RE: An Act To Facilitate the Personal Importation of Prescription Drugs from International Mail Order Prescription Pharmacies

OUR KEY CONCERNS
Our primary concerns about the new law are a lack of safety and privacy, unlicensed practice, and it's illegal.

SAFETY AND PRIVACY:
This new law breaks the safe and secure drug supply system in the US. FDA inspections have revealed that up to 69% of Rx drugs in mail shipments from foreign countries are unsafe and Canadian parcels accounted for 80% of those prescriptions. Examples of potentially dangerous products included counterfeit drugs, unapproved drugs, controlled substances, drugs withdrawn from the US market for safety reasons, and improperly packaged drugs.

This year, the FDA shut down 1,677 illegal pharmacy websites that sell potentially dangerous, unapproved prescription medications. The National Association of Boards of Pharmacy has reviewed over 10,000 online pharmacies and found that 97% are not compliant with practice standards.

Furthermore, international mail order brokers are not required to be HIPAA compliant. They can violate and sell your protected health information without any consequences.

UNLICENSED PRACTICE:
This new law has absolutely no reasonable measures to protect the public. Who's going to hold the unlicensed international mail-order brokers accountable? This is much bigger than CanaRx. This new law allows unlicensed brokers anywhere in the world to ship and sell drugs to people in Maine. When a Rx drug from an international broker causes an adverse event because it was misfilled, counterfeit or adulterated, what recourse will the patient have under this new law? Absolutely none! They can't file a complaint against an unlicensed broker with the Maine Board of Pharmacy. They have no regulatory or legal recourse against an unlicensed international broker.
The FDA reported in June of 2013 that, "Many of these websites appeared to be operating as part of an organized criminal network that falsely purported its websites to be "Canadian Pharmacies." "These websites displayed fake licenses and certifications to convince US consumers to purchase drugs they advertised as ‘brand name’ and ‘FDA approved.’" Just because a website dresses up with the Canadian flag and posts a certificate doesn't mean it's a legitimate pharmacy. CanaRx is NOT a licensed pharmacy and does NOT provide Rx medications for Canadians.

Professionals licensed under the Maine Pharmacy Act are subject to a broad array of rules, requirements including education and examination, restrictions, duties, fees and obligations under federal and state law. Prior to enactment of the Maine Importation Law, these federal and state rules and requirements formed a closed system for distributing prescription drugs in Maine with the paramount concern of protecting patient health, safety, and welfare.

**IT'S ILLEGAL:**
The Importation Law Is Directly Contrary To Federal Law. Although this Importation Law is the first of its kind, the notion of importing pharmaceuticals from foreign countries is not a new one. Indeed, Maine acted against a backdrop of the FDA’s clear warnings of the serious risks posed by imported prescription drugs. The FDA has repeatedly stated that federal law preempts any and all state laws that would facilitate the private importation of foreign pharmaceutical products. Based on the serious legal and public-health concerns outlined above, the FDA has advised officials in at least 15 states that state laws purporting to authorize the importation of prescription drugs from Canada or other foreign countries—including state laws limiting such importation to private individuals for their personal use—run afoul of the Food Drug and Cosmetic Act (FDCA) and are preempted. As the FDA has reasoned: “Clearly, Congress created [the] import provisions in the FDCA with the goal of controlling the types of drugs that could be legally imported into the United States.” This federal scheme “is comprehensive in that it promulgates national standards that are to be applied equally to all ports of entry, regardless of the states in which they are situated.” Thus, “By definition, the scheme cannot allow the individual states to enact laws that erode federal standards; otherwise, importers could simply circumvent the federal law by routing all their unapproved drugs into the state (or states) that allowed such imports.” The goal of this restriction is to protect patients from counterfeit and adulterated prescription drugs.

Respectfully,

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President | Maine Pharmacy Association