

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL: SB 1528

INTRODUCER: Senators Bean and Gruters

SUBJECT: Prescription Drug Importation Programs for Public Programs

DATE: March 22, 2019

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Brown	HP	Pre-meeting
2.			AHS	
3.			AP	

I. Summary:

SB 1528 creates the Canadian Prescription Drug Importation Program (program). The Agency for Health Care Administration (AHCA) is directed to establish the program for the safe and effective importation of prescription drugs from Canada which will have the highest potential cost savings to the state.

The AHCA must contract with a vendor by December 1, 2019, to administer the program, and develop a plan for federal approval of the program to be submitted by July 1, 2020, to the federal Department of Health and Human Services. Once federal approval is granted, AHCA is directed to begin operations within six months.

The bill contains numerous requirements for the vendor and for program participants designed to ensure the program is safe and effective and results in cost-savings.

An annual report is due every December 1st to the Governor, the President of the Senate, and the Speaker of the House of Representatives, and must include specified components. The AHCA may adopt rules to implement the program.

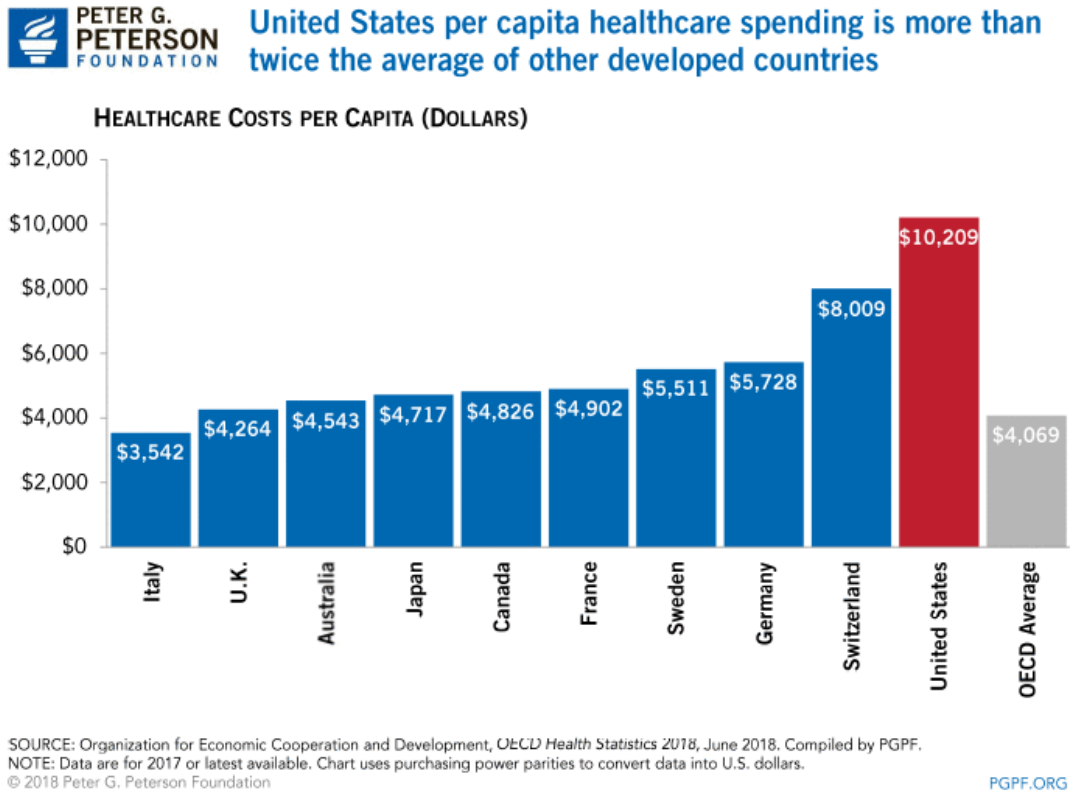
The bill has an incomplete fiscal impact analysis at this time with the expectation that there will be start-up costs associated with implementation prior to any achievement of potential savings under the program.

The effective date is July 1, 2019.

II. Present Situation:

U.S. Healthcare Marketplace

In 2017, health care spending in the United States increased 3.9 percent over the prior year to \$3.5 trillion, or an average of \$10,739 per person.¹ Health care spending represents over 17 percent of the nation’s Gross Domestic Product.² In comparison to other countries, the United States’ per capita health care costs can be double that of other countries of comparable size and wealth as the chart below shows.³



Retail prescription drug costs ranked third behind hospital care and physician and clinical services, representing 10 percent of health spending.⁴ Prescription drugs posted a slower growth rate for 2017 of 0.4 percent compared to the prior year when the growth rate was 2.3 percent.

¹ Centers for Medicare and Medicaid Services, *National Health Expenditures 2017 Highlights*, p. 1, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf> (last visited March 21, 2019).

² Centers for Medicare and Medicaid Services, *National Health Expenditure Data, Historical*, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html> (last visited March 21, 2019).

³ Peter J. Peterson Foundation, *Per Capita Healthcare Costs-International Comparison* (Aug. 10, 2018), www.pgpf.org, https://www.pgpf.org/chart-archive/0006_health-care-oecd (last visited March 21, 2019).

⁴ Centers for Medicare and Medicaid Services, *National Health Expenditures 2017 Highlights*, *Supra* note 1.

The 2017 growth rate in prescription drugs equated to an increase of \$333.4 billion.⁵ Of that amount, the vast majority, \$285 billion, is paid through health insurance coverage which includes private health insurance, Medicare, Medicaid and other health insurance coverage.⁶ The next highest category is private health insurance within with the health insurance coverage category (\$100.9 billion) followed by out-of-pocket costs (\$46.7 billion).⁷

The key drivers for prescription drug costs each year depend on the balance between consumers' usage of generic and brand drugs, the release of drugs from patent protection, and sales volumes of higher cost drugs.

Spending by different blocks of purchasers fluctuates each year. The federal government is the largest group purchaser of health care services, accounting for 28 percent of the health care market, with private business next at 20 percent, and then state and local governments with 17 percent for 2017.⁸ Two out of three of these purchasing blocks experienced a deceleration in their health care spending rates: private households (decrease to 3.8 percent) and private business (decrease to 4.1 percent), and the third, state and local governments, had an increase from 3.8 percent in 2016 to 4.1 percent in 2017.⁹

A majority of adults aged 18-64, nearly 60 percent, reported being prescribed a medication in the past 12 months in one study sponsored by the federal Centers for Disease Control and Prevention.¹⁰ Approximately 70 percent of all prescriptions carry out-of-pocket costs, such as requirements for co-insurance, co-payments, or deductible, with generics having an average cost of \$6 per prescription and brand names an average cost of \$30 per prescription.¹¹

Many adults who are prescribed drugs with higher out-of-pocket costs will forego their prescriptions or will take other measures, including considering other non-medication therapies, to avoid the out-of-pocket costs. Researchers found that while the number of adults who asked their health care provider for an alternative medical treatment option with a lower out-of-pocket cost had dropped from the prior study, the percentage was still 19.8 percent.¹² Other strategies that adults used included not taking the medication as prescribed, which could mean skipping doses, taking less than the prescribed dose, delaying a refill; or using alternative therapies instead of the prescribed medication.¹³

⁵ Centers for Medicare and Medicaid Services, *National Health Expenditures 2017 Highlights*, *Supra*, Note 1.

⁶ Centers for Medicare and Medicaid Services, *National Health Expenditures, Table 16 – Retail Prescription Drugs Expenditure; Levels, Percent Change, and Percent Distribution by Source of Funds: Selected Calendar Year 1970-2017*, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html> (last visited March 21, 2019).

⁷ U.S. Department of Health and Human Services, *National Health Expenditures, Table 16 – Retail Prescription Drugs Expenditure; Levels, Percent Change, and Percent Distribution by Source of Funds: Selected Calendar Year 1970-2017*, *Id.*

⁸ U.S. Department of Health and Human Services, *National Health Expenditures 2017 Highlights*, *Id.* at 2.

⁹ *Id.*

¹⁰ Robin A. Cohen, et al, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, *Strategies Used by Adults Aged 18-64 to Reduce Their Prescription Drug Costs, 2017*, *NCHS Data Brief (March 2019)*, p. 1, <https://www.cdc.gov/nchs/data/databriefs/db333-h.pdf> (last visited March 21, 2019).

¹¹ Robin A. Cohen, *supra note*, 10.

¹² Robin A. Cohen, *supra note*, 10.

