(DRAFT/UNAPPROVED)

VIRGINIA SECRETARY OF HEALTH AND HUMAN RESOURCES
MINUTES OF THE DRUG IMPORTATION WORK GROUP MEETING

September 20, 2024

Department of Health Professions
Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233

CALL TO ORDER: A meeting of a Drug Importation Work Group was called to order at 1:05PM.

PRESIDING: **Leah Mills**, Deputy Secretary of Health and Human Resources

PARTICIPANTS PRESENT IN-PERSON:

Rebekah Allen, Chief Policy Advisor, Bureau of Insurance, Virginia State Corporation Commission
Nicole Wood, Pharmaceutical Research and Manufacturers of America (left approximately 2:40pm, **Anne Leigh Kerr** took her place)
Heidi Dix, Virginia Association of Health Plans
JoeMichael Fusco, PharmD, MCO Pharmacy Compliance Manager, Pharmacy | Office of the Chief Medical Officer, Department of Medical Assistance Services
Jodi Roth, Government Affairs, Virginia Retail Federation, Virginia Association of Chain Drug Stores
Nicara Neely, PharmD, Virginia Pharmacy Association
Joshua Crawford, PharmD, Virginia Society of Health-System Pharmacists
Stephanie Wheawill, PharmD, Director, Division of Pharmacy Services, Office of Epidemiology, Virginia Department of Health (arrived approximately 1:50pm)
Dr. Jessica Flanigan, Professor, University of Richmond

PARTICIPANTS PRESENT VIRTUALLY:

Nai Chen, PharmD, CPh, Health Care Policy-Agency for Health Care Administration
Michelle Adams, MPH, Acting Director of Intergovernmental Affairs, Office of the Commissioner, U.S. Food and Drug Administration (FDA)
Chris Campbell, M.A., Senior Intergovernmental Affairs Specialist, OC, FDA
Leigh Verbois, PhD, Director, Office of Drug Security, Integrity, and Response (ODSIR), Center for Drug Evaluation and Research (CDER), FDA
Carole Jones, Director, Division of Global Drug Distribution and Policy (DGDDP), ODSIR, CDER, FDA
Andrei Perlloni, Branch Chief, Imports Compliance Branch (ICB), DGDDP, ODSIR, CDER, FDA

Paul George, Senior Regulatory Counsel, DGDDP, ODSIR, CDER, FDA
Mara Baer, Founder and President, AgoHealth LLC
Aaron Kearsley, Senior Economist at U.S. Department of Health and Human Services (HHS)
Karen Meister, Senior Policy Advisor, FDA
Jennifer Roe

STAFF PRESENT:

Arne Owens, Director, Virginia Department of Health Professions (DHP)
Caroline Juran, RPh, Executive Director, Virginia Board of Pharmacy
Erin Barrett, JD, Director of Legislative and Regulatory Affairs, DHP (left approximately 2pm, returned at 3:10pm)
Sorayah Haden, Executive Assistant, Virginia Board of Pharmacy

APPROVAL OF AGENDA:

Three handouts were provided to the in-person participants and public: a list of participants, comments from VACDS, and comments from Dr. Flanigan regarding the ethics and effectiveness of drug importation. The agenda was approved as presented.

PUBLIC COMMENTS:

No public comment was not offered.

REVIEW SB 186 AND OTHER BACKGROUND MATERIALS INCLUDED IN AGENDA

Leah Mills provided an overview of the work group's charge pursuant to SB 186 which required the Secretary of Health and Human Resources to convene a work group composed of relevant stakeholders, including representatives from pharmaceutical manufacturers, health plans, and Virginia pharmacists, to (i) investigate wholesale prescription drug importation programs in other states, including the procedures for start-up and continued execution; (ii) evaluate best practices for the establishment and application of such a program; and (iii) consider the effectiveness of implementing such a program in the Commonwealth. The bill further required the work group to take into consideration the cost and safety of such a program. The Secretary is to provide a report on the feasibility of such a plan in the Commonwealth to the Governor, the Chairmen of the House Committees on Appropriations and Health and Human Services, and the Senate Committees on Finance and Appropriations and Education and Health by November 1, 2024.

FEDERAL ALLOWANCE FOR IMPORTATION PATHWAY OF CERTAIN DRUGS FROM CANADA UNDER SECTION 804 OF THE FEDERAL FOOD,

Leigh Verbois, PhD, Director, ODSIR, CDER, FDA provided a PowerPoint presentation (Attachment 1) explaining the pathway authorized by the FDA that allows the importation of certain prescription drugs from Canada to significantly reduce the cost of drugs to American consumers without imposing any additional risks to public health and safety. An overview of the application process for drug importation proposals was provided. The

DRUG, AND COSMETIC ACT

presentation provided an overview of FDA regulations, the basic requirements of a Section 804 Importation Program (SIP) proposal, and the SIP proposal evaluation and decision process.

