



KV Pharmaceutical Company Compliance Program*

I. INTRODUCTION

KV Pharmaceutical Company and its subsidiaries (collectively, “KV” or “the Company”) are firmly committed to compliance with federal, state, and local laws and regulations in all facets of their corporate activities. Accordingly, KV has instituted a Corporate Compliance Program (the “Compliance Program” or “Program”) covering all of its operations and is applicable to (1) all Company employees and directors¹, and (2) temporary workers, consultants, independent contractors, agents, and representatives (collectively, “contractors”) of KV who have notice of the provisions of the Compliance Program. This document provides an overview of KV’s Compliance Program and explains how KV administers the Program.

The KV Board of Directors has reviewed and approved KV’s Compliance Program, and has delegated authority to KV’s Chief Compliance Officer to implement and administer the Program.

II. DEFINITION AND PURPOSE

KV’s Compliance Program is an integrated, enterprise-wide set of policies, practices, and internal controls designed to prevent, detect, and correct illegal or other improper activity, and to promote compliance with federal, state, and local laws and Company policies. A primary goal of the Compliance Program is to promote within KV a culture of commitment to the prevention, detection, and resolution of situations that may not conform to applicable standards of conduct or business ethics.

KV is committed to producing high quality products and providing high quality services in full compliance with all applicable requirements and authorities, and an effective Compliance Program will help achieve these goals. An effective Compliance Program can help prevent misconduct from occurring, and can identify and resolve potential problems before they become time-consuming distractions or violations. A commitment to compliance is also good business: customers and suppliers not only expect companies to have effective compliance programs, but frequently take a company’s commitment to

¹ The term “director” as used throughout this Program refers to any member of the Company’s Board of Directors.

* Formerly “Compliance Plan”

compliance into account when deciding whether to do business with that firm. Employees, shareholders, contractors, and other stakeholders also benefit from an effective compliance program, because morale and productivity are higher when all involved are aware of KV's commitment to high ethical standards.

III. ELEMENTS OF KV'S COMPLIANCE PROGRAM

A. COMPLIANCE DOCUMENTS

The following documents constitute the foundation of KV's Compliance Program: (1) this Compliance Program document, (2) KV's Employee Handbook, (3) HR Policy 800.029, "Standards of Business Ethics" (the "Corporate Compliance Policy"), (4) compliance-related memoranda, publications, and training materials, and (5) official written policies and procedures governing the duties, activities, and responsibilities of KV employees ("Policies and Procedures"). These documents support KV's Compliance Program in the following ways:

1. This Compliance Program document provides an overview of how KV intends to structure, administer, enforce, and otherwise effectively implement the Compliance Program, and describes the compliance-related activities, responsibilities, and authority of KV directors, officers, managers, and others.
2. The Employee Handbook sets forth policies, principles, and rules governing ethical conduct of employees, and provides an overview of KV's philosophy, culture, mission statement, and general corporate statements of ethical and compliance principles (i.e., code of conduct).
3. The Corporate Compliance Policy sets forth a detailed statement of KV's compliance philosophy and commitment to compliance, as well as practical guidance on how to handle compliance issues arising in specific areas.
4. Compliance-related memoranda, publications, and training materials provide timely and targeted guidance to personnel on discrete compliance-related topics.
5. Policies and Procedures are official written Company documents detailing purpose, duties, responsibilities, and activities involved in an individual's daily work. Many Policies and Procedures incorporate specific regulatory requirements, e.g., compliance with Medicaid rebate regulations or federal procurement laws. Examples include the following:
 - a. Policies on "Complying with Federal Health Care Program Rules & Requirements" and "Compliance with Federal Health Care Program Laws and Regulations Regarding Sales, Marketing, and Government Price Reporting/Contracting" set standards, assign responsibilities, and provide guidance on topics of particular

concern relating to Federal Health Care Programs (e.g., Medicare, Medicaid, Department of Veterans Affairs (VA) contracting, etc.). Topics covered by these policies include internal reviews of price proposals, disclosure and reporting of discounts, separation of functions when awarding educational grants, and prohibitions on kickbacks and “marketing the spread.”

