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State of Maine
Canadian Drug Importation Program

Considerations

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for the
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Table of Contents

Introduction

This report to the Maine Department of Health and Human Services facilitates the next step in the development of a program for the wholesale importation of prescription drugs from Canada pursuant to LD1272 as passed by the legislature and signed into law by the Governor on June 24, 2019. This report presents ideas and options for discussion about the shape and scope of a Maine importation program that will benefit State residents.

The Maine Department of Health and Human Services will convene public meetings to discuss how a program could best be structured to comply with State and Federal law while meeting the needs of healthcare payers, providers and patients.

Federal Law Permitting Importation from Canada

There is a provision of federal law that allows the Secretary of the U.S. Department of Health and Human Services (US DHHS) to permit importation of drugs from Canada. Under Section 804 of the Federal Food Drug and Cosmetic Act (FFDCA)[1], Congress permits a program of wholesale or personal importation of prescription drugs from Canada -- provided the U.S. DHHS Secretary certifies to Congress that implementation of such a program will:

- pose no additional risk to the public's health and safety beyond the current U.S. prescription drug supply chain; and
- result in a significant reduction in the cost of prescription drugs to the American consumer.

Until recently, the US DHHS had only received state proposals for *personal* importation programs and did not approve them.[2] Personal importation is limited to a 90-day supply of a drug received by the person for whom the prescription was written.

On July 31, 2019, the Federal government released its Safe Importation Action Plan and announced its intent to promulgate rules governing prescription drug importation demonstration projects by states, wholesalers, and pharmacists. On December 23, 2019, the US DHHS published proposed rules that lay out the Department's proposed approach by which it would approve state wholesale importation programs. The proposed rule outlines a pathway for states to gain federal approval for limited-duration pilots of wholesale drug importation from Canada. The rules are currently open for public comment through March 9, 2020. The expectation is that the rule will be finalized following the comment period, but exactly when it will become final is not known.

[1] Last amended by Congress in 2003.

[2] While Maine did not submit a proposal to HHS, a Maine law was enacted in 2013 to facilitate personal importation for residents. The State intended to use a company CanaRx (which is still filling U.S. prescriptions). The U.S. pharmaceutical industry, joined by Maine pharmacists, filed suit charging the program was unsafe and illegal under federal law. The federal court agreed with the industry about Maine law running counter to federal law – because the State did not have the requisite federal approval.

Maine is proposing an approach that is consistent with direction of the proposed federal rule – a program of wholesale importation where a state government takes responsibility for assuring safety and cost savings of prescription drugs imported from Canada.

Most people do not realize that more than 70 percent of the U.S. prescription drug supply is already imported, and more than 80 percent of the raw pharmaceutical ingredients are imported for U.S. manufacturing of finished products. Our prescription medications are already part of a safe, efficient, global supply chain. A Maine importation program would use the existing global manufacturing and supply chain system to improve prescription drug affordability.

How a Maine Importation Program Could Work in Brief

In brief, the State of Maine could administer a State wholesale importation program that would make a limited number of high-cost drugs available to Maine consumers. Assuming federal approval, the Maine program would use State-contracted prescription drug wholesalers to import and State-contracted Canadian-licensed pharmaceutical suppliers to export a limited number of high-cost drugs to Maine.[3] The imports would be distributed to Maine pharmacies and other providers, such as hospitals that dispense drugs. The program could take several forms. For example, it could:

- Make drugs available through pharmacies, clinics, hospitals, physicians, nursing homes, and / or any other entity licensed to dispense or administer prescription drugs;
- Be open to all Maine providers, health plans and employer-sponsored plans or be limited to certain payers and/or purchasers;[4]
- Be open to multiple, competing, U.S. wholesalers, U.S. distributors, and Canadian suppliers or a single contracted wholesaler and a single Canadian supplier; and
- Prohibit resale of the imported drugs outside the State of Maine to limit exposure to having to pay Medicaid rebates to other states and to assure ease of recall should that ever be necessary;

For approval by the Secretary, the program would:

- Import Canadian drugs produced in FDA-approved manufacturing facilities;
- Import drugs that are safe and have FDA-approved labeling;
- Use U.S. National Drug Codes (NDCs) to enable provider billing;
- Comply with U.S. rules on electronic tracking of drugs through the U.S. supply chain and capture pedigree information from the Canadian supplier, which would be required via contract;[5]
- Include requirements to ensure that savings from the program benefit consumers;
- Prohibit resale of the imported drugs outside the State of Maine to limit exposure to having to pay Medicaid rebates and to assure ease of recall should that ever be necessary; and
- Be audited to ensure that prices to consumers are low and that safety requirements are being met.

