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March 15, 2018

The Honorable Kevin Brady
Chairman
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U.S. House of Representatives
1011 Longworth House Office Building
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The Honorable Peter Roskam
Chairman, Health Subcommittee
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The Honorable Richard Neal
Ranking Member
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The Honorable Sander Levin
Ranking Member, Health Subcommittee
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Dear Chairmen Brady and Roskam and Ranking Members Neal and Levin:

On behalf of the more than 80,000 members of the American College of Surgeons (ACS), we would like to thank you for your leadership in addressing the opioid epidemic, which is impacting far too many of our communities. The use and abuse of both prescription and illicit drugs has increased dramatically in recent years and has become a major public health concern. Policymakers at both the federal and state level are now struggling with the fallout of this increase in the abuse of opioids. The ACS is committed to working with Congress and the Administration to help address this problem.

Many factors have contributed to the opioid epidemic and we need a multi-pronged approach to address this problem moving forward. The ACS has been extremely proactive in providing and evaluating surgeon-specific education regarding pain management options with minimal to no prescribed opioids, along with patient and caregiver education on safe and effective pain control techniques. The ACS is committed to addressing the societal imperative to avoid overprescribing through both patient and provider education, as well as through continued research into non-opioid pain treatments and other alternative remedies to reduce the number of individuals who improperly or unnecessarily receive opioid prescriptions. We appreciate this opportunity to partner with Congress to consider the impact of policies on patient safety, pain, and suffering.

Overprescribing and Data Tracking

1. Perverse Incentives in Medicare

The ACS encourages Congress to work with the Centers for Medicare and Medicaid Services (CMS) to re-evaluate pain control methods reimbursed in certain bundled services. Some bundled surgical procedures include opioids as the pre-approved pain control method, when other non-opioid treatments relieve pain just as well with far fewer short and long-term side



effects. Unbundling Medicare reimbursement for non-opioid medications and removing obstacles to multi-modal pain management techniques should be part of any legislative initiative.

Reducing the risk in opioid prescribing involves both an assessment of addiction risk and accommodation of that risk into the perioperative plan for pain control. The ACS recommends establishing new Healthcare Common Procedure Coding System (HCPCS) codes to appropriately reimburse surgical practitioners for the additional opioid risk screening. In addition, specialty-specific pre- and post-surgical monitoring and education related to low or non-opioid strategies need to be made available and appropriately reimbursed. Surgeons are keenly aware that while 70 percent of the population needing an operation are opioid naïve, the other 30 percent are in chronic pain and have been either prescribed pain management options or have been self-medicating (often for years) for pain that may or may not be related to the needed procedure. Surgical teams have worked to advance multi-modal pain strategies that utilize local pain control and non-opioid options. These have been effective in reducing opioid use and optimizing recovery.

2. Second Fill Limits

ACS believes that medical decisions should be left to the prescribing physician and that limits should not adversely impact patient care. Strict governmental restrictions which do not allow for patient specific evaluation and appropriate exceptions may have unintended consequences such as hindering patient care and possibly resulting in additional misuse. There has been wide variation in the limits and restrictions placed on prescribers. Surgical patients are unique and while their pain may be acute, it is also often intense and can limit mobility, thereby restricting the patient's ability to retrieve multiple prescriptions. The ACS is acutely aware of the balance that must be achieved between controlling opioid distribution and maintaining access for surgical patients with a legitimate need. Removing access could easily push people to illicit drug sources to deal with the foreseeable pain associated with many surgical procedures, while simultaneously removing the support and guidance of a medical professional.

