COMMONWEALTH OF VIRGINIA
Meeting of the Secretary of Health and Human Resources

Perimeter Center, 9960 Mayland Drive, Third Floor **(804) 367-4456 (Tel)**
Henrico, Virginia 23233 **(804) 527-4472(Fax)**

Tentative Agenda of Drug Importation Work Group Meeting
September 20, 2024
1PM- 4:30PM

TOPIC	**PAGES**
Call to Order: Leah Mills, Deputy Secretary of Health and Human Resources • Welcome & Introductions • Approval of Agenda	
Call for Public Comment: The Board will receive public comment at this time. The Board will not receive comment on any regulation process for which a public comment period has closed or any pending disciplinary matters.	
Review SB 186 and other Background Materials included in Agenda	**2-43**
Packet Brief Overviews:	
• Federal allowance for importation pathway of certain drugs from Canada under Section 804 of the Federal Food, Drug, and Cosmetic Act, *FDA representative*	**Handout**
• Florida's Drug Importation Program, *Nai Chen, PharmD, CPh – Senior Pharmacist, Health Care Policy, Agency For Health Care Administration*	**Handout**
• Colorado's Drug Importation Program, *Mara S. Baer, Founder & President, AgoHealth, LLC*	**44-57**
Discussion Topics taking into Consideration Cost and Safety: • What action have other states taken to implement a drug importation program, including their procedures for startup and continued execution? • Evaluate best practices for the establishment and application of such a program. • Consider effectiveness of implementing such a program in Virginia.	
Identify Next Steps	
Adjourn	

Agenda Topic: Review SB 186 and other Background Materials included in Agenda Packet

Included in Agenda Packet:

- SB 186 - **Page 3**
- Executive Order 13938-Increasing Drug Importation to Lower Prices for American Patients, *Administration of Donald J. Trump, 2020* - **Pages: 4-5**
- Fulfilling President Trump's Executive Order on Facilitating Drug Importation to Lower Prices for American Patients, Request for Industry Proposals for Personal Importation of Prescription Drugs, *HHS, September 24, 2020* - **Pages: 6-9**
- Executive Order on Promoting Competition in the American Economy, *Administration of Joseph R. Biden, Jr., July 9, 2021* - **Pages: 10-29**
- Importation Program under Section 804 of the FD&C Act, *from FDA website* - **Pages: 30-32**
- Letter of Authorization for Florida's Section 804 Importation Program, *January 5, 2024* - **Pages: 33-36**
- National Association of Boards of Pharmacy Report of the Task Force on State Oversight of Drug Importation, *September 2021* - **Pages: 37-41**
- Pharmacy organizations raise concerns about Florida's drug importation program, *January 17, 2024* - **Pages: 42-43**

CHAPTER 620

An Act to direct the Secretary of Health and Human Resources to convene a work group to investigate wholesale prescription drug importation programs in other states and evaluate best practices for the establishment and application of such a program in the Commonwealth; report.

[S 186]

Approved April 8, 2024

Be it enacted by the General Assembly of Virginia:

1. *§ 1. That the Secretary of Health and Human Resources (the Secretary) shall 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 work group shall take into consideration the cost and safety of such a program. The Secretary shall 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.*

Executive Order 13938—Increasing Drug Importation To Lower Prices for American Patients

July 24, 2020

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Purpose. Americans spend more per capita on pharmaceutical drugs than residents of any other developed country. Americans often pay more for the exact same drugs, even when they are produced and shipped from the exact same facilities.

One way to minimize international disparities in price is to increase the trade of prescription drugs between nations with lower prices and those with persistently higher ones. Over time, reducing trade barriers and increasing the exchange of drugs will likely result in lower prices for the country that is paying more for drugs. For example, in the European Union, a market characterized by price controls and significant barriers to entry, the parallel trade of drugs has existed for decades and has been estimated to reduce the price of certain drugs by up to 20 percent. Accordingly, my Administration supports the goal of safe importation of prescription drugs.

Sec. 2. Permitting the Importation of Safe Prescription Drugs from Other Countries. The Secretary of Health and Human Services shall, as appropriate and consistent with applicable law, take action to expand safe access to lower-cost imported prescription drugs by:

(a) facilitating grants to individuals of waivers of the prohibition of importation of prescription drugs, provided such importation poses no additional risk to public safety and results in lower costs to American patients, pursuant to section 804(j)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 384(j)(2);

(b) authorizing the re-importation of insulin products upon a finding by the Secretary that it is required for emergency medical care pursuant to section 801(d) of the FDCA, 21 U.S.C. 381(d); and

(c) completing the rulemaking process regarding the proposed rule to implement section 804(b) through (h) of the FDCA, 21 U.S.C. 384(b) through (h), to allow importation of certain prescription drugs from Canada.

Sec. 3. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

DONALD J. TRUMP

The White House,
July 24, 2020.

[Filed with the Office of the Federal Register, 2 p.m., July 24, 2020]

NOTE: This Executive order was published in the *Federal Register* on July 29.

Categories: Executive Orders : Drug importation to lower prices for patients, expansion efforts.

Subjects: Health and medical care : Prescription drugs, affordability and costs.

DCPD Number: DCPD202000540.

Fulfilling President Trump's Executive Order on Facilitating Drug Importation to Lower Prices for American Patients

Request for Industry Proposals for Personal Importation of Prescription Drugs

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law.

Frequently Asked Questions

Q: What has been announced?

A: The Department of Health and Human Services (HHS) has announced a request for proposals (RFP) asking private sector partners for information on how they might operate programs to allow Americans to obtain prescription drugs at lower prices through importation for personal use. The prescription drugs subject to these programs will be FDA-approved/licensed products.

Q: What does the RFP on personal importation do?

A: This RFP asks the private sector to propose ways that American patients could purchase their prescription drugs at the same or lower prices compared with those paid in other countries. State-licensed pharmacies would be allowed to operate as authorized Individual Waiver Importation Plans (IWIPs) and would be permitted to dispense an FDA-approved prescription drug imported from an Acceptable Foreign Source. Individuals would then be able to apply for waivers through a portal, and receive the drug through such a pharmacy.

Only proposals that have a clear path for the importation of FDA-approved, safe, and efficacious therapies in a cost-effective manner will be accepted. Proposals will be required to meet applicable legal requirements.

Q: Why is this action being taken now?

A: President Trump has been firm and unwavering in his determination to give Americans access to fair drug prices. While the Trump Administration would prefer that Congress act to lower the price of prescription drugs, to date they have failed to do so. Consistent with the laws Congress has already passed, President Trump is taking action to fulfill his commitment to the American people.

Q: What type of entities can apply to become an authorized Individual Waiver Importation Plan (IWIP)?

A: An IWIP sponsor may be any interested person, including a distributor, wholesaler, or pharmacy.

Q: How do you get a waiver?

A: HHS will establish a process and an electronic portal by which individuals seeking to import prescription drugs through an authorized IWIP can seek, on a case-by-case basis, section 804(j)(2) waivers from the Secretary.

Q: Can you buy from an online pharmacy?

A: Prescription drugs in the program would be dispensed to patients through authorized state-licensed pharmacies. These pharmacies would be specified in an authorized Individual Waiver Importation Plan (IWIPs). This pathway would not authorize individuals in the United States to purchase prescription drugs through the Internet, directly from a foreign pharmacy, or from any other foreign seller.

Q: When does this go into effect? When can patients expect to access prescription drugs through the program?

A: HHS and FDA will begin accepting proposals on September 24, 2020, and continue indefinitely. The Secretary may authorize a personal importation program provided the criteria described in the RFP are met. Patients would be able to access prescription drugs soon after a program is authorized. The Secretary may similarly revoke an authorization if the criteria are no longer met or for other reasons, provided that the Secretary gives due consideration for the reliance interests of patients and their health care providers.

Q: How significant of price reductions can patients expect?

A: As the President's recent executive order explained:

> Americans spend more per capita on pharmaceutical drugs than residents of any other developed country. Americans often pay more for the exact same drugs, even when they are produced and shipped from the exact same facilities.
>
> One way to minimize international disparities in price is to increase the trade of prescription drugs between nations with lower prices and those with persistently higher ones. Over time, reducing trade barriers and increasing the exchange of drugs will likely result in lower prices for the country that is paying more for drugs.

The amount of the price reductions will depend on the details of programs under which patients access safe, effective prescription drugs obtained from abroad. HHS believes the savings to American patients would likely to be substantial.

Q: How quickly will there be a price reduction?

A: The timing of the price reductions will depend on industry's response to the RFP. HHS is committed to reviewing applications in a timely manner.

Q: Can individuals trust that imported prescription drugs are safe?

A: Only drugs that have already been approved by the FDA and that are manufactured in FDA-registered facilities will qualify for the personal importation program. A recent study based on the largest ever comparative test of the quality attributes of prescription drugs legally marketed in the United States concluded that "difficult-to-make prescription pharmaceuticals marketed in the US consistently meet quality standards even when manufactured outside the US." The FDA's review of the proposals for safety and efficacy will ensure these pathways are not available unless sponsors demonstrate that they have a plan to ensure the safety and efficacy of the imported drugs.

Q: How is this action different from the actions taken through the state importation final rule?

A: While the state importation rule, as planned, would allow for varying drugs to be imported via agreements with individual states, this RFP would harness the power of private sector stakeholders to facilitate personal importation of prescription drugs for those truly in need at lower costs than Americans are paying today.

Q: Why not just make manufacturers lower the prices they charge American patients?

A: The Trump Administration is exploring all options available under the law to put an end to current price gouging practices. American patients continue to pay higher amounts for prescription drugs than patients abroad, in effect subsidizing each drug company's inability—or unwillingness—to negotiate better prices with other countries. While these policies take shape, the implementation of the President's executive order will bring needed relief to everyday Americans who need affordable access to prescription drugs now.

Q: How would patients receive prescription drugs?

A: Private-sector partners would, as part of their proposals, provide a plan for the importation of FDA-approved/licensed prescription drugs. Patients would obtain drugs through U.S.-licensed pharmacies operating in connection with an approved plan. The plans themselves must demonstrate how safe, effective products will reach Americans in a way that complies with applicable laws.

Q: The RFP says that the FDA would work with HHS on reviewing proposals. Who would be responsible for approving any of these programs?

A: The proposals would be reviewed by the FDA for the safety and efficacy of the prescription drugs listed in the proposals. By law, the Secretary of HHS grants the waiver to import prescription drugs. But only proposals that have a clear path for the importation of FDA-approved, safe, and efficacious therapies in a cost-effective manner will be accepted.

Q: Is personal importation limited to Canada? What countries will patients be able to import prescription drugs from?

A: The personal importation program is not limited to Canada. Foreign sources from which patients will be able to import prescription drugs (defined as an "Acceptable Foreign Source" in the RFP) include the following countries: Australia, Canada, the European Union or a country in the European Economic Area, Israel, Japan, New Zealand, Switzerland, South Africa, or the United Kingdom.

Q: Once an individual receives a waiver, how will they get their drug?

A: Individuals would apply for a waiver for a specific drug, and waiver in hand, along with a valid prescription, can pick up the prescription drug from an American pharmacy operating under an approved plan.