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[3] There may be other options to Maine contracting directly with Canadian-licensed suppliers, such as obligating the Maine-contracted wholesale importer responsible for the Canadian market relationships.

[4] The federal Notice of Proposed Rulemaking (NPRM) for state wholesale prescription drug importation would, if finalized, limit states to contracting with only one Canadian exporter and one U.S. wholesale importer. The proposal is particularly problematic on the Canadian import side due to the potential for drug manufacturers to use contracts to prohibit sales into the U.S.

[5] The federal NPRM suggests a way to comply with U.S. tracking requirements in the context of a state wholesale drug importation program.

The following sections provide greater detail about how an importation program could ensure consumer savings and safety of imported drugs on par with the safety of the current U.S. system. Appendices discuss the interplay of a Maine importation program with Medicaid and 340B government programs, as well as potential implications of federal rules governing the program.

Who Could Participate?

The Choices

- The wholesale importation could be open to all payers and purchasers, which would maximize the number of state residents who would benefit from the program as enrollees of participating payers, patients of participating hospitals or clinics, whether they are insured or uninsured.
- The wholesale importation program could initially include a limited number of payers and purchasers, (e.g., government payers and/or government purchasers, or a different, limited selection of pilot participants).

Question

Are there particular populations who most clearly may benefit from drug importation? Are there scenarios in which importation is most promising for providing relief from high prices?

Question

Can the program be designed to ensure it is viable if a segment rather than all Maine purchasers and providers participate?

- Is there a threshold of payer/provider participation necessary to make it viable for pharmacies and other providers to stock imports alongside US versions of the drugs?
- Are there certain drug classes that make pharmacy dual stocking less burdensome/more feasible?

Question

If the Department phases-in the program by phasing in payer and/or provider participation, what should be the criteria to determine when different entities would be included?

Assuring Cost Savings

Selecting Drugs to Source from Canada

The first task to determine the feasibility of an importation program is to identify high cost drugs and the potential savings for the people of Maine.

This could be done by DHHS or through a data collection process. For example, Maine officials could create a standing group of insurers, hospitals and other large purchasers to decide which drugs to import based on which drugs will save the most money.
Identifying the drug importation candidates could be done by:

- Collecting lists of top-spend drugs from large purchasers and all payers, where net top-spend drugs are calculated after all price concessions have been applied.[6] [7]
- The National Academy for State Health Policy (NASHP) has offered technical assistance to support analysis that identifies the drugs common to all submitted lists and then provide information on the Canadian public program prices for those drugs that are in common.
- That analysis would be returned to each payer and large purchaser so each can assess whether there are enough potential savings to a drug on that combined list for it to remain on the list.
- The final proposed list would result from the second payer/purchaser analysis.

The list of drugs to be imported would most likely need to be revised over time.

- NOTE that Federal law at this time does not permit the importation of biologics, narcotics, IV or infused drugs, and drugs inhaled during surgery. Insulin is considered a biologic as of January 2020. These drugs should not be part of the top spend exercise.
- Medicaid can be part of this process and their net cost calculation should *only* count the rebate amount the state retains for each drug based on State Medicaid matching percentage.[8]

Question

How many top-spend drugs should each payer or purchaser include in their analysis in order to arrive a common list of savings-generating drugs? How many drugs should be included in the common list developed through this process?

Question

How often would the cost savings need to be re-evaluated in order to ensure that the imported drug remains the least costly for consumers, and what entity should be responsible for conducting that evaluation?

Question

How would the program address the need for continuity and reliability of the imported supply?

Question

Should the lists include generic drugs? It may be less complex to import generics than brands because generics have a business model that is different than brands. Some generics and off-patent brands remain expensive in the U.S.

Question

Should payers and purchasers compare US and Canadian prices to select drugs for importation with largest differential prices, or should they select drugs that have the largest total savings by including the

[6] Using data from the State All Payer Claims Database is an option, however, the APCD system captures pharmacy claims but not payer net costs. Payer and large purchaser analysis would still be needed.

[7] There is no need for participants to submit proprietary gross or net spending for this exercise. The submission of the list of drugs is based on each entity's determination of high cost drugs using a common methodology and time period.