FLORIDA'S DRUG IMPORTATION PROGRAM

Nai Chen, PharmD, CPh, Healthcare Policy, Agency for Health Administration provided a PowerPoint presentation (Attachment 2) explaining Florida's Canadian Prescription Drug Importation Program. The presentation explained the federal requirements of the FDA and Florida's legislation regarding drug importation. While Florida is the only state to receive approval from the FDA for a SIP proposal, the drug importation program has not been fully implemented. Efforts toward this cause began in 2018, state legislation was passed in 2019, initial SIP was submitted in 2020, and FDA approval was received in January 2024. The importation process explaining the roles of the Canadian manufacturers, foreign sellers, importers, and state agencies was provided in detail. Dr. Chen provided a timeline of the implementation process utilized by Florida to receive their drug importation approval in January 2024. The cost savings of Florida's drug importation implementation was provided as well. Dr. Chen provided the following five questions to Virginia to consider during their journey of submitting a SIP proposal:

- Who should receive imported prescription drugs?
- Which functions should be delegated to vendors?
- Who should bear the risk of logistics and testing?
- What medications should be included?
- What is the proper number of personnel?

COLORADO'S DRUG IMPORATION PROGRAM

Mara Baer, Founder and President, AgoHealth LLC provided a PowerPoint presentation (pages 44-57 of agenda packet) regarding the implementation status of the Drug Importation Program in Colorado. The overview detailed Colorado Senate Bill 19-005 authorizing the submission of an importation application, annual appropriation, and expected savings of the program. A diagram displaying the contracts and program participants were provided. Ms. Baer provided a timeline of the implementation process utilized by Colorado as they are currently in the process of seeking approval from the FDA to allow drug importation from Canada. The presentation consisted of the best practices and procedures for start-up and ongoing SIP proposals. The presentation explained possible implementation challenges such as the need to negotiate to secure a drug supply, the resistance by drug manufacturers, and the lack of regulatory clarity. Ms. Baer explained the proposed cost savings and safety measures because of the implementation of Colorado's Drug Importation program.

DISCUSSION TOPICS TAKING INTO CONSIDERATION COST AND SAFETY

As required by SB 186, the work group reviewed and discussed the following factors to take into consideration of Virginia submitting a SIP proposal:

- What actions have other states taken to implement a drug importation program including their procedures for startup and continued execution?
- Evaluate the best practices for the establishment and application of such a program.
- Consider effectiveness of implementing such a program in Virginia

There was consensus that Virginia should continue to monitor this subject and take no further action at this time. The following comments were offered:

- Dix: She didn't hear of a benefit to the consumer. Medicaid already very complicated. Rebates and state plan exceptions would likely take years to resolve. Virginia may need to take a more nuanced approach than Florida.
- Flanigan: Expanded access to drugs may create general cost-savings but may disincentive pharmaceutical innovation leading to higher costs. Difficult to estimate savings since importation does not exist in the market. Lowering cost of one drug may be offset by an increased cost of another drug. US patent system is a problem. She has previously advocated for regulatory reciprocity wherein deference is given to another country's regulatory approval process.
- Roth: Aligns her comments with Dix's. Additionally, her members have concerns with drug safety associated with allowing importation.
- Crawford: Manufacturers not likely to participate. Why would a state go through testing vs. obtaining a cheaper contract?
- Fusco: Important to consider which population would be recipients. Is the vulnerable HIV positive population really the right group to test out this process?
- Wheawill: Most HIV medications currently purchased under 340B contracting. Concerned with access equity.
- Kerr: How do you ensure safety? How much would such a program cost Virginia? Florida has already spent at least $39 million dollars and no drugs have been imported. Canada continues to say they will not support exportation of its drugs for this purpose or ensure safety of drugs. Florida's population is equivalent to 2/3 of Canada's. Virginia should not proceed until we see if Canada will export drugs.
- Neely: Concerned with how long the SIP approval process has taken so far.
- Allen: Observed that Florida's legislation was very prescriptive, and Colorado has procurement flexibility that Virginia does not currently have. Procurement flexibilities must be considered and an acknowledgment that Florida's agencies are structured differently than Virginia's. The Florida agency primarily responsible for overseeing its program appears to be a combination of DMAS, VDH OLC, and VHI.

MEETING ADJOURNED: Having completed all business on the agenda, the meeting was adjourned at 4:15 PM.

_____
Caroline Juran,
Executive Director
Virginia Board of Pharmacy

_____
DATE:

Attachment 1

Section 804 Importation Program: Overview of Regulations and Implementation

September 2024

Office of Drug Security, Integrity and Response
Center for Drug Evaluation and Research, Office of Compliance
U.S. Food and Drug Administration

Introduction

FDA has developed a pathway authorized under section 804 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that **allows importation of certain prescription drugs from Canada** to:

- **significantly reduce** the cost of these drugs to the American consumer,
- **without imposing additional risk** to public health and safety.

- FDA is committed to continuing to work with states and Indian tribes that seek to develop an importation proposal. States and Indian tribes may submit importation program proposals to FDA for review and authorization.

