United States Senate
WASHINGTON, DC 20510

October 10, 2019

The Honorable Alex Azar II
Secretary
U.S. Department of Health & Human Services
200 Independence Ave SW
Washington, DC 20201

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health & Human Services
200 Independence Ave SW
Washington, DC 20201

Dear Secretary Azar and Administrator Verma:

We are writing to request information from the Centers for Medicare and Medicaid Services (CMS) regarding the details of its review of Medicare payment policies to ensure that providers are not incentivized to use opioid-based pain management treatments over non-opioid alternatives. In order to prevent the next generation of substance misuse, it will be critical to make certain that appropriate incentives are in place so that patients can receive non-addictive pain treatments, particularly during and after surgery.

In many cases under Medicare's payment systems for services furnished at hospital outpatient departments and ambulatory surgical centers (ASCs), non-opioid drugs and devices used to treat post-surgical pain are not separately paid. Instead, these non-opioid alternatives are paid for under a single "packaged" Medicare payment for the underlying surgery. By contrast, if a health care provider prescribes an opioid medication to treat post-surgical pain, that drug is reimbursed separately through Medicare Part D. Due to the fact that Medicare's packaged payments are designed to cover the average cost of a procedure and many surgical procedures do not utilize non-opioid alternatives, the packaged payment rate for outpatient surgeries may not always cover the cost of incorporating non-opioid pain management treatments.

As you know, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act requires that CMS review payments under Medicare's Outpatient Prospective Payment System (OPPS) and ASC Payment System to ensure that there are not financial incentives to use opioids instead of non-opioid alternatives for pain management. Specifically, the SUPPORT for Patients and Communities Act required CMS to:

- Review payments for opioids and evidence-based non-opioid alternatives for pain management (including drugs) "with a goal of ensuring there are not financial incentives to use opioids instead of non-opioid alternatives;" and
- Consider the extent to which payment policy revisions "(such as the creation of additional groups of covered OPD services to classify separately those procedures that utilize opioids and non-opioid alternatives for pain management) would reduce payment incentives to use opioids instead of non-opioid alternatives for pain management."

In the Calendar Year (CY) 2019 OPPS and ASC Payment System Final Rule, the agency concluded that in certain circumstances it is appropriate to pay separately for evidence-based, non-opioid pain management drugs that function as "supplies" in a surgical procedure in the ASC setting and to encourage use of these types of therapies rather than prescription opioids.

However, the agency has applied the separate payment policy to only one drug to date – despite evidence showing the effectiveness of other perioperative treatments in reducing opioid use. For example, nerve blocks, including continuous peripheral nerve blocks (cPNBs) are a proven opioid alternative, and have been shown to reduce opioid use by approximately 60 percent compared to patients who received only opioids for their post-operative pain. In addition, an ophthalmic drug recently approved by the Food and Drug Administration (FDA) to prevent pupil constriction and reduce post-operative pain has been shown to reduce the need for opioid use during cataract surgery by nearly 80 percent, while also decreasing pain scores by approximately 50 percent. This same drug has exhibited an outstanding safety profile and has no FDA-approved alternative. In another randomized controlled clinical trial, the use of opioid-sparing liposomal bupivacaine resulted in a 90-percent reduction in opioid consumption among Medicare-aged patients within 48 hours after knee replacement surgery.

Following the CY 2019 OPPS and ASC Payment System Final Rule in which CMS requested public comments on its non-opioid policy, CMS received stakeholder feedback about innovative drugs and devices that are currently packaged or are slated to be packaged. When CMS issued the CY 2020 proposed rule earlier this year, it reiterated its position that it was appropriate to pay separately for certain non-opioid pain management treatments that function as surgical supplies in the ASC setting, but not the hospital outpatient department. In the final rule, we expect that CMS will consider the peer reviewed data submitted by stakeholders, including studies related to the use of opioids used during surgery or after surgery and any data demonstrating decreased utilization of the non-opioid pain management medication when drugs and devices are packaged. We anticipate that CMS will also provide specific evidence regarding its analysis in an effort to be fully transparent.

Without changes to current payment policy, health care providers may face financial disincentives that could undermine their ability to use non-opioid pain management treatments. In such cases, we are concerned that providers would continue to rely on addictive opioid pain medications, which expose patients to the risk of developing opioid use disorder.

We respectfully request that CMS provide details on its statutorily required review process, including the agency's rationale and supporting data for its decision regarding each individual product that it evaluated. We urge CMS to examine the evidence to ensure that reimbursement policies are working in the best interests of patients. Thank you for your attention to this important issue.

Sincerely,

Jeanne Shaheen
United States Senator

Shelley Moore Capito
United States Senator