Q: Are all prescription drugs eligible for personal importation?

A: No. While most prescription drugs in the FDA's Orange Book will qualify for importation, this policy excludes controlled substances, biological products, infused drugs, intravenously injected drugs, intrathecally injected drugs, infused drugs, drugs inhaled during surgery, and parenteral drugs.

JULY 09, 2021

Executive Order on Promoting Competition in the American Economy

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to promote the interests of American workers, businesses, and consumers, it is hereby ordered as follows:

Section 1. Policy.

A fair, open, and competitive marketplace has long been a cornerstone of the American economy, while excessive market concentration threatens basic economic liberties, democratic accountability, and the welfare of workers, farmers, small businesses, startups, and consumers.

The American promise of a broad and sustained prosperity depends on an open and competitive economy. For workers, a competitive marketplace creates more high-quality jobs and the economic freedom to switch jobs or negotiate a higher wage. For small businesses and farmers, it creates more choices among suppliers and major buyers, leading to more take-home income, which they can reinvest in their enterprises. For entrepreneurs, it provides space to experiment, innovate, and pursue the new ideas that have for centuries powered the American economy and improved our quality of life. And for consumers, it means more choices, better service, and lower prices.

Robust competition is critical to preserving America's role as the world's leading economy.

Yet over the last several decades, as industries have consolidated, competition has weakened in too many markets, denying Americans the benefits of an open economy and widening racial, income, and wealth inequality. Federal Government inaction has contributed to these problems, with workers, farmers, small businesses, and consumers paying the price.

Consolidation has increased the power of corporate employers, making it harder for workers to bargain for higher wages and better work conditions. Powerful companies require workers to sign non-compete agreements that

restrict their ability to change jobs. And, while many occupational licenses are critical to increasing wages for workers and especially workers of color, some overly restrictive occupational licensing requirements can impede workers' ability to find jobs and to move between States.

Consolidation in the agricultural industry is making it too hard for small family farms to survive. Farmers are squeezed between concentrated market power in the agricultural input industries — seed, fertilizer, feed, and equipment suppliers — and concentrated market power in the channels for selling agricultural products. As a result, farmers' share of the value of their agricultural products has decreased, and poultry farmers, hog farmers, cattle ranchers, and other agricultural workers struggle to retain autonomy and to make sustainable returns.

The American information technology sector has long been an engine of innovation and growth, but today a small number of dominant Internet platforms use their power to exclude market entrants, to extract monopoly profits, and to gather intimate personal information that they can exploit for their own advantage. Too many small businesses across the economy depend on those platforms and a few online marketplaces for their survival. And too many local newspapers have shuttered or downsized, in part due to the Internet platforms' dominance in advertising markets.

Americans are paying too much for prescription drugs and healthcare services — far more than the prices paid in other countries. Hospital consolidation has left many areas, particularly rural communities, with inadequate or more expensive healthcare options. And too often, patent and other laws have been misused to inhibit or delay — for years and even decades — competition from generic drugs and biosimilars, denying Americans access to lower-cost drugs.

In the telecommunications sector, Americans likewise pay too much for broadband, cable television, and other communications services, in part because of a lack of adequate competition. In the financial-services sector, consumers pay steep and often hidden fees because of industry consolidation. Similarly, the global container shipping industry has consolidated into a small number of dominant foreign-owned lines and alliances, which can disadvantage American exporters.

The problem of economic consolidation now spans these sectors and many others, endangering our ability to rebuild and emerge from the coronavirus disease 2019 (COVID-19) pandemic with a vibrant, innovative, and growing economy. Meanwhile, the United States faces new challenges to its economic

standing in the world, including unfair competitive pressures from foreign monopolies and firms that are state-owned or state-sponsored, or whose market power is directly supported by foreign governments.

We must act now to reverse these dangerous trends, which constrain the growth and dynamism of our economy, impair the creation of high-quality jobs, and threaten America's economic standing in the world.

This order affirms that it is the policy of my Administration to enforce the antitrust laws to combat the excessive concentration of industry, the abuses of market power, and the harmful effects of monopoly and monopsony — especially as these issues arise in labor markets, agricultural markets, Internet platform industries, healthcare markets (including insurance, hospital, and prescription drug markets), repair markets, and United States markets directly affected by foreign cartel activity.

It is also the policy of my Administration to enforce the antitrust laws to meet the challenges posed by new industries and technologies, including the rise of the dominant Internet platforms, especially as they stem from serial mergers, the acquisition of nascent competitors, the aggregation of data, unfair competition in attention markets, the surveillance of users, and the presence of network effects.

Whereas decades of industry consolidation have often led to excessive market concentration, this order reaffirms that the United States retains the authority to challenge transactions whose previous consummation was in violation of the Sherman Antitrust Act (26 Stat. 209, 15 U.S.C. 1 *et seq.*) (Sherman Act), the Clayton Antitrust Act (Public Law 63-212, 38 Stat. 730, 15 U.S.C. 12 *et seq.*) (Clayton Act), or other laws. *See* 15 U.S.C. 18; *Standard Oil Co. v. United States*, 221 U.S. 1 (1911).

This order reasserts as United States policy that the answer to the rising power of foreign monopolies and cartels is not the tolerance of domestic monopolization, but rather the promotion of competition and innovation by firms small and large, at home and worldwide.

It is also the policy of my Administration to support aggressive legislative reforms that would lower prescription drug prices, including by allowing Medicare to negotiate drug prices, by imposing inflation caps, and through other related reforms. It is further the policy of my Administration to support the enactment of a public health insurance option.

My Administration further reaffirms the policy stated in Executive Order 13725 of April 15, 2016 (Steps to Increase Competition and Better Inform Consumers and Workers to Support Continued Growth of the American

Economy), and the Federal Government's commitment to the principles that led to the passage of the Sherman Act, the Clayton Act, the Packers and Stockyards Act, 1921 (Public Law 67-51, 42 Stat. 159, 7 U.S.C. 181 *et seq.*) (Packers and Stockyards Act), the Celler-Kefauver Antimerger Act (Public Law 81-899, 64 Stat. 1125), the Bank Merger Act (Public Law 86-463, 74 Stat. 129, 12 U.S.C. 1828), and the Telecommunications Act of 1996 (Public Law 104-104, 110 Stat. 56), among others.

Sec. 2. The Statutory Basis of a Whole-of-Government Competition Policy.

(a) The antitrust laws, including the Sherman Act, the Clayton Act, and the Federal Trade Commission Act (Public Law 63-203, 38 Stat. 717, 15 U.S.C. 41 *et seq.*), are a first line of defense against the monopolization of the American economy.

(b) The antitrust laws reflect an underlying policy favoring competition that transcends those particular enactments. As the Supreme Court has stated, for instance, the Sherman Act "rests on the premise that the unrestrained interaction of competitive forces will yield the best allocation of our economic resources, the lowest prices, the highest quality and the greatest material progress, while at the same time providing an environment conducive to the preservation of our democratic political and social institutions." *Northern Pac. Ry. Co. v. United States*, 356 U.S. 1, 4 (1958).

(c) Consistent with these broader policies, and in addition to the traditional antitrust laws, the Congress has also enacted industry-specific fair competition and anti-monopolization laws that often provide additional protections. Such enactments include the Packers and Stockyards Act, the Federal Alcohol Administration Act (Public Law 74-401, 49 Stat. 977, 27 U.S.C. 201 *et seq.*), the Bank Merger Act, the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417, 98 Stat. 1585), the Shipping Act of 1984 (Public Law 98-237, 98 Stat. 67, 46 U.S.C. 40101 *et seq.*) (Shipping Act), the ICC Termination Act of 1995 (Public Law 104-88, 109 Stat. 803), the Telecommunications Act of 1996, the Fairness to Contact Lens Consumers Act (Public Law 108-164, 117 Stat. 2024, 15 U.S.C. 7601 *et seq.*), and the Dodd-Frank Wall Street Reform and Consumer Protection Act (Public Law 111-203, 124 Stat. 1376) (Dodd-Frank Act).

(d) These statutes independently charge a number of executive departments and agencies (agencies) to protect conditions of fair competition in one or more ways, including by:

(i) policing unfair, deceptive, and abusive business practices;

(ii) resisting consolidation and promoting competition within industries through the independent oversight of mergers, acquisitions, and joint ventures;

(iii) promulgating rules that promote competition, including the market entry of new competitors; and

(iv) promoting market transparency through compelled disclosure of information.

(e) The agencies that administer such or similar authorities include the Department of the Treasury, the Department of Agriculture, the Department of Health and Human Services, the Department of Transportation, the Federal Reserve System, the Federal Trade Commission (FTC), the Securities and Exchange Commission, the Federal Deposit Insurance Corporation, the Federal Communications Commission, the Federal Maritime Commission, the Commodity Futures Trading Commission, the Federal Energy Regulatory Commission, the Consumer Financial Protection Bureau, and the Surface Transportation Board.

(f) Agencies can influence the conditions of competition through their exercise of regulatory authority or through the procurement process. *See* 41 U.S.C. 1705.

(g) This order recognizes that a whole-of-government approach is necessary to address overconcentration, monopolization, and unfair competition in the American economy. Such an approach is supported by existing statutory mandates. Agencies can and should further the polices set forth in section 1 of this order by, among other things, adopting pro-competitive regulations and approaches to procurement and spending, and by rescinding regulations that create unnecessary barriers to entry that stifle competition.

Sec. 3. Agency Cooperation in Oversight, Investigation, and Remedies.

(a) The Congress frequently has created overlapping agency jurisdiction in the policing of anticompetitive conduct and the oversight of mergers. It is the policy of my Administration that, when agencies have overlapping jurisdiction, they should endeavor to cooperate fully in the exercise of their oversight authority, to benefit from the respective expertise of the agencies and to improve Government efficiency.

(b) Where there is overlapping jurisdiction over particular cases, conduct, transactions, or industries, agencies are encouraged to coordinate their efforts, as appropriate and consistent with applicable law, with respect to:

(i) the investigation of conduct potentially harmful to competition;

(ii) the oversight of proposed mergers, acquisitions, and joint ventures; and

(iii) the design, execution, and oversight of remedies.

(c) The means of cooperation in cases of overlapping jurisdiction should include, as appropriate and consistent with applicable law:

(i) sharing relevant information and industry data;

(ii) in the case of major transactions, soliciting and giving significant consideration to the views of the Attorney General or the Chair of the FTC, as applicable; and

(iii) cooperating with any concurrent Department of Justice or FTC oversight activities under the Sherman Act or Clayton Act.

(d) Nothing in subsections (a) through (c) of this section shall be construed to suggest that the statutory standard applied by an agency, or its independent assessment under that standard, should be displaced or substituted by the judgment of the Attorney General or the Chair of the FTC. When their views are solicited, the Attorney General and the Chair of the FTC are encouraged to provide a response to the agency in time for the agency to consider it in advance of any statutory deadline for agency action.

Sec. 4. The White House Competition Council.

(a) There is established a White House Competition Council (Council) within the Executive Office of the President.

