

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
KING PHARMACEUTICALS, INC.**

I. PREAMBLE

King Pharmaceuticals, Inc., and its United States subsidiaries that manufacture or sell pharmaceutical products (collectively, “King”) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) in which King participates and the requirements of other government programs in which King participates (collectively, “Federal Health Care Programs”) specified below in Section II.C.2 (Federal Health Care Program Requirements). Contemporaneously with this CIA, King is entering into a settlement agreement with the United States (Settlement Agreement), and this CIA is incorporated by reference into the Settlement Agreement. King also will enter into settlement agreements with various States, and King’s agreement to this CIA is a condition precedent to those agreements.

Prior to the Effective Date of this CIA (as defined below), King established a voluntary compliance program which, as represented by King, includes, among other things, the appointment of a Corporate Compliance Officer, the development and dissemination of a Code of Conduct, the establishment of written policies and procedures, a Disclosure Program, screening measures for Ineligible Persons, review and disciplinary proceedings, regular training to Covered Persons concerning King’s Code of Conduct and policies and procedures, and regular internal auditing.

King shall continue the operation of its compliance measures in accordance with the terms set forth below for the term of this CIA. King may modify its voluntary compliance measures as appropriate, but, at a minimum, King shall ensure that during the term of this CIA, it shall comply with the integrity obligations enumerated in this CIA.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by King under this CIA shall be 5 years from the effective date of this CIA, unless otherwise specified. The effective date shall be the date on which the final signatory of this CIA executes this CIA (Effective Date). Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, VIII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) King's final Annual Report; or (2) any additional materials submitted by King pursuant to OIG's request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. "Covered Persons" means:

a. all officers, directors, and employees of King based in the United States; and

b. except for the Third Party Personnel (as defined below), all contractors, subcontractors, agents, and other persons who perform Government Pricing and Medicaid Drug Rebate Related Functions, as defined below in Section II.C.2, on behalf of King.

Notwithstanding the above, this term does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year.

King has entered joint venture agreements and agreements to co-market its products with other entities (hereafter "Relevant Third Party Agreements"), including Wyeth Pharmaceuticals (Wyeth). The personnel of the entities with whom King has or may, in the future, have such agreements shall be collectively referred to as "Third Party Personnel." King has represented that: i) the Third Party Personnel are employed by other pharmaceutical manufacturers; ii) King does not control the Third Party Personnel; and iii) it would be unable to compel their compliance with the requirements set forth in this CIA.

For purposes of this CIA, King agrees to promote, to the maximum extent practicable, compliance by the Third Party Personnel with Federal Health Care Program Requirements. In order to fulfill this obligation, King agrees to the following:

- a. within 120 days after the Effective Date and annually thereafter by the anniversary of the Effective Date, King shall send a letter to all entities with which King has entered Relevant Third Party Agreements. The letter shall outline King's obligations under this CIA and its commitment to full compliance with all Federal Health Care Program Requirements. The letter shall include a description of King's compliance program. King shall attach a copy of its Code of Conduct to the letter and ask that the Code of Conduct and the description of King's compliance program be distributed to all relevant Third Party Personnel; and
 - b. King shall submit: 1) a copy of each letter (including all attachments); and 2) a list of all King's existing Relevant Third Party Agreements to the OIG with the Implementation Report, the first Annual Report (to the extent the information changes from the date of the Implementation Report) and with each subsequent Annual Report.
2. "Relevant Covered Persons" means the following categories of Covered Persons:

1) all employees of King whose job responsibilities relate to the collection, calculation, verification, or reporting of information for purposes of the Medicaid Drug Rebate Program (codified at 42 U.S.C. § 1396r-8, et seq.), the Medicare Program (42 U.S.C. § 1395-1395ggg), or other government programs (including the 340B Drug Pricing Program, codified at 42 USC § 256b (the “340B Program”) and the Veterans Administration pricing programs (the “VA Programs”), as set forth in the Federal Supply Schedule and the Veteran’s Healthcare Act of 1992) (hereafter collectively, “Government Pricing and Medicaid Drug Rebate Related Functions”). This group includes, but is not limited to, those individuals whose job responsibilities include the calculation and reporting of Average Sales Price, Average Manufacturer Price, Best Price, and all other price information reported and used in connection with reimbursement under the Federal Health Care Programs described in this paragraph; and

2) all contractors, subcontractors, agents, and other persons who perform Government Pricing and Medicaid Drug Rebate Related Functions on behalf of King.

III. CORPORATE INTEGRITY OBLIGATIONS

To the extent not already accomplished, King shall establish and maintain a Compliance Program throughout the term of this CIA that includes the following elements:

A. Corporate Compliance Officer and Committee.

1. *Corporate Compliance Officer.* King presently has a Corporate Compliance Officer (the “Compliance Officer”) with responsibility for administering King’s compliance program. King shall continue to employ an individual to serve as its Compliance Officer during the term of this CIA. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed

to ensure compliance with the requirements set forth in this CIA and with Federal Health Care Program Requirements. The Compliance Officer shall be a member of senior management of King, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Audit Committee of the Board of Directors of King, and shall be authorized to report on such matters to the Audit Committee of the Board of Directors at any time.¹ The Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by King as well as for any reporting obligations created under this CIA.

King shall report to OIG, in writing, any changes in the identity or position description of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

2. *Compliance Committee.* Prior to the Effective Date, King established a Compliance Committee (Compliance Committee) and King shall maintain a Compliance Committee during the term of this CIA. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as sales, marketing, government contracting/pricing, regulatory affairs, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

King shall report to OIG, in writing, any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

¹ King has represented that the Audit Committee of the Board of Directors is comprised entirely of independent directors, and that the Compliance Officer makes at least annual reports to the full Board of Directors.

B. Written Standards.

1. *Code of Conduct.* Prior to the Effective Date, King developed, implemented, and distributed a written code of conduct known as the Corporate Code of Conduct and Ethics (the “Code”) to all Covered Persons. King shall make the promotion of, and adherence to, the Code an element in evaluating the performance of all employees. The Code shall, at a minimum, set forth:

a. King’s commitment to full compliance with all Federal Health Care Program Requirements, including its commitment to comply with all government contracting and price reporting requirements, and to market, sell, promote, and advertise its products in accordance with Federal Health Care Program Requirements (including but not limited to, the Federal anti-kickback Statute, codified at 42 U.S.C. § 1320a-7b);

b. King’s requirement that all of its Covered Persons shall be expected to comply with all Federal Health Care Program Requirements and with King’s own Policies and Procedures as implemented pursuant to this Section III.B (including the requirements of this CIA);

c. the requirement that all of King’s Covered Persons shall be expected to report to the Compliance Officer or other appropriate individual designated by King suspected violations of any Federal Health Care Program Requirements or of King’s own Policies and Procedures;

d. the possible consequences to both King and Covered Persons of failure to comply with Federal Health Care Program Requirements and with King’s own Policies and Procedures and the failure to report such noncompliance; and

e. the right of all individuals to use the Disclosure Program described in Section III.E, and King’s commitment to nonretaliation

and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

To the extent not already accomplished, within 120 days after the Effective Date, each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by King's Code. New Covered Persons shall receive the Code and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later.

