AtriCure

The Honorable Senator Orrin G. Hatch
United States Senate
Committee on Finance
Washington, DC 20510-6200

February 8, 2018

Dear Senator Hatch,

We would like to thank the Committee on Finance for requesting policy recommendations on prevention and treatment of opioid related adverse events. As the Committee on Finance has highlighted, opioid use has increased dramatically in the U.S. and contributes to over 50,000 deaths and costs more than $96 billion annually[1].

Pain management requiring the use of opioids can be classified as either acute or chronic. Patients treated acutely may continue to take opioids and transition to chronic use. For example, those treated with major surgery have a 200-300% risk of prolonged opioid use compared to less invasive procedures.[2] Moreover, recent research presented at the 2018 Society for Thoracic Surgeons meeting highlighted that 1 in 7 (14%) lung surgery patients are at risk for opioid dependence.[3] The reduction of opioid use amongst surgical candidates acutely is one strategy to help target this challenging epidemic. Our comments will focus on cardiac and thoracic surgery pain management strategies in which over 500,000 procedures are performed annually in the U.S.

Question 1. How can Medicare and Medicaid payment incentive be used to promote evidenced-based care for beneficiaries with chronic pain that minimizes the risk of developing OUD or other SUD?

As addressed in our opening comment, *non-opioid therapies can be used during surgery to treat pain and potentially reduce the risk of chronic long-term opioid use for pain control.* Research suggests that high doses of opioid during surgery for pain management is associated with higher hospital readmits and healthcare costs post-surgery compared to not utilizing opioids for pain management.[4]

---

[1] http://www.modernhealthcare.com/article/20171116/NEWS/171119908
[2] Clarke H., et al. Rates and risk factors for prolonged opioid use after major surgery: population based cohort study. *BMJ* 2014;348:g1251 doi: 10.1136/bmj.g1251
[3] The Society of Thoracic Surgeons. (2018). 1 in 7 Lung Surgery Patients at Risk for Opioid Dependence [Press release]. Retrieved from http://sts.org/sites/default/files/press-releases/Opioid_Brescia_FINAL%20FMTb.pdf
[4] Xie, L., et al. Differences in healthcare utilization and associated costs between patients prescribed vs. nonprescribed opioids during an inpatient or emergency department visit. *Pain Pract.* 2014 14(5):446-56.

7555 Innovation Way
Mason, Ohio 45040
www.atricure.com

AtriCure

We recommend two different evidence based strategies. The first recommendation focuses on new quality programs. The Center for Medicare and Medicaid (CMS) has employed several quality bundled payment programs to reward excellence in patient care. CMS could develop quality payment programs that rewards hospitals and providers for non-opioid pain management strategies that reduces opioid use, hospital length of stay or readmits related to opioid use.

A second strategy that CMS should consider is expanding its use of coverage with evidence development (CED) for promising newer therapies that have less efficacy data established, but good safety data. After an agreed upon time period CMS could review collected data and if the therapy is effective and safe, agree to make coverage permanent. CED is one strategy CMS employs today and could be expanded to include non-opioid pain treatment therapies.

Question 2. What barriers to non-pharmacological therapies for chronic pain currently exist in Medicare and Medicaid? How can these barriers be addresses to increase utilization of those non-pharmaceutical therapies when clinically appropriate?

As addressed in our opening comment, *non-opioid therapies can be used during surgery to treat pain and potentially reduce the risk of chronic long-term opioid use for pain control.* However, there are reimbursement barriers for use during surgery. AtriCure® has an FDA 510k clearance (K142203) on the cryoICE® CRYO2 Probe, https://www.atricure.com/cryoice-cryoanalgesia-probe) that is used by cardiac and thoracic surgeons to block pain by temporarily ablating peripheral nerves. The probe can be used during heart valve replacement, pneumonectomy, thoracoabdominal, lung transplant, NUSS, and other surgeries involving access through the thoracic space. Preliminary research suggests that use of this probe during surgery may reduce patient pain and the use of post-surgery opioids.[5] One challenge is that reimbursement for pain management during surgery is bundled within the hospital Medicare Severity Diagnosis Related Group (MS-DRG) reimbursement code for the cardiac procedure and not reimbursed separately. The addition of non-opioid therapies during surgery is cost prohibitive for some hospitals given this bundling. Consequently, *this lack of adequate reimbursement for non-opioid pain therapies during surgery prevents some surgeons from treating post-operative pain effectively.* **We suggest uncoupling hospital payment for pain management for non-opioid therapies performed during surgical procedures from the MS-DRG. The creation of a separate hospital payment for non-opioid pain therapy during surgery would encourage providers to treat patient pain with other therapies and potentially limit the risk of downstream opioid use.**

A second recommendation is the creation of new Current Procedure Terminology (CPT®[6]) reimbursement codes that allow providers to treat pain during surgery and obtain compensation for the use of non-opioid pain treatments; as the primary CPT® codes available today are for

---

[5] Keller BA, et al. Intercostal nerve cryoablation versus thoracic epidural catheters for postoperative analgesia following pectus excavatum repair: Preliminary outcomes in twenty-six cryoablation patients. *J Ped Surg* 51 (2016) 2033–2038

[6] CPT® is a registered trademark of American Medical association

7555 Innovation Way
Mason, Ohio 45040
www.atricure.com

AtriCure

anesthesiologist and pain management specialists. Creation of new CPT® codes would allow surgeon providers to be compensated for time to adequately manage patient pain.

Question 3. How can Medicare and Medicaid payment incentives be used to remove barriers or create incentives to ensure beneficiaries receive evidence based prevention, screening, assessment and treatment for OUD and other SUD to improve patient outcomes?

Our suggestions as outlined in Questions 1 and 2 include: 1) decoupling pain management reimbursement during surgery from the surgical MS-DRG to allow surgeons to treat post-operative pain with non-opioid therapies, including the creation of supplemental reimbursement for non-opioid pain management; 2) addition new physician payment CPT® codes to allow payment for providers using non-opioid pain management during surgery; and 3) allowing earlier/quicker Medicare reimbursements for novel therapies for non-opioid pain management that show adequate safety, possibly as part of CED. We believe that by encouraging cardiac and thoracic surgeons to treat pain with non-opioid therapies has the potential to positively impact patient outcomes.

We again thank the Senate Finance Committee in working on this huge health problem and allowing us to make recommendations on specific policies. We welcome the opportunity to participate in this discussion and offer potential solutions.

Respectfully,

Michael Carrel
President and Chief Executive Officer
AtriCure

7555 Innovation Way
Mason, Ohio 45040
www.atricure.com