¹³ Robin A. Cohen, *supra note*, 10 at 2-4.

As with the comparison of general health care costs, the United States' prescription drug spending on its own also stands in stark contrast to other industrialized nations. By 2015, the United States' spending on prescription drugs had exceeded \$1,000 per person per year and was 30 to 190 percent higher than nine other western countries.¹⁴

Role of Price Controls

Reasons given for the price differentials among the countries primarily are related to the fact that most of these nations have some type of price control over drug pricing. In the United States, only two federal entities, the Department of Defense and the Department of Veterans Affairs, negotiate directly with drug manufacturers for drug prices, and they pay approximately 50 percent of what is paid at a retail pharmacy.¹⁵ The discount is equal to 24 percent off of a drug's average price or the lowest price paid by other non-federal buyers, as well as other discounts if a drug's price outstrips inflation.¹⁶

The United States typically uses drug price controls in one of two ways. First, in the manner described above with the Department of Defense and the Department of Veterans' Affairs with price controls in the form of a required discount of the average price paid by other purchasers of the same product. The other manner is through negotiated pricing when the government wields its market power as a large purchaser of health care services to bargain for more favorable rates from pharmaceutical suppliers.¹⁷

Medicaid is also the recipient of manufacturer discounts and rebates, receiving whichever is lower: typically 23.1 percent less than the average price paid for the drug by other buyers, or the lowest price at which the drug is sold to other buyers.¹⁸ Medicaid can also negotiate additional rebates and will receive additional discounts if the price of the drug rises faster than inflation.¹⁹

Medicare Part D, the prescription drug benefit for Medicare, differs with Medicaid in the prices paid for prescription drugs and in the measures used to control prescription drug spending. These differences are often a function of the different options that are statutorily available relating to copayment restrictions, rebate levels, and the fact that the two programs do not serve the same constituencies, and therefore, the drug usage between the programs do not match up.²⁰

¹⁴ Dana O. Sarnak, et al, *Paying for Prescription Drugs Around the World: Why is the U.S. an Outlier?*, The Commonwealth Fund, www.commonwealthfund.org, <https://www.commonwealthfund.org/publications/issue-briefs/2017/oct/paying-prescription-drugs-around-world-why-us-outlier> (last visited March 21, 2019). The nine western countries being used in comparison are Switzerland, Germany, Canada, France, United Kingdom, Australia, Netherlands, Norway, and Sweden.

¹⁵ Dana O. Sarnak, et al, *supra note 15*.

¹⁶ David Blumenthal, M.D. and David Squires, *Drug Price Control: How Some Government Programs Do It*, The Commonwealth Fund, (May 10, 2016) www.commonwealthfund.org, https://www.commonwealthfund.org/blog/2016/drug-price-control-how-some-government-programs-do-it?redirect_source=/~/media/2aca550e3b1446fd91b0f5d0b16eb87c.ashx (last visited March 21, 2019).

¹⁷ David Blumenthal, M.D. and David Squires, *supra note 21*.

¹⁸ David Blumenthal, M.D. and David Squires, *supra note 21*.

¹⁹ David Blumenthal, M.D. and David Squires, *supra note 21*.

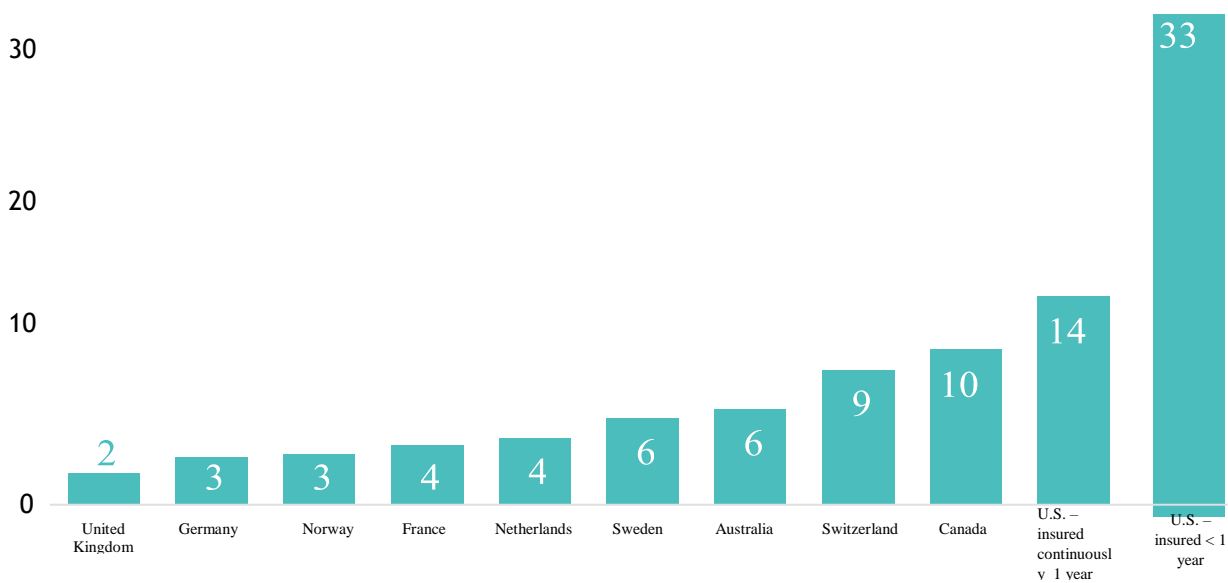
²⁰ Congressional Budget Office, *Competition and the Cost of Medicare's Prescription Drug Program* (July 2014), p. 30, <https://www.cbo.gov/sites/default/files/113th-congress-2013-2014/reports/45552-PartD.pdf> (last visited March 21, 2019).

Programmatic Differences – Prescription Drugs – Federal Programs ²¹		
	Medicare Part D	Medicaid Fee for Service
Average Rebate	15 percent of retail price (2010) <i>Top 53 therapeutic classes</i>	54 percent of retail price - Brand <i>Top 53 Therapeutic Classes</i> Average Rebate – 56 percent
Use of Generics	75 percent	70 percent
Use of Drugs Within Therapeutic Class	\$49	\$36

Out of Pocket Costs

Out of pocket prescription drug spending per capita varies widely, country by country, from a low in \$0 in France and the United Kingdom for certain individuals or in certain areas of the United Kingdom (Scotland, Wales, or Northern Ireland) to a high of \$221 in Switzerland.²² Many of these national drug plans come with further protections for lower income individuals such as reduced copayments or spending caps, and exemptions for the chronically ill.

Adults Who Cited Cost as a Reason for Skipping Prescriptions or Doses, 2016²³



From a cost perspective, 58 percent of respondents to a survey reported spending \$100 or more a month on prescriptions and those who were in fair or poor health said they were taking four or more prescriptions a month (49 percent).²⁴ The public also viewed the profits made by the pharmaceutical companies as the largest contributor to prescription drug prices (80 percent) followed by the cost of research and development (69 percent), profits made by pharmacy benefit managers or PBMs (63 percent), and the cost of marketing and advertising

²¹ Congressional Budget Office, *supra note 25*, 31-32.

²² Dana O. Sarnak, et al, *supra note 15*, Appendix – Patient Exposure to Out of Pocket Prescription Drug Costs.

²³ Dana O. Sarnak, *supra note 15*. Credit for chart specifically: R. Langreth, B. Migliozi, and K. Gokhale, (Bloomberg, Dec. 18, 2015) (last visited March 22, 2019).