[8] Maine Medicaid retains no more than 36.31% of paid rebates for drugs because the federal government pays 63.69 percent of Maine's Medicaid spending and that is the amount Maine returns to the federal government from manufacturer rebates.

calculation of how many prescriptions for the drug would be written/filled multiplied by the unit savings?

Question

Should the analysis assume an increase in the Canadian unit price by some percentage to account for Maine's program administrative costs and profits along the supply chain? NASHP has used 45 percent in their work with other states. Is there feedback about whether that markup would be sufficient or excessive?

Question

Is there value in approximating the savings that might be available through participation in an importation program by comparing what the state employee pharmacy benefit spends now relative to what it would spend if Canadian drugs were used in its programs? Is there another way to assess cost savings?

Question

Would there be implications for pharmacy-wholesaler contracts by importing a limited set of medications? If so, how could any negative impact be addressed by the State?

Managing Supply Chain Price Mark-ups:

Beyond identifying the drugs that have the potential for significant savings to payers, the importation program will need to assure cost *savings to consumers.* This is an important part of the program design since there are multiple steps in the supply chain before drugs reach consumers and prices are generally raised at each point in the supply chain to generate revenues. Achieving consumer savings is also one of the two key program requirements listed in federal law. The Maine program needs to be confident that price mark-ups along the supply chain will be measured/reasonable. The goal would to eliminate the possibility of shadow-pricing or price gouging.

Question

How should Maine ensure that savings from imports reach consumers?

Option:

Make sure the import price is widely, publicly, available so consumers, payers and purchasers know what they should be charged.

Option:

Specify the amount of mark up along the supply chain together with widely available public information about the import price.

Option:

Each payer establishes the upper payment limit for each import, so claims are paid at that amount. Each payer establishes provider network requirements for charges and billing of imported products. Each payer excludes from its network providers who will not purchase and dispense imported products. Claims payment system management and provider network requirements are a routine activity of health plans and should not create new or exceptional costs – particularly relative to total expected pharmacy benefit savings. Payers may need to compensate for reduced margins among purchasers by increasing professional fees.

Question

How should 340B entities and drugs be handled? 340B hospitals are required under federal rules to purchase all their drug product from one 340B supplier. Even though it is not clear that the 340B rule would apply to non-U.S. products, these hospitals may need to continue to purchase the U.S. product depending on how federal law is interpreted.

Option:

Allow 340B entities to continue to use the U.S. 340B supply chain and products but require them to bill participating payers for reimbursement not to exceed the imported price.

Option:

Allow 340B entities to continue to use the U.S. 340B supply chain and products and bill all payers (importation participants and others) at the market price as they do now.[9]

Question

How would pharmacies be reimbursed by health plans? Health plan/pharmacy benefit manager pharmacy drug reimbursement methods vary. Often pharmacies are reimbursed for a filled prescription based on a national average of pharmacy costs for a drug, which can be much more than actual costs for large national chain pharmacies and much less than actual costs of small chains or independent pharmacies.

Option:

Require participating payers to reimburse pharmacies at least actual acquisition cost for prescriptions filled with imported medication. It should not be necessary to rely on national average drug prices or national average pharmacy purchase costs for reimbursement of imported medications because the cost of a Maine import will be public, and the cost of the product through the Maine supply chain to the pharmacy should not vary much, if at all. As result, the pharmacy actual acquisition cost will be known. Health plan payment systems can be updated if and when the price of the import changes, which would also be public.

Option:

Leave pharmacy reimbursement for imports at the discretion of health plans.

Question

What data can be produced to demonstrate consumer cost savings?

Option:

Maine's insurers could align their drug benefit design to import costs. Consumers in their deductible period would pay only up to the allowed amount based on import costs and co-insurance would be based on the import cost, rather than a U.S. list price.

Option:

Maine payers could submit data to the Department of Insurance showing any savings on import dispensing costs relative to dispensing the U.S. product. Payers may also be able to show impact on premiums (price increases in absence of import program).

Option:

Large purchasers could provide data on savings from imports relative to prior net costs or current market prices, with an explanation of how savings were passed through to enrollees.

[9] There is some nuance about who can bill what to whom, particularly pertaining to Medicaid/MaineCare. More detail on 340B is found in the appendices.

