

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 Appropriations

BILL: CS/CS/SB 1528

INTRODUCER: Appropriations Committee (Recommended by Appropriations Subcommittee on Health and Human Services); Health Policy Committee; and Senators Bean and Gruters

SUBJECT: Prescription Drug Importation Program

DATE: April 19, 2019

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Lloyd</u>	<u>Brown</u>	<u>HP</u>	<u>Fav/CS</u>
2.	<u>McKnight</u>	<u>Kidd</u>	<u>AHS</u>	<u>Recommend: Fav/CS</u>
3.	<u>McKnight</u>	<u>Kynoch</u>	<u>AP</u>	<u>Fav/CS</u>

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/CS/SB 1528 establishes two programs to safely import federal Food and Drug Administration (FDA) approved prescription drugs into the state. The Canadian Prescription Drug Importation Program (CPDI Program) and the International Prescription Drug Importation Program (IPDI Program) both establish 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, safety standards, drug distribution requirements, and penalties for violations of program requirements. The bill requires both programs to seek federal approval or cooperation prior to importing prescription drugs.

The CPDI Program has an overall indeterminate fiscal impact at this time with an expectation that there will be start-up costs associated with the implementation prior to any achievement of potential savings, including costs associated with competitively soliciting a qualified vendor and hiring additional personnel to manage the contract and conduct appropriate oversight and monitoring activities. The Agency for Health Care Administration (AHCA) anticipates requiring six additional full-time equivalent positions for Fiscal Year 2019-2020, estimating a total cost of \$572,495, and an estimated total recurring cost of \$545,837 for Fiscal Year 2020-2021 and beyond. The AHCA will need to determine the level of federal financial participation in the Program.

The IPDI Program has a significant fiscal impact on the Department of Business and Professional Regulation (DBPR). If federally approved, the 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.

See Section V.

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

II. Present Situation:

U.S. Healthcare Marketplace

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

Spending on prescription drugs in 2017 was \$333.4 billion.⁴ Of that amount, the vast majority, \$285 billion, was paid through health insurance coverage which includes private health insurance, Medicare, Medicaid, and other health insurance coverage.⁵

In a study sponsored by the federal Centers for Disease Control and Prevention (CDC), a majority of adults aged 18-64, nearly 60 percent, reported being prescribed a medication in the past 12 months.⁶ Further, approximately 70 percent of prescription medications carry out-of-pocket costs, such as requirements for co-insurance, co-payments, or a deductible, with generics costing an average of \$6 per prescription and brand names an average cost of \$30 per prescription.⁷

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,

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 28, 2019).

² Peter J. Peterson Foundation, *Per Capita Healthcare Costs-International Comparison* (August 10, 2018), https://www.pgpf.org/chart-archive/0006_health-care-oecd (last visited March 28, 2019).

³ *Supra* note 1.

⁴ *Id.*

⁵ 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).

⁶ 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 28, 2019).

⁷ *Id.*

to avoid the out-of-pocket costs. The CDC study 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 a prior study, the percentage remained relatively constant from 2015 through 2017 at 19.5 percent.⁸ 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.⁹

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.¹⁰

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 U.S. Department of Defense (DoD) and the U.S. Department of Veterans Affairs (VA), negotiate directly with drug manufacturers for drug prices, and they pay approximately 50 percent of what is paid at a retail pharmacy.¹¹ 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.¹²

The United States typically uses drug price controls in one of two ways. First, in the manner described above with the DoD and the VA 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.¹³

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.¹⁴ Medicaid can also negotiate additional rebates and will receive additional discounts if the price of the drug rises faster than inflation.¹⁵

Medicare Part D, the prescription drug benefit for Medicare, differs from Medicaid in the prices paid for prescription drugs and in the measures used to control prescription drug spending. These

⁸ *Id.*

⁹ Robin A. Cohen, *supra* note 6, at 2 - 4.

¹⁰ Dana O. Sarnak, et al, *Paying for Prescription Drugs Around the World: Why is the U.S. an Outlier?*, The Commonwealth Fund, <https://www.commonwealthfund.org/publications/issue-briefs/2017/oct/paying-prescription-drugs-around-world-why-us-outlier> (last visited March 28, 2019). The nine western countries used in comparison are Switzerland, Germany, Canada, France, United Kingdom, Australia, Netherlands, Norway, and Sweden.

¹¹ Dana O. Sarnak, et al, *supra* note 10.

¹² 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 28, 2019).

¹³ David Blumenthal, M.D. and David Squires, *supra* note 12.

¹⁴ David Blumenthal, M.D. and David Squires, *supra* note 12.

¹⁵ *Id.*

differences are often a function of the varying options 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.¹⁶

Programmatic Differences – Prescription Drugs¹⁷		
	Medicare Part D	Medicaid Fee for Service
Average Rebate	17 percent	56 percent
Use of Generic Drugs	75 percent	70 percent
Average Price of Drugs in 53 Therapeutic Classes	\$49	\$36

Out of Pocket Costs

From a cost perspective, 58 percent of respondents to a recent Kaiser Family Foundation survey reported spending \$100 or more a month on prescriptions, 49 percent reported being in fair or poor health, 35 percent said they were taking four or more prescriptions a month, and 35 percent reported an annual income of less than \$40,000. Further, three in ten of all adults (29 percent) reported not taking their medicines as prescribed at some point in the past year because of the cost and one in ten (8 percent) said their condition got worse as a result of not taking their prescription as recommended.¹⁸

The survey also demonstrated that the public views profits made by 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 (52 percent).¹⁹

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).²⁰

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

¹⁶ 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 28, 2019).