In the absence of evidence-based support to indicate levels for second fill limits, the ACS is developing a mechanism by which to obtain real time feedback from patient to provider about patterns of medication usage. *Strong for Surgery*, a quality program of the ACS, empowers hospitals and clinics to integrate checklists into the preoperative phase of clinical practice for elective operations. The checklists are used to screen patients for potential risk factors that can lead to surgical complications, and to provide appropriate interventions to ensure better surgical outcomes. *Strong for Surgery* targets areas known to be highly influential determinants of surgical outcomes. A new opioid sparing checklist will be released mid-2018. A web-based application to record responses and serve as a communication tool between the patient and provider will also be developed to accompany the opioid sparing checklist. Over time, results will show trends (averages) in medication usage, successes and challenges with patient learning,

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and real-time behavior feedback. The data will ultimately be used to make recommendations on fill limits.

The ACS further supports additional provisions such as:

- Allowing a patient, in consultation with their physician, to partially fill their prescription for an opioid.
- Development of state and federal guidelines on prescribing protocols to provide E-prescribing options for the postoperative and/or severely injured surgical patient who, in the professional opinion of the attending physician, is expected to require more than 7 days of postoperative pain relief necessitating opioids. Such protocols may improve tracking and reduce opportunities for fraud while allowing physicians to manage patients experiencing prolonged pain which cannot be controlled through other methods.
- Implementing targeted exceptions from prescriber mandates for patients undergoing cancer treatment, cancer rehabilitation, and palliative care.

These policies would ensure that patients continue to have access to medically necessary treatments to manage pain, while also limiting risk of abuse and diversion.

3. Tools to Prevent Opioid Abuse

ACS strongly supports programs such as *Strong for Surgery* (outlined above) to serve as a resource in preventing and reducing opioid abuse. Besides the greater promotion and utilization of E-prescribing, additional changes could include specific codes for opioid-related patient counseling (similar to the codes provided for smoking cessation) as well as a stronger examination of the effects of bundled payments and their inherent incentives against non-opioid alternatives. Recommendations also include incentives for groups using patient decision aids, screening, and fact sheets at the point of care. In addition, ACS encourages states to implement disposal programs to prevent misuse of unused prescribed opioids. A further outline of ACS' efforts relating to patient and provider education are detailed in the "prescriber notification and education" section.

4. Medication Therapy Management (MTM)

The ACS does not have an official position regarding the use of MTMs; however given the complexity surrounding surgical patients, especially those with other comorbidities, we suggest that an acute pain service should be provided by those knowledgeable and licensed to implement the best course of treatment. It is now well established that a small percentage of surgical patients continue to use opioids beyond their immediate postoperative recovery.¹⁻³ While there are a number of screening tools with predictive value to specifically screen for risk of opioid misuse in the context of chronic pain treatment, more research is needed for assessment of the surgical

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patient. Central to quality surgical patient care is the knowledge and skill necessary for pain management. This includes recognition of the degree of tissue damage during the operation, patient genetic variations and characteristics, preoperative management, and preferences of individual patients, who may be opioid naïve, opioid dependent, and/or opioid avoidant. This approach goes beyond dealing with pain to include screening for and managing complications, postoperative nausea and vomiting, and adjusting medications and therapies such as fluid therapy, oxygen therapy, and anticoagulant management. There is increasing tension between the need to balance postoperative pain control and managing other complications, while guarding against inappropriate opioid use and abuse.

5. Electronic Prior Authorizations (PA)

The ACS supports the *Standardizing Electronic Prior Authorization for Safe Prescribing Act*, H.R. 4841, which would allow for electronic prior authorization (PA) under Medicare Part D and allow for the creation of technical standards for the electronic transmission of PA. While this legislation is a good first step for electronic PA, the ACS would like to see it expanded to include all medical services, supplies, and prescription drugs. The ACS recommends that all processes needed to obtain PA for medical services and supplies be incorporated in electronic health records (EHRs) and urges Congress to direct the ONC to establish a plan for the adoption of standard electronic PA capabilities and functions in all certified electronic health record technology (CEHRT) systems as part of its 21st Century Cures Act mandated priorities.