(b) The Council shall coordinate, promote, and advance Federal Government efforts to address overconcentration, monopolization, and unfair competition in or directly affecting the American economy, including efforts to:

(i) implement the administrative actions identified in this order;

(ii) develop procedures and best practices for agency cooperation and coordination on matters of overlapping jurisdiction, as described in section 3 of this order;

(iii) identify and advance any additional administrative actions necessary to further the policies set forth in section 1 of this order; and

(iv) identify any potential legislative changes necessary to further the policies set forth in section 1 of this order.

(c) The Council shall work across agencies to provide a coordinated response to overconcentration, monopolization, and unfair competition in or directly affecting the American economy. The Council shall also work with

each agency to ensure that agency operations are conducted in a manner that promotes fair competition, as appropriate and consistent with applicable law.

(d) The Council shall not discuss any current or anticipated enforcement actions.

(e) The Council shall be led by the Assistant to the President for Economic Policy and Director of the National Economic Council, who shall serve as Chair of the Council.

(f) In addition to the Chair, the Council shall consist of the following members:

(i) the Secretary of the Treasury;

(ii) the Secretary of Defense;

(iii) the Attorney General;

(iv) the Secretary of Agriculture;

(v) the Secretary of Commerce;

(vi) the Secretary of Labor;

(vii) the Secretary of Health and Human Services;

(viii) the Secretary of Transportation;

(ix) the Administrator of the Office of Information and Regulatory Affairs; and

(x) the heads of such other agencies and offices as the Chair may from time to time invite to participate.

(g) The Chair shall invite the participation of the Chair of the FTC, the Chair of the Federal Communications Commission, the Chair of the Federal Maritime Commission, the Director of the Consumer Financial Protection Bureau, and the Chair of the Surface Transportation Board, to the extent consistent with their respective statutory authorities and obligations.

(h) Members of the Council shall designate, not later than 30 days after the date of this order, a senior official within their respective agency or office who shall coordinate with the Council and who shall be responsible for overseeing the agency's or office's efforts to address overconcentration, monopolization, and unfair competition. The Chair may coordinate subgroups consisting exclusively of Council members or their designees, as appropriate.

(i) The Council shall meet on a semi-annual basis unless the Chair determines that a meeting is unnecessary.

(j) Each agency shall bear its own expenses for participating in the Council.

Sec. 5. Further Agency Responsibilities.

(a) The heads of all agencies shall consider using their authorities to further the policies set forth in section 1 of this order, with particular attention to:

(i) the influence of any of their respective regulations, particularly any licensing regulations, on concentration and competition in the industries under their jurisdiction; and

(ii) the potential for their procurement or other spending to improve the competitiveness of small businesses and businesses with fair labor practices.

(b) The Attorney General, the Chair of the FTC, and the heads of other agencies with authority to enforce the Clayton Act are encouraged to enforce the antitrust laws fairly and vigorously.

(c) To address the consolidation of industry in many markets across the economy, as described in section 1 of this order, the Attorney General and the Chair of the FTC are encouraged to review the horizontal and vertical merger guidelines and consider whether to revise those guidelines.

(d) To avoid the potential for anticompetitive extension of market power beyond the scope of granted patents, and to protect standard-setting processes from abuse, the Attorney General and the Secretary of Commerce are encouraged to consider whether to revise their position on the intersection of the intellectual property and antitrust laws, including by considering whether to revise the Policy Statement on Remedies for Standards-Essential Patents Subject to Voluntary F/RAND Commitments issued jointly by the Department of Justice, the United States Patent and Trademark Office, and the National Institute of Standards and Technology on December 19, 2019.

(e) To ensure Americans have choices among financial institutions and to guard against excessive market power, the Attorney General, in consultation with the Chairman of the Board of Governors of the Federal Reserve System, the Chairperson of the Board of Directors of the Federal Deposit Insurance Corporation, and the Comptroller of the Currency, is encouraged to review current practices and adopt a plan, not later than 180 days after the date of this order, for the revitalization of merger oversight under the Bank Merger Act and the Bank Holding Company Act of 1956 (Public Law 84-511, 70 Stat. 133, 12 U.S.C. 1841 *et seq.*) that is in accordance with the factors enumerated in 12 U.S.C. 1828(c) and 1842(c).

(f) To better protect workers from wage collusion, the Attorney General

and the Chair of the FTC are encouraged to consider whether to revise the Antitrust Guidance for Human Resource Professionals of October 2016.

(g) To address agreements that may unduly limit workers' ability to change jobs, the Chair of the FTC is encouraged to consider working with the rest of the Commission to exercise the FTC's statutory rulemaking authority under the Federal Trade Commission Act to curtail the unfair use of non-compete clauses and other clauses or agreements that may unfairly limit worker mobility.

(h) To address persistent and recurrent practices that inhibit competition, the Chair of the FTC, in the Chair's discretion, is also encouraged to consider working with the rest of the Commission to exercise the FTC's statutory rulemaking authority, as appropriate and consistent with applicable law, in areas such as:

(i) unfair data collection and surveillance practices that may damage competition, consumer autonomy, and consumer privacy;

(ii) unfair anticompetitive restrictions on third-party repair or self-repair of items, such as the restrictions imposed by powerful manufacturers that prevent farmers from repairing their own equipment;

(iii) unfair anticompetitive conduct or agreements in the prescription drug industries, such as agreements to delay the market entry of generic drugs or biosimilars;

(iv) unfair competition in major Internet marketplaces;

(v) unfair occupational licensing restrictions;

(vi) unfair tying practices or exclusionary practices in the brokerage or listing of real estate; and

(vii) any other unfair industry-specific practices that substantially inhibit competition.

(i) The Secretary of Agriculture shall:

(i) to address the unfair treatment of farmers and improve conditions of competition in the markets for their products, consider initiating a rulemaking or rulemakings under the Packers and Stockyards Act to strengthen the Department of Agriculture's regulations concerning unfair, unjustly discriminatory, or deceptive practices and undue or unreasonable preferences, advantages, prejudices, or disadvantages, with the purpose of furthering the vigorous implementation of the law established by the Congress in 1921 and fortified by amendments. In such rulemaking or rulemakings, the Secretary of Agriculture shall consider, among other things:

(A) providing clear rules that identify recurrent practices in the

livestock, meat, and poultry industries that are unfair, unjustly discriminatory, or deceptive and therefore violate the Packers and Stockyards Act;

(B) reinforcing the long-standing Department of Agriculture interpretation that it is unnecessary under the Packers and Stockyards Act to demonstrate industry-wide harm to establish a violation of the Act and that the "unfair, unjustly discriminatory, or deceptive" treatment of one farmer, the giving to one farmer of an "undue or unreasonable preference or advantage," or the subjection of one farmer to an "undue or unreasonable prejudice or disadvantage in any respect" violates the Act;

(C) prohibiting unfair practices related to grower ranking systems — systems in which the poultry companies, contractors, or dealers exercise extraordinary control over numerous inputs that determine the amount farmers are paid and require farmers to assume the risk of factors outside their control, leaving them more economically vulnerable;

(D) updating the appropriate definitions or set of criteria, or application thereof, for undue or unreasonable preferences, advantages, prejudices, or disadvantages under the Packers and Stockyards Act; and

(E) adopting, to the greatest extent possible and as appropriate and consistent with applicable law, appropriate anti-retaliation protections, so that farmers may assert their rights without fear of retribution;

(ii) to ensure consumers have accurate, transparent labels that enable them to choose products made in the United States, consider initiating a rulemaking to define the conditions under which the labeling of meat products can bear voluntary statements indicating that the product is of United States origin, such as "Product of USA";

(iii) to ensure that farmers have greater opportunities to access markets and receive a fair return for their products, not later than 180 days after the date of this order, submit a report to the Chair of the White House Competition Council, with a plan to promote competition in the agricultural industries and to support value-added agriculture and alternative food distribution systems through such means as:

(A) the creation or expansion of useful information for farmers, such as model contracts, to lower transaction costs and help farmers negotiate fair deals;

(B) measures to encourage improvements in transparency and standards so that consumers may choose to purchase products that support fair treatment of farmers and agricultural workers and sustainable

agricultural practices;

(C) measures to enhance price discovery, increase transparency, and improve the functioning of the cattle and other livestock markets;

(D) enhanced tools, including any new legislative authorities needed, to protect whistleblowers, monitor agricultural markets, and enforce relevant laws;

(E) any investments or other support that could bolster competition within highly concentrated agricultural markets; and

(F) any other means that the Secretary of Agriculture deems appropriate;

(iv) to improve farmers' and smaller food processors' access to retail markets, not later than 300 days after the date of this order, in consultation with the Chair of the FTC, submit a report to the Chair of the White House Competition Council, on the effect of retail concentration and retailers' practices on the conditions of competition in the food industries, including any practices that may violate the Federal Trade Commission Act, the Robinson-Patman Act (Public Law 74-692, 49 Stat. 1526, 15 U.S.C. 13 *et seq.*), or other relevant laws, and on grants, loans, and other support that may enhance access to retail markets by local and regional food enterprises; and

(v) to help ensure that the intellectual property system, while incentivizing innovation, does not also unnecessarily reduce competition in seed and other input markets beyond that reasonably contemplated by the Patent Act (*see* 35 U.S.C. 100 *et seq.* and 7 U.S.C. 2321 *et seq.*), in consultation with the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, submit a report to the Chair of the White House Competition Council, enumerating and describing any relevant concerns of the Department of Agriculture and strategies for addressing those concerns across intellectual property, antitrust, and other relevant laws.

(j) To protect the vibrancy of the American markets for beer, wine, and spirits, and to improve market access for smaller, independent, and new operations, the Secretary of the Treasury, in consultation with the Attorney General and the Chair of the FTC, not later than 120 days after the date of this order, shall submit a report to the Chair of the White House Competition Council, assessing the current market structure and conditions of competition, including an assessment of any threats to competition and barriers to new entrants, including:

(i) any unlawful trade practices in the beer, wine, and spirits markets,

such as certain exclusionary, discriminatory, or anticompetitive distribution practices, that hinder smaller and independent businesses or new entrants from distributing their products;

(ii) patterns of consolidation in production, distribution, or retail beer, wine, and spirits markets; and

(iii) any unnecessary trade practice regulations of matters such as bottle sizes, permitting, or labeling that may unnecessarily inhibit competition by increasing costs without serving any public health, informational, or tax purpose.

(k) To follow up on the foregoing assessment, the Secretary of the Treasury, through the Administrator of the Alcohol and Tobacco Tax and Trade Bureau, shall, not later than 240 days after the date of this order, consider:

(i) initiating a rulemaking to update the Alcohol and Tobacco Tax and Trade Bureau's trade practice regulations;

(ii) rescinding or revising any regulations of the beer, wine, and spirits industries that may unnecessarily inhibit competition; and

(iii) reducing any barriers that impede market access for smaller and independent brewers, winemakers, and distilleries.