¹⁷ Congressional Budget Office, *supra* note 16, at 31-32.

¹⁸ KAISER FAMILY FOUNDATION, *Kaiser Health Tracking Poll – February 2019: Prescription Drugs*, <https://www.kff.org/report-section/kff-health-tracking-poll-february-2019-prescription-drugs-findings/> (last visited March 28, 2019).

¹⁹ *Id.*

²⁰ KAISER FAMILY FOUNDATION, *Kaiser Health Tracking Poll – February 2019: Prescription Drugs*, <https://www.kff.org/report-section/kff-health-tracking-poll-february-2019-prescription-drugs-findings/> (last visited March 28, 2019).

cannot be responsible for subsidizing the research and development costs for the world.²¹ 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.²² In remarks to stakeholders and the news media, the current Secretary of the U.S. Department of Health and Human Services (HHS), 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.”²³

Federal Regulation of Prescription Drugs

The U.S. 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).²⁴ 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. During the 2016 Legislative Session, Florida conformed its statutes to the revised federal standards.²⁵

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 adulterated²⁶ or misbranded drugs²⁷ and devices from being introduced, delivered for

²¹ 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 28, 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.

²² 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.

²³ 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 28, 2019).

²⁴ 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.

²⁵ See ch. 2016-212 Laws of Florida (CS/CS/HB 1211)

²⁶ 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...”

²⁷ 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...”

introduction, or received in interstate commerce.²⁸ 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.²⁹ 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.³⁰ 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.³¹ 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.
- 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.³²

Drug Manufacturer Compliance

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.³³ 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 in 21 Code of Federal Regulations (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 control, including tamper-evident package requirements, laboratory controls, requirements for records and reports, and returned and salvaged drug products.

²⁸ See 21 U.S.C. 331 (as amendment through P.L. 115-271, enacted October 24, 2018).

²⁹ 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 28, 2019).

³⁰ 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.

³¹ U.S. Food and Drug Administration, *New Drug Application*, <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm> (last visited March 28, 2019).

³² U.S. Food and Drug Administration, *supra* note 31.

³³ 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 28, 2019).

Drug Distribution

The Drug Supply Chain Security Act³⁴ (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 product 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 6 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 for the product to become mishandled or adulterated, whether it is in the United States or abroad.

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 circumstances, must issue a pedigree, which has since been superseded by the tracing requirements in the DQSA in 2015.³⁵

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 2013.³⁶ In her testimony, she referenced cases involving counterfeit and fraudulent versions of

³⁴ See Title II of DQSA, the Drug Supply Chain Security Act, Pub. Law 113-54 (2015).

³⁵ 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 28, 2019).

³⁶ Susan Thaul, Congressional Research Service, *supra* note 35, at 1.

Botox sold in the United States, Lipitor sold in the United Kingdom, and Avastin in the United States.³⁷

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.³⁸

Foreign companies that manufacture, prepare, propagate, compound, or process drugs that are offered for import in the United States must register with the FDA.³⁹ Today, there are 136,400 foreign facilities in more than 150 countries that export FDA-regulated products to the United States.⁴⁰ 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.⁴¹

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.⁴² In federal fiscal year 2017-18, the FDA conducted 94 on-site inspections of foreign drug manufacturing facilities, and historically, 381 since 2014-2015.⁴³ 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 describing the willingness and good-faith intentions of the countries to engage in cooperative activities.⁴⁴ International arrangements can have a variety of

³⁷ Susan Thaul, Congressional Research Service, *supra* note 35, at 2.

³⁸ U.S. Food and Drug Administration, *FDA Globalization*, <https://www.fda.gov/InternationalPrograms/FDABeyondOurBordersForeignOffices/default.htm> (last visited March 28, 2019).

³⁹ Section 510 of the federal Food, Drug, and Cosmetic Act.

⁴⁰ U.S. Food and Drug Administration, *FDA Globalization*, *supra* note at 38.

⁴¹ FDA Commissioner Margaret Hamburg, *The Safety of Prescription Drugs Made Outside the U.S.*, The Diane Rehm Show (February 20, 2014), transcript available at <https://dianerehm.org/shows/2014-02-20/safety-prescription-drugs-made-outside-us> (last visited March 28, 2019).

⁴² 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.

⁴³ 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 28, 2019).

⁴⁴ U.S. Food and Drug Administration, *International Agreements*, <https://www.fda.gov/InternationalPrograms/Agreements/default.htm> (last visited March 28, 2019); *See also, FAQs: The Mutual Recognition Agreement*, <https://www.fda.gov/downloads/InternationalPrograms/Agreements/UCM544394.pdf> (last visited March 28, 2019)

titles, including “cooperation agreement,” “memorandum of understanding,” or “mutual recognition agreement.” The FDA currently has at least 60 such international arrangements with foreign governments.⁴⁵

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.

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.

The 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.⁴⁶ Without this FDA-approval, these drugs are considered misbranded and illegal for importation. The FDCA prohibits interstate shipment, including importation, of ‘unapproved new drugs,’⁴⁷ 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).⁴⁸ The FDCA further prohibits importation of an FDA-approved drug by anyone other than the original manufacturer of the drug.⁴⁹

Additionally, the DSCSA requires all health care 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) that are licensed or registered with the state or federal government.⁵⁰

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.

⁴⁵ U.S. Food and Drug Administration, *Cooperative Arrangements* <https://www.fda.gov/InternationalPrograms/Agreements/MemorandaofUnderstanding/ucm2016755.htm> (last visited March 28, 2019).

⁴⁶ 21 U.S.C. s. 355(b)(1).