The ACS further encourages Congress to work with the Administration to leverage patient and health plan data in EHRs to notify physicians of PA requirements in real time, automate PA decisions for routine services or items, and pre-populate PA documents for cases in which further review may be needed such as in the prescription of opioids. The use of information already stored in EHRs to complete PA processes could streamline payor-provider communication, improve the accuracy and efficiency of administrative tasks, and ensure the timely provision of care.

A patient discharged after surgery without timely access to clinically appropriate prescribed opioids could experience unmanaged pain, which is unnecessary and will affect the patient's quality of care. ACS urges Congress to consider the:

- Automation of PA requests and decisions through uniform electronic transaction portals for medical and pharmacy services under Medicare Advantage, Medicare Part D, and Exchange plans in a way that is compliant with HIPAA and the National Council for Prescription Drug Programs.
- Transmission of PA decisions by a health plan to a provider through the appropriate electronic portal within 24 hours for urgent care and 48 hours for non-urgent care.
- Exemption of PA for services or supplies, including prescription drugs and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), that are standard

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for a specific condition or have been approved previously as part of a patient's care treatment plan.

- Further restriction of prior authorization requirements to complex cases or to clinicians whose ordering patterns differ substantially from other practitioners after adjusting for patient population.

6. Prescription Drug Monitoring Programs (PDMPs)

ACS supports the use of fully-functioning prescription drug monitoring programs (PDMPs) as a health care and research tool to assist physicians and other prescribers. Currently, there is wide variability between the functionality and accuracy of PDMPs from state to state. ACS strongly supports the utilization of governmental grant funding to enhance these programs and make them accessible to appropriate members of the health care team. For example, in some states there are restrictions that PDMP login credentials be accessed only by a physician. Not only do these parameters disrupt the day-to-day clinical workflow, they restrict the availability and accessibility of PDMP information to some providers who might otherwise be in a position to prevent abuse. When these programs are accessible by physicians and/or a physician's designee, this burden is decreased. As such, the ACS supports allowing physicians, licensed independent practitioners (LIPs), physicians' designated agents, and pharmacists to have access to the PDMP.

In addition, there must be interoperability across states in the data contained in PDMPs, and with electronic health records (EHRs) to streamline workflow and accessibility. The data contained in PDMPs should also be available in "real time" to ensure accurate information. Finally, ACS strongly believes that any PDMP use should be voluntary, not used for law enforcement purposes, and that PDMPs should be updated as frequently as possible to ensure accuracy, ideally in real time. This would be of particular value in conjunction with partial-fill prescriptions.

Communication and Education

1. Beneficiary Notification

Beneficiary education on alternative pain management techniques and other aspects of care can play an important role in reducing opioid abuse. Patients may be incentivized to play a more active role in their care by participating in preoperative education including (but not limited to) the use of postoperative home care or skills kits. Upon completion of patient skills training, patients could then receive a certificate of completion which could be submitted to the insurance company for patient reimbursement. Data supports that surgical and patient guidelines and education significantly decreased opioid prescriptions by 53 percent with no increase in refill prescriptions.⁴

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2. Prescriber Notification and Education

Patients and caregivers can benefit from technical training in opioid sparing, multi-modal management, and enhanced recovery methods. This includes things such as home management of local infusion catheters by patients and caregivers. Surgical teams can also benefit from technical training in additional areas such as use of local anesthetics and block procedures. The ACS recommends funding for workforce retraining and evaluation of these models to determine best practice for specific populations.

ACS has developed several educational guides and courses to assist with both patient and physician opioid-related education and welcomes governmental assistance in helping to disseminate and evaluate these materials and courses. Patient and physician education is key to ensuring patients receive the most appropriate pain management and appropriate doses of opioids, non-opioids, and therapies for side effect management. The ACS has been extremely active in developing ways to educate both patients and surgeons on the safe and appropriate use of opioids including the attached document, *Safe and Effective Pain Control After Surgery*. These educational venues will provide certified Continuing Medical Educational (CME) credits specific to the surgical team that should satisfy CME requirements.