(l) To promote competition, lower prices, and a vibrant and innovative telecommunications ecosystem, the Chair of the Federal Communications Commission is encouraged to work with the rest of the Commission, as appropriate and consistent with applicable law, to consider:

(i) adopting through appropriate rulemaking "Net Neutrality" rules similar to those previously adopted under title II of the Communications Act of 1934 (Public Law 73-416, 48 Stat. 1064, 47 U.S.C. 151 *et seq.*), as amended by the Telecommunications Act of 1996, in "Protecting and Promoting the Open Internet," 80 Fed. Reg. 19738 (Apr. 13, 2015);

(ii) conducting future spectrum auctions under rules that are designed to help avoid excessive concentration of spectrum license holdings in the United States, so as to prevent spectrum stockpiling, warehousing of spectrum by licensees, or the creation of barriers to entry, and to improve the conditions of competition in industries that depend upon radio spectrum, including mobile communications and radio-based broadband services;

(iii) providing support for the continued development and adoption of 5G Open Radio Access Network (O-RAN) protocols and software, continuing to attend meetings of voluntary and consensus-based standards development organizations, so as to promote or encourage a fair and representative

standard-setting process, and undertaking any other measures that might promote increased openness, innovation, and competition in the markets for 5G equipment;

(iv) prohibiting unjust or unreasonable early termination fees for end-user communications contracts, enabling consumers to more easily switch providers;

(v) initiating a rulemaking that requires broadband service providers to display a broadband consumer label, such as that as described in the Public Notice of the Commission issued on April 4, 2016 (DA 16–357), so as to give consumers clear, concise, and accurate information regarding provider prices and fees, performance, and network practices;

(vi) initiating a rulemaking to require broadband service providers to regularly report broadband price and subscription rates to the Federal Communications Commission for the purpose of disseminating that information to the public in a useful manner, to improve price transparency and market functioning; and

(vii) initiating a rulemaking to prevent landlords and cable and Internet service providers from inhibiting tenants' choices among providers.

(m) The Secretary of Transportation shall:

(i) to better protect consumers and improve competition, and as appropriate and consistent with applicable law:

(A) not later than 30 days after the date of this order, appoint or reappoint members of the Advisory Committee for Aviation Consumer Protection to ensure fair representation of consumers, State and local interests, airlines, and airports with respect to the evaluation of aviation consumer protection programs and convene a meeting of the Committee as soon as practicable;

(B) promote enhanced transparency and consumer safeguards, as appropriate and consistent with applicable law, including through potential rulemaking, enforcement actions, or guidance documents, with the aims of:

(1) enhancing consumer access to airline flight information so that consumers can more easily find a broader set of available flights, including by new or lesser known airlines; and

(2) ensuring that consumers are not exposed or subject to advertising, marketing, pricing, and charging of ancillary fees that may constitute an unfair or deceptive practice or an unfair method of competition;

(C) not later than 45 days after the date of this order, submit a report

to the Chair of the White House Competition Council, on the progress of the Department of Transportation's investigatory and enforcement activities to address the failure of airlines to provide timely refunds for flights cancelled as a result of the COVID-19 pandemic;

(D) not later than 45 days after the date of this order, publish for notice and comment a proposed rule requiring airlines to refund baggage fees when a passenger's luggage is substantially delayed and other ancillary fees when passengers pay for a service that is not provided;

(E) not later than 60 days after the date of this order, start development of proposed amendments to the Department of Transportation's definitions of "unfair" and "deceptive" in 49 U.S.C. 41712; and

(F) not later than 90 days after the date of this order, consider initiating a rulemaking to ensure that consumers have ancillary fee information, including "baggage fees," "change fees," and "cancellation fees," at the time of ticket purchase;

(ii) to provide consumers with more flight options at better prices and with improved service, and to extend opportunities for competition and market entry as the industry evolves:

(A) not later than 30 days after the date of this order, convene a working group within the Department of Transportation to evaluate the effectiveness of existing commercial aviation programs, consumer protections, and rules of the Federal Aviation Administration;

(B) consult with the Attorney General regarding means of enhancing effective coordination between the Department of Justice and the Department of Transportation to ensure competition in air transportation and the ability of new entrants to gain access; and

(C) consider measures to support airport development and increased capacity and improve airport congestion management, gate access, implementation of airport competition plans pursuant to 49 U.S.C. 47106(f), and "slot" administration;

(iii) given the emergence of new aerospace-based transportation technologies, such as low-altitude unmanned aircraft system deliveries, advanced air mobility, and high-altitude long endurance operations, that have great potential for American travelers and consumers, yet also the danger of early monopolization or new air traffic control problems, ensure that the Department of Transportation takes action with respect to these technologies to:

(A) facilitate innovation that fosters United States market leadership and market entry to promote competition and economic opportunity and to resist monopolization, while also ensuring safety, providing security and privacy, protecting the environment, and promoting equity; and

(B) provide vigilant oversight over market participants.

(n) To further competition in the rail industry and to provide accessible remedies for shippers, the Chair of the Surface Transportation Board (Chair) is encouraged to work with the rest of the Board to:

(i) consider commencing or continuing a rulemaking to strengthen regulations pertaining to reciprocal switching agreements pursuant to 49 U.S.C. 11102(c), if the Chair determines such rulemaking to be in the public interest or necessary to provide competitive rail service;

(ii) consider rulemakings pertaining to any other relevant matter of competitive access, including bottleneck rates, interchange commitments, or other matters, consistent with the policies set forth in section 1 of this order;

(iii) to ensure that passenger rail service is not subject to unwarranted delays and interruptions in service due to host railroads' failure to comply with the required preference for passenger rail, vigorously enforce new on-time performance requirements adopted pursuant to the Passenger Rail Investment and Improvement Act of 2008 (Public Law 110-423, 122 Stat. 4907) that will take effect on July 1, 2021, and further the work of the passenger rail working group formed to ensure that the Surface Transportation Board will fully meet its obligations; and

(iv) in the process of determining whether a merger, acquisition, or other transaction involving rail carriers is consistent with the public interest under 49 U.S.C. 11323-25, consider a carrier's fulfillment of its responsibilities under 49 U.S.C. 24308 (relating to Amtrak's statutory rights).

(o) The Chair of the Federal Maritime Commission is encouraged to work with the rest of the Commission to:

(i) vigorously enforce the prohibition of unjust and unreasonable practices in the context of detention and demurrage pursuant to the Shipping Act, as clarified in "Interpretive Rule on Demurrage and Detention Under the Shipping Act," 85 Fed. Reg. 29638 (May 18, 2020);

(ii) request from the National Shipper Advisory Committee recommendations for improving detention and demurrage practices and enforcement of related Shipping Act prohibitions; and

(iii) consider further rulemaking to improve detention and demurrage practices and enforcement of related Shipping Act prohibitions.

(p) The Secretary of Health and Human Services shall:

(i) to promote the wide availability of low-cost hearing aids, not later than 120 days after the date of this order, publish for notice and comment a proposed rule on over-the-counter hearing-aids, as called for by section 709 of the FDA Reauthorization Act of 2017 (Public Law 115-52, 131 Stat. 1005);

(ii) support existing price transparency initiatives for hospitals, other providers, and insurers along with any new price transparency initiatives or changes made necessary by the No Surprises Act (Public Law 116-260, 134 Stat. 2758) or any other statutes;

(iii) to ensure that Americans can choose health insurance plans that meet their needs and compare plan offerings, implement standardized options in the national Health Insurance Marketplace and any other appropriate mechanisms to improve competition and consumer choice;

(iv) not later than 45 days after the date of this order, submit a report to the Assistant to the President for Domestic Policy and Director of the Domestic Policy Council and to the Chair of the White House Competition Council, with a plan to continue the effort to combat excessive pricing of prescription drugs and enhance domestic pharmaceutical supply chains, to reduce the prices paid by the Federal Government for such drugs, and to address the recurrent problem of price gouging;

(v) to lower the prices of and improve access to prescription drugs and biologics, continue to promote generic drug and biosimilar competition, as contemplated by the Drug Competition Action Plan of 2017 and Biosimilar Action Plan of 2018 of the Food and Drug Administration (FDA), including by:

(A) continuing to clarify and improve the approval framework for generic drugs and biosimilars to make generic drug and biosimilar approval more transparent, efficient, and predictable, including improving and clarifying the standards for interchangeability of biological products;

(B) as authorized by the Advancing Education on Biosimilars Act of 2021 (Public Law 117-8, 135 Stat. 254, 42 U.S.C. 263-1), supporting biosimilar product adoption by providing effective educational materials and communications to improve understanding of biosimilar and interchangeable products among healthcare providers, patients, and caregivers;

(C) to facilitate the development and approval of biosimilar and interchangeable products, continuing to update the FDA's biologics regulations to clarify existing requirements and procedures related to the

review and submission of Biologics License Applications by advancing the "Biologics Regulation Modernization" rulemaking (RIN 0910-AI14); and

(D) with the Chair of the FTC, identifying and addressing any efforts to impede generic drug and biosimilar competition, including but not limited to false, misleading, or otherwise deceptive statements about generic drug and biosimilar products and their safety or effectiveness;

(vi) to help ensure that the patent system, while incentivizing innovation, does not also unjustifiably delay generic drug and biosimilar competition beyond that reasonably contemplated by applicable law, not later than 45 days after the date of this order, through the Commissioner of Food and Drugs, write a letter to the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office enumerating and describing any relevant concerns of the FDA;

(vii) to support the market entry of lower-cost generic drugs and biosimilars, continue the implementation of the law widely known as the CREATES Act of 2019 (Public Law 116-94, 133 Stat. 3130), by:

(A) promptly issuing Covered Product Authorizations (CPAs) to assist product developers with obtaining brand-drug samples; and

(B) issuing guidance to provide additional information for industry about CPAs; and

(viii) through the Administrator of the Centers for Medicare and Medicaid Services, prepare for Medicare and Medicaid coverage of interchangeable biological products, and for payment models to support increased utilization of generic drugs and biosimilars.

(q) To reduce the cost of covered products to the American consumer without imposing additional risk to public health and safety, the Commissioner of Food and Drugs shall work with States and Indian Tribes that propose to develop section 804 Importation Programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173, 117 Stat. 2066), and the FDA's implementing regulations.

(r) The Secretary of Commerce shall:

(i) acting through the Director of the National Institute of Standards and Technology (NIST), consider initiating a rulemaking to require agencies to report to NIST, on an annual basis, their contractors' utilization activities, as reported to the agencies under 35 U.S.C. 202(c)(5);

(ii) acting through the Director of NIST, consistent with the policies

set forth in section 1 of this order, consider not finalizing any provisions on march-in rights and product pricing in the proposed rule "Rights to Federally Funded Inventions and Licensing of Government Owned Inventions," 86 Fed. Reg. 35 (Jan. 4, 2021); and

(iii) not later than 1 year after the date of this order, in consultation with the Attorney General and the Chair of the Federal Trade Commission, conduct a study, including by conducting an open and transparent stakeholder consultation process, of the mobile application ecosystem, and submit a report to the Chair of the White House Competition Council, regarding findings and recommendations for improving competition, reducing barriers to entry, and maximizing user benefit with respect to the ecosystem.

(s) The Secretary of Defense shall:

(i) ensure that the Department of Defense's assessment of the economic forces and structures shaping the capacity of the national security innovation base pursuant to section 889(a) and (b) of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (Public Law 116-283, 134 Stat. 3388) is consistent with the policy set forth in section 1 of this order;

(ii) not later than 180 days after the date of this order, submit to the Chair of the White House Competition Council, a review of the state of competition within the defense industrial base, including areas where a lack of competition may be of concern and any recommendations for improving the solicitation process, consistent with the goal of the Competition in Contracting Act of 1984 (Public Law 98-369, 98 Stat. 1175); and

(iii) not later than 180 days after the date of this order, submit a report to the Chair of the White House Competition Council, on a plan for avoiding contract terms in procurement agreements that make it challenging or impossible for the Department of Defense or service members to repair their own equipment, particularly in the field.