²⁴ Jay Hancock, Kaiser Health News, *Id.*

(52 percent).²⁵ When the survey asked the public how prescription drug costs could be kept down, the top five answers were:

- Requiring drug companies to include list prices in ads (88 percent).
- Making it easier for generic drugs to come to market (88 percent).
- Allowing the government to negotiate with drug companies to get a lower price for people with Medicare (86 percent).
- Allowing Americans to buy drugs imported from Canada. (80 percent)
- Planning an annual limit on out-of-pocket drug costs for people with Medicare (76 percent).²⁶

Blame for prescription costs in the U.S. can likely be attributed to a number of different causes if the number of newspaper articles, blog posts, and magazine stories about the issue are anything to go by in the past several years. Representatives from the PBMs will argue that the country cannot be responsible for subsidizing the research and development costs for the world.²⁷ Drug makers often insist that comparing prices country to country or even payor to payor is not a true comparison of prices since comparisons do not include all of the discounts drug makers may provide.²⁸ In remarks to stakeholders and the news media, the current Secretary of the federal Department of Health and Human Services Alex Azar remarked that “the problem has multiple parts: high list prices, overpaying in government programs, high out-of-pocket costs, foreign government free-loading. They are connected in a way that attempting to squeeze one end of the balloon won’t lead to lasting change.”²⁹

Federal Regulation of Prescription Drugs

The United States Food and Drug Administration (FDA) is the federal agency responsible for ensuring that food, drugs, biological products, and medical devices are effective and safe for public consumption. The FDA regulates these areas under the authority of the Food, Drug, and Cosmetic Act (FDCA).³⁰ Generally, the state boards of pharmacy have primary responsibility for oversight and regulation of pharmacy; however, the FDA regulates, and in some cases preempts state action, through the FDCA and the Drug Quality and Security Act (DQSA). The DQSA created a national uniform standard and an electronic system for the tracing of drugs at the package level, preempting pedigree laws that previously existed in Florida and 28 other states. In the 2016 Legislative Session, Florida conformed its statutes to the revised federal standards.³¹

²⁵ Jay Hancock, Kaiser Health News, *Id.*

²⁶ Jay Hancock, Kaiser Health News, *Id.*

²⁷ Robert Langreth, et al, *The U.S. Pays a Lot More for Top Drugs Than Other Countries*, Bloomberg News (December 18, 2015), <https://www.bloomberg.com/graphics/2015-drug-prices/> (last visited March 21, 2019). “We can no longer sustain a system where 300 million Americans subsidize drug development for the entire world,” said Steve Miller, chief medical officer for Express Scripts Holding Co.

²⁸ Robert Langreth, et al, Bloomberg News. “The difference in prices here in the U.S. compared to other countries is often vastly overstated,” said Robert Zirkelbach, spokesman for the Pharmaceutical Research Manufacturers of America trade group.

²⁹ Alex M. Azar, II, *Remarks on Drug Pricing Blueprint (May 14, 2018) as prepared for delivery*, delivered in Washington, D.C., <https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html> (last visited March 21, 2019).

³⁰ Food, Drug, and Cosmetic Act, 21 U.S.C. ss. 301 et seq. 52 Stat. 1040 et. seq. as amended by the Drug Quality and Security Act, 21 U.S.C. 351 et seq.

³¹ See ch. 2016-212 Laws of Florida (CS/CS/HB 1211)

The FDCA prohibits any drug from being introduced or delivered for introduction or delivered for introduction into interstate commerce unless approved by the FDA. The FDCA further prohibits adulterated³² or misbranded drugs³³ and devices from being introduced, delivered for introduction, or received in interstate commerce.³⁴ In a warning letter dated February 26, 2019, to CanaRx, the FDA cited this statutory reference and at least five others it believed had been violated by a foreign pharmacy and its business associates in the delivery of prescription drugs from Canada to recipients in the United States.³⁵ CanaRx serves as a broker between foreign pharmacies and public and private employer sponsored health plans to provide employees with prescription drugs, according to the FDA. The letter identified issues with dispensing unapproved new drugs, substitution of FDA approved drugs with recalled or unapproved drugs, misbranded drugs, and drugs subject to the Risk Evaluation and Mitigation Strategy program.³⁶ More than 150 websites were included in the letter as affiliated with CanaRx. The FDA gave CanaRx 10 days to respond to the warning letter.

Drug Approval Process

The FDA process for new and innovative drugs is rigorous and requires an exhaustive and extensive series of clinical trials, first on animals and then on humans, before a new drug application (NDA) can even be formally filed with the FDA.³⁷ The NDA process has three goals:

- Whether the drug is safe and effective in its proposed uses(s), and whether the benefits of the drug outweigh the risks.
- Whether the drugs proposed labeling (package insert) is appropriate and what it should contain.

³² An “adulterated drug or device” is defined, in part, under 21 U.S.C. 351, as a drug or device that consists “in whole or in part of any filthy, putrid, or decomposed substance; or if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or if it is a drug and the methods used in or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess...”

³³ A “misbranded drug or device” is defined, in part, under 21 U.S.C. 352, as a drug or device whose “labeling is false or misleading in any particular. Health care economic information provided to a payor, formulary committee, or other similar entity with knowledge and expertise in the area of health care economic analysis, carrying out its responsibilities for the selection of drugs for coverage or reimbursement, shall not be considered to false or misleading under this paragraph if the health care economic information related to an indication approved under section 505 or under section 351 of the Public Health Service Act for such drug, is based on competent and reliable scientific evidence, and includes, where applicable, a conspicuous and prominent statement describing any material differences between the health care economic information and the labeling approved for the drug under section 505 or under section 351 of the Public Health Service Act...”

³⁴ See 21 U.S.C. 331 (as amendment through P.L. 115-271, enacted October 24, 2018).

³⁵ Letter to Gregory Anthony Howard, CanaRx Services, Inc. (Feb. 26, 2019), U.S. Food and Drug Administration Warning Letter, <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm632061.htm> (last visited March 21, 2019).

³⁶ The FDA’s Risk Evaluation and Mitigation Strategy (REMS) program is a drug safety program for drugs that have a narrow therapeutic index, and/or is the drug is indicated to treat a serious condition such as HIV, cancer, or hepatitis. A strategy is designed specific to a particular drug to address the safety and risk concerns unique to that drug, such as requiring that a drug only be administered in a health care facility or by a provider. Another strategy may be a special patient information pamphlet insert included with the prescription. All of the strategies are aimed at reducing the frequency or severity of an adverse event.

³⁷ U.S. Food and Drug Administration, *New Drug Application*, <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm> (last visited March 21, 2019).

- Whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity.³⁸

The first step in the process is for a sponsor, such as a company, research institution, or other organization, to take responsibility for developing the drug by showing the FDA results of preclinical lab testing on animals and how they propose to conduct human testing. The FDA must decide at that point whether it is reasonably safe for the sponsor to move forward with the proposed plan. Clinical trials only move forward after an investigation of a new drug application (IND) has been reviewed by the FDA and a local institutional review board (IRB). The IRB includes scientists and non-scientists in hospitals and research institutions who will oversee the clinical research.³⁹

In Phase One of the clinical trials, usually health volunteers are used to determine what the drug's most frequent side effects are, and how the drug is metabolized and excreted. The size of the clinical trial is between 20 and 80 people.⁴⁰ If unacceptable levels of toxicity in the drug are not revealed, then the clinical trial will usually move on to Phase II where the emphasis is on effectiveness of the drug. Patients receiving the drug will be compared against those who will not be receiving the drug, usually a placebo or a different drug. The number of participation in this phase ranges from a few dozen to about 300.⁴¹

At the end of Phase Two, the sponsors and the FDA will try to reach a consensus on how large of scale the study should be in Phase Three. Phase Three will occur only if the drug showed signs of effectiveness in Phase Two. Different strengths and doses may be tried in this phase and the drug may be used in combination with other drugs. The size of the participant pool may range from several hundred to upwards of 3,000.⁴²

The NDA is the formal step that the drug sponsor will decide to take to seek formal approval from the FDA at the end of Phase Three trials. An NDA application will incorporate all of the data from the clinical trials, animal and human, as well as how the drug behaves and will be manufactured. Once received by the FDA, the FDA has 60 days to decide whether to file it for review. The goal once the NDA is received is 10 months to review and act or 6 months for priority drugs.⁴³

When new drugs are approved, the sponsoring entities may apply for and receive a patent for the drug which gives the sponsor the right to exclude others from making, using, offering to sell, or selling the drug within the United States, 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.⁴⁴ This allows

³⁸ U.S. Food and Drug Administration, *supra note*, 42.

³⁹ U.S. Food and Drug Administration, *The FDA's Drug Review Process: Ensuring Drugs are Safe and Effective*, <https://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143534.htm> (last visited March 21, 2019).

⁴⁰ U.S. Food and Drug Administration, *The FDA's Drug Review Process: Ensuring Drugs are Safe and Effective*, *supra note*, 44.

⁴¹ U.S. Food and Drug Administration, *The FDA's Drug Review Process: Ensuring Drugs are Safe and Effective*, *supra note*, 44.

⁴² U.S. Food and Drug Administration, *The FDA's Drug Review Process: Ensuring Drugs are Safe and Effective*, *supra note*, 44.

⁴³ U.S. Food and Drug Administration, *The FDA's Drug Review Process: Ensuring Drugs are Safe and Effective*, *supra note*, 44.

