Adding a Prescription Drug Reimportation Component To Your Benefit Plan

Americans who live close to national boarders or regularly travel outside the United States have been purchasing medications in other countries for decades. Since that kind of travel is unrealistic for most people, working with a reputable source of imported prescription drugs can be a way for individual health care consumers to directly purchase prescription drugs from other countries in a safe, legal, and efficient manner.

Personal use drug importation isn't just an option for individual purchasers who are looking to reduce their pharmaceutical costs. Self-insured employer group health plans are increasingly capitalizing on the benefits of importation too. Employers who use reimportation methods like those offered by Angle Health to supplement their prescription drug plan are normally able to recognize a direct and immediate benefit in reduced claims costs.

Angle Rx requires the use of valid prescriptions and work with licensed U.S. and international pharmacies during their fulfillment process to ensure the safety of the medications they help clients access. The result is prescription drugs, in their original packaging, using safe and appropriate shipping and transport conditions, being delivered directly to the consumer's doorstep, at a significantly lower cost.

State and municipal governments employee plans, which are often considered to be laboratories for health coverage innovation due to their size, typically rich benefit packages and budget requirements have been very drawn to the cost-savings potential of including personal prescription drug importation options in their employee benefit plan design. Many municipalities and even some states have implemented intentional programs that allow employees the option of importation of certain medications for personal use.

Angle Rx's prescription drug reimportation program is not a replacement for traditional prescription drug benefit coverage. Instead, the option simply serves as a supplemental and cost-savings tool that employees can access at their option, much like telemedicine benefits.

Since the United States has long restricted the re-importation of prescription drugs originally manufactured in the United States for commercial sales purposes except by the manufacturer, the overall legality of the solution for employer plans is a natural question. The key distinction is that employers and employees who take advantage of a drug importation program that is integrated with an employer-sponsored health plan are not reimporting any prescription drugs to sell them commercially. Instead, their importation of the prescription medication is only and expressly to treat personal medical conditions.

There are no federal laws specifically banning personal drug importation, either through direct international purchase or by mail. However, Section 801 (d) (1) of the Food Drug and Cosmetic Act bans all importation of prescription drugs manufactured in the U.S. except by the manufacturer, [i] to prohibit wholesale distribution of U.S. prescription drugs bought in other countries by other commercial entities.

Given the reality of and often time need for personal purchases of approved prescription medications from other countries, U.S. Food and Drug Administration (FDA) has, since 1954, put into place a personal-use enforcement exemption that allows individuals to import up to a 90-day supply of non-scheduled prescription drugs for personal use. [ii] Further, the Department of Homeland Security, Customs and Border Protection (DHS/CBP), the primary enforcement agency for the FDA, has long applied a policy of allowing importation of

personal quantities of medications for personal use.[iii]

To ensure this legal standard is always met, Angle Health's program ensures that plan participants are always the ones to arrange and order their prescription medications. Further, prescriptions are never sourced and filled by the vendor with more than a three-month supply. Original prescriptions from a licensed, U.S. medical provider are required and then verified by a participating international physician. When the prescription medications are shipped to the United States, they are always be delivered directly to the individual beneficiary's home in their original packaging with original instructions and a copy of the individual's legitimate and verified prescription.

When drugs arrive in other countries via mail order, it is possible for a shipment to be flagged and sent to the FDA for review, if for some reason the shipment appear suspicious. However, the FDA has issued guidance on suspicious packages and it clearly indicates the personal use exemption, noting: "FDA personnel may use their discretion to allow entry of shipments of violative FDA regulated products when the quantity and purpose are clearly for personal use, and the product does not present an unreasonable risk to the user." [iv] Marcia Crosse, PhD, the director for the Health Care Team at the U.S. Government Accountability Office (GAO), has indicated that the FDA has never prosecuted any individual for personal drug importation, which is generally defined as importing small quantities of medication for personal use that is no more than a three-month supply of any given medication.[v]

One of the reasons why importation of prescription drugs has been historically limited in the United States is to ensure the safety of American patients and to guard against even inadvertent importation of counterfeit drugs. The FDA also wants to protect against importation of drugs that do not meet safety standards, drugs that are transported in a way that limits or destroys their effectiveness or drugs that may be purchased inappropriately, due to differences in brand names used in other countries. Angle Health's program makes it a top priority to verify all medicines sourced internationally are legitimate. Further, for safety and legal reasons, valid prescriptions that may also fall on the DEA's list of scheduled drugs or could be considered a controlled substances are not medications that are available for distribution under the reimportation program.

In short, providing employers and employees with a supplemental option to control prescription drug costs is a clear way to enhance employer-sponsored group health benefit plan design. The implementation of a personal use drug importation program to accompany a comprehensive traditional prescription drug benefit is an innovative, legal, and safe way for a self-funded employer plan sponsor to achieve that objective.

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[i] *Importation of Active Pharmaceutical Ingredients (APIs) Requirements FD&C Act 801 [21 USC 381] Imports and Exports (Tab G).* Retrieved from the Food and Drug Administration on January 10, 2017: http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ucm118010.pdf

[ii] *Personal Importation.* February 3, 2016. Retrieved from Food and Drug Administration: http://www.fda.gov/ForIndustry/ImportProgram/ImportBasics/ucm432661.htm

[iii] *Travelling With Medication.* November 14, 2016. Retrieved from U.S. Custom and Border Protection: https://help.cbp.gov/app/answers/detail/a_id/1160/kw/personal%20prescription%20drugs/session/L3RpbWUvMTQ4NDE5ODk0MS9zaWQvVHYzOGx0OG4%3D

[iv] Regulatory Procedures Manual. (June 19, 2015). 9-2 - Coverage of Personal Importations. Retrieved January 10, 2017 from Food and Drug Administration: http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm179266.htm#SUB9-2

[v] Crosse, Marcia. Health Care Team at the U.S. Government Accountability Office (GAO). Explanation of FDA's Personal Drug Importation Policies [Video File]. Retrieved on January 10, 2017 from http://www.tubechop.com/watch/6190570