



Application to Operate a Section 804
Prescription Drug Importation Program

Maine Department of Health and Human Services

May 1, 2020

Contents

I.	Introduction - Reason for Importation	1
II.	The New Maine Importation Law.....	1
III.	Limitations of the Federal Law and Regulation	2
A.	Federal Law Limits on State Wholesale Importation.....	2
IV.	Meeting Section 804 Importation-Specific Law Requiring Consumer Cost Savings	3
A.	Estimating Health Plan Savings:	3
B.	Estimating Consumer Savings.....	5
C.	Controlling Mark Up Along the Supply Chain.....	5
D.	Assuring Continued Savings	5
V.	Fulfilling Federal Safety Requirements	6
A.	Meeting the General Requirements of Food and Drug Law That Also Apply to the Maine Wholesale Importation Program.....	6
B.	Meeting Unique Safety Requirements of Section 804 Importation Provisions	9
VI.	Additional State Safety Requirements	10
A.	Licensing eligible participants.....	10
B.	Audits and Certifications	11
C.	Limit Sales of Imports to Individuals and Entities in the State	11
D.	Unique NDC for Maine as Private Label Distributor.....	11
VII.	Next Steps	12
VIII.	Appendix A, Maine Comments on Federal Notice of Proposed Rulemaking	13
IX.	Appendix B, P.L. 2019, ch. 472, An Act to Increase Access to Low-cost Prescription Drugs.....	17

I. Introduction - Reason for Importation

The cost of prescription drugs for residents of the State of Maine continues its inexorable rise. Cost containment has become more difficult as the market becomes more opaque. The government of Maine has implemented various programs and policies in the past two decades to improve residents' access to prescription drugs:

- a prescription drug access program for low-income seniors;
- steps to improve awareness of health insurance coverage, including a planned transition to a state-based insurance marketplace;
- expanded Medicaid eligibility for low-income adults; and
- a prescription drug cost transparency and market data collection effort.

While these initiatives improved resident access to prescription drugs, none of these programs or policies have had a salutary effect on prescription drug prices and costs. As drug prices challenge affordability, resident access to vital medications is imperiled.

The [Maine Health Data Organization](#) found that between 2018 and 2019:

- the volume of prescriptions in Maine grew less than 2 percent;
- the number of people filling prescriptions declined by 13 percent; but
- spending on drugs increased 11 percent.¹

Slowing the increase in volume has been the cornerstone of pharmacy benefit cost management for health plans and programs. These new data show that the traditional methods of cost containment are no longer enough.

II. The New Maine Importation Law

The State of Maine is turning to importation of prescription drugs as a concrete way to lower the price and cost of some prescription drugs for patients, providers, and payers. On June 24, 2019, Governor Mills signed into law P.L. 2019 Chapter 472, which requires the Maine Department of Health and Human Services (MDHHS) to submit a request to the U.S. Department of Health and Human Services (USDHHS) for approval of the Maine wholesale prescription drug importation program. Maine's law stipulates that the State's program meet the requirements of all relevant federal laws and regulations as directed by the USDHHS.

The Maine law and subsequent regulations require the implementing agency, MDHHS, to consult with stakeholders. There have been three public meetings in the first quarter of 2020 to discuss issues and concerns related to setting up a wholesale importation program. Participating

¹ The data includes commercial plans, Medicare plans, and Medicaid. ERISA plan data is not collected or included.

stakeholders included the Board of Pharmacy, the Maine Hospital Association, the Maine Pharmacy Association, the Maine Primary Care Association, the Healthcare Purchaser Alliance of Maine, Consumers for Affordable Health Care, The Maine Association of Health Plans, Maine Council on Aging, pharmaceutical manufacturers, individual pharmacists, and representatives of insurance carriers. Input from stakeholders is reflected in this submission.

There is general consensus among policymakers and stakeholders that a wholesale importation program, as described in this submission, would improve patient access to pharmaceuticals and provide savings to Maine consumers.

III. Limitations of the Federal Law and Regulation

This Maine submission should be viewed in context. Maine’s statute requires submission of an application to the federal government by May 1, 2020, despite the federal proposed rule not yet being finalized. This submission outlines the program Maine wishes to implement, and notes aspects of existing federal law and the proposed rule which would limit the potential of the program to generate meaningful savings for consumers.

A. Federal Law Limits on State Wholesale Importation

There are several key provisions of federal law, Section 804 of the Food, Drug and Cosmetic Act (FDCA) (21 USC Chap. 9 Subchap. V Sec. 384), that will limit the ability of Maine government to provide robust prescription drug cost relief for residents through importation of lower cost versions of the U.S. drugs.