⁴⁴ U.S. Food and Drug Administration, *Frequently Asked Questions on Patents and Exclusivity*, <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079031.htm#howlongpatentterm> (last visited March 21, 2019).

generic drug companies time to learn how to manufacture the drug in a process that would otherwise run them afoul of federal patent law and subject them potentially to patent infringement litigation.

Drug Manufacture

The FDA ensures the quality of the United States' drug products by carefully monitoring drug manufacturer's compliance with its Current Good Manufacturer's Practice Regulations. (CGMP), which are the main regulatory standard for ensuring pharmaceutical quality for human pharmaceuticals.⁴⁵ The CGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, packaging, and labeling pharmaceuticals. The regulations are found at 21 CFR Part 211 and specify the responsibilities of the quality control unit, personnel qualifications and responsibilities, the design and construction of facilities, the equipment requirements, production and process controls, packaging and labelling operation, including tamper-evident package requirements, and returned drug products.

Drug Distribution

The Drug Supply Chain Security Act⁴⁶ (DSCSA) establishes procedures to ensure the integrity of prescription drugs as they are distributed along the supply chain. Effective July 1, 2015, the DSCSA requires manufacturers, re-packagers, wholesale distributors, and dispensers to exchange product tracing information when transferring a product along the distribution chain. As noted earlier, this national product tracing process replaces Florida's previous pedigree paper system.

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 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 six years and provide them to the FDA upon request.

Drug Supply Chain Security

The path a drug takes from unfinished product to when it is handed to a patient, either at a hospital bedside or to a customer at a community pharmacy, is called the supply or distribution chain. Along that path, there are several opportunities in that chain for the product to become mishandled or adulterated, whether it is in the United States or abroad.

⁴⁵ U.S. Food and Drug Administration, *Questions and Answers on Current Good Manufacturing Practices (CGMPs)*, <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm124740.htm> (last visited March 21, 2019).

⁴⁶ See Title II of DQSA, the Drug Supply Chain Security Act, Pub. Law 113-54 (2015).

The first legislation that dealt with such issues was the 1906 Food and Drugs Act, which addressed the labeling of drugs; then the 1938 Food, Drug, and Cosmetics Act (FDCA), which introduced the concepts of adulteration, misbranding, registration, and inspection of manufacturing establishments, and the Prescription Drug Marketing Act (PDMA, P.L. 100-293), which required that wholesale distributors be licensed by the states and that a wholesale distributor, except in certain circumstance, must issue a pedigree, which has since been superseded by the tracing requirements in the DQSA in 2015.⁴⁷

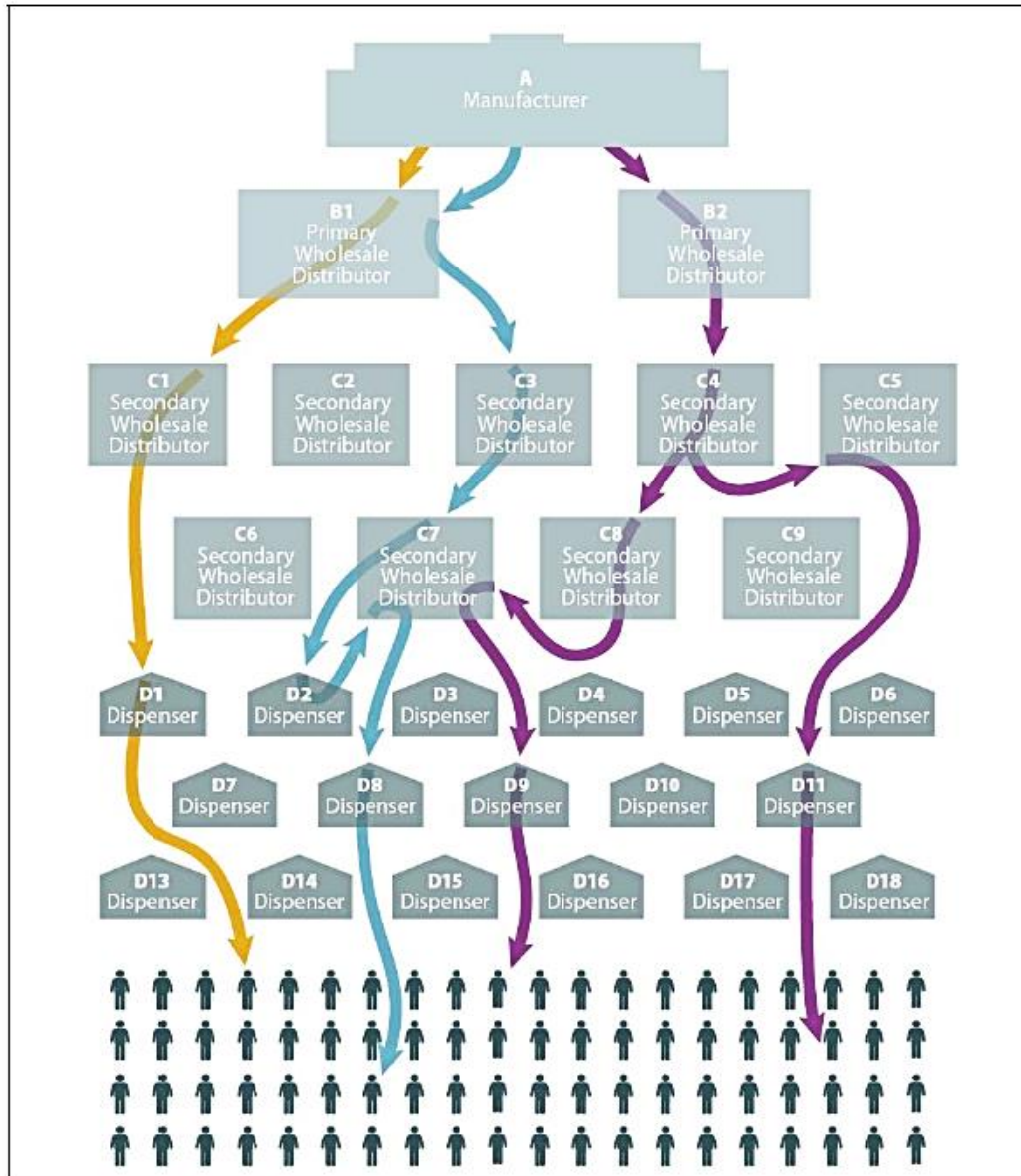
Supply security issues can include contamination of products, diversion, counterfeiting, and other adulteration, according to statements made by the Director of the Center for Drug Evaluation and Research (CDER) at the FDA, Dr. Janet Woodcock, in testimony to Congress in 2013.⁴⁸ In her testimony, she referenced cases involving counterfeit and fraudulent versions of Botox sold in the United States, Lipitor sold in the United Kingdom, and Avastin in the United States.⁴⁹ The chart below illustrates the downstream pharmaceutical supply chain and the different actors and components involved in the production and distribution process.

⁴⁷ Susan Thaul, Congressional Research Service, *Pharmaceutical Supply Chain Security (October 31, 2013)*, Summary, <http://www.ncsl.org/documents/statefed/health/CRS-PharmSupChSec2013.pdf> (last visited March 22, 2019).

⁴⁸ Susan Thaul, Congressional Research Service, *supra note 52*, at 1.

⁴⁹ Susan Thaul, Congressional Research Service, *supra note 52*, at 2.

Downstream Pharmaceutical Supply Chain⁵⁰



Interaction with the Foreign Market

As globalization has increased, the FDA has established foreign offices to work closely with foreign governments, industry, and other stakeholders to enable the FDA to more effectively protect American consumers, including inspections and investigations in those countries. The FDA indicates that about 35 percent of the medical devices used in the United States are imported.⁵¹

⁵⁰ Susan Thaul, Congressional Research Service, *supra note 52*, at 6.

⁵¹ U.S. Food and Drug Administration, *FDA Globalization*, <https://www.fda.gov/InternationalPrograms/FDABeyondOurBordersForeignOffices/default.htm> (last visited March 22, 2019).

Foreign companies that manufacture, prepare, propagate, compound, or process drugs that are offered for import in the United States must register with the FDA.⁵² Today, there are 136,400 foreign facilities in more than 150 countries that export FDA-regulated products to the United States.⁵³ 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.⁵⁴

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.⁵⁵ In federal fiscal year 2017-18, the FDA conducted 94 on-site inspections of foreign drug manufacturing facilities, and 381 historically since 2014-15.⁵⁶ This means that less than 1 percent of foreign FDA-registered drug manufacturing facilities are inspected by the FDA each year.

