October 5, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
CMS-1736-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted online via www.regulations.gov

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Potential Revisions to the Laboratory Date of Service Policy; Proposed Overall Hospital Quality Star Rating Methodology for Public Release in CY 2021 and Subsequent Years; and Physician-Owned Hospitals

Dear Administrator Verma:

We appreciate the opportunity to comment on the proposed rule entitled, "Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Potential Revisions to the Laboratory Date of Service Policy; Proposed Overall Hospital Quality Star Rating Methodology for Public Release in CY 2021 and Subsequent Years; and Physician-Owned Hospitals", as published in the *Federal Register* on August 12, 2020 (herein after "Proposed Rule"). We would specifically like to focus our comments on the opportunity before the Centers for Medicare and Medicaid Services (CMS) to leverage the Proposed Rule to facilitate robust patient and provider access to non-opioid therapies across site of care settings.

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 pain[i] patients. Our nearly 40 members[ii] 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.

CMS, as one of the largest purchasers of health care in the world,[iii] has the unique ability to re-focus health care practice and behavior through targeted regulatory policy and action. As part of this, we hope

that CMS will take action to prevent opioid abuse before it starts, including by enabling and increasing patient and provider access to non-opioid pain management approaches. In doing so, CMS can prevent more than 3 million cases of new persistent opioid use that occur every year following an acute pain incident.[iv]

Research shows that, given the choice, patients overwhelmingly prefer non-opioid approaches to manage their pain.[v] Not only does exposure to opioid-based pain approaches put patients at-risk for developing opioid use disorder, they also present significant clinical disadvantages, including:

- Higher patient-reported pain scores,[vi]
- Harmful health effects such as drowsiness, confusion, nausea, constipation, and slowed breathing,[vii] and
- Increasing tolerance for opioids, requiring higher and higher doses to achieve the same pain relief.

Non-opioid pain management approaches, on the other hand, offer significant clinical and health advantages when compared to traditional, opioid-based pain approaches. These advantages include:

- Providing more effective pain relief (when compared to opioid-based pain approaches),[viii]
- Drastically reducing opioid consumption,[ix]
- Allowing for more rapid hospital discharge,[x]
- Reducing rates of opioid-related adverse events,[xi]
- Expediting patient recovery after surgery,[xii] and
- Reducing overall health system costs.[xiii]

Unfortunately, despite these clear benefits, accessing non-opioid pain management approaches remains a challenge for both patients and providers. Current Medicare policy encourages the use of less expensive opioids in the surgical setting, leaving tens of millions of surgical patients every year without a choice in how they manage their pain.[xiv] National experts, convened at the request of Congress, have issued a clarion call for this policy to be changed. In 2019, the Pain Management Best Practices Inter-Agency Task Force ("the Task Force") issued its final report, which urged shifting the standard of pain care away from opioids by increasing the availability and utilization of approaches that prioritize non-opioids as a "first line therapy" for acute pain patients.[xv]

Make no mistake: the time for action is now as the opioid epidemic continues to devastate communities across the country. There were nearly 71,000 Americans who died of a drug overdose in 2019.[xvi] This marked a significant departure from recent progress in 2017 and 2018 showing declining numbers of overdose deaths.[xvii] Now, in large part due to the added stress, isolation and increased rates of mental illness in the country, opioid-related overdose deaths are again on the rise. In fact, according to a recent analysis by the White House Office of Drug Policy, opioid-related fatalities are 11.4 percent higher in 2020 than in 2019.[xviii]

In recognition of the urgency of the challenge we face, we hope that CMS will take immediate action to:

Unpackage and pay separately for non-opioid pain management approaches for <u>all</u> patients

Voices believes that patients should be afforded access to the wide array of available, safe, and effective acute pain management approaches regardless of where they are treated.

Beginning in CY 2019, CMS recognized that current reimbursement policy inadvertently disincentivized the utilization of non-opioid pain management strategies, and established policy to pay separately for non-opioid approaches provided to patients in the Ambulatory Surgery Center (ASC) setting.[xix] CMS failed to make this change in the Hospital Outpatient Setting (HOPD). As a result, ASC patients were afforded greater access to non-opioid pain management approaches. Preliminary evidence shows[xx] that, since implementation of this policy in 2019, the utilization rate of non-opioid pain management therapy in the ASC has, for the first time, increased.