The first federal law limitation is that the State can only import drug products licensed for sale in Canada [21 USC Sec 384(b)]. The State is confident that importing a limited number of drug products for some portion of Maine’s 1.35 million residents will not create supply shortages for Canada’s 38 million residents. The Government of Canada has expressed concern about the impact of broad importation on the Canadian drug supply, however.² The Food and Drug Administration (FDA) already allows imports from around the world to address U.S. drug shortages and to facilitate the development of biosimilars to spur price competition in the U.S. market.³ If the Administration is considering wide-scale importation of prescription drugs as part of a long-term solution to the problem of high drug costs, it should engage with Congress to change the federal law to permit importation of drugs from any country where there is an FDA-registered manufacturing facility.

Second, federal law prohibits the importation of biologic products (21 USC Sec 384(a)(3)(B)). Biologics are generally understood to be the costliest of drugs and several are widely used including insulin and autoimmune treatments for rheumatoid arthritis or psoriasis. Biologics are typically administered intravenously, and IV drugs are also prohibited under federal law. The

² Government of Canada, “[Comments on the Proposed Rule ‘Importation of Prescription Drugs’ \(DOCKET NO. FDA-2019-N-5711\)](#),” Posted March 10, 2020.

³ US Department of Health and Human Services, Food and Drug Administration. “Considerations in Demonstrating Interchangeability with a Reference Product, [Guidance for the Industry](#).” May 2019. And “Questions and Answers on Biosimilar Development and the BPCI Act, [Guidance for the Industry \(Revision 1\)](#).” December 2018.

Administration should also consider working with Congress to permit these drugs to be safely included in a State importation program, in order to maximize savings available.

B. Proposed Federal Regulations Limits on State Wholesale Importation

Limitations of the federal proposed rule⁴ would also create barriers to Maine's goal of importing lower cost versions of U.S. drugs. Specifically, the proposed rule would limit the supply chain for importation to one foreign seller that has purchased directly from the drug manufacturer and that sells directly to the one wholesale importer working on behalf of the Maine importation program. This is unnecessarily restrictive and is likely to limit the ability of Maine to import any drug. The manufacturer will likely only sell to foreign sellers that agree not to sell to a U.S. wholesaler. To overcome the expected opposition of drug manufacturers, Maine will need a more diverse supply chain in Canada – to purchase one product from multiple licensed foreign sellers that have purchased directly from a manufacturer, or a licensed foreign seller(s) that has purchased the licensed product from the supplier that bought directly from a manufacturer.

While there are a variety of other issues of concern in the proposed rule that could impact the administrative cost of the program, these supply chain limitations are the most significant impediments to the wholesale importation program envisioned by the government of Maine.

Maine's full comments on the proposed rule are in Appendix A.

IV. Meeting Section 804 Importation-Specific Law Requiring Consumer Cost Savings

A. Estimating Health Plan Savings:

In order to determine the set of drugs to import, the Maine Department of Health and Human Services (MDHHS) will work with all interested commercial plans, ERISA plans, and the Maine state employee plan⁵ to produce a list of approximately 30 prescription drugs common to most or all plans on which payers spend the most money. The list of proposed import products submitted to the USDHHS will only include drugs as allowed by law.⁶

The process by which MDHHS will develop the final proposed list for USDHHS review is described below and will be conducted without the need for the State to obtain proprietary data.

In the first round of analysis, MDHHS will request a list of the 40 top spend drugs from each payer that chooses to participate. Plans' calculations of their top spend drugs will be net of all price concessions.

MDHHS will then identify the drugs common to all or most payers, which presumably will be less than 40 drugs.

⁴ US Department of Health and Human Services, Food and Drug Administration, Docket No. FDA-2019-N-5711. Federal Register, Vol 84, No. 246, 12/23/2019.

⁵ Medicaid may or may not participate in the wholesale importation program contingent on whether the proposed import products are less expensive than the net cost to Medicaid after federally required rebates are included.

⁶ The lists will exclude controlled substances, biologics, infused and intravenous drugs, drugs inhaled during surgery, and any other drugs excluded by the federal rule.

MDHHS will look at available data about the Canadian price of each of the drugs that are common to all participating payers. MDHHS will add a 45 percent mark up to each of the Canadian product prices.⁷ MDHHS will pass back to all payers the estimated, expected unit cost of the drugs on the common list, including the mark up for administrative costs.

In the second round of payer analysis, each participating payer will compare the estimated per unit import cost with their own net unit cost of each drug on the list passed back to payers by MDHHS. Each participating payer would inform MDHHS which drugs still represent a cost savings for that payer, based on unit cost and utilization.

MDHHS will then take all the second-round input of participating plans to develop a common list of drugs for which participating payers anticipate savings after accounting for supply chain costs.

The near-final list of potential imports will then be discussed in a third round of analysis with all participating plans, the Maine Board of Pharmacy, Maine hospitals and providers, Maine pharmacists, consumer representatives, and any other interested stakeholder. One issue to be addressed in this third round is whether all the drugs on the list are suitable to dispensers. If all payers are not participating, pharmacies, hospitals and dispensing physicians will have to stock two versions of any imported product – the import and the US version of the product. The logistical issues of dual stocking may affect the choice of drugs to be imported – the volume of product needed to meet the needs of patients prescribed the drug relative to dispenser shelf space available for stocking versions of the same product.

