



September 14, 2018

The Honorable Lamar Alexander
Chair
Committee on Health, Education, Labor and
Pensions
United States Senate
Washington, DC 20510

The Honorable Patty Murray
Ranking Member
Committee on Health, Education, Labor and
Pensions
United States Senate
Washington, DC 20510

The Honorable Orrin Hatch
Chairman
Committee on Finance
United States Senate
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate
Washington, DC 20510

Dear Chairman Alexander, Ranking Member Murray, Chairman Hatch, and Ranking Member Wyden:

On behalf of the American College of Physicians (ACP), I am writing to applaud your committees for the bipartisan nature with which you have worked to address the ongoing opioid crisis in this country and to comment on key aspects of the Opioid Crisis Response Act of 2018. This legislation, a product of your committees' efforts, provides a multi-faceted approach to combat the opioid epidemic through policies that will reduce use and supply, encourage recovery, and support caregivers and families. Our physicians see first-hand the devastating and deadly impact that opioid use disorder imposes on our patients, and we have been pleased to engage with Congress on this important issue throughout the process. Based on the latest version of the Opioid Crisis Response Act of 2018, as provided by your committees, we would like to offer our feedback on certain provisions that most directly impact the care we provide to this patient population.

ACP is the largest medical specialty organization and the second largest physician group in the United States. ACP members include 154,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

Internists are uniquely suited to treat individuals with opioid and substance use disorders as they are often the first point of contact into the health system for patients with chronic pain. Our physicians have an ethical obligation to manage and relieve pain in a manner that reflects the best available clinical evidence. The challenge for physicians and public policymakers is how to deter prescription drug misuse while maintaining patient access to appropriate treatment.

Expanding Alternatives to Opioid Treatment

ACP supports removing barriers to evidence-based non-opioid and non-pharmacologic pain management services that do not involve potentially addictive medications. We are pleased that this legislation takes important steps to promote the use of new non-addictive medical products intended to treat pain or addiction other than opioids. One barrier to the use of these products is the lack of research on the most effective non-pharmacologic and non-opioid treatment intervention to use to manage patient's pain.

Based on our understanding, section 1301 of this bill would clarify the pathway of Food and Drug Administration (FDA) regulation of alternatives to opioids to treat pain or addiction, a move that ACP supports. It would require the FDA to hold one or more public meetings on the challenges and barriers to developing non-addictive medical products intended to treat pain. It would also require the FDA to take multiple steps to improve access to alternatives to opioids such as: incorporating the risk of misuse and abuse of opioids into FDA assessments, novel clinical trial designs for opioid alternatives, and evidentiary standards to help advance the use of products that can reduce, replace, or avoid patient's use of opioids to control pain.

Many barriers to non-pharmaceutical therapy exist within Medicare and Medicaid as these programs often limit coverage of non-opioid pain management treatment options. With the growing evidence for the efficacy of these interventions, more state Medicaid programs are electing to cover non-opioid pain management services, but few encourage their use. Section 2204 of this legislation could expand access to integrative, non-pharmaceutical therapies within Medicaid by directing CMS to issue guidance on state options for treating and managing beneficiaries' pain through non-opioid pain treatment and management options under Medicaid.

Increasing Access to Medication Assisted Treatment and Recovery Programs

ACP is supportive of lifting barriers to ensure that our patients receive access to medications to treat opioid use disorders and to reverse overdoses. Medication assisted treatment (MAT) using buprenorphine and naloxone has an impressive success rate for treating patients with opioid use disorders. According to the Substance Abuse and Mental Health Services Administration (SAMHSA) "when patients and physicians were surveyed about the effectiveness of buprenorphine, they reported an 80 percent reduction in illicit opioid use, along with significant increases in employment and other indices of recovery." ACP supports expanding education opportunities for physicians who prescribe MAT to ensure this therapy is properly administered to patients.

