

**CORPORATE INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
AMERISOURCEBERGEN CORPORATION**

**I. PREAMBLE**

AmerisourceBergen Corporation (ABC) 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 by ABC and ABC Affiliates (as defined below) 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)) (Federal health care program requirements) and with the statutes, regulations, and written directives of the Food and Drug Administration (FDA) and Drug Enforcement Agency (DEA) (“FDA requirements” and/or “DEA requirements”, as applicable). Contemporaneously with this CIA, ABC is entering into a Settlement Agreement with the United States. ABC is also entering into settlement agreements with various states (State Settlement Agreements) and ABC’s agreement to this CIA is a condition precedent to those agreements.

Prior to the Effective Date, ABC established a compliance program that ABC represents addresses all seven elements of an effective compliance program and that is designed to address compliance with Federal health care program and other requirements (Compliance Program). ABC shall continue the Compliance Program throughout the term of the CIA and shall do so in accordance with the terms set forth below. ABC may modify the Compliance Program as appropriate. However, at a minimum, ABC shall ensure that during the term of the CIA, it shall maintain a compliance program to comply with the obligations set forth in this CIA.

## II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by ABC under this CIA shall be five years from the effective date of this CIA. The “Effective Date” shall be the date on which the final signatory of this CIA executes this CIA. 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, X, and XI shall expire no later than 120 days after OIG’s receipt of: (1) ABC’s final Annual Report; or (2) any additional materials submitted by ABC pursuant to OIG’s request, whichever is later.

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

1. “Business Unit” means an operational division of ABC.
2. “Covered Persons” includes:
  - a. all owners of ABC and any ABC Affiliate who are natural persons (other than shareholders who: (i) have an ownership interest of less than 5% and (ii) acquired the ownership interest through public trading);
  - b. all officers and directors of ABC and any ABC Affiliate;
  - c. all employees of ABC and any ABC Affiliate who are engaged in or who supervise personnel who are engaged in Covered Functions (as defined below in Section II.C.9); and
  - d. all contractors, subcontractors, agents, and other persons who perform any of the Covered Functions on behalf of ABC or any ABC Affiliate and who, in the course of performing Covered Functions, either (i) interact with government payers, pharmacy benefit managers, or other individuals or entities under contract with or acting on behalf of government payers; or (ii) interact directly with healthcare providers with respect to the promotion of products or services or the negotiation of financial arrangements.

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

3. “Government Reimbursed Products” refers to all products that are: (a) marketed, sold, distributed, or dispensed by ABC or any ABC Affiliate in the United States (or pursuant to contracts with the United States) and (b) reimbursed by Federal health care programs. Government Reimbursed Products includes branded and generic drugs, specialty pharmaceuticals, over-the-counter medications, medical devices, related supplies, and other patient care items.

4. “Compounding/Manufacturing Functions” includes: (a) the manufacture, preparation, production, compounding, processing, packaging, repackaging, compounding, labeling, relabeling, and supply of Government Reimbursed Products; and (b) the collection, calculation, verification, or reporting of information for purposes of the Medicaid Drug Rebate Program (codified at 42 U.S.C. § 1396r-8), the Medicare Program (42 U.S.C. §§ 1395-1395hhh), other government programs (including the 340B Drug Pricing Program, codified at 42 U.S.C. § 256b (the 340B Program)), and in connection with the purchase of Government Reimbursed Products by the U.S. Department of Veterans Affairs. Persons engaged in these functions include individuals whose job responsibilities relate to the calculation and reporting of Average Sales Price (ASP), Average Manufacturer Price (AMP), Best Price, the 340B Program ceiling price, Average Wholesale Price (AWP) (if applicable), and all other information calculated and reported by ABC or an ABC Affiliate and used in connection with Federal health care programs.

5. “Distribution Functions” includes the sale, distribution, delivery, and/or supply of Government Reimbursed Products to retail pharmacies, institutional pharmacies, physician practices, other medical providers, and all other customers.

6. “Specialty Distribution and GPO Functions” includes: (a) the sale, distribution, delivery, and supply of specialty Government Reimbursed Products (including but not limited to blood plasma products, specialty drugs, vaccines, chemotherapy and oncology drugs, ophthalmology, rheumatology, gastroenterology, urology, dermatology and cardiology drugs, and related supplies); and (b) the provision of group purchasing organization (GPO) services and other items and services (e.g., practice management software, electronic medical records management, and consultative services) and the provision of data and information to pharmaceutical manufacturers and other customers.