Assuring Safety

Overall Import Program Administration

Efficient and effective administration of an importation program will be key to assuring safety. Maine has several options for administering the overall program. Different State agencies and offices could have specific program oversight roles including the Department of Health and Human Services, Bureau of Insurance, International Trade Center, and the Board of Pharmacy. Those oversight roles would be directly related to the administrative functions of the agency or office. For example, the Board of Pharmacy currently licenses pharmacies, drug wholesalers, and manufacturers among others, the Insurance Department licenses and regulates health insurers.

The administrative functions needed will vary depending on the scope of the program Maine pursues. The functions that may be needed include:

- Ensuring compliance with program rules by wholesalers, pharmacies and other certain healthcare providers;
- Oversight of participating health plans/payers in their oversight of provider networks and formulary benefit design that reflects coverage of imported medicines;
- Oversight of the import product testing for purity and potency; and
- Auditing the safety and cost savings of the overall importation program.

Additionally, careful consideration of program funding will be needed. Here again, there are several choices to consider and some funding options are discussed below.

Licensing, Participation, Inspection/Auditing

Maine State government could either operate the physical importation, storage, and distribution of imported drugs directly, or contract with one or more state-licensed wholesalers who would be responsible for ordering and importing drugs from one or more licensed suppliers in Canada. Maine could contract with Canadian suppliers directly or have the Maine wholesale importer establish business relationships with Canadian exporting entities approved by the State. Program requirements would be met via contracts. This section discusses how Maine might approach establishment and oversight of U.S. wholesale importer(s) and Canadian supplier(s)/exporter(s).

The U.S. Wholesale Importer(s) of Canadian Product

The U.S. entity or entities that import drugs from Canada to Maine could be licensed in one of several ways. The State of Maine, Board of Pharmacy could:

- Use its existing Board of Pharmacy licenses: pharmacist, pharmacy, mail order pharmacy, wholesaler and manufacturer (which may be useful if Maine pursues import of generics). These licenses could be amended to address any needed requirements of the importation program; or
- Create a new, specific prescription drug wholesale importer license that has additional licensure requirements for testing of imports, responsibility to see that imported Canadian product is re-labeled to meet FDA rules, and limiting distribution and sales to businesses located in Maine, among other potential new requirements; and
- Establish sub-categories of licenses for some third-party contract service providers who would have limited program roles such as receiving, warehousing, forwarding drugs, but who do not take ownership of a drug like a supplier or wholesaler.

Under the program, the importing wholesaler would be required to be registered with the FDA as a U.S.-licensed wholesaler, but the entity would have new obligations and requirements as an importer for Maine.[10]

Question

How could Maine incentivize a wholesaler to participate in the program?

Question

Should the state consider acting as a wholesaler itself? If so, what would be the risks and costs associated with creating a new division of state government with the capacity to meet wholesaler requirements?

Question

How would existing or planned Verified-Accredited Wholesale Distributor (VAWD) accreditation requirements impact the ability of Maine-licensed wholesalers to participate in the importation program? If the wholesaler entity is not VAWD accredited, will that limit the ability of some pharmacies to participate because of health plan requirements that the pharmacy is only supplied by a VAWD wholesaler?

The Canadian Exporter/Supplier of Canadian Product to Maine

The State could manage the Canadian supplier or suppliers[11] through the Board of Pharmacy, Department of Health and Human Services or another State agency or department.
Maine may:

- Require that a Canadian licensed Canadian supplier/wholesaler meet Maine wholesaler or pharmacy licensure requirements and use contracts to manage specific obligations for participation in the import program,[12] or
- Place responsibility for Canadian supplier compliance with the Maine wholesale importer and stipulate Canadian supplier requirements in the Maine importer contract.

The Canadian Exporter/Supplier would have to register with FDA as Foreign Prescription Drug Seller and identify the name and place of business of its establishment and the name of its U.S. Agent (21 U.S.C 384(f)).

[10] States with importation laws like Maine's law have found that U.S. wholesalers have not yet shown much interest in the program. Low interest in the program could be due to the fact that until approved by the federal government, these programs are not legal. Additionally, there is risk of engendering pharmaceutical manufacturer ire even before a program is officially approved.

[11] The federal NPRM proposes that states have only one Canadian wholesaler/supplier/exporter which is the entity that purchases product *directly* from the manufacturer. This could be highly problematic if finalized as proposed because it is not certain that a manufacturer would sell to a Canadian company that intended to export the product to a state in the U.S. These are policy questions as well as legal questions that will have to be addressed.

