Alliance of Specialty Medicine

Sound Policy. Quality Care.

April 11, 2018

The Honorable Lamar Alexander
Chairman,
Committee on Health, Education, Labor,
and Pensions (HELP)
Washington, DC 20510

The Honorable Patty Murray
Ranking Member,
Committee on Health, Education, Labor,
and Pensions (HELP)
Washington, DC 20510

Sent electronically (in Word format) to HELPfightsopioids@help.senate.gov

RE: Response to the Opioid Crisis

Dear Chairman Alexander and Ranking Member Murray:

The Alliance of Specialty Medicine (the "Alliance") represents more than 100,000 specialty physicians from thirteen specialty and subspecialty societies. The Alliance is deeply committed to improving access to specialty medical care through the advancement of sound health policy.

The undersigned members of the Alliance appreciate the opportunity to provide feedback regarding your discussion draft responding to the opioid crisis. Consider that every day, 46 Americans die as a result of prescription opioid overdose,[1] and the rate of heroin-related overdose deaths has seen a 6.2 fold increase since 2002.[2] In addition to these tragic figures, the nation is seeing an increase in opioid-related pediatric exposures and poisonings. There has been a distressing rise in neonatal abstinence syndrome (NAS) as a result of women being exposed to opioids during pregnancy. Misuse by older adults has also become an increasing concern. The rate of opioid-related hospital admissions has increased significantly over the last two decades across all age cohorts. Because of higher rates of substance use disorders in the current "baby boomer" cohort, illicit and non-medical drug use among older adults is expected to increase in the future. Physicians are well positioned to understand the complexities of medical and nonmedical opioid use and to lead change in safe ways that do not marginalize segments of the population through reactionary policies and actions. While many non-opioid analgesics exist and use of these should be optimized moving forward, physicians must help guide policymakers regarding the valid and necessary roles for opioids.

According to the Centers for Disease Control and Prevention (CDC), the amount of opioids prescribed in the US peaked in 2010 and then decreased each year through 2015. However, prescribing remains high and varies widely from county to county. In 2015, six times more opioids per resident were dispensed in the highest-prescribing counties than in the lowest-prescribing counties. County-level characteristics, such as rural versus urban, income level, and demographics, only explained about a third of the

[1] Hedegaard H, Warner M, Miniño AM. Drug overdose deaths in the United States, 1999–2016. NCHS Data Brief, no 294. Hyattsville, MD: National Center for Health Statistics. 2017/ CDC. Wide-ranging online data for epidemiologic research (WONDER). Atlanta, GA: CDC, National Center for Health Statistics; 2016. Available at http://wonder.cdc.gov

[2] https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates

differences. This suggests that people receive different care depending on where they live. Healthcare providers have an important role in offering safer and more effective pain treatment.

Already, there are studies that suggest specialties have shown discretion in their opioid prescribing patterns, including ophthalmology[3] and spinal surgery.[4] At the same time, however, physicians must ensure that their patients have appropriate pain management.

In response to your discussion draft, the Alliance provides the following comments in the order that they appear in the "Opioid Crisis Act of 2018."

Avoid limits on acute pain prescriptions. The Alliance remains concerned that any limits, including a proposed seven-day limit is problematic for certain circumstances, including trauma and post-surgical acute pain management [such as major spine surgery (e.g., fusion, deformity) and joint replacement]. As noted below, the CDC guidelines relate to *chronic* pain, not acute pain. Specifically, the guidelines note that "[o]pioid treatment for post-surgical pain is outside the scope of this guideline. . . ." With respect to trauma, a sudden accident is not planned for and can take weeks to months to resolve in the case of major multisystem injuries. These are not chronic pain patients, but certainly three to seven days is unrealistic and inhumane to restrict appropriate pain management. There should be further work to construct a possible pain management framework for major surgery, including Polytrauma, where you can prescribe more than seven days with added monitoring. *Given these concerns, the Alliance urges caution with section 302, which would provide the FDA with the authority to require certain blister packs for opioids. While the Alliance appreciates that the legislation does not explicitly require certain blister packs, we remain concerned that the implementation may be detrimental to our patients' access to appropriate acute pain management.*

Disposing of unused medication. Unused medications increase the risk of non-medical use by adolescents who live in the home or by their friends. Unused medication also can be ingested by young children who are curious about what is inside the pill container. Implementing campaigns to educate the public on the importance of storing opioid medications locked and out of the reach of children and properly disposing opioid medications following the end of use can encourage these safe practices. *For these reasons, the Alliance appreciates the changes within section 302 to provide the Food and Drug Administration (FDA) with the authority to allow manufacturers to include safe disposal methods with the valid prescription.*

Support state-based innovation. In the past two to three years, several hundred new policies have been enacted at the state and local levels to address the opioid epidemic. The Alliance strongly urges that efforts be undertaken to fully evaluate how these new laws and policies effect access to opioids, impact pain care, or might be associated with unintended consequences. As the nation's opioid epidemic is increasingly fueled by heroin and fentanyl and other illicit, synthetic derivatives, the Alliance urges the Committee to consider how public policies focusing on opioid supply need to be balanced by policies that offer a measure of hope to those individuals and families already affected by this epidemic. *For these reasons, the Alliance supports the inclusion of section 501, which would require the Secretary of Health and Human Services and the Attorney General to provide an evaluation of these new policies, with a focus on the impact on providers as well as the illicit drug trade.*