Unfortunately, because the majority of surgeries performed in the United States every year occur in a HOPD setting,[xxi] the proposed rule does little to ensure that these patients can access the array of available, safe, and effective non-opioid pain management approaches. For example, many common orthopedic procedures are currently required to take place in a HOPD. Because CMS has yet to unpackage and pay separately for non-opioid pain management approaches administered to HOPD patients, this means that 8 million Medicare beneficiaries are potentially denied access to non-opioid pain management approaches every year.[xxii]

Given that the majority of procedures – and associated opioid prescribing – take place in the HOPD setting, we urge CMS to revise the proposed rule to adopt policies that better incentivize the utilization of non-opioid pain management approaches. To accomplish this, we hope that the final rule will include a policy to provide separate payment for non-opioid pain management approaches for patients treated in both the HOPD and ASC settings.

Facilitate expedited migration of clinically appropriate and safe ASC-based care

The ASC is currently the only setting that affords patients and providers robust access to non-opioid pain management approaches. Accordingly, Voices supports policies that will expedite patient migration to safe, clinically appropriate, ASC-based care.

Over the years, CMS has implemented a number of safeguards to ensure and enhance patient safety and the quality of care provided to patients in ASCs. Unsurprisingly, as a result of these policies, research shows that ASC patients experience similar postsurgical outcomes to those patients treated in an HOPD.[xxiii] In fact, because of the increased availability of non-opioid pain management approaches CMS has made available to ASC patients, some patients may experience better health outcomes achieved through quicker recovery, fewer opioid adverse events, and other benefits derived from multimodal pain management approaches, which prioritize non-opioid therapies.

The proposed rule outlines several proposals that would promote patient migration to ASC-based care. Voices supports these policies so long as protocols are in place to ensure that these procedures are performed on appropriate, carefully selected patients whose outcomes are most likely to be safe, predictable, and successful.

The proposed rule describes three proposals designed to vastly expand the ASC Covered Procedures (CPL) list. One of these proposals would add 267 codes to the ASC CPL in 2021 (alternative 2). Voices recommends the adoption and implementation of alternative 2 in the final rule as it represents the

quickest and most immediate opportunity to migrate patients to the ASC. In doing so, CMS can ensure more patients can access non-opioid pain management approaches.

Promote cost transparency for surgical patients

Voices also strongly supports policies that promote cost transparency and parity across care settings. In recognition of this, Congress enacted legislation in 2016 requiring the Department of Health and Human Services (HHS) to develop a cost comparison tool for Medicare patients. This website is now publicly available as a resource for patients, including those considering or scheduled for an outpatient surgery.

Unfortunately, because of the way that patient out-of-pocket expenses (OOPs) are determined for outpatient surgeries, many procedures performed in an ASC have higher patient OOPs compared to the same procedure being performed in an HOPD. This statute creates a disincentive for patients to be treated in an ASC where they can access non-opioid pain management approaches. As it currently stands, this payment determination could potentially needlessly expose patients to opioids.

Voices is committed to working with lawmakers to address this disincentive and will be working with Congress to ensure patients have transparency in their OOPs expectations and that these payments do not slow patient migration to the ASC for procedures deemed to be safe and appropriate by a healthcare professional.

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We hope that CMS will, in the final iteration of this rule, take the opportunity to prevent new cases of persistent opioid use in America. We urge CMS to revise the current draft to adopt policies – including those mentioned above – that will serve more Americans, reflect best in clinical practice approaches, and are consistent with recommendations from the Task Force.

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/
[iii] As referenced at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CFOReport/Downloads/2018_CMS_Financial_Report.pdf (accessed September 23, 2020)

[iv] Brummett CM, Waljee JF, Goesling J, Moser S, Lin P, Englesbe MJ, Bohnert ASB, Kheterpal S, Nallamothu BK. New Persistent Opioid Use After Minor and Major Surgical Procedures in US Adults. JAMA Surg. 2017 Jun 21;152(6):e170504. doi: 10.1001/jamasurg.2017.0504. Epub 2017 Jun 21. Erratum in: JAMA Surg. 2019 Mar 1;154(3):272. PMID: 28403427; PMCID: PMC7050825.

[v] Choices Matter: Exposing a Silent Gateway to Persistent Opioid Use. October 2018; Available at: https://www.planagainstpain.com/wp-content/uploads/2018/10/ChoicesMatter_Report_2018.pdf

[vi] Hallway, Alexander, et al. "Patient Satisfaction and Pain Control Using an Opioid-Sparing Postoperative Pathway" *Journal of the American College of Surgeons*, Volume 229, Issue 3, September 2019, Pages 316-322

[vii] National Institute on Drug Abuse, NIH. "Prescription Opioids Fact Sheet: National Institute on Drug Abuse." Available at: https://www.drugabuse.gov/publications/drugfacts/prescription-opioids (Accessed on September 23, 2020).

