

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 19 Prescription Drug Importation Programs
SPONSOR(S): Leek
TIED BILLS: HB 7073 **IDEN./SIM. BILLS:** SB 1452

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	12 Y, 2 N	Gilani	McElroy
2) Appropriations Committee	20 Y, 8 N	Keith	Pridgeon
3) Health & Human Services Committee		Gilani	Calamas

SUMMARY ANALYSIS

The U.S. spends \$3.5 trillion on health care, or \$10,739 per person, each year. One-tenth of that, approximately \$333.4 billion, is spent on retail prescription drugs, with 14 percent (\$46.7 billion) paid out-of-pocket by consumers. The U.S. overall spends 30 to 190 percent more on prescription drugs than other developed countries and pays up to 174 percent more for the same prescription drug.

The federal Food and Drug Administration (FDA) regulates the manufacture, sale, and distribution of prescription drugs to ensure safety and effectiveness of drugs. In Florida, the Department of Business and Professional Regulation (DBPR) Division of Drugs, Devices, and Cosmetics and the Department of Health (DOH) Board of Pharmacy together regulate prescription drugs in the state from manufacture to distribution and dispensing.

Federal law currently prohibits anyone other than the original manufacturer from importing FDA-approved drugs into the country, thereby prohibiting access to cheaper FDA-approved drugs and increasing price disparities between the United States and comparable wealthy and developed nations. However, 40 percent of drugs in the U.S. market are imported from other countries by manufacturers. Similarly, 80 percent of U.S. drug ingredients are imported from other countries, primarily India and China.

HB 19 establishes two programs to safely import FDA-approved prescription drugs into the state: the Canadian Drug Importation Program and the International Drug Importation Program. For both programs, the bill establishes eligibility criteria for the types of prescriptions drugs which may be imported and the entities that may export or import prescription drugs. The bill also outlines the importation process, safety standards, drug distribution requirements, and penalties for violations of program requirements. Both programs require federal approval or cooperation before prescription drug importation under the programs can begin.

The bill has a significant, negative fiscal impact on the Agency for Health Care Administration and DBPR. HB 19 is linked to HB 7073, which authorizes DBPR and DOH to charge fees relating to new permits. See Fiscal Comments.

The bill provides an effective date of July 1, 2019.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

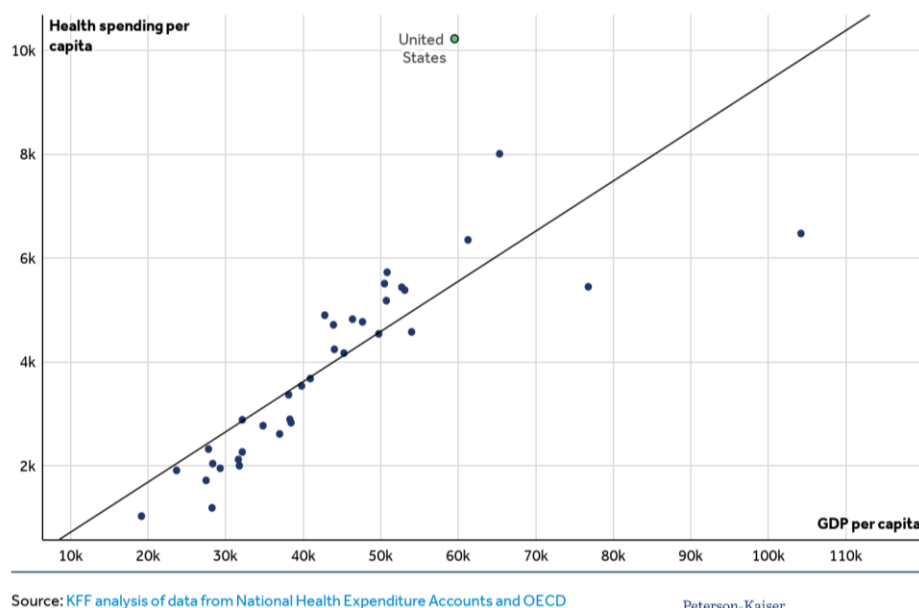
A. EFFECT OF PROPOSED CHANGES:

Background

Prescription Drugs

The United States spends \$3.5 trillion on health care, or \$10,739 per person, each year. One-tenth of that, approximately \$333.4 billion, is spent on retail prescription drugs,¹ with 14 percent (\$46.7 billion) paid out-of-pocket by consumers.² Relative to the size of its wealth, the United States spends significantly more on healthcare than any country in the world and is an outlier even when compared to other developed and wealthy nations and even after adjusting for drug industry rebates.³ The United States overall spends 30 to 190 percent more on prescription drugs than other developed countries and pays up to 174 percent more for the same prescription drug.⁴

GDP per Capita and Health Spending per Capita, 2017 (U.S. Dollars, PPP Adjusted)⁵



Medication adherence can affect quality and length of life, health outcomes, and overall healthcare costs.⁶ Approximately one in three people do not fill a prescription or will not adhere to a regimen due

¹ *National Health Expenditures 2017 Highlights*, CENTERS FOR MEDICARE & MEDICAID SERVICES, Dec. 6, 2018, available at: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf> (last visited Feb. 15, 2019).

² *National Health Expenditures by Type of Service and Source of Funds, CY 1960-2017*, CENTERS FOR MEDICARE & MEDICAID SERVICES, available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html> (last visited Feb. 16, 2019).

³ PETERSON-KAISER HEALTH SYSTEM TRACKER, *How Does Health Spending in the U.S. Compare to Other Countries?*, <https://www.healthsystemtracker.org/chart-collection/health-spending-u-s-compare-countries/#item-start> (last visited Mar. 8, 2019); Robert Langreth, *The U.S. Pays a Lot More for Top Drugs Than Other Countries*, BLOOMBERG, (Dec. 18, 2015), <https://www.bloomberg.com/graphics/2015-drug-prices/> (last visited Mar. 8, 2019).

⁴ PETERSON-KAISER HEALTH SYSTEM TRACKER, *What Are the Recent and Forecasted Trends in Prescription Drug Spending?*, <https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/#item-start> (last visited Mar. 8, 2019); See also, David O. Sarnak, et. al, *Paying for Prescription Drugs Around the World: Why is the U.S. an Outlier?*, THE COMMONWEALTH FUND, Issue Brief: Oct. 2017, available at: https://www.commonwealthfund.org/sites/default/files/documents/_media_files_publications_issue_brief_2017_oct_sarnak_paying_for_rx_ib_v2.pdf (last visited Mar. 8, 2019).

⁵ Id. Adjusted for purchasing power parity.

to the cost of prescription drugs.⁷ To save money, people will either not fill their prescriptions, use over-the-counter medications instead, skip doses or cut pills in half, purchase drugs from other countries, or use alternative therapies.⁸ Non-adherence to medication can account for up to 50 percent of treatment failures, approximately 125,000 deaths, and up to 25 percent of hospitalizations each year in the United States.⁹ This translates to between \$105 billion and \$289 billion in avoidable healthcare costs annually.¹⁰

Numerous factors contribute to the increasingly high drug prices in the United States. Changes in utilization such as the introduction of new drugs, increases in the unit cost or cost per dosage, delayed introduction of cheaper generic alternatives, and U.S. patents or exclusivities all contribute to drug prices.¹¹ Numerous links in the pharmacy supply chain, such as wholesalers, pharmacy benefit managers, hospitals and physicians, and retail pharmacies, paired with a lack of price transparency also increases costs.¹²

The disparity between drug prices in the U.S. and other comparable countries is mainly attributable to the fact that the federal government does not impose drug price controls as is the case in many European countries and Canada.¹³ Federal law also prohibits anyone other than the original manufacturer from importing prescription drugs into the country. As such, manufacturers may charge higher prices in the United States and wholesalers, pharmacies, and individuals cannot access cheaper versions of the same drug sold in other countries even if they are otherwise FDA-approved.

Proponents for this importation ban argue that removing the ban would equate to importing foreign price controls and jeopardize research and development of new prescription drugs if drug companies can no longer recoup costs for expensive clinical trials.¹⁴ However, others argue that this ban forces the United States to effectively subsidize the rest of the world's prescription drug costs, and removing the ban would allow free market forces to stabilize the prices and spread the costs more equitably across markets.¹⁵

Federal Regulation of Prescription Drugs

The United States Food and Drug Administration (FDA) is the federal agency responsible for ensuring that foods, drugs, biological products, and medical devices are effective and safe for public consumption.¹⁶ The FDA regulates these areas under the authority of the Federal Food, Drug, and Cosmetic Act (FDCA).¹⁷ The FDCA prohibits any drug from being introduced or delivered for introduction into interstate commerce unless approved by the FDA. The FDCA further prohibits

⁶ Andrea B. Neiman, Ph.D., et. al, *CDC Grand Rounds: Improving Medication Adherence for Chronic Disease Management – Innovations and Opportunities*, U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION MMWR, 66 MORB. MORTAL. WKLY REP. (2017), available at: <https://www.cdc.gov/mmwr/volumes/66/wr/mm6645a2.htm> (last visited Mar. 8, 2019).

