Application for Section 804 Importation Program

New Hampshire Department of Health and Human Services

April 21, 2021

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Name of the Program:	New Hampshire Prescription Drug Importation Program
Importation Program Sponsor:	The New Hampshire Department of Health and Human Services (DHHS) Address: 129 Pleasant Street, Concord, NH 03301
Responsible Individuals:	Interim Margaret A. Clifford, RPh Margaret.a.Clifford@dhhs.nh.gov (603) 271- 9098 129 Pleasant Street, Concord, NH 03301
Name and Address of Foreign Seller (must include a copy of their license to operate in Canada)**:**	To be determined.
Name and Address of Importer:	To be determined.
Name and Address of the FDA-Registered Relabeler (must include inspection history)	To be determined.

EXECUTIVE SUMMARY

Under the Federal Food Drug and Cosmetic Act (FDCA) Section 804, Congress permits importation and reimportation of prescription drugs[1] from Canada by a pharmacist or wholesaler, provided the drugs meet certain minimum standards and the Secretary of Health and Human Services (HHS) certifies to Congress that implementation of such a program will (A) pose no additional risk to the public's health and safety; and (B) result in a significant reduction in the cost of covered products to the American consumer. *See* 21 U.S.C. 384.

This provision is specifically designed to promote importation of drugs to make them available at lower cost to American citizens while not increasing the risks to health and safety that do not already exist within the current drug supply. If the Secretary so certifies, the law directs HHS to promulgate regulations as necessary to implement the program. On December 23, 2019, the United States Food and Drug Administration (FDA) published a Notice of Proposed Rulemaking (NPRM) for the Importation of Prescription Drugs. The final rule was posted in the Federal Register on October 1, 2020 and goes into effect on November 30, 2020. This application is filed with the Secretary of HHS in accordance with the New Hampshire Legislature's passage of House Bill 1280-FN of the 2020 legislative session.

House Bill 1280-FN of 2020, *An act establishing a wholesale prescription drug importation program,* required the Department of Human and Human Services (DHHS) to establish a wholesale importation program for prescription drugs from Canada. New Hampshire DHHS has designed an application request that we believe meets the conditions for federal approval by the Food and Drug Administration, and will produce savings to the citizens of NH. The savings are estimated to be in the range of $7 million - $22.3 million per year.

The State of New Hampshire submits this application for a Section 804 Importation Program (SIP) consistent with the final rule.

[1] "Prescription Drug" is defined in 21 U.S.C. § 384(a)(3).

SECTION 804 IMPORTATION PROGRAM (SIP) DESIGN

New Hampshire House Bill 1280-FN of 2020, requires that NH DHHS establish a wholesale importation program for prescription drugs from Canada and seek approval from the Secretary of the U.S. Department of Health and Human Services. The implementation and administration of a wholesale prescription drug importation program shall comply with the applicable requirements of 21 U.S.C. § 384, including the requirements regarding safety and cost savings. As such, DHHS is the Section 804 Importation Program (SIP) Sponsor and will be the entity responsible for the importation of FDA-approved drugs from Canada to the State of New Hampshire.

New Hampshire's proposed SIP is aimed at reducing costs for consumers served by commercial health plans in the state, with the possibility of phasing in public payers after the launch of the program. This approach was selected following cost-savings analyses for New Hampshire which indicated the most significant savings for consumers would be garnered for those served by commercial plans, with conservative estimates putting savings in the range of $7 million to $22.3 million per year. Please see, "Savings to Consumers" on page 17. The minimum characteristics for selecting qualifying drugs for importation are: they must reach a broad New Hampshire patient population, be likely to generate significant savings to consumers and commercial payers and pose no additional risk to the public's health and safety compared to domestically sourced prescription drugs.

As of this application, the Division of Medicaid Services (DMS), within NH DHHS, determined that drug importation from Canada would not provide savings to the state's Medicaid program, at least during the early stages of implementation, because the existing Medicaid prescription drug rebate program already yields substantial savings. There would also be minimal benefit to Medicaid members as their copays are limited to $1 and $2 dollars, and a significant number of Medicaid members do not have copays. However, DMS believes there may be a small number of specific drugs that may yield cost-savings through Canadian importation for a limited period-of-time. Though such drugs may be phased into New Hampshire's importation program at a later time, it is not envisioned Medicaid would be part of the importation program upon its launch. NH Department of Administrative Services (DAS) also determined that drug importation from Canada would not provide savings to the New Hampshire State Employees

Prescription Drug Plan because their existing drug rebate program yields substantial savings.

Payers that meet federal eligibility requirements for the 340B Drug Discount Program, similar to Medicaid, are not likely to see savings from Canadian importation because 340B drug pricing is so low. The State of New Hampshire is committed to the importation program operating independently without impacting the 340B program, while importation would create a new pathway to increase drug affordability for consumers not served by Medicaid, the State Employees Prescription Drug Plan or 340B programs.