Maine Providers That Administer or Dispense Prescription Drugs

For Maine pharmacies, physicians, hospitals, clinics, nursing homes and other state-licensed entities that want to participate in the importation program, the State Board of Pharmacy or other agency may want to establish participation obligations such as limiting billing and charge amounts based on Canadian price or limiting mark-up, and barring sales to entities or people not present in Maine for example.

Question

What is the best to method by which to formalize conditions of participation agreements to different entities participating in the importation program?

Option:

The State has direct conditions of participation agreements with each participating entity;

Option:

Health plans and hospital systems use *their* provider network agreements to stipulate importation program obligations that are established by the State;

Option:

Use some combination of the first two options depending on the type of participating entity.

The cost of ensuring that participating entities are aware of, and have agreed to, conditions of participation will depend how Maine chooses to oversee their participation. Executing participation agreements through health plan and hospital system provider agreements may be less costly than State agreements with individual entities.

Inspection/Audit of Participating Entities

Maine may want to have (and the final federal rules may require) an inspection/audit procedure of entities obtaining and maintaining wholesale importer or Canadian Rx drug supplier/importer licenses and contracts. This audit might be more frequent than the regular State Board of Pharmacy licensee review activity and it may have additional audit content. This work could be done by the Board of Pharmacy, other state agency or an accredited third party. The audits and other administrative costs could be funded through licensing fees.

Sourcing of Rx Drugs in Canada

Which drugs will be imported is a key aspect of a Maine importation program – both in terms of cost savings (discussed above) and in terms of safety (discussed here).

Drugs that can be imported in a federally approved wholesale program are:

- The same chemical formulation as the FDA-licensed U.S. product;
- Manufactured by a facility that is FDA-registered;[13]
- Exported and/or shipped to the U.S. by the licensed Canadian Rx Drug Supplier;

[13] FDA registers and inspects manufacturing facilities all over the world and has reciprocity agreements with many countries to accept manufacturing site inspection results. U.S. manufacturers must specify where a drug will be manufactured as part of their FDA drug approval application. For each drug to be imported, Maine can request information from the manufacturer or FDA about the approved manufacturing site for the drug.

- Exported directly to the Maine-licensed drug wholesale importer (pending requisite approval by the U.S. Customs and Border Patrol (as happens now when manufacturer-sponsored drugs enter the U.S.);
- **NOT** "donated or otherwise supplied at no charge by the manufacturer of the drug to a charitable or humanitarian organization including the United Nations and affiliates) or to a government of a foreign country" 21 U.S.C 384(i); and
- **NOT** drugs for which importation is prohibited by federal law --biologics, narcotics, infused and IV drugs, and drugs inhaled during surgery. (21 U.S.C 384(a)(3)).

Some drug manufacturers may work to impede a Maine importation program and restrict those Canadian wholesalers who buy direct from the manufacturer from selling to the United States. Thus, Maine may prefer to rely on a Canadian wholesaler who is the "second owner" of the drug. So, the Canadian supplier that sells to Maine has purchased the drug from another Canadian licensed, regulated wholesaler that purchased direct from the manufacturer. This may add some cost to the unit price of imported drugs and will have to be factored into calculations of how much savings an imported product will generate.

Importantly the federal NPRM has proposed that state importation programs have a "short" supply chain: one Canadian exporter that purchases directly the manufacturers of all the products Maine would import and one U.S. wholesaler that imports the product. The NPRM solicits comments on the implications of a short supply chain, so hopefully there is an opportunity to allow the idea of a "second purchaser" as part of the export supply chain.

Repackaging/relabeling of drugs

A Maine prescription drug importation program will need to repack and relabel Canadian product to meet U.S. FDA requirements for how the drug is labeled. This process of relabeling and repacking is common in the industry – for drugs shipped to the U.S. by a manufacturer from its manufacturing site outside the U.S., and in the U.S. as drugs go from large wholesaler bulk packaging to pharmacies, hospitals and nursing homes. Repackers/relabelers are registered with and regulated by the FDA. Once labeled for the U.S. market, under a program approved by the FDA, Maine's drug imports would be FDA-approved drugs.

Every U.S.-approved drug has a National Drug Code (NDC), the first digits of the code identify "manufacturer", which can be the original manufacturer, a repackager/relabeler, or a private label. Private label is the company that owns the drug and markets/sells it without being the manufacturer of the drug.

The rest of the NDC provides information about the specific drug product name, strength, dosage form and package size. So, while the chemical information, dosage form and strength of an NDC will not change, the "manufacturer", as well as the package size aspects of the NDC can change as the drug moves through the supply chain. Maine has choices to make about this part of the importation process.

