September 10, 2025

The Honorable Mehmet Oz
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted online via www.regulations.gov

RE: **CMS-1834-P: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Overall Hospital Quality Star Ratings; and Hospital Price Transparency**

Dear Administrator Oz,

On behalf of Voices for Non-Opioid Choices ("Voices"), our Board of Directors, our more than 200 member organizations, and our tens of thousands of advocates from around the country, thank you for the opportunity to share our comments on the Fiscal Year 2026 Hospital Outpatient Prospective Payment System Proposed Rule.

We appreciate the agency's continued investment in efforts to reduce barriers to necessary care and in implementing the Non-Opioids Prevent Addiction in the Nation ("NOPAIN") Act. In this comment letter, Voices would like to offer our insights and support as CMS prepares to measure the impact of NOPAIN, as well as our thoughts around the current interpretation of the NOPAIN Act outlined in the proposed rule.

About Voices

Founded in 2019, Voices is the nation's leading nonpartisan advocacy organization dedicated to preventing opioid addiction through enhancing patient access to non-addictive acute pain treatment options.*

We understand that, despite progress, the opioid addiction crisis persists in the United States. In 2017, the United States declared the crisis a public health emergency.[1] At the time, we were losing approximately 130 Americans every day to an opioid-related drug overdose. According to data from the Centers for Disease Control and Prevention, we lost nearly 150 Americans to an opioid-related drug overdose in 2024.[2] This represents a **15 percent increase** in opioid-related deaths since we declared opioid addiction a public health emergency.

* For more information about Voices, our partners, or our work, please visit our website at www.nonopioidchoices.org.

Voices – and our members – know that, for some, opioid addiction can start after being prescribed an opioid to manage an acute pain incident, such as an accident, sports injury, trauma, or surgery. The latest research shows that up to 10 percent of opioid-naive patients prescribed opioids after surgery will develop long-term opioid use.[3]

Simply put: millions of Americans will be placed at a higher risk for opioid dependency or Opioid Use Disorder (OUD) this year after being prescribed an opioid to manage their pain.[4,5]And many will die from an opioid-related drug overdose.[2]

Voices and our members believe that we can prevent this by increasing access to and use of non-addictive forms of pain management. In doing so, we can save lives.

Federal Response to Opioid Addiction Crisis

For too many Americans**, prescription opioids are the only accessible pain management option**. In fact, **ninety percent of post-surgical pain patients** receive opioids.[6] Patients in the United States consume **eighty percent** of the global supply of opioids, including **ninety-nine** percent of the global supply of hydrocodone.[7]

While for some, opioid-based pain management may represent the best (or only) clinical option, clinicians should have access to the full range of safe, effective, and FDA-approved options to treat their patients. Accordingly, Voices supports access to these approaches when used responsibly and clinically appropriate.

Congress agreed and passed legislation – the NOPAIN Act – that makes clear its belief that CMS must continue to use its considerable influence to enact payment policies that create parity between opioids and non-opioid approaches. This law arose from clear evidence that such measures have a profound impact on pain management prescribing patterns. In fact, CMS data show that use of non-opioids more than doubled as a result of a decision in 2019 to pay separately for the qualifying non-opioid tools in an ambulatory surgery center (ASC) setting.

The NOPAIN Act **enjoyed tremendous bicameral and bipartisan support** among Members of Congress. When the legislation was signed into law, there were more than **175 Members of Congress** who supported the legislation.[8, 9]

The NOPAIN Act was also supported by **every major clinical advocacy society**, including the American Medical Association (AMA),[10] American College of Surgeons (ACS),[11] American Society of Anesthesiology,[11] and many more.[11] The legislation was also supported by every major patient and recovery advocacy organization.[11]

The aim of the law is simple: prevent unnecessary exposure to opioids by **enhancing patient access to non-opioid pain management approaches** used in surgical procedures performed in both the hospital outpatient and ambulatory surgery center (ASC) setting. In doing so, the law aims to prevent opioid addiction by providing separate payment[†] for the use of qualifying non-opioid products beginning January 1, 2025 through December 31, 2017.

In crafting the legislation, the intent was **clear and intentional**: to facilitate patient access to all appropriate non-opioid products that can treat acute, postoperative pain. However, as CMS implements this law, it is important to stay true to its intent of making available ***all*** clinically-appropriate, safe, effective, and FDA-approved non-opioid approaches that have the demonstrated ability to treat postsurgical pain and reduce opioid requirements.

Comments on the Proposed Rule

[†] The amount of the separate payment was to be the lesser of ASP + 6 or 18 percent of the covered service.