⁴⁷ 21 U.S.C. s. 355(a).

⁴⁸ Marvin Blumberg, *Information on Importation of Drugs Prepared by the Division of Import Operations and Policy*, FDA, U.S. Food & Drug Admin., (September 25, 2015), <https://www.fda.gov/ForIndustry/ImportProgram/ucm173751.htm> (last visited March 28, 2019).

⁴⁹ 21 U.S.C. s. 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 28, 2019).

⁵⁰ [Pub.L. 113-54](#)

However, federal law does authorize the HHS 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.⁵¹ The FDA has stated in guidance documents that enforcing such prohibitions against individual persons was not considered a priority.⁵²

The Medicare Modernization Act of 2003⁵³

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 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, the HHS is required to adopt regulations to allow licensed pharmacists and wholesalers to import prescription drugs⁵⁴ from Canada into the United States. 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 HHS 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 HHS Secretary certifies to the U.S. 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.⁵⁵ 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.⁵⁶

⁵¹ 21 U.S.C. s. 384(j).

⁵² 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 28, 2019).

⁵³ Pub. L. No. 108-173 s. 1121.

⁵⁴ Excluding controlled substances, biological products, infused drugs, IV-injected drugs, drugs inhaled during surgery, or a parenteral drug the HHS Secretary deems to pose a threat to public health.

⁵⁵ Additionally, in March 2017, the four 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.” *letter available at* http://www.safemedicines.org/wp-content/uploads/2017_03_16_commissioners_letter_final.pdf (last visited March 28, 2019).

⁵⁶ 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 28, 2019).

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.⁵⁷ Only prescriptions that were refills, did not require refrigeration, were not controlled substances, and were for chronic conditions, would be allowed under the program.⁵⁸ Pharmacies that participated would also have to agree to allow state inspectors on-site.⁵⁹ 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 2008.⁶⁰

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.⁶¹ 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.⁶² 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.⁶³ 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

⁵⁷ Donna Young, *Illinois Initiates Importation Plan*, https://www.ashp.org/news/2004/08/17/illinois_initiates_importation_plan (last visited March 28, 2019).

⁵⁸ Donna Young, *supra* note at 57.

⁵⁹ *Id.*

⁶⁰ 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 28, 2019).

⁶¹ 2013 Me. Laws 373. See <http://legislature.maine.gov/ros/LawsOfMaine/breeze/Law/getDocById/?docId=20663> (last visited March 28, 2019).

⁶² Thomas Hemphill, *Prescription Drug Imports: Maine Leads, the Nation Follows?*

<https://www.americanactionforum.org/insight/prescription-drug-imports-maine-leads-the-nation-follows/> (last visited March 28, 2019).

⁶³ *Ouellette et al v. Mills et al*, 13-347 - Order on Parties Competing Motions on Facial Preemption (Docket No: 1:13-cv-00347-NT)(U.S. D.Ct. Maine)(February 23, 2015).

first state to pass wholesale prescription drug importation program legislation.⁶⁴ 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 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.⁶⁵ The initial program design focused on providing savings to the Vermont Medicaid program; however, the benefit to Medicaid was minimal because Vermont's Medicaid program 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.⁶⁶

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.⁶⁷ 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.⁶⁸

As part of the proposed regulatory process, Vermont plans to create two new licenses: Rx Drug Importer Wholesaler and Canadian Rx Drug Supplier. Vermont will extend the DCSA requirements to the licensees and has also established other participation requirements for both licenses.⁶⁹ Licensure will provide a potential revenue sources for the program through application, registration, and audit fees.⁷⁰

Vermont has not yet sent a plan to the federal government for approval. The state still has a list of tasks and options that need to be worked through before a plan is 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.⁷¹ 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.

⁶⁴ NATIONAL ACADEMY FOR STATE HEALTH POLICY, *State Legislative Action to Lower Pharmaceutical Costs* (updated March 1, 2019), <https://nashp.org/rx-legislative-tracker-2019/> (last visited March 28, 2019).

⁶⁵ 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 28, 2019).

⁶⁶ Vermont Agency of Human Services, *supra* note 65, at 3.

⁶⁷ Vermont Agency of Human Services, *supra* note 65, at 3.

⁶⁸ Vermont Agency of Human Services, *supra* note 65, at 4.

⁶⁹ Vermont Agency of Human Services, *supra* note 65, at 5-6.

⁷⁰ Vermont Agency of Human Services, *supra* note 65, at 10.

⁷¹ 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 28, 2019).

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.

In July 2018, the HHS directed the FDA to establish a work group on drug importation.⁷² 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 the 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.⁷³ The HHS has not yet implemented this provision, 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.⁷⁴ 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.⁷⁵

The FDA does not examine personal baggage or mail, leaving that to the U.S. Customs and Border Protection (CBP). The 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.⁷⁶

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.

⁷² 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 28, 2019).

⁷³ 21 U.S.C. s. 384(j).

⁷⁴ U.S. Food and Drug Administration, *Personal Importation*, <https://www.fda.gov/ForIndustry/ImportProgram/ImportBasics/ucm432661.htm> (last visited March 28, 2019).

⁷⁵ U.S. Food and Drug Administration, *Regulatory Procedures Manual, Chapter 9: Import Operations and Actions*, (December 2017) at 9-2, available at <https://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074300.pdf> (last visited March, 28, 2019).