- The Section 804 Program is one of several federal efforts to provide cost savings. This presentation focuses on general information about this program only.

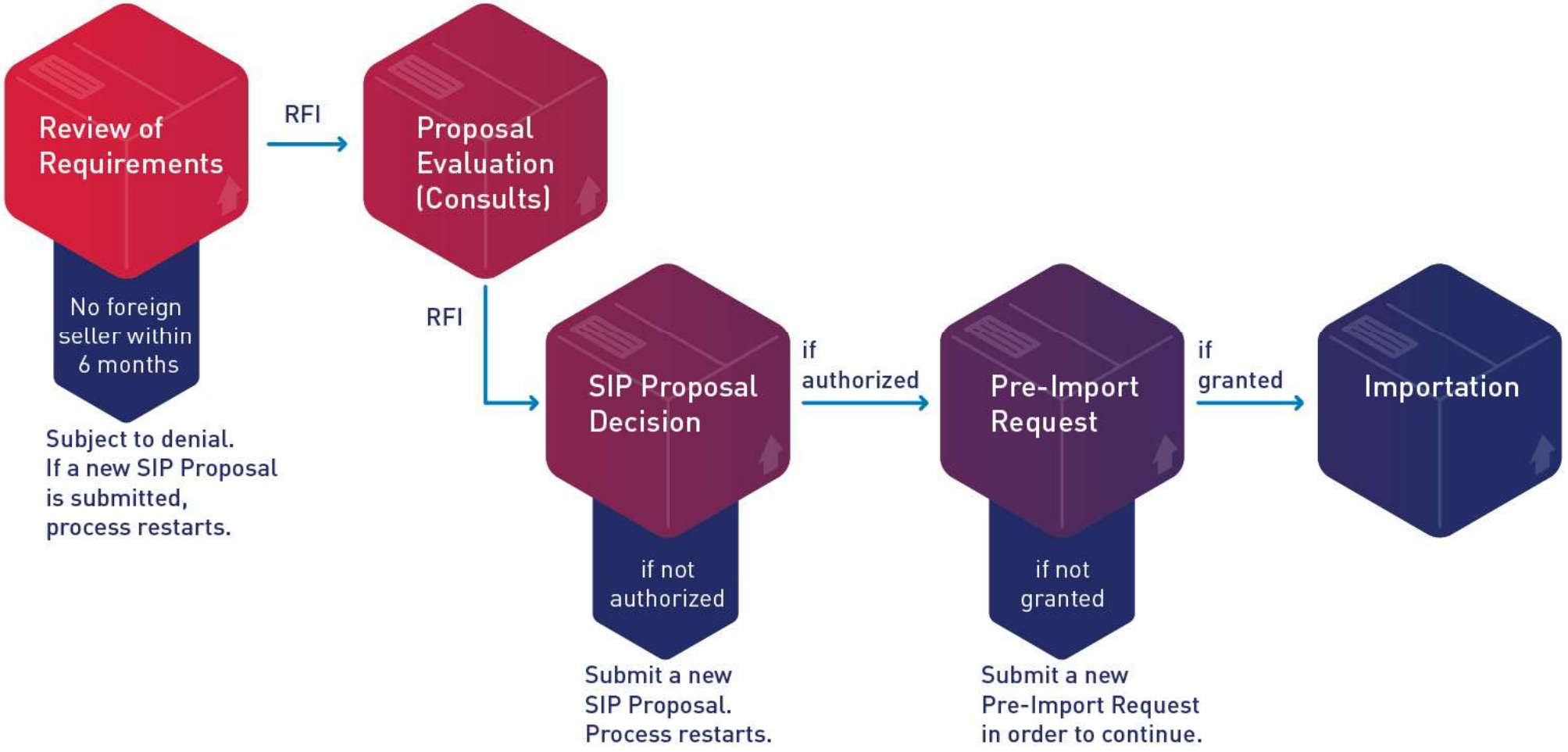
Other Cost Savings Programs

- **Section 804 is not the only federal effort to reduce the price of drugs to the American consumer:**
  - **340B Drug Pricing Program (Health Resources & Services Administration)**: requires pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs at discounted prices to health care organizations that care for many uninsured and low-income patients. Enrolled hospitals and other covered entities can achieve average savings of 25% to 50% in pharmaceutical purchases.
  - **Medicaid Drug Rebate Program (Centers for Medicare & Medicaid Services)**: gets back about half the cost of prescription drugs utilized in Medicaid, with both costs and rebates shared between the federal government and the states. Medicaid expansion thus helps states address prescription drug needs at lower cost.
  - **Inflation Reduction Act (Centers for Medicare & Medicaid Services)**: authorizes the Secretary of the Department of Health and Human Services (HHS) to negotiate Medicare drug prices directly with participating manufacturers for selected drugs and reduces Medicare Part B coinsurance for drugs whose prices rise faster than inflation.

