



June 23, 2016

Andrew Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Attention CMS-5517-P
PO Box 8013
7500 Security Blvd
Baltimore MD 21244

Dear Mr. Slavitt:

The American Society of Hematology (ASH) is pleased to offer comments on the proposed regulations governing the Merit-Based Incentive Payment System and Alternative Payment Models under the Physician Fee Schedule as proposed in the Federal Register on May 9, 2016. ASH represents more than 16,000 physicians, researchers, and medical trainees, who are committed to the study and treatment of blood and blood-related diseases, such as leukemia, lymphoma, and myeloma; non-malignant conditions, including anemia and hemophilia; and congenital disorders, such as thalassemia.

ASH was strongly supportive of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) which these proposed regulations are intended to implement. For more than a decade, physician payments under Medicare were under constant threat of large cuts. The threat of these cuts may have undermined previous efforts to modernize payment. The Society believes that the elimination of this threat as well as some of the increased regulatory flexibility offered by MACRA will accelerate the move towards quality improvement and greater flexibility for care improvement for Medicare beneficiaries. However, the Society believes that the programs proposed in this regulation are largely built up around common diseases and considerable care is required to ensure that these program adequately serve patients with rare diseases like those treated by hematologists.

Hematologists treat patients with blood cancers such as leukemia and lymphoma and non-malignant blood diseases such as hemophilia and sickle cell disease. ASH surveys of practicing hematologists have demonstrated two factors that are important in framing these comments; first that more than fifty percent of the patients seen by clinical hematologists focusing on adults are Medicare patients; second that most hematologists are employed in large groups, with a large percentage of those belonging to multispecialty groups such as the faculty of an academic medical center. ASH comment's therefore focus on ensuring that incentives remain to treat patients with difficult and uncommon diseases in the context of large groups. The fact that most diseases that hematologists treat are rare can complicate measuring quality and properly accounting for resource use and it is important that CMS focus on the goal of improving care for all patients. ASH offers comments on a number of components of the proposed rule below focusing around this theme.

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Unit of Accountability

Under the previous pay-for-performance program called the Value-Based Payment Modifier (VBM), payment accountability for performance was calculated at the group level using the tax identification number. Because of requirements of the MACRA legislation, this will change to be an option for the unit of accountability to be identified as an individual physician or group. ASH is unsure how large groups will proceed with this opportunity but supports the option for physicians to choose either unit of accountability. Some hematologists may wish to identify measures from the existing measure set or from qualified clinical data registries (QCDRs) to better differentiate themselves, but others may find that the group measures are an appropriate reflection since they cover more patients.

CMS requests comments on whether there should be an opportunity for a group to select individual accountability for one portion of the new merit-based incentive payment system (MIPS) and group accountability for another. For simplicity purposes, ASH recommends that the selection of group accountability encompass all elements of the MIPS system. If a group wishes to pick a more diverse set of quality measures (for example), they are offered the opportunity to measure accountability at the individual level. ASH supports the CMS proposal to not require a separate registration process to indicate that a group has elected to report via this method.

Quality Measurement

ASH supports the CMS proposals for quality measurement under the MIPS which retain components of flexibility in reporting of methods and measures. This flexibility is necessary because of the great diversity of physician practices as compared to healthcare entities like hospitals. There are a couple of major changes from existing reporting requirements that ASH wishes to comment on. First, CMS has reduced the required number of measures for most physicians from nine to six measures. ASH supports this change as it will make it easier for physicians, particularly those in specialties, to identify measures which are appropriate. The second change is the required threshold for reporting. Under the existing programs, successful reporting can be achieved by reporting on 50% of eligible patients, regardless of the submission mechanism. CMS has proposed to increase that threshold to 80% for claims-based reporting and 90% for all other mechanisms. ASH encourages a graduated increase in the threshold rather than this sudden shift upward. The 50% threshold was established in the current program because higher thresholds originally used caused many participants who attempted to report to fail. Although there have been some improvements since that time, this issue is a difficult one. ASH suggests moving to 80% and 90% over a multi-year period in order to evaluate and ensure that physicians may be able to reach that threshold.

