



State Efforts to Design and Implement Drug Importation Programs

Wisconsin Governor's Task Force on Reducing Prescription Drug Prices

**National Governors Association
June 18, 2020**

Agenda

- **Introductions, Haven Healthcare and Overview of Drug Importation Landscape**
 - Kate Johnson, NGA Health
- **Federal Regulations and State Drug Importation Efforts**
 - Jane Horvath, Horvath Health Policy
- **Utah Perspective on Drug Importation**
 - Rep. Norm Thurston, Utah House of Representatives
- **Prescription Drug Affordability Boards**
 - Jane Horvath, Horvath Health Policy

Haven Healthcare

- Non-profit established by Amazon, Berkshire Hathaway, and JPMorgan Chase in January 2018
 - Focus on improving health outcomes, patient experience, and lowering costs for U.S.-based employees and families from the three companies
 - Objectives include:
 - Easier access to primary care
 - Simpler and more user-friendly insurance benefits
 - Affordable prescription drugs
 - Effective use of data and technology
- Amazon and JPMorgan Chase piloting new health plans for employees in select states
- Atul Gawande, recently stepped down as CEO, now Chairman

Drug Importation Landscape

Federal Action

- Current law allows for wholesale importation of certain drugs from Canada if certain conditions are met, including certification by the Secretary of the U.S. Department of Health and Human Services (HHS), no additional risk to health and safety and significant reduction in cost to the consumer.
- July 2019 – Safe Importation Action Plan
 - Pathway 1: States, wholesalers, or pharmacists can submit plans for importation of Health-Canada approved drugs for HHS
 - Pathway 2: Manufacturers may import versions of drug products that they sell in foreign countries that are the same as the U.S. approved versions
- December 2019 – Notice of Proposed Rule Making (Pathway 1)

State Action

- Bills introduced in 23 states in 2020

Laws Enacted (2018 – 2020)	Concept Papers Submitted to HHS
<ul style="list-style-type: none">• <u>Colorado</u>• <u>Florida</u>• <u>Maine</u>• <u>New Mexico</u>• <u>Vermont</u>	<ul style="list-style-type: none">• <u>Colorado</u>• <u>Florida</u>• <u>Maine</u>• <u>Vermont</u>

6/18/2020

Jane Horvath

With Support of Arnold Ventures

WI Governor's Task Force

Importation: Federal Law

- **In general**, importing Rx into the US is not legal except under the control of the original manufacturer, except as follows:
- **Personal:** The FDA does not enforce the law for importation of drugs for individuals when quantity \leq 90 pills
- **Wholesale:** With Federal DHHS Secretarial approval, allows importation of wholesale quantities of drugs from Canada by wholesalers or pharmacies if safe and consumer savings are guaranteed
 - Biologics (including insulin and vaccines) excluded from importation
 - Imports only from Canada allowed

Importation: Proposed Regulation

- Federal Proposed Rule, December 2019.
 - Rule would effectuate the federal law that permits wholesale importation. Unclear when final rule will be published.
 - Several barriers for state wholesale importation under NPRM (list not exhaustive)
 - Imported product will be in finished packaging when imported, rather than large container shipments.
 - Number of Canadian suppliers will be limited which could complicate or stymie importation.
 - Product to be held at facility near a Customs office until tested
 - Unclear how many warehouse facilities are available at the US side of the border
 - In general, ~70% of US Rx supply is imported already by manufacturers. Federal law and regulation establish a safe, transparent, global supply chain that state wholesale import programs would use. Proposed regulation tries to add more requirements to wholesale importation that are not needed and make state importation very difficult on several levels.

Importation: State and Local Activities

- Enacted Wholesale Importation Laws: VT, FL, CO, ME, NM
 - Submitted Proposals: FL, VT, CO, ME
- Without change in federal law, state importation is unlikely to be very effective as more states attempt it.
 - Expand countries from which to import EU, United Kingdom, Japan
 - Permit wholesale importation of biologics (insulins, vaccines, other biologics)
- CanaRx: 500 US Employers (including state and local governments)
- Utah: to be discussed

State Importation Law and Bills

- VT, FL, CO, ME, NM have laws
- VT, ME, NM follow NASHP model act – statewide access to imported Rx through state-designated, limited number of wholesale importers
- FL – focus on government payers initially, then statewide. Law allows individual pharmacies to import (order and receive).
- CO- statewide and allows health plans and pharmacists to import.
- The proposed regs may not permit the FL or CO models as enacted. Proposed regs would allow one Canadian exporter, 1 state importer (that then distributes product)

Utah Perspective on Drug Importation

Prescription Drug Affordability Board

- Enacted in MD and ME – basically to help state and local government purchase and/or negotiate for lower costs
 - MD Board has open option to go statewide in several years with upper payment limits for some high cost drugs
 - Governor vetoed Board funding bill – assessment on plans, pbms and pharma companies
- WA Board bill vetoed by Governor
- States may not need legislation to create inter-departmental PBM contracts or multi-agency consolidated purchasing
- Rx Board bills introduced in ~11 other states in 2020



STATE OF WISCONSIN

**GOVERNOR'S TASK FORCE ON
REDUCING PRESCRIPTION DRUG PRICES**

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