⁷ *Supra* note 6; KAISER FAMILY FOUNDATION, *KFF Health Tracking Poll: February 2019: Prescription Drugs*, June 16, 2015, available at: <https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/> (last visited Mar. 8, 2019).

⁸ *Id.*; See also, Robin A. Cohen, Ph.D. and Maria A. Villarreal, Ph.D., *Strategies Used by Adults to Reduce Their Prescription Drug Costs: United States, 2013*. CENTER FOR DISEASE CONTROL AND PREVENTION, NCHS Data Brief No. 184 (Jan. 2015), <https://www.cdc.gov/nchs/data/databriefs/db184.pdf> (last visited Mar. 8, 2019).

⁹ Jennifer Jim, PharmD, et. al, *Medication Adherence: The Elephant in the Room*, 43(1) U.S. Pharm 30-34 (2018).

¹⁰ IMS INSTITUTE FOR HEALTHCARE INFORMATICS, *Avoidable Costs in U.S. Healthcare* (June 2013), available at: http://offers.premierinc.com/rs/381-NBB-525/images/Avoidable_Costs_in%20US_Healthcare-IHII_AvoidableCosts_2013%5B1%5D.pdf (last visited Mar. 8, 2019); See also, Meera Viswanathan, Ph.D., et. al, *Interventions to Improve Adherence to Self-Administered Medications for Chronic Diseases in the United States: A Systematic Review*, 157(11) ANN. INTERN. MED. 785-795 (2012).

¹¹ AMERICAN ACADEMY OF ACTUARIES, *Prescription Drug Spending in the U.S. Health Care System*, Issue Brief (Mar. 2018), available at: <http://www.actuary.org/files/publications/PrescriptionDrugs.030718.pdf> (last visited Mar. 9, 2019).

¹² *Id.*

¹³ *Id.* However, the federal government does negotiate drug prices for its Medicaid Program and military veterans.

¹⁴ Roger Pilon, *Drug Reimportation: The Free Market Solution*, CATO INSTITUTE, Policy Analysis No. 521, Aug. 4, 2004, available at: <https://object.cato.org/sites/cato.org/files/pubs/pdf/pa521.pdf> (last visited Mar. 9, 2019).

¹⁵ *Id.* See also, Roger Bate, *Drug Importation Should Lower Prices, But the FDA Can Do More*, AMERICAN ENTERPRISE INSTITUTE, (July 20, 2018), available at: <http://www.aei.org/publication/drug-importation-should-lower-prices-but-the-fda-can-do-more/> (last visited Mar. 10, 2019).

¹⁶ U.S. FOOD & DRUG ADMINISTRATION, *What We Do*, <https://www.fda.gov/AboutFDA/WhatWeDo/default.htm> (last visited Mar. 10, 2019).

¹⁷ 21 U.S.C. § 355(a).

adulterated or misbranded drugs and devices from being introduced, delivered for introduction, or received in interstate commerce.

Drug Approvals

The FDA process for new or innovative drugs is rigorous and requires an extensive series of clinical trials, first on animals and then on humans, before the new drug application can even be formally filed with the FDA.¹⁸ The company then sends the FDA the evidence from these trials to prove the drug is safe and effective for its intended use. The FDA's physicians, statisticians, chemists, pharmacologists, and other scientists review the company's data and proposed labeling. The FDA will only approve a new drug application if it determines that the drug is safe and effective for its proposed use and that the benefits of the drug appear to outweigh the known risks.¹⁹

When new drugs are approved, the sponsoring entities may apply for and receive a patent for the drug, which gives them the right to exclude others from making, using, offering to sell, or selling the drug within the U.S. or importing it into the U.S., generally for a period of 20 years. There is a research exemption that protects generic drug companies from patent infringement lawsuits during the time in which the generic drug company is preparing its application for the FDA.²⁰ This allows generic drug companies to learn how to manufacture the drug, manufacture test batches, and run bioequivalence studies that would otherwise subject them to patent infringement litigation.²¹

When a drug patent expires, generic versions of the drug may enter the market. Drug companies wanting to make a generic drug must also apply for FDA approval. This process is shorter because companies do not have to perform the extensive clinical trials and can use the brand-name drug company's data to demonstrate the safety and effectiveness of the drug.²² Instead, the FDA requires applicants to produce enough data to demonstrate that they can make a drug that can appropriately substitute the brand-name drug.²³ The FDA will only approve a generic drug if it meets the bioequivalence, quality, and labeling requirements of the FDCA.²⁴

Drug Manufacture

FDA ensures the quality of drug products by carefully monitoring drug manufacturers' compliance with its Current Good Manufacturing Practice (CGMP) regulations, which are the main regulatory standard for ensuring pharmaceutical quality for human pharmaceuticals.²⁵ The CGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The regulations make sure that a product is safe for use, and that it has the ingredients and strength it claims to have. The approval process for new and generic drug marketing applications includes a review of the manufacturer's compliance with the CGMPs. FDA assessors and inspectors determine whether the firm has the necessary facilities, equipment, and ability to manufacture the drug it intends to market.²⁶

¹⁸ U.S. FOOD & DRUG ADMINISTRATION, *New Drug Application (NDA)*, <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm> (last visited Mar. 10, 2019).

¹⁹ *Id.*
²⁰ 35 U.S.C. § 271(e)(1).

²¹ *Id.*
²² U.S. FOOD & DRUG ADMINISTRATION, *FDA Fact Sheet: What's Involved in Reviewing and Approving Generic Drug Applications?*, <https://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/GenericDrugs/UCM510852.pdf> (last visited Mar. 10, 2019).

²³ The "Drug Price Competition and Patent Term Restoration Act of 1984," also known as the Hatch-Waxman Amendments, established bioequivalence as the basis for approving generic copies of drug products. These Amendments permit the FDA to approve applications to market generic versions of brand-name drugs without repeating costly and duplicative clinical trials to establish safety and efficacy.

²⁴ Alexander Gaffney, *Generic Drug Approvals are Soaring at the FDA. Here's Why.*, PWC US, HEALTH RESEARCH INSTITUTE (Oct. 22, 2018), <https://www.pwc.com/us/en/industries/health-industries/library/generic-drug-approvals-increasing.html> (last visited Mar. 10, 2019).

²⁵ U.S. Food & Drug Administration, *Facts About the Current Good Manufacturing Practice (CGMPs)*, <https://www.fda.gov/drugs/developmentapprovalprocess/manufacturing/ucm169105.htm> (last visited Mar. 8, 2019).

²⁶ *Id.*

Adherence to the CGMPs assures the identity, strength, quality, and purity of drug products by requiring that manufacturers of medications adequately control manufacturing operations.²⁷ This includes establishing strong quality management systems, obtaining appropriate quality raw materials, establishing robust operating procedures, detecting and investigating product quality deviations, and maintaining reliable testing laboratories. This formal system of controls at a pharmaceutical company, if adequately put into practice, helps to prevent instances of contamination, mix-ups, deviations, failures, and errors.²⁸

Drug Distribution

Generally, the state boards of pharmacy are responsible for regulating the practice of pharmacy. However, in some instances, the FDCA preempts state regulation of pharmacy. The Drug Supply Chain Security Act²⁹ amended the FDCA to establish national uniform procedures to ensure the integrity of prescription drugs as they are distributed along the supply chain.³⁰ Effective July 1, 2015, the Act requires manufacturers, repackagers, wholesale distributors, and dispensers to exchange product tracing information at the package level when transferring a product or ownership along the distribution chain. In 2016, Florida conformed its law to these revised federal standards.³¹ This tracing information includes the following:

- Name of the drug.
- Strength and dosage form of the drug.
- National Drug Code number of the drug.
- Container size and number of containers.
- Lot number of the drug.
- Date of the transaction.
- Date of the shipment, if more than 24 hours after the date of the transaction.
- Business name and address of the person from whom ownership is being transferred.
- Business name and address of the person to whom ownership is being transferred.

These entities must maintain these records for 6 years and provide them to the FDA upon request.

Additionally, the Act requires all healthcare entities that distribute, dispense, and administer prescription drugs to patients to purchase their prescription drug products only from authorized “trading partners” (wholesale distributors, manufacturers, re-packagers, and dispensers) licensed or registered with the state or federal government.³²

Interaction with Foreign Market

As globalization increased, the FDA established foreign offices to work closely with foreign governments, industry, and other stakeholders to enable FDA to more effectively protect U.S. consumers, including inspections and investigations in those countries.³³

Foreign companies that manufacture, prepare, propagate, compound, or process drugs that are offered for import into the U.S. must register with the FDA.³⁴ Today, there are 136,400 foreign facilities from

²⁷ Id.

²⁸ Id.

²⁹ Title II of DQSA, the Drug Quality and Security Act. Pub.L. 113–54.

