

Reducing Opioid Risk Act

Senator Elizabeth Warren and Senator Shelly Moore Capito

Major increases in the prescribing of dangerous painkillers have significantly contributed to the opioid epidemic. From 2000 to 2015, the number of opioid prescriptions in Massachusetts increased by about 7% annually,¹ and West Virginia's opioid prescribing rate remained 44% higher than the national average in 2016.²

In 2016, Senators Warren and Capito introduced the *Reducing Unused Medications Act*, which allows prescriptions for opioid medications to be partially filled by pharmacists at the request of patients or doctors.³ The bipartisan bill, which became law as part of the *Comprehensive Addiction and Recovery Act of 2016*, gave families, health care providers, and states additional tools to limit the number of unused pills left in family medicine cabinets.⁴

However, in order for these new tools to make a difference in the opioid crisis, patients and their doctors and pharmacists need to know about the option to partially fill a prescription. During 2017, Senators Warren and Capito sent a series of letters to every governor in the country and major medical organizations, soliciting feedback on the implementation of the new partial fill option.⁵ Responses indicated that while states and medical groups are eager to increase the partial filling of prescriptions, implementation of the new law remains uneven.

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The bipartisan *Reducing Opioid Risk Act* builds on the *Reducing Unused Medication Act* by clarifying the FDA's authority to require drug companies to educate health care providers about state and federal regulations of controlled substances, including the partial fill option.

The bill adds language to the part of the Food, Drug, and Cosmetic Act that specifies the FDA's authority with regard to Risk Evaluation and Mitigation Strategies (REMS), one of the major tools used by the FDA to ensure drug safety. REMS are risk-management plans that drug companies must develop and deploy to ensure that a product can be used safely, and that the benefits of its use outweigh the risks.⁶ For instance, if a drug could cause a serious allergic reaction, the FDA might require a REMS in which the drug is only administered in a health care setting.⁷ REMS strategies also commonly require drug companies to provide continuing education to doctors about how to safely prescribe a product.

¹ Massachusetts Department of Public Health, "The Massachusetts Opioid Epidemic" (online at: <http://www.mass.gov/chapter55/#chapter55>).

² Centers for Disease Control and Prevention, "U.S. Prescribing Rate Maps," (July 31, 2017) (online at: <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html>).

³ "Warren, Capito, Clark and Stivers Introduce Bipartisan, Bicameral Bill to Allow Partial Filling of Opioid Prescriptions" (February 24, 2016) (online at: <https://www.warren.senate.gov/newsroom/press-releases/warren-capito-clark-and-stivers-introduce-bipartisan-bicameral-bill-to-allow-partial-filling-of-opioid-prescriptions>).

⁴ "Warren, Capito, Alexander, Bennet, Clark, Stivers Applaud Incorporation of Reducing Unused Medications Act in Final Passage of Bipartisan, Bicameral Legislation" (July 14, 2016) (online at: <https://www.warren.senate.gov/newsroom/press-releases/warren-capito-alexander-bennet-clark-stivers-applaud-incorporation-of-reducing-unused-medications-act-in-final-passage-of-bipartisan-bicameral-legislation>).

⁵ "Warren and Capito Press FDA, Governors, and Medical Organizations to Implement New Partial Fill Law in Battle Against National Opioid Crisis" (September 6, 2017) (online at: <https://www.warren.senate.gov/newsroom/press-releases/warren-and-capito-press-fda-governors-and-medical-organizations-to-implement-new-partial-fill-law-in-battle-against-national-opioid-crisis>).

⁶ U.S. Food and Drug Administration, "Risk Evaluation and Mitigation Strategies" (February 2, 2018) (online at: <https://www.fda.gov/Drugs/DrugSafety/REMS/default.htm>).

⁷ U.S. Food and Drug Administration, "Frequently Asked Questions (FAQs) about REMS" (January 26, 2018) (online at: <https://www.fda.gov/Drugs/DrugSafety/REMS/ucm592627.htm>).