⁷⁶ U.S. Food and Drug Admin., *supra* note 72.

households have bought prescription drugs from Canada or other countries in order to pay a lower price.⁷⁷

A limited exception applies to individuals with terminal illnesses, who can legally import non-FDA approved drugs.⁷⁸ 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 the DBPR or the DOH, as applicable. Due to the overlap in these two industries, the law requires entities permitted or licensed under either the DBPR or the DOH to comply with the laws and rules of both.⁷⁹

The DBPR's 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.⁸⁰ The Florida Drug and Cosmetic Act conforms to the FDA drug laws and regulations and authorizes the DBPR to issue permits to Florida drug manufacturers and wholesale distributors and register drugs manufactured, packaged, repackaged, labeled, or relabeled in Florida.⁸¹

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.⁸² The 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.⁸³

⁷⁷ KAISER FAMILY FOUNDATION, *Kaiser Health Tracking Poll: November 2016*, <http://files.kff.org/attachment/Kaiser-Health-Tracking-Poll-November-2016-Topline> (last visited March 28, 2019).

⁷⁸ Right to Try Act of 2017, Pub. Law No 115-176.

⁷⁹ Sections 499.067 and 465.023, F.S.

⁸⁰ Department of Business and Professional Regulation, *Division of Drugs, Devices, and Cosmetics*, <http://www.myfloridalicense.com/DBPR/drugs-devices-and-cosmetics/> (last visited March 28, 2019).

⁸¹ Section 499.01, F.S.

⁸² 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. Section 499.01(1), F.S.

⁸³ Section 499.051, 499.062, 499.065, 499.066, 499.0661, and 499.067, F.S.

Prescription Drug Manufacturer Permit

Drug manufacturing includes the preparation, deriving, compounding, propagation, processing, producing, or fabrication of any drug.⁸⁴ 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.⁸⁵ 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.⁸⁶ 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.⁸⁷

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.⁸⁸ 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.⁸⁹

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.⁹⁰ 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.⁹¹

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.⁹² To operate a pharmacy, an entity must first obtain a pharmacy permit with the Board.⁹³ 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.

⁸⁴ Section 499.003(28), F.S.

⁸⁵ Section 499.01(2), F.S.

⁸⁶ Section 499.01(2), F.S.

⁸⁷ Section 499.003(16), F.S.

⁸⁸ Section 499.003(48), F.S.

⁸⁹ Section 499.01(2), F.S.

⁹⁰ Section 499.01(2), F.S.

⁹¹ Section 499.01(2), F.S.

⁹² Chapter 465, F.S.; Florida Board of Pharmacy, <https://floridaspharmacy.gov/> (last visited March 28, 2019).

⁹³ Section 465.022, F.S.

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. The 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.⁹⁴

III. Effect of Proposed Changes:

Canadian Prescription Drug Importation Program

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

An importation process for the CPDI Program is established which includes the selection of a vendor by the AHCA, the identification of eligible importers and Canadian suppliers, and establishment of eligibility for these entities. Criteria is also established for eligible prescription drugs as well as requirements for distribution and prescription drug supply chain documentation.

Steps in the implementation process delegated to the vendor or other entities to perform are reflected in the chart below.

The AHCA is also:

- Provided the authority to immediately suspend importation of a specific drug by an importer upon learning that any drug activity is in violation of the CPDI Program or any federal or state law or regulation.
- Required to request approval of the CPDI Program from the HHS Secretary by July 1, 2020, and upon receipt of federal approval, begin operating the CPDI Program within 6 months and notify the President of the Senate, the Speaker of the House of Representatives, and the relevant legislative committees. After approval is received, the AHCA is also required to submit to all parties a proposal for CPDI Program implementation and funding prior to the start of the next regular session of the Legislature in which the proposal could be funded.
- Submit an annual report to the Governor, President of the Senate, and Speaker of the House of Representatives by December 1, entailing specific information about the operation of the CPDI Program during the previous year.
- Authorized to adopt rules necessary to implement the CPDI Program.

Canadian Prescription Drug Importation Program Responsibilities of the Parties	
AHCA	
<i>Vendor Contract</i>	Contract with a vendor to provide services.

⁹⁴ Section 465.0465(1), F.S.

Canadian Prescription Drug Importation Program Responsibilities of the Parties	
<i>Safety Concerns – Immediate Suspension</i>	<p>Authorized to immediately suspend the importation of a specific drug or the importation of specific drugs by a specific importer if there are safety concerns or there is any activity in violation of Canadian, federal, or state law or regulation.</p> <p>The suspension may be revoked if, after conducting an investigation, the AHCA determines that no threat to public safety exists from unsafe drugs.</p>
<i>Program Plan</i>	<p>Submit a request for federal approval to the HHS by July 1, 2020, and include, at a minimum, the following elements:</p> <ul style="list-style-type: none"> • The AHCA’s plan for operating the CPDI 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 demonstration of how the drugs imported into the state under the CPDI Program will comply with federal tracing procedures. • 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. • Inclusion of an estimate of the total cost savings attributable to the CPDI Program. • Inclusion of an estimate of the total costs of CPDI Program implementation to the state. • 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 as well as applicable federal and state laws and regulations.
<i>Federal Approval</i>	<p>Once approved by the HHS, the AHCA is required to:</p> <ul style="list-style-type: none"> • Begin operating the CPDI Program within 6 months; • Notify the President of the Senate, the Speaker of the House of Representatives, and the relevant committees of the Senate and the House of Representatives. <p>After approval is received, the AHCA is also required to submit to all parties a proposal for CPDI Program implementation and funding prior to the start of the next regular session of the Legislature in which the proposal could be funded.</p>
<i>Annual Report</i>	<p>Submit an annual report by December 1, to the Governor, President of the Senate, and Speaker of the House of Representatives containing required information about the operation of the CPDI Program during the previous year, including at a minimum:</p> <ul style="list-style-type: none"> • A list of prescription drugs that were imported under the CPDI Program; • The number of participating entities; • The number of prescriptions dispensed through the CPDI Program; • The estimated cost savings during the previous fiscal year and to date attributable the program; • A description of the methodology used to determine which drugs should be included on the Wholesale Prescription Drug Importation List; and • Documentation on how the CPDI Program ensures the following:

Canadian Prescription Drug Importation Program Responsibilities of the Parties	
	<ul style="list-style-type: none"> ○ Participating Canadian suppliers are of high quality, of high performance, and in full compliance with relevant Canadian federal and provincial laws and regulations as well as federal laws and regulations and state laws and rules; ○ Prescription drugs imported under the CPDI Program are not shipped, sold, or dispensed outside of the state once in the possession of the importer; ○ Prescription drugs imported under the CPDI Program are pure, unadulterated, potent, and safe; ○ The CPDI Program does not put consumers at a higher health and safety risk than if the CPDI Program did not exist; and ○ The CPDI Program provides cost savings to the state on imported prescription drugs.
<i>Rulemaking</i>	Adopt rules necessary to implement the CPDI Program.
Vendor	
<i>Vendor Eligibility</i>	Submit evidence of two surety bonds or comparable security arrangements each in the minimum amount of \$25,000 to ensure payment of penalties for non-performance and payment of any civil and criminal causes of action.
<i>List of Prescription Drugs</i>	<p>Develop a Wholesale Prescription Drug Importation List, list by December 1, 2019, and each year thereafter, identifying the prescription drugs that have the highest potential for cost savings to the state. At a minimum, the vendor is required to consider which drugs will provide the greatest cost savings to the state, including which drugs have shortages, specialty prescriptions, and high volume prescription drugs.</p> <p>The AHCA is also:</p> <ul style="list-style-type: none"> ● Required to review the list every 3 months, in consultation with the DOH, to ensure it continues to meet program requirements. ● Authorized to direct the vendor to revise the list.
<i>Relationship with Suppliers, Importers, and the AHCA</i>	<ul style="list-style-type: none"> ● Identify Canadian suppliers that are in full compliance with Canadian federal and provincial laws and regulations and the Federal Act who have agreed to export drugs on the list. ● Verify Canadian suppliers on the list meet all program requirements, while meeting or exceeding federal track and trace requirements and will export drugs at prices that will provide the state with cost savings. ● Contract with or facilitate contracts between eligible Canadian suppliers and eligible importers to import drugs under the CPDI Program. ● Maintain a list of all registered importers that participate in the program. ● Ensure compliance with Title II of the DQSA by all suppliers, importers, and other distributors and participants in the CPDI Program. ● Assist the AHCA in the presentation of the annual report and timely provide any requested information. ● Provide an annual financial audit of its operations to the AHCA and quarterly financial reports on the performance of its subcontractors and vendors.

Canadian Prescription Drug Importation Program Responsibilities of the Parties	
<i>Sample and Test</i>	<p>For an imported shipment, the vendor is required to statistically sample and test for authenticity and degradation in a manner consistent with the Federal Act:</p> <ul style="list-style-type: none"> • For the initial shipment: Each batch of the drug in the shipment. • For each subsequent shipment: A statistically valid sample of the shipment.
<i>Lab Testing</i>	<ul style="list-style-type: none"> • Maintain qualified laboratory records, including data derived from all tests necessary to ensure drug comply with these requirements. • Maintain information and documentation which demonstrates required testing was done in compliance with the Federal Act and any required federal and state testing guidelines. • Require all testing to be performed in a qualified lab which meets federal standards under the Federal Act, applicable federal laws and regulations, and state laws and regulations.
<i>Certification & Record Retention</i>	<ul style="list-style-type: none"> • Certify that any imported drug is approved for marketing in the U.S., is not adulterated or misbranded, and meets all of the required U.S. labeling standards. • Maintain records, information, and documentation under this section for at least seven years. • Maintain a list of all registered importers participating in the CPDI Program.
Importers and Eligible Drugs for Importation	
<i>Importer Eligibility</i>	<ul style="list-style-type: none"> • Must comply with federal tracking and tracing requirements and may not distribute, dispense, or sell prescription drugs imported under the CPDI Program outside of the state. • The following entities may import prescription drugs from a Canadian supplier: <ul style="list-style-type: none"> ○ The DOH’s central pharmacy, for distribution to a county health department or free clinic ○ Medicaid recipients ○ Department of Corrections ○ Developmental disabilities center ○ Treatment centers, such as a state-owned, -operated, or -supported hospital, center, or clinic treatment facility
<i>Eligible Prescription Drugs</i>	<p>Eligible importers may import a drug from an eligible Canadian supplier, if the importer:</p> <ul style="list-style-type: none"> • Meets the FDA’s standards related to safety, effectiveness, misbranding, and adulteration; • Importation would not violate U.S. patent laws; • Importation is 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 HHS Secretary to pose a threat.