Question

What entity should be the manufacturer of record in the National Drug Code (NDC) assigned to Maine imported medicines?

The federal NPRM suggests that the repackager/relabeler or the wholesaler will request the NDC. What may be important is that the "labeler" part of the NDC (the first 5 digits of the NDC) be unique to the Maine import program for a variety of reasons (as distinct from using the US importing wholesaler's labeler number). Having a distinct NDC that identifies the Maine import program in some way would help the state and its wholesaler track the drug if product leaves the state. It would help in the event of recall and it should be of help in terms of issues related to Medicaid/MaineCare rebates.[14] A distinct private label for all the Maine import products could facilitate patient choice of the U.S. product if patients do not want to be treated with an imported product.

Question

When and where should repacking/relabeling occur?[15]

U.S. Option:

Imports are repacked/relabeled by an FDA-registered U.S. repackagers/relabelers once in the U.S. (This may be the only option permitted under final federal rules for the program.) Maine will have to decide whether to state-license this entity, contract with this entity, or obligate the Maine wholesale importer to contract with this entity.

Canadian Option:

Imports repacked/relabeled by an FDA-registered, Canadian-regulated laboratory that meets international laboratory standards. This would be done prior to export to the U.S. If permitted to do so by the US DHHS, Maine should explore whether these FDA-registered entities should/could also be Maine-licensed.

Border Transactions, Shipment of Drugs from Canada to Maine

Certain operations will be performed by the U.S. government as Maine's imported drugs cross the border from Canada. The U.S. Customs and Border Patrol is generally responsible for verifying the proper importation of drugs and verifies with the FDA data accompanying the shipment prior to releasing the shipment into the U.S. The Customs process is a generally a paper review – there is generally no testing of imported drugs at the border today because the product comes from an importer under contract to the actual manufacturer. The documentation is either complete and accurate, or it is not.

There is a U.S. Customs data system that verifies the import drug shipment product code, assigns an FDA compliance code, certifies the FDA status of Maine wholesale importer, and verifies the FDA registration of the Canadian exporter. Imports without proper documentation are seized upon entry into the U.S

[14] The intersection with the Medicaid rebate program with importation will have to be discussed with the federal Department of Health and Human Services.

[15] The U.S. DHHS has proposed that testing as well as repackaging/relabeling occur by U.S. companies at facilities near a single Customs and Border Control site where Maine's imports would enter the country. It is not clear that there are facilities, or enough facilities, near a CBP border site to comply with this requirement.as more states develop importation programs.

The U.S. DHHS has proposed that it will assign one U.S. Border Customs Office to each wholesale importation program it approves. A Maine program would be assigned one port of entry through which all its imports would pass.

Health Canada has data requirements for Canadian manufacturers, shippers, and pharmaceutical importers. The Canadian supplier/exporter to the U.S. will provide documentation of "pedigree", which is the history of ownership and handling of the drug along the supply chain from the point of origin/point of manufacture. Pedigree tracking and documentation is routine in both Canada and the U.S. It appears that the Canadian and U.S. pedigree tracking data systems are similar which could simplify data exchange across systems.

The documentation that accompanies imported shipments – including any codes assigned in the Customs review process, will be available to Maine and will accompany the import shipments through the Maine in-state distribution to pharmacies, hospitals, etc.

Maine may want to make the U.S. wholesale importer responsible for proper execution of federally required batch testing of the imported product. The testing assures purity and potency of the product. Alternately, Maine could contract directly (without going through the importer/wholesaler) for batch testing of imports.

It may be helpful to know that in the U.S., as part of the repackaging process, drugs are routinely tested to verify the potency (to validate expiration date) as part of their repackaging process. This testing will have to be done by a licensed, qualified laboratory. Laboratory qualifications are part of the federal NPRM.

The relabeling and repackaging will add costs to the importation program. In the U.S. today, the cost of the repackaging and relabeling is incorporated into the product price as it moves to the next part of the supply chain.

Distribution of Drugs in Maine

If Maine implements the program statewide, the supply and distribution chains in the Maine importation program would look much like every other prescription drug supply chain in Maine or the U.S. generally. Wholesale distribution of prescription drugs is governed by the federal Drug Supply Chain Security Act of 2013 ("DSCSA") and Maine imports will be part of that system.