King shall periodically review the Code to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code shall be distributed within 30 days after any revisions are finalized. Each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by the revised Code within 30 days after the distribution of the revised Code.

2. Policies and Procedures. To the extent not already accomplished, within 120 days after the Effective Date, King shall implement written Policies and Procedures regarding the operation of King's compliance program and its compliance with Federal Health Care Program Requirements. At a minimum, the Policies and Procedures shall address:

- a. the subjects relating to the Code identified in Section III.B.1;
- b. collecting, calculating, verifying and reporting the data and information reported to the Centers for Medicare & Medicaid Services (CMS), State Medicaid programs or other government entities in connection with Government Pricing and Medicaid Drug Related Functions;
- c. selling, marketing, and promoting King products in compliance with all applicable Federal Health Care Program Requirements, including, but not limited to, the Federal anti-kickback statute, codified at 42 U.S.C. § 1320a-7b; and

- d. disciplinary policies and procedures for violations of King's Policies and Procedures, including policies relating to Federal Health Care Program Requirements.

To the extent not already accomplished, within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be distributed in hard-copy or electronic format to all individuals whose job functions relate to those Policies and Procedures. Distribution may include publishing such Policies and Procedures on King's intranet or a web site, including the Axentis Corporate Governance System. If King publishes such Policies and Procedures on its intranet or a web site, King must notify the relevant persons receiving such Policies and Procedures that the Policies and Procedures will be distributed in such a manner and King must track distribution to ensure that all appropriate relevant persons received the Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), King shall assess and update as necessary the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all individuals whose job functions relate to those Policies and Procedures.

C. Training and Education.

1. *General Training.* Within 120 days after the Effective Date, King shall provide at least two hours of General Training to each Covered Person². This training, at a minimum, shall explain King's:

- a. CIA requirements;
- b. Compliance Program (including the Code and the Policies and Procedures as they pertain to general compliance issues); and

² Independent directors of King shall receive training on the topics set forth in Sections III.C.1.a-b of the CIA. King has represented that its independent directors sit on King's Board of Directors and are not members of King's management.

- c. in general, in a manner appropriate for the individual's job function, the proper methods of promoting, marketing and selling, and contracting for products in accordance with Federal Health Care Program Requirements; the need to calculate and report accurate pricing and other information in connection with the Government Pricing and Medicaid Drug Rebate Related Functions; and a general discussion of King's systems relating to the Government Pricing and Medicaid Drug Rebate Related Functions.

New Covered Persons shall receive the General Training described above within 45 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training annually.

2. *Specific Training.* Within 120 days after the Effective Date, each Relevant Covered Person shall receive at least two hours of Specific Training in addition to the General Training required above. This Specific Training shall include a discussion of:

- a. in detail, and as appropriate for the individual's job functions, King's systems for gathering relevant data and calculating, verifying, and reporting information to CMS and/or the State Medicaid Programs for purposes of the Medicaid Drug Rebate Program, the Medicare Program, the 340B Program or the VA Programs;
- b. all applicable Federal Health Care Program Requirements (including the sanctions for violations) relating to Government Pricing and Medicaid Drug Rebate Related Functions;
- c. the personal obligation of each individual to comply with Federal Health Care Program Requirements, and, as appropriate for the individual's job functions, applicable legal requirements referenced above in Section III.C.2.b. and to track and review any pricing or

contract exceptions, variations, or outliers identified within King's systems;

d. the legal sanctions for violations of the Federal Health Care Program Requirements referenced above in Section III.C.2.b; and

e. examples of proper and improper practices related to Government Pricing and Medicaid Drug Rebate Related Functions.

Relevant Covered Persons shall receive this training within 45 days after the beginning of their employment or becoming Relevant Covered Persons, or within 120 days after the Effective Date, whichever is later. A King employee who has completed the Specific Training shall review a new Relevant Covered Person's work, to the extent that the work relates to Government Pricing and Medicaid Drug Rebate Related Functions, until such time as the new Relevant Covered Person completes his or her Specific Training.

After receiving the initial Specific Training described in this Section, each Relevant Covered Person shall receive at least two hours of Specific Training annually.

3. *Certification.* Each individual who is required to attend training shall certify, in writing, or in electronic form, if applicable, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

4. *Qualifications of Trainer.* The training and education required under this Section III.C may be provided by supervisory employees, knowledgeable staff, King trainers, and/or outside consultant trainers selected by King. The Specific Training requirements outlined in Section III.C.2 may be satisfied through relevant continuing education programs offered by established and knowledgeable providers, so long as the programs cover the topics outlined in Section III.C.2. Persons providing the training shall be knowledgeable about the applicable subject areas, including the relevant Federal Health Care Program Requirements relating to the promotion, sales, and marketing of

King's products and requirements applicable to Government Pricing and Medicaid Drug Rebate Related Functions.

5. *Update of Training.* King shall annually review the training, and, where appropriate, update the training to reflect changes in applicable Federal Health Care Program Requirements, any issues discovered during internal audits or the IRO Reviews, and any other relevant information.

6. *Computer-based Training.* King may provide the training required under this CIA through appropriate computer-based training approaches. In that event, all applicable references to "hours" in this Section III.C shall mean "normative hours" as that term is used in the computer-based training industry. If King chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

7. *Miscellaneous Training – Related Provisions.* To the extent that King has provided training that satisfies the General or Specific Training requirements set forth above within 180 days prior to the Effective Date, the OIG shall credit that training for purposes of satisfying King's training obligations for the first Reporting Period of the CIA. For purposes of the General Training requirements, if King provided General Training that satisfies the requirements set forth in Section III.C.1 above to Covered Persons within 180 days prior to the Effective Date, King may satisfy its remaining General Training obligation for the first year of the CIA by notifying those Covered Persons of the fact that King entered a CIA and notifying them of King's requirements and obligations under the CIA.

King provides training on a regular basis concerning a variety of topics to its employees. The training required by this CIA need not be separate and distinct from the regular training provided by King, but instead may be integrated fully into such regular training to the extent the training satisfies the requirements set forth in this CIA.

To the extent a Covered Person is on a leave of absence when the required training is offered, the Covered Person shall receive the training within 30 days of the conclusion of the leave of absence.

D. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 120 days after the Effective Date, King shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter the “Independent Review Organization” or “IRO”), to perform reviews to assist King in assessing and evaluating its systems, processes, policies, and practices related to the Government Pricing and Medicaid Drug Rebate Related Functions. The applicable requirements relating to the IRO are outlined in Appendix A to this Agreement, which is incorporated by reference.

Each IRO engaged by King shall have expertise in the applicable Federal Health Care Program Requirements and other applicable legal requirements, as may be appropriate to the Engagement for which it is retained. Each IRO shall assess, along with King, whether it can perform the IRO review in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or other engagements that may exist.

The IRO(s) review shall evaluate and analyze King’s systems, processes, policies, and practices relating to the Government Pricing and Medicaid Drug Rebate Related Functions (the “Government Pricing and Medicaid Drug Rebate Engagement” or the “Engagement”).

b. *Frequency of Engagement.* The Government Pricing and Medicaid Drug Rebate Engagement shall be performed annually and shall cover each of the Reporting Periods.

c. *Retention of Records.* The IRO and King shall retain and make available to OIG, upon request, (i) all work papers relating to the

Engagement, and (ii) all supporting documentation, correspondence, and draft reports (those exchanged between the IRO and King) related to the Engagement.

d. Entity Performing Engagements. The Engagements shall each be performed by the IRO, as specified in this Section III.D and the Appendices to this CIA, during the five Reporting Periods of the CIA. However, after the IRO(s) performs the first three Government Pricing and Medicaid Drug Rebate Engagements, King, at its option, may request the OIG to permit that those Engagements be conducted internally and subject only to verification by the IRO for the remainder of the term of the CIA. The OIG retains sole discretion over whether to permit those Engagements to be conducted internally by King and subject to validation by the IRO. In making its decision, the OIG will consider, among the factors, the results of the Engagements during the first three Reporting Periods of the CIA and King's demonstrated audit capabilities to perform the Engagements internally. If the OIG denies King's request to shift the audit responsibilities, King agrees to engage the IRO to complete the remaining Engagements in accordance with the CIA.

2. Government Pricing and Medicaid Drug Rebate Engagement. As set forth more fully in Appendix B and below, the Government Pricing and Medicaid Drug Rebate Engagement shall consist of two components - a Systems Review and a Transactions Review. If there are no material changes in King's Government Pricing and Medicaid Drug Rebate related systems, processes, policies, and practices during the term of the CIA, the IRO shall perform the Government Pricing and Medicaid Drug Rebate Engagement Systems Review covering the second and fourth Reporting Periods. If King materially changes its systems, processes, policies and practices relating to government pricing or the Medicaid Drug Rebate Program, then the IRO shall perform a Government Pricing and Medicaid Drug Rebate Engagement for the Reporting Period in which such changes were made in addition to conducting the Medicaid Drug Rebate Engagement for the second and fourth Reporting Periods. The Transactions Review shall be performed annually and shall cover each of the five Reporting Periods.

3. Government Pricing and Medicaid Drug Rebate Engagement Report.

The IRO shall prepare a report based upon the Engagement performed (Engagement Report). Information to be included in the Engagement Report is described in Appendix B.

4. Validation Review. In the event OIG has reason to believe that: (a) King's Engagement fails to conform to the requirements of this CIA; or (b) the IRO's findings or Engagement results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Engagement complied with the requirements of this CIA and/or the findings or Engagement results are inaccurate (Validation Review). King shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of King's final Annual Report must be initiated no later than one year after King's final submission (as described in Section II.B) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify King of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, King may request a meeting with OIG to: (a) discuss the results of any Engagement submissions or findings; (b) present any additional information to clarify the results of the Engagement or to correct the inaccuracy of the Engagement; and/or (c) propose alternatives to the proposed Validation Review. King agrees to provide any additional information as may be requested by OIG under this Section in an expedited manner. OIG will attempt in good faith to resolve any Engagement issues with King prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

5. Independence/Objectivity Certification. The IRO shall include in its report(s) to King a certification or sworn affidavit that it has evaluated its professional independence and/or objectivity, as appropriate to the nature of the Engagement, with regard to the Engagement and that it has concluded that it is, in fact, independent and/or objective.

E. Disclosure Program.

Prior to the Effective Date, King established a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with King's policies, conduct, practices, or procedures with respect to a Federal Health Care Program Requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. King shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas), and King shall maintain the Disclosure Program during the term of the CIA.

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure that relates to a Federal Health Care Program Requirement, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the inappropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, King shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a disclosure log, which shall include a record and summary of each disclosure received that relates to a Federal Health Care Program Requirement (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be made available to OIG upon request.

F. Ineligible Persons.

1. *Definitions.* For purposes of this CIA:

a. an "Ineligible Person" shall include an individual or entity who:

i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal Health Care Programs or in Federal procurement or nonprocurement programs; or

ii. has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. "Exclusion Lists" include:

i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://oig.hhs.gov>); and

ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://epls.arnet.gov>).

c. "Screened Persons" means prospective and current owners (other than shareholders who: (1) have an ownership interest of less than 5%; and (2) acquired the ownership interest through public trading), officers, directors, employees, contractors, and agents of King.

2. *Screening Requirements.* King shall ensure that all Screened Persons are not Ineligible Persons, by implementing the following screening requirements:

a. King shall screen all Screened Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or

contracting process, shall require such persons to disclose whether they are an Ineligible Person.

b. King shall screen all Screened Persons against the Exclusion Lists within 120 days after the Effective Date and on an annual basis thereafter.

c. King shall implement a policy requiring all Screened Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

To the extent that King has screened certain Screened Persons against the Exclusions Lists and required disclosure of eligibility status within 180 days prior the Effective Date, such actions will satisfy King's obligations with regard to those Screened Persons for purposes of Section III.F.2.b for the first year of the CIA.

3. *Removal Requirement.* If King has actual notice that a Screened Person has become an Ineligible Person, King shall remove such person from responsibility for, or involvement with, King's business operations related to the Federal Health Care programs and, if applicable, shall remove such person from any position for which the person's compensation or the items or services furnished, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal Health Care Programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If King has actual notice that a Screened Person is charged with a criminal offense that falls within the ambit of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during his or her employment or contract term, King shall take all appropriate actions to ensure that the responsibilities of that person have not and shall not affect the accuracy of any claims submitted to any Federal Health Care Program.

G. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery by senior management at King's corporate headquarters, King shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to King conducted or brought by a governmental entity or its agents involving an allegation that King has committed a crime or has engaged in fraudulent activities in the United States (including the United States, the District of Columbia, and the territories and possessions of the United States). This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. King shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

H. Reportable Events.

a. **Definition of Reportable Events.** For purposes of this CIA, a "Reportable Event" means anything that involves a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal Health Care Program for which penalties or exclusion may be authorized. A Reportable Event may be the result of an isolated event or a series of occurrences.

b. **Notification of Reportable Events.** If King determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, King shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:

i. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal Health Care Program authorities implicated;

ii. a description of King's actions taken to correct the Reportable Event; and

iii. any further steps King plans to take to address the Reportable Event and prevent it from recurring.

King's notification of OIG of any Reportable Event pursuant to this CIA does not preclude King from making the same disclosure through OIG's Self-Disclosure Protocol.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date, King changes locations or sells, closes, purchases, or establishes a new business unit or other location engaged in Government Pricing and Medicaid Drug Rebate Related Functions or in the promotion, sales, or marketing of items that may be reimbursed by Federal Health Care Programs (collectively "Relevant Activities"), King shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change of location, sale, closure, purchase, or establishment. This notification shall include the address of the new business unit or other location, phone number, fax number, Federal Health Care Program provider or supplier number (if any), and the corresponding contractor's name and address that has issued each provider or supplier number. Each new business unit or location that is engaged in the Relevant Activities shall be subject to all the requirements of this CIA.

King shall use its best efforts to implement the requirements of this CIA in new business units or other locations engaged in Relevant Activities. Notwithstanding any other provisions to the contrary, the requirements of this CIA shall not become effective for new business units or other locations until 120 days after the purchase or establishment or acquisition of such new business units or locations.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. **Implementation Report.** Within 120 days after the Effective Date, King shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;

2. the names and positions of the members of the Compliance Committee required by Section III.A;

3. a copy of King's Code required by Section III.B.1;

4. a copy of all Policies and Procedures required by Section III.B.2;

5. the number of individuals required to complete the Code certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

6. the following information regarding each type of training required by Section III.C:

a. a description of such training, including a summary of the topics covered, the length of sessions and a schedule of training sessions; and

b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials used in the training required by Section III.C and the documentation supporting this information shall be available to OIG, upon request.

7. a description of the Disclosure Program required by Section III.E;

8. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) a summary and description of any and all current and prior engagements and agreements between King and the IRO; and (d) the proposed start and completion dates of the Engagement;

9. a certification from the IRO regarding its professional independence and/or objectivity with respect to King;

10. a description of the process by which King fulfills the requirements of Section III.F regarding Ineligible Persons;

11. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken in response to the screening and removal obligations set forth in Section III.F; and the actions taken to identify, quantify, and repay any overpayments to Federal Health Care Programs relating to items or services furnished, ordered or prescribed by an Ineligible Person;

12. a list of all of King's locations (including locations and mailing addresses) as required by Section IV; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal Health Care Program provider or supplier number(s) (if any); and the name and address of each contractor to which King currently submits claims (if any);

13. a description of King's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business;

14. the certifications required by Section V.C, and

15. a list of all King's existing Relevant Third Party Agreements, as required by Section II.C.1.

B. Annual Reports. King shall submit to OIG annually a report with respect to the status of, and findings regarding, King's compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee described in Section III.A;
2. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in contractor policy) and copies of any such Policies and Procedures that have changed since previously provided to the OIG;
3. the number of individuals required to complete the Code certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
4. the following information regarding each type of training required by Section III.C:
 - a. a description of such training, including a summary of the topics covered, the length of sessions and a schedule of training sessions; and
 - b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

5. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letter (if applicable);
6. King's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.D;

7. a summary and description of any and all current and prior engagements and agreements between King and the IRO, if different from what was submitted as part of the Implementation Report;

8. a certification from the IRO regarding its professional independence and/or objectivity with respect to King;

9. a summary of Reportable Events (as defined in Section III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;

10. a summary of the disclosures in the disclosure log required by Section III.E that relate to Federal Health Care Program Requirements;

11. any changes to the process by which King fulfills the requirements of Section III.F regarding Ineligible Persons;

12. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken by King in response to the screening and removal obligations set forth in Section III.F; and the actions taken to identify, quantify, and repay any overpayments to Federal Health Care Programs relating to items or services furnished, ordered or prescribed by an Ineligible Person;

13. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

14. a description of all changes to the most recently provided list of King's locations (including addresses) as required by Section V.A.12; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal Health Care Program provider or supplier number(s) (if any); and the name and address of each Federal Health Care Program contractor to which King currently submits claims (if any);

15. the certifications required by Section V.C; and

16. a list of all King's existing Relevant Third Party Agreements, as required by Section II.C.1.

The first Annual Report shall be received by OIG no later than 90 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that:

1. except as expressly provided in the certification relating to policies and materials under development or subject to revision, all policies and procedures, standardized contracts, promotional materials, and training materials relating to Government Pricing and Medicaid Drug Rebate Related Functions and to the promotion, sales, or marketing of King's products have been reviewed by legal counsel and been found to be in compliance with all applicable Federal Health Care Program Requirements;

2. King has provided to the OIG the Medicaid Drug Rebate certification as set forth in Appendix C covering the applicable Reporting Period(s), and such certification is true and correct in all respects;

3. to the best of his or her knowledge, except as otherwise described in the applicable report, King is in compliance with all of the requirements of this CIA;

4. he or she has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information in the Report is accurate and truthful; and

5. if applicable, King has complied with its obligations under the Settlement Agreement: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise

seek payment from Federal or State payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs.

D. Designation of Information. King shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. King shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: (202) 619-2078
Facsimile: (202) 205-0604

King:

Frederick Brouillette, Jr.
King Pharmaceuticals, Inc.
Corporate Compliance Officer
501 Fifth Street
Bristol, TN 37620

Telephone: (423) 989-8751
Facsimile: (423) 274-8612

with a copy to:

General Counsel
King Pharmaceuticals, Inc.
501 Fifth Street
Bristol, TN 37620
Telephone: (423) 989-8000
Facsimile: (423) 990-2566

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of King's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of King's locations for the purpose of verifying and evaluating: (a) King's compliance with the terms of this CIA; and (b) King's compliance with the requirements of the Federal Health Care Programs. The documentation described above shall be made available by King to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of King's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. King shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. King's employees may elect to be interviewed with or without a representative of King present.

VIII. DOCUMENT AND RECORD RETENTION

King shall maintain for inspection all documents and records relating to reimbursement from the Federal Health Care Programs, or to compliance with this CIA, for six years from the Effective Date (or longer if otherwise required by law).

