

April 11, 2018



The Honorable Lamar Alexander
Chairman, U.S. Senate Committee on Health,
Education, Labor & Pensions
428 Senate Dirksen Office Building
Washington, D.C. 20510

The Honorable Patty Murray
Ranking Member, U.S. Senate Committee on
Health, Education, Labor & Pensions
428 Senate Dirksen Office Building
Washington, D.C. 20510

Dear Chairman Alexander and Ranking Member Murray:

The Patient Quality of Life Coalition (PQLC) appreciates the opportunity to provide feedback on your Committee's discussion draft of the Opioid Crisis Response Act of 2018. The PQLC was established in 2013 to advance the interests of patients and families facing serious illness. The Coalition includes over 40 organizations dedicated to improving quality of care and quality of life for these patients – from pediatrics to geriatrics – and to advancing public policies that improve and expand access to palliative care and appropriate pain management for these individuals. PQLC members represent patients, health professionals, and healthcare systems.

The PQLC is mindful of the serious and growing public health crisis caused by the inappropriate use of opioids, and supports evidence-based efforts to reduce harm and adverse events associated with such misuse. At the same time, we want to make sure that public policies intended to reduce inappropriate use of opioids do not simultaneously create access barriers to pain management and symptom relief for patients suffering from serious illness – such as cancer, heart disease and Alzheimer's – for whom opioids are medically indicated, and who can safely benefit from these medications.

Pain management is an integral part of palliative care for many patients with serious illness.¹ These patients commonly experience pain due to their underlying illness(es) and sometimes the treatment itself, yet pain and other symptoms tend to be under-recognized and under-treated as part of regular care.² Poorly managed pain in this population can contribute to decreased productivity, poorer quality of life, increased health care utilization, and even increased mortality.³ Palliative care helps prevent and relieve pain by systematically screening and assessing for pain and other symptoms, tailoring pharmacological and other interventions to patients' individual circumstances (including medical history and stated goals of care), and carefully monitoring and adjusting treatment regimens as needed over the course of the illness.⁴

¹ "Serious illness" is defined as a health condition that carries a high risk of mortality and either negatively impacts a person's daily function or quality of life, or excessively strains their caregivers. See Kelley AS, Bollen-Lunds E. Identifying the Population with Serious Illness: The "Denominator" Challenge. *J Palliat Med.* 2017 Nov 10. doi: 10.1089/jpm.2017.0548.

² Wilkie DJ, and Ezenwa MO. Pain and symptom management in palliative care and at end of life. *Nurs Outlook.* 2012; 60(6):357-364. doi: 10.1016/j.outlook.2012.08.002. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3505611/pdf/nihms408159.pdf>

³ "Management of pain in older adults." *Geriatric Palliative Care.* Eds. Chai E, Meier DE, Morris J, and Goldhirsch S. New York: Oxford University Press, 2014. 159-169. Print.

⁴ Morrison LJ, and Morrison RS. Palliative care and pain management. *Med Clin N Am.* 2006; 90(5):983-1004. doi: 10.1016/j.mcna.2006.05.016. Retrieved from <https://www.ncbi.nlm.nih.gov/pubmed/16962853>

We have the following comments regarding specific sections of the Opioid Crisis Response Act of 2018:

TITLE II – RESEARCH AND INNOVATION

The legislation includes the ACE Research Act, which increases the flexibility for the National Institutes of Health (NIH) to approve “high impact, cutting-edge projects” that address the opioids crisis more quickly and efficiently, including finding new, non-addictive pain treatments. The PQLC is supportive of increasing funding for research in these areas, and increasing focus on finding new ways to treat pain. This will help palliative care patients maintain their quality of life while dealing with serious illness.

TITLE III – MEDICAL PRODUCTS AND CONTROLLED SUBSTANCES SAFETY

Just as increasing research on pain and new methods of pain management is important, it is also important that the U.S. Food and Drug Administration (FDA) is focusing on bringing potential new and better treatments to market. The legislation includes several provisions that help FDA focus on developing non-opioid or non-addictive medical products intended to treat pain. The PQLC is supportive of this focus, as it will increase the options palliative care clinicians have in effectively treating their patient’s symptoms, and hopefully lead to better outcomes for patients.

