April 11, 2016

Patrick Conway, MD
Deputy Administrator
Innovation and Quality
Centers for Medicare and Medicaid Services

Dear Dr. Conway:

The American Society of Hematology (ASH) asks that the Center for Medicare and Medicaid Innovation (CMMI) explore models aimed to improve the care of patients with sickle cell disease. ASH represents more than 15,000 physicians, researchers, and medical trainees 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 members also include clinicians who specialize in treating children and adults with sickle cell disease and researchers who investigate the causes and potential treatments of sickle cell disease manifestations.

ASH has been impressed with the efforts of CMMI in designing innovative payment models to facilitate care improvement. However, the Society is concerned that these models are not designed to meet the needs of patients who have rare diseases. Existing models either focus on common conditions such as coronary artery disease or require provider groups to take risk for all patients regardless of their diseases. Neither of these approaches will provide a significant incentive for a group of physicians to focus on patients with rare diseases.

Sickle cell disease is a particularly strong candidate for a rare disease-focused model for CMMI, since the disease predominantly affects individuals of African descent, who are also disproportionally covered by Medicaid insurance plans. Many individuals also qualify for Medicare, due to disability caused by the severe manifestations of this disease. In the past, sickle cell disease was a disorder that took the lives of many children. In recent years, most individuals afflicted with this disease live to adulthood. However, the median age of death for those afflicted with sickle cell disease is still quite young, with most individuals dying before the age of 50. Those who are able to live longer and have more productive lives benefit from access to specialized treatment centers that are most typically affiliated with university medical centers or that have grants from existing Health Resource and Service Administration (HRSA) programs.

For adults with sickle cell disease who reside in areas without specialized sickle cell centers, their care is more likely scattered among various physicians, and unfortunately includes numerous emergency room and hospital visits to manage pain and other complications. Most primary care physicians are not able to adequately care for these patients, given the limited time and payment associated with office-based evaluation and management codes. ASH believes that any payment model that attempts to address sickle
cell disease must focus on this most vulnerable population. In order for clinicians and experts to have the greatest flexibility to design care coordination efforts and not focus on administrative requirements, ASH proposes a risk-based model in which a single organization would be responsible for costs associated with patients with sickle cell disease in a given region. This model will be designed so that participants have a strong incentive to improve care for patients who are outside of their existing care network.

The development of promising new research, care, and treatment options has led ASH to invest in a multi-faceted initiative to improve outcomes for individuals with sickle cell disease. ASH has been fortunate to meet with representatives from CMMI to discuss this issue on a number of occasions, and we hope that the Centers for Medicare & Medicaid Services will become an active partner in this effort. We hope that the economic realities of practice do not serve as a barrier to ensuring that patients receive state-of-the-art care. ASH urges CMMI to invest the necessary resources to test payment models to help individuals suffering from this disease. ASH has enclosed a draft payment model as a starting point for the development of this project, focusing on individuals with sickle cell disease.

Thank you for your consideration of ASH’s comments and recommendations. If we can provide additional information or expertise, please contact ASH Senior Manager for Policy and Practice, Brian Whitman (bwhitman@hematology.org).

Sincerely,

[Signature]

Charles S. Abrams, MD
President
Risk-Based Care for Rare Disease

Many risk-based payment models are appropriately focused on common diseases to ensure that a large enough population is present and ensure that changes in spending are not the result of random variation. However, an approach that only focuses on common diseases such as coronary artery disease and diabetes ignores the needs of those struggling with rare disease. While such patients could be managed in broad alternative payment models such as accountable care organizations, it may be more expedient for those in risk-based contracts to simply avoid those patients through various means.

ASH proposes a new model that could be used for specialized populations. This initial effort focuses on sickle cell disease but could be expanded to include other diseases. Sickle cell is an excellent candidate for the following reasons:

- Sickle cell disease is a genetic disease for which all states mandate screening at birth. Patients should therefore be aware of this disease.
- The disease predominantly affects African-Americans and many of the patients are covered through Medicaid plans due to poverty. Some estimates indicate approximately 2/3 of individuals with sickle cell disease are covered by Medicaid. Due to the manifestations of the disease, many patients are also covered by Medicare under disability, although few patients reach Medicare on the basis of age.
- There is no proven cure for sickle cell disease, although stem cell transplants have proven effective for some patients.

Payment Model

Most existing payment models have relied on an attribution of existing patients to a practice or service provider. However, there has been no incentive to treat new patients, particularly those who may be difficult or expensive. Since ASH believes that organizations that participate in such a model may manage patients in a non-traditional fashion, we recommend that the organization be at risk for the overall cost of care for sickle cell disease. Such an arrangement would require upfront funding similar to an advanced payment ACO model. In addition, the risk included would be capped at some level to insure against dramatic losses.

Participants in this program will be responsible for a large region which may potentially include an entire state. In many cases, much of their initial work will be outreach to identify sickle cell patients. Some patients with sickle cell disease may be well-managed by existing relationships but many are not well managed and spend more time than appropriate in the emergency room and the hospital.

Since virtually all sickle cell patients would have an encounter with the healthcare system in a given year, it will be relatively simple to track overall spending in Medicare and Medicaid for these patients. This model would allow for the experts in sickle cell to work with primary care physicians and community oncologists to implement best practices in pain control and avoiding hospitalization. Claims will continue to be filed according to normal rules – requiring no changes in the healthcare billing system.

Quality Measurement
To ensure that costs are not being reduced by eliminating necessary medical care for sickle cell disease patients, quality measures will be required. ASH envisions a mix of quality measures. The first group of measures can be administrative measures that would include admission rate, readmission rate, and mortality for sickle cell disease patients. The second group of measures would include quality of life. Recent efforts by the Sickle Cell Disease Foundation of America have established a registry of patient-reported outcomes that could be used in this model.

Comparison Group
This study could be matched with a control group in which there was no contract awarded to improve sickle cell care quality – if contracts were to be awarded on a statewide basis, another state could be compared.

Study Population
Approximately 100,000 Americans have sickle cell disease. Approximately 2/3 of those are covered by public insurance. Florida has the largest state sickle cell population with nearly 9,000 patients but many other states include more than 3,000 patients.