Another issue to be addressed in the third round is whether any prescription drug on the list will lose U.S. patent rights in the next several years and if the State should still pursue importation of those drugs.

The third round of analysis and discussion will also include an exploration of continuity of supply for the drugs on the list. If supply cannot be generally ensured or otherwise addressed, the drug may need to be removed from the list of proposed imports.

Based on the operational issues discussed in the third round, a final list of drugs to be imported under the auspices of the Maine wholesale program will be provided to USDHHS for approval. The list will include the Canadian drug identification number (DIN), the U.S. National Drug Code (NDC), the New Drug Application (NDA) or Abbreviated New Drug Application (ANDA) number, confirmation that the U.S. version is currently marketed in the U.S., as well other information as specified by USDHHS.

The estimated, aggregate amount of savings on drug spend in dollars and as a percentage of health plan drug spend will be provided to USDHHS at that time.

⁷ Maine expects administrative costs to be somewhat less than 45 percent of the Canadian price, but is using a conservative number for planning purposes. The 45 percent markup estimate was developed by the National Academy for State Health Policy and has been used by other states in estimates of importation program savings.

B. Estimating Consumer Savings

Each participating health plan will provide MDHHS with information on how the proposed list of imported drugs will be treated on their formularies – change in tier placement, first dollar coverage (exempt from deductible), as well as the impact of lower prices on coinsurance payments as appropriate for each of the proposed imports. Each participating health plan will estimate the aggregate savings their enrollees can expect, based on the impact of the import price on enrollee out of pocket spending. These estimates will be based on recent claims experience or another method approved by MDHHS.

MDHHS will submit to the USDHHS information describing changes in plan formulary design relative to imports and MDHHS will provide the aggregate of plan-provided information on savings their enrollees can expect. MDHHS will conduct additional analysis of savings for other residents not enrolled in participating plans, particularly the uninsured.

C. Controlling Mark Up Along the Supply Chain

A critical aspect of assuring savings is preventing shadow pricing or profiteering from imported product. Maine anticipates soliciting bids from companies interested in contracting as the program's U.S. wholesale importer and Canadian exporter supplier(s). Successful bids will demonstrate low administrative cost. It is Maine's current expectation that contractors will generate margin from administrative fees rather than mark up on the product price, in order to increase transparency in our drug supply chain. Maine will encourage participating health plans to reimburse pharmacies at actual acquisition costs (which will be publicly known and not an estimate as it is today) plus a dispensing fee. The State will work with pharmacies and participating health plans to establish appropriate professional dispensing fees that, to the extent possible, account for the margin on the U.S. version of the import for pharmacies.

The State will make the list of imported products and the import price publicly available so that people without adequate coverage can be informed of what they should expect to pay if they are uninsured or in a deductible period. The State will also work with plans to ensure enrollees are informed of the out-of-pocket cost of the imported drugs at the point of dispensing.

Participating health plan provider network agreements will include provisions about compliance with rules of the importation program, including preferred use of imports and billing. Health plans will need to know which network pharmacies will participate in the importation program. Health plans and the state will let enrollees and residents know which pharmacies (if any) will not dispense imported product so those establishments can be avoided by patients filling prescriptions for any of the imported products.

D. Assuring Continued Savings

These processes to determine which drugs to import and estimate savings will be repeated as needed to assess the utility of continuing to import specific drugs. There will be market changes, such as branded therapeutic competition or U.S. generic entry of a product on the Maine import list that could indicate if a change to the imported product list is warranted.

V. Fulfilling Federal Safety Requirements

In addition to establishing a process for determining maximum savings potential, the State will also ensure that the program will meet the safety requirements of relevant parts of the federal law. The program will comply with all relevant provisions of the Federal Food, Drug, and Cosmetic Act, which includes Section 804 specifically pertaining to wholesale importation programs, as well as rules and laws for accountability along the supply chain that apply to all products on the U.S. market. These general laws and rules for all U.S. prescription drugs address all aspects of the supply chain, including but not limited to:

- licensure and registration;
- shipping, handling and storage;
- product labeling;
- tracking pedigree and every transaction where ownership changes;
- package serialization including machine and human readable 2-D bar codes; and
- attestation from the seller in each transaction of authorization to sell.

Since much of the current U.S. drug supply is produced overseas, Maine will be leveraging that global supply chain that is today registered and regulated by the FDA and must meet these important requirements already.

A. Meeting the General Requirements of Food and Drug Law That Also Apply to the Maine Wholesale Importation Program

1. Licensing and Registration

For a Maine wholesale importation program to obtain and sell product in the State, all participants in the program supply chain must be registered with the FDA. Maine will only contract and include supply chain participants who are FDA registered and in good standing. Additionally, Maine licenses drug wholesalers, pharmacies including mail order pharmacies, and manufacturers of prescription drugs. Domestic import program participants will have to be licensed in Maine and in good standing.

