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VIA EMAIL

Senator Orrin G. Hatch, Chairman
Ron Wyden, Ranking Member
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, DC 20510-6200
opioids@finance.senate.gov

RE: Pacira Pharmaceuticals' Response to the Senate Finance Committee's Request for Policy Recommendations to Address the Opioid Crisis

Dear Chairman Hatch and Ranking Member Wyden:

Pacira Pharmaceuticals, Inc. (Pacira) writes in response to the request from the Senate Finance Committee (the Committee) to provide input on Medicare and Medicaid policy recommendations to address the root causes that lead to opioid use disorder (OUD) and other substance use disorders (SUDs). Pacira is a specialty pharmaceutical company dedicated to innovation in the treatments for acute and chronic pain, with a focus on pharmaceutical products used primarily in hospitals and ambulatory care centers (ASCs). Our corporate mission is to provide alternative treatments to opioids for as many patients as possible. We commend the Committee's focus on an area of government policy in which certain limited changes can have an outsized impact on reducing the number of patients suffering from OUD and SUDS: Medicare and Medicaid reimbursement policies.

Pacira appreciates the opportunity to provide feedback to the Committee on these important issues. Since 2012, we have manufactured and distributed EXPAREL, a non-opioid, local analgesic that provides up to several days of pain relief with a single-dose administration by a physician. As an early leader in efforts to develop and encourage the adoption of non-opioid treatments for pain, Pacira works closely with many of the leading patient and clinical stakeholders, including Shatterproof (a national nonprofit dedicated to ending the devastation addiction causes families) and the American Society for Enhanced Recovery (a nonprofit founded by physicians dedicated to promoting the practice of optimizing patient preparation and recovery through education and research).

The initial responses to the opioid crisis from the Centers for Medicare & Medicaid Services (CMS) and U.S. Department of Health & Human Services (HHS) have focused on

prescription controls, funding for treatment of OUD and SUDs, and other initiatives, but have not addressed a key finding of the President's Commission on Combating Drug Addiction and the Opioid Crisis (the Commission): that "current CMS reimbursement policies . . . create barriers to adoption" of effective pain management strategies. The Commission's Final Report included the following recommendation related to this observation:

> The Commission recommends that CMS review and modify rate-setting policies that discourage the use of non-opioid treatments for pain, such as certain bundled payments that make alternative treatment options cost prohibitive for hospitals and doctors, particularly those options for treating immediate post-surgical pain.

This letter addresses those Medicare reimbursement policies and provides recommendations for the Committee to take action, either through direct legislative action or urging HHS and CMS to act on these recommendations. Specific responses to the Committee's questions are enclosed below, all of which provide context for two key policy changes that are within the Committee's jurisdiction over Medicare Parts A and B and that would lead to a near-term and demonstrable reduction in the number of beneficiaries that develop OUD each year:

1. **Provide separate Medicare reimbursement for non-opioid postsurgical pain management drugs administered by healthcare providers in connection with surgical procedures; and**

2. **Provide appropriate reimbursement to healthcare practitioners for additional time spent screening, educating, and treating patients with opioid-sparing protocols and non-opioid pain treatments.**

By ensuring hospitals and physicians receive appropriate Medicare reimbursement for the implementation of opioid-sparing protocols and use of non-opioid treatments, the Committee would ensure that Medicare beneficiaries have equal access to safer pain treatment options that mitigate and prevent OUD.

I. THE OPERATING ROOM IS THE PRIMARY GATEWAY TO OPIOID ADDICTION, BUT NON-OPIOID TREATMENT ALTERNATIVES EXIST.

A key contributor to the opioid epidemic has been the prescription and use of opioids for the treatment of postsurgical pain. It is well-established that the operating room serves as a gateway to OUD, as approximately 40% of all outpatient prescriptions written by surgeons are for opioids;[i] 9 in 10 patients undergoing surgical procedures receive opioids;[ii] and approximately 6% of patients undergoing a surgical procedure transition to persistent opioid use after surgery.[iii] Patients undergoing certain types of outpatient procedures are even more susceptible to persistent opioid use after surgery: Approximately 17.6% of patients undergoing colectomies and 16.7% of patients undergoing total knee replacements transition to persistent opioid use after surgery.[iv] Researchers have estimated that as many as 3 million individuals may transition to persistent opioid use following elective surgery each year.[v] The risk that postsurgical opioid use will transition to OUD is even higher for patients with certain risk factors, including patients who are opioid naïve, those with a history of depression, and those with a self-perceived risk of

addiction.[vi] As a result, there are more than 20 million Americans in recovery from surgery for whom opioids are contraindicated.[vii]

