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[H.R. 471, the Ensuring Patient Access and Effective Drug Enforcement Act of 2015, as amended](#)

FLOOR SITUATION

On Tuesday, April 21, 2015, the House will consider [H.R. 471](#), the *Ensuring Patient Access and Effective Drug Enforcement Act of 2015, as amended*, under a suspension of the rules. The bill was introduced on January 22, 2015 by Rep. Tom Marino (R-PA) and was referred to the Committee on Energy and Commerce, and in addition to the Committee on Judiciary. The Committee on Energy and Commerce ordered the bill reported by voice vote on February 12, 2015.¹

SUMMARY

H.R. 471 amends the Controlled Substances Act² to promote consistency in Department of Justice regulatory and enforcement activities related to the distribution of controlled substances. The bill clarifies two key phrases under the Act in an effort to provide the Attorney General with clearly defined rules for providers. The bill also provides registrants under the Controlled Substances Act with an opportunity to submit a corrective action plan prior to having their registration revoked or suspended, unless there is an imminent danger to the public health or safety and an immediate suspension order has been issued.

H.R. 471 defines the phrase “imminent danger to the public health or safety” to mean, in the absence of an immediate suspension order, controlled substances will continue to be distributed or dispensed by a registrant (pharmacies and other prescription drug providers) who knows or should know through fulfilling the obligations of the registrant under this Act; (1) the dispensing (of controlled substance prescriptions) is outside the usual course of professional practice; (2) the distribution or dispensing poses a present or foreseeable risk of adverse health consequences or death due to the abuse or misuse of the controlled substances; or (3) the controlled substances will continue to be diverted outside of legitimate distribution channels.

The bill also defines the phrase “factors as may be relevant to and consistent with the public health and safety” to mean those that are consistent with the findings and declarations included in Section 101 of the Controlled Substances Act.

¹ <http://energycommerce.house.gov/markup/hr-734-hr-212-hr-471-hr-639-hr-647-and-hr-648>

² See [Public Law 91-513](#)

In addition, within one year of enactment, the bill would require the Secretary of the Department of Health and Human Services, acting through, and in consultation with, other specified agencies, to assess the effect of law enforcement activities on patient access to medications, examine potential benefits to patients from collaborations between governments and stakeholders, and report findings to Congress.

BACKGROUND

According to the Centers for Disease Control and Prevention (CDC), since 1999, the amount of prescription painkillers prescribed and sold in the United States has nearly quadrupled, yet there has not been an overall change in the amount of pain Americans report experiencing. In 2013, nearly two million Americans abused prescription painkillers and, on average, 44 Americans die every day from prescription drug overdoses. The CDC attributes this epidemic, in part, to changes in how providers prescribe pain killers, and wide variation in their prescription among states that cannot be explained by differences in health issues from state-to-state.³

The prescription drug supply chain involves many stakeholders, including drug manufacturers, wholesale distributors, doctors, nurses, pharmacists, hospitals, and retail pharmacies. Protecting the system from criminal exploitation and ensuring its efficiency requires significant resources for government enforcement and oversight agencies and clear standards and rules for prescription drug providers. H.R. 471 would clarify these rules by providing certainty about how federal authorities will apply the law when undertaking enforcement actions. The clear and consistent enforcement standards are designed to help prevent drug abuse and ensure patients have access to needed medications by promoting greater collaboration among government agencies, industry stakeholders and patients.

A similar bill, [H.R. 4709](#), passed the House by voice vote on July 29, 2014.⁴ The Senate did not act on the House-passed bill in the 113th Congress.

COST

[CBO estimates](#) that implementing the bill would cost less than \$500,000 over the 2015 to 2016 period; any spending would be subject to the availability of appropriated funds. Enacting the legislation would not affect direct spending or revenues; therefore, pay-as-you-go procedures do not apply.

STAFF CONTACT

For questions or further information please contact [John Huston](#) with the House Republican Policy Committee by email or at 6-5539.

³ <http://www.cdc.gov/drugoverdose/epidemic/index.html>

⁴ See [CR H7004-7005](#).