Maine will create a new license category for the entities that repackage and relabel product generally and there will be a new specific license for companies that re-label and repackage prescription drug products that participate in the importation program. Fees from these licenses will support the administrative costs of the program. (See Section VI for information on Additional State Safety Requirements.)

2. Examination of Drugs at the U.S. Border

Currently, there are numerous requirements in general U.S. drug law and regulations for drugs intended to be imported into the U.S. Importers may be third party logistics providers (who ship on behalf of a manufacturer or other owner of the product), and other authorized distributors.

Importers of any and all prescription drugs must submit detailed information about the product to Customs and Border Protection (CBP) and FDA for their review prior to releasing the drug for the U.S. market. Information required includes, but is not limited to:

- Country of origin;
- Product code;
- Intended use;
- Importer of record;
- Manufacturing facility;
- NDA, BLA, or ANDA number; and
- Other supply chain requirements such as a 2-D bar code with NDC, serial number, lot number, expiration date.

Customs and Border Patrol (CBP) coordinates with FDA to verify the importer data submission with FDA. FDA can request samples for testing. FDA can reject any prescription drug offered for import that is not in compliance with reporting or testing or that appears illegitimate (e.g., that appears to be adulterated, misbranded, unapproved, or manufactured in an unregistered facility for example).

3. Labeling/Relabeling

For a Maine wholesale importation program to obtain and sell product in Maine, the product must be properly labeled in accordance with FDA rules and law – like any other drug product intended for the U.S. market. Once the product is re-labeled to meet FDA requirements, the drug is considered FDA-approved and not mis-branded.

Maine prefers that this re-labeling function occur in Canada, prior to entry into the U.S. In contrast, the federal proposed rules would require ‘mis-labeled’ products to be imported and held in a U.S. warehouse at the CBP Office that will be assigned as the point of entry for all Maine import shipments. Under the proposed rule, Maine imports would be held proximate to the CBP Office until testing and relabeling has been accomplished.

In contrast, the routine importing of drugs authorized by manufacturers or their designees are appropriately labeled prior to U.S. entry. Maine cannot anticipate the CBP Office to which it will be assigned and cannot know if relabeling operations will be geographically proximate to the assigned port of entry. If the necessary services are not close by, program costs will increase unnecessarily.

In addition to proposing that Maine imports be relabeled after entering the U.S., the proposed rule would require that the Canadian exporter serialize the import shipment which requires the U.S. NDC and serial number generated by the exporter. The shipment would be serialized again when it is relabeled in the U.S.

Maine would prefer that the product be relabeled and serialized by the repackager/relabeler under contract with Maine but while in Canada. This could eliminate the need for two serializations for the same shipment. In this arrangement, the pedigree information and complete transaction history with all required data elements would be given to Maine’s relabel contractor. The information would include pedigree, testing history, lot number, among the other required data elements and include the specifics of the Canadian exporter’s transactional information. The re-labeler would add serialization to the shipment and input their transaction data to the history of the shipment in accord with U.S. federal law.

4. Record Keeping and Reporting

The Maine wholesale importation program will comply with the requirements of the Drug Supply Chain Security Act (DCSA) including Title II, The Drug Quality and Security Act (DQSA) whether or not shipments are relabeled in Canada as discussed in the previous section. Like other drugs coming to the U.S. market from overseas, Maine will require that its Canadian export supplier(s), the U.S. wholesale importer, and other Maine distributors and dispensers in the program comply with provisions of the law as currently implemented and maintain compliance with new or changed requirements as the law is fully implemented, expected in 2023, and thereafter. The law currently requires certain data to follow drugs through all transactions from the manufacturing plant to the point of service at the pharmacy or other site of care. The data are labeled TI (transaction information), TH (transaction history), and TS (transaction statement). The data to be tracked include but are not limited to:

- Product identifier which includes the drug's U.S. National Drug Code (NDC), a serial number assigned by product owner or on behalf of product owner and is generated by the owner of the shipment, lot number and expiration date.⁸
- The shipment lot size, container size and number of containers;
- The business name of the buyer and the seller, transaction date, and shipment date if later than the sale date;
- Records of shipment product testing; and
- The transaction history for the shipment back to the point of origin.

Additionally, the U.S. regulated supply chain, whether located in the U.S. or overseas, must be able to retain, add to, and transmit with each change of ownership, the transaction history of a drug.

Maine's foreign seller will have to provide verification of the pedigree of the product, back to the FDA-registered, ex-U.S. manufacturing facility and manufacturer-authorized distributor. FDA law and rules allow this pedigree and all transaction tracking information to be conveyed on paper as well as electronically. The State expects that the data from the foreign seller will be transferred electronically but there is a permitted alternative process if needed. To the extent that the pedigree information is not electronic, the data will be entered into the U.S system by the Maine-contracted importer prior to release by the CBPO or at the point the product is labeled for the U.S. market while the product is still in Canada prior to export into the U.S. The U.S. supply chain in Maine will comply with the federal track and trace rules for imports as they do for every non-imported prescription drug product.