In addition to the necessary oversight of Foreign Sellers and Prescription Drug Importer-Wholesalers, the NH DHHS will be responsible for the development and ongoing maintenance of the list of drugs that would be eligible for importation. This activity will necessarily be in concert with participating commercial health plans as the list of drugs will be influenced by price and utilization patterns for plan members. Any interested commercial health plan is invited to participate, so long as the plan agrees to the conditions for guaranteeing savings from imported drugs to New Hampshire consumers. The NH DHHS will also oversee all vendors in the supply chain as well as any additional vendors deemed necessary for management or oversight of the program.

Should this application be approved, New Hampshire's Office of Professional Licensure and Certification (OPLC) will create two new categories of licenses under general authority to license wholesalers. The OPLC's Board of Pharmacy may issue wholesale-distributor-exporter and wholesale-distributor- importer licenses to drug outlets that comply with federal, state, and Board requirements to import prescription drugs through a program approved by the Secretary of Human Services.

Licensed Importers will contract with pharmacy providers, including brick and mortar and/or mail-order pharmacies that want and agree to stock drugs imported from Canada.

GUARANTEEING PUBLIC HEALTH AND SAFETY

New Hampshire's proposed SIP would operate under both Federal FDCA Section 804 requirements and existing FDCA requirements to ensure no additional risk to health and safety. Drugs imported under the SIP would be subject to all U.S. laws that apply to prescription drugs marketed in the U.S. related to their approval, formulation, manufacturing, packaging, labeling, importation, and distribution, as well as additional FDCA section 804 requirements (such as testing by qualified labs for authenticity and degradation). FDCA section 804 and the supplemental oversight by the New Hampshire DHHS and OPLC adds additional layers of public health protection to ensure that the qualifying prescription drugs imported under New Hampshire's SIP pose no additional risk to the public's health and safety. The only FDCA provision with which prescription drugs imported under New Hampshire's Program *do not* have to comply is FDCA section 801(d)(1), which ordinarily prohibits reimportation of prescription drugs by anyone other than the manufacturer and importation of foreign-made prescription drugs by anyone without the authorization of the manufacturer. Prescription drugs imported in accordance with FDCA section 804 are expressly exempt from FDCA 801(d)(1).

Qualifying prescription drugs imported under New Hampshire's Program must be the same as the drug originally intended for the U.S. market with respect to key factors such as active pharmaceutical ingredient (API), strength, purity, and route of administration. Further, such drugs must be made in the FDA-approved facility and must have been initially purchased from either the FDA- approved manufacturer or from their authorized distributor (or foreign equivalent).

Any differences in the original packaging and labeling of a drug obtained from Canada compared to U.S. marketed product will be addressed under New Hampshire's Program by duly FDA-registered, licensed, and regulated repackagers and/or relabelers, as currently permitted by the FDCA and FDA regulations. Statutory required testing, repacking and relabeling of qualifying prescription drugs under New Hampshire's Program shall be performed after importation of the drugs into the U.S. (in an authorized foreign trade zone), to ensure no misbranded or unapproved drugs enter the U.S. under New Hampshire's SIP.

The repackager and/or relabeler proposed here would be regulated by all requirements as defined in the FDCA and the FDA Current Good Manufacturing Practices (cGMP) regulations as well as applicable provisions of the Drug Supply Chain Security Act (DSCSA). In compliance with the final rule, all testing results will be subject to review and acceptance by the FDA and drugs shall be relabeled consistent with FDA approved labeling before the drugs can be distributed in New Hampshire.

The Drug Supply Chain Security Act (DSCSA), which was enacted in 2013, addresses and resolves many of the concerns about importing drugs from Canada that existed when FDCA section 804 was enacted in 2003. Compliance with FDCA registration and listing requirements, and the DSCSA under New Hampshire's SIP, particularly when in combination with the additional FDCA section 804 protections discussed below, will ensure the accountability of the supply chain back to the FDA-approved manufacturer or its authorized distributor.

Under the FDCA (including the DSCSA), all parties in the prescription drug distribution chain – drug manufacturers, Canadian Foreign Sellers, repackagers, relabelers, Importers' third-party logistics providers, and dispensers (pharmacies for the most part), whether foreign or domestic – must hold various registrations, licenses, and/or permits from appropriate federal and/or state authorities, and must maintain certain records establishing a pedigree, ownership, and distribution history for each lot of prescription drug sold, purchased, received, stored, and distributed. All federally required FDA-registrations and drug listings (connecting relevant National Drug Code (NDC) numbers) will be required for New Hampshire's SIP. Note that the NDC declared on the drug label need not be that of the repackager or relabeler, but may be a Private Label Distributor's NDC. The OPLC can impose additional state requirements, as needed, to satisfy any FDA concerns regarding the testing, repackaging or relabeling of drugs under the Program. This application does not identify Foreign Seller or Importer partners nor does it identify repackagers/and or relabelers or labs. Instead, this application asks for conditional approval of a SIP to enable New Hampshire to evaluate partners under the rubric of the lawful program proposed here.