Canadian Prescription Drug Importation Program Responsibilities of the Parties	
<i>Information provided to vendor</i>	Participating importers must provide the following information to the vendor: <ol style="list-style-type: none"> 1. The name and quantity of the active ingredient of the drug. 2. A description of the dosage form of the drug. 3. The date on which the drug is received. 4. The quantity of the drug that is received. 5. The point of origin and destination of the drug. 6. The price paid by the importer of the drug.
Canadian Suppliers	
<i>Supplier Eligibility</i>	<ul style="list-style-type: none"> • Must comply with federal tracking and tracing requirements and may not distribute, dispense, or sell prescription drugs imported under the CPDI Program outside of the state. • A supplier may export prescription drugs into this state if the supplier: <ul style="list-style-type: none"> ○ Fully complies with relevant Canadian federal and provincial laws and regulations; ○ Complies with track and trace at the package level. ○ Is identified by the vendor as eligible to participate in the CPDI Program. ○ Submits an attestation that the supplier has a registered agent in the United States, including the name and United States address of the registered agent.
<i>Information and Documentation</i>	<ul style="list-style-type: none"> • A participating Canadian supplier must submit the following information and documentation to the vendor specifying all of the following: <ol style="list-style-type: none"> 1. The original source of the drug, including: <ol style="list-style-type: none"> a. The name of the manufacturer of the drug. b. The date the drug was manufactured. c. The location (country, state/province, and city) where the drug was manufactured. 2. The date the drug was shipped. 3. The quantity of the drug shipped. 4. The quantity of each lot of the drug originally received and from which source. 5. The lot or control number and the batch number assigned to the drug by the manufacturer. • The AHCA may require that the vendor collect any other information necessary to ensure the protection of the public health.

International Prescription Drug Importation Program

Creates the International Drug Importation Program (IPDI Program) under newly created s. 499.0285, F.S. The DBPR is directed to establish the IPDI Program for the safe and effective importation of prescription drugs from foreign nations with which the United States has current mutual recognition agreements, cooperation agreements, memoranda of understanding, or other federal mechanisms recognizing adherence to current good manufacturing practices for pharmaceutical products.

The bill:

- Requires the IPDI Program to be open to individual Florida residents and to those participating in the CPDI Program.
- Establishes requirements for eligible prescription drugs, identical to the CPDI Program.
- Allows the following permitted or licensed entities to import prescription drugs into the state:
 - A wholesale distributor;
 - A pharmacy; and
 - A pharmacist
- Allows only three types of entities permitted with the DBPR or the Board of Pharmacy to export prescription drugs into the state, and creates two new permit categories for this purpose.
 - Entities authorized to export prescription drugs:
 - An international prescription drug wholesale distributor;
 - A nonresident prescription drug manufacturer; and
 - An international export pharmacy.
 - New permit categories created:
 - International Prescription Drug Wholesale Distributor Permit
 - International Export Pharmacy Permit
- Authorizes the 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, or secure any other evidence needed for prosecution.
- Establishes prescription drug supply chain documentation requirements for participating importers and exporters, as well as specific information participating importers are required to submit to the DBPR. The bill also authorizes the DBPR to require additional information necessary to ensure the protection of public health.
- Requires the vendor to maintain information and documentation for a minimum of 7 years.
- Provides for an approval process by the Legislature:
 - Implementation is contingent upon authority granted under federal law and rule. The International program will only be implemented under a specific federal law or rule that authorizes the implementation of such a program. There is no such authorization for an international importation program currently in federal law or regulation;
 - Requires the DBPR to notify the Legislature and the relevant committees prior to implementation of the pilot program; and
 - Requires the DBPR to submit an implementation and funding plan proposal to all parties.

The DBPR is also:

- Granted authority to inspect and investigate violations.
- Provided the authority to immediately suspend the importation of a specific prescription drug or the importation of prescription drugs by a specific importer if it discovers that any prescription drug or activity in violation.
- Authorized to adopt rules necessary to implement the IPDI Program.

The bill 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 pharmacy groups sued the state under a variety 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 pointed 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.”⁹⁵

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,⁹⁶ particularly if the state law is a matter involving issues regulating public health.⁹⁷ 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.”⁹⁸ To preempt state law, Congress must clearly preempt state law when it is regulating in an area where the state traditionally regulates.⁹⁹ In *Ouellette*, the Plaintiffs’ argument was that preemption should apply because the amendments passed by the state of Maine to allow for the drug importation program

⁹⁵ *Ouellette et al v. Mills et al*, *supra* note 63, at 9.

⁹⁶ *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 661 (2003); quoted in *Ouellette v. Mills*, at 10.

⁹⁷ See *Hillsborough County, Fla. v. Automated Med. Lab., Inc.*, 471 U.S. 707, 718 (1985); quoted in *Ouellette et al v. Mills et al*, at 10.

⁹⁸ *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).

⁹⁹ *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.

touch on foreign affairs and that subject matter is reserved traditionally for the federal government.¹⁰⁰

The Court noted in *Ouellette* 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.¹⁰¹ The Eighth Circuit had also weighed in on this issue and the *Ouellette* 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 384.¹⁰²

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 less likely since a federal statute sets forward a path for federal approval of a program. Concerns regarding intersections with other pharmaceutical programs and arguments, such as those about multiple regulatory schemes, may be issues to be aware of, but they should not have an impact on international relations.¹⁰³

Recently in a case from Maryland, the U.S. Supreme Court declined to review a decision from the U.S. Circuit Court of Appeals for the Fourth Circuit finding that Maryland's state-based price-gouging statute was a violation of the dormant commerce clause because it interfered with interstate commerce as it regulated transactions outside of the state.¹⁰⁴ "The principle against extraterritoriality as it relates to the dormant

¹⁰⁰ *Supra* note 63, at 11.

¹⁰¹ *Ouellette v. Mills*, *supra* note 63, at 15.

¹⁰² *In re Canadian Import Antitrust Litig.*, 470 F.3d 785, 790 (8th Cir. 2006) (cited in *Ouellette v. Mills*).

¹⁰³ 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 28, 2019).