(t) The Director of the Consumer Financial Protection Bureau, consistent with the pro-competition objectives stated in section 1021 of the Dodd-Frank Act, is encouraged to consider:

(i) commencing or continuing a rulemaking under section 1033 of the Dodd-Frank Act to facilitate the portability of consumer financial transaction data so consumers can more easily switch financial institutions and use new, innovative financial products; and

(ii) enforcing the prohibition on unfair, deceptive, or abusive acts or

practices in consumer financial products or services pursuant to section 1031 of the Dodd-Frank Act so as to ensure that actors engaged in unlawful activities do not distort the proper functioning of the competitive process or obtain an unfair advantage over competitors who follow the law.

(u) The Director of the Office of Management and Budget, through the Administrator of the Office of Information and Regulatory Affairs, shall incorporate into its recommendations for modernizing and improving regulatory review required by my Memorandum of January 20, 2021 (Modernizing Regulatory Review), the policies set forth in section 1 of this order, including consideration of whether the effects on competition and the potential for creation of barriers to entry should be included in regulatory impact analyses.

(v) The Secretary of the Treasury shall:

(i) direct the Office of Economic Policy, in consultation with the Attorney General, the Secretary of Labor, and the Chair of the FTC, to submit a report to the Chair of the White House Competition Council, not later than 180 days after the date of this order, on the effects of lack of competition on labor markets; and

(ii) submit a report to the Chair of the White House Competition Council, not later than 270 days after the date of this order, assessing the effects on competition of large technology firms' and other non-bank companies' entry into consumer finance markets.

Sec. 6. General Provisions.

(a) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(b) Where not already specified, independent agencies are encouraged to comply with the requirements of this order.

(c) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(d) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

JOSEPH R. BIDEN JR.

THE WHITE HOUSE,
July 9, 2021.

Importation Program under Section 804 of the FD&C Act

FDA has developed a pathway under section 804 (https://uscode.house.gov/view.xhtml?req=(title:21%20section:384%20edition:prelim)) 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.

Section 804 Importation Program (SIP) Proposals

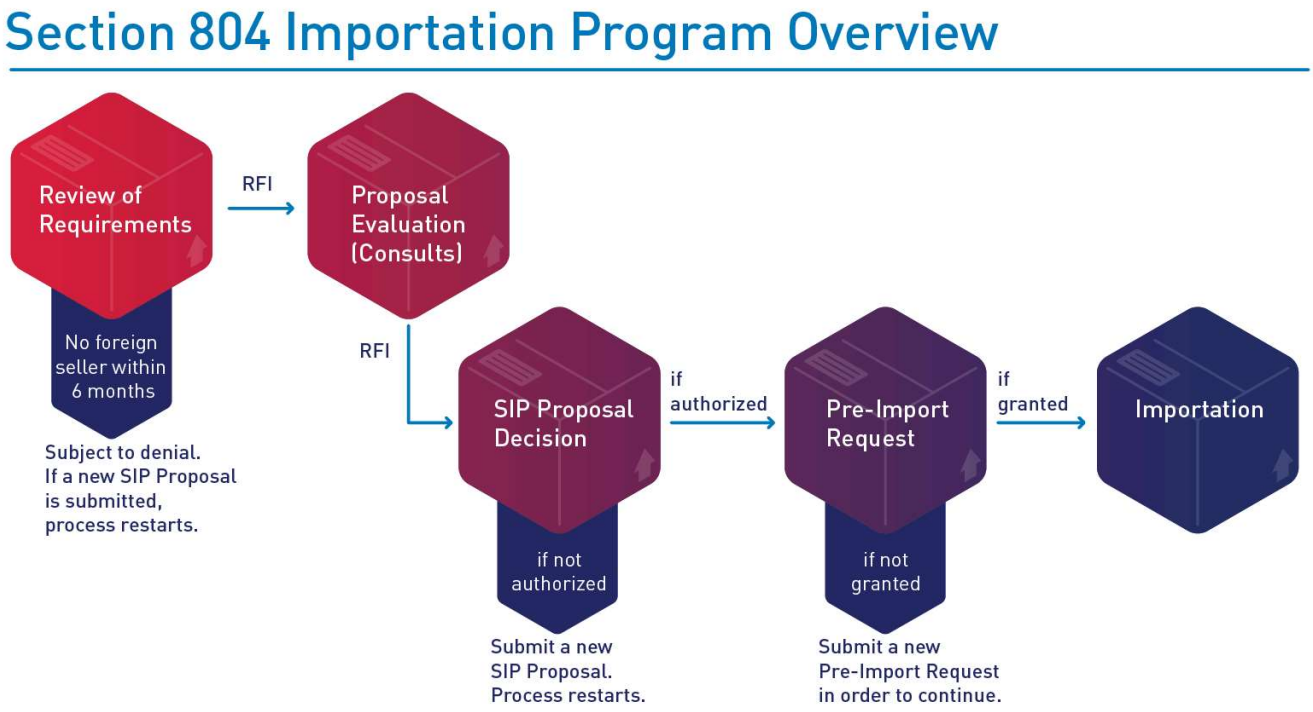
A SIP proposal needs to provide all the information required by the FD&C Act and FDA's regulations. HHS provided information about demonstrating cost savings for the American (/media/158564/download) consumer. A full list of requirements is provided in FDA's regulations (https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-251).

In particular, FDA regulations (https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-251#251.3) at 21 C.F.R. part 251 (https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-251) describe the requirements necessary for a sponsor of a SIP to demonstrate that their importation program will result in a significant reduction in the cost of eligible prescription drugs to the American consumer without posing any additional risk to the public's health and safety. FDA has developed a resource, *Tips for SIPs*, (/about-fda/reports/tips-sips) which provides information to assist sponsors as they work to develop and implement a SIP proposal. A small entity compliance guide in question and answer (/regulatory-information/search-fda-guidance-documents/importation-prescription-drugs-final-rule-questions-and-answers-small-entity-compliance-guide) format is also available to help in proposal development.

Visit responses to comments in the rulemaking (https://www.federalregister.gov/documents/2020/10/01/2020-21522/importation-of-prescription-drugs) for more information.

FDA Review Process

FDA's evaluation of SIP proposals may include requests for additional information necessary to ensure the proposal meets the requirements in the statute and final rule. An example of FDA's SIP proposal evaluation and potential implementation process is depicted below:



Policies and Actions

- FDA published Importation of Prescription Drugs Final Rule Questions and Answers; Small Entity Compliance Guide (/regulatory-information/search-fda-guidance-documents/importation-prescription-drugs-final-rule-questions-and-answers-small-entity-compliance-guide) to help small entities better understand the final rule (May 2022)
- FDA met with representatives from several states, the National Academy for State Health Policy and HHS to discuss the development of SIP proposals (March 2022). Visit HHS presentation for more information: Projecting Cost Savings for the American Consumer (/media/158564/download?attachment) (PDF - 195 KB)
- FDA issued a final rule, Importation of Prescription Drugs (https://www.federalregister.gov/documents/2020/10/01/2020-21522/importation-of-prescription-drugs), which describes the requirements for SIPs and provides FDA responses to comments about the proposed rule (October 2020)

- Executive Order 14036 on Promoting Competition in the American Economy (https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/) (July 2021)

FDA Authorization

- FDA Authorizes Florida's Drug Importation Program (/news-events/press-announcements/fda-authorizes-floridas-drug-importation-program)
- FDA authorization letter to Florida's Agency for Health Care Administration (/media/175237/download?attachment)

Contact Us

In accordance with Executive Order 14036 (https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/), FDA engages directly with states or Indian tribes who want to propose a program or would like more information about SIP proposals.

If you represent a state or Indian tribe, ask questions or submit a SIP proposal by emailing the FDA at: SIPDrugImportsandRFP@fda.hhs.gov (mailto:SIPDrugImportsandRFP@fda.hhs.gov).

States and Indian tribes interested in working with the agency on a SIP proposal can also contact FDA's Intergovernmental Affairs Staff at IGA@fda.hhs.gov (mailto:IGA@fda.hhs.gov) to begin the conversation.

January 5, 2024

Jason Weida, Secretary
Florida Agency for Health Care Administration
2727 Mahan Drive, Mailstop 1
Tallahassee, FL 32308

Re: Letter of Authorization for Florida's Section 804 Importation Program

Dear Secretary Weida:

FDA is committed to continuing to work with states, such as Florida, and Tribes that propose to develop Section 804 Importation Programs (SIP) in accordance with section 804 of the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act) and FDA's implementing regulations. Numerous subject matter experts at FDA and other components of the Department of Health and Human Services (HHS) have carefully and thoroughly reviewed your revised SIP proposal. Based on FDA's review of your most recent SIP proposal that was submitted on November 16, 2023,[1] and clarifying communications,[2] FDA has determined that this SIP proposal meets the requirements of section 804 and 21 CFR part 251, and therefore Florida has demonstrated that it meets the statutory obligation to ensure that importation under section 804 will significantly reduce the cost of covered products to the American consumer without posing additional risk to the public's health and safety. FDA is therefore authorizing, for a period of 2 years, Florida's Agency for Health Care Administration's SIP with the labeling corrections specified in the attachment to this letter.[3]

The Importer may now submit a Pre-Import Request to FDA. An eligible prescription drug may not be imported or offered for import under part 251 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). Importation may not proceed until:

[1] The SIP proposal was initially submitted by the Florida Agency for Health Care Administration to the FDA on November 23, 2020, and subsequently revised on: April 19, 2021, September 15, 2021, November 15, 2021, April 21, 2023, and October 20, 2023.
[2] The Florida Agency for Health Care Administration sent communications via email on October 27, 2023 and November 16, 2023.
[3] This time period begins when the Importer, or its authorized customs broker, files an electronic import entry for consumption for its first shipment of eligible prescription drugs under the SIP (21 CFR 251.6(b)). Authorization for the SIP will be terminated if the Importer, or its authorized customs broker, does not file an electronic import entry for consumption for a shipment of eligible prescription drugs under the SIP within 1 year of the date of this letter (21 CFR 251.6(c)).

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

1. The Importer submits a complete Pre-Import Request to FDA, by email to SIPDrugImportsandRFP@fda.hhs.gov, at least 30 calendar days before the scheduled date of arrival or entry for consumption of a shipment containing an eligible prescription drug covered by the SIP, whichever is earlier. Under 21 CFR 251.17(a) and 21 CFR 1.74(b), the entry for consumption, as defined in 19 CFR 141.0a(f), must be electronically filed in the Automated Commercial Environment (ACE) system for each eligible prescription drug imported or offered for import into the United States. These entries must be filed as formal entries.

