



October 5, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
CMS-1734-P
P.O. Box 8016
Baltimore, MD 212-44-8016

Submitted online via www.regulations.gov

Re: Medicare Program: CY 2021 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies

Dear Administrator Verma:

We appreciate the opportunity to comment on the proposed rule entitled, “CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies,” as published in the *Federal Register* on August 17, 2020 (herein after “Proposed Rule”).

Voices for Non-Opioid Choices (“*Voices*”) is a nonpartisan coalition dedicated to ensuring patient and provider access to FDA-approved, safe, and effective non-opioid pain management therapies for acute painⁱ patients. Our nearly 40 membersⁱⁱ include licensed healthcare professionals such as physicians, nurses, dentists, therapists, and related associations as well as patient advocacy groups, students, former addicts, and retirees who believe it is crucial to prevent addiction before it starts by increasing the availability and utilization of non-opioid approaches through systematic change.

Our comments focus on a proposed change to a current drug approval pathway that we fear could lead to unintended negative consequences for medical innovation, and make it more difficult for acute pain patients to access effective new formulations of existing medicines. As drafted, the proposal would substantially change how the Centers for Medicare and Medicaid Services (CMS) would pay for drugs approved through the Food and Drug Administration 505(b)(2) approval pathway. This process allows for the commercial viability for infusion and injectable treatments that are an improvement upon, but therapeutically different than, drugs that might share the same ingredient.

Voices was founded because our members believe that pain patients do not have enough readily available options to manage acute pain safely, effectively, and without the risk of opioid use disorder. Therefore, we believe the federal government should take every step it can to facilitate access to new and improved options that meet these criteria for pain patients. The stated goal of this policy proposal

was to address the increasing cost of drugs, and yet it will have little impact on the launch prices of new drug therapies. Instead, the proposed rule would negatively impacting patient access to continued innovation, by limiting manufacturers' ability to make improvements on existing therapies and approaches that may dramatically improve quality of life for pain patients.

If finalized, this proposal would impact all manufacturers of 505(b)(2) drugs that are covered under Medicare Part B, which could affect research and development (R&D) – and drug availability and access – in the years to come. We fear that patients may never benefit from new and improved formulations due to payment policies that render the development of these therapies economically unfeasible. This policy will eliminate the ability of manufacturers to innovate and develop new formulations of existing drugs, and will have a “domino effect” on these manufacturers’ pipeline more broadly, even to the detriment of a greater number of patients.

Voices strongly urges against CMS implementation of this policy in 2021. We would hope that CMS would instead take responsible and necessary action in requesting and receiving as much stakeholder input as possible – including from the patient and physician advocacy communities – before releasing a revised proposal. We stand ready to work with CMS and all other relevant stakeholders to promote sustainable access to new, innovative, and effective drug therapies. Together, we are confident that we can develop an approach that would better protect patient care, the needs of health care providers, and the ability of innovative companies to research, develop, and manufacture new and improved therapies.

Please do not hesitate to contact Chris Fox (chris@nonopioidchoices.org) with any questions you may have.

Thank you so much for your consideration of these comments.

Sincerely,

/s

Chris Fox
Executive Director

ⁱ Acute pain refers to an episodic pain incident such as an accident, trauma, sports injury, or surgery.

ⁱⁱ For a complete list of supporting Member Organizations, please see <https://nonopioidchoices.org/members/>