We urge Congress to provide grant funding for opioid education and awareness as well as specialty-specific and team-based CME on proper opioid prescribing protocols, non-opioid alternatives, the management of high risk patients susceptible to opioid use disorder, and the transition of care for chronic pain patients. While the prescribing guidelines provided by the CDC are a good first step, the guidelines were developed for primary care providers and focused on long-term, chronic pain. As such, they provide limited information on treating patients with acute pain. Surgical specialty societies should (and in some cases already do) provide opioid and pain management CME relevant to their specialty. It is critical that professional society certified continuing medical education programs be permitted to satisfy any CME requirements.

Surgical education efforts will seek to inform practitioners on accurate patient assessment techniques such as screening for Opioid Use Disorder (OUD) or Substance Use Disorder (SUD), utilizing perioperative multimodal analgesics, and best practices for patients who are opioid-naïve, experiencing chronic pain, or who are already opioid-dependent.

The ACS strongly feels that any opioid related training or CME should come directly from medical specialty societies and be regulated by the physician's state licensing board. The surgeon is the person ultimately responsible for both the surgical care received by a patient and the pain control options presented and is therefore best able to craft an individualized pain control plan. The impact of factors such as other disease state, genetic variations, other prescriptions, overall

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health status, and home support must also be recognized. This goes well beyond any specific drug education provided by a manufacturer and will allow a holistic approach to patient pain management rather than just a list of drugs and their side effects. Furthermore, specialty societies can best monitor the outcomes of education either through self-assessment questions or through documentation of patient outcomes and can provide feedback as to the effectiveness of the educational interventions.

Additionally, professionals who have high prescribing patterns may be identified by better utilizing data from the prescribing registry and tracking the number and frequency of opioid prescriptions, refills, and doses given to patients. Efforts to better identify and educate high opioid prescribers will likely result in more appropriate, safe, and effective pain control for patients.

Treatment

1. Opioid Treatment Programs (OTPs) and Medication Assisted Treatment (MAT)

Please see the answer to question number three under the Overprescribing/Data Tracking question.

2. Reimbursement

According to data from the 2012 National Health Interview Survey (NHIS), 11.2 percent of American adults (25.3 million people) have experienced some form of pain every day for the past three months. Recognizing that this population may also require surgery, the ACS encourages Medicare and Medicaid to support physician reimbursement for both opioid risk screening of patients and for presurgical pain control counseling for patients.

The ACS also supports the deployment of incentives espoused by Medicaid across Medicare and the private sector to encourage the use of non-opioid options, when medically appropriate. More consistent reimbursement for alternative pain management, such as massage therapy, physical therapy, and acupuncture should be part of the legislative agenda.

3. Alternative Options for the Treatment of Pain

ACS supports a range of non-opioid medications and therapies to assist with pain management, including: local anesthetics, non-opioid medications (acetaminophen/NASIDs), nerve blocks, ice therapy, and non-medical treatments (exercise/relaxation techniques and other alternatives noted in the previous response). ACS supports the use of a patient outcomes database related to safe and effective pain control. Studies have shown that physicians who monitor their patient

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outcomes have patients with better outcomes. ACS is in the initial stages of building a database that could be used by hospital systems or individual physicians to monitor patient outcomes. Additionally, the ACS is actively promoting educational materials on home care training for patients and caregivers consisting of, but not limited to self-assessment of pain based on function and utilizing alternatives to opioids to manage pain as well as engagement in post-discharge wellness curriculum aimed at increasing patient competence in care once home and the long-term maintenance of health. Together, these initiatives could have a meaningful impact in reducing opioid dependence and abuse.

We look forward to working with you to end the opioid crisis and ensure that all patients receive the most appropriate and highest quality care.

Sincerely,

David B. Hoyt, MD, FACS
Executive Director, American College of Surgeons

Attachment:

Safe and Effective Pain Control After Surgery

For more information on ACS' opioid-related efforts, please visit:

<https://www.facs.org/education/opioids>

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