



December 28, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5528-ANPRM
7500 Security Boulevard
Baltimore, MD 21244-1850

SUBMITTED ELECTRONICALLY VIA REGULATIONS.GOV

RE: CMS-5528-ANPRM

Administrator Verma:

The American Society of Hematology (ASH) is pleased to offer comments on the [advance notice](#) of proposed rulemaking (ANPRM) on the International Pricing Index Model (IPI) for Medicare Part B Drugs. We appreciate the opportunity to provide these comments to the Centers for Medicare and Medicaid Services (CMS) on how this model will impact our members and the patients they serve.

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 rapidly escalating cost of drugs. The Society appreciates that the Administration is taking bold steps to address this issue. The ANPRM states that one of the goals of the potential IPI model is to preserve or enhance quality of care for beneficiaries. The Society shares this goal. Yet, our perspective on this proposal to date, is that this it could negatively affect access to care for the patients our members serve. We have outlined these concerns in our comments below.

ASH looks forward to working closely with the Agency on issues related to drug pricing and offers the following comments on specific components of the model as well as the model as a whole.

Model Concept Design

One of the stated goals of the potential IPI model is to remove providers' financial incentive to prescribe higher-cost drugs. ASH wishes to dispute this notion 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. Hematology is a domain in which patients with life-threatening and high-risk conditions have historically had few, effective care options, yet our patients are now increasingly benefitting from

a new age of therapeutic innovation. These advances have, however, come at a high cost with the acquisition costs of these drugs rising to unprecedented levels. Given that many of these therapeutic agents represent single source pharmaceuticals and our patients do not have access to generic or biosimilar versions of many of these agents, it is unlikely that in most hematologic conditions there is ever much choice in the selection of treatment. For this reason, changes in the payment rate for individual drugs will not affect treatment decisions but could make it more difficult for some physician practices or hospitals to provide certain drugs if their acquisition and administrative costs are not covered.

Model Vendors

Under the potential IPI Model, CMS would intend to allow greater flexibility than under the prior Competitive Acquisition Program (CAP) in the type of entities that could be selected as a model vendor. ASH acknowledges that this greater flexibility could help attract more vendors, but stresses that many potential issues still need to be addressed. First, there is no guarantee that manufacturers will lower prices to match those of the new indexed prices, making this model unappealing to potential vendors. Secondly, the ANPRM notes that there was no guarantee for the CAP vendors that the CAP payments would cover their drug acquisition and operating costs; however, based on the information provided in the ANPRM, there is also no guarantee for this under the potential IPI model. This may, in fact, lead to the decision by some of these entities to not purchase those single source drugs for which there is a lack of price agreement, which in turn, could result in a lack of access by patients to life-saving drugs. ASH recommends if this model moves forward safeguards are put in place to ensure that all drugs included in the potential model will be readily available to beneficiaries. Thirdly, if groups of physicians or health systems are to serve as effective model vendors, regulatory relief from state pharmacy laws would be needed, especially if physician group or health system vendors are expected to provide these services across state lines.

Regarding the innovative delivery mechanisms of the included drugs referenced in the ANPRM, ASH recommends that the model vendors only be allowed to take title to the drug, rather than physical possession of the drug, and that the drug be shipped to the provider directly from the manufacturer. This would help to reduce the potential for “white-bagging” and “brown-bagging,” both of which create concerns about additional costs, as well as quality control and patient safety. When a drug is shipped directly from the manufacturer to the provider, there are fewer chances of improper handling.

ASH also recommends against a model that would tie each unit or vial of drug to a particular patient. A model, such as the CAP model, that includes this component, would require practices to have a different inventory system and potentially more storage. This 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 based on the patient’s condition on that particular day. For this reason, ASH recommends that any model with a third-party vendor be limited to expensive drugs which are always administered according to a planned schedule.

One of the questions for which CMS is seeking public comment is “Should the role for the model vendors include entering into value-based payment arrangements (for example, indication-based pricing or outcomes-based arrangements)? And if so, should there be requirements around these arrangements?” ASH encourages the development of value-based payment arrangements, especially for innovative therapies, as long as they are evidence-based and clinically appropriate. For example, Novartis, the manufacturer of the chimeric antigen receptor T-cell (CAR-T) therapy, Kymriah, holds outcome-based contracts with some of the institutions certified to provide this therapy. Novartis

provides Kymriah at no charge if the patient does not respond in a one-month timeframe; however, ASH members have expressed concern that 30 days is not a clinically appropriate indicator for this therapy. Furthermore, if the potential IPI model incorporates value-based payment arrangements, the Society believes that manufacturers must share the risk in these arrangements. Providers alone should not be held liable for the cost of a drug or therapy. We recommend that CMS work closely with physician specialties and manufacturers when developing these arrangements.

Potential Drug Add-on Payment

ASH recommends that practice size and type be considered when determining a potential drug add-on payment. Many smaller practices and provider groups operate on a very narrow margin and the treatment decisions recommended for patients, along with the practice's financial viability should not hinge on this new model. ASH would support the exclusion of small physician practices/ hospital outpatient departments (HOPDs) or the creation of a low-volume threshold, as mentioned in the ANPRM.