In addition to the safeguards applicable to all prescription drugs, as discussed above, prescription drugs imported under New Hampshire's SIP would be subject to requirements under FDCA

section 804. In conformity with section 804, the following types of drugs will not be imported under New Hampshire's:

- Controlled substances,
- Biological products,
- Infused drugs,
- Intravenously injected drugs,
- Parenteral drugs that the FDA determines pose a threat to the public health, and
- Drugs that are inhaled during surgery.

HHS/FDA has authority under FDCA section 804 to immediately suspended importation of a specific prescription drug or importations by a specific importer on discovery of a pattern of importation of drugs that are counterfeit or that are in violation of any requirement of FDCA section 804. Additionally, in accordance with FDCA section 804 no drugs may be imported under the New Hampshire's SIP if they were donated or otherwise supplied at no charge by the manufacturer of the drug to a charitable or humanitarian organization (e.g., to the United Nations) or to a government of a foreign country.

Licensing Requirements

The OPLC will establish two new license categories for Foreign Sellers and Importers through the NH Board of Pharmacy. These license types are:

1. "Canadian Prescription Drug Supplier," an entity registered with FDA as a Foreign prescription drug seller, which exports Canadian drugs to a recipient-wholesaler in the United States, and
2. "Prescription Drug Importer-Wholesaler," the recipient-wholesaler.

The OPLC will ensure that the license numbers, class of activity, and establishment locations are publicly available, to facilitate verification of pedigrees by downstream importers, wholesalers, and pharmacies. Prescription Drug Importer-Wholesalers under New Hampshire's SIP must also certify to OPLC, for each shipment of qualifying prescription drugs that they import, that the shipment complies with FDCA section 804 requirements and other key requirements of the Program.

In accordance with FDCA section 804, New Hampshire would not allow any drug to be

imported under the SIP from any Canadian supplier who has not registered with HHS/FDA the name and place of business of the establishment and the name of the U.S. agent for the establishment.

Verification via audit and international inspection of Canadian Prescription Drug Supplier licensees and New Hampshire Prescription Drug Importer-Wholesaler licensees would be performed by or guaranteed by the OPLC. Inspections and audits may be conducted by other states (e.g., for Pharmacy Drug Importer-Wholesalers located in and permitted by other states), by Health Canada, by the appropriate Canadian provincial authority, or by qualified third-party contractors. A successful inspection or audit of a program applicant will be required for them to obtain a New Hampshire license under the SIP. Periodic audits will be performed to assess whether the licensee continues to meet the requirements for the license. Reports of these audits will be shared with FDA, enabling FDA to evaluate whether a particular prescription drug or its importer should be suspended from the Program.

Prescription Drug Importer-Wholesaler licensees and Canadian Prescription Drug Supplier licensees will annually report to FDA their state licensure information for each facility, contact information for each facility, and any significant disciplinary actions taken by a state or the federal government, as required by the DSCSA. The New Hampshire licensees involved in the SIP will file a similar report with OPLC as a condition of maintaining their licenses.

Foreign Sellers/Canadian Prescription Drug Suppliers

For successful partnership, Foreign Sellers are required to hold an active drug establishment license as a wholesale distributor from Health Canada, and a registration with a provincial pharmacy regulatory authority qualifying it to distribute Health Products and Food Branch (HPFB)-approved drugs. Foreign Sellers will also be required to register with the FDA as required by Section 804. Finally, as described above eligible Foreign Sellers will be licensed and in good standing with the OPLC as "Canadian Prescription Drug Suppliers."

Key activities of the Foreign Seller would include:

- Ensuring that a Section 804 serial identifier (SSI) is affixed or imprinted to each package or homogeneous case of the drugs and that it maintains records of its affixation or

imprinting;

- Maintaining records regarding its process for developing and implementing SSIs;
- Separating drugs intended for the U.S. in its supply chain from drugs intended for Canada;
- Conducting due diligence to ensure the drugs are authentic and promptly responding to any associated information requests; and
- Providing the Importer with comprehensive information about the drug and its supply chain history.

Drugs imported through FDCA Section 804 are intended for Canada and will likely not have a product identifier (PI) attached to the drug because this is not a requirement of Canadian labeling. When a PI is not present, the final rule requires the Foreign Seller to affix to the drugs an identifier called a Section 804 serial identifier (SSI), which is defined as "an alphanumeric serial number unique to each package or homogeneous case that is affixed or imprinted to each package or homogeneous case of the drugs.

Under the New Hampshire SIP, the drug manufacturer would sell the drug directly to the Canadian Foreign Seller. This direct transaction would be comprehensively documented, and the Canadian Foreign Seller would affix or imprint an SSI to the drug that would be linked with the PI for which the Importer would be ultimately responsible. The SSI will be cross-linked to the transaction records to guarantee the data being captured is equivalent to that of the PI under Drug Supply Chain Security Act **(**DSCSA). With these steps in place, the supply chain of the drug is no less safe and transparent under the proposed New Hampshire SIP than if the manufacturer had affixed a PI to the drugs.