   Entry and arrival of a shipment containing an eligible prescription drug is limited under 21 CFR 251.17(b) to the U.S. Customs and Border Protection (CBP) port of entry authorized by FDA (currently the only authorized port is 3801—Detroit)[4]. Once the shipment arrives or is entered at the port of entry, it will be examined by a government agency. Be advised that this process may take longer than 30 calendar days.

   FDA must grant your Pre-Import Request before products may be imported or offered for import. The timeframe necessary for FDA to grant your Pre-Import Request will vary depending on the circumstances of the request—such grant may take more than 30 calendar days. Therefore, it is advisable to submit the Pre-Import Request sooner than the required 30 calendar days.

2. The manufacturer or the Importer conducts testing of the eligible prescription drugs for authenticity, degradation, and to ensure that the eligible prescription drugs are in compliance with established specifications and standards (i.e., Statutory Testing) in accordance with section 804(e)(1) of the FD&C Act. Unless the manufacturer has notified the Importer that it intends to conduct the required testing as provided in 21 CFR 251.16(e), the Pre-Import Request must contain, for each drug covered by the Pre-Import Request, a Statutory Testing plan that includes: (A) a description of how the samples will be selected from a shipment for the Statutory Testing; (B) the name and location of the qualifying laboratory in the United States that will conduct the Statutory Testing; and (C) a description of the testing method(s) that will be used to conduct the Statutory Testing (21 CFR 251.5(c)(4)(xi)).

3. You make the labeling corrections specified in the attachment to this letter. To facilitate the importation process and ensure that the requirements of the FD&C Act and 21 CFR part 251 are met, you should submit the corrected labeling by email to SIPDrugImportsandRFP@fda.hhs.gov for FDA's review prior to the submission of a Pre-Import Request.

In accordance with 21 CFR 251.17(g), after an eligible prescription drug has been shown by testing and relabeling to meet the requirements of section 804 and 21 CFR part 251, the Importer or the manufacturer must provide to FDA the written certification described in section 804(d)(1)(K).

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[4] *See* U.S. Customs and Border Protection Cargo Systems Messaging Service bulletin, Nov. 9, 2020, at https://content.govdelivery.com/accounts/USDHSCBP/bulletins/2aabc2f. *See also* FDA Supplemental Guide for the Automated Commercial Environment/International Trade Data System (ACE/ITDS), https://www.cbp.gov/document/guidance/fda-supplemental-guide.

FDA also notes the following, this is not an exhaustive list of all relevant ongoing requirements, and you should consult 21 CFR part 251 for more information:

A Foreign Seller must review and update its registration information in accordance with 21 CFR 251.10.

A SIP Sponsor must submit a report to FDA each quarter in electronic format by email to SIPDrugImportsandRFP@fda.hhs.gov containing the information set forth in FDA's regulations, beginning after the SIP Sponsor files an electronic import entry for consumption for its first shipment of drugs under the SIP (21 CFR 251.19).

A SIP Sponsor may request that FDA extend the authorization period of an authorized SIP (21 CFR 251.8(f)). To be eligible for an extension, a SIP must be up to date on all of the information and records-related requirements of section 804 of the FD&C Act and FDA's regulations. FDA may extend the authorization period for up to 2 years at a time. Such a request must be submitted at least 90 calendar days before the SIP's authorization period will expire.

Additionally, a SIP Sponsor may propose to modify an authorized SIP (21 CFR 251.8). In reviewing a proposal to modify a SIP, among other things, FDA may consider information learned subsequent to authorization of the SIP (21 CFR 251.8(b)). A SIP Sponsor must not make or permit any changes to a SIP without FDA's authorization (21 CFR 251.8(e)). If FDA authorizes changes to a SIP, the Importer must submit a new Pre-Import Request in accordance with 21 CFR 251.5 (21 CFR 251.8(d)).

FDA may suspend or revoke a SIP, in whole or in part, including with respect to one or more drugs in the SIP, at any time, under any circumstances set forth in the FD&C Act and FDA's regulations, including circumstances in FDA's discretion (21 CFR 251.7, and 251.18). An eligible prescription drug cannot be shipped into the United States under section 804 and FDA's regulations, and is subject to refusal of admission into the United States, if FDA has suspended the SIP or revoked its authorization.

We recommend that you stay up-to-date on relevant FDA requirements, including those that are referenced in 21 CFR part 251, and any associated FDA guidance on such requirements.

An article that is imported or offered for import into the United States in violation of section 804 of the FD&C Act or 21 CFR part 251 is subject to refusal under section 801 of the FD&C Act (21 CFR 251.21(a)). The importation of a prescription drug in violation of section 804 of the FD&C Act; the falsification of any record required to be maintained or provided to FDA under section 804; or any other violation of 21 CFR part 251 is a prohibited act under section 301(aa) of the FD&C Act (21 CFR 251.21(b)).

We encourage you to bring any questions you may have to FDA's Office of Drug Security, Integrity and Response, Division of Global Drug Distribution and Policy via the mailbox at: SIPDrugImportsandRFP@fda.hhs.gov.

Sincerely,

Sandi L. Verbois -S

Digitally signed by Sandi L. Verbois -S
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S. Leigh Verbois, PhD
Director
Office of Drug Security, Integrity & Response
Office of Compliance
Center for Drug Evaluation and Research

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

NABP
National Association of Boards of Pharmacy

Report of the Task Force on

STATE OVERSIGHT OF DRUG IMPORTATION

Members Present

Andrew Funk (IA), *chair*; Paul Brand (MT); Robert Carpenter (VT); John Colaizzi, Jr (NJ); Brenda McCrady (AR); Shanea McKinney (TN); Rich Palombo (NJ); Jeanne Waggener (TX); Stuart Williams (MN); and Linda Witzal (NJ).

Others Present

Jeffrey J. Mesaros, *Executive Committee liaison;* Cheranne McCracken, New Mexico Board of Pharmacy; Lauren Reveley, Colorado Drug Importation Program; Kelly Swartzendruber, Colorado Drug Importation Program; Caroline D. Juran, NABP president; *Guests;* Lemrey "Al" Carter, Josh Bolin, William "Bill" Cover, Melissa Madigan, Eileen Lewalski, Gregg Jones, Maureen Schanck, Cameron Orr, and Andrea Busch, *NABP staff*.

Introduction

The task force met on September 20-21, 2021, at NABP Headquarters in Mount Prospect, IL. This task force was established pursuant to Caroline D. Juran's 2021-2022 presidential initiative, which is to increase efforts to support the boards of pharmacy and to educate and protect the public about state drug importation plans.

Review of the Task Force Charge

Task force members reviewed their charge and accepted it as follows:

1. Evaluate the current regulatory environment related to prescription drug importation and the challenges that states will face with regulating importation.
2. Review NABP programs to determine how they may support states that implement drug importation programs.
3. Develop educational tools to assist states in the oversight of drug importation.

Background and Discussion

The meeting began with guest presentations provided by representatives from Colorado's Canadian Drug Importation Program and the New Mexico Board of Pharmacy, who detailed their states' Section 804 Importation Programs (SIPs). As task force members asked numerous questions during their presentations, it became apparent that these particular state SIPs failed to address many of their concerns. It was noted that some state legislatures are passing laws that provide for the development of a SIP without board of pharmacy input or consultation; however, members' concerns could be alleviated if boards are involved with a SIP's preliminary planning. A summary of the questions and/or concerns that arose during the meeting, accompanied by the member discussion, is provided below.

Supply Chain Issues

The task force's main concern was basic supply chain issues as it was duly noted that the safest drug supply chain will always be the shortest route from the manufacturer to the patient. Members recognized that the presented SIPs failed to consider the intricacies in supply chain logistics but rather seemed focused on acquiring foreign-sourced drugs, and not what happens as medications continue through the supply chain and ultimately to patients. Members voiced concern that the supply chain is already a global issue as foreign countries, such as China and India, provide most of the active pharmaceutical ingredients with questionable oversight. This concern, in conjunction with other state and federal authority oversight, increases the complexity of the boards' responsibility to oversee public health and patient safety. It was noted that 10 states are actively considering legislation to implement a SIP due to the fact that these plans have bipartisan support and will likely be considered in many more states as an opportunity to save patients' money. The task force agreed that boards of pharmacy should be consulted during SIP development to provide insight into supply chain security to ensure public protection, and NABP should assist boards of pharmacy in monitoring bills for legislation on prescription drug importation and proactively communicating these to the boards. Additionally, NABP should assist boards in developing talking points based on the 2020 NABP comments to the United States Department of Health and Human Services (HHS) regarding the federal importation proposal and other resources that include NABP's guiding principles and concerns that can be used to educate legislatures on importation issues.

Enforcement Responsibility

Task force members also voiced concerns over which entities would have enforcement responsibility, particularly when multiple agencies in different countries are involved. Questions arose regarding which agency would oversee the Canadian drug source so that there would be confidence that the drugs were safe and not counterfeit. The New Mexico SIP provides for the US Food and Drug Administration (FDA) to approve the foreign drug seller that ships to the US-based importer(s). Members discussed how these importers would be licensed as it appears there will be a very limited number, thus the issue of nonresident licensure will need to be addressed if they are not required to be domiciled in the state in which they are selling the imported drugs. This could pose significant interjurisdictional enforcement issues if an importer is domiciled in a state that has not authorized importation. One member shared that a known wholesale distributor domiciled in Florida will likely be one of the few, thereby states such as New Mexico and Colorado will have to determine if a special nonresident license category will need to be promulgated. Accordingly, it was noted that everything is dependent on what might ultimately happen with the entire federal importation of prescription drugs rule based on policy decisions made by the current and future administrations. Ultimately, the task force agreed that NABP should communicate with National Association of Pharmacy Regulatory Authorities (NAPRA), Health Canada, as well as pharmacy regulators in the individual Canadian provinces and foreign jurisdictions, to discuss importation issues, particularly the regulation of their wholesale distributors that will be selling prescription medications to the approved US importers. Additionally, NABP should discuss with the aforementioned Canadian regulators, state and federal agencies, as well as other foreign countries if and as they are approved, information

about NABP programs, such as the Supply Chain Inspection program, that could assist with regulatory oversight by possibly being utilized for nonresident importers within the US. However, it will be challenging for NABP to ensure the safety of imported prescription drugs.

Related SIP Issues

While discussing the broader topic of drug importation during the SIP presentations, the task force touched upon several miscellaneous but important issues that need to be considered. Members were concerned with the availability of Canadian drugs and whether drug shortages would result if and when larger states passed SIP legislation and entered the importation arena. It was noted that the Colorado SIP only provides for therapeutic categories that currently include respiratory, oncology, and HIV drugs. The expectation is that the states can partner with Canadian manufacturers to ensure that SIPs will be able to provide less expensive prescription medications to US patients, while not negatively impacting the drug supply for Canadian patients. Another concern expressed by several task force members was how negligible the actual savings to US patients would be, particularly in light of the additional costs associated with a SIP. Colorado's SIP mandates for authenticity testing and relabeling of the imported medications to include new National Drug Codes, and while the representatives informed the members that these costs were taken into consideration, it is still unknown what the actual savings to patients will be. Along the lines of medication costs arose the concern of reimbursement issues and whether the medications would be considered FDA-approved and subsequently billed to federally funded programs. Another issue members discussed was whether nonresident patients would be able to obtain medications from a state that is obtaining prescription drugs from Canada. The Colorado representatives informed the members that their SIP stated that imported medications were only allowed to be dispensed to Colorado residents, and their medications will be labeled accordingly. While the task force was extremely interested in these various miscellaneous issues and voiced that they should be monitored, members decided not to make any specific recommendations for NABP upon which to act.

