NABP
National Association of Boards of Pharmacy

Drug Importation Talking Points

Background

In September 2021, NABP convened the Task Force on State Oversight on Drug Importation. The Task Force evaluated the current regulatory environment related to drug importation and identified several challenges that states will face in the regulation of drug importation.

Specifically, the Task Force identified several challenges and concerns with the existing Section 804 Importation Programs (SIP):

- Lack of board of pharmacy involvement in the development of the SIP;
- Creation of a separate, poorly regulated prescription drug supply chain within a state;
- Lack of funding/resources for appropriate regulation and enforcement; and
- Potential interjurisdictional issues with importers located in states that have not authorized importation.

Regulatory Guidelines for State Importation Programs

As states consider legislative or executive action to implement a drug importation plan, NABP recommends that state importation plans include the following characteristics/components to mitigate the negative impact on patient safety:

- All SIPs should include active participation of the state board of pharmacy, and other relevant regulatory boards.
- Establish new licensure/registration categories for foreign sellers and for importers.
- The new licensure/registration process should include, at a minimum:
    - Extensive background checks should be performed on foreign sellers and their affiliated businesses, agents, and principals, including at least five years of records for all foreign sellers;
    - If a foreign seller has been licensed for less than five years, they should be ineligible to participate in a SIP;
    - Foreign sellers should be licensed by Health Canada and their respective provincial authority;
    - Extensive background checks should be performed on all importers and their affiliated businesses, agents, and principals, including at least seven years of records for all importers;
    - If an importer has been licensed for less than seven years, they should be ineligible to participate in a SIP;
    - Importers should be either: (1) wholesalers appropriately licensed by all relevant state authorities and registered with Food and Drug Administration (FDA); or (2) pharmacists licensed by all appropriate boards of pharmacy where they are providing services;
    - All background checks should include a review by and recommendation from FDA's Office of Criminal Investigations (OCI). Although OCI's recommendation should be an important factor in evaluating a SIP Proposal, the recommendation should be kept confidential and remain within FDA;
    - Importers should submit an inspection of their facility conducted by a state regulatory agency or an approved third-party entity within the prior two years.

    - A conviction or final disciplinary action should not be required to deny a SIP Proposal; and
    - Foreign sellers should have an authorized agent registered and domiciled in the jurisdiction of the government sponsor of the importation plan that can be held.
- All SIP Proposals should be published and open to a reasonable public comment period.
- SIP Proposals should include and account for all licensure and enforcement costs, including, but not limited to initial and ongoing inspections, audits, and appropriate product testing.
- SIP Proposals should have a detailed methodology for detecting drug products that are suspected of transshipment.
- All SIP Proposals should include a consumer education campaign that informs patients about legal state importation programs vs illegal importation and the dangers of purchasing prescription drugs over the internet or social media.
- All SIP Proposals must include a process to collaborate with Health Canada and the relevant provincial regulatory authority to share information on licensing, inspections, drug shortages, and other information relevant to the SIP.