

FDA Compliance & The Customer Journey

Each PriceMDs (PMDs) member is assigned a specific Nurse Navigator who stays with that member for as long as they are on the program. Our Nurse Navigators are rock stars! All are U.S. citizens, U.S. educated & trained, and U.S. licensed. Our staff physicians are U.S. citizens, U.S. educated & trained, and U.S. double board certified sub-specialists. Employees love the white glove service they receive.

THE CUSTOMER JOURNEY

A simple one-time on-boarding process:

- 1 The employer notifies employee (EE) of new program.
- 2 The EE is sent a Welcome Packet, with program description, FAQs, and ID card with their nurse's name and contact info.
- 3 A PMDs Nurse Navigator contacts the EE to review their Welcome Packet. They secure a HIPAA release, gather the patient's medical records, and confirm that lab work is up to date. If the member doesn't have a valid passport, PMDs helps them acquire one at PMDs's cost (in 3-5 days). This preliminary call generally takes ~20 minutes.
- 4 An initial telehealth call with a PMDs physician reviews their case to ensure that records and labs are up to date and confirms their existing U.S. prescription. Members gain a second opinion without interrupting their primary treating doctor or medication regimen. (~20 min call).
- 5 Telehealth call #2 is with a board certified PMDs physician, licensed in the state in which the customer resides, to complete the process. Medication is sourced and a 90-day fill arrives within 14 - 21 days directly to the patient's door.
- 6 The PMDs Nurse follows up with member to ensure complete satisfaction and address any storage/usage questions.

The FDA allows an individual to import up to 90-day supply of medication, as per the FDA personal importation guidelines for US citizens and Green Card holders.

ACHIEVING COMPLIANCE

- Nurse Navigators engage the employee, and upon obtaining a HIPAA release, gather the patient's medical records (PHI).
- An initial live video consultation is conducted by a U.S. trained/boarded PMDs physician, based in Israel or the Bahamas.
- A second telehealth consultation is conducted by a U.S. trained/boarded physician licensed in the state where meds are to be delivered.
- The exact same medications (no generics, no re-compounding) the patient receives from U.S. sources are sourced from the OEM, and delivered to the member's door.
- All documentation required for personal importation required by the FDA, USDA, & CBP (Custom & Border Control) is provided by PMDs.
- PMDs has been vetted by the Office of Personnel Management for drug importation as a vendor for federal agencies. PMDs is approved and compliant with:

KEY REQUIREMENTS

- A personal importation is a product not for further sale or distribution into U.S. commerce. These products may be carried in patient's baggage or shipped by courier.
- The drug must be approved for use and sale by the FDA in the United States.
- The manufacturer and place of manufacture must be documented and presented to the FDA.
- Medications requiring cold chain are tracked and documented from the source to the member's door.
- Live telemedicine consultations are required for patients receiving medication via medical courier and must include a physician based outside the U.S., and a physician licensed in the state where the patient's medications will be delivered.

"The package was really good. It was still cold. Those were pretty impressive ice packs and cooler. Thanks for all your hard work getting it to me!"

– Robert T.



LEGAL / ERISA