. Such an agreement should not be proprietary for a government payer. A meaningful clinical endpoint must be established in order to ensure that patients’ lives are being improved. Such a clinical endpoint should be established through a public process and consultation with expert stakeholders.
A value-based purchasing arrangement could be established so that the existing payment system is maintained. In that case, ASH believes that the entirety of the rebate should be paid by the manufacturer. Funds from the rebate should be distributed according to their source, split between the Medicare Part B trust fund and the patient. The physician or hospital that provided the service should not be held liable and the rebated amount should cover only the drug in question, not the separate payment for infusion or injection of these drugs.

**Part B Drug Competitive Acquisition Program**

The Medicare Modernization Act of 2003 (MMA) initiated the current system of payment for Part B drugs. It also mandated the creation of a voluntary Competitive Acquisition Program that was intended to remove the step of a physician or hospital purchasing a medicine for infusion or injection and then charging the patient. Instead, an external contractor would deliver the drug to a physician’s office or hospital and bill Medicare and the patient directly. In this rule, CMS asks for comments on reinstating this program as a value-based tool.

The Competitive Acquisition Program 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, some demonstrated by the last Medicare demonstration and others by models similar to this in the private insurance market. 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 and potentially more storage.

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 intervene in the process of receiving this drug which is administered in a physician office or hospital.

Because ASH believes that the distribution needs to 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 need, 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. For that reason, ASH recommends that competitive acquisition, if implemented, be limited to expensive drugs which are always administered according to a planned schedule.
It is clear that the competitive acquisition program is the most radical of the potential value-based solutions as it fundamentally changes the market for Part B drugs. For this reason, it is the approach which will require the most caution.

**Episode-Based or Bundled Pricing Approach**

Episode bundles have been among the most prominent payment innovations in specialty care. Rather than pay for individual units of service, CMS and other payers have been testing payments for larger units of care – most frequently surrounding a surgical procedure. ASH believes that this approach only makes sense in clinical areas in which there is little deviation from a common practice and little innovation. There are few if any diseases in hematology which include Part B drug payment where this is the case. On the contrary, innovation in hematologic diseases has been rapid and often this innovation comes in the form of new drugs or the combination of drugs. Because of the small populations which they are designed to treat, drugs treating hematologic conditions are often very expensive. An episode payment would be a significant barrier to innovation in this category of illness. ASH believes that efforts such as the Oncology Care Model provide a better incentive for the reduction in unnecessary expenses and a stronger focus on reducing unnecessary emergency room and hospital visits.

If CMS wishes to establish bundles for therapy, they should extend beyond the narrow category of Part B drugs. In some diseases, treatment options can include Part B drugs, Part D drugs, radiation, surgery, or watchful waiting. All of these are part of the cost of care for Medicare and the patient and should not be ignored.

**Interactions with Other Shared Savings Provisions**

The Medicare Oncology Care Model is a prominent payment innovation that will begin in the fall of 2016. This model rewards physicians for reducing costs and improving quality for patients undergoing chemotherapy. Even though the Part B demonstration covers all physician-administered drugs, many of the most expensive are used to treat cancer. ASH opposes the CMS proposal to include practices in the Oncology Care Model in this new demonstration. It is preferable to keep the two demonstrations separate so that results can be separately studied. This will be particularly true if CMS significantly reduces the size of the Part B payment model demonstration.

If the Oncology Care Model proves successful, it may be a more effective way of reducing spending than some of the payment adjustments and tools included in this proposal. ASH looks forward to studying all attempts to increase efficiency in care delivery.

**Provider, Supplier, and Beneficiary Protections**

CMS must ensure that the efforts of this demonstration project do not hurt beneficiaries. ASH supports the CMS proposal to establish a Pre-Appeals Payment Review Exception Process for patients affected by the policies that are established as part of Phase 2 of the demonstration project. Patients and physicians should be given the opportunity to discuss the issues associated with these new tools before the patient must face the choice of potentially paying for a treatment out-of-pocket.

ASH supports the above approach, but does not believe it is sufficient for a program of this magnitude. CMS should establish a real time monitoring of access to care. CMS has proposed to monitor access to care through the use of claims data. While this may be a valuable approach for some services, some infused and injected drugs must be provided immediately. The monitoring of access should include
active data collection as well as an opportunity for patients who are unable to access specific drugs to reach out and seek access. This availability should not be limited to those in phase 2 of the study, but should be available for all areas affected by the demonstration project.

Conclusions
ASH continues to support innovation in healthcare payment and delivery and will continue to engage with CMMI. Although the Society has many concerns with this proposal, it wishes to continue to work with CMMI to address the cost and appropriate use of drugs as well as broader models covering populations with rare diseases. If you have any questions about this letter or wish to discuss further, please contact Brian Whitman, Senior Manager for Policy and Practice at bwhitman@hematology.org or (202) 292-0264.

Sincerely,

Charles Abrams, MD
President