As outlined in the final rule, the Foreign Seller must also provide to the Importer documentation regarding the drug. This documentation is largely the same as transaction information and transaction statement documents required by the DSCSA. In some instances, the documentation goes above and beyond DSCSA requirements. The Foreign Seller will be required to provide the following information to the Importer:

- Proprietary name of the product,
- Strength and dosage form,

- Container size,
- Number of containers,
- Lot number,
- Quantity of each lot that the Foreign Seller originally received from the manufacturer (requirement is specific to drugs imported under a SIP, in addition to documentation required by DSCSA),
- Date of transaction and shipment (if more than 24 hours after the transaction),
- Business name and address of the person associated with the Foreign Seller from whom ownership is being transferred,
- Business name and address of person associated with the Importer to whom ownership is transferred,
- SSI for each package or homogeneous case,
- Canadian DIN,
- Documentation specifying the original source of the drug (i.e., the original manufacturer) (this requirement is specific to drugs imported under a SIP, in addition to documentation required by the DSCSA),
- Verification that the drug is not a suspect or illegitimate foreign product, and
- Applicable certifications required by the DSCSA, i.e. that the Foreign Seller received the product from an authorized trading partner and that, to the best of its knowledge, the Foreign Seller did not alter the transaction history.

Importers/Prescription Drug Importer-Wholesalers

As specified, eligible Importers must be licensed and in good standing as a "Prescription Drug Importer-Wholesaler," with the New Hampshire's OPLC. Prescription Drug Importer-Wholesalers would be permitted to import drugs from a Foreign Seller if the drug meets federal standards for safety, effectiveness, marketing, misbranding and adulteration, and complies with all DSCSA rules not exempted by the FDA. Documentation regarding compliance with these rules must be submitted to the New Hampshire's SIP and to the FDA as required under the FDCA. The Importer will be responsible for ensuring the drug is properly tested and relabeled by an FDA-registered and FDCA- compliant repackager and/or relabeler (in an authorized

foreign trade zone), and that a fully DSCSA-compliant product identifier, which includes the NDC number and a unique alphanumeric serial number is affixed or imprinted on each package or homogeneous case and linked to the SSI assigned and affixed by the Foreign Seller. The Importer is also responsible for screening imported shipments to verify that labeling is consistent with Health Canada's HPFB has a valid SSI. This includes a visual screening comparing a sample of the received drug to a sample of the HPFB-approved drug, as required by the final rule.

In considering the eligibility of Importer partners, the New Hampshire SIP would evaluate the following:

- Their current record keeping practices are stable and robust,
- Records demonstrate drugs they currently distribute are DSCSA-compliant and can be traced to the original manufacturer,
- All their policies and procedures are well documented, robust, current and being followed,
- They have detailed screening process for evaluation of drugs they receive, to ensure the drugs are not adulterated, counterfeit, damaged, tampered with or expired, and
- Their drug storage policies, including climate and temperature control policies, are clear, sufficient and followed.

Labeling Requirements

Supply chain participants under New Hampshire's SIP will comply with transaction document requirements under the DSCSA. In accordance with the DSCSA, Importers under New Hampshire's program would have to ensure that the prescription drugs received from Foreign Sellers are accompanied by adequate documentation reflecting the drug originated at the FDA-approved manufacturer or its distributor as well as the drug transaction information and transaction statement.

Labeling requirements for drugs imported from Canada through the New Hampshire SIP include the affixation of product identifiers (PI), adherence to cGMPs and compliance with all FDA labeling requirements for the drug. The New Hampshire SIP would also require detailed recording and reporting of testing and relabeling/repackaging activities. The DSCSA requires the affixation of a product identifier (PI), defined under Section 581(14), as a standardized

human- and machine-readable graphic that contains a standardized numerical identifier, lot number and expiration date. The intent of the PI is to ensure the ability of interested parties to electronically (and manually, if necessary) trace each drug back to the original manufacturer. The New Hampshire SIP would require the original manufacturer to sell the drug directly to the Foreign Seller and require comprehensive documentation of that transaction. Under the New Hampshire SIP, the SSI would be affixed to the drug by the Foreign Seller. The SSI would be treated like a standardized numerical identifier for DSCSA purposes, and the PI would be affixed to the drug by the Importer (or through a contract between the Importer and repackager/relabeler) at the relabeling stage.

Unique National Drug Code for New Hampshire as Private Label Distributor

The New Hampshire SIP would obtain its own FDA "Private Label Distributor" (PLD) labeler code, which would identify New Hampshire as the private labeler for all qualifying prescription drugs imported under the Program. New Hampshire would also list each qualifying prescription drug with FDA using New Hampshire's labeler code. As part of this process New Hampshire will obtain a valid NDC code for each qualifying prescription drug under the Program. 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 NDC number applied to each drug under the New Hampshire SIP would indicate the drug is specific to New Hampshire's importation program. New Hampshire shall use a single PLD. The PLD registrant would be determined at a later date.

The qualifying drug label reflecting New Hampshire's PLD NDC will enhance visibility within the supply chain and ensure New Hampshire's and FDA's ability to connect a specific package of a qualifying prescription drug under the Program with that specific drug's supply chain. Because the product identifiers must be both human-readable and machine-readable, repacked and relabeled qualifying prescription drugs will be immediately identifiable. This will also help ensure that no drugs imported under the New Hampshire SIP are distributed, dispensed, or sold outside of New Hampshire's borders. The New Hampshire PLD NDC will be included in the third-party payment system utilized currently to ensure proper coding for reimbursement.

