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A BALANCING ACT: PENDING LEGISLATION SEEKS TO IMPROVE PRESCRIPTION DRUG ACCESS WHILE CURBING ABUSE

EXECUTIVE SUMMARY

On July 29, 2014, legislation designed to both combat prescription drug abuse and ensure patient access to prescription drugs advanced by voice vote in the House of Representatives. This legislation, bolstered by bipartisan sponsorship from Reps. Marsha Blackburn (R-TN), Judy Chu (D-CA), Tom Marino (R-PA) and Peter Welch (D-VT) is designed to clarify prescription drug laws to both improve compliance by pharmaceutical industry stakeholders and limit what some perceive as excessive enforcement by regulators.

The Ensuring Patient Access and Effective Drug Enforcement Act ("Act"), H.R. 4709, was introduced to the House of Representatives on May 21, 2014. Individuals involved in any step along the supply chain for pharmaceuticals, including patient groups, pharmacies, drug manufacturers, distributors, hospitals and law enforcement will want to familiarize themselves with the Act's provisions so that they better understand the government's enforcement tools and Drug Enforcement Administration's ("DEA") registrants' rights. On July 30, 2014, the Act was introduced to the Senate, read twice and referred to the Committee on Health, Education, Labor, and Pensions ("Committee"). The Committee will consider the Act and decide whether the Senate as a whole will vote on it.

DISCUSSION

The Act has two main objectives. One is to maintain medically legitimate patient access to prescription drugs. The Act attempts to accomplish this in part by modifying the Controlled Substances Act ("CSA") to enable the Attorney General to request that DEA registrants, facing a potential denial, revocation or suspension of their registration under Section 303 of the CSA, submit a corrective action plan. The Attorney General would review the corrective action plan and determine whether the denial, revocation or suspension proceedings should be discontinued or modified. This legislation aims to increase patient access to prescription drugs by enabling more registrants to keep their registrations when their CSA violations may be correctable. Registrants would not have the right to submit a corrective action plan if the Attorney General finds there is imminent danger to the public health and issues an immediate suspension order.

The other objective is to improve communication and coordination among a variety of stakeholders in the pharmaceutical industry. Within a year of enactment, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, the Director of the Centers for Disease Control and Prevention, along with the Administrator for the DEA and the Director of National Drug Control policy, must submit a report to Congress outlining:

- How legitimate patient access to controlled substances could be adversely affected by state and federal law enforcement activity;
- Issues with diversion of controlled substances; and
- Identifying how collaboration among agencies and stakeholders can benefit patients while preventing diversion and prescription drug abuse.

This report must incorporate feedback from patient groups, pharmacies, drug manufacturers, common or contract carriers, warehousemen, health care providers, state attorneys general, law enforcement, health benefit plans and wholesale drug distributers.

NEXT STEPS

The fact that the House of Representatives passed the Act demonstrates an increasing focus on a cooperative approach to help curb prescription drug abuse. If enacted, stakeholders may want to consider taking the opportunity to collaborate with government regulators to develop solutions to the prescription drug abuse epidemic that will help achieve the regulators objectives without being overly burdensome on those being regulated.

The Act has drawn support from the Healthcare Distribution Management Association and the National Association of Chain Drug Stores. With support from these national trade groups as well as bipartisan sponsorship and support, this Act potentially has a greater likelihood of being enacted.

The pharmaceutical industry and health care providers should continue to expect the government to spend substantial resources on combatting prescription drug abuse. To this end, pharmacies should ensure they have policies in place to address potential prescription drug diversion to mitigate the risk that the DEA will discipline them.

This article is educational in nature and is not intended as legal advice. Always consult your legal counsel with specific legal matters. If you have any questions or would like additional information about this topic, please contact Susan Bizzell at 317.977.1453 or sbizzell@hallrender.com, Nicholas Gonzales at 414.721.0486 or ngonzales@hallrender.com or your regular Hall Render attorney.

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