The legislation requires FDA to issue draft and final guidance to “clarify the circumstances under which the FDA considers misuse and abuse of drugs in making determinations of safety” of drugs. We note that FDA has already established the Risk Evaluation Mitigation Strategies (REMS) process to make such considerations. We encourage the Committee, and FDA upon implementation of this provision, to consider what authority the REMS process already gives the agency, and whether the goals of this provision could be accomplished by updating or improving the REMS for opioids rather than creating new policy or a new process.

The legislation clarifies FDA’s authority to require drug manufacturers to package certain drugs, including opioids, to allow a set treatment duration – for example, a “blister pack,” for patients who may only need a 3- or 7-day supply. The PQLC is supportive of FDA requiring manufacturers to make this type of packaging available as an option, as it will reduce the supply of unused medication available for diversion. However, we caution the Committee and FDA from a policy that would require opioids *only* be available in blister packs or other such limited duration packaging. In many cases, blister packs would not be convenient or appropriate for patients being treated for chronic pain, cancer-related pain or serious illness who are taking these medications long-term. In fact, some patients with serious illness have decreased dexterity and would find it impossible to extract their medication from blister packs. Blister packs should be an option for prescribers and pharmacists to use for shorter-duration treatment, but standard packaging options must still be available.

The legislation clarifies FDA’s authority to require manufacturers to provide patients a simple and safe way to dispose of leftover drugs as part of the packaging. The PQLC is supportive of this authority as it will reduce the supply of unused medication available for diversion. This will also make it easier for palliative care patients – or family members of such patients who have passed away – to dispose of their unused medication in a convenient manner. This is an extra convenience for individuals who are already dealing with complex, stressful situations.

On a similar matter, the legislation will allow hospice care providers to safely and properly dispose of controlled substances following a patient's death, by requiring the Drug Enforcement Agency (DEA) to issue regulations to specify how hospice programs should dispose of unneeded substances in the hospice care setting. However, we would point out that there are instances where living patients may change medications or formulations (from pill to liquid for example), leaving unused medications in the home that could be diverted for misuse. We recommend the legislation's authority be modified to allow hospice employees to dispose of *any* unused medications during *any* time during the election of hospice. Furthermore, we recommend refining the legislation to specify the clinical disciplines to which the authority would apply so that there is no confusion over which personnel would be permitted to destroy the medications. We recommend the authority to destroy medication include all members of the appropriate clinical hospice team.

TITLE V – PREVENTION

The legislation requires HHS to release a study on the impact of federal and state laws and regulations that limit the length, quantity, or dosage of opioid prescriptions. Legislative text specifically requires the report to address the impact of these prescribing limits on the medically appropriate use of and access to opioids, pain management outcomes for patients taking opioids, any associated negative health outcomes, patient access to treatment or to providers, and burdens for prescribers of opioids. The PQLC continues to be very concerned about the impacts of these limits on patient access to pain management and palliative care more broadly. We are encouraged that this legislation would require HHS to address these impacts, and upon enactment would urge HHS to make sure these questions are thoroughly explored in the report, including through data tracking and quantitative analysis.

We also urge the Committee to add language to this section requiring that the analysis of impacts includes provisions that specifically address patient populations that are supposed to be excluded from current prescribing limits – populations which sometimes include hospice, palliative care, and/or cancer patients. This concept could be included by inserting the following language to Sec. 501(1)(D): “including for patient populations exempted from such limits.”

The legislation also reauthorizes the Program for Education and Training in Pain Care, administered by the Health Resources and Services Administration (HRSA), which awards grants to entities to train health care professionals in pain care. This program was established in 2010, with strong support from many members of the PQLC, to address the need to education providers in diagnosing and treating pain for patients with serious and advanced illness. The PQLC strongly endorses this program, as we believe more clinicians need quality training in pain management.

