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**2011**

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**RE: CMS-1345-P – Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations**

Dear Administrator Berwick:

The American Society of Hematology (ASH) appreciates the opportunity to respond to the Center for Medicare & Medicaid Services (CMS) proposed rule on the Medicare Shared Savings Program: Accountable Care Organizations, published in the Federal Register on April 7, 2011. ASH members evaluate and treat patients with malignant hematologic disorders such as leukemia, myeloma and lymphoma. They also treat non-malignant bleeding and clotting disorders, including anemia, thrombosis and hemophilia. While many of ASH's 16,000 members practice in academic health centers or large hospital systems and are actively involved in research, a significant portion of the membership provides hematology care in small and medium size group practices serving community hospitals. ASH's comments on the proposed rule reflect the complexities related to the treatment of hematologic diseases and disorders and are more directly focused on the issues relevant to hematologists who work in smaller, community based physician practices.

**Accountable Care Organizations and the Practice of Hematology**

ASH supports innovation by CMS to assure that health care delivery focuses on better care for individuals, better health for populations and lower growth in expenditures. ASH is concerned, however, that the complexity of the proposed rule to implement Accountable Care Organizations (ACOs) is burdensome and might result in a lost opportunity for many small and medium sized community based practices that provide specialized health care services, such as hematology. Start up and first year costs are deterrents to smaller practices, as are administrative and legal considerations such as the contractual agreements between subspecialty practices and an ACO. As a result, it is possible that many ASH members will not be able to help establish or participate in ACOs.

ASH does support and recommends keeping the provision in the proposed rule that allows small, independent specialty medical practices to contract with multiple ACOs. This provision should help assure patients critical access to hematologists and should encourage hematologists to participate. For example, many patients with hematologic cancers receive treatments in different geographical areas according to their residence in different seasons of the year.

ASH believes that patients receive the highest value care when providers are able to use evidence-based medicine. ASH participates actively in generating evidence-based treatment guidelines and clinical practice metrics through organizations such as the AMA Physician Consortium for Performance Improvement. We wish to stress, however, that the practice of hematology encompasses a large number of different benign and malignant disorders many of which are uncommon as single disorders but which when added together create a significant set of illnesses that an ACO may be called upon to manage. Examples include thrombotic thrombocytopenic purpura, immune thrombocytopenic purpura, anti-phospholipid syndrome, aplastic anemia, myelodysplastic syndrome, sickle cell disease, management of inherited and acquired coagulation disorders, hypereosinophilia, porphyria, hemochromatosis, bone marrow transplantation, leukemia, lymphomas, myeloma, amyloidosis, complex anemias, and many others. These disorders can acutely present patients and hematologists with clinical circumstances requiring expensive intervention when there may be a lack of randomized clinical trials to determine the optimum course of treatment. ASH supports a final rule allowing ACOs to contract with several specialty and subspecialty practices that can diagnose, treat and manage these uncommon, complex illnesses, so that every patient has access to subspecialty hematology care when needed. Similarly, ASH supports the policy in the proposed rule that allows ultimate choice by patients for the subspecialists they see and for seeking second opinions. This is important for patients for whom hematology consultation and care are necessary because the spectrum of disease, and unpredictable changes that can occur in the natural history of many of these diseases might exceed expertise initially contained within the ACO entity.

ASH also emphasizes the fundamental role clinical trials play in generating and improving evidence-based medicine. ASH urges CMS to protect access by patients to clinical trials in the final rule. More importantly, the final rule should strongly encourage all physicians and patients to participate in clinical trials as results from clinical trials may produce better targeted treatment and more cost effective medical care. As metrics used to assess quality of care in ACO's evolve, consideration should be given to exploring the enrollment of a proportion of assigned beneficiaries into clinical trials as a potential measure of quality.

### **Definition of Primary Care**

ASH understands the definition of primary care physician used in the proposed rule, i.e. physicians who have a primary specialty designation of internal medicine, general practice, family practice, or geriatric medicine, to assign beneficiaries to ACOs. ASH also notes the proposed rule recognizes that "certain specialists are often the principal primary care provider for elderly and chronically ill patients who do not otherwise have a primary care provider, and it is reasonable to expect them to take responsibility for these patients' care." The Society stresses that hematologists and other specialists may provide extensive primary care or work with primary care physicians to incorporate hematologic therapy into a patient's overall health care plan. For example, chemotherapy or other hematologic drugs can interact significantly with medications used to manage chronic diseases such as heart disease, kidney disease and diabetes. The hematologist often manages appropriate medication adjustments. Another common example is hematologists assuming the management of anticoagulation rather than primary care physicians because the lowering of platelet counts by chemotherapy can increase the risk of bleeding for patients on coumadin. A specialist's management of a patient's health in its entirety, for example a patient on Medicare disability with sickle-cell disease, can eliminate unnecessary hospitalizations and emergency room visits or more costly treatment interventions. As CMS finalizes the rule, ASH urges that CMS consider the impact of the definition of primary care and recognize the major role specialists, such as hematologists, provide in coordinating and managing primary care conditions along with specialty care to their patients.