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify King prior to any release by OIG of information submitted by King pursuant to its obligations under this CIA and identified upon submission by King as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, King shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

A breach of this CIA does not constitute a breach of the Settlement Agreement between King and the United States or the settlement agreements with the individual States referred to in the Preamble to this CIA. Any breach of the terms of those agreements does not constitute a breach of the CIA, except to the extent that such a breach independently also constitutes a breach of this CIA. This Section X specifies all of the remedies available to the OIG if King fails to satisfy its obligations under this CIA. The remedies available to the OIG under this Section X do not preempt or limit any actions that individual States may take against King under the appropriate authorities not specified in this CIA.

King is expected to fully and timely comply with all of its CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, King and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day King fails to establish and implement any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. a written Code of Conduct;
- d. written Policies and Procedures;
- e. the training of Covered Persons;
- f. a Disclosure Program;
- g. Ineligible Persons screening and removal requirements; and
- h. Notification of Government investigations or legal proceedings.

2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day King fails to engage an IRO, as required in Section III.D and Appendix A.

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day King fails to submit the Implementation Report or the Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day King fails to submit the annual Engagement Report in accordance with the requirements of Section III.D and Appendix B.

5. A Stipulated Penalty of \$1,500 for each day King fails to grant access to

the information or documentation as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date King fails to grant access.)

6. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of King as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of \$1,000 for each day King fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to King, stating the specific grounds for its determination that King has failed to comply fully and adequately with the CIA obligation(s) at issue and the steps King shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after King receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-6 of this Section.

B. Timely Written Requests for Extensions. King may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after King fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after King receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter*. Upon a finding that King has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify King of: (a) King's failure to comply; and (b) OIG's

exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the “Demand Letter”). Such demand letter shall state the conduct that the OIG contends constitutes the basis for imposing the Stipulated Penalty.

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, King shall either: (a) cure the breach to OIG’s satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG’s determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event King elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until King cures, to OIG’s satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier’s check, payable to: “Secretary of the Department of Health and Human Services,” and submitted to OIG at the address set forth in Section VI.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG’s decision that King has materially breached this CIA, which decision shall be made at OIG’s discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

1. *Definition of Material Breach.* A material breach of this CIA means:

- a. a failure by King to report a Reportable Event and take corrective action, as required in Section III.H;
- b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;

c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or

d. a failure to engage and use an IRO in accordance with Section III.D.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by King constitutes an independent basis for King's exclusion from participation in the Federal health care programs. Upon a determination by OIG that King has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify King of: (a) King's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* King shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

a. King is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;

b. the alleged material breach has been cured; or

c. the alleged material breach cannot be cured within the 30-day period, but that: (i) King has begun to take action to cure the material breach; (ii) King is pursuing such action with due diligence; and (iii) King has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, King fails to satisfy the requirements of Section X.D.3, OIG may exclude King from participation in the Federal health care programs. OIG shall notify King in writing of its determination to exclude King (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of King's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and

nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, King may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to King of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, King shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether King was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. King shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders King to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless King requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the

United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

- a. whether King was in material breach of this CIA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) King had begun to take action to cure the material breach within that period; (ii) King has pursued and is pursuing such action with due diligence; and (iii) King provided to OIG within that period a reasonable timetable for curing the material breach and King has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for King, only after a DAB decision in favor of OIG. King's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude King upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that King may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. King shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of King, King shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

XI. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Settlement Agreement pursuant to which this CIA is entered, and into which this CIA is incorporated, King and OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns, and transferees of King;
- B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;
- C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA;
- D. The undersigned King signatories' represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA; and
- E. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same agreement.

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KING PHARMACEUTICALS

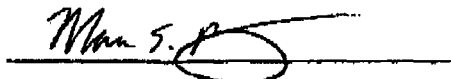
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ON BEHALF OF KING PHARMACEUTICALS, INC.



Frederic Brouillette, Jr.
Corporate Compliance Officer

10/31/05
DATE



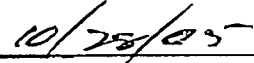
Marc S. Rosenberg, Esq.
Counsel for King Pharmaceuticals, Inc.

10/31/05
DATE

**ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**



Lewis Morris
Chief Counsel to the Inspector General
Office of Inspector General
U. S. Department of Health and Human Services



DATE

Corporate Integrity Agreement
King Pharmaceuticals, Inc.

APPENDIX A INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.D of the CIA. Capitalized terms used in this Appendix A and not defined herein have the meanings assigned to them in the CIA.

A. IRO Engagement.

King shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and/or objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify King if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, King may continue to engage the IRO.

If King engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix A. If a new IRO is engaged, King shall submit the information identified in Section V.A.8 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify King if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, King may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the Government Pricing and Medicaid Drug Rebate Engagement who have expertise in the Federal Health Care Program Requirements;
2. assign individuals who are knowledgeable about the appropriate statistical sampling techniques and select the samples required for the Government Pricing and Medicaid Drug Rebate Engagement; and
3. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities.

The IRO shall:

1. perform each Government Pricing and Medicaid Drug Rebate Engagement in accordance with the specific requirements of the CIA;

2. follow all applicable Federal Health Care Program Requirements in making assessments in the Government Pricing and Medicaid Drug Rebate Engagement;

3. request clarification from the appropriate authority (e.g., CMS), if in doubt as to the application of a particular Medicare or Medicaid Drug Rebate Program policy or regulation that is not addressed in King's Policies and Procedures;

4. respond to all OIG inquiries in a prompt, objective, and factual manner; and

5. prepare timely, clear, well-written reports that include all the information required by Appendix B.

D. IRO Independence/Objectivity.

The IRO must perform the Government Pricing and Medicaid Drug Rebate Engagement in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and King.

E. IRO Removal/Termination.

1. *Provider.* If King terminates its IRO during the course of the engagement, King must submit a notice explaining its reasons to OIG no later than 30 days after termination. King must engage a new IRO in accordance with Paragraph A of this Appendix A.

2. *OIG Removal of IRO.* In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B of this Appendix A, is not independent and/or objective as set forth in Paragraph D of this Appendix A, or has failed to carry out its responsibilities as described in Paragraph C of this Appendix A, OIG may, at its sole discretion, require King to engage a new IRO in accordance with Paragraph A of this Appendix A.

Prior to requiring King to engage a new IRO, OIG shall notify King of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, King may request a meeting with OIG to discuss any aspect of the IRO's qualifications, independence or performance of its responsibilities and to present additional information regarding these matters. King shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO

with King prior to requiring King to terminate the IRO. However, the final determination as to whether or not to require King to engage a new IRO shall be made at the sole discretion of OIG.

**Appendix B to the CIA for King Pharmaceuticals, Inc.
Government Pricing and Medicaid Drug Rebate Engagement**

This Appendix B contains the requirements relating to the Engagement required to be performed by the Independent Review Organization under Section III.D of the CIA. Capitalized terms used herein and not defined herein have the meanings assigned to them in the CIA.