³⁰ U.S. Food & Drug Administration, *Drug Supply Chain Security Act*,

<https://www.fda.gov/drugs/drugsafety/drugintegrityandsupplychainsecurity/drugsupplychainsecurityact/> (last visited Mar. 10, 2019).

³¹ Ch. 2016-212, LAWS OF FLA.

³² [Pub.L. 113–54](#)

³³ U.S. FOOD & DRUG ADMINISTRATION, *FDA Globalization*,

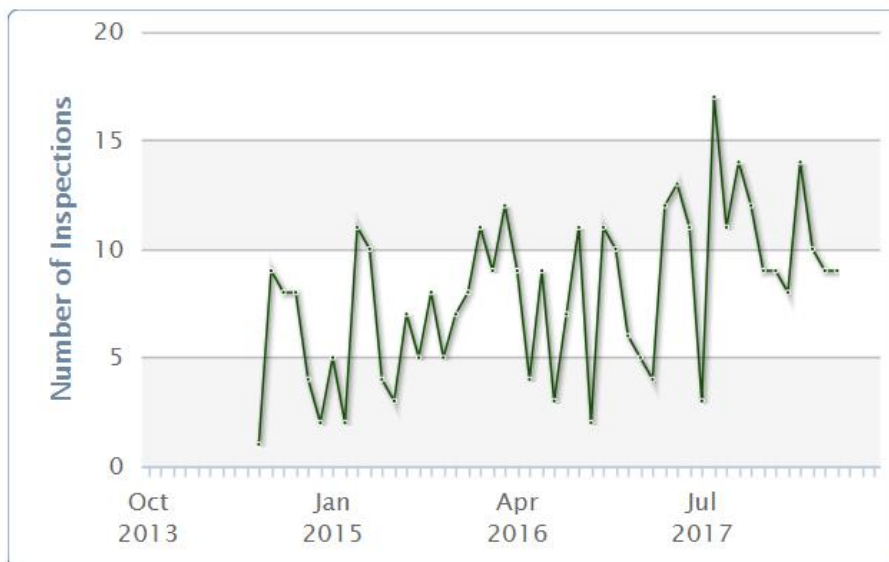
<https://www.fda.gov/internationalprograms/fdabeyondourbordersforeignoffices/default.htm> (last visited Mar. 1, 2019).

³⁴ Section 510 of the Federal Food, Drug, and Cosmetic Act.

more than 150 countries exporting FDA-regulated products to the United States.³⁵ The FDA estimates that 80 percent of the active pharmaceutical ingredients and 40 percent of the finished drugs in the U.S. market are actually manufactured in FDA-registered facilities in other countries, primarily India and China.³⁶

The FDA does not regularly inspect every foreign facility and instead relies on a risk-based assessment to determine which facilities to inspect and how often.³⁷ In FY 17-18, the FDA conducted 94 on-site inspections of foreign drug manufacturing facilities, and 381 historically since FY 14-15.³⁸ This means that less than 1 percent of foreign FDA-registered drug manufacturing facilities are inspected by the FDA each year.

Total Number of FDA Inspections of Foreign Drug Manufacturing Facilities, by Month³⁹



Since the FDA does not have the resources to effectively enforce drug manufacturing regulations in every facility overseas, it must instead rely on cooperation with the governments of each country to ensure the safety of drugs or pharmaceutical products imported into the United States. The FDA may memorialize these partnerships in an international arrangement, which is a written understanding between two or more countries recognizing one another's conformity with certain processes or procedural standards and describes the willingness and good-faith intentions of the countries to engage in cooperative activities.⁴⁰ International arrangements can have a variety of titles, including "cooperation

³⁵ U.S. FOOD & DRUG ADMINISTRATION, *FDA Globalization*,

<https://www.fda.gov/InternationalPrograms/FDABeyondOurBordersForeignOffices/default.htm> (last visited Mar. 1, 2019).

³⁶ FDA Commissioner Margaret Hamburg, "The Safety of Prescription Drugs Made Outside the U.S.," *The Diane Rehm Show* (Feb. 20, 2014).

Transcript available at: <https://dianerehm.org/shows/2014-02-20/safety-prescription-drugs-made-outside-us> (last visited Mar. 10, 2019); U.S.

GOVERNMENT ACCOUNTABILITY OFFICE, *Report to the Committee on Energy and Commerce: Drug Safety, FDA Has Improved its Foreign Drug*

Inspection Program, but Needs to Assess the Effectiveness and Staffing of its Foreign Offices, (Dec. 2016), available at:

<https://www.gao.gov/assets/690/681689.pdf> (last visited Mar. 10, 2019).

³⁷ Section 705 of the FDA Safety and Innovation Act, 2012. Factors considered include the establishment's compliance history or history and nature of recalls, the inherent risk of the drug being manufactured, whether the establishment has been inspected in the last 4 years, whether a foreign government has inspected the establishment, and anything else the FDA determines is important in determining where inspection resources should be spent.

³⁸ U.S. FOOD & DRUG ADMINISTRATION, *Total Number of Inspections Completed in the Month*,

[https://www.accessdata.fda.gov/scripts/fdatrack/view/track.cfm?program=oip&id=OIP-Number-of-inspections-completed-in-country-by-](https://www.accessdata.fda.gov/scripts/fdatrack/view/track.cfm?program=oip&id=OIP-Number-of-inspections-completed-in-country-by-commodity)

[commodity](https://www.accessdata.fda.gov/scripts/fdatrack/view/track.cfm?program=oip&id=OIP-Number-of-inspections-completed-in-country-by-commodity) (last visited Mar. 8, 2019).

³⁹ *Id.*

⁴⁰ U.S. FOOD & DRUG ADMINISTRATION, *International Arrangements*, <https://www.fda.gov/InternationalPrograms/Agreements/default.htm> (last

visited Mar. 8, 2019); *See also*, U.S. FOOD & DRUG ADMINISTRATION, *FAQs: The Mutual Recognition Agreement*,

<https://www.fda.gov/downloads/InternationalPrograms/Agreements/UCM544394.pdf> (last visited Mar. 10, 2019).

agreement,” “memorandum of understanding,” or “mutual recognition agreement.” The FDA currently has at least 80 such international arrangements with foreign governments.⁴¹

In instances where the U.S. determines that another country adheres to current good manufacturing practices for pharmaceutical products, it may enter into an international arrangement and authorize the foreign government to conduct facility inspections on the FDA’s behalf. The FDA has such international arrangements with Australia, Austria, Belgium, Canada, China, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Greece, Hungary, Ireland, Italy, Japan, Latvia, Lithuania, Malta, Romania, Poland, Portugal, Slovenia, Spain, Sweden, Switzerland, and the United Kingdom.⁴²

Drug Importation

The FDCA generally prohibits the importation of foreign drugs into the U.S. unless the drug has been approved for the U.S. market and is being introduced in the U.S. by the original manufacturer.⁴³ The manufacturer may manufacture the drug in a foreign facility as long as it is registered with the FDA and may reimport a drug after it has left the U.S.⁴⁴ Wholesalers and pharmacies are not able to import or reimport the same drugs even though they must comply with federal regulations, including the tracking and tracing requirements of the Drug Supply Chain Security Act.

The FDCA prohibits interstate shipment, including importation, of ‘unapproved drugs.’⁴⁵ The FDA considers a drug ‘unapproved’ for a variety of reasons. An ‘unapproved drug’ can include a drug that has not been approved for the U.S. market (i.e. hasn’t had a drug application approved by the FDA), foreign-made versions of U.S.-approved drugs (i.e. drugs manufactured in a foreign facility not registered with the FDA or by a manufacturer not approved by the FDA), or drugs that do not have the same labeling as approved for the U.S. market (i.e. does not have the same instructions for use).⁴⁶ This means that even in instances where the drug is pure and unadulterated, is safe and effective for its intended purpose, and is exactly what it purports to be, the FDA may deem it ‘unapproved.’

Therefore, any importation, by any person or entity other than the original manufacturer, of drugs not FDA-approved in the manner described above would be a violation of federal law. However, federal law does authorize the Department of Health and Human Services to grant individuals waivers to import drugs, exercise discretion in enforcing the law against individuals importing for personal use, and focus enforcement efforts on cases that pose a significant threat to public health.⁴⁷

*The Medicare Modernization Act of 2003*⁴⁸

The federal Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) included a provision on the importation of pharmaceutical drugs. It authorizes a wholesaler or pharmacist to import prescription drugs from Canada under certain conditions with the approval of the Department of Health and Human Services (HHS). Specifically, after consulting with relevant federal agencies and determining that such importation would produce costs savings and would not pose an additional risk to

⁴¹ U.S. FOOD & DRUG ADMINISTRATION, *Cooperative Arrangements*

<https://www.fda.gov/InternationalPrograms/Agreements/MemorandaofUnderstanding/ucm2016755.htm> (last visited Mar. 10, 2019).

