



September 13, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1772-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted online via www.regulations.gov

RE: CMS-1772-P: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating

Dear Administrator Brooks-LaSure,

On behalf of [Voices for Non-Opioid Choices](http://www.voicesfornonopioid.org) (“Voices”) and our nearly 100 member organizations from around the country, thank you for the opportunity to share our comments on the proposed rule entitled, “Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating,” (herein after referred to as the “Proposed Rule”) as published in the *Federal Register* on July 26, 2022.

The Proposed Rule provides a tremendous opportunity for the Centers for Medicare and Medicaid Services (CMS) to address the nation’s crippling and worsening opioid addiction epidemic by advancing thoughtful policies to prevent opioid addiction. Unfortunately, the Proposed Rule does little to seize that opportunity.

Background

Voices was founded in 2019 and is dedicated to reducing opioid addiction in the United States. Voices – and our members – joined together to address the opioid addiction crisis in the United States by increasing the availability and use of non-opioid pain management approaches among acute, episodic

pain patients¹. In doing so, Voices and our partners believe that we can reduce the risk of misusing prescription opioids and save lives.

In 2019, when Voices launched, Center for Disease Control and Prevention (CDC) data showed that 130 Americans died every day from an opioid-related drug overdose².

The situation has not improved.

In 2021, data from the Centers for Disease Control and Prevention (CDC) estimate that approximately 80,000 Americans died of an opioid-related drug overdose³. This data shows that, in 2021, 220 Americans died every day from a drug-related overdose⁴. This represents a 90 percent increase in the number of opioid-related overdose deaths in just 3 years.

Opioid Use Among Acute Pain Patients

By all accounts, opioid prescribing in the United States is on the decline. In 2012, there were more than 255 million prescriptions for opioids dispensed in the United States⁵. This is nearly enough for every American to have had their own personal opioid prescription.

The number of opioid prescriptions dispensed has decreased every year since this time. In 2020, there were 142 million opioid prescriptions dispensed in the United States⁶. Much of the decrease in opioid prescribing can likely be attributable to heightened awareness of the opioid addiction crisis in the country as well as state and other local policies that have limited provider access to opioids.

However, there is no indication that surgical patients have benefited from this decrease. Opioid use and prescribing among some patients – including acute pain patients – continues to be the standard of care.

Current Medicare policy incentivizes the use of opioid-based pain management approaches in the hospital outpatient setting (HOPD). As a result, 90 percent of surgery patients are prescribed opioids to manage their postsurgical pain⁷.

¹ Available at: <https://nonopioidchoices.org/about/>

² Understanding the Epidemic. Injury Center. Available at: <https://www.cdc.gov/drugoverdose/epidemic/index.html>

³ U.S. Overdose Deaths in 2021 Increased Half as Much as in 2020- But Are Still Up 15%. National Center for Health Statistics. Available at: https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2022/202205.htm

⁴ U.S. Overdose Deaths in 2021 Increased Half as Much as in 2020- But Are Still Up 15%. National Center for Health Statistics. Available at https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2022/202205.htm

⁵ U.S. Opioid Dispensing Rate Maps. Drug Overdose. Available at: <https://www.cdc.gov/drugoverdose/rxrate-maps/index.html>

⁶ U.S. Opioid Dispensing Rate Maps. Drug Overdose. Available at: <https://www.cdc.gov/drugoverdose/rxrate-maps/index.html>

⁷Hill MV, McMahon ML, Stucke RS, Barth RJ Jr. Wide Variation and Excessive Dosage of Opioid Prescriptions for Common General Surgical Procedures. *Ann Surg.* 2017 Apr;265(4):709-714. Available at: <https://pubmed.ncbi.nlm.nih.gov/27631771/>

There are approximately 50 million outpatient surgical procedures that are performed in the United States every year⁸. Research shows that anywhere from 10⁹ to 20 percent¹⁰ of these patients will initiate a long-term opioid use habit following such procedures.

This situation is entirely avoidable.

Expanding ASC Payment System Policy for Non-Opioid Pain Management Options to the Hospital Setting

CMS is uniquely positioned – as the largest health insurer in the world – to impact the trajectory of the opioid crisis, including by addressing the barriers that limit patient and provider access to non-opioid approaches.

Beginning in calendar year 2019, your agency started providing separate payments for non-opioid pain management approaches given to patients in the ambulatory surgical (ASC) setting. By your agency's own analysis¹¹, this payment change has been an indisputable success: use of non-opioid pain management approaches increased significantly.

From 2019 to 2020, use of non-opioid pain management approaches increased by 120 percent¹² – which created opportunities for providers to reduce opioid prescribing in this setting and, in turn, the risk of ASC patients misusing prescription opioids.

The Proposed Rule fails to expand separate maybe for such approaches to the HOPD setting. In doing so, the Proposed Rule risks needlessly exposing tens of millions of surgical patients¹³ to prescription opioids in 2023. This will ultimately and unfortunately result in millions of Americans¹⁴ initiating an opioid use habit in 2023 and beyond.

CMS has dedicated significant time and attention on efforts to combat the opioid addiction, but this rule has the potential to undermine these efforts. To avoid a major step in the wrong direction, the final iteration of this rule must expand the current ASC payment system policy for non-opioid pain management options to the HOPD setting.