I. Government Pricing and Medicaid Drug Rebate Engagement - General Descriptions

As specified more fully below, King Pharmaceuticals, Inc. (King), shall retain an Independent Review Organization (IRO) to perform reviews to assist King in assessing and evaluating its systems, processes, policies, and practices (including the controls on the systems, processes, policies, and practices) related to its government price reporting requirements for Best Price (BP) and Average Manufacturer Price (AMP) under the Medicaid Drug Rebate Program and for Average Sales Price (ASP) for purposes of the Medicare program. The IRO shall perform two types of engagements: 1) a systems review of King's systems, processes, policies, and practices relating to the calculation and reporting of AMP, BP and ASP (collectively "Systems Review Consulting Engagement"); and 2) testing of samples of transactions to assess whether King is calculating AMP and BP in accordance with the policies, procedures, and methodologies developed by King relating to the Medicaid Drug Rebate Program (Medicaid Drug Rebate Transactions Engagement).

Prior to performing the Government Pricing and Medicaid Drug Rebate Engagement, the IRO and King shall design Consulting Procedures outlining the specific work to be performed by the IRO, and the Consulting Procedures may be submitted to the OIG for comment. However, any comments or recommendations made by the OIG in connection with a review of the submitted workplan(s) will not preclude the OIG from making further comments or recommendations for future workplan(s) after reviewing the reports from the Government Pricing and Medicaid Drug Rebate Engagement.

If there are no material changes in King's systems, processes, policies, and practices during the term of the CIA, then the IRO shall perform the Systems Review Consulting Engagement covering the second and fourth Reporting Periods. If King materially changes its systems, processes, policies, and practices as they relate to the calculation of AMP, BP, or ASP, then the IRO shall perform a Systems Review Consulting Engagement

covering the Reporting Period in which such changes were made in addition to conducting the Engagement for the second and fourth Reporting Periods. The additional Systems Review Consulting Engagement(s) shall consist of: 1) an identification of the material changes; 2) an assessment of whether the systems, processes, policies, and practices already reported on did not materially change; and 3) an update on the systems, processes, policies, and practices that materially changed.

The Medicaid Drug Rebate Transactions Engagement shall be designed to test whether King is calculating AMP and BP in accordance with the policies, procedures, and methodologies developed by King relating to the Medicaid Drug Rebate Program. The Medicaid Drug Rebate Transaction Engagement shall consist of two parts, the "Reported Prices Procedures for AMP," and the "Reported Prices Procedures for BP."

Consistent with Section III.D.1.d of the CIA, after the third Reporting Period, the OIG may, at its discretion and upon written request of King, permit King to perform the engagements described in this Appendix B, subject to verification by the IRO.

II. Systems Review Consulting Engagement

A. Average Sale Price Systems Review

For at least the second and fourth Reporting Periods, the IRO shall review King's systems, processes, policies, and practices (including the controls on the systems, processes, policies, and practices) associated with the tracking, gathering, verifying, and accounting for all relevant data for purposes of calculating ASP reported to the Centers for Medicare and Medicaid Services (CMS) as required under the Medicare program.

In general terms, the IRO shall review the following:

1. the systems, processes, policies, and practices in place to track, gather, and appropriately account for price terms and transactions with King customers that are relevant for purposes of the ASP calculation and reporting requirements. Specifically, this includes:
 - a) the process, policies, and procedures used to determine which customers are included in the calculation of ASP for ASP covered products;

- b) the process, policies, and procedures used to determine whether and which particular transactions reflecting final sales prices are included in or excluded from the ASP calculation;
- c) a review of King's methodology for applying transactions to the ASP calculations;
- d) the relevant flow of data and information by which price terms and transactions with King customers are accumulated from source systems and entered and tracked in King's ASP system for purposes of calculating ASP;
- e) a review of any King inquiries to CMS regarding the ASP calculation and reporting requirements and any responses to those inquiries; and
- f) the controls and processes in place to examine and address system reports that require critical evaluation (such as reports of variations, exceptions, and outliers). This shall include a review of the basis upon which variations, exceptions, and outliers are identified and the follow-up activities undertaken to identify the cause of any variations.

B. Medicaid Rebate Systems Review

For at least the second and fourth Reporting Periods, the IRO shall review King's systems, processes, policies, and practices (including the controls on the systems, processes, policies, and practices) associated with the tracking, gathering, and accounting for all relevant data for purposes of calculating and reporting AMP and BP to CMS under the Medicaid Drug Rebate Program.

In general terms, the IRO shall review the following:

- 1. The systems, processes, policies, and practices that are in place to track, gather, and appropriately account for contract terms and transactions with King customers that are relevant to the calculation of AMP and BP under Medicaid Drug Rebate Program. Specifically, this includes a review of:
 - a) the process used to determine which customers are

included in the calculation of AMP and BP for Medicaid rebate eligible products;

- b) the process used to determine whether and which discounts or rebates in King customer contracts, or other price terms or transactions with King customers, are included in the calculation of BP and AMP for Medicaid rebate eligible products;
- c) a review of the methodology for applying transactions to the AMP and BP calculations;
- d) the relevant flow of data and information by which price terms and transactions with King customers are accumulated from the source systems and entered and tracked in King's information systems for purposes of calculating the AMP and BP;
- e) a review of any King inquiries to CMS regarding the Medicaid Drug Rebate Program (including those pertaining to the determination of AMP and BP) and any responses to those inquiries; and
- f) the controls and processes in place to examine and address system reports that require critical evaluation (such as reports of variations, exceptions, and outliers). This shall include a review of the basis upon which variations, exceptions, and outliers are identified and the follow-up activities undertaken to identify the cause of any variations.

C. Systems Review Consulting Engagement Report

For each relevant Reporting Period, the IRO shall prepare a report based upon the Systems Review Consulting Engagement. This report may be combined with the report for the Medicaid Drug Rebate Transactions Engagement and shall include the following:

1. A description of the systems, processes, policies, and practices in place to track, gather, and account for price terms, contract terms, and transactions with King customers that are relevant to the calculation and reporting of AMP, BP, and ASP including, but not limited to:

- a) the computer or other relevant systems (including the source systems, and any other information systems (as applicable) used to calculate and report AMP, BP, and ASP;
 - b) the information input into King's relevant computer or other systems used to calculate AMP, BP, and ASP;
 - c) the system logic or decisional rationale used to determine which King customers are included for purposes of calculating AMP, BP, and ASP;
 - d) the system logic or decisional rationale used to determine whether contract terms, discounts, rebates and all other relevant transactions with King customers are included or excluded when calculating AMP, BP and ASP; and
 - e) the policies and practices of the Government Contracts and Commercial Contracts subgroups of King's Contract Administration Group in examining system reports for variations that require critical evaluation, including the bases upon which variations, exceptions, and outliers are identified, and the follow up actions taken in response.
2. A description of the documentation, information, and systems reviewed and the personnel interviewed, if any, including a description of the following:
- a) King's inquiries to CMS regarding the Medicaid Drug Rebate Program or the Medicare Program (including those pertaining to the determination of AMP, BP, and ASP) and any responses to those inquiries;
 - b) King's systems and practices for reporting AMP, BP, and ASP to CMS for purposes of the Medicaid Drug Rebate Program on a quarterly basis; and
 - c) King's systems and practices for making any adjustments to reported AMP, BP, or ASP or additional information related to the submissions.