⁴² Id; U.S. FOOD & DRUG ADMINISTRATION, *Mutual Recognition Agreement*,

<https://www.fda.gov/InternationalPrograms/Agreements/ucm598735.htm> (last visited Mar. 10, 2019). FDA, News Release: *FDA Takes Unprecedented Step Toward More Efficient Global Pharmaceutical Manufacturing Inspections* (Oct. 31, 2017), available at: <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm583057.htm> (last visited Mar. 1, 2019).

⁴³ 21 U.S.C. § 355(b)(1). FDA approval requires the manufacturer to submit documentation establishing the drug’s safety and efficacy, which includes information as to the method, facilities, and manner of manufacture. Without this FDA-approval, these drugs are considered misbranded and illegal for importation.

⁴⁴ 21 U.S.C. § 381(d)(1). This prohibition also applies to wholesalers, 21 U.S.C. § 384(a)(5)(B). The FDA justifies this by saying that the safety and integrity of the drugs cannot be ensured by any other entity but the manufacturer, *Imported Drugs Raise Safety Concerns*, U.S. Food & Drug Admin. (May 4, 2016), <https://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143561.htm> (last visited Mar. 4, 2019).

⁴⁵ 21 U.S.C. § 355(a).

⁴⁶ Marvin Blumber, *Information on Importation of Drugs Prepared by the Division of Import Operations and Policy*, FDA, U.S. Food & Drug Admin., (Sept. 25, 2015), <https://www.fda.gov/ForIndustry/ImportProgram/ucm173751.htm> (last visited Mar. 4, 2019).

⁴⁷ 21 U.S.C. § 384(j).

⁴⁸ P.L. 108-173 § 1121.

public health and safety, HHS must adopt regulations to allow licensed pharmacists and wholesalers to import prescription drugs⁴⁹ from Canada into the U.S. These regulations must:

- Require compliance with safeguard requirements of 21 U.S. sections 355 (regarding new drugs) and 351 (regarding adulteration) and 352 (regarding misbranding);
- Require an importer of a prescription drug to comply with the documentation and sample testing requirements of the MMA⁵⁰; and
- Contain any additional provisions the Secretary deems appropriate to safeguard public health or to facilitate the importation of prescription drugs.

This would allow licensed or permitted entities to import FDA-approved drugs from Canada, whereas currently only the original manufacturer may do so.

However, to date, no HHS Secretary has implemented this provision or otherwise authorized an importation program under this provision.⁵¹ Shortly after the MMA passed and the federal government did not authorize importation under the MMA, some states and local governments either began operating importation programs without federal approval or requested waivers from the FDA in an attempt to import prescription drugs within their jurisdictions. These operations were either found to violate the supremacy clause for operating without federal approval or were denied waivers on the basis that their programs did not provide mechanisms to ensure safety of drugs that would be imported.⁵²

Since 2015, there has been renewed interest in drug importation and this unused provision of the MMA. Over a dozen states each year have considered drug importation legislation and in 2018, Vermont was the first state to pass a wholesale prescription drug importation program.⁵³ The majority of these proposed laws, including Vermont's, require federal approval under the MMA before the program can implement the program.⁵⁴ Vermont has not yet requested or received approval, but has been studying how to implement the program. In its research, Vermont found that while its Medicaid program would see minimal benefit from the program due to its existing rebate program, there were still a small number of drugs that would be more cost-effective if imported from Canada for limited periods of time.⁵⁵ When reviewing cost savings on drugs purchased through commercial insurance plans, Vermont's study

⁴⁹ Excluding controlled substances, biological products, infused drugs, IV-injected drugs, drugs inhaled during surgery, or a parenteral drug the Secretary deems to pose a threat to public health.

⁵⁰ This includes: the name and quantity of the active ingredient; a description of the dosage; the date on which it is shipped; the quantity that is shipped; the point of origin and destination; the price paid by the importer; documentation from the foreign seller specifying the original source of the drug and the quantity of each lot of the drug originally received by the seller from that source; the lot or control number assigned by the manufacturer; the name, address, telephone number, and professional license number, if any, of the importer; in cases where the drug is shipped directly from the first foreign recipient from the manufacturer, documentation demonstrating the drug was received by the recipient from the manufacturer and subsequently shipped by the first foreign recipient to the importer, documentation of the quantity of each lot received by the first foreign recipient showing that the quantity being imported to the U.S. is not more than what was received by the first foreign recipient, and documentation demonstrating that each batch in the shipment was statistically sampled and tested for authenticity and degradation for the initial and any subsequent shipments; in cases where the drug is not shipped directly from the first foreign recipient from the manufacturer, documentation demonstrating that each batch in each shipment offered for importation into the U.S. was statistically sampled and tested for authenticity and degradation; certification from the importer or manufacturer that the drug is approved for marketing in the U.S. and is not adulterated or misbranded, and meets all labeling requirements; laboratory records, including complete data derived from all tests necessary to ensure the drug is in compliance with FDA regulations; documentation demonstrating that the testing required by this section was conducted by a qualifying laboratory; and any other information the Secretary deems necessary to ensure protection of public health.

⁵¹ Additionally, in 2017, the 4 most recent FDA commissioners sent a letter to Congress attesting that drug importation would "harm patients and consumers and compromise the carefully constructed system that guards the safety of our nation's medical products." The letter can be viewed here: http://www.safemedicines.org/wp-content/uploads/2017_03_16_commissioners_letter_final.pdf (last visited Mar. 10, 2019).

⁵² Peral, Eloy A., *FDA Regulation on the Importation of Prescription Drugs: Opportunities and Barriers to Legal Importation*, HEALTH LAW & POLICY Brief 3, no. 1 (2009): 48-55, available at:

<https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=1094&context=hlp> (last visited Mar. 10, 2019); *Maine Pharmacy Association v. Maine*. S.D. Ct., D. Maine, (2015), available at: <http://www.fdalawblog.net/wp-content/uploads/archives/docs/Maine%202-23-15%20Decision.pdf> (last visited Sep. 26, 2018).

⁵³ NATIONAL ACADEMY FOR STATE HEALTH POLICY, *State Legislative Action to Lower Pharmaceutical Costs*, updated Mar. 1, 2019, <https://nashp.org/rx-legislative-tracker-2019/> (last visited Mar. 8, 2019).

⁵⁴ Id.

⁵⁵ VERMONT AGENCY OF HUMAN SERVICES, *Wholesale Importation Program for Prescription Drugs Legislative Report*, Dec. 31, 2018, available at: https://nashp.org/wp-content/uploads/2019/01/Report-to-VT-Legislature-on-Rx-Wholesale-Importation-1_3_2019.pdf (last visited Mar. 22, 2019).

estimated \$1-\$5 million in savings each year, even when accounting for a 45 percent markup to cover costs for program administration and allow a 20 percent profit to flow across the distribution chain.⁵⁶

The Trump Administration has also shown interest in drug importation. In July 2018, HHS directed the FDA to establish a work group on drug importation.⁵⁷ The work group is examining the potential for importation to promote competition for drugs that are off-patent or off-exclusivity and produced by one manufacturer. The work group has not yet issued any recommendations or reports.

Personal Importation

The MMA also authorized HHS to allow individuals to import drugs from Canadian-licensed pharmacies for personal use without penalty in certain circumstances, either on a case-by-case waiver basis or by regulation.⁵⁸ HHS has not implemented this provision either; however the FDA uses its enforcement discretion and does not generally enforce violations of drug importation for personal use.

The FDA generally does not object to a person importing a drug from any country so long as it is for personal use even though such importation would violate the FDCA.⁵⁹ The FDA recognizes there are situations where foreign medications may be appropriate for a particular individual consumer and that the FDA's resources are better served enforcing regulations against commercial shipments of foreign medication into the United States.⁶⁰

The FDA does not examine personal baggage or mail, leaving that to the U.S. Customs and Border Protection (CPB). CPB is instructed to only notify the FDA when it appears that there is an FDA-regulated drug intended for commercial distribution, the FDA has specifically requested that drug be detained, or the drug appears to represent a health fraud or an unknown risk to health.⁶¹

This FDA policy is not intended to cover importation of foreign-made chemical versions of drugs available in the U.S. (i.e. cheaper, foreign versions of U.S. drugs). However, since there is a permissive attitude towards drugs for personal use shipped or brought into the U.S., it is likely that people are importing such drugs undetected. A 2016 poll showed that 8 percent of U.S. households have bought prescription drugs from Canada or other countries in order to pay a lower price.⁶²

A limited exception applies to individuals with terminal illnesses, who can legally import non-FDA approved drugs.⁶³ They must have exhausted all other treatment options in the United States and be unable to participate in a clinical trial for an investigational drug. The particular drug imported must be actively pursuing FDA-approval and have completed the first phase of clinical trials.