Patient Safety

Additionally, the task force discussed the overarching issue of patient safety as the public's general knowledge about drug importation may cause confusion. Members were especially concerned that patients' perceptions regarding importation plans may lead to the erroneous belief that all prescription drugs obtained from foreign sources are safe. Also members discussed the various ways in which NABP can educate the public regarding patient safety and agreed that NABP should collaborate with other stakeholders, such as the Tri-Regulator Collaborative, pharmacy organizations, industry organizations, FDA, Drug Enforcement Administration (DEA), US Pharmacopeial Convention (USP), International Pharmaceutical Federation (FIP), and consumer groups, to develop nationwide consumer education programs that inform patients about legal state importation programs versus illegal importation with a focus on the dangers associated with the latter. The task force also agreed that NABP should continue to drive consumers to *safe.pharmacy* and encourage the use of the Buy Safely and Drug Disposal Locator Tool.

Drug Supply Chain Security Act

Lastly, members discussed the importance that the Drug Supply Chain Security Act (DSCSA) plays in ensuring the integrity of the US prescription drug supply and how to bridge the gap in educating health care providers, including pharmacists about this Act. It was noted that in 2023 the DSCSA will require the collecting and sharing of transaction data and the requirement that it must be interoperable throughout the supply chain. Thus, the task force agreed that NABP should collaborate with other stakeholders to develop DSCSA educational programs and tools for health care providers and regulators to ensure compliance for domestic and, in the event that any SIPs are approved, imported drugs.

After careful review and deliberation, the task force recommended that NABP do the following:

1. Assist boards of pharmacy by monitoring bills for legislation on prescription drug importation and proactively communicating these to the boards. Develop resources for boards to use in educating their legislators when an importation bill is being considered that are based on the 2020 NABP comments to HHS regarding federal importation proposals and that include NABP's guiding principles and concerns that encompass the boards of pharmacy. Such resources may include:
    a. Developing a one-pager with talking points that include NABP's guiding principles and concerns over proposed legislation, the current federal landscape, and the fact that HHS has yet to approve a SIP;
    b. Assisting boards of pharmacy, when requested, to provide educational and technical assistance to policymakers; and
    c. Providing information about dangers of procuring drugs from rogue online foreign sellers.
2. Communicate with NAPRA, Health Canada, as well as pharmacy regulators in the individual Canadian provinces and foreign jurisdictions, about importation issues, particularly the regulation of wholesale distributors that sell prescription medications to approved state agents.
3. Discuss with the aforementioned Canadian regulators, state and federal agencies, as well as other foreign countries if and as they are approved, NABP programs, such as Supply Chain Inspection, that could assist with regulatory oversight and can possibly be utilized for nonresident importers within the US.
4. Collaborate with other stakeholders (ie, Tri-Regulator Collaborative, pharmacy organizations, industry organizations, FDA, DEA, USP, FIP, and consumer groups) to develop nationwide consumer education programs that inform patients about legal state importation programs versus illegal importation, focusing on the dangers associated with the latter. Continue to drive consumers to *safe.pharmacy* to use the Buy Safely and the Drug Disposal Locator Tools.
5. Collaborate with other stakeholders to develop DSCSA educational programs and tools for health care providers and regulators to ensure compliance for domestic and imported drugs.

FOR IMMEDIATE RELEASE
January 17, 2024

Pharmacy organizations raise concerns about Florida's drug importation program

WASHINGTON - Our pharmacy organizations are deeply concerned about FDA's recent authorization of a state drug importation program, which could open the door for harmful and counterfeit drugs to enter our nation's drug supply, with no evidence that this will result in cost savings for our patients.

FDA recently authorized Florida's Agency for Health Care Administration to import certain drugs under specific conditions. Under current law, FDA can only authorize importation if the program will significantly reduce the cost to the American consumer without imposing additional risk to public health and safety. FDA's announcement did not contain any data or information that assure that this standard has been met.

While our organizations share concerns regarding the high cost of medicines in the United States, patient safety should not be compromised under any circumstance. As pharmacists, we are on the front lines protecting our nation's drug supply chain and ensuring the delivery of safe and effective medicines to our patients. State importation programs introduce several opportunities for mix-ups, mishandling, mislabeling, and other rogue activity that would place some of our most vulnerable patient communities at risk.

Pharmacists have been working with manufacturers and wholesalers for over ten years to implement the Drug Supply Chain and Security Act (DSCSA), a law that requires tracing of drugs through the supply chain by creating a closed drug distribution system in the U.S. to protect patients from receiving harmful drugs. DSCSA imposes protections and requires documentation that follows the drug from the manufacturer to the pharmacy, so it is clear who owned the product, and that the product is legitimate. Canada does not have a similar law, leaving our drug supply chain at risk under Florida's program.

We look forward to continuing to work with FDA and other policymakers to implement meaningful solutions to lower the high cost of prescription drugs without compromising patient safety.

American Pharmacists Association
Academy of Managed Care Pharmacy
American Association of Colleges of Pharmacy
American Association of Psychiatric Pharmacists
American College of Clinical Pharmacy
American Society of Health-System Pharmacists
Hematology/Oncology Pharmacy Association
National Alliance of State Pharmacy Associations
National Association of Boards of Pharmacy
National Community Pharmacists Association
National Pharmaceutical Association
Society of Infectious Disease Pharmacists
Alabama Pharmacy Association
Alaska Pharmacy Association

Arizona Pharmacy Association
Arkansas Pharmacists Association
California Pharmacists Association
Colorado Pharmacists Society
Connecticut Pharmacists Association
Delaware Pharmacists Society
Georgia Pharmacy Association
Hawaii Pharmacists Association
Illinois Pharmacists Association
Indiana Pharmacy Association
Iowa Pharmacy Association
Kansas Pharmacists Association
Kentucky Pharmacists Association
Maine Pharmacy Association
Maryland Pharmacists Association
Michigan Pharmacists Association
Minnesota Pharmacists Association
Mississippi Pharmacists Association
Missouri Pharmacy Association
Montana Pharmacy Association
Nebraska Pharmacists Association
Nevada Pharmacy Alliance
New Jersey Pharmacists Association
North Carolina Association of Pharmacists
North Dakota Pharmacists Association
Ohio Pharmacists Association
Oklahoma Pharmacists Association
Oregon State Pharmacy Association
Pennsylvania Pharmacists Association
Pharmacists Society of the State of New York
Rhode Island Pharmacists Association
South Carolina Pharmacy Association
South Dakota Pharmacists Association
Tennessee Pharmacists Association
Utah Pharmacy Association
Virginia Pharmacy Association
Washington D.C. Pharmacy Association
Washington State Pharmacy Association
West Virginia Pharmacists Association
Wyoming Pharmacy Association

Alabama Society of Health-System Pharmacists, Inc
Arkansas Association of Health-System Pharmacists
Colegio de Farmaceuticos de Puerto Rico
Colorado Pharmacists Society
East Alabama Health
Georgia Society of Health-System Pharmacists
Illinois Council of Health-System Pharmacists
Kansas Council of Health-System Pharmacy
Kentucky Society of Health-System Pharmacists
Louisiana Society of Health-System Pharmacists
Michigan Society of Health-System Pharmacists
Minnesota Society of Health-System Pharmacists
Mississippi Society of Health-System Pharmacists
Missouri Society of Health-System Pharmacist
New Jersey Society of Health-System Pharmacy
New York State Council of Health-System Pharmacists
Pennsylvania Society of Health-System Pharmacists
Rhode Island Society of Health System Pharmacists
Texas Society of Health-System Pharmacists
Virginia Society of Health-System Pharmacists
Vermont Society of Health-System Pharmacists
Washington State Pharmacy Association

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COLORADO'S IMPORTATION PROGRAM

9.20.24

Mara Baer, Founder & President, AgoHealth

Program Overview

- Colorado Senate Bill 19-005 authorized HCPF to submit an importation application
- Program focuses on commercial market
- Annual appropriation: $2.1million
  - Includes 9 contract partners
- Estimated savings $50.9 million (2025-2027)
- Awaiting approval or RFI

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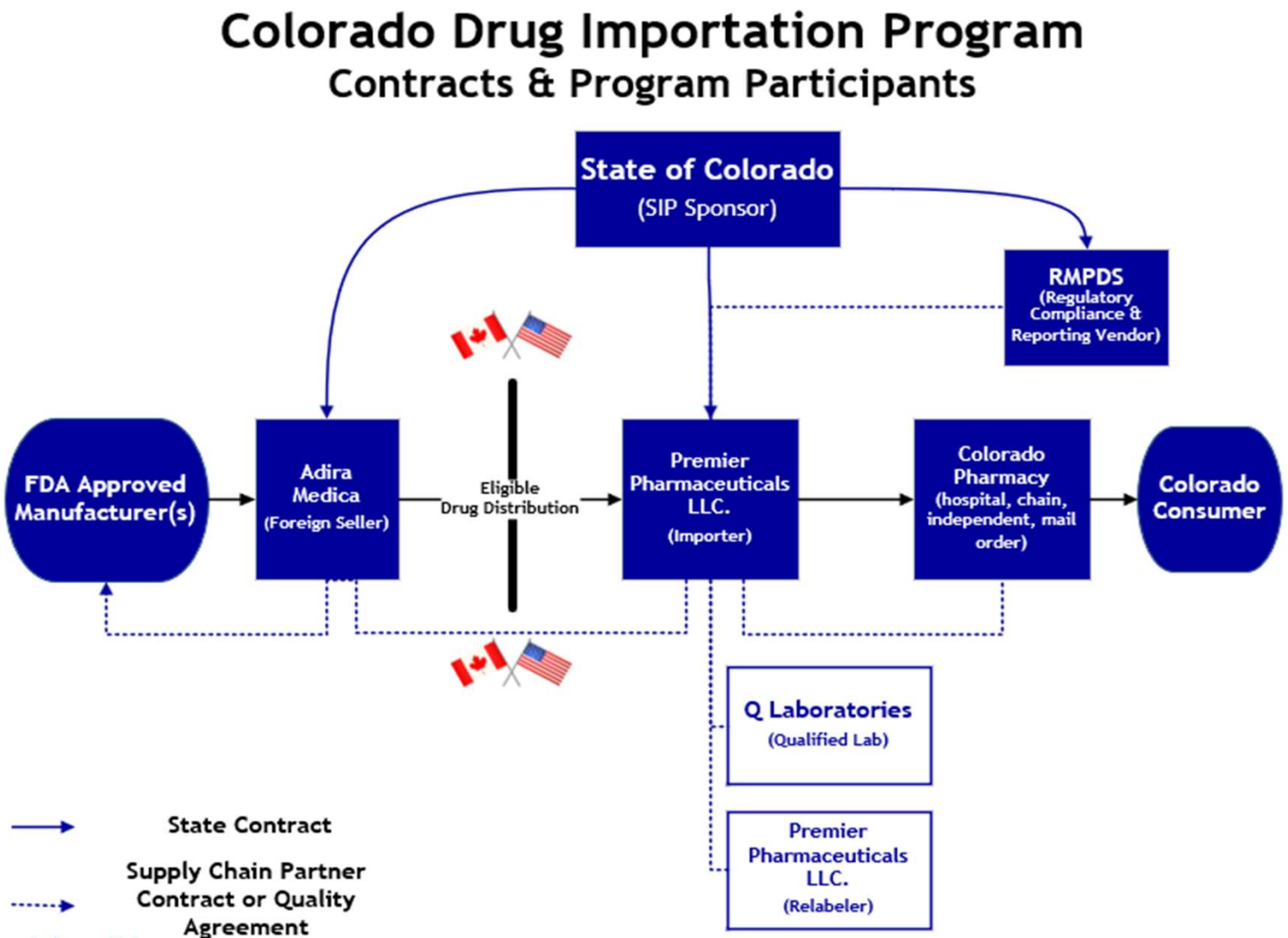
Distribution Chain & Partners



