



## **Prescription Drug and Device Regulatory Compliance Policy**

### ***Overview***

Direct Relief is a nonprofit, public benefit corporation under section 501(c)(3) of the Internal Revenue Code. Dedicated to the public good, Direct Relief seeks to fill gaps in healthcare delivery not met by governments or commercial markets, supporting a network of nonprofit community health centers and clinics in all 50 states, serving low-income and uninsured patients, and an international network of locally-run charitable healthcare entities in more than 80 countries.

Direct Relief strives to serve as a model in regulatory compliance for the humanitarian aid sector, protecting both the integrity of the pharmaceutical supply chain and the products in its trust, to ensure the delivery of authentic medicines to people in need around the world.

### ***Licensing***

Direct Relief's strong commitment to regulatory compliance is maintained throughout all operational areas. Direct Relief's policies meet standards established by the U.S. Food and Drug Administration (FDA), the California Board of Pharmacy (CABOP), and all federal and state laws governing wholesalers. Direct Relief complies with all applicable statutes and regulations governing wholesale distribution where licensed or registered and complies with the more stringent law or regulation as determined by conflicts of law rules. Direct Relief has held a CABOP Wholesale Drug Permit since 1991 and also maintains the following licenses and registrations:

- Chemical Exporter Registration (U.S. Drug Enforcement Administration)
- Wholesale Drug Distributor Registration (FDA)
- Food Facility Registration (FDA)
- Processed Food Registration (California Department of Public Health, Food and Drug Branch).

Direct Relief staff includes a licensed pharmacist, a licensed California Designated Representative in Charge, licensed California Designated Representatives, and a licensed Florida Designated Representative.

Direct Relief is authorized to distribute pharmaceuticals throughout all 50 U.S. states, Washington, D.C., and Puerto Rico and is the first non-profit organization awarded the Verified-Accredited Wholesale Distributor (VAWD) accreditation by the National Association of Boards of Pharmacy (NABP).

### ***Product Integrity***

Direct Relief is committed to ensuring the integrity of the pharmaceutical products it distributes, adhering to strict standard operating procedures for examination and authentication, and quarantining and destroying any contraband, damaged, or expired products. Direct Relief maintains authenticated products in a secure manner on its premises and in accordance with California Pharmacy Law.

The vast majority of products accepted by Direct Relief are donated for humanitarian distribution by major pharmaceutical companies, which ship donated products to Direct Relief's distribution facility or via a licensed third-party logistics provider directly to the end dispensary. Direct Relief does not import prescription products. Any prescription product obtained from a vendor outside the U.S. is

shipped to an international partner via a third party logistics provider or drop-shipped directly to the international partner.

Direct Relief operations run on the SAP Enterprise Resource Planning system to ensure a high level of inventory controls and management, enabling traceability of pharmaceutical products to the lot level and compliance with increasingly rigorous industry standards, including those set forth in the Drug Supply Chain Security Act (DSCSA), which allows for seamless collaboration with company donor partners.

### ***Distribution Standards***

Direct Relief abides by the Interagency Guidelines for Medicine Donations published by the World Health Organization (WHO) for the international distribution of pharmaceutical products, distributing only products that are registered in-country by the Ministry of Health and that have been requested and approved by the licensed partner or importer of record. The majority of prescription drugs shipped by Direct Relief are primary and secondary drugs on the WHO Model List of Essential Medicines.

### ***Supply Chain Integrity***

Direct Relief maintains a commitment to the integrity of the pharmaceutical supply chain by accepting product donations only from licensed manufacturers, their authorized distributors of record, licensed third-party logistics providers, or wholesalers licensed as resident or non-resident distributors by the CABOP.

Direct Relief distributes pharmaceutical products only to authorized, licensed entities and engages authenticated Interstate Commerce Commission licensed and regulated carriers to transport products. Partners must verify that they are authorized to distribute and/or dispense such products and must agree to implement reasonable measures to prevent the diversion of donated products. Direct Relief and its partners enter into a contractual agreement whereby they commit to work together to implement best practices that support supply chain integrity and cooperate fully in the investigation of any suspected diversion of donated products. Partners found to be involved in or having failed to establish appropriate controls against counterfeiting, illegal diversion, handling of stolen products, or violation of anti-bribery or anti-kickback regulations are terminated from partnership with Direct Relief.

### ***Compliance Audits***

In the spirit of full transparency and with the aim of continuous quality improvement, Direct Relief welcomes compliance audits. Direct Relief has a strong record of conclusion with no deficiencies and seeks to implement auditor recommendations. Since 2009, Direct Relief has successfully undergone dozens of audits by major pharmaceutical companies in addition to licensing and accrediting agencies including the DEA, NABP, CABOP, and the California Department of Public Health. Direct Relief also undergoes ongoing scrutiny of its operations in order to maintain state licensing.

Direct Relief strives to be a trustworthy partner to the company donors that supply pharmaceutical products, as well as the partner organizations that depend on them. The compliance program serves to protect the integrity of the products in Direct Relief's trust, in the interest of effectuating Direct Relief's mission and delivering authentic medical products to those in need.