5. Recalls/Managing Suspect and Illegitimate Drugs

In addition to the recordkeeping and reporting, the law requires that all parts of the U.S. supply chain – from manufacturers, wholesalers, repackagers/relabelers, to dispensers must be proactive

⁸ The serial number can be created and applied by relabelers/repackagers. In today's system, repackagers and relabelers apply their own labeler code and generate their own serial number that contains the NDC with their labeler code for all drugs handled by relabelers/repackagers.

in identifying drugs that are suspect of not being FDA-approved, such as counterfeit product. The supply chain must be able to:

- Investigate all suspected illegitimate drugs;
- Notify the FDA;
- Respond quickly to notification of illegitimate or otherwise misbranded drugs – destruction, quarantine; and
- Help others in receipt of illegitimate product.

All these requirements currently exist for the entities and are part of the Maine importation program.

B. Meeting Unique Safety Requirements of Section 804 Importation Provisions

In accordance with FDCA Section 804 (21 USC Sec. 384), the Maine prescription drug importation program has safeguards in place beyond the already comprehensive general food and drug law and regulations concerning quality and safety. It is important to note that Section 804 was enacted years before the Drug Quality and Security Act was created. The DSCSA/DQSA created a set of requirements to address the growing volume of drug imports that resulted from the industry shift from domestic drug manufacturing to manufacturing overseas and importing those drugs into the U.S. The DSCSA/DQSA also address domestic production, shipment and dispensing. There are a few requirements in Section 804 not found in the DSCSA with which the Maine program supply chain will comply.

1. Excluded Imports

In addition to the safeguards applicable to all prescription drugs, as discussed above, prescription drugs imported under the State's Program would be subject to requirements under FDCA section 804 (21 USC Sec 384). The following types of drugs will not be imported under Maine's program even though these products are otherwise manufactured overseas and shipped to the U.S. by manufacturers:

- controlled substances;
- biological products;
- infused drugs;
- intravenously injected drugs;
- drugs that are inhaled during surgery;
- any other drugs that the USDHHS decides should not be imported
 - The proposed rule would disallow imports of drugs under REMS requirements.
 - The proposed rule would disallow import of drugs injected intrathecally or intraocularly; and
- drugs donated or otherwise supplied at no charge by the manufacturer to a charitable or humanitarian organization (e.g., to the United Nations) or to a government of a foreign country.

2. Additional Data Collection and Reporting

The importer of a prescription drug under Maine's program will submit to the FDA additional information about each shipment (in addition to the information in the previous section of this proposal), including documentation from the Canadian exporter lot or control number that was assigned to the shipment by the manufacturer.

3. Additional Testing of Maine Imports

Batches of each shipment of the prescription drug will be subjected to testing for authenticity and degradation by a qualified laboratory at various points in the supply chain. In addition to the routine testing of product, Maine imports will be tested prior to distributing the product in Maine. The State will contract with a qualified, independent, accredited laboratory that meets the L7025:2017 standard of the International Standards Organization (ISO).⁹

Importers will submit documentation of this testing to CBP and FDA, including the complete data derived from all tests necessary to ensure that the prescription drug is in compliance with established specifications and standards, and the documentation demonstrating that the testing was conducted at a qualified laboratory.

This testing is in addition to the testing that manufacturers do prior to shipping drugs and testing of product changing ownership. This additional level of testing for authenticity and degradation will provide an extra level of assurance about the imported product. Drugs will be retested if they are repackaged in Maine to meet the needs of particular healthcare facilities.

4. FDA Suspension Authority

When there is violation of any requirement of the general federal food and drug laws and regulations, or violation of wholesale importation program rules, FDA has authority to immediately suspend importation of a specific prescription drug, a specific importer or the entire state program. The proposed rule is more expansive than the statute, which allows for importation to resume pending the outcome of an investigation. The proposed rule does not provide for resumption of activity and FDA can act in its sole discretion.

VI. Additional State Safety Requirements

A. Licensing eligible participants

Maine will establish new prescription drug importer-wholesaler licenses for State pharmacies, State wholesale distributors, and relabelers/repackagers. These licenses will be issued and maintained by the State Board of Pharmacy.

The Board of Pharmacy currently maintains a public database of licensed entities, with information such as name, address, license number and so forth. The current public database can only be accessed by query about a specific licensee. In other words, one cannot go into the

⁹The ISO has existed since 1946. It is a member organization primarily of government regulators and experts in various fields. Both the U.S. and Canada are members. Its standards are supported and distributed by the American National Standards Institute.

system and see all the licensed wholesalers or pharmacies without some information about the licensee.

In order to create more transparency and readily available public information for this new program, the database for importation licensees will be more accessible, so the public can scroll through all entities licensed to participate in the importation program without having any specific information about a specific licensee.