Key Questions for Section 804

- Z kr: Currently, section 804 programs may only be sponsored by **states** or **Indian tribes**
- Z kdw: Section 804 importation allows importation of certain prescription drugs from Canada
- Z k|: There has been interest for many years in allowing the importation of less expensive drugs from Canada to help American consumers benefit from lower prices.
- Krz : If you represent a state or Indian tribe, ask questions or submit a SIP proposal by emailing the FDA at: SIPDrugImportsandRFP@fda.hhs.gov.

Section 804 Importation Program Overview



Overview of FDA's Regulations

- Under section 804 of the FD&C Act, FDA has the authority to promulgate regulations "permitting pharmacists and wholesalers to **import prescription drugs from Canada into the United States.**" The regulations had to include safeguards to ensure that the imported drugs met certain FD&C Act requirements and require that importers meet certain provisions of section 804, and the regulations could contain additional provisions "to **protect the public health** or as a means to facilitate the importation of prescription drugs."

- FDA promulgated the Final Rule, "Importation of Prescription Drugs" which was published October 1, 2020 (85 FR 62094) and became effective November 30, 2020.

- Under the Final Rule (*see* 21 CFR § 251), section 804 of the FD&C Act was implemented through time-limited Section 804 Importation Programs (SIPs) that FDA must approve prior to importation.

- The rule allows FDA-authorized programs to **import certain prescription drugs from Canada** under specific conditions that ensure, as required by section 804, that the importation **poses no additional risk to the public's health and safety** while **achieving a significant reduction in the cost of covered products to the American consumer.**

Basic Requirements of SIP Proposal

FDA regulations specify (§251.3) what must be included and adequately explained in the SIP proposal for FDA to authorize a SIP proposal. FDA performs a review of the SIP proposals before authorization. FDA ensures all required elements are appropriately addressed.

Broadly, this includes (among other things specified in the final rule):

1. Names and information for all responsible individuals (i.e., sponsor, co-sponsors, foreign seller, importer)
2. Table of contents
3. Overview of the SIP Proposal
4. The SIP Sponsor's importation plan
5. The name and address of the manufacturer of the finished dosage form of the eligible prescription drug
6. The name and address of the manufacturer of the active ingredient or ingredients of the eligible prescription drug

Basic Requirements of SIP Proposal: Continued

7. The name and address of the Foreign Seller
8. A copy of the Foreign Seller's Health Canada Drug Establishment License
9. The name and address of the Importer
10. The name and address of the FDA-registered repackager or relabeler, if different from the Importer, that will relabel the eligible prescription drugs, along with adequate evidence of registration and of satisfactory resolution of any objectionable conditions or practices identified during its most recent FDA inspection
11. A plan to ensure among other things that:
    - statutory testing requirements are met, supply chain is secure, labeling requirements are met, pharmacovigilance requirements are met, that the SIP will result in a significant reduction in the cost of the eligible prescription drug

Basic Requirements of SIP Proposal: Continued

12. Explain how the SIP Sponsor will educate pharmacists, healthcare providers, pharmacy benefit managers, health insurance issuers and plans, as appropriate, and patients
13. Include the SIP's recall plan, including an explanation of how the SIP Sponsor will obtain recall or market withdrawal information and how it will share that information
14. Include the SIP's return plan, including an explanation of how the SIP Sponsor will ensure that product that is returned if it is a non-saleable return, in order to protect patients from expired or unsafe drugs, and an explanation of how the SIP Sponsor will prevent the non-saleable returned eligible prescription drugs from being exported from the United States
15. Include the SIP's compliance plan describing responsible individual's responsibilities
16. Explain how the SIP Sponsor will ensure that information that the manufacturer supplies is kept confidential

SIP Proposal Evaluation and Decision

- Overall, the proposal must demonstrate that the importation **poses no additional risk to the public's health and safety while achieving a significant reduction in the cost of covered products to the American consumer**
  - FDA will rigorously evaluate all SIP proposals to ensure that all the specific requirements under the final rule are met, and that the SIP proposal meets this overall requirement
- The timeframe for review will be dependent upon the complexity of the SIP proposal and whether the proposal includes all the requirements specified in the final rule
- FDA may issue an authorization decision or respond to the sponsor with a Request For Information (RFI)
- If an RFI is issued, it will provide feedback to the SIP sponsor and specify items that are missing or inadequate in the current SIP proposal
  - Allows SIP sponsor to amend the SIP proposal
  - Multiple RFIs may be issued until the SIP proposal meets requirements

Pre-Import Request

If a SIP is authorized, an eligible prescription drug may not be imported or offered for import under FDA's regulations unless the Importer has filed a Pre-Import Request for that drug, in accordance with 21 CFR 251.5, and FDA has granted the Pre-Import Request.