Moreover, the prescription of opioids for surgical patients creates a reservoir of unused opioids that fuels addiction. One study found that as much as 71% of dispensed opioids goes unused,[viii] and another study found that an average surgical patient was prescribed about 80 pills while taking opioids for just 7 days, leaving about 30 pills unused and available for diversion.[ix] Of the more than 91 Americans who die each day from an opioid overdose, more than 40 will die from prescription opioid medications such as morphine, codeine, oxycodone, or hydrocodone.[x] Abuse of prescription opioid products also leads to illicit drug use in many cases.[xi] Data from the U.S. National Survey on Drug Use and Health indicate that up to four in five heroin users in the U.S. misused prescription opioids before using heroin, underscoring the importance of preventing initial prescription opioid misuse and diversion.[xii] The relationship between opioid prescription and opioid abuse has led some experts to conclude that "[n]onopioid and nonpsychotropic pain relief treatment options should be utilized whenever possible to provide effective pain relief."[xiii]

While much of the attention to the government's response to the opioid crisis has focused importantly on prescription controls and developing new therapies to replace opioids, healthcare professionals do already have non-opioid treatment options available. A key issue is that utilization has been limited by certain reimbursement policies. For instance, Pacira's product EXPAREL is a bupivacaine liposome injectable suspension indicated for single-dose infiltration into a surgical site to produce postsurgical analgesia. As a physician-administered, non-opioid drug effectively used to manage postsurgical pain, EXPAREL reduces or even eliminates the need for opioid medications to control acute postsurgical pain. In a recent study evaluating the use of EXPAREL as part of a multimodal pain management protocol for patients undergoing total knee arthroplasty ("TKA"), the EXPAREL group showed a **78% reduction** in opioid consumption compared to the control group at 72 hours post-surgery.[xiv] Importantly, opioids were not part of the pain management protocol in this study, but rather were used only as rescue medication, which allowed 10% of patients in the EXPAREL group to remain completely opioid free (compared to 0% in the control group) for the most critical time period for controlling acute pain related to surgery. Other studies have found similar reductions in postsurgical opioid consumption when EXPAREL is administered in connection with shoulder arthroplasty,[xv] gynecologic oncology procedures,[xvi] breast reconstruction,[xvii] hysterectomy,[xviii] and colectomy.[xix]

II. CURRENT MEDICARE POLICIES RESTRICT ACCESS TO NON-OPIOID POSTSURGICAL PAIN THERAPIES.

The Opioid Commission identified specific Medicare payment policies that incentivize the prescribing of opioids while limiting access to non-addictive treatments for pain. Revising these policies to equalize patient access to non-opioid therapies could meaningfully reduce opioid use in the surgical setting, which is a primary gateway to OUD.

First, the most important CMS policy requiring modification is the current Outpatient Prospective Payment System (OPPS) packaging policy that bundles payments to hospitals for surgical supplies. Specifically, in 2014, CMS implemented a payment policy under the OPPS

whereby the Agency packages Medicare payment for all drugs and biologicals that function as supplies in a surgical procedure with the Medicare payment to the hospital or ASC for the surgical procedure itself.[xx] Starting in 2015, CMS subjected postsurgical pain medicines to the surgical supply packaging policy, meaning Medicare does not reimburse hospitals separately for the costs of these drugs.[xxi] Hospitals and ASCs incur the cost of these drugs—including non-opioid postsurgical pain management drugs like EXPAREL—but have limited ability to recoup that cost. Though the expense is modest in the context of the cost of a typical surgical procedure (a dose of EXPAREL costs about $315), the hospital can choose to incur no cost at all by simply not stocking the drug. Without on-site access to EXPAREL, surgeons typically treat postsurgical pain by writing a prescription for pharmacy-dispensed opioids, which are then covered by a different Medicare benefit at no cost to the hospital. Because the hospital receives the same Medicare payment for the procedure regardless of whether it assumes the added expense of providing a non-opioid treatment, the payment policy creates an effective barrier to adoption of non-opioid therapies in a time of tightening hospital operating margins and budgets.[xxii]