B. Audits and Certifications

Maine will perform audits of program and program participants. The State will also rely on existing national and international inspections of importation program participants by the FDA, Health Canada, international standard setting organizations, Canadian provincial authorities, and qualified third-party contractors. Program licensee applicants will be audited prior to obtaining an import-program specific license. The State will conduct or authorize to be conducted, periodic financial and other audits to ensure program compliance. Reports of these audits will be shared with FDA.

The program will audit to ensure that imported product is not leaving the state in significant quantities; such an audit will be facilitated by current-law DSCSA requirements.

C. Limit Sales of Imports to Individuals and Entities in the State

Maine will limit sales of imports to in-state healthcare facilities and people physically present in Maine, and will limit prescription amounts to no more than 90 days. These two provisions will stymie efforts to purchase quantities of imported product and re-sell at a higher prices outside the state. If data and program experience suggest additional limitations are necessary, the State will consider limiting dispensing to 30 days, and limiting sales to state residents and people in Maine for specific reasons such as inpatient or urgent care, students, and long-term care facility residents. Limiting sales in this way should facilitate more rapid response to notification of illegitimate product resulting in quarantine or product destruction.

D. Unique NDC for Maine as Private Label Distributor

Maine would obtain its own labeler code as the distributor of approved imported products. Such a label, referred to "Private Label Distributor" (PLD) code is part of the entire FDA-registered National Drug Code (NDC). The NDC will be on all imported product and will replace the Canadian market drug identifier. Maine's labeler code will be associated with approved imports in databases that list drugs and their NDCs. This is consistent with current contract drug manufacturing, repacking and relabeling regulations and practice under the FDCA and FDA review in the international drug supply chain.

The PLD labeler will also help ensure that no drugs imported by the Maine import program are distributed, dispensed, or sold outside of the State's borders. Keeping drugs in-State will assist in the unlikely event of a recall of drugs in the importation program. It will also facilitate the State's ability to audit the program.

VII. Next Steps

Maine will amend this SIP application following the finalization of the proposed rule concerning state wholesale importation programs. Subject to a final rule that allows the State to meet the goal of safely importing drugs that generate a substantial savings for consumers, the State will pursue the selection of drugs for importation, continue discussions with potential participating entities, and address all the detail necessary for a successful SIP application and program.

Most of what is needed for a safe and successful Maine wholesale importation program is already in place in federal law and regulations. The enhanced drug supply chain rules have created standard operating procedures for domestic and international entities serving the U.S. market.

Maine will leverage the U.S. compliant global supply chain, comply with additional requirements for older federal law, and select products for import that will provide savings for the people of Maine.

VIII. Appendix A, Maine Comments on Federal Notice of Proposed Rulemaking

Janet T. Mills
Governor

Jeanne M. Lambrew, Ph.D.
Commissioner



Maine Department of Health and Human Services
Commissioner's Office
11 State House Station
109 Capitol Street
Augusta, Maine 04333-0011
Tel.: (207) 287-3707; Fax: (207) 287-3005
TTY: Dial 711 (Maine Relay)

March 9, 2020

VIA ELECTRONIC SUBMISSION

Stephen M. Hahn, MD, Commissioner
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Notice of Proposed Rulemaking, Importation of Prescription Drugs, Docket No. FDA-2019-N-5711, 84 Fed. Reg. 70,796 (December 23, 2019)

Dear Commissioner Hahn:

Thank you for the opportunity to provide comments on the Food and Drug Administration's proposed rule to allow importation of certain prescription drugs from Canada.

One of the greatest drivers of health care costs for individuals and businesses in Maine is the financial burden of prescription drugs. According to a recent survey by the Kaiser Family Foundation, one in four Americans have trouble affording their prescription medications, and those who are low income or nearing retirement are even more likely to have challenges in paying for the medicine they need.¹ Given the demographics of our State, it is no surprise that we regularly hear stories of Maine people rationing their prescriptions or making difficult decisions between filling a prescription or their oil tank.

In the absence of meaningful action at the federal level, Maine has joined other states in taking steps to make use of all available levers to address this pressing issue for our residents. On June 24, 2019 Governor Janet Mills signed in to law a package of bills that included LD 1272, An Act to Increase Access to Low-cost Prescription Drugs. That law directs the Department of Health and Human Services to design a Wholesale Prescription Drug Importation program that meets the requirements of 21 United States Code, Section 384, and to apply for federal approval of the program by May 1, 2020.

Although we continue to urge the Administration to take steps to address the underlying cause of this problem by supporting federal policy to directly lower the price of drugs, we appreciate FDA and HHS proposing this rule to allow states to operate wholesale prescription drug importation programs to provide some measure of relief for their residents. We also share the Administration's focus on ensuring the safety and efficacy of drugs imported through the program and are grateful for the consideration that has been shown to ensuring that programs pose no additional risk to the public while providing meaningful cost savings. After reviewing the proposed rule, however, we are concerned that in some cases the rule far exceeds the requirements of the statute and the structure of the current international drug supply chain. Some requirements of the rule are so stringent that we anticipate they would effectively

¹ KFF Health Tracking Poll - February 2019: Prescription Drugs, (KFF, March 1, 2019):
<https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/>

render it impossible for Maine to establish a Section 804 Importation Programs (SIP) that meets the cost-savings requirements in state and federal law.