The repackager and/or relabeler under contract with the Importer, would relabel the drug in compliance with the FDCA (e.g., FDCA Sections 502, 505, 804), and applicable regulations (e.g., 21 CFR 201 and the final drug importation rule), to ensure that:

- All wording is displayed prominently and is not false or misleading,
- The PI is affixed,
- The NDC has been assigned to the drug and is affixed to the label, and
- The labeling features all labeling required by the approved NDA or ANDA and CFR 201, including: the proprietary and established name of the drug, product strength, lot number, name of the manufacturer and the Importer, all warnings, indications, etc., and the statement, "This drug was imported from Canada under the New Hampshire Section 804 Importation Program to reduce its cost to the New Hampshire consumer."

DSCSA requirements for supply chain documentation and track-and-tracing

FDA has implemented most of the DSCSA already, and through the year 2023 will continue phase-in of DSCSA requirements, standards, and an electronic system for product tracing. Supply chain participants under New Hampshire's SIP will continue to comply with DSCSA tracking and tracing requirements as they are established and implemented by the FDA, and to the extent practical should incorporate existing and available supply chain track-and-trace technology (e.g., practical, feasible, and effective blockchain applications).

Examination at the Border

Importation of prescription drugs from Canada to the U.S. under New Hampshire's SIP will occur under the ordinary course of business utilizing international logistics companies and customs brokerage services under existing Customs and Border Protection (CBP) and FDA import laws and regulations. The importer of any prescription drug must submit comprehensive information about the product to CBP and FDA for their review prior to importation of the product. Such information submitted under the New Hampshire's SIP would include the information currently required for importation of prescription drugs (see, e.g., 21 CFR Part 1 Subpart D) and any additional information FDA would require to be submitted in accordance with FDCA section 804. FDA exercises broad discretion to examine and sample essentially any

prescription drug offered for import, and FDA can detain and refuse admission of any prescription drug that appears to be violative (e.g., that appears to be adulterated, misbranded, unapproved, or manufactured in an unregistered facility).

Testing of Drugs by Qualified Laboratories

New Hampshire's SIP will require testing of prescription drugs imported under the program to include batch testing. Such testing must be conducted by FDA-qualified laboratories in the U.S. The Program contemplates requiring laboratories at a minimum be certified as in conformance with ISO 17025 by either A2LA or NCLA, two widely recognized laboratory accreditation authorities. The Prescription Drug Importer will be required to contract with a FDA-qualified laboratory to: authenticate the prescription drug being tested and conduct batch testing. The Importer must maintain and provide access to the following documentation as confirmed by the FDA-qualified laboratory:

- Documentation demonstrating that the prescription drug was received by the recipient from the manufacturer and subsequently shipped by the first foreign recipient to the importer;
- Documentation of the quantity of each lot of the prescription drug received by the first foreign recipient demonstrating that the quantity being imported into the United States is not more than the quantity that was received by the first foreign recipient;
- In the case of an initial imported shipment, documentation demonstrating that each batch of the prescription drug in the shipment was statistically sampled and tested for authenticity and degradation;
- In the case of any subsequent shipment, documentation demonstrating that a statistically valid sample of the shipment was tested for authenticity and degradation; and
- In the case of a prescription drug that is not shipped directly from the first foreign recipient of the prescription drug from the manufacturer, documentation demonstrating that each batch in each shipment offered for importation into the United States was statistically sampled and tested for authenticity and degradation.

Testing must be done by U.S. Qualified Laboratory,[2] the New Hampshire SIP proposes that this may be contracted by the Importer.

Handling of suspect and illegitimate products

Manufacturers, Foreign Sellers, repackagers/relabelers, Importers, and pharmacy dispensers of drugs under the New Hampshire SIP must also establish and implement systems for verification and handling of suspect or illegitimate product, as required by the DSCSA. If a manufacturer, wholesale distributor, dispenser, or repackager has reason to believe that a drug is potentially illegitimate (e.g., potentially counterfeit, diverted, or otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans) it must:

- Quarantine the suspect products;
- Investigate whether the prescription drugs are illegitimate products and notify FDA regardless of the outcome of the investigation; and
- If the investigation finds that the prescription drugs are illegitimate products, take certain corrective measures including appropriately disposing of the product and providing reasonable assistance for disposition to parties who have received the illegitimate product.

Recordkeeping & Reporting

Participants in the New Hampshire SIP, whether Foreign Sellers, Importers, or other entities registered and/or licensed with the New Hampshire's OPLC and/or FDA, will establish and maintain records to document compliance. Such documentation will include, for example, identification of the testing conducted and the applicable DSCSA-related records. In all cases, New Hampshire will attempt to add few new record keeping obligations but will require access to records that are already necessary to comply with existing federal and state programs. Some records will be unique to the Program, such as the prescription drug importer-wholesaler certification of compliance. Audits of participants in the Program may include review of relevant records.