- A list of items that a complete Pre-Import Request must include, at a minimum, is specified at 21 CFR 251.5(c)
- Among other things, this includes:
  - Identification of the Importer, including license number(s)
  - Identification of the FDA-authorized SIP
  - Identification of the Foreign Seller, including license number(s)
  - Identification and description of **each drug covered** by the Pre-Import Request
    - Among other items, this includes required **statutory testing information** and detailed **supply chain information** for the covered drug

Importation (§ 251.17)

- FDA must grant the Pre-Importation Request before the eligible prescription drug(s) may be offered for import

- Entry and arrival of a shipment containing an eligible prescription drug is limited to the U.S. Customs and Border Protection (CBP) port of entry authorized by FDA which is located in **Detroit, Michigan**
  - Imported drugs must be stored within 30 miles of that port of entry

- At the time of importation products must be declared in the CBP Automated Commercial Environment (ACE) using the Government Agency Processing Code for the Section 804 Importation Program. Additional information is available in the FDA Supplemental Guide.

Importation Continued

- Section 804 drugs must be approved in Canada and they must meet the conditions in an FDA-approved NDA or ANDA. Before they are imported, they must be relabeled so that their labeling is the same as the FDA-approved labeling, except that the labeling must bear conspicuously the items identified at 21 CFR 251.13(b)(4). Includes a statement indicating that drug was imported from Canada without the manufacturer's authorization
- Section 804 drugs must also be tested before they are imported. FDA will review the testing, conducted by an approved laboratory, of the eligible prescription drugs for authenticity, degradation, and to ensure that the eligible prescription drugs are in compliance with established specifications and standards
- Once approved by FDA, the importation of the eligible drug may proceed

Post-Importation Requirements

Sponsors have **several continuing obligations** under the SIP even once a drug has been imported (21 CFR 251.18 & 251.19)

Requirements include:

- Each SIP Sponsor is required to provide FDA with data and information about its SIP, including the SIP's cost savings to the American consumer on a quarterly basis (i.e., quarterly reports)
- An Importer is required to submit adverse event, field alert, and other reports to a drug's manufacturer and to FDA. If FDA or any participant in a SIP determines that a recall is warranted, the SIP Sponsor is responsible for effectuating the recall.
- Each SIP proposal must contain a written recall plan that describes the procedures to perform a recall of the product and to specify who will be responsible for performing recall procedures.
- SIP Sponsors and other SIP participants must also agree to submit to audits of their books and records and inspections of their facilities as a condition of participation in a SIP.

Additional Considerations

- **Can a sponsor import any drug?**
  - No. Not all drugs are eligible for importation under the SIP program. Eligible prescription drugs are those that could be sold legally on either the Canadian market or the American market with appropriate labeling.
  - Certain types of drug product are excluded by the final rule. For example, if it is not possible to relabel a product without affecting the container closure system, such as a blister pack, then the product cannot be imported under a SIP.
- **Can a sponsor just show that a drug is cheaper in Canada? Is that sufficient?**
  - That would not be sufficient. The SIP proposal must explain how the SIP sponsor will ensure that the SIP will result in a significant reduction in the cost to the American consumer of the eligible prescription drugs that the SIP sponsor seeks to import.
- **How can a sponsor demonstrate that the SIP will result in a significant reduction in cost?**
  - The HHS presentation Projecting Cost Savings for the American Consumer outlines methods and considerations for providing that explanation in the SIP proposal.

Additional Considerations

- **What must be done to relabel the drug(s)?**
  - Section 251.13(b)(4) requires that the labeling of the drug is the same as the FDA-approved labeling under the applicable new drug application (NDA) or abbreviated new drug application (ANDA) at the time the drug is sold or dispensed, with certain exceptions
  - Specifically, an eligible prescription drug's labeling can only deviate from the FDA-approved labeling in the ways listed at 251.13(b)(4)(i)-(vii). The sponsor must ensure that the content and format of the container and carton labeling of each eligible prescription drug included in the SIP proposal is the same as the FDA-approved carton and container labeling.
- **Can a sponsor use any port of entry to import drugs under a SIP?**
  - No. Entry and arrival of a shipment containing an eligible prescription drug is limited to the U.S. Customs and Border Protection (CBP) port of entry authorized by FDA. At this time, the only port of entry that has been authorized by FDA is located in: **Detroit, Michigan**.
- **How long will an authorized SIP last?**
  - A SIP may be authorized for up to 2 years from the date of importation of its first shipment and FDA may extend the authorization period for up to 2 years at a time

Questions and Point of Contact

- More information can be found at: https://www.fda.gov/about-fda/reports/importation-program-under-section-804-fdc-act
- States and tribes interested in working with the agency on a SIP proposal can contact FDA's Intergovernmental Affairs Staff at IGA@fda.hhs.gov to begin the conversation
- States and tribes may submit a SIP proposal for agency review or ask questions about an existing proposal by email to: SIPDrugImportsandRFP@fda.hhs.gov


FDA
U.S. FOOD & DRUG
ADMINISTRATION

Attachment 2

Florida's Canadian Prescription Drug Importation Program

Sep 20, 2024

AHCA

AGENCY FOR HEALTH CARE ADMINISTRATION

Agency for Health Care Administration (AHCA)