State Regulation of Prescription Drugs

The Department of Business and Professional Regulation's (DBPR) Division of Drugs, Devices, and Cosmetics and the Department of Health's (DOH) Board of Pharmacy together regulate prescription drugs in the state from manufacture to distribution and dispensing. All entities engaged in any process along this continuum must be either licensed or permitted to engage in such activity, subject to relevant laws and rules and enforcement authority of DBPR or DOH, as applicable. Due to the overlap in these

⁵⁶ *Id.*

⁵⁷ U.S. HEALTH & HUMAN SERVICES, *Press Release: HHS Secretary Azar Directs FDA to Establish Working Group on Drug Importation to Address Price Spikes*, July 19, 2018, available at: <https://www.hhs.gov/about/news/2018/07/19/hhs-secretary-azar-directs-fda-establish-working-group-drug-importation-address-price-spikes.html> (last visited Mar. 10, 2019).

⁵⁸ 21 U.S.C. § 384(j).

⁵⁹ U.S. FOOD & DRUG ADMINISTRATION, *Person Importation*, <https://www.fda.gov/ForIndustry/ImportProgram/ImportBasics/ucm432661.htm> (last visited Mar. 10, 2019).

⁶⁰ *Supra* note **Error! Bookmark not defined.**48.

⁶¹ *Id.*

⁶² KAISER FAMILY FOUNDATION, *Kaiser Health Tracking Poll: November 2016*, <http://files.kff.org/attachment/Kaiser-Health-Tracking-Poll-November-2016-Topline> (last visited Mar. 8, 2019).

⁶³ Right to Try Act of 2017, P.L. No: 115-176.

two industries, the law requires entities permitted or licensed under either DBPR or the Board to comply with the laws and rules of both.⁶⁴

DBPR Division of Drugs Devices and Cosmetics

The DBPR's Division of Drugs, Devices, and Cosmetics protects the health, safety, and welfare of Floridians from adulterated, contaminated, and misbranded drugs, drug ingredients, and cosmetics by enforcing Part I of ch. 499, F.S., the Florida Drug and Cosmetic Act.⁶⁵ The Florida Drug and Cosmetic Act conforms to FDA drug laws and regulations and authorizes DBPR to issue permits to Florida drug manufacturers and wholesale distributors and register drugs manufactured, packaged, repackaged, labeled, or relabeled in Florida.⁶⁶

Florida has 18 distinct permits based on the type of entity and intended activity, and includes permits for entities within the state, out of state, or even outside of the United States.⁶⁷ DBPR has broad authority to inspect and discipline permittees for violations of state or federal laws and regulations, which can include seizure and condemnation of adulterated or misbranded drugs or suspension or revocation of a permit.⁶⁸

Prescription Drug Manufacturer Permit

Drugs manufacturing includes the preparation, deriving, compounding, propagation, processing, producing, or fabrication of any drug.⁶⁹ A prescription drug manufacturer permit is required for any person that is a manufacturer of a prescription drug and that manufactures or distributes such prescription drugs in this state.⁷⁰ Such manufacturer must comply with all state and federal good manufacturing practices. A permitted prescription drug manufacturer may engage in distribution of its own manufactured drug without requiring a separate permit.⁷¹ The distribution of drugs includes the selling, purchasing, trading, delivering, handling, storing, and receiving of drugs, but does not include the administration or dispensing of drugs.⁷²

Nonresident Prescription Drug Manufacturer Permit

A nonresident prescription drug manufacturer permit is required for any person that is a manufacturer of prescription drugs located outside of this state or outside the United States and that engages in the distribution in this state of such prescription drugs.⁷³ Such manufacturer must comply with all of the same requirements as prescription drug manufacturers operating in the state. The permittee must also comply with the licensing or permitting requirements of the state or jurisdiction in which it is located and must comply with federal and Florida laws and regulations when distributing any prescription drugs in the state. If the manufacturer intends to distribute prescription drugs for which it is not the original manufacturer, an out-of-state prescription drug wholesale distributor permit is required.⁷⁴

⁶⁴ Ss. 499.067 and 465.023, F.S.

⁶⁵ FLORIDA DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION, *Division of Drugs, Devices, and Cosmetics*, <http://www.myfloridalicense.com/DBPR/drugs-devices-and-cosmetics/> (last visited Mar. 7, 2019).

⁶⁶ S. 499.01, F.S.

⁶⁷ A permit is required for a prescription drug manufacturer; a prescription drug repackager; a nonresident prescription drug manufacturer; a prescription drug wholesale distributor; an out-of-state prescription drug wholesale distributor; a retail pharmacy drug wholesale distributor; a restricted prescription drug distributor; a complimentary drug distributor; a freight forwarder; a veterinary prescription drug retail establishment; a veterinary prescription drug wholesale distributor; a limited prescription drug veterinary wholesale distributor; an over-the-counter drug manufacturer; a device manufacturer; a cosmetic manufacturer; a third party logistics provider; or a health care clinic establishment. S. 499.01(1), F.S.

⁶⁸ Ss. 499.051, 499.062, 499.065, 499.066, 499.0661, and 499.067, F.S.

⁶⁹ S. 499.003(28), F.S.

⁷⁰ S. 499.01(2), F.S.

⁷¹ S. 499.01(2), F.S.

⁷² S. 499.003(16), F.S.

⁷³ S. 499.01(2), F.S.

⁷⁴ S. 499.01(2), F.S.

Permittees located outside of the United States must have a current FDA establishment registration, adhere to FDA approval standards, and only import prescription drugs that are approved by the FDA for importation and marketing in the United States.⁷⁵ They must also provide proof of federal approval for each prescription drug imported into the state.⁷⁶ There are currently 126 permitted nonresident prescription drug manufacturers located outside of the United States.⁷⁷

Prescription Drug Wholesale Distributor Permit

Wholesale distribution is the distribution of a prescription drug to a person other than a consumer or patient, or the receipt of a prescription drug by a person other than the consumer or patient, with various exceptions for activities related to healthcare entities, governmentally-contracted public health services, and charitable organizations.⁷⁸ A prescription drug wholesale distributor permit is required for any person who is a wholesale distributor of prescription drugs and that wholesale distributes such prescription drugs in this state.⁷⁹

Out-of-State Prescription Drug Wholesale Distributor Permit

An out-of-state prescription drug wholesale distributor permit is required for any person that is a wholesale distributor located outside this state, but within the United States or its territories, which engages in the wholesale distribution of prescription drugs into this state.⁸⁰ The out-of-state prescription drug wholesale distributor must maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with laws of the state in which it is a resident. If the state from which the wholesale distributor distributes prescription drugs does not require a license to engage in the wholesale distribution of prescription drugs, the distributor must be licensed as a wholesale distributor by the FDA.⁸¹

Board of Pharmacy

The Board of Pharmacy (Board), within the Department of Health (DOH), regulates the practice of pharmacy by enforcing the Florida Pharmacy Act (Act), adopting rules that set the standards of practice in the state, and licensing and monitoring pharmacists and pharmacies to ensure safe practice.⁸² To operate a pharmacy, an entity must first obtain a pharmacy permit with the Board.⁸³ Any person or entity licensed, permitted, or registered pursuant to ch. 465, F.S., must practice pharmacy in accordance with the provisions of the Act and the Board rules.

The practice of pharmacy is also subject to the requirements of ch. 499, F.S., the Florida Drug and Cosmetic Act, ch. 893, F.S., the Florida Comprehensive Drug Abuse Prevention and Control Act, the FDCA, and the Federal Comprehensive Drug Abuse Prevention and Control Act. DOH has broad authority to inspect pharmacies for violations and the Board can discipline a person or entity's license, permit, or registration for violation of any of these provisions, including suspension or revocation of the ability to practice pharmacy in the state.⁸⁴

⁷⁵ Florida Department of Business and Professional Regulation, Agency Analysis for 2019 HB 19, p. 2 (Mar. 5, 2019)(on file with Health Quality Subcommittee staff).

⁷⁶ S. 499.01(2), F.S.

⁷⁷ *Supra* note 65.

⁷⁸ S. 499.003(48), F.S.

⁷⁹ S. 499.01(2), F.S.

⁸⁰ S. 499.01(2), F.S.

⁸¹ S. 499.01(2), F.S.

⁸² Ch. 465, F.S.; FLORIDA BOARD OF PHARMACY, <https://floridaspharmacy.gov/> (last visited Mar. 10, 2019).

⁸³ S. 465.022, F.S.

⁸⁴ S. 465.0465(1), F.S.

Effect of the Bill

HB 19 establishes two prescription drug importation programs: The Canadian Drug Importation Program and the International Drug Importation Program. For both programs, the bill establishes eligibility criteria for the types of prescription drugs which may be imported and the entities that may export or import prescription drugs. The bill also outlines the importation process, the safety standards that must be adhered to, drug distribution requirements, and measures that may be taken against those who violate any program requirements. Lastly, both programs require cooperation at the federal level before prescription drug importation under the programs can begin.

Canadian Prescription Drug Importation Program

The bill establishes the Canadian Prescription Drug Importation Program within the Agency for Health Care Administration (AHCA) to create a process by which certain state-funded entities may import safe and effective prescription drugs from eligible Canadian suppliers at lower cost to the state. AHCA must apply for and receive federal approval to operate under the MMA before it can implement the program.

Importation Process

The bill requires AHCA to contract with a vendor that will identify eligible prescription drugs for importation, identify eligible Canadian suppliers, and facilitate contracts between the Canadian suppliers and state programs that are eligible to import under the program.