[2] Under the New Hampshire SIP, a U.S. Qualified Laboratory is one that is accredited to ISO 17025 standards by A2LA or NCLA or other nationally established third-party laboratory accreditor.

Recall Management

As noted above, under the DSCSA manufacturers, wholesale distributors, dispensers, and repackagers of drugs must investigate suspect products, and if the product is unfit for distribution such that the product would result in serious adverse health consequences or death to humans, they must quarantine and dispose of the product and provide reasonable assistance for disposition to parties who have received the illegitimate products. New Hampshire shall cooperate with FDA to help facilitate any recalls under the New Hampshire SIP. In the event of a recall, as required in the final rule, the Importer, in cooperation with the Foreign Seller, the FDA and the New Hampshire SIP, would be required to:

- Immediately cease distribution of the drug(s) affected by the recall;
- Directly notify consignees of the drug(s) included in the recall, including how to return or dispose of the recalled drugs;
- Notify the FDA and the New Hampshire SIP of the recall;
- Specify the depth to which the recall will extend;
- Notify the public about any hazards presented by the recalled drug(s) when appropriate to protect the public health;
- Conduct recall effectiveness checks to verify that all consignees at the specified recall depth have received notification about the recall and have taken appropriate action;
- Appropriately dispose of recalled product; and
- Upon request by the FDA, provide the transaction history, information and statement of the recalled drug(s), as those terms are defined in sections 581(25), 581(26) and 581(27) of the FDCA, respectively. Importers and Foreign Sellers under a SIP would be required to cooperate with the recalling entity (e.g., the Importer, the manufacturer, the FDA). The New Hampshire DHHS would expect New Hampshire SIP participants to effectuate the recall, as necessary, in coordination with the FDA.

SAVINGS TO CONSUMERS

Determining Savings from Wholesale Drug Importation from Canada

New Hampshire DHHS looked at the top drugs by spend in the All Claims Payer Database. The net spend for these drugs was calculated assuming a 10 % - 18% discount off gross spend. The same 45% markup was added to the Canadian price to account for 20% profit along the supply chain as well as costs to the supply chain such as repackaging, relabeling, testing, record keeping, and recall management.

Even with the conservatively-high mark-up of 45%, the estimated savings is in the range of $7 million - $22.3 million per year. If biologics, including insulin, could be considered in this analysis, potential savings from Canadian drugs could increase significantly.

Medicaid Fee-for-Service (FFS) and the New Hampshire State Employees Prescription Drug Plan participated in the aforementioned analysis to provisionally determine the opportunity for savings from drugs imported from Canada. The payers identified top spend drugs that would be eligible for importation according to federal law. (Ineligible drugs are narcotics, biologics, drugs inhaled during surgery, IV and infused drugs.) Top spend was determined by multiplying the net cost of each drug by utilization. Canadian prices were located for the identified drugs using the Quebec Public Drug Program List and converted to US dollars. A mark-up of 45% was added on top of the Canadian price. The 45% mark-up allows for 20% profit along the supply chain as well as costs to the supply chain such as repackaging, relabeling, testing, record keeping, and recall management. To determine savings, plans were asked to determine their net spend (i.e. net of rebates) on the identified drugs and to compare that total to the would-be net spend for the same drugs if imported from Canada with a 45% mark-up. The analysis indicated that there might not be a savings for these programs in the early stages of implementation.

Assuring Cost Savings

The State of New Hampshire can utilize and rely on market competition at any or all levels of the supply chain to keep costs and prices low. Market competition should work if there are multiple participants at each stage of the supply chain and the price at importation is known to everyone,

including purchasers and payers.

At any level in the supply chain where there is no market competition, the state can establish a limit on mark-up or fees for each stage of the supply chain. The allowed mark-up will account for the routine and exceptional costs of importing and distributing product throughout the state. The mark-up limits for the non-competitive parts of the supply chain will be enforced by payers and purchasers who will know the import price and the state margin limits. In order to ensure the significant savings from importing certain prescription drugs wholesale from Canada would be passed on to consumers, New Hampshire could amend its annual rate review filing requirements for health plans doing business in the state and require health plans to document savings from importation as well as how those saving were passed on to consumers.

Options for passing savings to consumers may include:

- Lowering premiums.
- Lowering deductibles, and
- Reducing or eliminating co-pays.

In addition to the rate review process described above, the New Hampshire would establish a transparent, public price list of the imported drugs in order to ensure that mark-up along the supply chain was not exceeding the allowed amount at the expense of consumer savings.

Conclusion

Now more than ever, one of the biggest pressures on New Hampshire families' pocketbooks is the high cost of health care in the Granite State and prescription drugs are a driver of these health care costs. We look forward to the Administration's continued action to create a formal pathway for prescription drug importation from Canada and to its partnership with states on this important initiative.