- b. KV’s “Corporate Governance Guidelines” addresses the role of the Board of Directors, the directors’ relationship with management, director qualifications and responsibilities, director independence, board committees, director access to officers and employees, management evaluation and succession, director compensation and education, and annual board self-evaluations.
- c. The “Senior Executive Code of Ethics” policy sets forth supplemental ethical standards of conduct for certain senior officers, including the obligations to produce full, fair, timely, and accurate disclosures in reports; to report violations of the Code to the Chief Compliance Officer; and to comply with applicable laws, rules, and regulations.
- d. The policy on “Calculation of PHS Pric[ing]” addresses the timely and accurate calculation of Public Health Service (PHS) “ceiling prices” under section 340B of the Public Health Service Act.
- e. “Price Reductions to the Federal Supply Schedule (Department of Veterans Affairs)” addresses obligations imposed by the Price Reductions clause in VA Federal Supply Schedule (FSS) contracts.
- f. KV has policies relating to various pricing-related topics relevant to the Medicaid, Medicare, and VA programs, including “Establishment of ‘Best Price’,” “Quarterly Calculation of AMP,” and “Quarterly and Annual NFAMP Calculation.”
- g. The Company also has policies addressing various sales and marketing compliance standards, including prescription drug sample management, sales representative training, PhRMA Code guidelines, quarterly reconciliations, and additional policies regarding non-price-related compliance topics, such as unlawful harassment, worker health and safety, trading in securities of the Company, Current Good Manufacturing Practices (cGMP), etc.

For purposes of compliance with California Health & Safety Code §§ 119400-119402, KV has established for each of its entities a specific annual dollar limit of \$2,500.00 for gifts, promotional materials, or items or activities that it may give or otherwise provide to an individual California-based medical

or health care professional. This limit does not include spending that is exempt under sections 119400-119402.

Additionally, KV has a marketing code of conduct in compliance with the Massachusetts Department of Public Health (DPH) regulation 105 C.M.R. 970.000, and has adopted a program to routinely train appropriate employees, including, without limitation, all sales and marketing staff, regarding this marketing code of conduct.

B. RESPONSIBILITIES

1. Chief Compliance Officer

The Chief Compliance Officer (“CCO”) oversees the Compliance Program, functioning as an independent and objective body that reviews and evaluates compliance issues/concerns within the organization. The CCO ensures that the Board of Directors, management and employees are in compliance with the rules and regulations of regulatory agencies, that Company compliance policies and procedures are being followed, and that behavior in the organization meets the Company’s standards of conduct.

The CCO has direct access to the Company’s Chief Executive Officer (“CEO”) and Presidents, Board of Directors and Board committees, all senior management, and in-house legal counsel, as well as subject matter expert external legal counsel. This includes the authority to communicate promptly and personally with KV’s Board of Directors or the Audit Committee of KV’s Board of Directors regarding any matter involving criminal conduct or potential criminal conduct.

The Company has a thorough Position Description detailing the duties and responsibilities of the CCO position. Fundamental responsibilities are as follows:

- a. Developing, implementing, and updating of Policies and Procedures to promote compliance with applicable laws, regulations, and ethical standards.
- b. Reporting to KV’s Board of Directors and/or Audit Committee and the KV entities’ CEOs/Presidents on compliance matters. The CCO will personally report on the implementation and effectiveness of the Compliance Program to the KV Board of Directors or the Audit Committee of KV’s Board of Directors at least annually, and provide quarterly updates to the Audit Committee of the Board on compliance issues and compliance cases
- c. Effectively communicating the Compliance Program to employees and affected contractors.
- d. Oversight of the Company’s compliance education and training requirements.

- e. Establishing and applying effective monitoring and auditing processes to identify compliance issues and evaluate the effectiveness of ongoing compliance efforts.
- f. Promoting and administering reporting systems, including the Compliance Hotline, whereby employees and contractors can report potential or actual violations of the Compliance Program.
- g. Responding to compliance questions or concerns and, in coordination with counsel, as appropriate, designing and coordinating internal investigations and any resulting corrective actions.
- h. Participating with outside subject matter expert counsel in the appropriate reporting of self-discovered violations to government officials.

The CCO has the authority, subject to any restrictions of law, to review all documents and records created or controlled by any KV department or business unit. This authority includes, but is not limited to, the authority to review records regarding employees, contractors, regulatory matters, manufacturing, financial, security, training, sales and marketing, and contracts.