⁸Dobson GP. Trauma of major surgery: A global problem that is not going away. *Int J Surg*. 2020 Sep;81:47-54. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7388795/>

⁹ Hah JM, Bateman BT, Ratliff J, Curtin C, Sun E. Chronic Opioid Use After Surgery: Implications for Perioperative Management in the Face of the Opioid Epidemic. *Anesth Analg*. 2017 Nov;125(5):1733-1740. Available at: <https://pubmed.ncbi.nlm.nih.gov/29049117/>

¹⁰ Côté C, Bérubé M, Moore L, Lauzier F, Tremblay L, Belzile E, Martel MO, Pagé G, Beaulieu Y, Pinard AM, Perreault K, Sirois C, Grzelak S, Turgeon AF. Strategies aimed at preventing long-term opioid use in trauma and orthopaedic surgery: a scoping review. *BMC Musculoskelet Disord*. 2022 Mar 11;23(1):238. Available at: <https://pubmed.ncbi.nlm.nih.gov/35277150/>

¹¹ CMS Action Plan to Enhance Prevention and Treatment for Opioid Use Disorder. Center for Medicare & Medicaid Services. Available at: <https://www.cms.gov/files/document/action-plan-behavioral-health-strategy.pdf>

¹² Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals. *Federal Register*. Available at: <https://www.federalregister.gov/documents/2021/08/04/2021-15496/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment>

¹³ Available at: <https://public-inspection.federalregister.gov/2022-15372.pdf>

¹⁴ Available at: <https://public-inspection.federalregister.gov/2022-15372.pdf>

Policy Change is Especially Important for Vulnerable Populations

The Proposed Rule sought feedback on the need to expand the current ASC payment system policy for non-opioids pain management options to the HOPD setting. We understand that a full reversal of the packaging policy is a major policy decision. Therefore, we want to reiterate our common-sense, targeted payment proposal for the agency's consideration. We propose that the agency remove all barriers to accessing non-opioids for those patients who face an increased risk of long-term opioid use after addiction: patients with or in recovery from a substance use disorder (SUD), those with an active opioid use disorder (OUD), and those with mental illness.

There are approximately 22 million Americans living with an active SUD. Current Medicare policy would likely result in these patients being prescribed prescription opioids if they suffered an acute pain incident. For Medicare beneficiaries in this group, current policy would exacerbate their current health condition and pose an unnecessary burden on these patients and those around them. **The federal government must offer these patients the choice of opioid-free pain management options.**

Additionally, one of the fastest growing cohorts of new persistent opioid use is among elderly Americans¹⁵. In 2020, more than 1 million Medicare beneficiaries were diagnosed with an OUD in 2020 alone¹⁶. Research shows that opioid misuse-related emergency department (ED) visits increased by nearly 220 percent among adults over 65 years old from 2006 to 2014¹⁷. **The federal government must offer these patients the choice of opioid-free pain management options.**

Finally, the third cohort of patients who would benefit from increased availability and access to non-opioid pain management approaches is patients suffering with mental illness. The link between mental illness and addiction is quite clear. Patients with mental illness are often predisposed to addiction and face rates of substance use disorder that is two times higher than the national average¹⁸. As a result, there are 17 million patients living with both a mental illness and a substance use disorder¹⁹. **The federal government must offer these patients the choice of opioid-free pain management options.**

¹⁵ Santosa KB, Hu HM, Brummett CM, Olsen MA, Englesbe MJ, Williams EA, Waljee JF. New persistent opioid use among older patients following surgery: A Medicare claims analysis. *Surgery*. 2020 Apr;167(4):732-742. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7216555/>

¹⁶ Many Medicare Beneficiaries Are Not Recovering Medication to Treat Their Opioid Use Disorder. U.S. Department of Health and Human Services. Office of Inspector General. Available at: <https://oig.hhs.gov/oei/reports/OEI-02-20-00390.asp#:~:text=WHAT%20WE%20FOUND,beneficiaries%20face%20challenges%20accessing%20treatment.>

¹⁷ Carter MW, Yang BK, Davenport M, Kabel A. Increasing Rates of Opioid Misuse Among Older Adults Visiting Emergency Departments. *Innov Aging*. 2019 Mar 7;3(1):igz002. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6404687/>

¹⁸ NIDA. 2021, April 13. Part 1: The Connection Between Substance Use Disorders and Mental Illness. Retrieved from <https://nida.nih.gov/publications/research-reports/common-comorbidities-substance-use-disorders/part-1-connection-between-substance-use-disorders-mental-illness>. Available <https://nida.nih.gov/publications/research-reports/common-comorbidities-substance-use-disorders/part-1-connection-between-substance-use-disorders-mental-illness>

¹⁹ Substance Use Disorders. National Alliance on Mental Illness. Available at: <https://www.nami.org/about-mental-illness/common-with-mental-illness/substance-use-disorders#:~:text=According%20to%20the%20National%20Survey,substance%20use%20disorder%20in%202020.>

Access to non-opioid pain management options, especially among these patient populations, is especially critical and underscores the need to extend separate payment for the administration of non-opioid pain management options to the HOPD setting.

Conclusion

We urge CMS to, in the final iteration of the Proposed Rule, enact a policy change that would expand the current ASC payment system policy for non-opioid pain management options to the HOPD setting. Because the majority of surgeries performed every year take place in the HOPD, increasing the availability of non-opioid pain management options in this setting is critical to preventing potential opioid misuse among surgical patients. As discussed above, expanding the availability of non-opioid pain management options is even more critical to avoid opioid misuse among at-risk patients.

Thank you again for your consideration of these comments. Voices looks forward to continuing our dialogue about how we can partner towards our shared goal of preventing addiction before it starts, including through policies that can increase the availability and use of non-opioid pain approaches for acute pain patients. If you have any questions or comments, please feel free to reach me at chris@nonopioidchoices.org.

Sincerely,

A handwritten signature in black ink, appearing to read 'CMFX', written in a cursive style.

Chris Fox
Executive Director