April 2, 2020

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
ATTN: CMS-4190-P
7500 Security Boulevard
Baltimore, MD 21244

Submitted Electronically via http://www.regulations.gov

RE: Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (CMS-4190-P)

Dear Administrator Verma,

The American Society of Hematology is pleased to offer comments on the proposed rule outlining revisions to the Medicare Advantage Program, the Medicare Prescription Drug Benefit Program, the Medicaid Program, the Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly.

ASH represents more than 18,000 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 sickle 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.

Specifically, ASH has provided comments on the provisions of the proposed rule related to sickle cell disease (SCD). In short, we agree with the language of the proposed rule that recognizes many people with SCD have chronic severe pain and need access to effective pain control.

**Exemption of Individuals with Sickle Cell Disease from Drug Management Programs**

The Society supports the proposal to classify the SCD patient population as exempt from drug management programs (DMPs) beginning in plan year 2021 and thanks the Centers for Medicare and Medicaid Services (CMS) for recognizing “the unique clinical nature of SCD.” If finalized, individuals living with sickle cell disease would join beneficiaries with active cancer-related pain, those residing in a long-term care facility, or receiving hospice, palliative, or end-of-life care as exempted individuals.
ASH understands the importance of DMPs in light of the current opioid epidemic and the Society appreciates that these programs aim to help beneficiaries at-risk for misuse or abuse of frequently abused drugs. Ultimately, however, DMPs have the ability to limit at-risk beneficiaries’ access to coverage of frequently abused drugs to a selected network prescriber(s) and/or network pharmacy(ies). Individuals living with SCD, who many times rely on opioids to manage recurrent severe acute painful crises and chronic daily pain, both of which are common complications of SCD, should not be subject to DMPs and potential restrictions to needed pain medication.

Furthermore, the SCD patient community has unfortunately faced years of neglect and discrimination by the health care system, which includes barriers for access to needed medication. Many adult SCD patients often need to bring an advocate for emergency care to increase the chance of receiving appropriate treatment for pain. Again, ASH supports the proposed exclusion of individuals with SCD from DMPs and appreciates that CMS has recognized the unique clinical nature of this disease.

**Inappropriate Prescribing of Opioids**

To help reduce fraud and abuse, Medicare Advantage (MA) organizations and Part D Plan Sponsors must report actions they take related to inappropriate prescribing of opioids. CMS is proposing a new definition of inappropriate prescribing of opioids and has requested comments on specific populations or diagnoses that could be excluded for purposes of this definition, such as cancer, hospice, and/or sickle cell patients. ASH supports the exclusion of sickle cell disease from this definition.

Many individuals with SCD are on long acting and short acting opioids. Recurrent severe acute painful crises and chronic daily pain are the most common complications of SCD. Severe acute painful crises often require treatment in the hospital emergency department. Chronic pain from a variety of causes including avascular necrosis (death of bone tissues due to a lack of blood supply), leg ulcers, and other neuropathic pain, is also prevalent. Opioids may be the only option to provide relief and allow patients to function. ASH is concerned that if individuals with SCD are not excluded from this new definition it could potentially mean that SCD patients who need opioids are less likely to get them if the provider and/or institution does not want to be penalized by CMS for “inappropriate prescribing.”

For appropriate clinical prescribing of opioids for an individual living with SCD, ASH refers CMS to ASH’s soon-to-be-released Guidelines for Sickle Cell Disease: Management of Acute and Chronic Pain. These guidelines, scheduled for publication in May 2020, will outline the management of acute and chronic pain for individuals living with SCD, including clinical scenarios that may necessitate the prescribing of opioids but also those that may allow for non-opioid pharmacological therapies. ASH will forward a copy of these guidelines to you as soon as they are available and we share the following statement from the lead author, Dr. Amanda Brandow:

“ASH developed evidence-based guidelines for the treatment of acute and chronic sickle cell disease pain. The multidisciplinary guideline panel included people with expertise in hematology, pain medicine, emergency medicine, nursing, psychology/psychiatry and patients/patient representatives. The guidelines include recommendations for both pharmacologic and integrative therapies in order to address comprehensive pain management. Importantly, these guidelines address the use of chronic opioid therapy for the treatment of chronic sickle cell disease pain. In summary, the panel recommends a comprehensive approach to pain management and suggests shared decision-making for continuation of chronic opioid therapy for patients that are functioning well and have perceived benefit from chronic opioid therapy.”

The Federal government has recently recognized the unique needs of individuals with sickle cell disease through the following:

- The **Centers for Disease Control and Prevention** (CDC) clarified that its **Guideline for Prescribing Opioids for Chronic Pain** is not intended to deny any patients who suffer with chronic pain from opioid therapy as an option for pain management. The CDC specifically noted the challenges of managing the painful

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complications for sickle cell disease and highlighted the importance of clinical practice guidelines addressing use of opioids as part of pain control in patients with sickle cell disease, including the NHLBI’s *Evidence-Based Management of Sickle Cell Disease Expert Panel Report* for guidance for management of sickle cell disease, to guide treatment and reimbursement decisions.

- The [Centers for Medicare and Medicaid Services](https://www.cms.gov) in the CY 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, recommended beneficiaries with SCD be excluded from the opioid safety edits. This is reiterated in CMS’s [Opioid Prescription in Medicare Beneficiaries: Prescription Opioid Policies and Implications for Beneficiaries with Sickle Cell Disease](https://www.cms.gov).


Additionally, ASH has outlined its position regarding this important matter in its [Statement on Opioid Use in Patients with Hematologic Diseases and Disorders](https://ash.org).

Thank you for the opportunity to offer comments on this proposed rule. We welcome the opportunity to discuss these comments with you and your team. If 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,

Stephanie J. Lee, MD, MPH
President