



Description of Piramal Critical Care Compliance Program Overview

I. INTRODUCTION: Piramal Critical Care, Inc. (“PCC”) is committed to establishing and maintaining an effective compliance program in accordance with the “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”). PCC’s Compliance Program is one of the key components of our commitment to the highest standards of corporate conduct.

It is PCC’s expectation that all personnel will comply with the company’s Code of Conduct, and with the company’s policies and procedures. However, as the HHS-OIG Guidance recognizes, the implementation of such a program cannot guarantee that improper employee conduct will be entirely eliminated. In the event that PCC 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.

PCC 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.

II. COMPLIANCE PROGRAM OVERVIEW:

A. Leadership and Structure:

1. Compliance Officer: We have designated a senior-level executive to serve as our corporate Compliance Officer. We are committed to ensuring that the Compliance Officer has the ability to make change within the organization, as necessary, and to exercise independent judgment. The Compliance Officer is charged with the responsibility for developing, operating and monitoring the Compliance Program.
2. Compliance Committee: PCC has established a Compliance Committee to advise the Compliance Officer and assist in the implementation of the Compliance Program.

B. Written Standards:



1. PCC's Code of Conduct is our statement of ethical and compliant 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.

2. 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.

C. **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. PCC is committed to taking all necessary steps to effectively communicate our standards and procedures to all affected personnel. Moreover, PCC will regularly review and update its training programs, as well as identify additional areas of training on an "as needed" basis.

D. **Internal Lines of Communication:** PCC is committed to fostering dialogue between management and employees. Our goal is that all employees, when seeking answers to questions or reporting suspected or observed misconduct, should know who to turn to for a meaningful response and should be able to do so without fear of retaliation.

E. **Auditing and Monitoring:** PCC'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.

F. **Responding to Potential Violations:** Although each situation is considered on a case-by-case basis, we will consistently undertake appropriate disciplinary action to address misconduct and deter future violations.



G. 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 that the company responds promptly to potential violations of law or company policy, takes appropriate disciplinary action, assesses whether the violation is in part due to gaps in our policies, practices, or internal controls, and takes action to prevent future violations.

CALIFORNIA – ANNUAL DECLARATION OF COMPLIANCE:

PCC is committed to conducting its business ethically and in accordance with all applicable laws. We have developed a Comprehensive Compliance Program (“CCP”) in accordance with California Health and Safety Code sections 119400 and 119402. The CCP is consistent with both the April 2003 Compliance Program Guidance for Pharmaceutical Manufacturers published by the Office of Inspector General of the U.S. Department of Health and Human Services and the Pharmaceutical Research and Manufacturers of America (“PhRMA”) Code on Interactions with Health Care Professionals. PCC has set the annual aggregate limit on covered promotional expenditures at \$2,000.00 per covered California medical or healthcare professional. This limit may be revised by PCC from time to time.

To the best of our knowledge and based on our good faith understanding of the statutory requirements of this California law, we are, in all material respects, in compliance with the CCP and these statutory requirements.

The HHS OIG has recognized in the Compliance Program Guidance for Pharmaceutical Manufacturers that the implementation of an effective compliance program cannot entirely eliminate the chance of improper conduct. PCC’s CCP is reasonably designed with the goal of preventing, detecting, and addressing improper conduct. In the event PCC becomes aware of potential violations of law or Company policy, PCC will, where appropriate, investigate the matter, take disciplinary action, and/or implement corrective measures to prevent future violations. This description of our Compliance Program reflects the plan we have implemented. We will periodically reassess the program to improve it, and may refine the elements as necessary. PCC is committed to upholding the highest standards of business conduct and ethics in its relationships with customers, employees, shareholders, the business community, and state and federal governments.

Dated: 22-July-2024