Department of Planning and Budget
2016 Fiscal Impact Statement

1. **Bill Number:** HB528ER

House of Origin	☐	Introduced	☐	Substitute	☐ Engrossed
Second House	☐	In Committee	☐	Substitute	☒ Enrolled

2. **Patron:** Hodges

3. **Committee:** Health, Welfare and Institutions.

4. **Title:** Manufacture and distribution of prescription drugs in the Commonwealth.

5. **Summary:** Eliminates the requirement that the Board of Pharmacy establish and implement a pedigree system for recording each distribution of a controlled substance from sale by a pharmaceutical manufacturer to a dispenser or person who will administer the controlled substance; defines "co-licensed partner" as a person who, with at least one other person, has the right to engage in the manufacturing or marketing of a prescription drug, consistent with state and federal law, and specifies that a co-licensed partner may be a manufacturer of a controlled substance; and defines "third-party logistics provider" as a person who provides or coordinates warehousing of or other logistics services for a drug or device in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of the drug or device but does not take ownership of the product or have responsibility for directing the sale or disposition of the product. The bill specifies that bulk drug substances used for compounding drugs distributed by a supplier other than a licensed wholesale distributor or registered nonresident wholesale distributor must be provided by a supplier who is approved by the Board of Pharmacy as well as the federal Food and Drug Administration and requires every pharmacy, nonresident pharmacy, wholesale distributor, and nonresident wholesale distributor to comply with federal requirements for an electronic, interoperable system to identify, trace, and verify prescription drugs as they are distributed. The bill authorizes the Board of Pharmacy to deny, revoke, suspend, or take other disciplinary actions against holders of a third-party logistics provider permit, manufacturer permit, or nonresident manufacturer permit; applies the inspection and audit requirements that apply to wholesale distributors to nonresident wholesale drug distributors, third-party logistics providers, manufacturers, and nonresident manufacturers; creates a permitting process for third-party logistics providers; allows holders of a manufacturer permit to distribute the drug manufactured, made, produced, packed, packaged, repackaged, relabeled, or prepared to anyone other than the end user without the need to obtain a wholesale distributor permit; and creates a process for registration of nonresident manufacturers of prescription drugs.

6. **Budget Amendment Necessary**: No.

7. **No Fiscal Impact.**

8. **Fiscal Implications:** This bill would not have a fiscal impact on the Commonwealth. Costs for registration would be offset by fees paid by regulants.

9. **Specific Agency or Political Subdivisions Affected:** None.

10. **Technical Amendment Necessary:** No.

11. **Other Comments:** None.