However, we are concerned about the changes to the language regarding the responsibilities and focus of awarded entities. In several places, the bill changes the authorizing language to include prevention and detection of addiction within the scope of funded education and training. We are concerned that these changes take the focus of the program away from pain treatment for seriously ill patients and shifts it to prevention of abuse and misuse. Research does not indicate that the seriously ill patient population – which this program is intended to serve – is at any higher risk for opioid addiction, misuse

or abuse than the general population. Therefore, we strongly urge the Committee to remove the language changes that shift the focus of this program away from pain treatment.

We also note that the changes to the authorizing language in Sec. 502 of the bill represent language more inclusive of non-addictive and non-pharmacological treatments for pain. PQLC has long supported ensuring that palliative care patients have access to all treatments and care that are proven to help maintain quality of life so that clinicians can make the best treatment choices for their patients. We support the updates to the language because they are inclusive of more treatments.

PALLIATIVE CARE AND HOSPICE EDUCATION AND TRAINING ACT (PCHETA)

Lastly, we urge the Committee to consider including bi-partisan legislation that addresses the proactive need to expand research in pain, palliative care and symptom management at the National Institutes of Health, and expand education and training of providers in the medical subspecialty of palliative care who are on the front lines of treating patients with serious illness. The Palliative Care and Hospice Education and Training Act (PCHETA), S. 693 in the Senate and H.R. 1676 in the House of Representatives, has strong bi-partisan support in both chambers, and has been identified as legislation that includes balanced policy solutions that would positively impact care for patients with serious illness who live with pain and other distressing symptoms due to a serious illness.

PCHETA will complement the provisions in the Discussion Draft by ensuring an improved infrastructure to teach and implement best practices for pain management. S. 693 facilitates enhanced training opportunities for doctors, nurses and other health professionals who treat patients suffering from chronic or acute pain related to serious illness or multiple chronic conditions and who have legitimate need for opioid therapy and can benefit safely from these medications.

It is critical to elevate the knowledge of appropriate prescribing of controlled substances across various providers and specialties. Today, there is little to no curricula on managing pain in medical and nursing schools. PCHETA would expose students (medical students, nursing students, pharmacy students, social work students, etc.) to palliative care education and training early on (before they choose the area in which they will practice) so they develop skills in assessing and managing pain, leading to more effective, evidence-based prescribing. Palliative care also focuses on care coordination (across providers, pharmacists, etc.), so expanding these skills can further play a role in stemming opioid misuse. Further, PCHETA ensures we have trained faculty in medical, nursing, and other health professions schools who can incorporate appropriate pain management education into their teaching.

In addition, PCHETA would require the NIH to expand and intensify research programs in pain and palliative care. Currently a fraction of one percent of NIH funds are spent in this area. This holds great potential to strengthen clinical practice and health care delivery, including integrative approaches to pain care.

We would welcome the opportunity to discuss the PCHETA legislation further and attach a document offering additional detail for your review.

Thank you again for the opportunity to provide feedback on the important issues in this draft legislation. The PQLC commends the Committee for the bi-partisan and transparent process it has employed in bringing this draft forward, including multiple hearings on the topic of opioid misuse and abuse, and our members look forward to working with you to advance sound policy that balances efforts to stem to the opioid crisis with preserving access for patients with serious illness who legitimately require opioids for treatment of their pain and other distressing symptoms. If you have any questions, please contact Keysha Brooks-Coley, Chair of the Patient Quality of Life Coalition, at 202-661-5720 or Keysha.Brooks-Coley@cancer.org.