3. Observations, findings, and recommendations on possible improvements to King's systems, processes, policies, and practices.

III. Medicaid Drug Rebate Transactions Engagement

Except for the first Reporting Period as provided below, following the end of each Reporting Period, the IRO shall randomly select one quarter for review in the Medicaid Drug Rebate Transactions Engagement, including both the BP and AMP procedures described in this Section III. For the first Reporting Period, the selected quarter shall be one in which King's new system for performing Medicare and Medicaid calculations was installed and in use.

A. Reported Prices Procedures for BP

For each Reporting Period, the IRO shall conduct Reported Prices Procedures for BP to test whether King calculated and reported BP in accordance with King's policies and procedures and methodology developed for the Medicaid Drug Rebate Program.

The Reported Prices Procedures for BP shall consist of two parts:

1. Part One of Reported Prices and Procedures for BP

The IRO will obtain a listing of all King Customers¹ to whom sales of Medicaid rebate eligible products were made at contracted prices during the selected quarter of the Review Period. The IRO will randomly select a sample of 20 King Customers using the following methodology. The IRO will aggregate the number of NDCs² for each King Customer and will categorize each King Customer as "large" or "small" based upon the total volume of sales³ of the contracted Medicaid rebate eligible NDCs to that King Customer in the Reporting Period quarter selected. The IRO shall randomly

¹ A King Customer is any commercial (a) customer with whom King contracts directly for the sale of pharmaceutical products at discounted prices and (b) managed care entity to which King pays rebates based on the utilization of its pharmaceutical products by covered persons.

² For purposes of this Appendix B, "NDC" means a single dosage, form, and strength of a pharmaceutical product, without regard to package size (i.e., an NDC 9).

³ For purposes of this Section III, "volume of sales" means: (i) with respect to purchasers of King's pharmaceutical products, net sales before government rebates; and (ii) for managed care entities, utilization (equal to WAC less unit rebate amount), in either case, in the most recent quarter for which complete data is available.

select 10 King Customers from the large King Customer pool and 10 King Customers from the small King Customer pool.

The IRO's review shall cover the five NDCs for which King paid the largest amount (i.e., total dollars) of Medicaid rebates for the Reporting Period and five randomly selected NDCs (collectively, the "Selected BP NDCs"); provided that if King paid less than \$20,000 in Medicaid rebates for the Reporting Period for any randomly selected NDC, the IRO will replace such NDC with a randomly selected NDC for which King paid at least \$20,000 in Medicaid rebates for the Reporting Period.

For each King Customer selected, the IRO will identify all contracts with King and all Selected BP NDCs for which the King Customer had a contract price with King. The IRO will then test for each King Customer selected that each contract price for each Selected BP NDC is accurately reflected in King's government pricing system(s) and that the contract price is appropriately considered for purposes of determining BP in accordance with the policies, procedures, and methodology developed by King relating to the Medicaid Drug Rebate Program. To the extent possible, the IRO shall perform this work using automated database inquiries.

2. Part Two of Reported Prices Procedures for BP

The IRO will obtain the following information:

- a) the five Medicaid rebate eligible NDCs for which King paid the largest amount (i.e., total dollars) of Medicaid rebates for the Reporting Period;
- b) for each of the five Medicaid rebate eligible NDCs selected, obtain a copy of the internal King report(s) that identifies for each of the selected NDCs all unique prices lower than the reported BP for the selected quarter that existed within King's systems used to determine BP; and
- c) for each unique price lower than the reported BP identified in the applicable report(s), the IRO will review a minimum of five randomly selected contracted transactions associated with each of those unique lower prices (or, if there are fewer

than five such transactions, all such transactions) to assess if each was properly excluded from the determination of BP for that Medicaid rebate eligible NDC in the quarter under review in accordance with King's stated methodology and/or policies and procedures.

3. Additional Investigations

If the IRO identifies any prices reviewed in Part One or Part Two of the Reported Prices Procedures for BP that were not accurately reflected in King's systems and/or were not appropriately included in, or excluded from, King's BP determination in accordance with King's policies, procedures, and methodologies, such prices shall be considered an error. The IRO shall conduct such Additional Investigation as may be necessary to determine the root cause of the error. For example, the IRO may need to review additional documentation, conduct additional interviews with appropriate personnel, and/or review additional contracts to identify the root cause of the error.

Upon completion of this review and Additional Investigation, if warranted, the IRO will report to the OIG its findings relating to any errors and their root cause(s).

In the event the IRO finds more than one error for the quarter under review in Part One or Part Two testing, the IRO will perform a second set of Part One or Part Two testing procedures (*i.e.*, Part One or Part Two testing depending which Part of the Reported Prices Procedures for BP resulted in an Additional Investigation being warranted) for the same quarter and population of data after King has submitted its management response to the IRO findings to the OIG, after the OIG has reviewed and considered King's management response, and the OIG has determined that additional Part One or Part Two testing is warranted following consultations with King and the IRO.

Should it be determined that additional Part One or Part Two testing is warranted, the IRO shall:

- a) If additional Part One testing is required, test a random selection of an additional five King Customers and contract

prices associated with those Customers from the large King Customer pool; and/or

- b) If additional Part Two testing is required, test the next five Medicaid rebate eligible NDCs with the highest amounts of Medicaid rebates (total dollars) paid by King.

B. Reported Prices Procedures for AMP

1. The IRO shall select AMPs that were reported to CMS for five products for the selected quarter. The selected NDCs shall be: (i) the three NDCs for which King paid the largest amount (i.e., total dollars) of Medicaid rebates in the Reporting Period and (ii) two NDCs selected at random (collectively, the “Selected AMP NDCs”); provided that if King paid less than \$20,000 in Medicaid rebates in the Reporting Period for any randomly selected NDC, the IRO will replace such NDC with a randomly selected NDC for which King paid at least \$20,000 in Medicaid rebates in the Reporting Period.