¹⁰⁴ *Association for Accessible Medicines v. Frosh*, 887 F.3d 664 (U.S. App. 4th Cir. 2018).

commerce clause is derived from the notion that ‘a state may not regulate commerce occurring wholly outside of its borders.’¹⁰⁵

The Fourth Circuit held that Maryland illegally regulated wholesale pricing by drug companies through a provision 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.¹⁰⁶ 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 then requires the manufacturers and wholesalers to act in accordance with Maryland law outside of Maryland.¹⁰⁷

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.¹⁰⁸ Specifically, a state law may not have the practical effect of establishing a scale of prices for use in other states.”¹⁰⁹
- 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.”¹¹⁰ The statute’s “practical effect” is the focus of the inquiry.¹¹¹
- 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 not one, but many or every, State adopted similar legislation.¹¹² This is because “the Commerce Clause protects against inconsistent legislation arising from the projection of one state regulatory regime into the jurisdiction of another State.”¹¹³

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.¹¹⁴

¹⁰⁵ *Id.* (citing *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.*, 457 U.S. 624, 642-43 (1982)(plurality opinion)).

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ *Healy* at 336.

¹⁰⁹ *Healy* (quoting *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 528 (1935)).

¹¹⁰ *Id.*

¹¹¹ *Id.*

¹¹² *Healy* at 336.

¹¹³ *Healy* at 336-37.

¹¹⁴ *Supra* note 104, at 19-21.

“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’¹¹⁵ is therefore both real and significant. We are thus pressed to invalidate the Act.”¹¹⁶

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 entities that purchase those drugs in Florida.

C. Government Sector Impact:

Canadian Prescription Drug Importation Program

The bill has an indeterminate fiscal impact on the AHCA. The AHCA anticipates needing additional resources to implement the bill before any cost savings from the importation Program are implemented.¹¹⁷

While the bill has the potential to bring savings to the Florida Medicaid program and to other state government programs through lowering the cost of prescription drugs to individuals served by those programs, the amount of those savings currently cannot be quantified. However, since the federal law requires the Program to generate significant savings in order to be approved, this impact should be offset by drug price savings.

The AHCA is required to contract with a vendor to provide services under the Canadian Prescription Drug Importation Program. The AHCA did not provide an estimate of the cost to procure a contract with a qualified third-party vendor to administer the Program.

The AHCA indicated the need for six additional personnel dedicated to the project who will be developing, procuring, and managing and conducting oversight and monitoring activities. These expenditures are estimated to be \$575,495 of General Revenue funding in the first year of implementation and \$545,837 recurring General Revenue funding

¹¹⁵ *Healy* at 337.

¹¹⁶ *Supra* note 104, at 21.

¹¹⁷ Agency for Health Care Administration, *House Bill 19 Analysis* (March 1, 2019) (on file with the Senate Committee on Health Policy).

thereafter. The AHCA will need to determine the level of federal financial participation in the Program.

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 Board of Pharmacy, within the DOH, would be responsible for the licensing and permitting of business entities acting as importers, wholesalers, or suppliers.

International Prescription Drug Importation Program

The bill has a significant fiscal impact on the DBPR. The amendment establishes a new program which will require federal approval for full implementation.

If federally approved, the DBPR estimates a need of three full-time equivalent (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 amendment 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.

VI. Technical Deficiencies:

The DBPR indicates that the 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.¹¹⁸

VII. Related Issues:

Canadian Drug Supply

In 2015, Canada’s population (35 million) was one-ninth the population of the United States (318 million).¹¹⁹ 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 imports was

¹¹⁸ Department of Business and Professional Regulation, *Senate Bill 1528 Analysis*, at 11 (March 5, 2019) (on file with the Senate Committee on Health Policy).

¹¹⁹ Marv Shepherd, *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 28, 2019).

150.83 days.¹²⁰ In 2010, the number of days' supply was 201 days before the then-existing Canadian drug supply was depleted.¹²¹

That researcher pointed 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 way from a regulatory standpoint, or calling a halt to foreign sales of prescriptions.¹²² That researcher also noted that Canada imported \$13.180 billion in pharmaceuticals with \$5.16 billion coming from the United States in 2015. In other words, the United States was Canada's largest supplier of pharmaceuticals in 2015, representing 33.1 percent of all drugs imported by Canada.¹²³

Another concern maybe 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.¹²⁴ How Canada moves forward with this plan may impact how pharmacies and vendors in Canada operate in the future.

Canadian Law

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.¹²⁵ 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" in 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.¹²⁶ 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.¹²⁷

Federal Approval

The bill directs the AHCA, by July 1, 2020, to submit a request to the 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 under 21 USC s. 384 becomes effective only if the Secretary certifies to the U.S. 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

¹²⁰ Marv Shepherd, *supra* note 132, at 3.

¹²¹ Marv Shepherd, *supra* note 132, at 3.

¹²² Marv Shepherd, *supra* note 132, at 4.

¹²³ Marv Shepherd, *supra* note 132, at 4.

¹²⁴ 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).

¹²⁵ R.S., c. F-27, s. 8. (Can.)

¹²⁶ C.R.C., SOR/80-318, s-1(Can.)

¹²⁷ R.S.C., 1985, C. F-27, Part II(23)

of covered products to the American consumer. No HHS Secretary has yet sent such a certification to the U.S. Congress. The cited subsection also provides for termination of the federal program. However, the subsection contains no authority for the HHS Secretary to approve any state-based drug importation program under any circumstances, nor to waive any aspects of the federal program regarding public health and safety or cost reduction, which other states have requested through the FDA for their own state-based program proposals.

VIII. Statutes Affected:

This bill creates the following sections of the Florida Statutes: 381.02035, 465.0157, and 499.0285.