Proposed Drug List

Drug Name	Active Ingredient	NDC	US Price	NDA/ANDA	Canadian Name	Sold in US
Abilify Maintena	Aripiprazole	59148-0019-71	$2,179.10	NDA202971	Abilify Maintena	Yes

Drug Name	Active Ingredient	NDC	US Price	NDA/ANDA	Canadian Name	Sold in US
Advair Diskus 100-50mcg	Fluticasone Propion / Salmeterol	00173-0695-00	$303.60	NDA021077	Advair 100 Diskus	Yes
Advair Diskus 250-50mcg	Fluticasone Propion / Salmeterol	00173-0696-00	$377.40	NDA021077	Advair 250 Diskus	Yes
Advair Diskus 500-50mcg	Fluticasone Propion / Salmeterol	00173-0697-00	$496.80	NDA021077	Advair 500 Diskus	Yes
Aubagio 14mg	Teriflunomide	58468-0210-02	$268.64	NDA202992	Aubagio	Yes
Bikyarvy 50-200-25	Bictegrav / Emtricit / Tenofov Ala	61958-2501-01	$104.52	NDA210251	Biktarvy	Yes
BREO ELLIPTA 100-25mcg	FLUTICASONE / VILANTEROL	00173-0859-10	$5.96	NDA204275	Breo Ellipta	Yes
BREO ELLIPTA 200-25mcg	FLUTICASONE / VILANTEROL	00173-0882-10	$5.96	NDA204275	Breo Ellipta	Yes
Chantix 0.5 (11)-1 (Champix in Canada)	Varenicline Tartrate	00069-0471-03	$8.00	NDA021928	Champix	Yes
Chantix 0.5mg	Varenicline Tartrate	00069-0468-56	$7.62	NDA021928	Champix	Yes
Chantix 1mg	Varenicline Tartrate	00069-0469-56	$8.00	NDA021928	Champix	Yes
Eliquis 2.5mg	Apixaban	00003-0893-21	$7.52	NDA202155	Elequis	Yes
Eliquis 5mg	Apixaban	00003-0894-21	$7.53	NDA202155	Elequis	Yes
Epclusa 400-100mg	Sofosbuvir, Velpatavir	61958-2210-01	$869.05	NDA208341	Epclusa	Yes
Genvoya 150-200-10	Elviteg / Cob / Emtri / Tenof Alafen	61958-1901-01	$104.93	ANDA207561	Genvoya	Yes
Gilenya 0.5mg	Fingolimod HCL	00078-0607-15	$280.83	NDA022527	Gilenya	Yes
Harvoni 90-400mg	Ledipasvir, Sofosbuvir	61958-1801-01	$1,098.94	NDA205834	Harvoni	Yes
Ibrance 75 mg	Palbociclib	00069-0284-21	$592.83	NDA207103	Ibrance	Yes
Ibrance 100mg	Palbociclib	00069-0188-21	$592.83	NDA207103	Ibrance	Yes

Drug Name	Active Ingredient	NDC	US Price	NDA/ANDA	Canadian Name	Sold in US
Ibrance 125mg	Palbociclib	00069-0189-21	$592.83	NDA207103	Ibrance	Yes
Imbruvica 140mg	Ibrutinib	57962-0140-09	$154.36	NDA205552	Imbruvica	Yes
Ingrezza 80mg	Valbenazine Tosylate	70370-1080-01	$234.77	NDA209241	Ingrezza	Yes
Jakafi 5mg	Ruxolitinib Phosphate	50881-0005-60	$236.45	NDA202192	Jakavi	Yes
Jakafi 10mg	Ruxolitinib Phosphate	50881-0010-60	$236.45	NDA202192	Jakavi	Yes
Jakafi 15mg	Ruxolitinib Phosphate	50881-0015-60	$236.45	NDA202192	Jakavi	Yes
Jakafi 20mg	Ruxolitinib Phosphate	50881-0020-60	$236.45	NDA202192	Jakavi	Yes
Januvia 100mg Tab	Sitagliptin Phosphate	00006-0277-31	$15.14	NDA021995	Januvia	Yes
Januvia 25mg Tab	Sitagliptin Phosphate	00006-0221-31	$15.13	NDA021995	Januvia	Yes
Januvia 50mg Tab	Sitagliptin Phosphate	00006-0112-31	$15.13	NDA021995	Januvia	Yes
Jardiance 10mg	Empagliflozin	00597-0152-30	$17.41	NDA204629	Jardiance	Yes
Jardiance 25mg	Empagliflozin	00597-0153-30	$17.41	NDA204629	Jardiance	Yes
Kuvan 100 mg	Sapropterin Dihydrochloride	68135-0301-22	$40.30	NDA205065	Kuvan	Yes
Latuda 120mg Tab	Lurasidone HCL	63402-0312-30	$61.13	NDA200603	Latuda	Yes
Latuda 20mg Tab	Lurasidone HCL	63402-0302-30	$40.99	NDA200603	Latuda	Yes
Latuda 40mg Tab	Lurasidone HCL	63402-0304-30	$41.00	NDA200603	Latuda	Yes
Latuda 60mg Tab	Lurasidone HCL	63402-0306-30	$41.04	NDA200603	Latuda	Yes
Latuda 80mg Tab	Lurasidone HCL	63402-0308-30	$41.03	NDA200603	Latuda	Yes
Lupron Deopt-Ped 30mg	Leuprolide Acetate	00074-9694-03	$10,078.56	NDA020263	Lupron Deop	Yes
Mavyret 100-40mg	Glecaprevir, Pibrentasvir	00074-2625-80	$153.11	NDA209394	Maviret	Yes

