

AMERICAN ASSOCIATION OF
NEUROLOGICAL SURGEONS

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American
Association of
Neurological
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Congress of
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CONGRESS OF
NEUROLOGICAL SURGEONS

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President
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March 20, 2018

The Honorable Marsha Blackburn
U.S. House of Representatives
2266 Rayburn Office Building
Washington, DC 20515

The Honorable Tim Ryan
U.S. House of Representatives
1126 Longworth Office Building
Washington, DC 20515

The Honorable Tom MacArthur
U.S. House of Representatives
506 Cannon House Office Building
Washington, DC 20515

The Honorable Ann McLane Kuster
U.S. House of Representatives
137 Cannon House Office Building
Washington, DC 20515

SUBJECT: H.R.5311, the CARA 2.0 Act of 2018

Dear Representatives Blackburn, Ryan, MacArthur and Kuster:

On behalf of the American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS), representing more than 4,000 practicing neurosurgeons in the United States, we applaud the bipartisan efforts of the U.S. House of Representatives to address our country's opioid crisis and appreciate the ability to be involved in this process.

Limits on Opioid Prescribing

As neurosurgeons, we support legislation that reduces the risk of opioid abuse. Limiting the availability of excess opioid medication in the postoperative period is one potential way to accomplish this, and we generally concur with this approach.

There are, however, some postoperative scenarios, common in the practice of neurosurgery, where a 3-day limit would be inappropriate and burdensome for patients. For example, complex spinal surgery typically necessitates that patients appropriately utilize opioid medication to manage their postoperative pain for 2-3 weeks (or even longer) after the surgery. Another example is polytrauma patients suffering from several concurrent major injuries (e.g., multiple spine and limb fractures, head injury, etc.). These operations are often performed by subspecialists in tertiary care medical centers that are located far from the patients' residences. In this situation, the patient would be forced to commute a long distance, merely to get a prescription refill, thus subjecting these patients to an undue burden that likely would lead to under-treatment of their pain, and expose them to unnecessary postoperative complications and poor outcomes.

Rather than try to delineate in legislation every possible scenario that could occur, as the legislation advances through Congress, perhaps you would consider adding language to the bill that allows for exceptions in appropriate medical situations, such as has been described above. Language that we favor is included in H.R. 4482, the Opioid Abuse Deterrence, Research, and Recovery Act, which was introduced by Reps. Mark Meadows (R-N.C.) and Jim Renacci (R-Ohio). It allows physicians to prescribe opioids for immediate, post-operative pain relief, and to prescribe opioids in excess of an initial 7-day supply if the practitioner:

- (i) provides a specific reason for exceeding the 7-day limit that is in accordance with a clear medical standard of care whose implementation necessarily exceeds such limit;
- (ii) documents such reason and medical standard of care in the patient's medical record; and
- (iii) consults the applicable State's electronic health record system or prescription drug monitoring program.

Incorporating these additional criteria in your bill will help ensure that patients in these specific clinical contexts can continue to receive optimal postoperative care, while all patients can still benefit from the protections that this legislation offers.

Additional options that you may wish to consider (which would help manage the opioid epidemic, without having the burden placed solely on physicians and potentially restrict our ability to treat patients adequately) include:

- Changes to pharmacy policies to allow patients to fill a portion of their opioid prescriptions rather than being required to fill the entire script. This would enable prescribers to write a prescription for a sufficient amount of pain medication, but would still potentially limit the number of excess/unused opioids pills in each household.
- Encouraging prescribers to give patients a multi-modal pain management treatment regimen, which includes non-narcotic medications — being mindful that there are still scenarios, as mentioned above, in which a longer duration of opioids is nonetheless indicated to ensure better recovery and outcomes for our patients.
- Encouraging prescribers to give patients educational materials and/or a referral to an addiction specialist (if available)¹ or an addition prescription of naloxone with each opioid prescription that is written, as this is an underutilized, highly valuable resource.

Prescription Drug Monitoring Programs

The AANS and CNS support the use of Prescription Drug Monitoring Programs (PDMPs), and as a member of the American Medical Association's Opioid Task Force, we actively encourage neurosurgeons to register for and use their state's PDMP to make more informed prescribing decisions. As a result of these collective efforts, America's physicians and health care professionals are registered for and using state PDMPs more than ever. As of 2016, more than 1.3 million physicians and other health care professionals are using PDMPs, and this same year, PDMPs were checked 136.1 million times. Thus, these voluntary efforts are clearly paying off.

