

THE OPIOID ABUSE DETERRENCE, RESEARCH, AND RECOVERY ACT

SECTION-BY-SECTION SUMMARY

Summary. This legislation would deter opioid abuse and addiction, establish additional registration requirements for prescribers of opioids, encourage the development of abuse-deterrent formulations, require a study and report on policy changes that may have contributed to the opioid epidemic.

Section 1. Short Title. The “Opioid Abuse Deterrence, Research, and Recovery Act of 2017.”

Section 2. Registration Requirements for Prescribers.

The legislation amends Section 303 of the Controlled Substances Act (21 U.S.C. 823) by requiring any practitioner licensed under State law who prescribes schedule II or III controlled substances to submit to the Attorney General a certification during his or her registration and renewal that he or she will not prescribe any opioid for the initial treatment of acute pain unless the prescription is for less than 7 days or falls within a State-established prescription limit.

This certification does not prevent a practitioner from prescribing a schedule II or III opioid that is approved by the FDA for opioid use disorder treatment, for immediate, post-operative pain relief; or for more than 7-days if the prescription aligns with a clear medical standard of care, is documented in the patient’s medical record and consults the applicable State electronic health record system or prescription drug monitoring program.

The legislation defines “Acute Pain” as pain with abrupt onset and caused by an injury or other process that is diagnostically determined to have minimal risk of escalating in intensity. The legislation does not classify chronic pain or pain being treated as part of cancer care, hospice, end-of-life care, or palliative care as “Acute Pain.”

Section 3. Encouraging Development of Abuse-Deterrent Formulations.

The legislation instructs the FDA Commissioner to continue working with stakeholders to encourage the development of abuse-deterrent opioids.

Section 4. GAO Study and Report on Policy Changes that May have Contributed to the Opioid Epidemic.

Not later than 2 years of enactment, the Comptroller General must complete a study and submit a report to Congress analyzing the health care policy changes that may have contributed to the increase in opioid overdoses and deaths. This study will include:

- (1) A review of the health-care related legislative, administrative, and judicial decisions by the Federal Government that have had affected access to pharmaceutical pain management strategies;
- (2) An analysis of the financial and non-financial costs and benefits of reversing or revising such decisions;
- (3) An analysis of the differences and effectiveness of State-based prescription drug monitoring programs;
- (4) An analysis of the impacts of State and Federal prescribing limitations on patient medical outcomes,
- (5) An analysis of the costs of using abuse-deterrent opioids compared to non-abuse-deterrent opioids.

Section 5. Study on the Feasibility of Replacing Statutory Limits with Clinical Guidelines on Opioid Prescribing.

The Commissioner of the FDA shall conduct a study of the feasibility of replacing this bill’s prescribing limits with evidence-based clinical guidelines, including a limitation on the first opioid prescription for an acute pain diagnosis and the incorporation of evidence-based screening tools into routine medical visits to monitor misuse of opioids and other controlled substances.

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