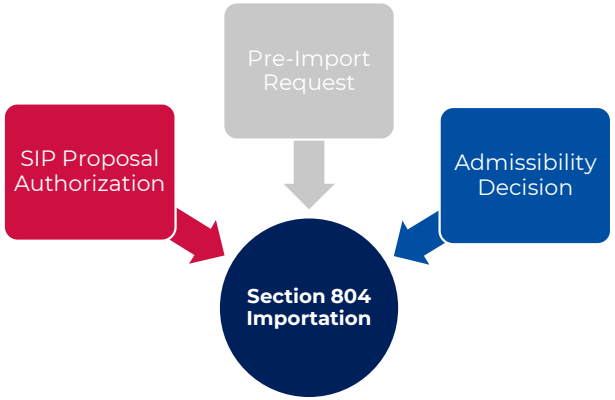
- Single State Agency for Florida Medicaid.
  - Administers State Medicaid Managed Care (SMMC) program
- Regulates and licenses health care facilities.
  - Florida Center for Health Information and Transparency.

Federal Authority

- The U.S. Food and Drug Administration (FDA) regulates most aspects of prescription drugs (Federal Food, Drug, and Cosmetic Act, 1938).
  - Does not regulate price.
  - Joint regulation with Customs and Border Patrol (CBP) on imported drugs.
  - Licensure of wholesale distributors is delegated to the States.
- Medicare Modernization Act (2003) gave the FDA authority to allow States to import certain prescription drugs from Canada.
  - Former Sec. Alex Azar certified the program will not cause additional risk and will generate cost savings in 2019.
  - FDA published Final Rule for importation in 2020.

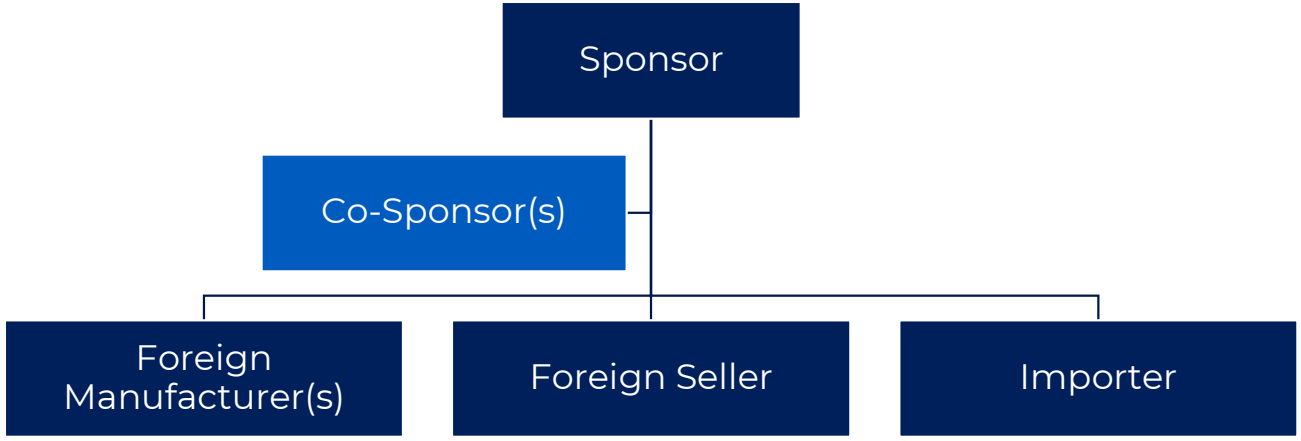
Federal Authority

- Each Section 804 Importation Program (SIP) authorization lasts two years from the moment the first Pre-Import Request is approved.
- States can, as of October 2020, submit SIP proposals to the FDA for authorization.
  - SIPDrugImportsandRFP@fda.hhs.gov
- SIP proposal requires demonstration of safety and cost savings.
- Importation requires three approvals from the FDA:



Federal Authority

- Requires an initial supply chain of Foreign Manufacturer, Foreign Seller, and Importer.
  - Foreign seller can be added to SIP proposal up to six months after initial submission date.



Florida Legislation

- In 2019, Florida passed HB 19 to establish Florida's Canadian Prescription Drug Importation Program.
  - Incorporated as 381.02035, F.S.
- Each year since 2020, Florida's General Appropriations Act has provided fixed funding for the program (HB 5001 or SB 2500).
  - Proviso language for the annual budget (Implementing the General Appropriations Act) is either HB 5003 or SB 2502.
  - Provides funds for the vendor to establish and maintain readiness.

Florida Legislation

- Authorized AHCA to serve as the Sponsor and the Department of Business and Professional Regulations (DBPR) to serve as the Co-Sponsor.
- Tasked AHCA with:
  - Applying to the FDA for the authorization of Florida's SIP.
  - Contracting with a vendor to provide all logistic services (directly or through sub-contracts).
  - Develop and maintain a Wholesale Prescription Drug List with the consultation with the Department of Health.

Florida Legislation

- Agencies that will utilize imported prescription drugs:

- Prescription drugs imported under the program are not shipped, sold, or dispensed outside of this state once in the possession of the importer.