CCO Designated Assistants – Internal Legal Counsel, the Vice President of Human Resources, and the Vice President of Quality have each been designated to assist the CCO in implementing KV's Compliance Program. The CCO may from time to time delegate specific compliance duties to one or more of these designees or other appropriate Legal or Human Resource Department representatives or managers, but the CCO will remain sufficiently involved to fulfill the compliance oversight function.

In the event the CCO is the subject of a complaint or investigation, s/he will recuse him/herself from investigation of the matter, and any investigation and related activity will be coordinated under the direction of KV's CEO, Board of Directors, and/or Audit Committee, depending on the presenting circumstances.

2. Chief Executive Officers and Presidents

KV's CEO and the CEOs/Presidents of KV's subsidiaries are ultimately responsible for their respective entities and for their employees' compliance with law, regulation, and Company policy. Assisted by the CCO and other members of management, the CEOs and Presidents develop corporate policy, oversee the Compliance Program, and have overall responsibility for their entities' adherence to legal and contractual obligations.

3. KV Law Department or Outside Counsel

The CCO will consult, or ensure that a designee consults, with subject matter expert legal counsel (internal or external) for guidance on matters requiring legal advice or analysis. Consulting counsel will provide legal direction and guidance on the legal framework governing compliance matters, and will assist the CCO in formulating appropriate corrective action and reporting misconduct to the CEOs/Presidents as appropriate, to the Audit Committee if reasonable responsiveness is not demonstrated by the CEO/President, or subsequently to proper authorities in the event reasonable responsiveness is not demonstrated by the previously listed channels. They may also assist the CCO if requested to participate in internal investigations of suspected wrongdoing. The Law Department will normally be responsible for coordinating responses to government requests for information and records in the possession or control of KV. In the event Counsel is the subject of a complaint and ensuing investigation, s/he will recuse him/herself from any involvement in the investigation.

4. Managers and Supervisors

KV managers and supervisors will assist the CCO by implementing the Compliance Program, enforcing standards, reporting misconduct, and ensuring that personnel within their area of management are aware of and comply with all applicable laws, regulations, and corporate policies. In particular, management and supervisory personnel are responsible for:

1. Monitoring changes in the industry and advising the CCO regarding the need to alter Policies and Procedures for the areas within the manager's or supervisor's responsibility;
2. Implementing, maintaining, and enforcing the Policies and Procedures for the areas within the manager's or supervisor's responsibility;
3. Incorporating compliance considerations as part of the employee performance evaluation process;
4. Ensuring that the relevant Policies and Procedures, Compliance Program documents, and training and education materials are distributed to all individuals whose duties and activities are governed by the policies set forth in the materials;
5. Planning and coordinating compliance-related education and training;
6. Supporting execution of audits and surveys, corrective actions, gap analyses and preventive activities; and
7. Reporting all potential and actual violations as well as any situation with high risk for potential violations.

5. Corporate Compliance Committee

KV has established a Corporate Compliance Committee to assist and advise the CCO in overseeing the Compliance Program with respect to: (i) awareness of and compliance with the laws and regulations applicable to the Company's industry and business; and (ii) compliance with the Company's Code of Conduct and related policies by employees, officers, directors, and other agents and associates of the Company. A Compliance Committee Charter outlines the Committee's purpose, membership and meetings, duties and responsibilities, authority, and resources.

C. EDUCATION AND TRAINING

KV has developed and implemented compliance education and training requirements for all employees, directors and affected contractors. The CCO will, in consultation with the CEO and Presidents, the KV Law Department, KV Learning & Development personnel, and appropriate subject matter experts, oversee KV's compliance training and education program. This compliance training program includes broad compliance training for all sales and marketing employees, targeted training on selected compliance-related topics for affected employees, directors and contractors, and periodic compliance training for other key functional areas on an ad hoc basis. Compliance training is documented and records maintained.

It is KV's policy that each new employee will receive training on compliance responsibilities as part of their initial orientation. More intensive training may be provided based on issues identified during internal reviews. Compliance with Company training requirements will be a condition of employment, and failure to comply will result in disciplinary action.

