

Congress of the United States
Washington, DC 20515

September 19, 2022

Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Brooks-LaSure,

As Congress and the entire Federal government continue working to address the devastating effects of the opioid epidemic, we write to reinforce the critical need to ensure that all Americans have access to expanded chronic pain treatment options that divert the use of oral opioids. During the 12-month period ending in October 2021, annual drug overdose deaths reached record levels as deaths from opioids surged.¹ We urge **the Centers for Medicare and Medicaid Services (CMS) to take further steps to remove barriers preventing Medicare beneficiaries from accessing treatment options that reduce the use of oral opioids and more effectively alleviate chronic pain and spasticity as part of the final CY 2023 Physician Fee Schedule (PFS) rule.**

One example of this kind of therapy is targeted drug delivery (TDD), also known as intrathecal pain therapy. TDD is the continuous administration of medication into a patient's spinal canal via a catheter that is attached to a surgically implanted pump. Individuals who use the therapy have typically failed other treatment modalities and are some of the most vulnerable patients suffering chronic pain. This alternative to oral opioids significantly decreases patients' pain symptoms while allowing many to regain their ability to walk, socialize, and participate in daily activities. **Unlike oral opioids, the potential for abuse and diversion with TDD is virtually nonexistent.**² Pain pumps deliver only 1/100th to 1/300th of the typical oral dosage, substantially reducing unwanted and often harmful side effects. Because the treatment is delivered directly into a patients' spinal canal, there is no opportunity for a patient to independently increase, share, sell or have their medication used by someone else. Patients utilizing the therapy report high degrees of satisfaction, allowing them to transition off long-term oral opioid use.³

In 2012, CMS finalized a policy requiring physicians to use a "buy-and-bill" model for TDD, thus no longer allowing a compounding pharmacy or Durable Medical Equipment supplier to bill Medicare. This means physicians purchase the drug from pharmacies and bill Medicare when it is administered to patients. Many physicians, particularly in rural areas, are understandably unwilling and unable to take on the financial risk required to purchase and hold individually compounded drugs.

¹ McPhillips, Deidre, "US Drug overdose deaths reach another record high as deaths from fentanyl surge," CNN, March 16, 2022.

² Hatheway, J.A., Bansal, M. and Nichols-Ricker, C.I. (2020), Systemic Opioid Reduction and Discontinuation Following Implantation of Intrathecal Drug-Delivery Systems for Chronic Pain: A Retrospective Cohort Analysis. *Neuromodulation: Technology at the Neural Interface*, 23: 961-969. <https://doi.org/10.1111/ner.13053> ("[TDD] allows for more provider control over drug dosing, with a lesser probability of drug diversion issues related to systemic opioids.")

³ Schultz, David M et al. "Patient Satisfaction Following Intrathecal Targeted Drug Delivery for Benign Chronic Pain: Results of a Single-Center Survey Study." *Neuromodulation: Journal of the International Neuromodulation Society* vol. 23,7 (2020): 1009-1017. doi:10.1111/ner.13167

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When patients miss appointments -- which chronic pain patients often do -- the drug is discarded and the physician is not reimbursed. This has created a roadblock for Medicare beneficiaries trying to access this virtually non-addictive therapy even when it is the most clinically appropriate option. Given your agency's dedication to fighting the scourge of the opioid epidemic, CMS should reevaluate its current policy related to this therapy that is preventing safer alternatives to oral opioids from being fully deployed for these vulnerable beneficiaries.

In 2018, Congress overwhelmingly passed the bipartisan SUPPORT for Patients and Communities Act, or the SUPPORT Act (P.L. 115-271) which included section 6086, the Dr. Todd Graham Pain Management Study and section 6032, which required CMS to issue a Report to Congress and develop a related Action Plan to review coverage and payment policies in Medicare and Medicaid related to the treatment of opioid use disorder and for non-opioid therapies to help manage acute and chronic pain. As part of implementing the SUPPORT Act, we are pleased to see CMS set forth coding and payment proposals to address acute pain and chronic pain management in this year's proposed PFS rule.⁴ We believe CMS can go further and update payment policies for targeted drug delivery so that patients with chronic pain can access an effective alternative to oral opioids.

Existing statute does not compel the agency's current position, which is why we are requesting that CMS address this important access issue in the final CY 2023 PFS rule. Doing so would increase access to a lifechanging and non-addictive therapy. We look forward to working with your agency to help ensure that Medicare beneficiaries have expanded access to safe and effective alternatives to oral opioids.

Sincerely,



Ann McLane Kuster
Member of Congress



Brad Wenstrup
Member of Congress



Terri Sewell
Member of Congress



Michael C. Burgess, M.D.
Member of Congress

⁴ See "(33) Chronic Pain Management and Treatment (CPM) Bundles" in the CY 2023 PFS proposed rule, which was publicly released on July 7, 2022 and is open for comments until September 6, 2022.