The DSCSA requires that all parties in the prescription drug distribution chain doing business in the U.S. (drug manufacturers, wholesale distributors, repackagers/relabelers, and pharmacies for example) hold various registrations, licenses or permits from each State authority. Each must maintain certain records establishing a pedigree/ownership history for each lot of drug received, stored and distributed.

The Maine program supply chain participants would incorporate existing track-and-trace technology, pedigree requirements under DSCSA and state laws, to reduce the risk of an unapproved drug from slipping into the supply chain and ensuring the imported prescription drug was handled properly to ensure its safety and efficacy.

While not expected, a process for managing product recalls can be a point of discussion between the State and the U.S. wholesale importer. There is a U.S. system in place to handle the physical aspects of U.S. drug product recalls that can be adapted for the importation program. Compensating purchasers for recalled product would be a separate issue for Maine to consider. This compensation for recalled product could be part of a contract negotiation with the Canadian suppliers.

The Board of Pharmacy may want to ensure that insurers or pharmacy benefit managers cannot create pharmacy network participation requirements that exceed the state requirements and regulations. An example of this was mentioned previously, where an insurer or its pharmacy management company stipulates that its network pharmacies purchase from particular wholesalers with VAWD accreditation. Requirements like this could undermine the Maine importation program if the excess requirements would not have the practical effect of limiting pharmacy or wholesaler participation in the Maine importation program.

Appendix A

The 340B Program

The federal 340B program requires drug manufacturers to sell all their prescription drugs at deeply discounted prices to thousands of safety-net medical providers. The discounts are generally equal to Medicaid prices after federally required rebates. 340B entities can only use program medicines for people treated in outpatient clinics and their associated pharmacies. There are 650 340B drug program participants registered in Maine; many of these are specific outpatient clinics associated with 340B hospitals.

In general, 340B entities generate revenue on each 340B drug dispensed because they bill payers and insured patients at the general U.S. market price while their acquisition cost for the drug is low.

A Maine importation program that includes 340B entities should only minimally impact the prescription drug revenue of 340B entities. The actual impact will depend on the amount of participation by health plans and the number of drugs that would be imported. Participating health plans may insist that if there is an imported product, they will not pay more than the imported price regardless of whether the import was dispensed or the U.S. version in the 340B program. Such a payment policy will reduce the 340B revenues on that drug.

U.S. hospitals have raised significant revenue from the 340B program. It has been estimated that the volume of drugs in the program is about $24 billion, up from $16 billion several years ago.

Appendix B

MaineCare and the Drug Rebate Program

The MaineCare program will have to evaluate whether to participate in the importation program – paying for all, some, or none of the imported drugs. This analysis is needed because Medicaid gets at least a 15 percent rebate on all brand drugs and 13 percent rebate on all generic drugs (of which the State retains ~36 percent of the actual dollar amount of the rebate). Medicaid would not be able to bill U.S. manufacturers for rebates of imported products because they are not products of U.S. manufacturers.

If Medicaid does not participate, outpatient providers will have to carry the U.S. and the Canadian version of each imported project, which may not be a large burden, since many pharmacies may be familiar with dual stocking from participation in the 340B program. Dual stocking was a common feature of the program in years past. The burden on outpatient pharmacies will depend on the volume of an import that has to be stocked and the number of different imports.

However, the State Medicaid program should do a careful analysis before deciding whether to participate. The calculation gets more complex if a brand manufacturer has offered a price concession in the private market that exceeds the basic 23 percent Medicaid rebate amount. That deep price concession is called the Medicaid 'best price.'[16]

The other point to consider is that if Medicaid participated in the importation program, its up-front outlay for pharmacy claims would be reduced for imported outpatient drugs because pharmacies will be paying less and billing less for imports, which could be an important factor to consider since Medicaid rebates are paid quite a bit it has reimbursed the pharmacy for the prescription.

It should be noted that in the Canadian system, older patented drugs tend to become less costly over time (due to Canadian price reporting and calculation of the federal ceiling rate) whereas they become more costly in the U.S. This may mean that the Canadian price may still be competitive to the Medicaid rebate on older drugs where the Medicaid rebates grow large.

If Medicaid were to participate and pay for imports rather than the U.S. drug, it could still 'cover' the U.S. version/U.S. NDC, so it is not 'excluding' the drug from Medicaid coverage (a violation of federal Medicaid law). The Medicaid claims payment system would still accept and pay on the U.S. manufacturer NDC if it was dispensed. Structured in this way, no waiver should be needed for Medicaid to participate in the import program. In fact, Medicaid and other payers will need to retain the U.S. manufacture NDC for the drug in claims payment systems because an insured resident may be out of state and need a drug.

