

# Sepracor Inc.

## Code of Conduct and Ethics

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## **Message from the President and CEO of Sepracor Inc.**

### **Our Mission:**

*Sepracor is dedicated to discovering, developing and commercializing innovative pharmaceutical products and services that improve health and quality of life. We understand our responsibility to ensure that decisions are guided first and foremost by what is in the best interests of patients. We are committed to the welfare of the patients we serve, the success of our employees and to increasing shareholder value.*

### **Introduction - Purpose of the Code**

The Sepracor Code of Conduct and Ethics (the “Code”) is our guide to understanding how our mission statement translates into our everyday activities. Our Code builds upon our cherished Sepracor values by establishing general compliance, legal and ethical standards that apply not only to our relationships with customers and patients, but to each other as well. This Code applies to all of us – from the Board of Directors and the Company’s officers to every employee, whether in Marlborough, outside the U.S., or in the field.

As an employee of Sepracor, you are expected to uphold our Company’s reputation day after day, in matters both large and small. By adhering to legal standards, acting in an ethical manner and making business decisions that are consistent with our policies, procedures and values, you can make a positive difference in helping Sepracor achieve our shared goal of *Improving Health Through Innovation*. This Code is designed to assist you in this regard by providing general guidance when faced with legal and ethical questions.

However, the Code is by no means exhaustive and does not provide a comprehensive or complete explanation of all laws, state and federal regulations, and business policies we encounter in the course of our everyday activities. If you have any questions about interpreting or applying the Code or our policies and procedures, you should discuss the matter with your supervisor or a member of the Compliance, Legal Affairs or Human Resources Departments.

Following the letter and spirit of the Code is critical to our future success.

Thank you for your continued support and commitment to upholding the highest ethical conduct.

Sincerely,



Adrian Adams  
President and Chief Executive Officer

## **Compliance with Laws, Regulations and Standards**

Sepracor Inc. and all of its subsidiaries and affiliates (“Sepracor” or the “Company”) will conduct all its activities in accordance with the laws of the states and countries in which it operates. All employees are required to comply with federal, state, local, and foreign laws and regulations in the places where they conduct business. In addition, all employees are expected to follow this Code in all respects, except where (1) different requirements are mandated by local laws; or (2) a waiver has been obtained pursuant to this Code (see page 15).

Although by no means exhaustive of all the rules and standards governing our industry and our business, an overview of some of the key laws is provided below.

### **The Federal Food, Drug, and Cosmetic Act (“FDCA”)**

The FDCA established the Food and Drug Administration (“FDA”) in 1938. The FDCA and its implementing regulations set forth the essential regulatory structure for the marketing and promotion of prescription drugs in the United States. The primary purpose of the FDCA is to ensure the safety and efficacy of drugs before they become available to the public and to regulate prescription drug marketing and promotion. The FDCA and FDA regulations require that drug manufacturers provide information about their products that are (a) truthful and accurate, (b) fairly balanced, in both content and form, and (c) consistent with FDA-approved prescribing information. If a drug manufacturer disseminates labeling or promotional material that the FDA determines to be “false or misleading”, the drug is deemed “misbranded”. The FDCA prohibits the manufacture and distribution of misbranded drugs.

It is Company policy to keep the FDA and the medical community fully informed of the uses, safety, contraindications and side effects of its products, including the timely reporting of adverse event experiences. Sepracor and its employees, officers and directors will practice a policy of disclosure and transparency to the FDA and the health care community at all times.

### **The Prescription Drug Marketing Act of 1987 (“PDMA”)**

The PDMA requires controls and tracking for prescription drug samples in the United States. The PDMA was designed to improve the distribution and dispensing of prescription drug samples by providing a “closed” system for legitimate handlers of these drugs. Such a closed system is intended to prevent the diversion of these samples out of legitimate channels. Under the PDMA, it is a violation to:

- Sell, barter, or trade prescription drug samples;
- Deliver prescription drug samples to anyone who is not licensed to prescribe prescription drugs;
- Deliver prescription drug samples to a retail pharmacy; and
- Deliver prescription drug samples without a written request from the practitioner.

## **Government Health Care Programs – Fraud and Abuse Laws**

The U.S. federal fraud and abuse laws cover all products or services that may be reimbursed, in whole or in part, by federal healthcare programs, such as Medicare or Medicaid. The fraud and abuse laws encompass various risk areas, including improper payments to healthcare professionals and federal reimbursement based on false claims.

### **The Anti-kickback Statute**

The federal anti-kickback statute prohibits “remuneration” to induce or reward the purchasing of any item or service that is paid, in whole or in part, by the federal government, such as the purchase of prescription medicines through Medicare or Medicaid. This statute is extremely broad and covers a wide variety of arrangements. The statute may be violated if only one of the purposes of an arrangement is to induce or reward the purchase of a product by the federal government even though additional, legitimate purposes may also exist. Remuneration is considered anything of value, including cash, grants, consulting payments, services, free goods, entertainment, etc. Absent safeguards, many common industry practices and arrangements may be construed as inappropriate and implicate the anti-kickback statute.

Although there are a number of narrow exceptions that do not violate the anti-kickback statute, such as bona fide consulting arrangements between a pharmaceutical company and healthcare professionals, these so-called “safe harbors” must be followed scrupulously in order to avoid even the perception that an improper activity may be taking place and the risk of possible enforcement action. The consequences of an enforcement action are severe for both the individuals involved and the Company. Violations of the anti-kickback statute can result in criminal prosecution, civil monetary penalties, and/or exclusion from participation in federal healthcare programs like Medicare and Medicaid.

