September 27, 2019

Seema Verma, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: CMS-1717-P: CY 2020 Hospital Outpatient PPS Policy Changes and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates

Dear Administrator Verma:

We appreciate the opportunity to comment on the proposed rule entitled, "Hospital Outpatient PPS Policy Changes and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates", as published in the *Federal Register* on August 9, 2019 (herein after "proposed OPPS rule"). Specifically, we would like to address our comments towards pages 39423 *et seq*, Section "3 b", entitled "*Packaging Policy for Non-Opioid Pain Management Treatments"*.

Voices for Non-Opioid Choices ("*Voices*") is a nonpartisan coalition dedicated to ensuring patient and provider access to safe and effective non-opioid pain management therapies through responsible policy changes. Our 30 members[i] 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.

The Centers for Medicare and Medicaid Services (CMS), as one of the largest purchasers of health care in the world,[ii] has the unequaled ability to re-focus health care practice and behavior through targeted regulatory policy and action. However, by failing to incentivize greater use of non-opioid treatments through separate item reimbursement in the hospital outpatient department, CMS is missing a unique opportunity to reshape how acute and surgical pain is managed by health care professionals across all treatment settings. By removing non-opioid therapies from existing packaging categories or surgical bundles, CMS will promote the use of non-addictive alternatives over opioids after surgery and help stop the cycle of opioid dependency. Hence, we strongly urge CMS to reconsider its proposal to

take no action, and retain the policy of packaging non-opioid pain management treatments used in hospital outpatient departments in the proposed OPPS rule.

The battle against opioid addition is a priority for this Administration, and a war the President is committed to win.[iii] In a statement released September 6, 2019, recognizing Opioid Crisis Awareness Week, President Trump stated that he was determined to "***use every resource at our disposal to release the grip of addiction plaguing our citizens***."[iv] This statement was only the most recent in an admirable, years-long effort to combat the crisis. The President has repeatedly directed federal agencies to take action: "we should not compound the tragedy [*of addiction*] with government policies and bureaucratic rules that make it even harder for [patients] to get help."[v] The Vice President and the HHS Secretary have echoed President Trump's call to action. CMS must also carry through on the Administration's unwavering commitment to combatting this crisis with thoughtful, proactive policies that help treat and prevent opioid use disorder. Although we commend CMS for taking the initial step towards non-opioid pain management by providing separate payment in Ambulatory Surgery Centers (ASCs), this action is not enough. It is imperative that CMS follow through on the President's directive and expand this policy to hospital outpatient departments to further "bend the curve" on opioid addition.

The over-prescription of opioids following an acute pain incident is a significant contributing factor to the current U.S. opioid epidemic. On average, these patients receive 80 opioid pills to manage their pain,[vi] which is well above what is necessary to help these patients adequately control their symptoms.[vii] All told, this leads to more than 10.5 billion opioid pills being prescribed in the United States every year.[viii] We know how to reverse this trend -- increased use of non-opioids has been proven in numerous peer-reviewed studies to reduce unnecessary opioid use after surgery. Unfortunately, the rule, in its current state, fails to incentivize greater use of non-opioids, and as such, the agency is missing the opportunity to save millions of Americans from persistent opioid use. CMS must act now and make this change to promote broad use of non-opioid treatment as a first line pain management therapy across all surgical and treatment settings.

Our view is shared far more broadly than among our coalition's members – both expert panels and peer reviewed science stand in support.

First, the congressionally-mandated Pain Management Best Practices Inter-Agency Task Force ("the Task Force") completed a report that recommended shifting the standard of care away from opioids and to increase the availability and utilization of multimodal approaches to pain management as a first line therapy for acute pain patients.

The report makes specific recommendations on how to do so including by:

- **Improving reimbursement for non-opioid approaches** to acute pain management;
- Facilitating preoperative consultation between patients and providers to develop individualized pain plans; and

- Increasing patient access to the array of highly trained, specialized health professionals in helping patients manage their postsurgical pain.

Unfortunately, CMS failed to address or incorporate any of the recommendations in the proposed OPPS rule.

