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Submitted electronically via <http://www.regulations.gov>

RE: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements

Dear Administrator Verma,

The American Society of Hematology (ASH) is pleased to offer comments on changes to the Medicaid program, as outlined in the proposed rule issued on June 17, 2020.

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 value-based purchasing and limitations on opioids.

Changes to Address Medicaid Access to Drugs Using Value-Based Purchasing Arrangements

ASH supports the proposed changes that aim to help facilitate the creation of and implementation of value-based purchasing arrangements (VBP) in the Medicaid program. ASH believes that all individuals should have access to and be able to afford high-quality, clinically appropriate care, including innovative therapeutics. Advances in science have led to a recent surge of approvals and a robust pipeline for treatments for hematologic diseases and disorders. Chimeric antigen receptor T-cell (CAR-T) therapy, approved in 2017 for certain patients with lymphoma and leukemia, is a potentially life-saving cellular therapy for patients who have exhausted all other options. Several new CAR-T products and additional indications (e.g. multiple myeloma) are expected in the next few years. In addition, gene therapies are anticipated for hemophilia, beta thalassemia and sickle cell disease (SCD), creating the potential to transform the lives of individuals living with these

diseases. These innovative and effective treatments, however, come at a high cost, creating potential barriers to access.

Proposed changes to the Medicaid program to allow for and encourage the development of VBP arrangements is especially significant for the SCD community as the majority of these individuals are covered by Medicaid. According to data released by the Centers for Medicare and Medicaid Services (CMS), of the approximately 100,000 people living with SCD in the U.S., 55,349 were found to be covered by Medicaid.¹ Unfortunately, the SCD population has had limited treatment options but the possibility of a potentially life-changing gene therapy, is exciting – there are currently clinical trials underway to test gene therapies in individuals living with SCD. Promising results from one of those trials were recently presented at the European Hematology Association Annual Congress.² ASH's main priority is patient access to high-quality care and the Society is hopeful that VBP arrangements will allow for more patients to access these high-cost innovative therapies.

ASH encourages the development of VBP arrangements, especially for innovative therapies, as long as they are evidence-based and clinically appropriate. These arrangements must recognize the physician services associated with the provision of the treatment, including the cost of obtaining, storing, and direct administration of these therapies. Additionally, the Society only supports VBP arrangements that are patient centric – the only goal cannot be to reduce costs, it must include striving for and achieving superior patient outcomes.

Drug Utilization Review (DUR) Program and Electronic Claims Management System for Outpatient Drug Claims, Managed Care Standard Contract Requirements and Requirements for MCOs, PIHPs, or PAHPs that provide Covered Outpatient Drugs

The rule proposes to require states to establish safety edit limitations on the days' supply for an initial prescription opioid fill for beneficiaries who have not filled an opioid prescription within a defined period to be specified by the state. The patients who have not received opioids within a specified timeframe are referred to as opioid naïve and would be subjected to the days' supply limit on the opioid prescription. The rule goes on to say that states can consider the current Centers for Disease Control and Prevention (CDC) Guideline and other clinical guidelines when implementing initial fill limitations, being mindful of the context in which such guidelines are written. The proposed rule notes that in its 2019 clarification of the Guideline, the CDC noted that it was “intended for primary care clinicians treating chronic pain for patients 18 and older, and examples of misapplication include applying the Guideline to patients in active cancer treatment, patients experiencing acute sickle cell crises, or patients experiencing post-surgical pain.”

ASH strongly urges CMS to exempt individuals with sickle cell disease (SCD) from the limitation to opioid prescriptions as proposed in the rule because people with SCD may have intermittent but excruciating pain. This exemption would be consistent with other actions proposed by the agency. For example, in the proposed rule outlining revisions to the Medicare Advantage Program and the Medicare Prescription Drug Program for Contract Year 2021 and 2022, CMS proposed exempting individuals with SCD from drug management programs (DMPs) due to “concerns of misapplication of opioid restrictions in the sickle cell disease (SCD) patient population.” ASH strongly supported this proposal and hopes that CMS will finalize it in further rulemaking this year.

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 potential restrictions

¹ Prevalence of Sickle Cell Disease among Medicaid Beneficiaries in 2012. Centers for Medicare and Medicaid Services Office of Minority Health. June 2019. <https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Highlight-16-Sickle-Cell-Disease.pdf>

² Julie Kanter, John F. Tisdale, et al. Outcomes in Patients Treated with LentiGlobin for Sickle Cell Disease (SCD) Gene Therapy: Updated Results From the Phase ½ HGB-206 Group C Study. <https://library.chaweb.org/eha/2020/eha25th/295102/julie.kanter.outcomes.in.patients.treated.with.lentiglobin.for.sickle.cell.html?pf=listing%3D0%2Abrowseby%3D8%2Asortby%3D1%2Asearch%3DOUTCOMES+IN+PATIENTS+TREATED+WITH+LENTIGLOBIN+FOR+SICKLE+CELL+DISEASE+%28SCD%29+GENE+THERAPY%3A+UPDATED+RESULTS+FROM+THE+PHASE+1%2F2+HGB-206+GROUP+C+STUDY>

to needed pain medication. Until additional products, both therapeutic and alternative, are approved to mitigate pain crises, individuals living with SCD should not be subject to limitations placed on access to clinically needed opioids. 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 urges CMS to exclude individuals with SCD from any limitations on opioid supply.

The Society would also like to highlight that in June of this year, ASH published SCD Guidelines: [Management of Acute and Chronic Pain](#).³ These guidelines, the [fourth of five for SCD](#), 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.

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 716-361-2764 (cell).

Sincerely,



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President

³ Amanda M. Brandow, C. Patrick Carroll, Susan Creary, Ronisha Edwards-Elliott, Jeffrey Glassberg, Robert W. Hurley, Abdullah Kutlar, Mohamed Seisa, Jennifer Stinson, John J. Strouse, Fouza Yusuf, William Zempsky, Eddy Lang; American Society of Hematology 2020 guidelines for sickle cell disease: management of acute and chronic pain. *Blood Adv* 2020; 4 (12): 2656–2701.
doi: <https://doi.org/10.1182/bloodadvances.2020001851>