Sincerely,

Academy of Integrative Pain Management
Association of Oncology Social Work
Association of Pediatric Hematology / Oncology Nurses
American Academy of Hospice and Palliative Medicine
American Cancer Society Cancer Action Network
Cancer Support Community
Catholic Health Association of the US
Center to Advance Palliative Care
Hospice and Palliative Nurses Association
National Palliative Care Research Center
National Patient Advocate Foundation
Oncology Nursing Society
ResolutionCare Network
Pediatric Palliative Care Coalition
Physician Assistants in Hospice and Palliative Medicine
Supportive Care Coalition

ATTACHMENT: PCHETA Bill Summary



Palliative Care & Hospice Education and Training Act

H.R. 1676 / S. 693

Background

Palliative care improves quality of life, enhances patient and family satisfaction with care, and controls costs for the rapidly expanding population of individuals with serious illness or multiple chronic conditions. In 2000, less than 25% of U.S. hospitals had a palliative care program, compared with 75% in 2015. Yet, not all these programs have in place the interdisciplinary team necessary to provide comprehensive, high-quality palliative care. At the same time, palliative care is increasingly being provided in community settings. This growth comes in response to the increasing numbers and needs of Americans living with serious or complex chronic illnesses and the realities of the care responsibilities faced by their families. Palliative care is a relatively new medical specialty, and more must be done to ensure patients and providers understand its benefits and that an adequate, appropriately trained workforce is available to provide the pain and symptom management, intensive communication and level of care coordination that addresses the episodic and long-term nature of serious and complex chronic illness.

Bill Summary

PALLIATIVE CARE AND HOSPICE EDUCATION CENTERS

Establishes Palliative Care and Hospice Education Centers to improve the training of interdisciplinary health professionals in palliative care; develop and disseminate curricula relating to palliative care; support the training and retraining of faculty; support continuing education; provide students with clinical training in appropriate sites of care; and provide traineeships for advanced practice nurses.

PHYSICIAN TRAINING

Authorizes grants or contracts to schools of medicine, teaching hospitals and graduate medical education programs to train physicians (including residents, trainees, and fellows) who plan to teach palliative medicine. Such programs will provide training in palliative medicine through a variety of service rotations, such as consultation services, acute care services, extended care facilities, ambulatory care and comprehensive evaluation units, hospice, home health, and community care programs. Programs will be required to develop specific performance-based measures to evaluate the competency of trainees.

ACADEMIC CAREER AWARDS

Establishes a program to promote the career development of physicians who are board certified or board eligible in Hospice and Palliative Medicine and have a junior (non-tenured) faculty appointment at an accredited school of medicine. Eligible individuals must provide assurance of a full-time faculty appointment in a health professions institution and commit to spend a majority of funded time teaching and developing skills in interdisciplinary education in palliative care.

WORKFORCE DEVELOPMENT

Establishes fellowship programs within the new Palliative Care and Hospice Education Centers to provide short-term intensive courses focused on palliative care. Supporting the team approach to palliative care, the fellowships will provide supplemental training for faculty members in medical schools and other health professions schools, including pharmacy, nursing, social work, chaplaincy and other allied health disciplines in an accredited health professions school or program (such as a physician assistant education program) so providers who do not have formal training in palliative care can upgrade their knowledge and skills for the care of individuals with serious or life-threatening illness as well as enhance their interdisciplinary teaching skills.

CAREER INCENTIVE AWARDS

Provides grants or contracts for eligible health professionals who agree to teach or practice in the field of palliative care for at least 5 years. Eligible individuals include: advanced practice nurses, social workers, physician assistants, pharmacists, or students of psychology who are pursuing a doctorate, masters, or other advanced degree with a focus in palliative care or related fields in an accredited health professions school.

NURSE TRAINING

Creates special preferences in existing nurse education law for hospice and palliative nursing, in education, practice and quality grants, workforce development, and nurse retention projects.

PALLIATIVE CARE EDUCATION AND AWARENESS

Provides for the establishment of a national campaign to inform patients, families and health professionals about the benefits of palliative care and the services that are available to support patients with serious or life-threatening illness. Directs the dissemination of information, resources and materials about palliative care services to health professionals and the public in a variety of formats, in consultation with professional and patient stakeholders.

ENHANCED RESEARCH

Directs the National Institutes of Health to use existing authorities and funds to expand palliative care research to advance clinical practice and improve care delivery for patients with serious or life-threatening illness.
