September 27, 2019

Centers for Medicare & Medicaid Services,
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Administrator Verma,

Thank you for giving us the opportunity to comment on the Proposed Changes to the Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment Systems and Quality Reporting Programs, published in the Federal Register on August 9, 2019. We write to you as healthcare professionals dedicated to providing the best care and pain management for our patients post-surgery, which we believe includes the use of non-opioids.

As such, we anticipated the release of the proposed rule in hopes that it would continue to support access to opioid alternatives in the ASC space through separate reimbursement, and possibly, expand that access to include all hospital outpatient department (HOPD) settings. We applaud CMS' decision to continue the separate reimbursement of non-opioids in the ASC setting, as that is an important step to increase access to non-opioids. However, we strongly encourage the agency to reconsider their stance against reimbursing separately for non-opioids in HOPDs, so that patients across all outpatient settings can realize the benefits of low- or no-opioid surgery where clinically appropriate.

The signatories of this letter, and many of our colleagues, are denied access to liposomal bupivacaine and other non-opioids in our practice settings because of CMS' reimbursement policy. In the rule, the agency specifically highlighted that claims data analysis did not reveal a decrease in utilization of non-opioids in the HOPD setting, which supported their decision not to unbundle payment. However, we would suggest that that national data, while important, doesn't consider the regional and market-based disparities that impact hospitals. While utilization may be increasing nationally, providers and patients do not experience equitable access to non-opioids across the country. We represent those who want to do better for our patients but cannot – because of federal Medicare policy.

Unfortunately, opioid prescribing among US surgical patients can frequently be in excess of what is needed for pain control, with many receiving opioids unnecessary for adequate pain relief.[1] Furthermore, patients who were given opioids post-surgery were more likely to continue to use them after leaving the hospital.[2] This underscores the role of the surgical setting as an unintended gateway

[1] Bicket MC.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.amjsurg.2019.04.010

[2] Donohue JM, Kennedy JN, Seymour CW, Girard TD, Lo-Ciganic W, Kim CH, et al. Patterns of Opioid Administration Among Opioid-Naive Inpatients and Associations With Postdischarge Opioid Use: A Cohort Study. Ann Intern Med. [Epub ahead of print 18 June 2019]171:81–90. doi: 10.7326/M18-2864

for opioid addiction and abuse and highlights the need for both clinicians and CMS to do their part to provide non-opioid options to manage acute pain post-surgery.

Non-opioids like liposomal bupivacaine are extremely effective in reducing length of stay and prescription opioid use post-surgery.[3,4] For example, a study revealed that among Medicare patients undergoing total hip arthroplasty and receiving liposomal bupivacaine, there was a 23.7% decrease in post-surgical opioid consumption and a 0.7 day decrease in length of stay.[4] Furthermore, when the total hospitalization costs were multiplied over the 10 hospitals included in the study, there was an estimated cost savings of $2,031,942 in the Medicare patient population that received liposomal bupivacaine.[4]

Non-opioids administered as part of a multimodal regimen is also effective at reducing opioid consumption and post-surgical pain. Patients administered liposomal bupivacaine as part of a multimodal regimen consumed 64% less opioids post-surgery compared to the control group.[3] Importantly, 69% of patients that received liposomal bupivacaine in their multimodal regimen were opioid free 5 days post-surgery.[3]

Last but not least, a recent cutting edge study from the Dallas Veterans hospital revealed that six months post-surgery prescription opioid use was decreased by 47.5% in patients who utilized an Enhanced Recovery After Surgery protocol that utilized liposomal bupivacaine.[5] There are countless other published studies that support the importance of liposomal bupivacaine and other non-opioids in reducing opioid use and generating hospitalization cost savings and it is frustrating to face reimbursement barriers that prevent access to non-opioid drugs to manage our patients' pain in the HOPD setting.

While the ASC is important, the fact is that most surgeries are still performed in the HOPD, which means that the bulk of Medicare beneficiaries who undergo surgery can face barriers to accessing non-opioids given the current reimbursement policy. In fact, in 2010, 53 percent of all outpatient surgical procedures (25.7 million procedures) were performed in a hospital setting.[6] As you know, CMS prohibits Medicare beneficiaries from having many common orthopedic procedures performed outside of the hospital setting, which means that more than 8 million Medicare beneficiaries will have little – or no – access to non-opioid therapies.[7]

We write to you as willing and able partners in the fight against the opioid epidemic. Please give us the tools that are proven effective to reduce unnecessary opioid use and decrease the number of persistent

[3] 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

[4] 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 arthroplasty. Journal of Medical Economics. DOI: 10.1080/13696998.2019.1627363

[5] Collet, G, et al. Opioid Use and Length of Stay Significantly Reduced with Enhanced Recovery After Surgery Program Utilizing Liposomal Bupivacaine For Total Knee Arthoplasty. Military Health System Research Symposium. Kissimmee, FL August 19-22, 2019 Abstract: 01579

[6] 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 Feb; (102) Table A.

[7] 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) 1-15.

opioid users after surgery. In the final rule, include a HOPD payment policy change to broaden access to available non-opioid treatments.

Thank you for your consideration and please feel free to contact any one of us if you have any questions.

Sincerely,

Dr. Matthew McCord
Anesthesiologist

Dr. Andrew Cheung
Oral Surgeon

Dr. Mark Snyder
Orthopedic Surgeon

Dr. Leslie Fish
Oral Surgeon

Dr. Albert Dunn
Orthopedic Surgeon

Dr. Bruce Ramshaw
Ge*neral Surgeon*

Dr. Joseph Smith
Anesthesiologist

Dr. Alok Sharan
Orthopedic Surgeon

Dr. Lawrence Iteld
Plastic Surgeon

Dr. Shane Zamani
Anesthesiologist

Dr. Nick Connolly
Anesthesiologist

Dr. Lisa Hunsicker
Plastic Surgeon

Dr. Steven McCarus
Obstetrics and Gynecology Surgeon

Dr. Stephen Grinstead
Addictive Disorders

Dr. Thomas Amalfitano
Orthopedic Surgeon

Dr. Uma Srikumaran
Orthopedic Surgeon

Dr. Scott Sigman
Orthopedic Surgeon

Dr. Christine Botkin
Anesthesiologist

Dr. George Apostolides
Colorectal Surgeon

Dr. Arnold Conforti
Surgical Oncology

Dr. Alejandro Badia
Orthopedic Surgeon

Dr. Mario Leyba
General Surgeon

Dr. Brian Binetti
General Surgeon