S. 483

Ensuring Patient Access and Effective Drug Enforcement Act of 2015

S. 483 is a bipartisan bill reintroduced by Senators Orrin Hatch (R-UT) and Sheldon Whitehouse (D-RI) that seeks to prevent prescription drug abuse and diversion and ensure patient access to necessary medications by creating a more collaborative partnership between drug manufacturers, wholesalers, pharmacies, and federal enforcement and oversight agencies.

Background

Millions of Americans depend on prescription drugs to treat and cure illness, alleviate pain, and improve quality of life. Unfortunately, prescription drug abuse kills tens of thousands of Americans each year . Federal agencies and private parties in the drug supply chain are working diligently to prevent drug abuse and diversion; however, it is also imperative that patients with legitimate pain are able to obtain their prescriptions without disruption.

S. 483 seeks to facilitate greater collaboration between industry stakeholders and regulators so that pharmacists can fill their patients' prescriptions when they are needed.

The Ensuring Patient Access and Effective Drug Enforcement Act of 2015 will amend the Controlled Substances Act to:

Give pharmacies the opportunity to submit a corrective action plan prior to revocation or suspension of their license: Requires an order to show cause as to why such a registration should be denied, revoked, or suspended to: (1) contain a statement of the basis for the denial, revocation, or suspension, including specific citations to any laws or regulations alleged to be violated; (2) direct the applicant or registrant to appear before the Attorney General at a specific place no less than 30 days after receipt of the order; and (3) notify the applicant or registrant of the opportunity to submit a corrective action plan on or before such appearance; and

Requires a report to Congress on the effects of law enforcement activities on patient access to medications and that the report incorporate feedback and recommendations form pharmacies: Directs the Secretary of Health and Human Services to submit a report identifying: (1) obstacles to legitimate patient access to controlled substances; (2) issues with diversion of controlled substances; and (3) how collaboration between federal, state, local, and tribal law enforcement agencies and the pharmaceutical industry can benefit patients and prevent diversion and abuse of controlled substances.

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