Importation Process

Canadian Manufacturers

- Produce drugs for the Canadian market
- Sell drugs to the Foreign Seller

Foreign Seller

- Purchases drugs from Canadian manufacturers
- Sells drugs to the Importer

Importer

- Purchases drugs from the Foreign Seller
- Imports drugs into the U.S.
- Distributes drugs to State agencies

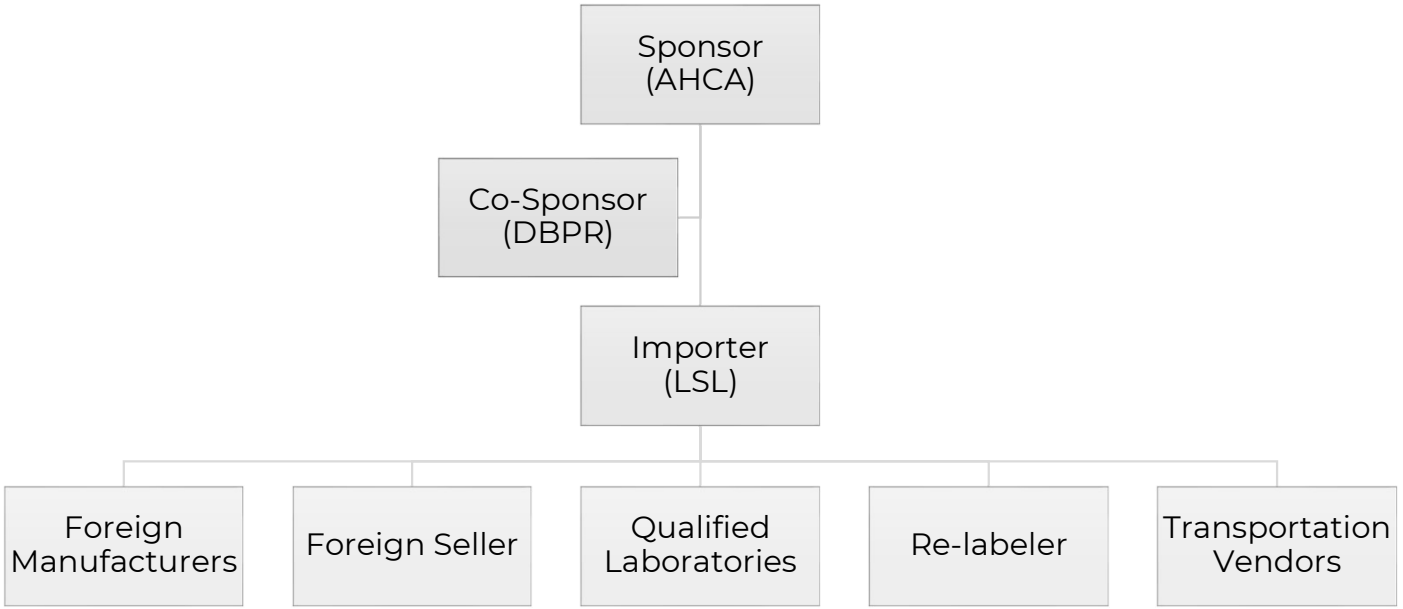
State Agencies

- Purchase drugs from the Importer
- Dispense to individuals under the care of State programs

AHCA
AGENCY FOR HEALTH CARE ADMINISTRATION

Florida's Implementation

Operational Structure:



AHCA
AGENCY FOR HEALTH CARE ADMINISTRATION

Florida's Implementation

Importer Contract

- The Vendor agreed to:
  - Bear the risk of transportation, storage, re-labeling, customs, and laboratory testing.
  - Provide customer service for all orders.
  - Create and maintain website for ordering.
  - Negotiate and Contract with all other entities.
- and is paid:
  - A fixed administrative fee after completing warehouse.
  - A fixed percentage for inventory.

Florida's Implementation - Timeline

Jun 2019	Governor DeSantis signs HB 19.
Dec 2019	FDA releases draft rule on drug importation.
Jan 2020	Agency submits Legislative Budget Request for the program.
Jun 2020	AHCA posts Invitation to Negotiate to procure an Importer.
Sep 2020	AHCA begins preparing Section 804 Importation proposal.
Nov 2020	AHCA submitted initial SIP Proposal to the FDA.

AHCA
AGENCY FOR HEALTH CARE ADMINISTRATION

Florida's Implementation - Timeline

Dec 2020	Life Science Logistics (LSL) selected to serve as Importer.*
Jan 2021	AHCA begins assembling team dedicated to SIP
Apr 2021	LSL contracted with Methapharm to serve as the Foreign Seller.
May 2021	LSL completed warehouse in Lakeland, FL for storage and distribution.
Aug 2021	AHCA received first Request for Information (RFI) from the FDA and submitted the amended SIP.
Nov 2021	AHCA received second RFI from the FDA and submitted the amended SIP.

