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S.483 - Ensuring Patient Access and Effective Drug Enforcement Act of 2016

114th Congress (2015-2016)

Sponsor: Sen. Hatch, Orrin G. [R-UT] (Introduced 02/12/2015)
Committees: Senate - Judiciary
Latest Action: 04/19/2016 Became Public Law No: 114-145. (TXT | PDF) (All Actions)
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Summary(3) Text(5) Actions(15) Titles(5) Amendments(0) Cosponsors(4) Committees(1) Related Bills(1)

There are 3 summaries for S.483. Public Law (04/19/2016) ▼

Bill summaries are authored by CRS.

Shown Here:
Public Law No: 114-145 (04/19/2016)

(This measure has not been amended since it was reported to the Senate on February 11, 2016. The summary of that version is repeated here.)

Ensuring Patient Access and Effective Drug Enforcement Act of 2016

(Sec. 2) This bill amends the Controlled Substances Act to define phrases related to the Drug Enforcement Administration's (DEA's) authority to register manufacturers, distributors, and dispensers of controlled substances.

Currently, the DEA registers a controlled substances manufacturer, distributor, or dispenser if it is in the public interest after considering certain factors, including factors relevant to and consistent with the public health and safety. This bill defines "factors as may be relevant to and consistent with the public health and safety" to mean factors relevant to and consistent with the specified purposes of the Controlled Substances Act.

Additionally, current law allows the DEA to immediately suspend a registration to prevent imminent danger to the public health and safety. This bill defines "imminent danger to the public health and safety" to mean an immediate threat of death, serious bodily harm, or abuse of a controlled substance due to a registrant's failure to maintain effective controls against diversion.

The bill revises and expands the required elements of an order to show cause issued by the DEA before it denies, revokes, or suspends a registration for a Controlled Substances Act violation. An order to show cause must specifically state the legal basis for the action and notify the registrant of the opportunity to submit a corrective action plan.

(Sec. 3) The Food and Drug Administration, the Substance Abuse and Mental Health Services Administration, the Agency for Research and Quality, and the Centers for Disease Control and Prevention, in coordination with the DEA, must report to Congress on:

- obstacles to legitimate patient access to controlled substances;
- diversion of controlled substances;
- how collaboration between law enforcement agencies and the pharmaceutical industry can benefit patients and prevent diversion and abuse of controlled substances;
- the availability of and gaps in medical education, training opportunities, and comprehensive clinical guidance for pain management and opioid prescribing;
- enhancements to prescription drug monitoring programs; and
- improvements to prescription opioid reporting requirements.