

Description of Comprehensive Compliance Program Pursuant to the California Marketing Practices Act (California Health and Safety Code §§ 119400-119402)

1. INTRODUCTION

Tonix Pharmaceuticals Holding Corporation (“Tonix”) is committed to establishing and maintaining an effective compliance program in accordance with “Compliance Program Guidance for Pharmaceutical Manufacturers,” published by the Office of Inspector General, U.S. Department of Health and Human Services (the “HHS OIG Guidance”). Our Comprehensive Compliance Program is one of the key components of our commitment to the highest standards of corporate conduct. The purpose of our Comprehensive Compliance Program is to prevent and detect violations of law or Company policy. As the HHS OIG Guidance recognizes, however, the implementation of such a program cannot guarantee that improper employee conduct will be entirely eliminated. Nonetheless, it is Tonix’s expectation that employees will comply with our Code of Conduct, and the policies established in support of such a Code. In the event that Tonix becomes aware of violations of law or Company policy, we will investigate the matter and, where appropriate, take disciplinary action and implement corrective measures to prevent future violations. Tonix has described below the fundamental elements of our Corporate Compliance Program. As HHS OIG calls for in its Guidance, we have tailored our Compliance Program to fit the unique environment of our Company. Moreover, our Compliance Program is dynamic; we regularly review and enhance our Compliance Program to meet our evolving compliance needs.

2. OVERVIEW OF COMPLIANCE PROGRAM

2.1. Leadership and Structure.

- Compliance Officer. We have designated a senior-level official in our organization to serve as our corporate compliance officer. We are committed to our Compliance Officer having the ability to effectuate change within the organization as necessary and to exercise independent judgment. Our Compliance Officer is charged with the responsibility for developing, operating and monitoring the Comprehensive Compliance Program.
- Compliance Committee. Tonix has established a Compliance Committee to advise the Compliance Officer and assist in the implementation of the Compliance Program.

2.2. Written standards.

- Tonix’s Code of Conduct is our statement of ethical and compliance principles that guide our daily operations. The Code establishes that we expect management, employees, and agents of the Company to act in accordance with law and applicable Company policy. The Code articulates our fundamental principles, values and framework for action within our organization.

- The HHS OIG Guidance has identified several potential risk areas for pharmaceutical manufacturers, and called on companies to develop compliance policies in these risk areas. These risk areas are (1) data integrity pertaining to government reimbursement practices; (2) kickbacks and other illegal remuneration; and (3) compliance with laws regulating drug samples.
- As required by the California Health & Safety Code §§ 119400–119402, we also have established an annual spending limit of \$2,000.00 for certain promotional activities directed toward healthcare professionals in California.

3. EDUCATION AND TRAINING.

A critical element of our Compliance Program is the education and training of our employees on their legal and ethical obligations under applicable federal health care program requirements. Tonix is committed to taking all necessary steps to effectively communicate our standards and procedures to all affected personnel. Moreover, Tonix will regularly review and update its training programs, as well as identify additional areas of training on an “as needed” basis.

4. INTERNAL LINES OF COMMUNICATION.

Tonix is committed to fostering dialogue between management and employees. Our goal is that all employees, when seeking answers to questions or reporting potential instances of fraud and abuse, should know whom to turn to for a meaningful response and should be able to do so without fear of retribution. To that end, we have adopted open-door policies, as well as confidentiality and non-retaliation policies.

5. AUDITING AND MONITORING.

Tonix’s Compliance Program includes efforts to monitor, audit, and evaluate compliance with the Company’s compliance policies and procedures. We note that in accordance with the HHS OIG Guidance, the nature of our reviews as well as the extent and frequency of our compliance monitoring and auditing varies according to a variety of factors, including new regulatory requirements, changes in business practices, and other considerations.

6. RESPONDING TO POTENTIAL VIOLATIONS.

Tonix's Compliance Program includes clear disciplinary policies that set out the consequences of violating the law or Company policy. Although each situation is considered on a case-by-case basis, we will consistently undertake appropriate disciplinary action to address inappropriate conduct and deter future violations.

7. CORRECTIVE ACTION PROCEDURES.

A Compliance Program increases the likelihood of preventing, or at least identifying, unlawful and unethical behavior. However, HHS OIG recognizes that even an effective Compliance Program may not prevent all violations. As such, our compliance program requires the Company to respond promptly to potential violations of law or Company policy, take appropriate disciplinary action, assess whether the violation is in part due to gaps in our policies, practices, or internal controls, and take action to prevent future violations.