Minimum Quality Assurance Standards

- All prescription drug products shipped through Vendor supply chains meet or exceed all safety concerns that have been addressed by the Food and Drug Administration (“FDA”).
- The Active Pharmaceutical Ingredients (“API”) of any product being sourced internationally are comparable to the United States (“U.S.”) FDA version. Vendor uses the following ways and means to demonstrate similarity:
    - Vendor warrants that it only ships drugs whose product monograph is substantially similar to the FDA approved version of that particular product monograph. The chemical name, chemical description, empirical formula, molecular weight, and the molecule of the active pharmaceutical ingredient, are identical but may be shown in different areas of the product monograph. Drug manufacturers are required by the regulatory bodies in each country to attest to the monographs annually and produce a monograph in every country that the particular drug is sold in.
    - Vendor only sources drug products from Good Manufacturing Process (“GMP”) countries whose regulatory environments are comparable to, or more robust than, the U.S.
    - Vendor warrants that it only ships drug products when purity and dissolution tests confirm absolute similarity based on the standards set by the United States Pharmacopeia (“USP”). To determine whether a particular drug meets this expectation, Vendor shall contract with an approved Good Laboratory Practices (“GLP”) certified prescription drug testing lab to test FDA approved drugs compared to their locally regulated and approved international counterparts.
    - Vendor affirms that all prescription medications shipped will only be manufactured in accordance with FDA manufacturing standards in facilities that maintain the designation, "FDA Approved Manufacturing Facility."
    - Vendor assures that prescriptions dispensed through Vendor and Vendor networks are labeled similarly to those dispensed in the US.
    - Vendor network is fully Health Insurance Portability and Accountability Act (“HIPAA”) compliant.
    - Utilizing Drug Utilization Reviews (“DUR”) at multiple points, a pharmacy administration management system and the dispensing pharmacist will red flag a contraindicated medication after reviewing a patient's drug history and current drug profile. Both the U.S. attending physician and the local dispensing pharmacist must complete a DUR process prior to prescribing or dispensing a drug to a patient.
- Multilingual phone support to eligible Members will be provided through a call center during U.S. business days and standard business hours, at a minimum.
- Members will be advised of potential prescription or non-prescription drug reactions, interactions, and adverse side effects or appropriate precautions, based on current information available to the dispensing pharmacist at the time the prescription is fulfilled. If available, a drug information sheet will be provided with every prescription fulfilled through the Vendor Network to the covered Members.
- Members and/or the U.S. attending physician will be contacted when a prescription item may be unduly delayed. In the event a delay occurs, the employee could obtain a limited quantity short-fill prescription through a local pharmacy.
- Vendor will create and maintain full medication profiles for all Members.
- Vendor will conduct both retrospective and prospective DUR’s including current non-prescription/over the counter ("OTC") medications and for herbal or nutraceutical type preparations, prior to dispensing the prescribed pharmaceutical medication.
- Vendor will ensure that all pharmaceuticals are maintained in accordance with appropriate temperature, light, and humidity standards, during warehousing, shipping, and storage, by our fully licensed regulated licensed pharmacy networks.
- Vendor will notify Members of any relevant prescription drug recalls, or any regulatory alerts associated with any prescription drug fulfillments.
- Requirements for the fulfillment of pharmaceuticals will be anticipated on a best effort basis to secure adequate inventory of such pharmaceuticals for Member on a timely basis. Vendor will always utilize the most cost-effective and competitive shipping rates.
- Vendor participating pharmacy networks will always maintain fully secure supply chains, warehousing, and retail pharmacy facilities.
- Vendor will ensure that all legal, regulatory, and other relevant documentation, including customs declarations to allow for the personal importation of the pharmaceuticals by the Member in to the U.S. diligently prepared, stored, and forwarded with all fulfilled prescription drug products
- Vendor will maintain Member confidentiality, protect Member identity and safeguard Member participant specific personal health information in order to meet and/or exceed both domestic and international privacy legislation guidelines.
- Any access to a Member profile is limited to authorized personnel only including the pharmacies/pharmacists/call center personnel and other designated Vendor contractors, employees, the Member who owns the personal health information, and the U.S. attending physician.