The IRO shall randomly select 50 transactions (sales transactions and price concessions) associated with each of the five selected AMPs. More specifically, the IRO shall review 25 transactions that were included from the calculation of AMP and 25 transactions that were excluded from the calculation of AMP. This review shall determine, in accordance with King’s policies, procedures, and methodologies, whether: 1) each transaction is supported by source documentation; and 2) the transaction was appropriately included or excluded from the AMP under review.

2. Additional Investigations

If the IRO identifies any transactions that were not supported by source documentation and/or were not appropriately included in, or excluded from, the calculation of AMP in accordance with King’s policies, procedures, and methodology, such transactions shall be considered an error. The IRO shall conduct such Additional Investigation as may be necessary to determine the root cause of the error. For example, the IRO may need to review additional

documentation, conduct additional interviews with appropriate personnel, and/or review additional contracts to identify the root cause of the error.

Upon completion of this review and Additional Investigation, if warranted, the IRO will report to the OIG its findings relating to any errors and their root cause(s).

In the event the IRO finds more than one error for the quarter under review, the IRO will perform a second set of review procedures relating to the AMP calculations for the same quarter and population of data as in the first review. These additional review procedures will be developed in consultation with the OIG after King has submitted its management response to the IRO findings to the OIG, after the OIG has reviewed and considered King's management response, and the OIG has determined that additional testing is warranted.

C. Medicaid Drug Rebate Transactions Report

The IRO shall prepare a report annually based upon each Medicaid Drug Rebate Transaction Engagement performed. The report shall contain the following general elements pertaining to the Reported Prices Procedures for AMP and the Reported Prices Procedures for BP (Part One and Part Two):

1. Testing Objective – a clear statement of the objective(s) intended to be achieved by each part of the Reported Prices Procedures;
2. Testing Protocol – a detailed narrative description of: (a) the procedures performed; (b) the sampling units; and (c) the universe from which the sample was selected; and
3. Sources of Data – a full description of documentation and/or other relevant information relied upon by the IRO when performing the testing.

The IRO's report shall include the following results for each engagement:

1. The Reported Prices Procedures for AMP

- a) a list of the five AMPs reported to CMS that were selected by the IRO for review, a descriptive list of the 50 selected transactions associated with each reported AMP, and the underlying documentation supporting the random selection of the AMPs and the transactions;
 - b) a description of the steps taken and the supporting documentation reviewed to assess whether: 1) supporting documentation exists for each of the selected transactions; and 2) each selected transaction was appropriately included in, or excluded from, the AMP calculation in accordance with King's policies, procedures, and methodologies;
 - c) a list of any transactions not supported by source documentation and/or not appropriately included in, or excluded from, King's AMP calculation; a description of any adjustments to AMP reported to CMS; and a description of any additional follow-up action taken by King;
 - d) a detailed description of any Additional Investigation or review undertaken with regard to any transactions that were not supported by source documentation and/or were not appropriately included in, or excluded from, King's AMP calculation and the results of any such investigation or review; and
 - e) the IRO's recommendations for changes in King's policies, procedures, and/or methodology to correct or address any weaknesses or deficiencies uncovered during the review.
2. The Reported Prices Procedures for BP – Part One
- a) a list of the 20 King Customers selected under Part One, the number of contracts associated with each King Customer; the NDCs tested; the contract prices for each NDC tested; a list of any supporting documentation reviewed;
 - b) a description of the IRO's stratification system for identifying the "large" and "small" customers and documentation supporting the random selection of the customers;

- c) for each selected King Customer, a description of the steps taken to test that the contract price(s) for each NDC selected was accurately reflected in King's systems;
 - d) for each selected King Customer, the results from testing whether each NDC contract price was accurately reflected in King's contracting systems. If the correct price was not reflected in the systems, the IRO should identify the correct price term;
 - e) a detailed description of any Additional Investigation or review undertaken with regard to any price not accurately reflected in King's systems and the results of any Additional Investigation or review undertaken with respect to any such price;
 - f) for each selected King Customer, a description of the steps taken to test that each contract price term was appropriately considered in King's determination of BP for that NDC in accordance with King's policies, procedures, and methodologies;
 - g) for each selected King Customer, a list of any price inappropriately included in, or excluded from, King's BP determination for that quarter based on King's policies, procedures, and methodologies; a description of any adjustments to BP reported to CMS; and a description of any additional follow-up action taken by King;
 - h) a detailed description of any Additional Investigation or review undertaken with regard to any price not appropriately included in, or excluded from, King's BP determination for the selected quarter, and the results of any Additional Investigation or reviews undertaken with respect to any such price; and
 - i) the IRO's recommendations for changes in King's policies and procedures and/or methodology to correct or address any weaknesses or deficiencies uncovered during the review.
3. The Reported Prices Procedures for BP – Part Two

- a) a narrative list of the five Medicaid rebate eligible NDCs with the highest rebates paid by King for the quarter under review and the BP reported by King to the Medicaid Drug Rebate Program for each of the five NDCs for the quarter under review, and the underlying documentation supporting the random selection of the five NDCs;
- b) a description of the steps and the supporting documentation reviewed to assess the unique lower prices identified in the King report(s) for each of the selected NDCs, which were below BP reported by King to CMS in the quarter. If more than five contracted transactions are associated with any of the unique lower prices, the IRO shall also identify how many such transactions exist for each unique lower price;
- c) a list of any prices not included in, or excluded from, King's BP determination for that quarter in accordance with King's policies, procedures and methodology; a description of any adjustments to BP reported to CMS; and a description of any additional follow-up action taken by King;
- d) a detailed description of any Additional Investigation or review undertaken with regard to any prices that were not accurately included in, or excluded from, King's BP determination for the quarter under review and the results of any such investigation or review; and
- e) the IRO's recommendations for changes in King's policies, procedures, and/or methodology to correct or address any weaknesses or deficiencies uncovered during the review.

Appendix C

Certification for CIA with King Pharmaceuticals, Inc.

CERTIFICATION

In accordance with the Corporate Integrity Agreement (CIA) entered between King Pharmaceuticals, Inc. (King) and the OIG, the undersigned hereby certifies the following to the best of my knowledge, information, and belief:

- 1) King has in place policies and procedures describing in all material respects the methods for collecting, calculating, verifying and reporting the data and information reported to the Centers for Medicare and Medicaid Services (CMS) and/or the State Medicaid programs in connection with the Medicaid Drug Rebate program (Medicaid Rebate Policies and Procedures);
- 2) the Medicaid Rebate Policies and Procedures have been designed to ensure compliance with King's obligations under the Medicaid Drug Rebate Program; and
- 3) King's Medicaid Rebate Policies and Procedures were followed in all material respects in connection with the calculation of Average Manufacturer Price and Best Price for King's products for each of the following four quarters: [specifically identify each quarter].

Frederick Brouillette, Jr.
Corporate Compliance Officer

Date