### **The False Claims Act**

In cases of reimbursement for pharmaceutical products under a federal healthcare program like Medicare and Medicaid, the federal government considers the promotion of an unapproved drug, or the promotion of an unapproved use or dose for an approved drug, a false claim against the Government and unlawful. Such “off-label” promotion, like violations of the anti-kickback statute, carries severe penalties for the individuals and companies involved.

Because pharmaceutical manufacturers are required to provide information that is truthful, accurate, fair balanced and consistent with FDA-approved prescribing information, all promotional materials regarding Sepracor’s products must relate to approved uses and dosing.

## **Anti-Bribery / Anti Corruption Laws**

Sepracor currently operates in the United States, Ireland and Canada and conducts business in many countries around the world. All of these countries prohibit a kickback to, or bribery of, government officials and have passed legislation making it illegal for a company or its employees to engage in bribing government officials outside of the country where the business is located. In the U.S., the Foreign Corrupt Practices Act (“FCPA”) is an example of such legislation and most large economies incorporate a similar international treaty called the OECD Convention. A kickback or bribe under these foreign bribery laws may be defined as any money, fee, commission, credit, gift, gratuity, thing of value or compensation of any kind that is provided, directly or indirectly, and that has as one of its purposes the improper obtaining or rewarding of favorable treatment from a foreign government official in a business transaction. Failure to comply with such laws could expose you and the Company to significant fines and/or criminal charges.

Recognizing that cultural difference and the complexity of local customs or laws may create issues under these laws, it is critical that you discuss any such issues with your manager and gain training on them from the Compliance or Legal Affairs Departments prior to engaging in any international business.

## **Government Price Reporting Laws**

Sepracor is party to numerous state and federal pricing agreements, and is subject to price reporting obligations under those agreements and under the various governing laws. We report to the government under the Medicaid Rebate Act, the Medicare Modernization Act, and the Veteran’s Healthcare Act, among others. These reporting requirements impact the level of rebates we pay to government programs, such as rebates under the Medicaid Rebate Act and certain state pharmaceutical assistance programs, the maximum prices charged to federal government purchasers under the Federal Supply Schedule or to federal government purchases under the Federal Supply Schedule or the Public Health Service Program, and the reimbursement paid by the Medicare program for certain drug products.

Any price reporting errors or omissions could lead to significant financial penalties, civil fines, and, in some cases, criminal penalties. Sepracor has developed and implemented policies and procedures that are designed to ensure price reporting accuracy and compliance. Thus, Sepracor marketing, sales and contracting activities must comply strictly with Sepracor policies, especially those policies that regulate relationships and transactions with customers. Any new program or new product contracting strategy that has the potential for conferring price concessions to customers, must undergo the appropriate legal review and approval. If you are involved in any contract discussions or arrangements with a customer regarding the sale of Sepracor products, you should consult with the Legal Affairs Department before entering into any transaction.

## **Anti-Trust and Fair Trade**

The purpose of the U.S. antitrust and fair competition laws is to ensure a fair and competitive free market system. Thus, while Sepracor competes vigorously in its many business activities, its efforts in the marketplace must be conducted in accordance with the letter and spirit of all applicable antitrust, unfair competition and fair trade practice laws (collectively, “antitrust laws”). Since antitrust laws can be highly technical and may vary from state to state and from country to country, it is important that you speak with a member of Sepracor’s Compliance or Legal Affairs Departments whenever you deal or interact with any of our competitors (e.g., discussions at trade association meetings), or suppliers.

Violations of antitrust laws can lead to criminal prosecution, monetary fines, civil penalties, and litigation that can result in damages of millions of dollars.

## **Accurate Books and Records and Public Company Reporting Laws**

It is Sepracor’s policy to provide full, fair, accurate, timely and understandable disclosure in reports and documents filed with, or submitted to, the U.S. Securities and Exchange Commission or any other regulatory authority (including any taxing authorities) and in all other public communications. Accurate books and records, maintained in accordance with applicable accounting policies, laws, rules and regulations, are essential to assure the maintenance of high ethical standards and compliance with various laws. These laws require, among other things, that Sepracor (1) maintain effective disclosure controls and procedures to ensure that all material information relating to Sepracor and its subsidiaries is made known to the persons responsible for preparing the Company’s financial reports and (2) have internal controls over financial reporting to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

It is a violation of this Code and Sepracor policy to (1) make false or inaccurate entries in any of the Company’s book or records; (2) understate or overstate reports of sales or expenses; and/or (3) alter any documents used to support any corporate reports. In addition, selective data reporting (e.g. recording only passing or within specification results) and recording results in other than official records is prohibited. All assets and liabilities of the Company must be recorded in its regular books of account using generally accepted accounting principles.

If any employee, manager, or an outside party, requests that you make a false or inaccurate record of any kind, or if you have a concern or complaint about questionable accounting or auditing matters, you have a duty to report that to a manager, the Compliance Department, the Legal Affairs Department, or, if you wish, to the Audit Committee of the Board or Directors. You may submit your concern anonymously to the Compliance Department and Audit Committee through Sepracor’s Compliance Hotline.