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.⁵⁷ International arrangements can have a variety of titles, including "cooperation agreement," "memorandum of understanding," or "mutual recognition agreement." The FDA currently has at least 80 such international arrangements with foreign governments.⁵⁸

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,

⁵² Section 510 of the federal Food, Drug, and Cosmetic Act.

⁵³ U.S. Food and Drug Administration, *FDA Globalization*, *supra note*, at 52.

⁵⁴ 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 March 22, 2019).

⁵⁵ 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.

⁵⁶ U.S. Food and 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-commodity> (last visited March 22, 2019).

⁵⁷ U.S. Food and Drug Administration, *International Agreements*, <https://www.fda.gov/InternationalPrograms/Agreements/default.htm> (last visited Mar. 8, 2019); *See also, FAQs: The Mutual Recognition Agreement*, <https://www.fda.gov/downloads/InternationalPrograms/Agreements/UCM544394.pdf> (last visited March 22, 2019)

⁵⁸ U.S. Food and Drug Administration, *Cooperative Arrangements*, <https://www.fda.gov/InternationalPrograms/Agreements/MemorandaofUnderstanding/ucm2016755.htm> (last visited March 22, 2019).

Italy, Japan, Latvia, Lithuania, Malta, Romania, Poland, Portugal, Slovenia, Spain, Sweden, Switzerland, and the United Kingdom.

Drug Importation

The FDCA generally prohibits the importation of foreign drugs into the U.S. unless the drug was manufactured by a foreign facility registered with the FDA and the foreign drug is specifically FDA-approved, or the drug was manufactured in the U.S., is FDA-approved, and is being reintroduced into the U.S. by the original manufacturer.

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.⁵⁹ Without this FDA-approval, these drugs are considered misbranded and illegal for importation. The FDCA prohibits interstate shipment, including importation, of 'unapproved new drugs,'⁶⁰ which includes any drugs, including foreign-made versions of U.S.-approved drugs, which have not been manufactured in accordance with and pursuant to FDA approval (i.e. not in an FDA-registered facility or by an FDA-approved manufacturer).⁶¹ The FDCA further prohibits importation of an FDA-approved drug by anyone other than the original manufacturer of the drug.⁶²

Additionally, the DSCSA requires all health care entities that distribute, dispense, and administer prescription drugs to patients must purchase their prescription drug products only from authorized "trading partners" (wholesale distributors, manufacturers, re-packagers, and dispensers) that are licensed or registered with the state or federal government.⁶³

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 individual persons 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.⁶⁴ The FDA has stated in guidance documents that enforcing such prohibitions against individual persons was not considered a priority.⁶⁵

⁵⁹ 21 U.S.C. § 355(b)(1).

⁶⁰ 21 U.S.C. § 355(a).

⁶¹ Marvin Blumberg, *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 March 21, 2019).

⁶² 21 U.S.C. sec. 381(d)(1). This prohibition also applies to wholesalers, 21 U.S.C. sec. 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 March 22, 2019).

⁶³ [Pub.L. 113-54](#)

⁶⁴ 21 U.S.C. § 384(j).

⁶⁵ U.S. Food and Drug Administration, *Importations of Drugs*, Information on the Importation of Drugs, <https://www.fda.gov/ForIndustry/ImportProgram/ucm173751.htm> (last visited March 22, 2019).

*The Medicare Modernization Act of 2003*⁶⁶

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 public health and safety, HHS must adopt regulations to allow licensed pharmacists and wholesalers to import prescription drugs⁶⁷ 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 MMA; 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, this section of the MMA provides that it becomes effective only if the Secretary certifies to the Congress that the implementation will pose no additional risk to the public's health and safety and will result in a significant reduction in the cost of covered products to the American consumer. To date, no HHS Secretary has done so or has otherwise authorized an importation program under this provision.⁶⁸ Shortly after the MMA passed, states and local governments requested waivers from the FDA in an attempt to import prescription drugs within their jurisdictions, but states that sought prior approval have all been denied on the basis that they did not ensure the safety of drugs that would be imported.⁶⁹

In 2004, Illinois announced a plan to allow residents to order medications through a pharmacy-benefits manager network based in Canada that would access pharmacies located in Canada, Ireland, or the United Kingdom.⁷⁰ Only prescriptions that were refills, did not require refrigeration, were not controlled substances, and were for chronic conditions, would be allowed under the program.⁷¹ Pharmacies that participated would also have to agree to allow state

⁶⁶ P.L. 108-173 § 1121.

⁶⁷ 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.

⁶⁸ 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 March 10, 2019).

⁶⁹ 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 March 10, 2019).

⁷⁰ Donna Young, *Illinois Initiates Importation Plan*, www.ashp.org, https://www.ashp.org/news/2004/08/17/illinois_initiates_importation_plan (last visited March 22, 2019).

⁷¹ Donna Young, *supra note*, at 72.

inspectors on-site.⁷² News reports indicated that the program incurred \$1 million in start-up costs and enrolled fewer than 4,000 before it was terminated at the end of 2008.⁷³

Maine passed legislation in 2013 to facilitate personal importation of prescription drugs through the mail from Canada, the United Kingdom, Australia, and New Zealand via retail pharmacies shortly after the passage of the MMA.⁷⁴ The law was introduced after the City of Portland, Maine, was banned in August 2012 by the state's then-Attorney General from purchasing pharmaceuticals from Canada.⁷⁵ Before implementation could begin, a lawsuit was filed by the Maine Pharmacy Association, Maine Society of Health-System Pharmacists, and the Retail Association of Maine alleging that the federal FDCA preempted the new state importation law and the changes to the Maine Pharmacy Act; jeopardized the safety of the nation's prescription drug supply; and opened the door to counterfeit and tainted medications.⁷⁶ The Seventh District Court in Maine agreed, citing the basics of federalism in its opinion:

Federalism, central to the constitutional design, adopts the principal that both the National and State Government have elements of sovereignty the other is bound to respect. From the existence of two sovereigns follows the possibility that laws can be in conflict or at cross-purposes. The Supremacy Clause provides a clear rule that federal law shall be the supreme Law of the Land and the Judges in every State shall be bound thereby, any Thing in the Constitution or Law of any State to the contrary notwithstanding." U.S. Const. art. VI, cl. 2. Under this principle, Congress has the power to preempt state law.

Arizona v. United States, 132 S. Ct. 2492, 2500 (2012) (citations omitted).

Since 2015, there has been renewed interest in drug importation. Over a dozen states each year have considered drug importation legislation in different formats, and in 2018, Vermont was the first state to pass wholesale prescription drug importation program legislation.⁷⁷ Vermont's program is not a waiver of existing law but is an importation program that seeks to satisfy both the safety and security assurances. Drugs may be imported only from Canada under this provision, 21 U.S.C. section 384, with the inclusion of the required laboratory testing. Controlled substances, biological products, infused drugs, intravenously injected drugs, and drugs inhaled during surgery are excluded.⁷⁸ The initial program design focused on providing savings to the Vermont Medicaid program; however, the benefit to the Medicaid was minimal because

⁷² Donna Young, *supra note*, at 72.

⁷³ Sally C. Pipes, *Blagojevich's failed drug importation plan a cautionary tale*, <https://www.pacificresearch.org/blagojevichs-failed-drug-importation-plan-a-cautionary-tale/> (last visited March 22, 2019).

⁷⁴ 2013 Me. Laws 373. See <http://legislature.maine.gov/ros/LawsOfMaine/breeze/Law/getDocById/?docId=20663> (last visited March 22, 2019)

⁷⁵ Thomas Hemphill, *Prescription Drug Imports: Maine Leads, the Nation Follows?* Americanactionforum.org, <https://www.americanactionforum.org/insight/prescription-drug-imports-maine-leads-the-nation-follows/> (last visited March 22, 2019).

⁷⁶ *Ouellette v. Mills*, 91 F.Supp 3d 1(2015).

⁷⁷ 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 March 8, 2019).

⁷⁸ Vermont Agency of Human Services, *Wholesale Importation Program for Prescription Drugs Legislative Report* (December 31, 2018), https://nashp.org/wp-content/uploads/2019/01/Report-to-VT-Legislature-on-Rx-Wholesale-Importation-1_3_2019.pdf (last visited March 22, 2019).