[3] https://www.ncbi.nlm.nih.gov/pubmed/28983558
[4] https://www.ncbi.nlm.nih.gov/pubmed/28763410

Enhance education of physicians and other providers. A key part of our commitment to reversing the opioid epidemic is supporting enhanced education, training and resources for physicians and other health care professionals across the continuum of medical education to ensure that they have the resources they need to make informed prescribing decisions. In 2015 and 2016, more than 118,000 physicians took educational courses related to opioid prescribing, pain management, substance use disorders, and related topics offered by national organizations as well as medical specialty and state medical societies. For instance, in partnership with CO*RE, the American Osteopathic Association (AOA) offers grants for hosting "Opioid Prescribing: Safe Practice, Changing Lives" programs. AOA affiliates can apply for a block grant to present live Category 1-A CME developed by the Collaborative for REMS Education (CO*RE).[5] In September 2017, the American Gastroenterological Association (AGA) published a new Clinical Practice Update to describe how opioids can affect diverse parts of the gastrointestinal tract. Patients can experience GI symptoms and side effects related to the intake of opioids, including opioid-induced constipation (OIC), esophageal dysmotility and delayed gastric emptying.[6] The AANS and CNS have sponsored continuing medical education courses to educate our members about the opioid epidemic, proper prescribing practices and alternative pain management strategies. The neurological surgery certifying board is also considering incorporating opioid-related topics into our board certification and continuing certification requirements.

The Alliance strongly supports efforts to enhance education, but believes that it should occur at the state level to avoid creating confusion and unnecessary federal overlap with existing state law. In addition, while attending CME courses, whether mandated or voluntary, does provide some benefit, benchmarking projects should be encouraged and funded. This has been one of the criticisms that we have heard regarding opioid prescribing. Medicine is evidence-based and training should be held to that standard as well.

For these reasons, the Alliance is concerned with language in section 502 related to provider education, given that it places an undue emphasis on that education happening at the Federal level.

Recognize the limitations of the CDC guidelines. In March of 2016, the CDC developed and published a guideline for prescribing opioid pain medications for adults 18 years of age and older *in primary care settings*. According to the White House Commission, prescriptions by primary care clinicians account for nearly half of all dispensed opioid prescriptions, and the growth in prescribing rates among these clinicians have been above average. However, while many professional organizations encourage use of the CDC guideline, it is important to note that patients who currently use opioid medications for legitimate medical reasons are worried about the guideline being too restrictive for their physicians to properly treat them. Clinicians have added their concerns about the CDC guideline, including the time required to discuss alternative forms of pain control, the difficulty in obtaining reimbursement for alternatives, how to address opioid tapering, and concerns with the prescribing guideline for specific forms of pain. Furthermore, it is important to point out that the CDC guideline is intended for primary care clinicians, who are treating patients for chronic pain in outpatient settings, and opioid treatment for post-surgical pain is outside the scope of this guideline, having been addressed elsewhere.[7] Thus, as it relates to acute

[5] https://www.osteopathic.org/inside-aoa/development/research-and-development/Pages/core-rems-programs.aspx
[6] http://www.gastro.org/news_items/aga-releases-new-clinical-guidance-on-opioids-in-gastroenterology
[7] Washington State Agency Medical Directors' Group. AMDG 2015 interagency guideline on prescribing opioids for pain. Olympia, WA: Washington State Agency Medical Directors' Group; 2015. http://www.agencymeddirectors.wa.gov/guidelines.asp

pain, more latitude in decision-making should be given to physicians that have specialized training in pain management and surgeons managing post-surgery pain.

Given those concerns, the Alliance would like section 503 regarding CDC's authority to disseminate and update guidelines to appropriately reflect the limitations of the current CDC guidelines.

Strengthen PDMPs. The Alliance encourages physicians, dentists and other prescribers of controlled substances to register for and use their local prescription drug monitoring programs (PDMP) — as one tool to identify when a patient may need counseling and treatment for a substance use disorder. The trend among policymakers has been to use PDMPs to identify "doctor shoppers." This, by itself, is important, but the real work is to understand why a patient is seeking medication from multiple prescribers or dispensers — and to offer a pathway for treatment and recovery. The information in PDMPs can play a helpful role in identifying patients in need of help.

Physician consultation of PDMPs has increased from 61 million inquiries in 2014 to more than 136 million in 2016. PDMPs are now functional in almost every state, and most state PDMPs can share data. To expand the use of these clinical support tools, the Alliance encourages increased research and funding to help integrate PDMPs into electronic health records and physician workflow in a meaningful, user-friendly manner. Without such PDMP integration, the administrative burden for compliance would be too difficult. Furthermore, it is important to adopt processes that allow PDMPs to communicate with one another to help prevent opioid seekers from crossing state lines for the purposes of avoiding prescription limits.

For these reasons, the Alliance is encouraged with section 505, which acknowledges some of the key limitations of the current PDMPs, as well as section 506 (language to be supplied), which reauthorizes the National All Schedules Prescription Electronic Reporting (NASPER) program.

We appreciate the opportunity to provide comments on the aforementioned issues of importance to the Alliance. Should you have any questions, please contact us at info@specialtydocs.org.

Sincerely,

The Alliance of Specialty Medicine