ASH also supports excluding PPS-exempt cancer hospitals from the pilot phase of this potential model. The PPS-exempt cancer hospitals are institutions that provide care only to patients with cancer. Their inclusion in a pilot program, while adding little to the data acquisition intended by the IPI model, has the potential to reduce access to high-cost, single source anti-cancer drugs or to penalize them financially simply based upon the population that they serve.

Additionally, CMS is seeking comment on creating a bonus pool, where model participants would achieve bonus payments for prescribing lower-cost drugs or practicing evidence-based utilization. Providing a bonus for prescribing of lower-cost drugs, would unfairly exclude specialists, such as hematologists, who have little choice in the selection of chemotherapeutic agents, many of which are high-cost, for treating hematologic malignancies. And as stated previously, ASH strongly disputes the notion that physicians select drugs on the basis of profit to themselves. Physicians should be recognized for providing the most clinically appropriate, evidence-based treatments to the patients they serve.

Potential Included Drugs

Based on experiences with the CAP, the Society is concerned about potential issues that could have a negative impact on patient access to timely care. Problems which arose under the CAP included lag time resulting from the provider having to take title of the drug from the manufacturer before the drug is available from the vendor, the lead time for the development of vendors' acquisition arrangements, and the potential unavailability of pricing benchmarks for new drugs immediately after a drug is marketed. If the Agency moves forward with this potential model, these issues must be addressed. Furthermore, ASH requests that the agency monitor for potential cost-shifting. If manufacturers are paid less for the drugs included in the model, it is possible that they will increase cost of other drugs, not included in the model.

The proposed IPI Model assumes that model vendors will be able to successfully negotiate lower prices with manufacturers based on the new internationally indexed prices that CMS will be paying for the included drugs. Alternatively, manufacturers could choose to stop supplying high-cost drugs. This was the case with radio-labeled therapeutic monoclonal antibodies for the treatment of patients with lymphoma. The effective agent 131I-tositumomab (Bexxar, GlaxoSmithKline) was withdrawn

largely due to diminishing sales.¹ Cancer is an area where newly developed drugs may significantly improve our patients' survival and the Administration should support changes that balance the cost of innovation with appropriate patient access.

Additionally, ASH is pleased that CAR-T is not included in the drugs suggested for this potential model, based on the description in the ANPRM. The challenges of CMS inpatient reimbursement for this set of therapeutics provide a cautionary perspective on the potential negative impact of well-intentioned regulatory rules. If the IPI model moves forward, and the Agency looks to expand the scope in the future, ASH recommends not including CAR-T therapy until providers have more experience providing this new treatment and until CMS implements equitable payment for this therapy and the associated care.

Model Payment Methodology for Vendor Supplied Drugs

ASH feels it inappropriate and detrimental to patient access to tie Part B drug payments to the costs and assessments of other countries. The countries included in the ANPRM, not only have different systems to manage their overall health care systems, they also make different value determinations about drugs. It is also important to keep in mind that many other countries do not offer the same access to potentially life-saving drugs that are offered to patients in the U.S. An article published in the *Journal of Managed Care & Specialty Pharmacy* compared the approval and coverage decisions for new anticancer drugs between the United States and 4 other countries: the United Kingdom, France, Australia, and Canada. Of the 45 anticancer drug indications approved in the United States between January 1, 2009, and December 31, 2013, 67% were approved by the European Medicines Agency (EMA), and 53% were approved in Canada and Australia before December 31, 2013. As of June 30, 2014, Medicare covered all 45 drug indications, while the United Kingdom, France, Canada, and Australia covered 58% (26), 42% (19), 29% (13), and 24% (11) of that number, respectively. For example, as of December 31, 2013, patients in Canada did not have access to Kyprolis, which treats multiple myeloma, Revlimid, which treats lymphoma, or Bosulif, which treats leukemia.²

ASH is a society made up of both US and international hematologists, and we greatly value the input we receive from all of our members. The Society recognizes that we can learn from other countries' experiences, and we encourage the Administration to continue exploring how other countries manage health care delivery as well as drug pricing.

Conclusion

ASH supports the Administration's goal to lower drug prices and believes that the patients we treat need relief from the financial burden associated with prescription drugs, particularly those used to treat complex conditions like cancer. However, we are concerned that the IPI model as outlined in the ANPRM does not guarantee lower prices from manufacturers and may negatively impact appropriate patient access to life-saving drugs.

Thank you for the opportunity to provide comments on the ANPRM on the IPI model for Medicare Part B Drugs. We welcome the opportunity to discuss these comments with you and your team. If

¹ Vinay Prasad, MD. The Withdrawal of Drugs for Commercial Reasons The Incomplete Story of Tositumomab. *Journal of the American Medical Association Internal Medicine*. 2014;174(12): 1887-1888.

² Zhang, Yuting, Hana Chantel Hueser, and Inmaculada Hernandez. Comparing the Approval and Coverage Decisions of New Oncology Drugs in the United States and Other Selected Countries. *Journal of Managed Care & Specialty Pharmacy*. Vol. 23, No. 2. February 2017.

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, appearing to read "Roy L. Silverstein". The signature is fluid and cursive, with the first name "Roy" and last name "Silverstein" clearly distinguishable.

Roy L. Silverstein, MD
President