AHCA
AGENCY FOR HEALTH CARE ADMINISTRATION

*287.057(6), F.S.

Florida's Implementation - Timeline

Mar 2022	FDA held all-state call for wholesale drug importation.
Aug 2022	Florida initiated litigation against the FDA for violation of APA*.
Nov 2022	AHCA received third RFI from the FDA.
Apr 2023	AHCA completed and submitted amended SIP proposal.
Aug 2023	AHCA received fourth RFI from the FDA.
Oct 2023	AHCA completed and submitted amended SIP proposal.

AHCA
AGENCY FOR HEALTH CARE ADMINISTRATION

*Administrative Procedure Act

Florida's Implementation - Timeline

Nov 2023	AHCA received clarification request from the FDA and submitted response.
Dec 2023	FDA requested additional time to grant decision.
Jan 2024	FDA authorizes Florida's SIP Proposal

Drugs Ineligible for Importation

- Both federal and Florida law prohibit the following drug classes from importation:
  - Controlled substances (e.g., opioids)
  - Biological products (e.g., insulin, Ozempic)
  - Injectables (e.g., epinephrine)
  - Infused drugs and drugs inhaled during surgery
  - High risk drugs* (e.g., clozapine)
- The FDA's relabeling requirements also prohibit drugs based on packaging, including those contained in blister packs or any other package type that requires breaching to relabel (e.g., inhalers).

AHCA AGENCY FOR HEALTH CARE ADMINISTRATION

*Drugs sold under any Risk Evaluation and Mitigation Strategies (REMS) programs

Wholesale Prescription Drug List

NAME	CLASS
Biktarvy (bictegravir-emtricitabine-tenofovir alafenamide)	HIV/AIDS
Descovy (emtricitabine-tenofovir alafenamide)	HIV/AIDS
Dovato (dolutegravir-lamivudine)	HIV/AIDS
Genvoya (elvitegravir-cobicistat-emtricitabine-tenofovir alafenamide)	HIV/AIDS
Juluca (dolutegravir-rilpivirine)	HIV/AIDS
Odefsey (emtricitabine-rilpivirine-tenofovir alafenamide)	HIV/AIDS
Prezcobix (darunavir-cobicistat)	HIV/AIDS
Prezista (darunavir)	HIV/AIDS
Ravicti (glycerol phenylbutyrate)	Congenital Metabolic Disorder
Rexulti (brexpiprazole)	Psychiatry
Symtuza (darunavir-cobicistat-emtricitabine-tenofovir alafenamide)	HIV/AIDS
Tivicay (dolutegravir)	HIV/AIDS
Vraylar (cariprazine)	Psychiatry
Xtandi (enzalutamide)	Cancer

Cost Savings

- In the March 2022 FDA-States meeting, the FDA stated 50% of the consideration for authorization will be based on cost savings.
  - Sponsor must demonstrate cost savings for all proposed drugs.
  - Applicants must compare the difference between the Base Scenario (cost of drugs without importation) and Plan scenario (cost of imported drugs and administrative costs).
  - Both scenarios must be projected into the future (for two years of approval).
  - Must show projected utilization, drug costs for both scenarios, discounts, and administrative costs for each drug.

Cost Savings

- AHCA projected to save $183 million in Federal FY 2023-2024 and $196 million in 2024-2025.
  - Contracted with its actuary vendor, Milliman, to provide price and utilization projections.
  - Assumes 100% utilization for the 14 drugs.
  - Only includes savings from Florida Medicaid, not the other State Agencies.
  - Includes net prices after rebate. Medicaid rebates were redacted from the proposal as they are confidential.

Safety

- Drug Safety and Supply Chain Act (DSCSA) standards are required for all Section 804 Imported Drugs.
- Requires laboratory testing (Statutory Testing) after importation to ensure authenticity and quality.
  - This is not required for FDA-approved drugs.
  - Samples must be sent to both the FDA and an authorized lab.
  - FDA will not give authorization without satisfactory results.
- All steps of storage, testing, and transportation require written procedures, and they must be submitted as part of the SIP application.

Questions to Consider

Whom should receive imported prescription drugs?

Which functions should be delegated to vendor(s)?

Who should bear the risk of logistics and testing?

What medications should be included?

What is the proper number of personnel?

AHCA
AGENCY FOR HEALTH CARE ADMINISTRATION

References

- Vendor Contract facts.fldfs.com/Search/ContractDetail.aspx?AgencyId=680000&ContractId=ME214
- Florida Statute 381.02035 www.flsenate.gov/laws/statutes/2021/381.02035
- Medicare Modernization Act www.congress.gov/bill/108th-congress/house-bill/1
- Final Rule (21 CFR Part 251) www.hhs.gov/sites/default/files/importation-final-rule.pdf
- FDA Presentation on Projecting Cost Savings for the American Consumer www.fda.gov/media/158564/download?attachment

THANK YOU

@AHCA_FL

@AHCAFLORIDA

FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION

FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION

AHCA

AGENCY FOR HEALTH CARE ADMINISTRATION