Vermont Medicaid was already yielding substantial savings through existing rebates, and implementation of the drug importation program for that population would not result in any net savings.⁷⁹

Vermont found that a small number of drugs imported through Canada may be more cost-effective for a limited period of time; however, the state's stakeholders decided to see if greater savings could be found for the state's commercial health insurers.⁸⁰ Using conservative estimates, participating plans estimated savings in the range of \$2.61- \$2.82 per member per month, or \$1-\$5 million per year, without taking into account the state's operating costs.⁸¹

As part of the proposed regulatory process, Vermont plans to create two new licenses: Rx Drug Importer Wholesaler License and a Canadian Rx Drug Supplier License. Vermont will extend the DCSA requirements to the licensees and has also established other participation requirements for both licenses.⁸² Licensure fees will be potential revenue sources for the program through application, registration, and audit fees.⁸³

Vermont has still not sent a plan to the federal government for approval. The state still has a list of tasks and options listed in its document that need to be worked through before a plan can be submitted.

The Trump Administration has also shown interest in lowering the costs of prescription drugs for American consumers, including the possibility of drug importation.

In May 2018, American Patients First, the Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs was released.⁸⁴ The Blueprint includes four challenges in the American drug market:

- High list prices for drugs.
- Seniors and government programs overpaying for drugs due to lack of the latest negotiation tools.
- High and rising out-of-pocket costs for consumers.
- Foreign governments taking advantage of American investments in innovation.

Some of the opportunities listed in the *Blueprint* for lower costs include restricting the use of rebates, calling for Medicaid demonstration projects to test coverage and financing reforms that build on private sector best practices with drug formularies, creating incentives to lower list prices, addressing transparency in pricing in Medicare and Medicaid, and seeking public comment on further ideas and opportunities.

⁷⁹ Vermont Agency of Human Services, *supra note 80*, at 3.

⁸⁰ Vermont Agency of Human Services, *supra note 80*, at 3.

⁸¹ Vermont Agency of Human Services, *supra note 80*, at 4.

⁸² Vermont Agency of Human Services, *supra note 80*, at 5-6.

⁸³ Vermont Agency of Human Services, *supra note 80*, at 10.

⁸⁴ U.S. Department of Health and Human Services, *American Patients First*, <https://www.hhs.gov/about/leadership/secretary/priorities/drug-prices/index.html> (last visited March 22, 2019).

In July 2018, HHS directed the FDA to establish a work group on drug importation.⁸⁵ 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.⁸⁶ 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.⁸⁷ 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.⁸⁸

The FDA does not examine personal baggage or mail, leaving that to the U.S. Customs and Border Protection (CBP). CBP 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.⁸⁹

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 eight percent of U.S. households have bought prescription drugs from Canada or other countries in order to pay a lower price.⁹⁰

A limited exception applies to individuals with terminal illnesses, who can legally import non-FDA approved drugs.⁹¹ 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.

⁸⁵ U.S. Department of Health and Human Services, *Press Release, July 19, 2018*: <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 March 22, 2019).

⁸⁶ 21 U.S.C. § 384(j).

⁸⁷ U.S. Food and Drug Administration, *Person Importation*, <https://www.fda.gov/ForIndustry/ImportProgram/ImportBasics/ucm432661.htm> (last visited March 22, 2019).

⁸⁸ U.S. Food and Drug Administration, *Regulatory Procedures Manual, Chapter 9: Import Operations and Actions*, at 9-2, Dec. 2017, available at <https://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074300.pdf> (last visited March, 22, 2019).

⁸⁹ U.S. Food and Drug Admin., *supra note*, 90.

⁹⁰ 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).

⁹¹ Right to Try Act of 2017, P.L. No: 115-176.

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 two industries, the law requires entities permitted or licensed under either DBPR or the Board to comply with the laws and rules of both.⁹²

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.⁹³ 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.⁹⁴

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.⁹⁵ 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.⁹⁶

Prescription Drug Manufacturer Permit

Drug manufacturing includes the preparation, deriving, compounding, propagation, processing, producing, or fabrication of any drug.⁹⁷ 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.⁹⁸ 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.⁹⁹ 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.¹⁰⁰

⁹² Sections 499.067 and 465.023, F.S.

⁹³ Florida Department of Business and Professional Regulation, *Division of Drugs, Devices, and Cosmetics*, <http://www.myfloridalicense.com/DBPR/drugs-devices-and-cosmetics/> (last visited March 22, 2019).

⁹⁴ Section 499.01, F.S.

⁹⁵ 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.

⁹⁶ Section 499.051, 499.062, 499.065, 499.066, 499.0661, and 499.067, F.S.

⁹⁷ Section 499.003(28), F.S.

⁹⁸ Section 499.01(2), F.S.

⁹⁹ Section 499.01(2), F.S.

¹⁰⁰ Section 499.003(16), F.S.

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.¹⁰¹ 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.¹⁰²

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.¹⁰³ 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.¹⁰⁴

Board of Pharmacy

The Board of Pharmacy (Board) within the 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.¹⁰⁵ To operate a pharmacy, an entity must first obtain a pharmacy permit with the Board.¹⁰⁶ 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.¹⁰⁷

III. Effect of Proposed Changes:

Section 1 creates the Canadian Prescription Drug Importation Program (program) under newly created s. 381.02035, F.S. The Agency for Health Care Administration is directed to establish the program for the safe and effective importation of prescription drugs from Canada which will have the highest potential cost savings to the state.

¹⁰¹ Section 499.003(48), F.S.

¹⁰² Section 499.01(2), F.S.

¹⁰³ Section 499.01(2), F.S.

¹⁰⁴ Section 499.01(2), F.S.

¹⁰⁵ Ch. 465, F.S.; Florida Board of Pharmacy, <https://floridaspharmacy.gov/> (last visited March 22, 2019).

¹⁰⁶ Section 465.022, F.S.

¹⁰⁷ Section 465.0465(1), F.S.

Definitions for the program are specifically created:

- *Agency* means the Agency for Health Care Administration.
- *Canadian supplier* means a manufacturer, wholesale distributor, or pharmacy appropriate licensed or permitted under Canadian law to manufacture, distribute, or dispense prescription drugs.
- *County health department* means a health care facility established under part I of chapter 154.
- *Free clinic* means a clinic that delivers only medical diagnostic services or nonsurgical medical treatment free of charge to low-income recipients.
- *Medicaid pharmacy* means a pharmacy licensed under chapter 465 which has a Medicaid provider agreement in effect with the agency and is in good standing with the agency.
- *Pharmacist* means a person who holds an active and unencumbered license to practice pharmacy pursuant to chapter 465.
- *Prescription drug* has the same meaning as in s. 499.003, F.S.
- *Program* means the Canadian Prescription Drug Importation Program.
-

An importation process for the Program is established which includes the selection of a vendor by the Agency, the identification of importers and suppliers, and establishment of eligibility for these entities. Some of these steps in the implementation process are delegated to the vendor or other entities to perform and have designated deadlines which are reflected in the chart below.

Responsibilities of the Parties – Drug Importation Program		
Party	Responsibility	Deadline
Agency	Contract with Vendor to provide services	No deadline, but vendor must submit first list of drugs by December 1, 2019
Vendor	Develop 1 st list of prescription drugs with highest potential for cost savings to the state.	December 1, 2019
	Vendor should consider which drugs have shortages, specialty prescriptions, and high volume prescription drugs.	
	List of prescription drugs must be reviewed every 3 months and revise as necessary	Reviewed every 3 months
Vendor	Identify Canadian suppliers who are in full compliance with Canadian federal and provincial laws and regulations and who have agreed to export drugs on the list.	No deadline
	Verify that all Canadian suppliers on the list meet all of the requirements and will export drugs at prices that will provide the state with cost savings.	
	Contract with eligible suppliers meeting all of the requirements and that will export drugs at prices that will provide the state cost savings.	No deadline.
	Contract with or facilitate contracts between eligible Canadian suppliers and eligible importers to import drugs under the program.	

