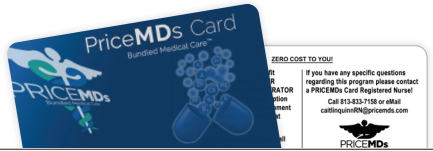


# FDA Compliance & The Customer Journey

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.
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- 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 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.

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:



LEGAL / ERISA

## 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.

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