Drug Name	Active Ingredient	NDC	US Price	NDA/ANDA	Canadian Name	Sold in US
Myrbetriq 25mg	Mirabegron	00469-2601-30	$13.50	NDA202611	Myrbetriq	Yes
Myrbetriq 50mg	Mirabegron	00469-2602-30	$13.50	NDA202611	Myrbetriq	Yes
Odefsey 200-25-25	Emtricitab / Rilpiviri / Tenof Ala	61958-2101-01	$95.77	NDA208351	Odefsey	Yes
Otezla 10-20-30mg	Apremilast	55513-0369-55	$65.30	NDA205437	Otezla	Yes
Otezla 30mg	Apremilast	55513-0137-28	$59.86	NDA205437	Otezla	Yes
Ozempic 1mg/0.75ml	Semaglutide	00169-4136-02	$270.35	NDA209637	Ozempic	Yes
Procysbi 75mg	Cysteamine Bitartrate	75987-0101-08	$101.32	NDA203389	Procysbi	Yes
Ravicti 1.1Gm/ml	Glycerol Phenylbutyrate	75987-0050-06	$201.24	NDA203284	Ravicti	Yes
Sabril 500mg	Vigabatrin	67386-0111-01	$175.20	NDA020427	Sabril	Yes
Spiriva Respimat 2.5mcg	Tiotropium Bromide	00597-0100-28	$18.75	NDA021936	Spiriva	Yes
Spiriva 18mcg Handihaler	Tiotropium Bromide	00597-0075-41	$15.75	NDA021395	Spiriva	Yes
Sprycel 20mg	Dasatinib	00003-0527-11	$140.20	NDA021986	Sprycel	Yes
Sprycel 50mg	Dasatinib	00003-0528-11	$244.57	NDA021986	Sprycel	Yes
Sprycel 70mg	Dasatinib	00003-0524-11	$280.39	NDA021986	Sprycel	Yes
Sprycel 100mg	Dasatinib	00003-0852-22	$466.07	NDA021986	Sprycel	Yes
Tecfidera 240mg	Dimethyl Fumerate	64406-0006-02	$137.93	NDA204063	Tecfidera	Yes
Tradjenta 5mg Tab	Linagliptin	00579-0140-30	$14.79	NDA201280	Tradjenta	Yes
Triumeq 600-50-300	Abacavir / Dolutegravir / Lamivudi	49702-0231-13	$98.19	NDA205551	Triumeq	Yes
Truvada 200-300	Emtricitabine / Tenofovir (TDF)	61958-0701-01	$59.70	NDA021752	Truvada	Yes

Drug Name	Active Ingredient	NDC	US Price	NDA/ANDA	Canadian Name	Sold in US
Victoza 0.6 MG/0.1ml (2-Pak)	Liraglutide	00169-4060-12	$107.57	NDA022341	Victoza	Yes
Victoza 0.6 MG/0.1ml (3-Pak)	Liraglutide	00169-4060-13	$107.57	NDA022341	Victoza	Yes
Vosevi	Sofosbuvir / Velpatas Voxilaprev	61958-2401-01	$890.00	NDA209195	Vosevi	Yes
Wellbutrin XL 150mg	Bupropion HCL	00187-0730-30	$46.97	NDA021515	Wellbutrin XL	Yes
Wellbutrin XL 300mg	Bupropion HCL	00187-0731-30	$62.03	NDA021515	Wellbutrin XL	Yes
Wixela Inhub 100-50mcg	Fluticasone Propion, Salmeterol	00378-9320-32	$123.00	ANDA208891	Wixela Inhub	Yes
Wixela Inhub 250-50mcg	Fluticasone Propion, Salmeterol	00378-9321-32	$150.00	ANDA208891	Wixela Inhub	Yes
Wikela Inhub 500-50mcg	Fluticasone Propion, Salmeterol	00378-9322-32	$153.10	ANDA208891	Wixela Inhub	Yes
Xarelto 2.5mg	Rivaroxaban	50458-0577-10	$8.21	NDA202439	Xarelto	Yes
Xarelto 10mg	Rivaroxaban	50458-0580-10	$16.42	NDA022406	Xarelto	Yes
Xarelto 15mg	Rivaroxaban	50458-0578-10	$16.42	NDA202439	Xarelto	Yes
Xarelto 20mg	Rivaroxaban	50458-0579-10	$15.03	NDA202439	Xarelto	Yes
Xifaxan 550mg	Rifaximin	65649-0303-02	$44.06	NDA022554	Xifaxan	Yes
Xtandi 40mg	Enzalutamide	00469-0125-99	$102.30	NDA203415	Xtandi	Yes