However, barriers to effective prescription drug monitoring remain. To help streamline this process, we encourage Congress to consider funding the creation of a national PDMP, which could either consist of a new national PDMP, or interlink existing state-based PDMPs. This national database would then be queried by the pharmacist before the medication is dispensed. Any red flags noted would prompt a hard stop on dispensing and a call to the prescriber from the pharmacist. This would be a more efficient method, as access to PDMP databases is not always available to prescribers at all points of patient care (emergency departments, walk-in clinics, satellite offices, etc.).

The purpose of a national PDMP is to both prevent patients from pill shopping across state lines and to identify trends in prescribing and dispensing that could indicate that certain pharmacies are dispensing inappropriately large amounts of opioids as part of diversion. Currently, a patient can obtain an opioid prescription in one state, and then immediately go across the border to another state and get a duplicate

¹ It should be noted, however, that many states do not have enough resources and specialists available to treat all the patients requesting help with opioid addictions, thus requiring patients to seek treatment in other states. Furthermore, insurance coverage for these resources is frequently limited and must also be addressed.

opioid prescription without triggering an alert in either state's PDMP. This situation is unacceptable and makes opioid abuse and diversion easier to camouflage.

Other Ideas for Consideration

In addition to the measures included in CARA 2.0, the AANS and CNS favor the development and implementation of a Risk Evaluation and Mitigation Strategy (REMS) tool through the FDA to facilitate the dispensing of appropriate opioid prescriptions when medically necessary. The standardized tool, which does not have to be overly complex and administratively burdensome, would be completed by the prescriber at the time the prescription is written and would accompany the prescription (either physically or electronically, as appropriate) to the pharmacy.

Every opioid prescription, regardless of the quantity of opioid prescribed, would have the REMS tool attached. This tool would allow the prescribing clinician to:

- a) specify the patient's diagnosis as appropriate for continued opioid therapy;
- b) specify the indication for continued opioid therapy, such as acute pain, chronic pain requiring maintenance opioid medication, acute postoperative pain, pain exacerbation requiring opioid dose escalation, or palliative care/cancer pain; and
- c) certify that the patient has either failed an appropriate non-opioid therapy prior to initiation of opioid therapy or particular non-opioid therapies (such as NSAIDs) are contraindicated.

This reasonable REMS mechanism, combined with a national PDMP, will both curb inappropriate opioid prescribing practices and preserve access to opioids to those patients who may benefit from them.

Improving Access to Non-Pharmaceutical Therapies for Chronic Pain

The AANS and CNS support the use of non-pharmacologic (i.e., procedural and behavioral) therapies for the treatment of chronic pain when appropriate. Interventions such as neuromodulation (i.e., spinal cord stimulation, peripheral nerve stimulation, and brain stimulation), nervous system ablation (destructive surgical treatments), comprehensive pain rehabilitation clinics, and pain psychology all have been shown to decrease pain-related disability and reduce opioid use. Indeed, advanced spinal cord stimulation (SCS) technologies allow chronic pain specialists to provide increased patient satisfaction and may lower overall health care costs through fewer provider visits and less opioid medication. However, Medicare, Medicaid and other third-party payers often deny the use of these treatments for chronic pain patients, despite substantial evidence supporting their use in addressing chronic pain. These restrictive policies only serve to encourage the use of opioids as physicians see few covered alternatives. Medicare, Medicaid and other insurers should allow coverage of these non-pharmacologic therapies for chronic pain when sufficient clinical evidence (including such resources as clinical trials, prospective data registries, and/or peer-reviewed clinical practice guidelines listing the therapy as a treatment option) exists. These noncoverage determinations are often based on the fact that studies for some of these treatments are relatively small compared to those for pharmaceuticals. It is important to understand that these treatments are not utilized in the same numbers as pharmaceuticals, and large studies may not be feasible.

Conclusion

As you know, the opioid epidemic is complex and a multi-faceted approach is necessary to solve this problem. However, care must be taken that the pendulum does not swing the other way by placing undue restrictions on medically necessary pain medication that will ease the suffering of our patients. Rather than implicating physicians as the primary problem and limiting treatments for patients who need

such interventions, we hope to work together to find solutions that will appropriately address this complex issue.

Thank you for considering our suggestions. If you have any questions or need additional information, please do not hesitate to contact us. In the meantime, we look forward to working with you on this and other important health policy issues.

Sincerely,



Alex B. Valadka, MD, President
American Association of Neurological Surgeons



Ashwini D. Sharan, MD, President
Congress of Neurological Surgeons

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