Responsibilities of the Parties – Drug Importation Program		
Party	Responsibility	Deadline
	Assist the Agency with the annual report and provide any requested information.	No deadline.
Importers – <i>Drug Eligibility</i>	<p>May import an eligible prescription drug from an eligible Canadian supplier, IF:</p> <ul style="list-style-type: none"> - Meets the U.S. FDA’s standards relating to safety, effectiveness, misbranding, and adulteration. - Does not violate patent law. - Expected to generate cost savings; and - The drug is not: <ul style="list-style-type: none"> *A controlled substance as defined in 21 U.S.C. section 802; *A biological product as defined in 42 U.S.C. section 262; *An infused drug; *An intravenously injected drug; *A drug that is inhaled during surgery; or *A drug that is a parenteral drug, a drug which is determined by the Secretary of Health and Human Services to pose a threat. 	No deadline.
Importers - <i>Eligibility</i>	To be eligible to import drugs from a Canadian supplier under the program: *A pharmacist or wholesaler employed by or under contract with the department’s central pharmacy, for distribution to a county health department or free clinic for dispensing to clients of a free clinic.	No deadline.
	A pharmacist or wholesaler employed by or under contract with a Medicaid pharmacy, for dispensing to the pharmacy’s Medicaid recipients.	
	A pharmacist or wholesaler employed by or under contract with the Department of Corrections, for dispensing to inmates in the custody of the Department of Corrections.	
	A pharmacist or wholesaler employed by or under contract with a developmental disabilities center, as defined in s. 393.063, F.S., for dispensing to clients treated in such a center.	
	A pharmacist or wholesaler employed by or under contract with a treatment facility, as defined in s. 394.455, F.S., for dispensing to patients in such a facility.	
Suppliers	A supplier may export prescription drugs into this state under the program IF the supplier is: *In full compliance with relevant Canadian federal and provincial laws and regulations;	No deadline.

Responsibilities of the Parties – Drug Importation Program		
Party	Responsibility	Deadline
	*Identified by the vendor as eligible to participate in the program.	
Distribution Requirements – <i>Suppliers and Importers</i>	Eligible Canadian suppliers and importers participating under the program must: <ol style="list-style-type: none"> 1. Comply with the tracking and tracing requirements under federal law. 2. May not distribute, dispense, or sell prescription drugs under the program outside of the state. 	No deadline.
Federal Approval of Program	The Agency must submit a request to the Secretary of the U.S. Department of Health and Human Services for approval of a program under 21 U.S.C. section 384(1) and begin operations within 6 month of receiving approval.	Plan must be submitted by July 1, 2020. Operations must begin 6 months after federal approval.
Annual Report	The Agency must submit an Annual Report to the Governor, the President of the Senate, and the Speaker of the House of Representatives on the operation of the program during the previous fiscal year along with other components detailed below.	December 1 each year.

The plan that is submitted for federal approval must include, at a minimum, the following elements:

- The Agency’s plan for operating the program.
- A demonstration of how the prescription drugs will be imported into the state and meet the applicable federal and state standards for safety and cost effectiveness.
- A list of prescription drugs that have the highest potential for cost savings to the state through importation at the time the request is submitted.
- An estimate of the total cost savings attributable to the program.
- Inclusion of a list of potential Canadian suppliers from which the state would import drugs and a demonstration that the suppliers are in full compliance with relevant Canadian federal and provincial laws and regulations.

The Agency is also responsible for an Annual Report and its components which must include, at a minimum, each 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 Wholesale Prescription Drug Importation List.
- Documentation demonstration 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.

Rulemaking authority is granted to the AHCA to implement the program.

Section 2 provides an effective date of July 1, 2019.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

Supremacy Clause

As noted earlier in the analysis, in Maine, several Maine pharmacy groups sued the state under a couple of theories, including the Supremacy Clause of the United States Constitution, art. VI, cl. 2, arguing that federal law preempted state law and that federal law had, for now, created a “closed regulatory scheme which strictly limited the introduction of prescription drugs into interstate commerce. The plaintiffs also point out that Congress contemplated the potential importation of prescription drugs from Canada in the MMA, but that this section had not taken effect because the HHS Secretary has not granted the necessary certification.”¹⁰⁸

The opinion further discusses those situations where state law can still rebut the presumption regarding preemption. The Court must begin with the “presumption that the state statute is valid,¹⁰⁹ particularly if the state law is a matter involving issues regulating

¹⁰⁸ *Oulette v. Mills*, *supra* note 82 at 9. (page number cited for slip opinion).

¹⁰⁹ *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 661 (2003); quoted in *Oulette v. Mills*, at 10.

public health.¹¹⁰ There is also a presumption for the state if the area and subject matter is “in any field in which there is a history of state law regulation, even if there is also a history of federal law regulation.”¹¹¹ Congress must clearly preempt state law if it is regulating in an area where the state traditionally regulates.¹¹² In the present case, *Oulette*, the Plaintiffs’ argument is that preemption should apply because the amendments made the state of Maine to allow for the drug importation program touch on foreign affairs and that subject matter is reserved traditionally for the federal government.¹¹³

The Court noted in *Oulette* that Congress had legislated explicitly with respect to the importation of drugs from Canada and the MMA has provided a specific path to legally permissible importation.¹¹⁴ The Eighth Circuit had also weighed in on this issue and the *Oulette* court repeated those findings:

That Congress created a special procedure for authorizing importation of prescription drugs from Canada supports our conclusion that the pre-existing system established by the FDCA does not permit such importation. While it is true that no federal statute by its express terms bans importation of prescription drugs from Canada, such an explicit country-by-country prohibition is unnecessary to accomplish the task. By creating the comprehensive regulatory system described above, Congress has effectively precluded importation of these drugs absent the sort of special authorization contemplated by 21 U.S.C. section 384.¹¹⁵

Foreign Dormant Commerce Clause

A state’s drug importation program must also be carefully reviewed to ensure that it can meet the constitutionality tests of the foreign dormant commerce clause and does not place an undue burden on foreign commerce and the role that the federal government plays in the implementation of foreign policy. The possibility of potential conflicts, therefore are likely less here since there is a federal statute that sets forward a path for federal approval of a program. Concerns of intersections with other pharmaceutical programs and arguments, such as those made below about multiple regulatory schemes, may be issues to aware of, but they should not have an impact on international relations.¹¹⁶

¹¹⁰ See *Hillsborough Cnty., Fla. v. Automated Med. Lab., Inc.*, 471 U.S. 707, 718 (1985); quoted in *Oulette v. Mills*, at 10 (slip opinion page number).

¹¹¹ *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 156., 176 (1st Cir. 2009) (citing *Wyeth*, 555 U.S. at 565, n. 3).

¹¹² *Nat’l Foreign Trade Council v. Natsios*, 181 F.3d 38, 73 (1st Cir. 1999)(citing *Rice*, 331 U.S. at 230). The *Natsios* case dealt with a claim by Massachusetts’ that its law restricting trade with Burma was an exercise of its procurement authority, a traditional area of state power.

¹¹³ *Supra* note, 123.

¹¹⁴ *Oulette v. Mills*, *Supra* note 82, (citing the slip opinion page at 15).

¹¹⁵ *In re Canadian Import Antitrust Litig.*, 470 F.3d 785, 790 (8th Cir. 2006). (cited in *Oulette v. Mills*)

¹¹⁶ Anna Zaret and Darien Shanske, *The Dormant Commerce Clause: What Impact Does It Have on the Regulation of Pharmaceutical Costs?*(November 2017) National Academy for State Health Policy, <https://nashp.org/wp-content/uploads/2017/11/DCC-White-Paper.pdf> (last visited March 22, 2019).

Most recently in Maryland, the U.S. Supreme Court declined to review an appeal from the U.S. District Court of Appeals for the Fourth Circuit on a determination that Maryland's state-based price-gouging statute was a violation of the dormant commerce clause as it interfered with interstate commerce as it regulated transactions outside of the state.¹¹⁷ "The principle against extraterritoriality as it relates to the dormant commerce clause is derived from the notion that 'a state may not regulate commerce occurring wholly outside of its borders.'"¹¹⁸

Maryland had sought an appeal at the U.S. Supreme Court of an unfavorable ruling in 2018 from the federal appeals court. That ruling had held that Maryland had illegally regulated wholesale pricing by drug in companies through a provision it had enacted in 2017 which prohibited what the state termed as "unconscionable" price increases for essential drugs no longer covered by patents or generics that were sold in the state.¹¹⁹ The conduct targeted by the law was the upstream pricing and sale of prescription drugs, all of which occurred outside of Maryland which as the court noted which the manufacturers and wholesalers to act in accordance with Maryland law outside of Maryland.¹²⁰

From its "cases concerning extraterritorial effects of state economic regulation," the Supreme Court outlined the principle against extraterritoriality in a Connecticut case where residents were prohibited from crossing state lines to purchase cheaper beer:

- 1) A state statute may not regulate "commerce that takes place wholly outside of the State's borders, whether or not the comer has effects within the State."¹²¹ Specifically, a state law may not have the practical effect of establishing a scale of prices for use in other states."¹²²
- 2) A statute that directly controls commerce occurring wholly outside the {legislating state's} boundaries... is invalid regardless of whether the statute's extraterritorial reach was intended by the legislature."¹²³ The statute's "practical effect" is the focus of the inquiry.¹²⁴
- 3) In evaluating a statute's "practical effect," the Court considers "not only... the consequences of the statute itself, but also ...how the challenged statute may interact with the legitimate regulatory regimes of other States and what effect would arise if...every {} State adopted similar legislation."¹²⁵ This is because "the Commerce Clause protects

¹¹⁷ *Association for Accessible Medicines v. Frosh*, No. 17-2177

¹¹⁸ *Star Sci., Inc. v. Beales*, 278 F. 3d 339, 355 (4th Cir. 2002) (citing *Healy v. Beer Inst.*, 324, 335-36 (1989); *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 582-83 (1986); *Edgar v. MITE Corp.*, 456 U.S. 624, 642-43 (1982)(plurality opinion).