This Compliance Program document, the Employee Handbook, and compliance policies and procedures are made available to employees on the Company's intranet, and employees are responsible for reviewing these documents. In addition, the CCO, the KV Law Department, and all supervisors/managers are available or will provide appropriate approved resources on a continuing basis to answer questions from employees who seek clarification of compliance issues.

In partnership with external and internal legal counsel and appropriate functional area managers, the CCO will ensure that relevant publications issued by or on behalf of the government or other regulatory bodies are appropriately distributed to CEOs/Presidents, supervisors and managers, and affected employees. In conjunction with counsel and/or the Vice President of Human Resources, the CCO will also periodically disseminate compliance-related memoranda announcing new Policies and Procedures or changes to Compliance Program documents as necessary to respond to new federal or

state laws, rules, regulations, or industry standards. The CCO should, where appropriate, include such publications and compliance-related memoranda in training manuals and materials.

D COMMUNICATION

1. Reporting Suspected Problems

All functional area heads and management personnel have an "open door policy" allowing employees to discuss any possible compliance problems. The CCO or one of the three designated assistants will be reasonably available to respond to individuals who seek clarification with respect to the Compliance Program or any related policy or procedure.

Employees and contractors are required to report any significant compliance problem of which they become aware. The failure to report a problem of which an employee or contractor is aware may itself represent a potential violation of KV's performance and conduct policy and/or the Compliance Program. Individuals who wish to remain anonymous may report suspected violations via the Compliance Hotline (see below). Where an individual making a report identifies him- or herself in the report but requests that his or her identity remain confidential, KV will endeavor to maintain the requested anonymity to the extent consistent with the best interests of the Company. In some instances, however, KV may need to reveal the person's identity, if known, in order to comply with legal requirements and/or to facilitate an investigation.

Generally, reports of possible compliance-related violations should be made to the employee's/contractor's supervisor or next level manager/executive, and/or directly to the CCO or one of the three designated assistants, either in person, by telephone, in writing or email, or through the Compliance Hotline (see below). Supervisory personnel who receive compliance-related reports should promptly report the information to the CCO, who will then review the report and take appropriate action, including, where appropriate, coordination of an internal investigation. Oral reports should be memorialized in writing. Reports concerning the conduct of supervisory or management personnel should be made to appropriate individuals who have functional or supervisory authority over such individuals and/or directly to the CCO or one of the three designated assistants.

2. Compliance Hotline

KV has established and publicized a Compliance Hotline to report any suspicion of wrongdoing or suspected violations of legal or ethical standards. The Compliance Hotline is operated by an independent third party service provider, and is available to callers at all times. Callers can request that their

identity not be disclosed, providing for complete anonymity, if desired. The Hotline is also available for posing questions regarding the requirements of the Compliance Program or related Policies and Procedures. The CCO will maintain a record of Hotline calls, including the nature and result of any investigation. The telephone number for the KV Compliance Hotline is 1-800-679-0187 (toll free). The Company's Human Resources and Legal departments will have ongoing access to the hotline call records and monthly reports.

3. Non-Retaliation

The successful implementation of this Compliance Program depends in part on the willingness of employees and contractors to ask questions and raise concerns about compliance issues. Accordingly, no form of retaliation may be taken against (1) directors, employees, or contractors who make good faith claims or complaints to the Company or to any agency charged with jurisdiction over the complaint or claims, or (2) witnesses to any such complaints or claims. Further, the initiation of such a claim or complaint will not affect the employee's employment, evaluation, wages, advancement, assigned duties, shifts, or any other condition of employment or career development. Because of the potentially serious nature of such complaints and claims, directors, employees, or contractors who knowingly make false allegations against the Company, a supervisor, or any other employee may be subject to discipline up to and including discharge.

Although the fact that an individual "self reported" may be taken into account when determining appropriate disciplinary action, the reporting individual remains subject to disciplinary actions for his or her improper acts.