Second, outside of the surgical supply packaging policy, CMS also packages payment for services and items provided in connection with specific outpatient procedures reimbursed under comprehensive APCs (C-APCs). This policy, which also became effective in 2015, packages payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the OPPS.[xxiii] Similar to the surgical packaging policy, the C-APC policy results in a single payment for the primary service, with no separate reimbursement for other items like non-opioid postsurgical pain management drugs. Accordingly, just like the surgical supply packaging policy, the C-APC policy creates a disincentive for hospitals to take on the additional expense to provide a non-opioid treatment to the patient rather than an opioid prescription. This result drives opioid use following procedures where high numbers of patients transition to persistent opioid use, such as total knee replacements and rotator cuff repair.[xxiv]

Third, while an increasing number of surgical procedures occur in an outpatient setting, many procedures continue to be performed in the hospital inpatient setting, such as hip and knee repair, revision, and/or replacement, as well as colorectal, bariatric, and spinal surgeries. Some of these procedures can be performed in the outpatient setting as well, but they are most commonly transitioned to an inpatient setting when the patient suffers from comorbid conditions or other health concerns, as is often the case with Medicare beneficiaries. Under Medicare's Inpatient Prospective Payment System (IPPS), hospitals receive a single prospective payment for all items and services provided during the inpatient stay. For a hospital pharmacist making purchase orders based on per-procedure cost, it can be difficult to justify stocking non-opioid treatments like EXPAREL when opioids are a less expensive pharmaceutical modality to treat postsurgical pain—regardless of whether using non-opioid treatments may be less expensive for the hospital and healthcare system in the long run. As a result, hospitals often stock less-expensive opioids to administer during admission, reducing access to non-opioid therapy alternatives.

Lastly, physicians are also required to expend their most valuable resource—their time—to evaluate patients for enhanced recovery after surgery (ERAS) protocols, administer these treatments, and ensure patients understand the opioid-sparing, multi-modal pain management approach needed to reduce opioid consumption. Under current Medicare policy, surgeons and anesthesiologists receive no additional reimbursement for time needed to screen patients for

opioid-sparing protocols, or to develop and employ such a protocol with patients and their caregivers. This lack of necessary reimbursement creates a disincentive for physicians to offer this critical service

III. RESPONSES TO THE COMMITTEE'S QUESTIONS

1. How can Medicare and Medicaid payment incentives be used to promote evidence-based care for beneficiaries with chronic pain that minimizes the risk of developing opioid use disorder (OUD) or other substance use disorders (SUDs)?

Whether opioids are prescribed to treat chronic pain or acute postsurgical pain, opioid prescriptions pose a serious risk to patients by exposing them to drugs that can lead to OUD or other SUDs. It is critical for Congress and CMS to structure Medicare payment policies so that hospitals and physicians can make evidence-based decisions regarding the most appropriate pain management therapy after surgery. Payment policies should not discourage physicians from administering non-opioid alternatives, as the current CMS payment policies described have the effect of doing. Effective, non-opioid alternatives currently exist and can be immediately employed in the operating room to reduce patients' dependence on opioids to treat acute post-surgical pain, assuming hospitals and physicians have equal access to reimbursement for these therapies.

Reducing the number of Medicare patients who use opioids to manage postsurgical pain would significantly reduce the number of beneficiaries that transition to persistent opioid use and OUD after outpatient surgery. A retrospective analysis of drug prescriptions and sales conducted in September 2017 found that just a 10% reduction in surgery-related opioid prescribing could: (1) result in 300,000 fewer people each year transitioning to OUD (and at high risk of SUDs); and (2) make 332 million fewer prescription opioid pills available for diversion and abuse.[xxv] Accordingly, revising Medicare payment policy to incentivize the use of non-opioid, physician-administered pain treatments would promote evidence-based care and minimize the risk of developing OUD for hundreds of thousands of Medicare beneficiaries each year.

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

The Medicare reimbursement policies described in detail above serve as significant barriers to utilization of non-opioid treatment options. The Opioid Commission found as much, concluding that these policies act as a "significant deterrent" to turning the tide of the opioid crisis. Revising these packaging policies to exclude non-opioid pain management therapies would equalize reimbursement and remove the financial disincentive that currently hampers hospitals' ability to stock and supply non-opioid alternatives like EXPAREL.