We hope that FDA will consider the following specific feedback before finalizing this rule.

1. SIPs should be permitted to include multiple Foreign Sellers both horizontally and vertically from their inception. We are concerned that the requirement to initially contract with only one Canadian foreign seller would effectively make the program contingent on manufacturers' voluntary participation, since contractual limitations or other means could be used to prohibit the initial Canadian purchasing entity from exporting any drug under a SIP.
2. The requirement that SIP applications specify the importer(s), foreign seller(s), relabeler(s), and repackager(s) is an unnecessarily high bar that may prevent otherwise prepared states from submitting applications. Given the novelty of these programs, wholesalers and other entities may be unwilling to publicly commit to participation without some assurance that the program will be approved and become operational. Instead, FDA should consider providing conditional approval of SIPs before specific participating entities are identified, followed by final approval when participation agreements are in place.
3. FDA should reconsider overly burdensome requirements of SIPs that are unnecessary to ensure the safety of the program. Although we recognize and appreciate the need to specify alternative requirements when aspects of the Drug Supply Chain Security Act (DSCSA) are being waived to accommodate importation, additional requirements of SIPs should consider the logistical and financial consequences of implementation. Otherwise, there is a significant risk that any savings generated by the SIP would be outweighed by the costs of operating it.
 - a. Geographic limitations on participating entities and functions of the SIP should be removed or relaxed when they are not necessary. Relabeling of drugs should be allowed to occur in Canada if a SIP sponsor determines it would be more efficient to do so. To accommodate this, sampling for statutory testing should be allowed to occur in Canada as well, or it should be permissible to conduct statutory testing in the U.S. following relabeling. The requirement that testing and relabeling in the U.S. occur within 30 miles of the port of entry should also be reconsidered. While we understand the need to maintain the security of imported drugs pending their formal admission, SIP importers should be able to make use of their existing infrastructure, including warehouses, rather than being required to establish new operations in a narrow geographic area.
 - b. SIPs should not be subject to other restrictions beyond those in the existing international drug supply chain unless necessary for safety. In particular, we are concerned that the requirement that a qualifying laboratory have an FDA inspection history could result in insufficient options of laboratory partners for SIPs, given our understanding that the vast majority of otherwise qualified independent laboratories are not currently subject to FDA inspection. We also ask that FDA limit any duplicative or redundant reporting requirements of SIPs, and reconsider the prohibition on including bulk eligible prescription drugs in SIPs.
4. More flexibility should be allowed in the administration of SIPs, in recognition of the significant investment of time and resources necessary to establish them.
 - a. Any state agency should be permitted to act as the lead sponsor of a SIP. Maine's statute requires the Department of Health and Human Services to submit an application for federal approval of a Wholesale Drug Importation Program,

although the Department is not responsible for regulation of pharmacies or wholesale drug distribution. FDA should allow any state agency to act as SIP sponsor, so long as the agency with oversight of pharmacies and wholesalers is a co-sponsor of the SIP.

- b. More discretion should be provided to SIPs in their response to problems. First, sponsors should be permitted to address specific deficiencies when they are identified, and demonstrate the corrective action to FDA, rather than being required to immediately halt importation under the SIP. SIPs should also be permitted to delegate recall monitoring to their contracted foreign sellers and importers, if those entities have prior experience or are better equipped to immediately respond to a recall announcement.
- c. SIPs will require significant infrastructure investments to establish and should not be automatically terminated following the two-year pilot period unless proactively extended by FDA. Instead, FDA should consider a regular recertification process, but presume that SIPs will continue to operate unless they are actively terminated by the sponsor or FDA.

Although it is not addressed in the rule, we also note that the Canadian government's response to the export of prescription drugs to the United States will impact the feasibility of operating a SIP. The State of Maine has a total population of about 1.3 million people, and it is our belief that a SIP could be operated by our State without causing any disruption to the Canadian drug market. We are not equipped, however, to respond to concerns from the Canadian government about the impact of a national pilot program that includes SIPs in other states. For that reason, we request that the Administration work with the Canadian government to address any concerns that could result in legal or regulatory impediments to the exportation of drugs to the U.S., and that those discussions be resolved before states invest resources in establishing SIPs.

Thank you for the opportunity to comment on this rule. We look forward to continued engagement and communication with the Administration as we work to provide Maine people with relief from high drug costs.