One barrier that impedes patient access to MAT occurs when physicians are limited in the number of patients to whom they can prescribe this type of treatment. We are pleased to support Section 1408 of this bill which codifies the ability for physicians to obtain a waiver to prescribing MAT for up to 275 patients. We remain concerned that, to date, few physicians have applied for a waiver to prescribe MAT to additional patients. As of August of 2016, just over 37,000 physicians – less than four percent of prescribers – have been granted waivers to prescribe buprenorphine. Physicians are reluctant to apply for waivers for MAT due to the complexity of this patient population, the lack of mental health and psychosocial support, and time constraints in their practice. More attention should be directed to preparing and supporting buprenorphine-waivered physicians to improve confidence and facilitate

team-based care. We support additional professional support resources that can link primary care physicians to specialists and other health care professionals experienced in substance use disorder treatment.

ACP is encouraged by Section 1401 of this legislation that authorizes a grant program through SAMSHA for entities to establish comprehensive opioid recovery centers that serve as resources for the community. These entities may utilize the Project ECHO model to support care management and medical education related to opioid use disorder. The comprehensive opioid recovery centers would utilize the full range of FDA-approved medication and evidence-based treatments, have strong linkages with the community, generate meaningful outcomes data, and potentially, dramatically improve the opportunities for individuals to establish and maintain long-term recovery and remain productive members of society.

Prescription Drug Monitoring Programs

ACP policy strongly supports reducing administrative burdens associated with the use of prescription drug monitoring programs (PDMPs), as well as other efforts to improve physician clinical workflow. ACP has long-supported the establishment of a national Prescription Drug Monitoring Program (PDMP), but until such a program is implemented ACP supports efforts to standardize state PDMPs through the federal National All Schedules Prescription Electronic Reporting (NASPER) program.

We strongly support Section 1507 of this legislation that would reauthorize the NASPER program to allow states to develop, maintain, or improve PDMPs through interoperability with other health information technology and across state lines. Improved interoperability will ensure that information from other states regarding controlled substances is readily accessible to physicians.

Along with the reauthorization of NASPER, we must ensure that states and localities have the resources necessary to improve their PDMPs to ensure that physicians may use them in an efficient manner to treat their patients. We are pleased to support Section 1505 as it provides support for states and localities to improve their PDMPs and implement other evidence-based prevention strategies, encourages data sharing between states, and supports other prevention and research activities related to controlled substances. ACP supports grants to states and localities designed to create greater coordination and integration of opioid-related data into the physician clinical workflow through state-run PDMPs. This includes encouraging users to register and use PDMPs; enabling users to access data in as close to real time as possible; providing tools for the PDMP to notify users of potential misuses of controlled substances including inappropriate prescribing; encouraging analysis of PDMP data to help prevent inappropriate prescribing, diversion and misuse; enhancing interoperability of health information technology and PDMPs; and facilitating and encouraging data exchange between PDMPs among the states.

Section 2105 of this legislation would require that prior authorizations related to Part D prescriptions that are processed electronically use a standard format; thereby, improving the efficiency in which authorizations are processed enabling beneficiaries to more promptly receive needed drugs. ACP is encouraged that this could be a good first step in streamlining administrative processes. During House consideration of the Standardizing Electronic Prior Authorization for Safe Prescribing Act of 2018, ACP

provided detailed [recommendations](#) on improving prior authorization within Medicare Part D but also pressed upon the need for greater harmonization of standards implementation and automation of prior authorization across the health care industry, as a goal for broader legislation in the future.

Prior authorization and other administrative burdens consume a massive amount of physician and staff time and contribute to physician burnout, delays in appropriate patient care, and medical errors. To facilitate the elimination, reduction, alignment, and streamlining of administrative tasks, all key stakeholders should collaborate in better utilizing existing health information technologies, as well as developing more innovative approaches.