E. COMPLIANCE MONITORING

1. Tracking and Recordkeeping

The CCO will ensure the proper processing and maintenance of records of compliance-related reports and communications, and will:

- a. Record and maintain reports of possible violations of the Compliance Program as well as all inquiries or complaints relating to the Compliance Program; the Company's Human Resources and Legal departments will have ongoing access to the hotline call records and monthly reports.
- b. Record the appropriate disposition of compliance-related reports, including the results of any investigation, whether corrective action or disciplinary measures were recommended, and whether any overpayments were identified;
- c. Handle all compliance matters in a manner that maintains the confidentiality of involved parties, to the extent permitted by law

and/or to the extent reasonable and consistent with KV's interests in light of the needs of the investigation;

- d. Monitor compliance files on a regular basis to ensure that prompt follow-up action has been taken on all outstanding complaints and concerns; and
- e. Maintain complete investigation files and make available for review as required by legal counsel or other appropriate party.

2. Reviews and Audits

The CCO will conduct periodic internal reviews (self-audits) of systems, processes, and procedures to ensure that KV entities comply with legal and policy requirements applicable to their operations. The frequency and comprehensiveness of such internal reviews will be based on such factors as the pervasiveness and complexity of relevant legal requirements, the risks and potential consequences of noncompliance, the importance of the system or process to the entity's operations, and the length of time that has passed since the system or process was reviewed previously. Regular assessments should be made of: (1) high-risk sales and marketing practices, (2) regulatory compliance, and (3) any other key areas identified by the CCO or legal counsel.

In addition, the CCO or another appropriate individual designated by management will arrange for periodic review of any deficiencies cited in reports by regulatory agencies. Significant variations from established benchmarks will trigger reasonable investigation by the CCO in conjunction with legal counsel, as appropriate. All internal reviews and audits conducted will be documented.

F. ENFORCEMENT OF THE COMPLIANCE PROGRAM

1. Non-Employment of Individuals or Entities Excluded From Participation in Federal Health Care Programs

KV will not knowingly (a) hire, retain, or do business with any person or organization that has been excluded from participation in federal health care programs²; or (b) hire, retain, or offer any type of appointment to any person as an officer, director, or senior manager (plant managers/functional area heads and above) who (1) has been debarred, suspended, proposed for debarment, or declared ineligible for the award of contracts by any federal agency³; (2) has been convicted of, or pleaded *nolo contendere* to, a criminal offense involving

² A listing of parties excluded from participation in federal health care programs is available on the internet at <http://oig.hhs.gov/fraud/exclusions.asp>

³ A listing of parties excluded from procurement and nonprocurement programs is available on the internet at <http://www.epls.gov/eplsearch.do>.

fraud in government programs; or (3) has been convicted of, or pleaded *nolo contendere* to, any felony within the past seven years. If a current employee or contractor becomes ineligible for continued employment, affiliation, or retention by virtue of any of the foregoing, KV will, unless exceptional circumstances exist, terminate the employment or other contract, subject to any union or contract rights.

The CCO will audit the work of Human Resources with respect to ensuring that an appropriate background check – in accordance with applicable law – is conducted as part of the new-hire process. All applicants as well as current employees and contractors have a continuing obligation to inform management as soon as possible if they become the subject of any action, charge, or investigation which could lead to their ineligibility from participation in federal procurement or health care programs.

2. Discipline

KV will implement corrective action and discipline in response to compliance problems on a fair and equitable basis. All violations of Compliance Program requirements by KV directors, officers, managers, and employees are subject to appropriate discipline. Violations subject to discipline include, without limitation, the failure to detect and report a problem of which the individual is aware or reasonably should have been aware. Intentional or reckless actions will subject individuals to more significant discipline than problems resulting from negligence.

The determination of appropriate discipline will take into account all relevant factors, to include existing contractual or other legal obligations affecting the individual.⁴ Performance for employees should also include an annual acknowledgment of individual adherence to the Compliance Program. A record of any discipline imposed under the Compliance Program will be maintained in the individual's personnel file.

In determining the appropriate discipline for violations under the Compliance Program, KV may consider:

- a. The extent to which the person acted knowingly, intentionally, or with reckless disregard or deliberate indifference;
- b. The nature and extent of potential criminal, civil, or administrative liability of individuals;
- c. The individual's prior employment or other affiliation history with KV;

⁴ Although no element of the Compliance Program or any document pertaining to the Compliance Program will create or affect any contract rights that may exist between a KV entity and a person or entity employed or retained by KV, all KV directors and employees are nonetheless bound by the provisions of this Compliance Program.