Sincerely,

Jeanne M. Lambrew, PhD Commissioner

JML/klv

IX. Appendix B, P.L. 2019, ch. 472, An Act to Increase Access to
Low-cost Prescription Drugs

STATE OF MAINE

—
IN THE YEAR OF OUR LORD
TWO THOUSAND NINETEEN

—
S.P. 392 - L.D. 1272

An Act To Increase Access to Low-cost Prescription Drugs

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 5 MRSA c. 167 is enacted to read:

CHAPTER 167

WHOLESALE PRESCRIPTION DRUG IMPORTATION PROGRAM

§2041. Authorization

The Wholesale Prescription Drug Importation Program, referred to in this chapter as "the program," is established to provide for the wholesale importation of prescription drugs from Canada by or on behalf of the State. The program must be designed in accordance with the requirements of this chapter. The program may not be implemented unless the State obtains approval and certification, pursuant to section 2042, subsection 3, from the United States Department of Health and Human Services.

§2042. Design of program

1. **Design requirements.** The Department of Health and Human Services, in consultation with appropriate federal and other state agencies, other states and interested parties, shall design the program to comply with the applicable requirements of 21 United States Code, Section 384, including requirements regarding safety and cost savings. The program design must:

A. Designate a state agency to become a licensed drug wholesaler or to contract with a licensed drug wholesaler in order to seek federal certification and approval, pursuant to section 2042, subsection 3, to import safe prescription drugs and provide cost savings to consumers in the State;

B. Use prescription drug suppliers in Canada regulated under the laws of Canada or of one or more Canadian provinces, or both;

C. Ensure that only prescription drugs meeting the federal Food and Drug Administration's safety, effectiveness and other standards are imported by or on behalf of the State;

D. Import only those prescription drugs expected to generate substantial cost savings for consumers in the State;

E. Ensure that the program complies with the transaction and tracing requirements of 21 United States Code, Sections 360eee and 360eee-1 to the extent feasible and practical prior to imported prescription drugs coming into the possession of the licensed drug wholesaler and that the program complies fully with those federal requirements after imported prescription drugs are in the possession of the licensed drug wholesaler;

F. Consider whether the program may be developed on a multistate basis through collaboration with other states;

G. Prohibit the distribution, dispensing or sale of imported prescription drugs outside of the State;

H. Recommend a charge per prescription or another method of financing to ensure that the program is adequately funded in a manner that does not jeopardize significant cost savings to consumers, including adequate funding for the initial start-up costs of the program;

I. Apply for and receive funds, grants or contracts from public and private sources; and

J. Include an audit function.

2. **Rules.** The Department of Health and Human Services shall adopt rules to design the program in accordance with the requirements of subsection 1 no later than January 1, 2020. Rules adopted pursuant to this subsection are major substantive rules as defined in chapter 375, subchapter 2-A.

3. **Request for federal approval and certification.** The Department of Health and Human Services shall submit a request for approval and certification of the program to the United States Department of Health and Human Services no later than May 1, 2020.

§2043. Implementation

1. **Implementation; operation.** Upon receipt of federal approval and certification under section 2042, subsection 3, the state agency designated to oversee the program pursuant to this chapter shall implement the program as required in subsection 2. The program must begin operating no later than 6 months following receipt of federal approval and certification.

2. **Requirements.** Prior to operating the program, the state agency designated to oversee the program pursuant to this chapter shall:

A. Become a licensed drug wholesaler or enter into a contract with a licensed drug wholesaler in the State;

- B. Contract with one or more distributors licensed in the State;
- C. Contract with one or more licensed and regulated prescription drug suppliers in Canada;
- D. Consult with health insurance carriers, employers, pharmacies, pharmacists, health care providers and consumers;
- E. Develop a registration process for health insurance carriers, pharmacies and health care providers authorized to prescribe and administer prescription drugs that are willing to participate in the program;
- F. Create a publicly accessible website for listing the prices of prescription drugs to be imported under the program;
- G. Create an outreach and marketing plan to generate public awareness of the program;
- H. Provide a telephone hotline to answer questions and address needs of consumers, employers, health insurance carriers, pharmacies, health care providers and others affected by the program;
- I. Develop a 2-year audit work plan; and
- J. Conduct any other activity determined necessary to successfully implement and operate the program.

§2044. Annual reporting

Beginning January 2021, and annually thereafter, the Department of Health and Human Services, or other state agency designated to oversee the program pursuant to this chapter, shall report to the joint standing committee of the Legislature having jurisdiction over health coverage and prescription drugs regarding the implementation and operation of the program during the previous calendar year, including:

1. **Prescription drugs included.** The prescription drugs included in the program;
2. **Participation.** The number of participating pharmacies, health care providers and health insurance carriers;
3. **Prescriptions dispensed.** The number of prescription drugs dispensed through the program;
4. **Estimated savings.** The estimated cost savings to consumers, health insurance carriers, employers and the State during the previous calendar year and to date;
5. **Audit findings.** Information regarding implementation of the audit work plan and audit findings; and
6. **Other relevant information.** Any other information the Department of Health and Human Services, or other state agency designated to oversee the program pursuant to this chapter, considers relevant.