Second, the research documenting the benefits of multimodal approaches to pain management, which **prioritize non-opioid use** and minimize opioids, show that such approaches provide better patient outcomes than patients receiving opioids following surgery. Multimodal protocols minimize unnecessary patient exposure to opioids while emphasizing the utilization of non-opioid approaches. Patients receiving a multimodal regimen report:

- Lower overall pain scores than patients treated with a traditional protocol;[ix]
- Recovering more quickly and leaving the hospital sooner;[x] and
- Fewer opioid pills consumed following surgery.[xi]
- Reduced overall opioid consumption and the subsequent risk for persistent use, dependence and addiction.[xii]

As previously noted, CMS has already recognized the need to ensure access to and utilization of these therapies for patients treated in an Ambulatory Surgery Center (ASC) and, as a result, provided separate reimbursement for pain management services for these patients. This approach provides important incentives to providers and care settings, which will meaningfully increase utilization of non-opioid approaches for patients treated in an ASC.

Unfortunately, inadequate patient and provider access to non-opioid therapies and approaches is not simply limited to those patients treated in an ASC setting. This approach is insufficient in that it fails to recognize that, because the majority of surgeries performed in the United States every year occur in a hospital outpatient setting (HOPD)[xiii]. The proposed rule does little to ensure that these patients can access non-opioid approaches to manage their acute postsurgical pain. On top of this, CMS prohibits many common orthopedic procedures from taking place outside of the HOPD setting, which means that more than 8 million Medicare beneficiaries are potentially denied access to non-opioid pain management approaches every year.[xiv]

Although we appreciate CMS's analysis of the data, we disagree with CMS's rationale for inaction. CMS indicates that the data demonstrated that the bundle was a financial disincentive to using non-opioids in the ASC but the claims did not indicate the same disincentive in the HOPD data, hence CMS limited the change to the bundle only in the ASC setting. However, the financial foundation is the same for both ASCs and HOPDs. To justify inaction by simply stating that the data suggests there is no DISINCENTIVE totally contradicts the President's proactive commitment to INCENTIVIZE the use of non-opioid alternatives in furthering the goal of reducing opioid prescriptions by one third[xv]. Clearly

CMS has the authority to act in this instance and, consistent with the President's commitment, CMS should do the same in both settings.

We hope that CMS will, in the final iteration of this rule, act on the Administration's stated priorities, and appropriately incentivize the utilization of non-opioid approaches by providing separate reimbursement for pain management therapies administered to patients treated in a HOPD setting. We urge CMS to revise the current draft to adopt policies that better reflect the state of the scientific evidence, the recommendations of a congressionally-mandated expert Task Force, and the clear imperative from the Administration to use every resource at our disposal to combat this epidemic.

Thank you so much for your consideration of these comments.

Sincerely,

Chris Fox
Executive Director

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[i] [i]For a complete list of supporting Member Organizations, please see https://nonopioidchoices.org/members/

[ii] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CFOReport/Downloads/2018_CMS_Financial_Report.pdf

[iii] https://www.whitehouse.gov/articles/will-win-war-opioids/

[iv] Presidential Proclamation on Opioid Crisis Awareness Week, 2019

[v] https://www.statnews.com/2016/10/15/trump-opioid-expanded-treatment/

[vi] Bicket M, et al. Prescription opioid oversupply following surgery. Journal of American Pain Society 2017.

[vii] Bicket M, et al. Association of new opioid continuation with surgical specialty and type in the United States. 2019. The American Journal of Surgery, DOI: 10.1016/j.amsurg.2019.04.010.

[viii] CM data INSERT citation

[ix] Halaszynski, T. Influences of the Aging Process on Acute Perioperative Pain Management in Elderly and Cognitively Impaired Patients. The Ochsner Journal 2013. Vol 13 228-247.

[x] Wang MY, Chang HK, Grossman J. Reduced Acute Care Costs With the ERAS® Minimally Invasive Transforaminal Lumbar Interbody Fusion Compared With Conventional Minimally Invasive Transforaminal Lumber Interbody Fusion. *Neurosurgery*. 2017. [epub ahead of print]

[xi] Mont MA, Beaver WB, Dysart SH, Barrington JW, Del Gaizo DJ. Local infiltration analgesia with liposomal bupivacaine improves pain scores and reduces opioid use after total knee arthroplasty: results of a randomized controlled trial. *J Arthroplasty*. 2018;33(1):90-96.

[xii] Sethi P et al. Liposomal bupivacaine reduces opiate consumption after rotator cuff repair in a randomized controlled trial. Journal of Shoulder and Elbow Surgery. May 2019 Volume 28, Issue 5, Pages 819-827 DOI: https://doi.org/10.1016/j.jse.2019.01.008

[xiii] 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.

[xiv] 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.

[xv] https://www.whitehouse.gov/briefings-statements/president-donald-j-trumps-initiative-stop-opioid-abuse-reduce-drug-supply-demand/