Congress and CMS have recognized in the past that payment packaging policies can raise barriers to the use of necessary treatments, and both entities have established exceptions and exclusions to ensure Medicare beneficiaries can access those treatments. For example, at the time Congress established the OPPS, Congress recognized that packaging payment for new drug

therapies and medical technology would discourage hospitals from adopting innovative treatments and limit Medicare beneficiary access. As a result, Congress created temporary "pass-through" payments under the OPPS for certain orphan drugs, cancer therapies, radiopharmaceuticals, and medical devices.[xxvi] When that original pass-through period expired, CMS began packaging payment for some brachytherapy seeds (radioactive isotopes used in cancer treatments) into payment for the brachytherapy procedures, reducing overall reimbursement for this treatment.[xxvii] Congress took note, and shortly thereafter passed legislation establishing separate payment for brachytherapy to ensure hospitals received appropriate reimbursement for the treatment.[xxviii] Because Congress took action, Medicare payment for a hospital to administer brachytherapy is directly tied to the actual cost of the service.

Similarly, Congress has passed legislation requiring CMS to pay separately for higher cost physician-administered drugs, recognizing that packaged payment discourages hospitals from purchasing and administering these vital drugs. In 2002, CMS determined to only pay hospitals separately for physician-administered drugs if the cost of the drug exceeded $150.[xxix] Congress concluded that packaging payment for drugs that cost between $50 and $150 created a strong disincentive for hospitals to administer these drugs because hospitals would not receive any additional payment to administer the drugs. To ensure Medicare beneficiaries had access to critical drugs that cost between $50 and $150, Congress passed legislation to require CMS to pay separately for drugs in this price range.[xxx]

While Congress has intervened to require CMS to provide separate payment for critical items, CMS has similarly recognized that packaging payment sometimes reduces beneficiary access to certain items that warrant separate payment. Specifically, prior to 2005, CMS payment policy allowed for separate reimbursement for certain anti-emetic drugs (drugs to prevent vomiting, often associated with chemotherapy), but CMS would package payment for other anti-emetic drugs.[xxxi] CMS observed that "packaging some of the 5HT3 anti-emetic products and paying separately for others may negatively impact a beneficiary's access to the particular anti-emetic that is most effective for him or her as determined by the beneficiary and his or her physician." As a result, CMS used its equitable adjustment authority to pay separately for all forms of anti-emetic products to ensure Medicare beneficiaries would have access to all forms of anti-emetics.[xxxii]

Like these examples, packaged payment for non-opioid therapies is a barrier to Medicare beneficiary access, and carving out payment for non-opioid alternatives to treat postsurgical pain will increase utilization of non-opioid therapies.

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 SUDs to improve patient outcomes?

In addition to removing barriers inhibiting the use of non-opioid pain medications, Medicare payment policy should incentivize treating practitioners to spend the additional time needed to implement opioid-sparing protocols. Specifically, Medicare should reimburse

healthcare practitioners for the additional time spent screening, educating, and treating patients with opioid-sparing protocols and non-opioid treatments. Physicians committed to assessing patients for risk of opioid misuse, implementing opioid-sparing protocols, and following patients' progress through postoperative care should have the opportunity to receive reimbursement for that time. Moreover, surgeons and anesthesiologists who spend additional intra-procedure time to administer a non-opioid pain management drug like EXPAREL should receive reimbursement for that additional time.

Failing to recognize and reimburse physicians for the extra time and effort spent implementing opioid reduction protocols will continue to limit the adoption of these important clinical policies. Yet establishing separate payment to compensate for that practitioner time, either through legislation or through encouraging CMS to establish payment for these services through the Medicare Physician Fee Schedule, would incentivize practitioners to implement opioid-sparing pain treatment protocols.

7. What best practices employed by states through innovative Medicaid policies or the private sector can be enhanced through federal efforts or incorporated into Medicare?

The private sector has already recognized the important role of non-opioid therapies, like EXPAREL, in achieving improved health outcomes at a lower cost. A large number of regional and national payors cover EXPAREL, including Aetna, Anthem, Cigna, and Wellpoint. These payors have expressed interest in not only opioid reduction, but also the reduced overall costs of major outpatient surgical episodes when EXPAREL is administered. Several commercial payors have begun demonstrations in which they pay separately for EXPAREL, while others are developing such programs.

The Committee requested recommendations that are also fiscally responsible. By reducing opioid consumption following surgery and the associated adverse effects, EXPAREL can facilitate a more effective transition of procedures historically performed in the inpatient setting to an outpatient setting, greatly lowering the cost of care. EXPAREL has been demonstrated to reduce opioid use and related adverse events, thereby reducing the need for many Medicare patients to be admitted to an inpatient hospital to undergo certain surgeries. Transitioning surgeries from inpatient to outpatient settings dramatically reduces the cost of care. For example, a 2017 study published in the *Orthopaedic Journal of Sports Medicine* found that performing knee arthroplasty in an outpatient setting instead of an inpatient setting reduced average hospital charges from $46,845 to $26,272—a 44% reduction.[xxxiii]

Because access to EXPAREL assists in transitioning procedures from inpatient to outpatient settings, and access to EXPAREL is improved through separate payment, commercial payors are increasingly interested in paying separately for EXPAREL. By separately paying for non-opioid alternative postsurgical pain management drugs administered by physicians, Medicare will not only reduce the number of beneficiaries that transition to OUD or other SUDs, but also help to reduce the cost of healthcare and financial burdens on the Medicare trust fund.