Please see our comments below on two aspects of the proposed rule and the continued implementation of the NOPAIN Act:

Report Evaluating Impact of Separate Payment on Opioid Prescribing

Subsection C of the NOPAIN Act mandates a report assessing the impact of the NOPAIN Act. The required report looks specifically at opioid prescribing patterns before and after the law is in effect across populations who received opioid and non-opioid pain management approaches.

Specifically, the law asks CMS to:

"compar[e], for the 12-month period following the first 6 months in which additional payment for non-opioid treatments for pain relief (as defined in clause (iv) of section 1833(t)(16)(G) of the Social Security Act, as added by subsection (a)) is made under such section 1833(t)(16)(G)—

> (i) with respect to Medicare beneficiaries who received a non-opioid treatment for pain relief (as so defined) as part of a covered OPD service, the quantity of opioids administered, dispensed, and prescribed for the same covered OPD service, including postoperative management; and
>
> (ii) with respect to Medicare beneficiaries who did not receive a non-opioid treatment for pain relief (as so defined) as part of the same covered OPD service in clause (i)), the quantity of opioids administered, dispensed, and prescribed for the same covered OPD service, including postoperative management."

Opioid prescribing is an important consideration when assessing the impact of this policy change. However, because clinician prescribing behavior takes time to evolve, there may be a lag before meaningful decreases in opioid prescribing can be attributable to this policy change. Clinician and institutional familiarity with these tools coupled with the temporary nature of the policy change may slow progress on this front.

To that end, we encourage the Agency to not only analyze initial opioid prescribing claims, but also opioid refills at 30/60/90 days for Medicare beneficiaries who received a non-opioid treatment for pain relief as part of a covered OPD service compared to those who did not. Findings may elucidate that although initial prescribing habits may take time to shift, patient opioid requirements—and risk for long-term use—are declining in the non-opioid treated population.

In addition to evaluating opioid prescribing resulting from this policy change, there are a variety of other outcomes-related factors that we would urge CMS to consider. These metrics may also be more readily apparent in the short window that CMS is to evaluate. These include:

- *Access to non-opioids*

The NOPAIN Act was intended to do one thing: increase access to non-opioid therapies. According to data released by CMS, the 2019 policy change made in ASCs to pay separately for non-opioids achieved this goal. We urge CMS to continue this important analysis and evaluate whether the policy increased utilization of qualifying products across the HOPD and ASC settings.

- *Improved patient and pharmacoeconomic outcomes*

Recovery after surgery is an important clinical consideration. Pain management is an important aspect of recovery, but also is the return of function. One way to measure

postsurgical recovery would be to evaluate the impact that access to non-opioids in the outpatient surgical setting has on patient time to discharge. Returning home more quickly after surgery is an important consideration for patients and facilities alike

Additionally, there has been significant research done on the economic benefits to facilities of multimodal pain approaches. Most of these analyses cite system-wide savings attributable to their use.[12,13,14] Other research has demonstrated reductions in pain-related healthcare resource utilization due to decreased emergency room visits, reduced physical or occupational therapy visit requirements, and less visits to the outpatient physician office environment for follow-ups.[15] We urge CMS to assess whether this policy change actually decreased overall spending in the outpatient setting.

List of Products Eligible for Separate Payment is Incomplete

In addition, we would like to share our concern that part of the agency's proposed policy unnecessarily restricts access to some non-opioid alternatives, narrowing patient and provider choice.

In previous rulemaking, CMS noted that its exclusion of several non-opioid alternatives was attributable to FDA labeling of those drugs for general acute pain without specific mention of postoperative or postsurgical use. We disagree with that interpretation as well as its continued application to the excluded therapies in the 2026 Proposed Rule.

We suggest that CMS may be neglecting to take into consideration FDA guidance on approval and labeling of general acute pain therapies, which states that such an indication is appropriate for a product that is supported by at least two clinical trials, including "two successful clinical trials in postoperative pain."[16] This makes clear the need for a more inclusive interpretation of the statutory language to ensure that more nuanced labeling that supports the intent of the NOPAIN Act is taken fully into consideration.

We believe the intent of the NOPAIN Act was to create a pathway for providers to have options for patients to treat pain without reliance on opioids. We urge the agency to amend their interpretation to consider labeling that includes acute pain products that have been studied in two successful clinical trials in postoperative pain, which would allow for equal consideration to non-opioid alternatives that have been studied for safety and efficacy in the postoperative setting.

Thank you for your consideration of these comments. Voices and our members look forward to continuing to partner with you and your agency toward our shared goal of improving patient care, reducing costs, and preventing addiction before it starts, including by ensuring robust access to non-addictive pain management approaches.

If you have any questions about the substance of these comments, or seek additional clarity, please feel free to contact us at chris@nonopioidchoices.org.

Sincerely,

/s
Chris Fox
Executive Director

References

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