Opioid Prescribing and Physician Education

ACP firmly believes that physicians are obligated by the standards of medical ethics and professionalism to practice evidence-based, conscientious pain management that prevents illness, reduces patient risk, and promotes health. The College recommends that physicians must become familiar with, and follow as appropriate, clinical guidelines related to pain management and controlled substances, such as prescription opioids, as well as nonopioid pharmacologic and nonpharmacologic interventions. The College has organized a collection of resources under the featured heading “Opioid Epidemic” as part of our Online Learning Center, aimed at helping physicians better treat patients with pain and/or opioid use disorder. The resources cover opioid therapy, pain management, behavioral health, and substance use disorder.

ACP believes that training in screening and treatment of substance use disorders should be embedded in the continuum of medical education and continuing medical education providers should offer courses to train physicians in addiction medicine, medication-assisted therapy, evidence-based prescribing, and identification and treatment of substance use disorders. We are also pleased that Section 1502 of this legislation would authorize grants to provide additional education and training for the health care workforce to improve treatment for individuals with opioid and substance use disorders. This section would increase education and training in pain care by requiring grant recipients to develop comprehensive education and training plans. Such plans would include information on the dangers of opioid abuse, early warning signs of opioid use disorders, safe disposal options, and other innovative deactivation mechanisms. It would update pain care programs to include alternatives to opioid pain treatment and promote non-addictive, non-opioid, and non-pharmacologic treatment.

Arbitrary partial fill limits that are not based on evidence or practice protocol may place a substantial burden on seniors, patients in rural or medically-underserved areas, and those recovering from surgery that may not be able to travel to receive a refill. ACP is concerned that establishing mandatory partial fill limits without an exception process or opportunity to re-evaluate whether a patient needs additional medication could place a serious burden on patients and physicians alike. ACP expressed similar concerns to the CDC regarding its Draft Guidelines for the Use of Opioids for Chronic Pain and noted that the proposed 3-day limit without modification can too easily be rigidly and inappropriately applied by payers. Section 1501 of this legislation would authorize a study on the implementation of prescribing limits on opioids and would require HHS, in consultation with the Attorney General, to submit to Congress a report on the impact of federal and state laws and regulations that limit the length, quantity, or dosage of opioid prescriptions. ACP would support a careful study and report of

federal and state laws and regulations that limit the length, quantity, or dosage of opioid prescriptions so that the effect of the policy on patients is better understood.

Integration of Behavioral Health in Primary Care

The College strongly supports reforming Medicare and Medicaid payment policies to integrate behavioral health-screening, referral, and treatment of opioid and substance use disorders-better into the primary care setting. Primary care is the appropriate platform to care for these patients as it is often the first point of contact of care for patients with these disorders. Many patients with chronic pain present co-morbid behavioral health conditions, including anxiety and depression that can impact pain and its management. Unfortunately, many barriers to the seamless integration of behavioral and primary care exist in the physician payment structures of Medicare and Medicaid. For example, behavioral and physical health care clinicians have a long history of operating in different care silos and reimbursement policies have not always incentivized integrated, team-based care.

An additional pathway for the integration of behavioral health may be found in Section 2109 of this legislation which would require that CMS conduct a five-year demonstration project to test Medicare coverage and payment for opioid use disorder treatment services furnished by an Opioid Treatment Program that meets SAMHSA requirements. It requires that CMS make a bundled payment for treatment services that covers: dispensing and administering FDA-approved opioid treatment medications, substance use disorder counseling; individual and group therapy; toxicology testing; and other services determined appropriate. This demonstration project provides an opportunity to show the benefits of integrated team-based care within Medicare so that patients in need of treatment for pain will benefit from improved care.

Conclusion

In closing, we would like to thank you for your efforts in developing comprehensive legislation, the Opioid Crisis Response Act of 2018, to address the opioid epidemic. We hope that our feedback on specific elements of the bill will be helpful to you as this legislation moves forward through the Senate and on to conference committee deliberations.

Sincerely,

A handwritten signature in cursive script that reads "Ana María López".

Ana María López, MD, MPH, FACP
President