IV. CONCLUSION

By urging HHS and CMS to improve access to non-opioid pain treatments, or by developing legislation to accomplish the same, the Committee can take action well-within its jurisdiction to reduce the number of Medicare beneficiaries exposed to opioids and the attendant risk of OUD. Revising Medicare's payment policies so that hospitals receive separate payment for non-opioid postsurgical pain therapies will shift hospital incentives to tangibly and measurably reduce opioid consumption, OUD and SUDs. Pacira would be happy to provide any additional detail or answer any further questions the Committee may have on these issues.

Sincerely,

David M. Stack
CEO, Chairman
Pacira Pharmaceuticals, Inc.

cc: Stuart S. Kurlander, Latham & Watkins LLP

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[i] *See* The American College of Surgeons, *Surgeon Stewardship of the Opioid Epidemic: An Introduction*, http://bulletin.facs.org/2017/08/surgeon-stewardship-of-the-opioid-epidemic-an-introduction/ (last visited Aug. 29, 2017) (citations omitted).

[ii] Compton *et al.*, *United States for Non-Dependence*, http://www.planagainstpain.com/wp-content/uploads/2017/09/PlanAgainstPain_USND.pdf (last visited Feb. 13, 2018). This study was independently conducted by QuintilesIMS Institute with funding from Pacira.

[iii] *See* Brummett *et al.*, *New Persistent Opioid Use After Minor and Major Surgical Procedures in US Adults*, JAMA SURGERY (Apr. 12, 2017).

[iv] Compton *et al.*, *United States for Non-Dependence*, http://www.planagainstpain.com/wp-content/uploads/2017/09/PlanAgainstPain_USND.pdf (last visited Feb. 13, 2018). This study was independently conducted by QuintilesIMS Institute with funding from Pacira.

[v] Compton *et al.*, *United States for Non-Dependence*, http://www.planagainstpain.com/wp-content/uploads/2017/09/PlanAgainstPain_USND.pdf (last visited Feb. 13, 2018). This study was independently conducted by QuintilesIMS Institute with funding from Pacira.

[v] *See id.*

[vi] Carroll et al, *supra* note 5; Eric C. Sun et al., *Incidence of and Risk Factors for Chronic Opioid Use Among Opioid-Naive Patients in the Postoperative Period*, 176 J. Am. Med. Ass'n Internal Med. 1286, 1286-93 (Sept. 1, 2016), http://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2532789; Gene M. Massey et al., *Toxicology Screening in Orthopedic Trauma Patients Predicting Duration of Prescription Opioid Use*, 24 J. Addictive Diseases 31, 31-41 (2005); Singh J, Lewallen D, *Predictors of Pain and Use of Pain Medications Following Primary Total Hip Arthroplasty (THA): 5,707 THAs at 2-years and 3,289 THAs at 5-years*, 11 BMC Musculoskeletal Disorders 90 (2010).

[vii] NIH, *Treatment Statistics* (Mar. 2011),

[viii] Bicket MC *et al*, *Prescription Opioid Analgesics Commonly Unused After Surgery: A Systematic Review*, JAMA Surgery, published online Aug. 2, 2017. https://www.drugabuse.gov/publications/drugfacts/treatment-statistics.

[ix] M.C. Bicket et al., *Prescription Opioid Oversupply Following Orthopedic Surgery: A Prospective Cohort Study*, 18 J. Pain S34 (Apr. 2017).

[x] Rose A. Rudd et al., CDC, *Increases in Drug and Opioid-Involved Overdose Deaths - United States, 2010-2015* (Dec. 30, 2016), https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm; CDC, *Drug Overdose Deaths in the United States Continue to Increase in 2015* (last updated Aug. 30, 2017), https://www.cdc.gov/drugoverdose/epidemic/index.html.

[xi] Nat'l Acads. of Sci., Med., & Eng'g, *Pain Management and the Opioid Epidemic* (July 13, 2017).