Specialty Specific Measure Sets

CMS proposes to create a series of specialty specific measure sets. These measure sets appear to be intended to simplify the measure selection process for physicians faced with a lengthy list of measures. Since no hematology or clinical oncology measure set is proposed, ASH encourages CMS to emphasize that the specialty specific measure sets are intended as a helpful tool as opposed to a required set of submissions. In some cases, reporting on the specialty specific measure sets could allow a physician to report on fewer than the six reported measures. While ASH appreciates the flexibility that is offered by this approach, the Society believes it is simpler to require six measures from all physicians who have

eligible patients within the denominators of the approved measures and require everyone to meet the same standards.

Resource Use

The MIPS program, like the program it replaces, includes an element that attempts to measure efficiency in practice, recognizing that physicians often have a significant influence on the volume of resources used by patients, either directly by prescribing or providing certain therapies, or indirectly by managing care to avoid costly additional services. There is universal agreement that physicians have a role in contributing to resource use for patients but there is still ongoing discussion about the level of influence and the best way to differentiate physicians from one another in this measurement category. In this rule, CMS has proposed to retain existing resource use measures that focus on annual costs for patients and costs surrounding hospital admission and add a number of measures for more defined episodes of care. All resource use measures require assumptions for attribution of patients and for risk adjustment.

As specialists in internal medicine, hematologists may see a patient once in order to diagnose and recommend treatment, may take over care for a long period of time in the event of a new disease such as leukemia, or may serve as long term primary care physician for patients with a lifelong blood disease such as sickle cell disease. Their level of influence on a given patient may differ substantially on the basis of that role.

The proposed measurement of per capita spending requires a minimum of 20 attributed patients per year, a number that many hematologists will meet based on being the physician that a patient sees most frequently in a given year. ASH strongly supports the proposal to adjust this measure based on the specialty of the provider. Without specialty risk adjustment, the risk adjustment would only be based on demographic factors and previously reported conditions. However, a diagnosis of a disease such as leukemia dramatically changes the expected costs. While specialty adjustment is far from perfect, it does recognize that patients often move from primary care to specialty care when their health status changes. ASH encourages CMS to continue to examine and develop the risk adjustment methodology to ensure that those that treat very ill patients are not inappropriately disadvantaged.

CMS has also proposed to add a series of episode measures in the resource use measurement category. An episode could include the events surrounding a surgical procedure such as a hip replacement or a medical episode such as a heart attack. ASH supports episode measures as they represent a more nuanced view of which resources are under the control of a physician. ASH is encouraged by the development of these measures but is concerned that there was not more transparency around their creation. The episode created for deep vein thrombosis, for example, did not include any interaction with ASH and may not have included a hematologist at all. For this reason, ASH encourages CMS to not include the deep vein thrombosis measure as a resource use measure until further feedback is obtained.

ASH supports the CMS proposal to set the benchmark for assessing resource use on the basis of the measurement year, as opposed to using a prior year benchmark. Unlike quality measurement in which using a previous year's performance provides a helpful target, using a previous year is not appropriate for resource use. Setting the benchmark to a previous year could make physicians responsible for changes in payment rates for services at hospitals or in diagnostic imaging centers. A previous

benchmark year could also provide a disincentive to use innovative technology that could improve the care of patients.

