Alliance for Regenerative Medicine

March 23, 2021

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Sent via: xavier.becerra@hhs.gov

Dear Mr. Secretary:

On behalf of the Alliance of Regenerative Medicine (ARM), we request that you move ahead on the planned timeline to implement the "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 Pay Liability (TPL) Requirements (CMS-2482-P)." Specifically, we strongly urge the Agency not to delay the implementation any further than is required by the Administration's existing "regulatory freeze pending review memorandum." The rule was proposed on June 19, 2020 and finalized December 31, 2020.

ARM is the leading international advocacy organization dedicated to realizing the promise of regenerative medicines and advanced therapies. ARM promotes legislative, regulatory, and reimbursement initiatives to advance this innovative and transformative sector, including cell therapies, gene therapies, and tissue-based therapies. Early products to market have demonstrated profound, durable, and potentially curative benefits that are already helping thousands of patients worldwide, many of whom have no other viable treatment options. In its 11-year history, ARM has become the global voice of the sector, representing the interests of 380+ members worldwide, including small and large companies, academic research institutions, major medical centers, and patient groups.

ARM and its members have long recognized the need for innovative payment models to make regenerative therapies available in the U.S. health care system. Value-based purchasing agreements are particularly well-suited for regenerative treatments due to complexities in how such therapies are administered, the severity of the conditions treated, and the fact that many of the potentially curative treatments proposed will realize their full clinical and economic value over time following a single or very limited course of treatment.

We were pleased when CMS proposed the rule and ARM provided formal comments in support of the approach taken to address current regulatory barriers that restrict widespread adoption

of VBP in the Medicaid program and other settings. The final rule, once implemented, will provide greater access to transformative therapies for patients, many of whom are facing daunting health challenges.

Thank you for your consideration.

Sincerely,

Robert J. Falb,
Director, U.S. Policy and Advocacy

Cc: Elizabeth Richter
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