



February 15, 2018

The Honorable Orrin Hatch, Chairman The Honorable Ron Wyden, Ranking Member Senate Finance Committee 219 Dirksen Senate Office Building Washington, D.C. 20510

Re: Response to Request for Comments on policy recommendations addressing root causes that lead to, or fail to prevent, opioid use disorder.

Dear Chairman Hatch and Ranking Member Wyden:

Given the alarming growth in drug addiction resulting from use of prescription opioids, in both the chronic and acute pain space, we at InfuSystem® and Smiths Medical appreciate the opportunity to provide comments on a solution for orthopedic post-surgical pain patients. The opioid epidemic is well documented and the severity of the issue is not disputed. The issues debated are how best to prevent patients from becoming addicted, and how best to treat currently addicted patients.

We welcome your commitment to helping find answers and appreciate the focus on chronic pain in your questions, however we also encourage you to look at preventive options for the acute pain population. 1 out of 15 acute surgical pain patients go on to become addicted, chronic users or abusers of opioids. Surgical pain patients are also often the source of left over pills in medicine cabinets that find their way to family or friends creating secondary access for addiction. InfuSystem® and Smiths Medical are happy to provide you with a solution for this acute pain population and look forward answering your questions as to how Medicare and Medicaid can remove barriers and provide incentives for this well-practiced solution.

Continuous peripheral nerve block (cPNB) is a long studied and actively practiced procedure by doctors in hospitals and ambulatory surgery centers. In recent years, many private payers and insurers also reimburse to receive cPNB in the home following orthopedic surgery. Continuing to expand the use of cPNB will successfully improve pain control, reduce opioid consumption and its related side effects and increase patient satisfaction. In addition to these benefits, the use of cPNB allows patients to participate in physical therapy earlier than with opioids and other drugs--over 96% of patients on a nerve block were able to participate in physical therapy on post-operative day one, as opposed to 57% of those on other medications. II

Smart ambulatory infusion pumps safely deliver anesthetic medications (such as bupivacaine and ropivacaine) through peripheral nerve catheters to patients in hospitals, home care settings, and alternative care facilities, reducing the use of oral pain medication and therefore risk of opioid dependency. Smart infusion pumps are safe, provide alarms to ensure medications are infused properly, and provide data to help providers monitor and assess current treatment plan. The 2017 Joint Commission Accreditation (JCAHO) mandate on pain management requires collection of data on pain





scores, patient satisfaction and opioid use. The last 3,000 patients using cPNB in the InfuBlock program had an average post-op day one pain score of 3 out of 10 and the average patient satisfaction score of those in the program was 9.31 out of 10. As shown, this solution provides for all of these metrics and has scored more favorably on the pain scale than those taking opioids.

CPNB for post-surgical patients in the home setting has emerged as a significant alternative to the use of opioids. Surgical pain patients deserve a standard of care that allows for access to treatments without the use of opioids. CPNB significantly reduces patient pain scores and expedites recovery time for patients. The Center for Medicare and Medicaid Services (CMS), has the authority to create codes to incentivize the use of non-addictive medications safely delivered by smart ambulatory pumps to patients after surgery, and can potentially eliminate the need for opioid use in these circumstances. This type of solution could be acted upon by CMS in the next quarter to start addressing this growing epidemic.

CMS has the authority to update the Medicare fee schedule database on a quarterly basis. These codes do not require rulemaking and are paid through the physician as a pass-through to the infusion provider and therefore do not interfere with any current home infusion obstacles. In short, in addition to billing the all-inclusive procedure fee, or "bundle", the physician then adds the G code fee for services and supplies for the infusion to continue in the home. The home infusion provider then creates a "pass-through" billing arrangement with the clinics, physicians or outpatient setting. Recently, this coding model was implemented for Chemotherapy.

These level II G codes are often created to define reimbursement practice. Similar in treatment to cPNB, in 2016 the Chemotherapy G code was developed to ensure patients are able to receive short-term home infusion therapy that is initiated in the physician office, by portable, ambulatory pump once returning home. CPNB is also a short-term infusion therapy, best performed in the home to allow for optimal recovery.

By providing a G code, similar to that for Chemotherapy, it provides an easy solution to incentivize the use of cPNB as an opioid alternative. Because this solution provides the doctor with a payment in addition to their procedure "bundle" payment, they have an incentive to provide the care to send the patient home with the ambulatory pump, rather than write a prescription for opioids for continued pain management during recovery. CMS currently has long lagged behind industries advancements in technology and best care practices. It is well-studied and understood in the medical community that home infusion is often best for the patient, reducing the risk of infection and improving recovery times.

In light of this opioid epidemic, we can no longer afford to wait for CMS to update long antiquated rules. We can work within their guidelines and still provide solutions and incentives to using opioid alternatives, such as continuous peripheral nerve block. CMS should create a G code for cPNB in the second quarter of 2018 to begin to show real progress in solving this epidemic. We can lessen and prevent the use opioids for acute pain patients and CMS can make this happen with immediate action.





We'd again like to thank you and the Committee for your commitment to finding solutions for the over prescribing and abuse of opioids. Working with CMS to act in a timely fashion, is of the utmost importance in bringing solutions to patients so they have options beyond opioids. We look forward to discussing this solution with you in greater detail and welcome your questions at any time.

Sincerely,

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^{1. &}lt;sup>i</sup> J. M. Richman, S. S. Liu, G. Courpas et al., "Does continuous peripheral nerve block provide superior pain control to opioids? A meta-analysis," Anesthesia and Analgesia, vol. 102, no. 1, pp. 248–257, 2006.

^{2.} ii Liu Q et al. Impact of peripheral nerve block with low dose local anesthetics on analgesia and functional outcomes following total knee arthroplasty: a retrospective study. Pain Med 2014 https://www.ncbi.nlm.nih.gov/pubmed/25545781