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[16] As an example: Using a $100 drug, if the best price of the drug is 25 percent of the drug cost, the total rebate is $25. Because the best price exceeds the federal minimum rebate of 23 percent, the federal government gets all of 8 percent all of the rebate or $8 and the State splits the remaining $17 with the federal government based on 64/36 percent federal matching formula, so an additional $10.88 goes to the federal government and $6.12 is retained by the State. Of the $25 rebate, Maine gets $6.12 and the federal government gets $18.88. The inflation penalty rebate is shared at the 64%/34% matching rate. MaineCare should run an analysis of its actual net costs of the specific drugs that may be imported to understand whether it would be financially ahead or financially behind reimbursing pharmacies at the import price and forgoing billing a US manufacturer for rebates on the U.S. price. The result of the calculation will likely vary drug by drug.

Appendix C

Key Issues in the Federal Notice of Proposed Rulemaking (NPRM)

Several aspects of the federal proposed rule would have significant implications for Maine's program design and the feasibility of implementing the program. Some of the most significant issues are summarized below, although the State will also submit comments to the federal government which may outline concerns about other aspects of the NPRM.

Short supply chain -- Exporter

Would limit the state program importation supply chain to one Canadian supplier that purchases drugs for Maine directly from the manufacturer ("first purchaser"). Pharmaceutical manufacturers may refuse to sell to any Canadian entity that intends to export product to the U.S. It seems more likely that allowing a "second purchaser" to be part of the Canadian supply chain would improve the chances that manufacturers could not stymie the program. All the requirements of participation and pedigree tracking would remain the same for both the first and second Canadian purchasers/suppliers.

The federal law has significant penalties on manufacturers for failure to provide data to the exporter and importer that are needed to comply with federal laws. However, it is not clear that the manufacturer obligations extend to being able to purchase product for sale into the U.S. Instead the requirements seem to apply after the Canadian exporter has purchased the product from the manufacturer. This would seem to leave a gap that may be addressed by allowing another Canadian supplier in the supply chain.

Short Supply Chain – Importer

The NPRM would limit the state to one wholesale importer. There are some states that would consider adding market competition to the state import supply as a way of providing that import prices are passed through the supply chain to the consumer. Multiple wholesale importers may be beneficial in larger states. Such a system would still need a regulatory backup to assure consumers are seeing significant cost savings.

Federal Approval Timeline

The NPRM does not mention that the FDA would subject itself to a turnaround time limit for approval of the initial state importation program approval request.

The NPRM would require a state to have in its initial approval request:

- The list of drugs to be imported
- The expected cost savings
- A named Canadian supplier with all the requisite information about the entity
- A named U.S. wholesale importer with all the requisite information about the entity

The problem could be that the list of drugs to be imported might change in the time between when the approval document is developed and when the US DHHS approves it. How long the US DHHS might need for approval is not mentioned in the NPRM.

Additionally, it may be difficult to sign a contract with an exporter and an importer for a program that still must be approved. Those entities may not remain committed depending on how long the approval process takes.

Finally, the proposed rule contemplates approving programs for 2-year increments, which must be proactively extended by the FDA to prevent termination of the program.

Manufacturer Compliance

The rules (and the law) require manufacturers to provide documentation to support testing and pedigree tracking to the importation supply chain. The NPRM anticipates that manufacturers may try not to comply, or delay compliance to a degree that FDA would provide needed information if that information is in its possession.

Location of Testing and Repackaging

As mentioned in earlier in the document, the US DHHS proposed rules would require that testing for potency and purity would have to be done in the US, while the product is held in warehouses near US Customs and Border Patrol locations. This could limit importation feasibility if there are not a sufficient number of warehouse and testing lab services proximate to the US Customs locations. It is also potentially inefficient to have the testing conducted in the US if the shipment needs to be returned to Canada and the State's importer has already taken ownership of the product.

Ability of the Proposed Rule to Sustain Legal Challenge

The proposed rule specifies that if any part of the rule is found to be illegal by the courts, then the entire rule will be deemed to be illegal. If that were to happen, state wholesale importation programs may not have a strong basis for operation. The provision seems particularly draconian, particularly if only a relatively minor aspect of the rule is found to be illegal, such as the testing laboratory accreditation standards.