The bill requires the vendor to develop a Wholesale Prescription Drug Importation List that identifies prescription drugs that have the highest potential for cost savings to the state. In developing this list, the vendor must consider, at a minimum, which prescription drugs will provide the greatest cost savings to state programs, including drugs for which there are shortages, specialty drugs, and high-volume drugs. The vendor must develop this list by December 1, 2019, and revise it annually thereafter. AHCA and the Department of Health (DOH) must review the list every 3 months to ensure that it continues to meet program requirements and may direct the vendor to revise the list, as necessary.

Once the vendor identifies drugs that provide the highest potential for cost savings to the state, it must identify Canadian suppliers who are in full compliance with relevant Canadian federal and provincial laws and regulations and who have agreed to export the identified prescription drugs. The vendor must verify that these Canadian suppliers meet all of the requirements of the program and will export prescription drugs at prices that will provide cost savings to the state.

The bill requires the vendor to then either contract with the eligible Canadian suppliers directly or facilitate contracts between the suppliers and the state programs to import prescription drugs under the program.

Eligible Prescription Drugs

Consistent with the MMA, the bill allows only certain types of prescription drugs to be imported and under certain circumstances. Specifically, eligible importers may import a prescription drug from an eligible Canadian supplier if:

- The drug meets the United States Food and Drug Administration's standards related to safety, effectiveness, misbranding, and adulteration;
- Importing the drug would not violate the patent laws of the United States;
- Importing the drug is expected to generate cost savings; and
- The drug is not:
 - A controlled substance;
 - A biologic product;
 - An infused drug;

- An intravenously injected drug;
- A drug that is inhaled during surgery; or
- A drug that is a parenteral drug, the importation of which the United States Secretary of Health and Human Services determines poses a threat to the public health.

Eligible Canadian Suppliers

Consistent with the MMA, the bill allows only certain entities to export prescription drugs into the state. A Canadian manufacturer, wholesale distributor, or pharmacy which is appropriately licensed or permitted under Canadian law to manufacture, distribute, or dispense prescription drugs may export prescription drugs into the state under the program if the entity is:

- In full compliance with relevant Canadian federal and provincial laws and regulations; and
- Identified by the vendor to participate in the program.

Eligible Importers

The bill allows Florida-licensed pharmacists or wholesale distributors employed by or under contract with the following state entities to import prescription drugs from a Canadian supplier under the program:

- DOH's central pharmacy,⁸⁵ for distribution to a county health department or free clinic for dispensing to clients treated in such department or clinic.
- A Medicaid pharmacy,⁸⁶ for dispensing to the pharmacy's Medicaid recipients.
- The Department of Corrections, for dispensing to inmates in its custody.
- A developmental disabilities center,⁸⁷ for dispensing to clients treated in such center.
- A treatment facility⁸⁸ for individuals who have a mental illness, for dispensing to patients treated in such facility.

The vendor may either contract directly with Canadian suppliers to import prescription drugs on behalf of these state programs or facilitate contracts between the suppliers and the state programs.

Distribution Requirements

The bill requires Canadian suppliers and importers under the program to comply with the federal tracking and tracing requirements for prescription drug distribution. Eligible importers under the program are Florida-licensed entities and as such, are already subject to these requirements. Canadian suppliers would be similarly regulated in Canada, and because the program will operate under the MMA, would also have to comply with the extensive drug testing requirements for drugs imported into the state under the program to ensure the integrity of the drug before it enters the U.S. The vendor under the bill must ensure that Canadian suppliers under the program comply with program requirements. This may be accomplished through the contract process.

The bill also prohibits Canadian suppliers and importers under the program from distributing, dispensing, or selling prescription drugs imported under the program to anyone outside of the state.

⁸⁵ DOH's central pharmacy under its Bureau of Public Health Pharmacy supports pharmaceutical services provided by its county health departments, including pharmaceutical drug repackaging, dispensing, and the purchase and distribution of immunizations and other pharmaceuticals. S. 381.0203, F.S.

⁸⁶ The bill defines "Medicaid pharmacy" as a pharmacy licensed under ch. 465, F.S., that has a Medicaid provider agreement in effect with the AHCA and is in good standing with AHCA.

⁸⁷ "Developmental disabilities center" means a state-owned and state-operated facility, formerly known as a "Sunland Center," providing for the care, habilitation, and rehabilitation of clients with developmental disabilities. S. 393.063, F.S.

⁸⁸ "Treatment facility" means a state-owned, state-operated, or state-supported hospital, center, or clinic designated by the department for extended treatment and hospitalization, beyond that provided for by a receiving facility, of persons who have a mental illness, including facilities of the United States Government, and any private facility designated by the department when rendering such services to a person pursuant to the provisions of this part. S. 394.455, F.S.

Importers under the program are Florida-licensed entities and as such, would be subject to discipline for violating any provisions of the program. Canadian suppliers may otherwise be authorized in law to import prescription drugs into the state. This prohibition would only apply to those prescription drugs which are imported under the program.

Federal Approval

The federal Department of Health and Human Services (HHS) must approve the program before anyone can begin importing prescription drugs under the program, consistent with the MMA. AHCA must apply for federal approval by July 1, 2020. In its request for federal approval, AHCA must, at a minimum:

- Describe the agency's plan for operating the program;
- Demonstrate how the prescription drugs imported into the state under the program will meet the applicable state and federal standards for safety and effectiveness;
- Include a list of prescription drugs that have been identified by the vendor to have the highest potential for cost savings to the state;
- Estimate the total cost savings attributable to the program; and
- Include a list of potential Canadian suppliers from which the state would import prescription drugs under the program and demonstrate that the suppliers are in full compliance with relevant Canadian federal and provincial laws and regulations.

The bill requires AHCA to implement the program within 6 months of receiving federal approval.

Annual Reporting

The bill requires AHCA to report to the Governor and Legislature on the operation of the program by December 1 of each year. The annual report must, at a minimum, include the following information for the previous fiscal year:

- A list of prescription drugs that were imported under the program;
- The number of participating entities;
- The number of prescriptions dispensed through the program;
- The estimated cost savings during the previous fiscal year and to date;
- A description of the methodology used to determine which prescription drugs should be included on the vendor's Wholesale Prescription Drug Importation List; and
- Documentation demonstrating how the program ensures that:
 - Canadian suppliers participating in the program are of high quality, of high performance, and in full compliance with relevant Canadian federal and provincial laws and regulations;
 - Prescription drugs imported under the program are not shipped, sold, or dispensed outside of the state once in the possession of the importer;
 - Prescription drugs imported under the program are pure, unadulterated, potent, and safe;
 - The program does not put consumers at a higher health and safety risk than if the program did not exist; and
 - The program provides cost savings to the state on imported prescription drugs.

The bill provides AHCA rulemaking authority to implement the program.

International Prescription Drug Importation Program

The bill establishes the International Prescription Drug Importation Program within the Department of Business and Professional Regulation (DBPR) to import safe and effective drugs from foreign nations into the state. These foreign nations must be ones that the federal government has recognized as adhering to current good manufacturing practices for pharmaceutical products, either through a current mutual recognition agreement, cooperation agreement, or memorandum of understanding, or through some other federal mechanism. These foreign entities must obtain appropriate licensing or permitting in Florida to participate in the program, and as such, will be subject to Florida's laws and regulations. The bill poses additional requirements for importers, exporters, and activities under the program to ensure safety of prescription drugs imported into the state. To implement the program, DBPR and the Department of Health must first negotiate a federal arrangement or obtain federal guidance on the program.

Eligible Prescription Drugs

The bill allows only certain types of prescription drugs to be imported and under certain circumstances. Specifically, eligible importers may import a prescription drug from an eligible exporter if:

- The drug meets the United States Food and Drug Administration's standards related to safety, effectiveness, misbranding, and adulteration;
- Importing the drug would not violate the patent laws of the United States;
- Importing the drug is expected to generate cost savings; and
- The drug is not:
 - A controlled substance;
 - A biologic product;
 - An infused drug;
 - An intravenously injected drug;
 - A drug that is inhaled during surgery; or
 - A drug that is a parenteral drug, the importation of which the United States Secretary of Health and Human Services determines poses a threat to the public health.

These conditions are the same as for the Canadian Prescription Drug Importation Program in the bill.

Eligible Importers

The bill allows the following entities to import prescription drugs into the state under this program:

- A wholesale distributor permitted under ch. 499, F.S.;
- A pharmacy permitted under ch. 465, F.S.; and
- A pharmacist licensed under ch. 465, F.S.

Eligible importers must register with DBPR before participating in the program and may not distribute, sell, or dispense any prescription drugs exported into the state under the program to any person residing outside of the state. Importers must maintain an active and unencumbered license or permit at all times to participate in the program. As entities licensed or permitted in Florida, all eligible importers must comply with DBPR's or the Board's regulations and will be subject to regular inspections and discipline for violations of any relevant laws or rules.