This bill amends the following sections of the Florida Statutes: 465.017, 499.005, 499.0051, 499.01, 499.012, 499.015, and 499.065.

IX. Additional Information:

- A. **Committee Substitute – Statement of Substantial Changes:**
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS/CS by Appropriations on April 18, 2019:

The committee substitute amends provisions of the Canadian Prescription Drug Importation Program and creates the International Prescription Drug Importation Program, establishing eligibility criteria for the types of prescription drugs which may be imported and the entities that may export or import prescription drugs. Specifically, the committee substitute:

Canadian Prescription Drug Importation Program

- Modifies the bond requirements. The amendment changes the vendor required amount from a minimum of \$1 million to \$25,000, and removes the requirements for importers and Canadian suppliers.
- Requires the vendor to provide an annual financial audit of its operations to the AHCA and provide quarterly financial reports specific to the program.
- Amends the entities or persons authorized to import prescription drugs to limit participation to the following public programs:
 - The Department of Health's central pharmacy, for distribution to a county health department or free clinic
 - Medicaid recipients
 - Department of Corrections
 - Developmental disabilities center
 - Treatment centers, such as a state-owned, -operated, or -supported hospital, center, or clinic treatment facility
- Modifies the program approval process to a notice and proposal process, requiring the AHCA to:
 - Begin operating the CPDI Program within 6 months of federal approval.
 - Notify the Legislature and relevant committees once federal approval has been received; and prior to the start of the next legislative session, submit an implementation and funding proposal to all parties.

International Prescription Drug Importation Program

- Requires the DBPR to establish the IPDI Program and provides eligibility criteria for prescription drugs, exporters, and importers and adopt rules necessary to implement the IPDI Program.
- Requires participating importers to submit certain documentation to the DBPR for imported prescription drugs.
- Requires the DBPR to immediately suspend the importation of a specific prescription drug or importation by a specific importer if a violation occurs and authorizes the DBPR to revoke a suspension under certain circumstances.
- Requires the DBPR, in consultation with the DOH, to negotiate a federal arrangement to operate a pilot program for importing prescription drugs into the state. The bill requires the proposal to operate a pilot program to demonstrate that safety standards are consistent with the current federal requirements for the manufacturing and distribution of prescription drugs. The bill further provides that implementation of the IPDI Program is contingent upon authority granted under federal law or regulation.
- Establishes an international export pharmacy permit and provides requirements for permit application and renewal.
- Authorizes the DOH to inspect an international export pharmacy permittee.
- Provides that importation of a prescription drug under the IPDI Program is exempted from criminal offenses.
- Requires nonresident prescription drug manufacturers to register with the DBPR to participate in the IPDI Program.
- Establishes an international prescription drug wholesale distributor permit and provides permitting requirements.
- Provides application requirements for international prescription drug wholesale distributors and nonresident prescription drug manufacturers to participate in the IPDI Program.
- Requires the DOH to inspect international prescription drug wholesale distributor establishments. The DOH is also authorized to determine if an international prescription drug wholesale distributor establishment is an imminent danger to the public and require its immediate closure under certain conditions.

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

CS by Health Policy on March 25, 2019:

The CS removes several provisions from the underlying bill, adds several safety and transparency components, clarifies existing components, and aligns the Program with updated tracing procedures under federal law. The CS:

- Removes from the underlying bill the provision that pharmacists or wholesalers may import Canadian prescription drugs under the Program only if they are employed by or under contract with:
 - The DOH's central pharmacy, for distribution to a county health department or free clinic for clients served in those settings;
 - A Medicaid pharmacy, for dispensing to the pharmacy's Medicaid recipients;
 - The Department of Corrections (DOC), for dispensing to inmates in DOC custody;

- A developmental disabilities center, for dispensing to clients treated in those settings; or
- A state-owned, state-operated, or state-supported treatment facility for persons with mental illness, or a private facility designated by the Department of Children and Families for that purpose, for dispensing to persons treated in those settings.
- Removes from the underlying bill the requirement for the AHCA to begin operating the Program within six months of receiving federal approval.
- Requires that any Canadian supplier must comply fully with U.S. law and any other federal and state laws and regulation relating to track and trace procedures. The definitions were updated to define what is meant by track and trace procedures.
- Requires the vendor, suppliers, and importers under the Program to post two surety bonds of at least \$1 million each at the time of contract execution to ensure contractual performance and non-payment of any administrative penalties over the contract term and to ensure participation in any civil or criminal litigation and payment of any claims or judgment that may arise from those actions. For suppliers and importers, the minimum amount of the bonds may escalate over time depending on Program volume.
- Requires the vendor under contract with the AHCA to maintain a list of all registered importers participating in the Program.
- Requires the vendor to ensure that all suppliers, importers, distributors, and other Program participants remain in compliance with all laws and regulations, U.S. and Canadian.
- Requires that a maximum administrative fee and profit margin amount or rate will be set by the state in the General Appropriations Act for any participating wholesaler, pharmacy, or pharmacist in the Program.
- Adds a limitation for participating suppliers and importers that drugs imported under this Program may not be sold outside of the Program.
- Sets a record retention requirement for laboratory testing records of seven years.
- Adds components to what should be included in the state's plan submission to the HHS to include information about the state's track and trace procedures, the state's estimated costs to implement the Program, and a list of Canadian suppliers willing to do business in Florida.
- Requires that the Program approved at the federal level to receive final approval from the Legislature before being implemented. Additional information about safety and cost effectiveness of the plan must accompany the approval request to the Legislature.
- Requires that the AHCA describe how it has complied with federal track and trace requirements in its Annual Report.

B. Amendments:

None.