Cost of Drugs

CMS proposes to continue to exclude the costs of Part D Medicare from resource use measures, which covers self-administered medications. Part D has been excluded due to complexity in determining the cost of drugs because they are paid by a private plan with some portions paid by the government. While ASH understands these complexities, the Society encourages CMS to work to include Medicare Part D drugs within the cost of care measurement.. For many conditions, the cost of drugs is a significant and at times largest contributor to overall resource use. In hematology, there may be drugs that can be provided via oral medication or intravenously. While an oral drug is generally preferable for convenience and safety reasons, high cost sharing associated with Medicare Part D may lead the physician to use available intravenous drugs for affordability. Because physician-administered drugs are covered by Medicare Part B, they are included in the resource measurement. Even when there are not circumstances in which intravenous or oral drugs are interchangeable, there are still decisions to be made regarding the provision of drugs. ASH understands that there are technical challenges to including Part D drug costs within the resource use measure but encourages CMS to address those challenges. The inclusion of Part D drugs must go hand-in-hand with improved risk adjustment to ensure that those treating very sick patients are not penalized for the use of appropriate drugs.

Clinical Practice Improvement Activities

Of the four components of the MIPS program, only the component focusing on clinical practice improvement activities is a new one. ASH supports the broad and flexible approach allowing for the reporting of many different types of practice improvement activities. Because this is a new program with a new data submission method, ASH encourages a focus in education on the responsibilities of groups and individual practitioners in successfully completing this requirement. ASH believes that most physicians and groups are participating in some form of clinical practice improvement that is included on the menu of options stated, but suspects that others could be included as well. Given that there is no way to reasonably assess the value of these structural measures to patients or any established body to review them, ASH encourages CMS to be as inclusive as possible in considering items to be categorized as clinical practice improvement activities.

Advancing Care Information

ASH strongly supports the CMS proposal to change the measurement of the use of health information technology from an “all or nothing” measure found in today’s Meaningful Use incentive program and replace it with a system that allows for partial credit for the use of certain components of electronic health record use. Nearly every hematologist uses an electronic health record that meets many of the requirements of Meaningful Use, but many are likely to be penalized due to not meeting a single component and ASH supports a move away from this “all or nothing” measurement.

Alternative Payment Models

The concept underlying the MACRA legislation was a choice between two paths, one more anchored in traditional fee-for-service (MIPS) and the other allowing for alternative arrangements. ASH supports the MACRA move towards alternative payment models. ASH understands that there is great interest in

alternative payment models and that there will be great concern that there is not enough opportunity for physicians to participate in these models. While this may be true, it is important to remember that the reason that alternative payment models should be created is because they better serve patients, either by improving quality or reducing cost. It is clear that the current payment system that focuses on individual services and disconnects physicians from their overall impact on patients is not serving all patients well. However, there are some patients who are particularly poorly served by this model and ASH recommends that CMS focus all efforts on approving alternative payment models on areas where there is a clear need. Although CMS will not necessarily have the responsibility to develop alternative payment models, the review and adjudication of multiple payment models will have significant administrative cost for the government if there is not an attempt to prioritize.

ASH believes that the Center for Medicare and Medicaid Innovation (CMMI) should retain a significant development role in assessing these priorities. Over the past year, ASH has met with officials from CMMI to discuss the importance of a new payment model focusing on individuals with sickle cell disease. There is clear need for this model given the prevalence of sickle cell patients in Medicaid and Medicare and the lack of coordination of care among many adults with the disease. Although our discussions have been collegial and productive, they have not yet resulted in a payment model and ASH is concerned that this population will again be ignored by the healthcare delivery system. Although there are opportunities that are created by the new flexibility that come with the implementation of this regulation, they require significant investment on the part of the alternative payment model entity. ASH encourages CMS to work on issues of rare disease in order to ensure that care is improved for everyone, not just those with more common diseases.

ASH appreciates the opportunity to offer comments on this extensive proposed rule. The Society expects that the rules for this program will continue to develop over the years as we learn more about pay for performance and look forward to contributing to the future of the program. If you have any questions about this letter, please contact Suzy Leous, Director of Government Relations and Practice at sleous@hematology.org.

Sincerely,

A handwritten signature in black ink that reads "Charles J. Abrams". The signature is written in a cursive, flowing style.

Charles Abrams, MD

President