Eligible Exporters

The bill allows only three types of entities permitted with DBPR or the Board of Pharmacy to export prescription drugs into the state under the program, and creates two new permit categories for this purpose. Eligible exporters must first register with DBPR before participating in the program and may not distribute, sell, or dispense any prescription drugs exported into the state under the program to any

person residing outside of the state. As Florida-permitted entities, all eligible exporters must comply with DBPR's or the Board's regulations and will be subject to regular inspections and discipline for violations of any relevant laws or rules.

The following entities may export prescription drugs into the state under the program:

- An international prescription drug wholesale distributor;
- A nonresident prescription drug manufacturer; and
- An international export pharmacy.

International Prescription Drug Wholesale Distributors

The bill creates a new permit under ch. 499, F.S., the international prescription drug wholesale distributor permit, for prescription drug wholesale distributors located outside of the United States to participate in the program. Such a wholesale distributor must be licensed or permitted to operate in a country which the United States has recognized as adhering to current good manufacturing practices for pharmaceutical products and must maintain at all times such license or permit in full compliance with that country's laws. DBPR may not issue this permit to a wholesale distributor if its home jurisdiction does not require licensing or permitting for wholesale distribution of prescription drugs.

To obtain or renew an international prescription drug wholesale distributor permit, an eligible wholesale distributor must submit an application to DBPR which contains all of the same information currently required by applicants for a prescription drug wholesale distributor permit or an out-of-state prescription drug wholesale distributor permit. This information includes: detailed ownership records, financial records, and information related to affiliates, managers, or designated representatives; a list of all licenses and permits issued to the applicant by any other state or jurisdiction to purchase or possess prescription drugs; and proof of inspection of its wholesale distribution establishments, among other things.

The bill additionally requires applicants for international prescription drug wholesale distributor permits to provide documentation demonstrating that the applicant is appropriately licensed or permitted by a country with which the United States has a mutual recognition agreement, cooperation agreement, memorandum of understanding, or other mechanism recognizing the country's adherence to current good manufacturing practices for pharmaceutical products.

DBPR may deny a permit application for a number of reasons relating to the applicant's experience, competency, integrity, disciplinary or criminal history, or affiliation with any entity with disciplinary or criminal history, or based on any information that indicates the applicant may pose a public health risk.⁸⁹

Consistent with other permits for prescription drug wholesale distributors, at least one person must serve as the designated representative of the international prescription drug wholesale distributor and must be certified by DBPR, which requires two years' related work experience, undergoing a criminal background check, and passing a laws and rules exam, among other things.⁹⁰

DBPR has broad authority to inspect and investigate violations at any permittee establishment under s. 499.051, F.S. In addition to this, the bill requires DBPR to inspect an international prescription drug wholesale distributor establishment as often as necessary to ensure compliance with applicable laws and rules. If DBPR determines that the establishment poses an imminent danger to the public health, DBPR must immediately close the establishment if it fails to comply with applicable laws and rules. In

⁸⁹ S. 499.01(10), F.S.

⁹⁰ A wholesale distributor may not operate under this permit for more than 10 business days after a designated representative stops working for the wholesale distributor unless another designated representative is employed and the department is notified within 10 business days.

the case of such closure, the establishment may only reopen if DBPR determines it no longer poses a threat to public health and safety or by a court order.

These requirements are consistent with DBPR's existing permitting requirements for in-state and out-of-state wholesale prescription drug distributors under ch. 499, F.S. International prescription drug wholesale distributors will be subject to disciplinary action under s. 499.067, F.S., for violation of any related state and federal laws and rules.

Nonresident Prescription Drug Manufacturers

A nonresident prescription drug manufacturer permit currently exists for manufacturers located outside of the United States. The bill allows such permitted entities to participate in the program under certain conditions.

To participate in the program, a nonresident prescription drug manufacturer must be appropriately licensed or permitted in a country which the United State has recognized as adhering to current good manufacturing practices for pharmaceutical products through a current mutual recognition agreement, cooperation agreement, memorandum of understanding, or other federal mechanism. The manufacturer must first register with DBPR before engaging in any export activities under the program and must maintain at all times an active and unencumbered license or permit to manufacture prescription drugs in its home country. Participation in the program does not affect a nonresident prescription drug manufacturer's ability to otherwise import prescription drugs under current law.

If the manufacturer distributes any prescription drugs for which it is not the original manufacturer, the manufacturer must also obtain an international prescription drug wholesale distributor permit with DBPR to export those prescription drugs under the program.

Currently, a nonresident prescription drug manufacturer permittee that exports prescription drugs into the state from a foreign country must provide DBPR documentation of FDA's approval for such exportation.⁹¹ The bill exempts such permittees from this documentation requirement if they are exporting prescription drugs under the program.

International Export Pharmacies

The bill creates a new permit under ch. 465, F.S., the international export pharmacy permit, for pharmacies located outside of the United States to participate in the program. Such pharmacy must be licensed or permitted to operate in a country which the United States has recognized as adhering to current good manufacturing practices for pharmaceutical products and must maintain at all times such license or permit in full compliance with that country's laws.

To obtain or renew an international export pharmacy permit, an eligible pharmacy must submit an application to the Board of Pharmacy which contains information consistent with what is currently required of nonresident pharmacies that similarly send prescription drugs into the state. This information includes: proof of a clear and active permit to operate the pharmacy in its jurisdiction; detailed information about owners, principal officers, and the managing pharmacist of the pharmacy; a current inspection report from an approved regulatory body; and affidavits from the owner, officer, and managing entity that they have read and understand the relevant laws in Florida, that prescription drugs sent into the state will meet its standards of safety and efficacy, and that no prescription drug sent into the state will be manufactured or distributed in violation of the laws in the jurisdiction where the pharmacy operates.

The bill additionally requires applicants for international export pharmacy permits to provide documentation demonstrating that the applicant is appropriately licensed or permitted by a country with

⁹¹ S. 499.01(2)(c)2., F.S.
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which the United States has a mutual recognition agreement, cooperation agreement, memorandum of understanding, or other mechanism recognizing the country's adherence to current good manufacturing practices for pharmaceutical products.

Section 465.022, F.S., requires criminal background checks for each person having an ownership interest of 5 percent or more in the pharmacy and any person who directly or indirectly manages, oversees, or controls the operation of the pharmacy, including officers and members of the board of directors of an applicant that is a corporation. DOH is required to annually run a background check on these entities and provide the records to wholesale distributors permitted under ch. 499, F.S.

Currently, the Board may deny an application for a pharmacy permit if the applicant or an affiliated person, partner, officer, director, or prescription department manager or consultant pharmacist of record of the applicant has violated or failed to comply with any provision of chs. 465, 499, or 893, F.S., or the Federal Food, Drug, and Cosmetic Act, the Comprehensive Drug Abuse Prevention and Control Act, or any related rules or regulations promulgated thereunder unless the violation or noncompliance is technical. Additionally, the Board is required to deny an application in various instances where the applicant or an affiliated person, partner, officer, director, or prescription department manager or consultant pharmacist of record of the applicant has certain criminal history⁹² or a history of fraudulent behavior related to pharmacy.⁹³ All of these conditions would apply to an applicant for an international export pharmacy under the bill.

The bill authorizes DOH to inspect an international export pharmacy to determine its compliance with relevant laws and rules, secure samples or specimens of any drug or medical supply,⁹⁴ or secure any other evidence needed for prosecution.⁹⁵

Consistent with existing pharmacy permit regulations, an international export pharmacy will be subject to disciplinary action under s. 465.023, F.S., for any violation of relevant federal or state laws or rules, including those under ch. 499, F.S.

Prescription Drug Supply Chain Documentation

The bill requires the importer to submit extensive documentation and information to ensure the integrity of the drug along the distribution chain, including testing conducted in a DBPR-approved laboratory.

A participating importer must submit the following information and documentation to the department:

- The name and quantity of the active ingredient of the prescription drug.
- A description of the dosage form of the prescription drug.
- The date on which the prescription drug is shipped.
- The quantity of the prescription drug that is shipped.
- The point of origin and destination of the prescription drug.
- The price paid by the importer for the prescription drug.
- Documentation from the exporter specifying:
 - The original source of the prescription drug; and
 - The quantity of each lot of the prescription drug originally received by the seller from that source.
- The lot or control number assigned to the prescription drug by the manufacturer.
- The name, address, telephone number, and professional license or permit number of the importer.

⁹² *E.g.*, Felony crimes related to health care fraud, pharmacy, theft, drugs,

⁹³ *E.g.*, obtaining a permit by fraud or misrepresentation, procuring or attempting to procure a permit for another by making fraudulent misrepresentations, dispensing a prescription drug when the pharmacist had reason to know the prescription was not valid.

⁹⁴ DOH must pay or offer to pay for such sample or specimen. S. 465.017, F.S.

⁹⁵ The permittee or pharmacy bears the cost for any such inspection. S. 465.017(2), F.S.

