

September 15, 2025

The Honorable Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
CMS-1834-P
P.O. Box 8010
Baltimore, MD 21244-8010

Submitted online via www.regulations.gov.

RE: 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:

The undersigned organizations are writing in response to the Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems Proposed Rule ("Proposed Rule") as posted by your agency on July 17th, 2025, and specifically in regard to the implementation of the Non-Opioids Prevent Addiction in the Nation ("NOPAIN") Act (section 4135 of Public Law No. 117-328).

This legislation went into effect on January 1st, 2025 and is designed to significantly increase patient and provider access to non-opioid products in the outpatient surgical setting. The legislation accomplishes this by providing separate payment for the use of qualifying non-opioid pain management approaches across all outpatient surgical settings.

Our organizations believe that increasing use of and access to such approaches can reduce reliance on prescription opioid medications for managing postsurgical pain. In effectively implementing this law, CMS can help minimize unnecessary exposure to prescription opioids.

In 2019, CMS began providing separate payments for the use of qualifying non-opioid approaches for outpatient procedures performed in Ambulatory Surgical Centers (ASCs). As a result, use of non-opioid pain approaches more than doubled in just one year (from 2019 to 2020). We believe that successfully implementing this new law can have a similar impact for patients undergoing an outpatient procedure in the hospital setting.

However, we are concerned that CMS is taking an inappropriately narrow approach to implementing this law, which could threaten the potential impact of this policy.

Your agency is tasked with identifying drugs and devices that qualify for separate payment under this new law. In making such determinations, we believe CMS is applying an overly rigid requirement for qualifying drugs and, as a result, limiting access to these products for patients and providers.

CMS appears to believe that, in order to qualify for separate payment under the NOPAIN Act, products must have an explicit indication for use in the postsurgical setting. This is evident in the fact that CMS allows separate payment for the use of an injectable version of a non-steroidal

anti-inflammatory drug (NSAID) that has the postsurgical indication on its label, but not the tablet form of the same medication, which does not.

However, it is common for products to receive a broader label that indicates their ability to treat moderate or severe acute pain. These products conduct clinical trials studying efficacy in patients experiencing moderate to severe acute pain, and are approved with the intention of being used in every setting in which that pain presents, including after surgery. Unfortunately, CMS appears to believe that these products do not qualify for separate payment because their label does not specifically reference a postsurgical application. This approach violates the spirit and intent of the NOPAIN Act, which was to ensure patients could reasonably and easily access all FDA-approved, safe, and effective non-opioid treatment options that are used in the post surgical setting.

We urge CMS to address this challenge and to ensure that such products qualify for separate payment under the NOPAIN Act. Doing so would increase use of non-opioid pain approaches in the postsurgical setting, decrease rates of opioid addiction occurring post-surgically, and save lives. It would also align well with this Administration's stated goal of addressing the opioid addiction crisis.

We look forward to continuing to work with you on meaningful improvements to the Proposed Rule to maximize the impact of this new law. We share CMS' commitment to improving patient care and ensuring that the law, as implemented, will achieve optimal outcomes for patients and providers.

Thank you for your attention to this matter.

Sincerely,

A Better Life-Brianna's Hope
A Voice in the Wilderness Empowerment Center
Ambulatory Surgery Center Association
American Association of Colleges of Nursing
American Association of Nurse Practitioners
American Association of Oral and Maxillofacial Surgeons
American Association of Orthopaedic Surgeons
Better Together CT, Inc.
Confidential Recovery
Country Doc Walk-in & Wellness, LLC
Country Wellness, LLC
Crux Wilderness Therapy
Danny's Ride
Downriver for Veterans, Michigan
Elderly Advocates
Endeavor Therapeutic Horsemanship Veteran Program
Facing Fentanyl
Families of Addicts
Freedom Through Recovery
Generation O
Goldfinch Health

H3 Heroes Helping Heroes 4Life
Ho'ōla Farms
Independence for Veterans
InStep, Inc.
Iron Tribe Network
Jake's Reach, Inc.
Jamie Daniels Foundation
Journey House Foundation
LITE Recovery Hub
Medicaid|Medicare|CHIP Services Dental Association
Mental Health America of Illinois
Michigan Women Veterans Empowerment
Montachusett Veterans Outreach Center
MOSAIC Foundation
National Transitions of Care Coalition
Oasis Recovery Community Organization
Operation Charlie Bravo
Operation First Response
Overdose Lifeline
Pledge for Life Partnership
Prevention Alliance of Tennessee
Project Restore Hope
PTSD Awareness Summit
Quest 4 Recovery Network, Inc.
REAL LIFE
Recovery Advocates in Livingston
Recovery Mobile Clinic
RetireSafe
Safe Haven Recovery Engagement Center
Shatterproof
She Recovers Foundation
Society for Opioid Free Anesthesia
SoldierStrong Access
Stayin' Alive, Franklin County LCC
Tea and Cake Addiction Recovery
Team Sharing, Inc.
The Addict's Parents United
The Battle Within
The Veteran Mentor Project, Inc.
Twelfth Step Ministry, Inc.
United Soldiers and Sailors of America
Veterans Helping Veterans Worldwide
Veterans Outreach Center
VetPark's A.T.V.
Voices for Awareness
Voices for Non-Opioid Choices

Warren Coalition
Will Bright Foundation
Wisconsin Veterans Network
Wyoming Valley Drug and Alcohol Services, Inc.
Young People in Recovery