[xii] *Christopher F. McNicoll et al., Surgical Leadership Is Required to Reverse the Opioid Crisis, Bull. of the Am. Coll. of Surgeons (Aug. 2, 2017), http://bulletin.facs.org/2017/08/surgical-leadership-is-required-to-reverse-the-opioid-crisis* (citing Pradip K. Muhuri et al., *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States*, CBHSQ Data Review (Aug. 2013), www.samhsa.gov/data/sites/default/files/DR006/DR006/nonmedical-pain-reliever-use-2013.htm).

[xiii] *See* Christopher D. Prater et al., *Successful Pain Management for the Recovering Addicted Patient*, 4 Primary Care Companion to J. Clin. Psych. 125 (2002).

[xiv] Michael A. Mont et al., *Local Infiltration Analgesia With Liposomal Bupivacaine Improves Pain Scores and Reduces Opioid Use After Total Knee Arthroplasty: Results of a Randomized Controlled Trial*. J. OF ARTHROPLASTY (2017).

[xv] Hannan *et al.*, *Liposomal bupivacaine vs interscalene nerve block for pain control after shoulder arthroplasty: a retrospective cohort analysis*, 45 AM. J. ORTHOPEDICS 424 (2016).

[xvi] Kalogera *et al.*, *Abdominal incision injection of liposomal bupivacaine and opioid use after laparotomy for gynecologic malignancies*, 128 OBSTETRICS & GYNECOLogy 1009 (2016).

[xvii] Jablonka *et al.*, *Abdominis Plane Blocks with Single-Dose Liposomal Bupivacaine in Conjunction with a Nonnarcotic Pain Regimen Help Reduce Length of Stay following Abdominally Based Microsurgical Breast Reconstruction*, 140 PLASTIC RECONSTRUCTIVE SURGERY 240 (2017); Afonso A, *et al.*, *Is Enhanced Recovery the New Standard of Care in Microsurgical Breast Reconstruction?* 139 PLASTIC RECONSTRUCTIVE SURGERY 1053 (2017).

[xviii] Hutchins *et al.*, *Ultrasound guided subcostal transversus abdominis plane (TAP) infiltration with liposomal bupivacaine for patients undergoing robotic assisted hysterectomy: a prospective randomized controlled study*, 138 GYNECOLOGIC ONCOLOGY 609 (2015).

[xix] Beck *et al.*, *Benefits of a Multimodal Regimen for Postsurgical Pain Management in Colorectal Surgery*, 15 OCHSNER J. 408 (2015).

[xx] *See* 78 Fed. Reg. 74826, 74930 (Dec. 10, 2013).

[xxi] *See* 79 Fed. Reg. 66770, 66874-75 (Nov. 10, 2014)

[xxii] See, e.g., Deloitte, Hospital Profit Margins, https://www2.deloitte.com/us/en/pages/life-sciences-and-health-care/articles/improve-hospital-profit-margins.html (last visited Feb. 13, 2018).

[xxiii] 79 Fed. Reg. 66770, 66798 et seq. (Nov. 10, 2014).

[xxiv] Total knee replacement surgery, described by CPT code 27447, is assigned to APC 5115, which is reimbursed at $10,122.92 in 2018. Shoulder arthroplasty with rotator cuff repair, described by CPT code 29827, is assigned to APC 5114, which is reimbursed at $5,606.42 in 2018.

[xxv] Compton *et al.*, *United States for Non-Dependence*, http://www.planagainstpain.com/wp-content/uploads/2017/09/PlanAgainstPain_USND.pdf (last visited Feb. 13, 2018). This study was independently conducted by QuintilesIMS Institute with funding from Pacira.

[xxvi] *See* Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, Pub. L. 106-113, Sec. 201, 113 Stat. 1501A-337 (Nov. 29, 1999).

[xxvii] *See* 67 Fed. Reg. 66718, 66779 (Nov. 1, 2002).

[xxviii] *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173, Sec. 621, 117 Stat. 2311 (Dec. 8, 2003).

[xxix] 67 Fed. Reg. 66718, 66771 (Nov. 1, 2002).

[xxx] *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-173, Sec. 621, 117 Stat. 2310 (Dec. 8, 2003).

[xxxi] 69 Fed. Reg. 65682, 65779 *et seq.* (Nov. 15, 2004).

[xxxii] *Id.*

[xxxiii] *See* Richter & Diduch, *Cost Comparison of Outpatient Versus Inpatient Unicompartmental Knee Arthroplasty*, 5 ORTHOPAEDIC J. OF SPORTS MED. (Mar. 2017).