S. 483, ENSURING PATIENT ACCESS AND EFFECTIVE DRUG ENFORCEMENT ACT OF 2015
ONE-PAGE SUMMARY

Background:

Prescription drugs play a crucial role in treating and curing illness, alleviating pain, and improving quality of life for millions of Americans. Unfortunately, these drugs can also be abused. A balance is necessary to ensure that individuals who need prescription drugs for treatment receive them but that such drugs are not diverted for improper purposes.

Ambiguity in several key provisions of the Controlled Substances Act (CSA) complicates the ability of drug manufacturers, distributors, and pharmacies to safely deliver prescription drugs to patients. This ambiguity concerns the standard a company must satisfy in order to obtain a CSA registration and the circumstances under which a registration may be suspended. In addition, companies who inadvertently violate the CSA do not currently have an opportunity to submit a corrective action plan before their registrations are suspended and the supply chain of drugs to patients is interrupted. Bringing clarity to these provisions and facilitating collaboration between registrants and the DEA will enable companies to better comply with the CSA's requirements in order to ensure that patients receive the prescription drugs they need for treatment and cure.

Key Provisions:

- Clarifies the meaning of the phrase "other factors as may be relevant to and consistent with the public health and safety" in section 303 of the CSA (21 U.S.C. § 823).
    - *Explanation*: To prevent the abuse of prescription drugs, the CSA directs the Drug Enforcement Administration (DEA) to consider several factors when deciding whether to register an applicant to manufacture or distribute controlled substances. These factors include "such other factors as may be relevant to and consistent with the public health and safety." This vague language creates uncertainty among applicants regarding the measures by which they will be judged. S. 483 reduces this uncertainty by clarifying that "such other factors" means factors that are relevant to Congress's introductory findings in section 101 of the CSA (21 U.S.C. § 801).

- Defines the meaning of the phrase "imminent danger" in section 304 of the CSA (21 U.S.C. § 824).
    - *Explanation*: Section 304 provides that the Attorney General may, in her discretion, immediately suspend a registration to manufacture or distribute controlled substances if she finds there is an "imminent danger to the public health and safety." But the CSA does not define what constitutes an "imminent danger," leaving the Attorney General's authority under this provision essentially open-ended. S. 483 clarifies the Attorney General's authority by providing that "imminent danger" means that, due to the failure of a regisrant to maintain effective controls against diversion, there is a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration.

- Provides companies who violate certain requirements of the CSA an opportunity to correct their practices before the Attorney General suspends or revokes their registration.
    - *Explanation*: Even inadvertent violations of the CSA can lead to suspension or revocation, disrupting the supply chain for a company's prescription drugs. This in turn can cause hardship for patients who rely on the company's drugs for treatment and cure. S. 483 alleviates this problem by allowing companies to correct violations before suspension or revocation, ensuring that supply chains remain intact. This provision does not apply to instances where the Attorney General determines there is an imminent danger to the public health and safety.