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Program Timeline

Action	Timing
Submit draft SIP & rule comments	March 2020
Final rule released	November 2020
Invitation to Negotiate (ITN)	January 2021
Submit application	December 2022
FDA RFI received	March 2023
Submitted 1st amendment	February 2024
Submitted 2nd amendment	August 2024

Best Practices

- Legislative
  - Flexible procurement process
  - Ensuring fiscal support
  - Consider capacity for regulatory “teeth”
- Implementation
  - Need policy/supply chain expertise
  - Due diligence to identify supply chain partners
  - Keep stakeholders informed & be ready for resistance by some

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Procedures (Start-up/Ongoing)

With clear budget, policy understanding & SMEs identified, focus has been on:

- Regular engagement with FDA
- Maintaining strong working relationship with supply chain partners
- Assessment of key stakeholder positions (carriers, PBMs, employers, pharmacy, manufacturers)
- Maintain ongoing transparency of activities
- Strategize with SMEs on issues (legal, supply chain, etc.)

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Implementation Challenges

- Securing drug supply = need to negotiate
  - Contract clauses in Canada create a barrier
- Resistance by drug manufacturers
  - With an approval we hope this opens dialogue
- Lack of regulatory clarity
  - Rule does not contemplate need to negotiate

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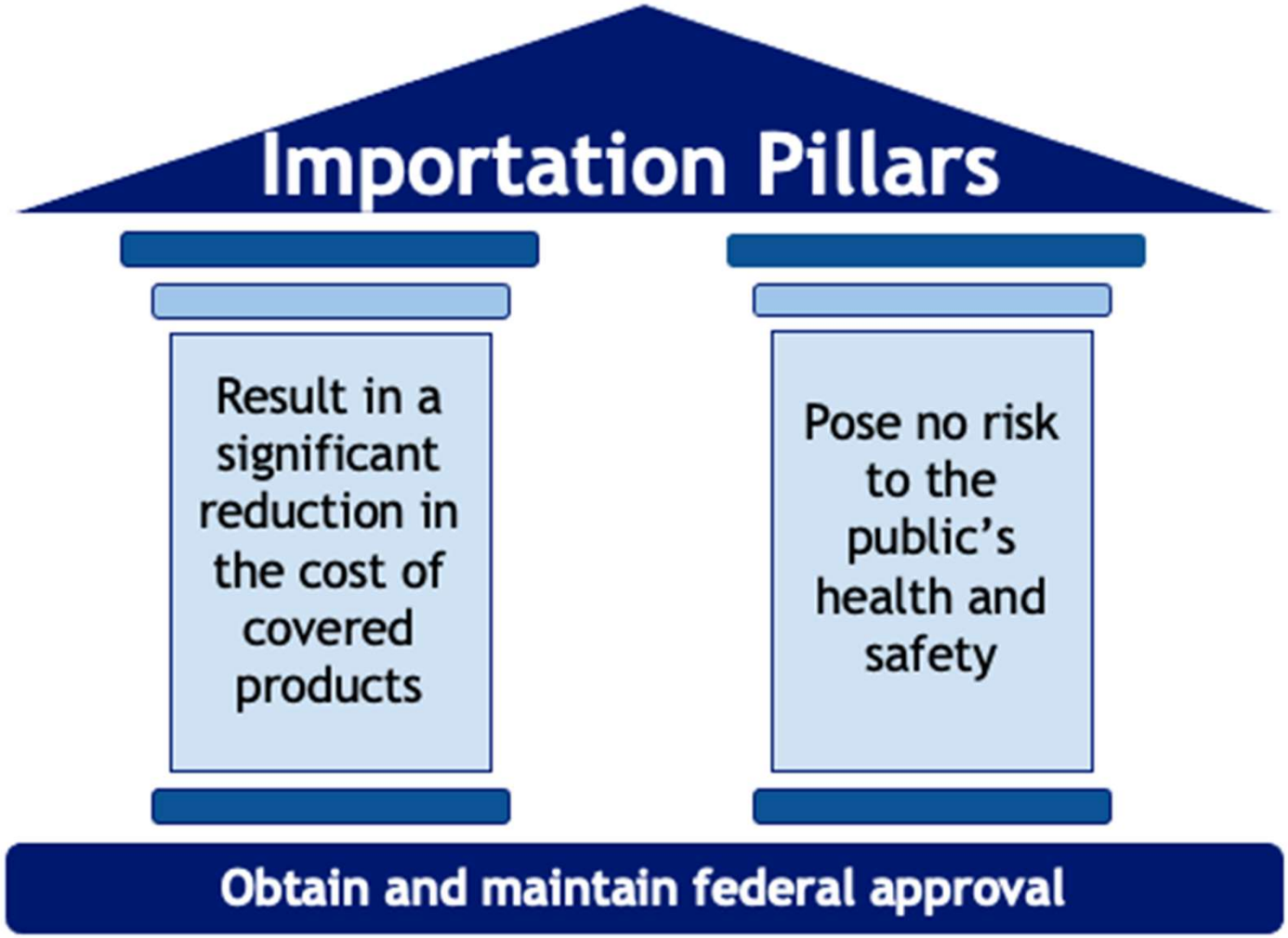
Cost Savings & Safety



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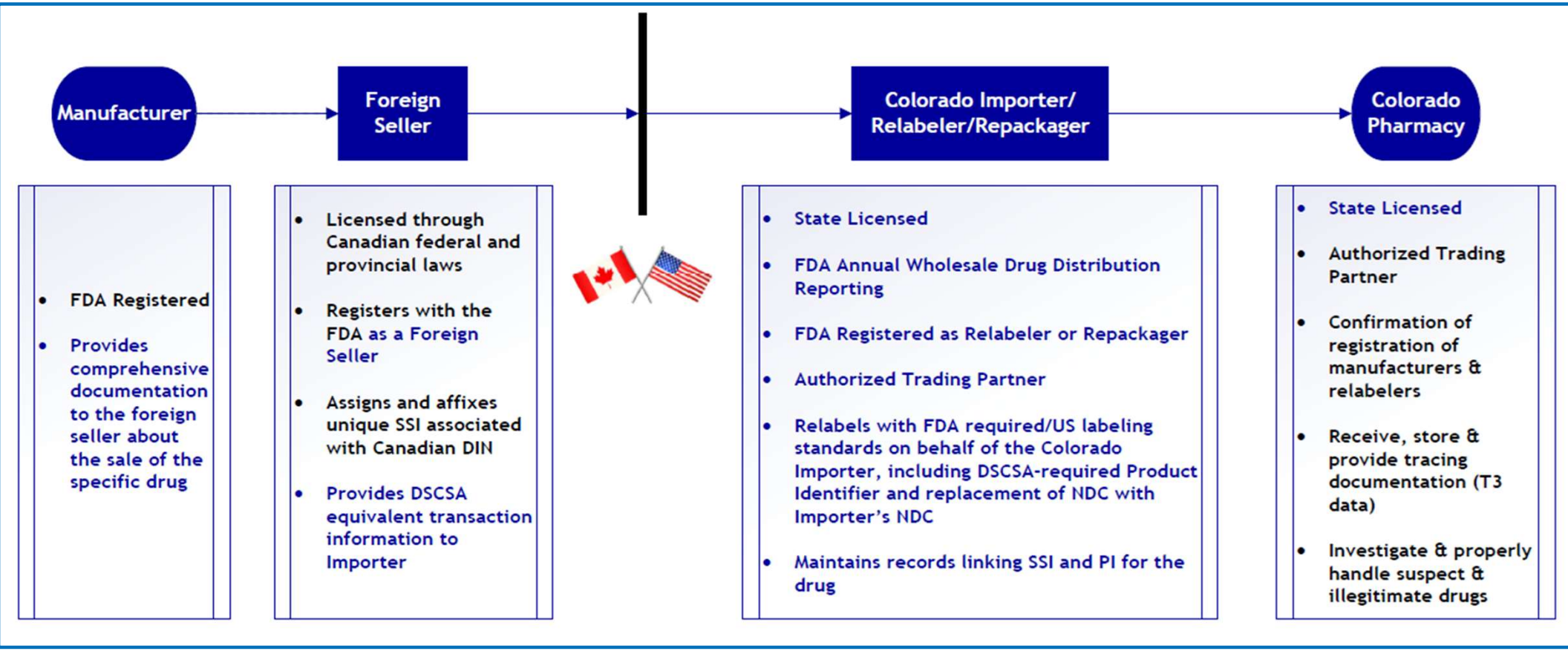
Safety



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Safety: Oversight & Monitoring

- Regular reporting, audits, inspections
- Maintain standards for physical space, security, SOPs, staff education & training
- Track and trace monitoring (DSCSA compliance)
- Return & recall detailed procedures
- Adverse event reporting

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Cost Savings

- HHS ASPE provided specific requirements for the cost analysis:
  - Comparison of a Baseline Scenario and Plan Scenario
  - Three years of analysis
- Methodology at-a-glance:
  - Conservatively estimated adoption: 6.2% (2025), 17.1% (2026), 22.5% (2027)
  - Some challenges in estimating savings (re: lack of self-insured data)
  - Needed to consider impact of lost rebates
  - Supply chain cost estimates impacted by volume

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Cost Savings

- Biktarvy- HIV
- Eliquis 2.5mg - blood thinner
- Erleada - cancer
- Ibrance - cancer
- Janumet - type 2 diabetes
- Januvia - type 2 diabetes
- Odefsey - HIV
- Otezla - psoriasis
- Ozempic - type 2 diabetes

- Prezcobix - HIV
- Rinvoq ER 15mg - RA
- Spiriva Respimat 2.5 - respiratory
- Sprycel 100mg - cancer
- Symtuza - HIV
- Tivicay - HIV
- Trikafta - cystic fibrosis
- Triumeq - HIV
- Victoza - type 2 diabetes

Actuarial cost analysis found $51 million in savings over first three years

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Next Steps

Await federal approval

Respond to FDA questions

More supply chain planning

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Thank you!

- My contact information: mara@agohealth.com
- Colorado's Program Website: https://www.colorado.gov/hcpf/drug-importation
- Program Contact email: hcpf_005drugimportation@state.co.us

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