[viii] Emerson et. al. Comparison of Local Infiltration Analgesia to Bupivacaine Would Infiltration as a Part of a Multimodal Pain Program in Total Hip Replacement. *Journal of Surgical Orthopaedic Advances*. Vol 24 No. 4. Winter 2015

[ix] Dysart, Stanley H. et al. Local Infiltration Analgesia With Liposomal Bupivacaine Improves Early Outcomes After Total Knee Arthroplasty: 24-Hour Data From the PILLAR Study. *The Journal of Arthroplasty*. Published online December 24, 2018; 34(5) 882 - 886.e1 Doi: https://doi.org/10.1016/j.arth.2018.12.026

[x] Asche CV et al. 2018. Impact of liposomal bupivacaine on opioid use, hospital length of stay, discharge status, and hospitalization costs in patients undergoing total hip arthroscopy. Journal of Medical Economics. Doi: 10.1080/13696998.2019.1627363

[xi] Krebs EE, Gravely A, Nugent S, et al. Effect of Opioid vs Nonopioid Medications on Pain-Related Function in Patients With Chronic Back Pain or Hip or Knee Osteoarthritis Pain: The SPACE Randomized Clinical Trial. *JAMA.* 2018;319(9):872–882. doi:10.1001/jama.2018.0899

[xii] Asche CV et al. 2018. Impact of liposomal bupivacaine on opioid use, hospital length of stay, discharge status, and hospitalization costs in patients undergoing total hip arthroscopy. Journal of Medical Economics. Doi: 10.1080/13696998.2019.1627363

[xiii] *Ibid.*

[xiv] Hall, MJ, Schwartzman A, Zhang J. Liu X. Ambulatory Surgery Data from Hospitals and Ambulatory Surgery Centers: United States, 2014. Natl Health Stat Report. 2017 Fe;(102) Table A.

[xv] U.S. Department of Health and Human Services (2019, May). Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations. Retrieved from U.S. Department of Health and Human Services website: https://www.hhs.gov/ash/advisory-committees/pain/reports/index.html (Accessed September 23, 2020)

[xvi] Centers for Disease Control and Prevention Drug Overdose Data: https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm

[xvii] Hedegaard H, Miniño AM, Warner M. Drug overdose deaths in the United States, 1999–2018. NCHS Data Brief, no 356. Hyattsville, MD: National Center for Health Statistics. 2020.

[xviii] Ehley, Brianna. "Pandemic unleashes a spike in overdose deaths." Politico. June 26, 2020. Updated July 2, 2020. https://www.politico.com/news/2020/06/29/pandemic-unleashes-a-spike-in-overdose-deaths-345183?mkt_tok=eyJpIjoiWm1KaU1qYzBZekV4WkRFeSIsInQiOiJ6N1B5U1F4VmVMS0ljN0tXeERqUFVZMVwvTkhpWXV2dDYrQjRwSFdBYkY0Um8yNTg4VGR4RU5GSHdHa25xSnorWnBCb0doZmN0VUtrQ1JjaDFXTEFyeExXbnZpWGlDcGVVRmJTS3Fqb0pxeVZOdHFlTGE1Wm1DdUdBV2VaN3Rrc0oifQ%3D%3D (Accessed September 28, 2020)

[xix] Hospital Outpatient Prospective Payment – Notice of Final Rulemaking with comment (NFRM) [CMS-1695-FC]. Centers for Medicare and Medicaid Services 2019. Available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1695-FC (Accessed on September 22, 2020)

[xx] Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician Owned Hospitals; Fed. Reg. Vol. 85, No. 156; *CMS-1736-P*, Pg. 48979. August 12, 2020

[xxi] Hall, MJ, Schwartzman A, Zhang J. Liu X. Ambulatory Surgery Data from Hospitals and Ambulatory Surgery Centers: United States, 2014. Natl Health Stat Report. 2017 Fe;(102) Table A.

[xxii] Hall MJ, Schwartzman A, Zhang J. Lui X. Ambulatory Surgery Data from Hospitals and Ambulatory Surgery Centers: United States, 2014. Natl Health Stat Report. 2017 Fe;(102) 1-15.
[xxiii] Elizabeth L. Munnich and Stephen Parente, "Returns to Specialization: Evidence from the Outpatient Surgery Market." *Journal of Health Economics*, 57, 2018.