- In the case of a prescription drug that is shipped directly by the first foreign recipient⁹⁶ from the manufacturer:
 - Documentation demonstrating that the prescription drug was received by the recipient from the manufacturer and subsequently shipped by the first foreign recipient to the importer;
 - Documentation of the quantity of each lot of the prescription drug received by the first foreign recipient demonstrating that the quantity being imported into the state is not more than the quantity that was received by the first foreign recipient;
 - For an initial imported shipment, documentation demonstrating that each batch of the prescription drug in the shipment was statistically sampled and tested for authenticity and degradation; and
 - For any subsequent imported shipment, documentation demonstrating that a statistically valid sample of the shipment was tested for authenticity and degradation.
- In the case of a prescription drug that is not shipped directly from the first foreign recipient, documentation demonstrating that each batch in each shipment offered for importation into the state was statistically sampled and tested for authenticity and degradation.
- Certification from the importer or manufacturer that the prescription drug:
 - Is approved for marketing in the United States and is not adulterated or misbranded; and
 - Meets all of the federal labeling requirements under 21 U.S.C. § 352.
- Qualified laboratory records, including complete data derived from all tests necessary to ensure that the prescription drug is in compliance with the requirements of this section.
- Documentation demonstrating that the testing required by this section was conducted at a qualified laboratory.
- Any other information the department determines is necessary to ensure the protection of the public health.

All testing required by the program must be conducted in a DBPR-approved laboratory. DBPR must maintain this submitted information and documentation for a period of at least 4 years.

Current law requires a person, other than the original manufacturer of a prescription drug, who manufactures, packages, repackages, labels, or relabels a drug or device in the state to register the drug with DBPR and pay a registration fee ranging from \$5 to \$15 for each separate and distinct product in package form.⁹⁷ A person cannot sell such a drug without this registration, which expires every two years. The bill exempts exporters and importers under the program from these registration requirements. However, DBPR will receive the prescription drug supply chain documentation for each drug imported under the program.

Suspension of Importation

The bill requires DBPR to immediately suspend importation of a specific prescription drug or importation by a specific entity if it discovers that any prescription drug or activity is in violation of the program requirements. DBPR may lift the suspension if after an investigation it determines that the public is adequately protected from counterfeit or unsafe prescription drugs being imported into the state.

Exemptions from Penalties

Sections 499.005(20) and 499.0051(12)(e), F.S., prohibit anyone other than the original manufacturer of a prescription drug from importing the prescription drug into the United States, subject to criminal penalties. The bill creates an exception for such importation if conducted pursuant to the International Prescription Drug importation Program.

⁹⁶ The bill defines “first foreign recipient” as an entity other than the original drug manufacturer that receives the prescription drug before its importation into the state under the program. e.g., a wholesale distributor or pharmacy.

⁹⁷ Ss. 499.015 and 499.041(6), F.S.

Federal Cooperation

To implement this program, the bill requires DBPR, in collaboration with DOH, to negotiate with the federal government to operate a pilot program in Florida that would import prescription drugs into the state notwithstanding the Federal Food, Drug, and Cosmetic Act. In their proposal, DBPR and DOH must demonstrate that the program:

- Sets safety standards consistent with current federal requirements for the manufacturing and distribution of prescription drugs;
- Limits the importation of prescription drugs to entities licensed or permitted by the state to manufacture, distribute, or dispense prescription drugs; and
- Includes inspection and enforcement authority.

The bill expressly provides that implementation of the program is contingent on entering into such an agreement with the federal government or obtaining federal guidance.

The bill provides DBPR rulemaking authority to implement the program.

The bill provides an effective date of July 1, 2019.

B. SECTION DIRECTORY:

- Section 1:** Creates s. 381.02035, F.S., relating to Canadian Prescription Drug Importation Program.
- Section 2:** Creates s. 499.0285, F.S., relating to International Drug Importation Program.
- Section 3:** Creates s. 465.0157, F.S., relating to international export pharmacy.
- Section 4:** Amends s. 465.017, F.S., relating to authority to inspect; disposal.
- Section 5:** Amends s. 499.01, F.S., relating to permits.
- Section 6:** Amends s. 499.012, F.S., relating to permit application requirements.
- Section 7:** Amends s. 499.005, F.S., relating to prohibited acts.
- Section 8:** Amends s. 499.0051, F.S., relating to criminal acts.
- Section 9:** Amends s. 499.015, F.S., relating to registration of drugs and devices; issuance of certificates of free sale.
- Section 10:** Amends s. 499.065, F.S., relating to inspections; imminent dangers.
- Section 11:** Creates an unnumbered section of law.
- Section 12:** Provides an effective date of July 1, 2019.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

See Fiscal Comments. Also, please see HB 7073, which authorizes DBPR and DOH to charge fees relating to new permits associated with the International Prescription Drug Importation Program.

2. Expenditures:

See Fiscal Comments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The International Prescription Drug Importation Program allows Florida-permitted wholesale distributors, pharmacies, and pharmacists to import prescription drugs, which they are currently not able to do. To the extent that such entities participate in the program to import cheaper versions of FDA-approved drugs, they may experience a cost savings. As a result of this competition, consumers may have increased access to cheaper FDA-approved drugs. Drug manufacturers will experience a negative fiscal impact to the extent that more entities import cheaper versions of their drugs under the program.

D. FISCAL COMMENTS:

The bill has a significant, negative fiscal impact on the AHCA and DBPR. The bill establishes a separate program under each of the agencies, both of which require federal approval for full implementation. Therefore, some components of the fiscal impact are staggered pending federal approval. Funding would not be needed until Federal approval has been provided.

Canadian Prescription Drug Importation Program – (AHCA)

The Canadian Prescription Drug Importation Program created within AHCA is contingent upon federal approval, but AHCA must first contract with a vendor for certain services prior to requesting this approval. AHCA anticipates a need of six FTE positions and recurring funding to procure a contract with a vendor for services required by the program. Expenditures for the six FTE positions are estimated to be \$572,495 for the first year of implementation and \$545,837 recurring thereafter. However, the funding required to procure a vendor is indeterminate at this time.⁹⁸

AHCA Fiscal Impact		
(Contingent Upon Federal Approval)	First Year of Implementation	2nd Year and Beyond: Recurring Expenditures
FTE:		
1.00 - AHCA Administrator - SES	\$ 98,345	\$ 98,345
5.00 - Government Analyst II	\$ 409,770	\$ 409,770
Operational Expenses:	\$ 64,380	\$ 37,722
Grand Total:	\$ 572,495	\$ 545,837

AHCA currently has over 100 long term vacant FTE positions within the agency. Analysis of current trust fund balances and prior year reversions indicates the availability of funds to procure the vendor required by the bill. AHCA has reversions in the Contracted Services category (Executive Direction and Support Services budget entity) for FY 2017-18 totaling \$13,700,370, and a three year average of reversions totaling \$15,265,572. Additionally, AHCA indicates that the program may bring cost savings to the Medicaid Program, the extent of which cannot be determined at this time.

Although AHCA estimates a need for additional FTE positions and funding to procure a vendor, analysis based upon current long term vacancies and existing fund balances indicates that the additional workload required due to provisions of the bill can be absorbed within existing resources

⁹⁸ Agency for Health Care Administration, Agency Analysis for HB 19, p. 11-13 (on file with Health Quality Subcommittee staff).

International Prescription Drug Importation Program – (DBPR & DOH)

The bill requires DBPR and DOH to negotiate with the federal government to obtain cooperation or guidance before implementing the program. If federally approved, DBPR estimates a need of three FTE positions, a consultant for qualified laboratory approvals, and modifications to the Controlled Substance Reporting (CSR) system. These expenditures are estimated to be \$520,191 of General Revenue funding in the first year of implementation and \$305,579 recurring General Revenue funding thereafter. In addition, the bill will require modifications to DBPRs Versa system as well as other software updates to implement the program, however, those modifications can be absorbed within existing resources.⁹⁹ The Division of Drugs, Devices, and Cosmetics within DBPR currently has no vacant FTE positions.

DBPR Fiscal Impact		
(Contingent Upon Federal Approval)	First Year of Implementation	2nd Year and Beyond: Recurring Expenditures
FTE:		
1.00 - Senior Pharmacist	\$ 118,709	\$ 118,709
1.00 - Senior Pharmacist Drug Inspector	\$ 118,709	\$ 118,709
1.00 - Regulatory Specialist II	\$ 46,457	\$ 46,457
Operational Expenses:	\$ 51,816	\$ 21,804
Consulting Services for Qualified Laboratory Approval:	\$ 117,000	\$ -
IT Staff Augmentation for CSR System Updates:	\$ 67,500	\$ -
Grand Total:	\$ 520,191	\$ 305,679

DOH indicates no fiscal impact as a result of provisions in the bill.¹⁰⁰

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to impact county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides sufficient rulemaking authority.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

⁹⁹ *Supra* note 71, at pp. 9-10.

¹⁰⁰ Florida Department of Health, Agency Analysis for HB 19, p. 4 (on file with Appropriations Committee staff).