



## California - Health and Safety Code §119402 and SB 657

### CA Health and Safety Code §119402

CA Health and Safety Code §119402 requires pharmaceutical companies to adopt a Comprehensive Compliance Program that is in accordance with the April 2003 publication "Compliance Program Guidance for Pharmaceutical Manufacturers," which was developed by the United States Department of Health and Human Services Office of Inspector General (OIG). The statute further specifies that pharmaceutical companies shall make conforming changes to its Comprehensive Compliance Program within six months of any update or revision to the "Compliance Program Guidance for Pharmaceutical Manufacturers."

In addition, the law requires that every pharmaceutical company include in its Comprehensive Compliance Program policies for compliance with the Pharmaceutical Research and Manufacturers of America (PhRMA) "Code on Interactions with Health Care Professionals," dated July 1, 2002. Pharmaceutical companies must make conforming changes to its Comprehensive Compliance Program within six months of any update or revision of the "Code on Interactions with Health Care Professionals."

Amneal has established a Corporate Ethics & Compliance Program in accordance with the OIG Compliance Guidance and have policies in place to foster compliance with the PhRMA Code for their pharmaceutical businesses. For purposes of compliance with the requirements of the California Compliance Law and as part of the Compliance Program, Amneal has established a specific annual aggregate dollar limit of \$3,500 on for qualified transfers of value given to California healthcare professionals.

The annual limits do not include the following:

- Drug samples given to physicians and healthcare professionals
- Financial support for continuing medical education forums
- Financial support for health educational scholarships
- Payments for legitimate professionals services, and any meals or expenses associated with the provision of such services
- Items of nominal value with a retail value of less than \$10 (e.g., visual aids, reprints of medical journal articles)
- Patient educational materials provided to patients by their physician with the purpose of educating the patient or enhancing the patient's understanding or management of the condition

### Amneal Pharmaceuticals, Inc. Ethics & Compliance Program Declaration

Amneal is committed to conducting its business ethically and in compliance with all applicable laws. To the best of its knowledge and based on a good faith understanding of the statutory requirements, the Company has established a Compliance Program that meets the requirements set forth in California Health & Safety Code, Sections 119400-119402. The Company has established an internal monitoring system designed to help ensure compliance with its respective annual spending limits in California and is working to establish additional corporate tracking and monitoring processes. Subject to the limitations described above, the Company declares that, based upon current tracking and monitoring systems, the Company is, in all material respects, in compliance with the Compliance Program and with the respective established annual spending limits for reporting period of January 1, 2023 through December 31, 2023.

## **Amneal Pharmaceuticals, Inc. California Transparency in Supply Chains Act (SB 657)**

Amneal is committed to establishing itself as a leader in the development, manufacturing and marketing of generic and specialty prescription pharmaceutical products, while attaining the highest levels of quality, safety, and business ethics. To achieve this goal, Amneal expects that its business partners also maintain appropriate ethical and professional standards, including compliance with applicable labor laws.

If Amneal has reason to believe that a supplier is not in compliance with their agreement with Amneal, company policies, or applicable laws and regulations the Company will provide the supplier an opportunity to remedy the non-compliant behavior or practice and provide Amneal with sufficient evidence to demonstrate they have taken corrective action. If the supplier does not remedy the non-compliant behavior or practice, or if the corrective action cannot be verified by Amneal, the Company will seek to terminate the supplier from its employ.

### **Verifying of Supply Chains and Supplier Audits**

As part of Amneal's overall commitment to the quality of our products, the Company conducts periodic audits of our suppliers. These audits are conducted by both in-house and third-party audit professionals utilizing a risk-based assessment of our supply chain. Risk levels are assigned based upon Amneal's knowledge of the industry and the country of origin for the materials we purchase. This risk-based assessment is conducted by the Company's Quality, Legal, Security, Internal Audit, and Corporate Compliance Functions.

Amneal has not employed a third-party to evaluate and address risks of human trafficking and slavery in its supply chain.

### **Certification**

Amneal requires that all material and service providers with whom we contract comply with all applicable laws, standard operating procedures, and consistent high standards of professionalism. Amneal direct suppliers are not currently required to certify that all materials incorporated into their products were sourced, processed, and manufactured in compliance with the human trafficking and slavery laws of the country or countries in which they operate.

If Amneal has reason to believe that a supplier is not in compliance with our agreement, policies, or applicable laws and regulations, the Company will provide the supplier the opportunity to remedy the non-compliant behavior or practices and to provide Amneal sufficient evidence to demonstrate corrective action. If the supplier does not remedy the non-compliant behavior or practice, or if the corrective action cannot be verified by Amneal, the Company will seek to terminate the supplier from its employ.

### **Training**

Amneal's procurement personnel are trained to identify and respond to supply chain risks such as child or forced labor as part of the procurement process. Additionally, all Amneal employees are required to acknowledge and adhere to the Company's Code of Conduct. Violations of the Amneal Code of Conduct may result in disciplinary action up to, and including, termination of employment.

## **Standards**

The company's Code of Business Conduct and Corporate Ethics and Compliance Program require Amneal employees to comply with all applicable laws and regulations, as well as company policies and procedures.

Amneal is committed to achieving the highest standards of integrity and complying with applicable legal and regulatory requirements. The company's Code of Business Conduct and Corporate Ethics and Compliance Program serve as a guide for all Amneal employees to maintain those standards. Any questions or comments regarding the company's business practices should be directed to the Amneal Ethics Hotline at [amneal.ethicspoint.com](http://amneal.ethicspoint.com) or by telephone at 1-877-412-8817.