¹¹⁹ Andrew Chung, *U.S. Top Court Rejects Maryland Bid to Revive Drug Price Gouging Law*, Reuters, <https://www.reuters.com/article/us-usa-court-pharmaceuticals-idUSKCN1Q81T9> (last visited March 22, 2019).

¹²⁰ *Supra* note 127, at 14.

¹²¹ *Healy* at 336.

¹²² *Healy* (quoting *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 528 (1935)).

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ *Healy* at 336.

against inconsistent legislation arising from the projection of one state regulatory regime into the jurisdiction of another State.”¹²⁶

Because the Act targets wholesale rather than retail pricing, the court notes that it has the potential to subject the manufacturers to conflicting state requirements.¹²⁷

“The manufacturer’s compliance would require more than modification of their distribution systems; it would force them to enter into a separate transaction for each state in order to tailor their conduct so as not to violate any state’s price restrictions... The potential for ‘the kind of competing and interlocking local economic regulation that the Commerce Clause was meant to preclude’¹²⁸ is therefore both real and significant. We are thus pressed to invalidate the Act.”¹²⁹

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Wholesalers, pharmacies, and pharmacists who are licensed entities would potentially be eligible under the bill to participate as importers under the program which they are not currently able to do. To the extent that such entities participate in the program to import less expensive FDA-approved drugs, they may experience cost savings which may be passed along to Florida residents who are enrollees in the designated programs.

C. Government Sector Impact:

The AHCA could need additional resources to implement the bill before any cost savings from the importation program is implemented.¹³⁰

The AHCA has identified the need for six additional personnel dedicated to the project who will be developing, procuring, and managing and conducting oversight and monitoring activities. The AHCA would begin recruitment activities immediately upon adoption of the bill as staff are needed to start program design activities, development of the competitive solicitation, request for federal authority, etc.

The positions will include:

- One AHC Administrator – SES Supervisor position
- Five Government Analyst II positions

¹²⁶ *Healy* at 336-37.

¹²⁷ *Supra note 127* at 17.

¹²⁸ *Healy* at 337.

¹²⁹ *Supra note 127*, at 18.

¹³⁰ Agency for Health Care Administration, *2019 Agency Legislative Bill Analysis – HB 19 (March 1, 2019)*(on file with the Senate Health Care Committee).

- Identify Canadian suppliers that are in full compliance with federal and provincial laws.
- Contract with eligible Canadian suppliers or facilitate contracts between eligible importers and Canadian suppliers as described in the bill.
- Complete a comprehensive pharmacy cost analysis to demonstrate the cost savings achieved through the importation of specific drugs.
- The program is expected to yield savings, but the AHCA is not able to quantify those savings at this time. There may be fewer opportunities under Medicaid to achieve savings than what is realized through federal and supplemental rebates; however, there are other state programs and other drugs that will come on the market that are not yet known.

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

The Board of Pharmacy, within the Department of Health, would be responsible for licensing and permitting of pharmacies, wholesalers, and suppliers.

VI. Technical Deficiencies:

The Department of Business and Professional Regulation raises several issues in its analysis:

- The proposed bill applies to “prescription drugs” which, pursuant to s. 499.003(40), F.S., applies not only to finished dosage forms, but also to active pharmaceutical ingredients (“API”) that are routinely imported for further manufacturing and/or distribution by Florida companies.¹³¹

VII. Related Issues:

Canadian Drug Supply

Canada’s population is one-ninth the population of the United States, 35 million, compared to 318 million in 2015.¹³² The number of prescriptions dispensed in the United States was almost seven times larger than in Canada and, taking into account the number of individuals and the number of prescriptions, one researcher in 2010, and again in 2015, calculated how long Canada’s drug supply would last if 20 percent of Americans sought to have their prescriptions filled in Canada. In 2015, the number of days’ supply without any additional manufacturing or

¹³¹ Dep’t of Business and Professional Regulation, *supra note 142*, at 11.

¹³² Marv Shephard, *U.S. Drug Importation: Impact on Canada’s Prescription Drug Supply*, Health Economics & Outcome Research: Open Access, Vol. 4, Iss.1 (February 5, 2018) <http://www.safemedicines.org/wp-content/uploads/2017/08/us-drug-importation-impact-on-canadas-prescription-drug-supply-2471-268X-1000146.pdf> (last visited March 22, 2019).

imports is 150.83 days.¹³³ In 2010, the days' supply was 201 days before the Canadian drug supply was depleted.¹³⁴

The researcher does point out that Canada has options to meet a growing demand, such as increasing its drug manufacturing output, increasing pharmaceutical imports, continuing the practice of allowing internet pharmacies to fill medications from foreign sources while looking the other from a regulatory standpoint, or calling a halt to foreign sales of prescriptions.¹³⁵ The researcher also noted that Canada imported \$13.180 billion in pharmaceuticals from the United States in 2015 and the United States was Canada's largest supplier of pharmaceuticals at 33.1 percent.¹³⁶

Another concern is that Canada has been experiencing its own access to drug issues and rising drug prices. Health Canada, Canada's national health ministry, recently released its own *Interim Report of the Advisory Council on the Implementation of National Pharmacare* on how to implement a national drug care program.¹³⁷ How Canada moves forward with this plan may impact how pharmacies and vendors in Canada operate in the future.

Canadian Law Provisions

The import and export of health products in Canada is regulated under Canada's *Food and Drugs Act* and its associated regulations. No drugs may be sold that are mislabeled, or adulterated.¹³⁸ Depending on how a product is labeled as it leaves Canada, for the Canadian market or the U.S. market, it may be considered "mislabeled" under one of the markets.

Additionally, under Canadian Federal Regulation A.01.045, all exports of food and drugs from Canada must have a certificate attached which is signed by the exporter attesting to the legality of the items and that the items being shipped are done so accordance with the laws of its destination.¹³⁹ An inspector is also authorized by law to take samples of an article at any reasonable time if the inspector believes that a package contains an item which is covered by the *Food and Drugs Act* and those items may also be subject to seizure.¹⁴⁰

Federal Approval

The bill directs the AHCA to, by July 1, 2020, submit a request to the federal HHS Secretary for approval of the Florida program under 21 USC s. 384(l). That subsection of federal law provides that the federal drug importation program becomes effective only if the Secretary certifies to the Congress that the implementation of the federal program will pose no additional risk to the public's health and safety and result in a significant reduction in the cost of covered products to

¹³³ Marv Shephard, *supra note 144*, at 3.

¹³⁴ Marv Shephard, *supra note 144*, at 3.

¹³⁵ Marv Shephard, *supra note 144*, at 4.

¹³⁶ Marv Shepard, *supra note 144*, at 4.

¹³⁷ Health Canada, *Advisory Council on the Implementation of National Pharmacare*, <https://www.canada.ca/en/health-canada/corporate/about-health-canada/public-engagement/external-advisory-bodies/implementation-national-pharmacare.html#a1> (last visited March 22, 2019).

¹³⁸ R.S., c. F-27, s. 8. (Can.)

¹³⁹ C.R.C., SOR/80-318, s-1(Can.)

¹⁴⁰ R.S.C., 1985, C. F-27, Part II(23)

the American consumer. No HHS Secretary has yet sent such a certification to Congress. The cited subsection also provides for termination of the federal program. However, the subsection contains no provision for the Secretary to approve any state-based drug importation program under any circumstances. Other states that have sought federal approval of their proposed drug importation programs have done so through the FDA, not the HHS.

VIII. Statutes Affected:

This bill creates section 381.02035 of the Florida Statutes

IX. Additional Information:

A. Committee Substitute – Statement of Changes:

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.