- d. Whether the matter at issue had been the subject of prior compliance training or audits at KV;
- e. The impact of the problem or incident on KV's operations; and
- f. The extent to which the problem or incident reflects a systemic or departmental failure to adhere to the Compliance Program.

**G. RESPONSES TO SUSPECTED COMPLIANCE PROBLEMS;
INVESTIGATION AND CORRECTIVE ACTION**

1. Internal Investigations

Upon receipt of a report of suspected or actual compliance violation, the CCO or his/her designee will, in coordination with and under any direction from legal counsel as appropriate, promptly conduct an internal investigation of credible allegations of violations in accordance with the procedures outlined in the Company's Human Resource Policy 800.029, "Standards of Business Ethics." Preliminary information may be such that the CCO should inform management executives of a potential compliance problem prior to investigation. If the CCO believes that the presence of employees under investigation may jeopardize the integrity of an investigation, the CCO may recommend to the affected management executive that the employee be temporarily suspended or temporarily reassigned to another work area. An internal investigation may include interviews and a review of relevant documents. The CCO or his/her designee will maintain documentation or other resources sufficient to memorialize the nature, scope, and outcome of any internal investigation that is undertaken.

2. Government Investigations

It is KV's policy to cooperate with government investigators. To assure that KV can do so appropriately, the CCO will coordinate with KV's Law Department on any responses to government requests for information and records pertaining to matters involving possible compliance violations. Any request for such information, including requests for interviews from government agencies, should be reported promptly to the CCO.

3. Corrective Action

Upon verifying the factual basis of a problem or suspected violation, the CCO, in consultation, as needed, with the affected management executive and appropriate external and/or internal legal counsel, will formulate and coordinate an appropriate response as soon as practicable. Corrective action may include:

- a. Conducting further investigation of the alleged problem;

- b. Preparing recommendations for corrective action in the form of a corrective action plan;
- c. Correcting the practices within the functional area which led to the problem and incorporating measurements to confirm that the problems are corrected;
- d. Disclosure of the matter to government entities;
- e. Notifying KV's Audit Committee or Board of Directors of the matter and the planned or actual response;
- f. Institution of appropriate disciplinary action against the director or employee who is involved in the problem;
- g. Exercising contractual remedies against a contractor who is involved in the problem;
- h. Undertaking a program of education within the appropriate business unit or functional area to prevent similar problems in the future;
- i. Revising KV policies, as warranted, based on results of or lessons learned from investigations;
- j. Identifying the harm that resulted from the conduct and evaluating whether restitutionary measures would be appropriate;
- k. Reassessing the effectiveness of the Compliance Program and making modifications if necessary to prevent similar conduct;
- l. Calculating the amount of any overpayment received and determining the method for making appropriate repayment; and
- m. Other action as would be appropriate given the presenting circumstances.

Credible evidence substantiating a violation of any law, whether criminal or civil, will be promptly referred to the appropriate external and/or internal counsel to evaluate the seriousness of the matter and the necessity and timing of any disclosure to appropriate state and/or federal authorities. If the investigation reveals that there is systemic non-compliance with Compliance Program requirements, the CCO will consult with counsel to evaluate: (a) the adequacy of corrective action taken, and (b) whether the Compliance Program should be modified to address the identified compliance problem.

H. MAINTENANCE AND AMENDMENT OF COMPLIANCE PROGRAM DOCUMENTS

1. COMPLIANCE PROGRAM FILES

The CCO will establish and maintain effective filing and documentation systems for securing compliance records. All documents that the CCO believes

to be subject to a legal privilege (e.g., the attorney-client privilege) should be conspicuously identified and secured.

2. CORPORATE DOCUMENT POLICY

All KV employees will comply with Company document retention policies governing the creation, alteration, distribution, retention, storage, retrieval, and destruction of documents. Each functional area manager will monitor compliance with this policy within his or her area of responsibility.

3. AMENDMENT OF COMPLIANCE PROGRAM DOCUMENTS

The CCO should perform periodic reviews of Compliance Program documents. Changes to the Compliance Program will be made at the direction of the CCO, KV's CEO, or the Audit Committee of the Board of Directors.

The CCO will ensure that all affected directors and employees are notified of amendments to Compliance Program documents, and that such amendments are promptly distributed or otherwise made available to directors and employees.