## **ACO Governance**

Section 1899(b)(1) of the Affordable Care Act requires that an ACO have a “mechanism for shared governance” including a leadership and management structure that includes clinical and administrative systems. The proposed ACO rule further expands this requirement by recommending that the ACO governance should allow for “appropriate proportionate control for ACO participants, giving each ACO participant a voice in the ACO’s decision making process and be sufficient to meet the statutory requirements regarding clinical and administrative systems.” ASH is supportive of the shared governance mechanism because it believes hematologists have the necessary expertise to provide scientific, clinical and economic input regarding the complexities in delivering high quality hematologic care. Allowing proportionate representation in a shared governance mechanism can only contribute to the success of an ACO as all entities, including hematologists, will have a voice in the decision making process.

The proposed rule also permits an existing legal entity to govern an ACO as long as the ACO provides evidence that its pre-existing governing structure meets all criteria required for ACO governing bodies. While ASH appreciates the flexibility in allowing a current legal entity to govern an ACO, it is concerned that medical specialties not be left out of the governance structure. For example, if a primary care medical group forms an ACO and uses its current governing board as the ACO’s governing board, but the current governing structure does not include representation by every medical specialty, then the concept of “appropriate proportionate control for ACO participants,” will be lost. ASH recommends that the final rule require that the ACO submit evidence demonstrating that all medical specialties employed by the current legal entity have representation in the governance structure, which seems to be the intent of the proposed rule on ACO governance.

ASH also supports the provision in the proposed rule that requires an ACO to employ a board-certified physician, licensed and physically present in the state where the ACO is located, who will serve as the senior level medical director responsible for clinical management and oversight. ASH appreciates that the proposed rule requires that a physician direct the quality assurance and improvement activities of the ACO. In the final rule, CMS should consider the possibility that certain ACOs may cross state boundaries and so the final rule will have to reconcile the state-specific provisions for licensing ACOs and maintaining state-based quality oversight with this possibility.

## **Quality Measures**

ASH supports developing value based payment and the central role that clinically meaningful quality measures must play in rewarding and incentivizing excellent medical care. The Society is pleased the proposed ACO rule encourages alignment with various quality measurement programs already in existence including the Physician Quality Reporting System (PQRS), which provides incentive payments to eligible physicians and other practitioners who satisfactorily report data on quality measures for covered services. ASH is a member of the AMA Physician Consortium for Performance Improvement and actively contributes and supports the development of metrics as generated by this organization. Some of ASH’s members participate in the PQRS program by assessing their quality of care by utilizing the hematology-related measures (Myelodysplastic Syndrome and Acute Leukemias, Myelodysplastic Syndrome, Multiple Myeloma, and Chronic Lymphocytic Leukemia). The hematology measures are currently endorsed by the National Quality Forum on a time-limited basis as we wait for the full endorsement process to occur. However, due to a lack of randomized clinical trials to determine the optimum course of treatment for complex and often rare hematologic diseases that affect small patient populations, there are insufficient quality measures for much of hematology practice. Consequently, it will be critical that CMS support and promote development of additional hematology measures for utilization by ACOs to ensure better, efficient care. ASH recommends that CMS provide the

necessary resources to organizations like the National Quality Forum and the AMA Physician Consortium for Performance Improvement to bolster this important quality improvement activity.

ASH values the concept of quality measurement but we are concerned that the proposed rule requiring that an ACO complete all 65 quality measures in order to be eligible for shared savings or risk is burdensome. Of the 65 proposed measures, none directly relate to the care of hematologic disorders, so hematologists who may have contracted with an ACO will be at risk for shared savings or shared losses even though the subspecialty care they provide is not measured for the patients for whom they care. The proposed rule leaves to the ACO the details of sharing such savings or losses among ACO participants through the contractual relationship between smaller subspecialty providers and the ACO. ASH appreciates that the proposed rule emphasizes that the metrics used within ACOs are intended to evolve, and wishes to strongly emphasize to CMS how important developing quality measure sets will be for specific patient populations such as those with hematologic disorders in the spirit of better care for individuals, better health for populations and lower growth in expenditures.

### **Conclusion**

ASH recommends that CMS consider issuing an interim final rule to ensure more feedback about this important initiative. This could give CMS the flexibility it needs to modify this program with the necessary improvements to ensure its success. ASH looks forward to additional clarification from CMS so that hematologists can be active participants in innovative care delivery models, including ACOs. The Society is committed to providing quality hematologic care to patients and would like to work with CMS to ensure that patients with hematologic disease will continue to have access to the care they require.

Again, thank you for the opportunity to comment. If you require additional clarification on ASH's comments, please contact Suzy Leous or Mila Becker in ASH's Government Relations and Practice Department at 202-776-0544.

Sincerely yours,

A handwritten signature in black ink, appearing to read "J. Evan Sadler". The signature is fluid and cursive, with a large initial "J" and a long, sweeping underline.

J. Evan Sadler, M.D., Ph.D.  
President