7. “Pharmacy Functions” includes: (a) dispensing of Government Reimbursed products; (b) the provision of medication management services for patients, payers, and manufacturers; (c) the operation of retail pharmacies; (d) the provision of pharmacy-related services (including consulting, bill recovery, staffing services, and outsourced pharmacy management); and (e) the provision of practice management tools and services (including, practice management software provided to specialty medical practices and data and information services provided to manufacturers.) Pharmacy Functions includes interactions and contracting activities between ABC and entities that provide a drug health benefit program for Government Reimbursed Products, including but not limited to government payers (e.g., Medicaid and Medicare) or individuals or entities under contract with or acting on behalf of government payers and commercial health plans (collectively referred to as “Payers”). Pharmacy Functions also include interactions with Payers related to formulary placement, contracting, and rebate activities.

8. “Consulting Services Functions” includes: (a) the provision of patient and provider support programs for pharmaceutical, biotech, and medical device manufacturers; (b) the provision of consulting services to pharmaceutical manufacturers and medical device companies; (c) the provision of reimbursement support services, billing services, and payer coverage services; and (d) the provision of integrated pharmacy and wholesale distribution services through patient assistance programs or foundations.

9. “Covered Functions” refers to “Compounding/Manufacturing Functions,” “Distribution Functions,” “Specialty Distribution and GPO Functions,” “Pharmacy Functions,” and “Consulting Services Functions,” collectively.

10. “ABC Affiliate” shall mean any subsidiary of ABC whose employees or contractors perform Covered Functions. All obligations set forth in Section III below shall apply to ABC Affiliates in the same manner as they apply to ABC and all references to “ABC” in the defined terms set forth in this Section II shall include ABC Affiliates. In addition, the requirements in Section V.C., Section VI, Section VII, Section VIII, and Section X below shall apply to both ABC and any ABC Affiliate(s).

### **III. CORPORATE INTEGRITY OBLIGATIONS**

ABC shall establish and maintain a Compliance Program that includes the elements discussed in Sections III.A-M below. In addition, ABC represents that it has established and will maintain policies, procedures and systems designed to meet all applicable DEA requirements with regard to the distribution and dispensing of controlled substances.

#### **A. Chief Compliance Officer and Committee, Board of Directors, and Management Compliance Obligations**

1. *Chief Compliance Officer.* Within 90 days after the Effective Date, ABC shall appoint a Chief Compliance Officer (Chief Compliance Officer) and shall maintain a Chief Compliance Officer for the term of the CIA. The Chief Compliance Officer shall be an employee and a member of senior management of ABC; shall report directly to the Audit Committee of the Board of Directors and administratively to the Chief Executive Officer of ABC; and shall not be, or be subordinate to, the General Counsel or Chief Financial Officer of ABC or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for ABC. The Chief Compliance Officer shall be responsible for, without limitation:

- a. 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 and FDA and DEA requirements;

- b. making periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of ABC and shall be authorized to report on such matters to the Board of Directors at any time. Written documentation of the Chief Compliance Officer's reports to the Board of Directors shall be made available to OIG upon request; and
- c. monitoring the day-to-day compliance activities engaged in by ABC as well as any reporting obligations created under this CIA.

Any noncompliance job responsibilities of the Chief Compliance Officer shall be limited and must not interfere with the Chief Compliance Officer's ability to perform the duties outlined in this CIA.

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

2. *Compliance Committee.* Within 90 days after the Effective Date, ABC shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Chief Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., legal, regulatory affairs, human resources, audit, finance, and operations). The Chief Compliance Officer shall chair the Compliance Committee and the Committee shall support the Chief Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of ABC's risk areas and shall oversee compliance monitoring and investigations). The Compliance Committee shall meet at least quarterly. The minutes of the Compliance Committee meetings shall be made available to OIG upon request.

ABC shall report to OIG, in writing, 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.

3. *Board of Directors Compliance Obligations.* The Board of Directors (or a committee of the Board) of ABC (Board) shall be responsible for the review and oversight of matters related to compliance with Federal health care program

requirements, FDA requirements, DEA requirements, and the obligations of this CIA. The Board must include among its membership independent (i.e., non-executive) members.

The Board shall, at a minimum, be responsible for the following:

- a. meeting at least quarterly to review and oversee ABC's Compliance Program, including but not limited to the performance of the Chief Compliance Officer and Compliance Committee;
- b. submitting to OIG pursuant to Section V.B a description of the documents and other materials it reviewed, as well as any additional steps taken, such as the engagement of an independent advisor or other third party resources, in its oversight of the compliance program and in support of making the resolution below during each Reporting Period; and
- c. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board, summarizing its review and oversight of ABC's compliance with Federal health care program requirements, FDA requirements, DEA requirements, and the obligations of this CIA.

At minimum, the annual resolution shall include the following language:

“The Board of Directors has made a reasonable inquiry into the operations of ABC's Compliance Program including the performance of the Chief Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, ABC has implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements, DEA requirements, and the obligations of the CIA.”

If the Board is unable to provide such a conclusion in the resolution, the Board shall include in the resolution a written explanation of the reasons why it is unable to

provide the conclusion and the steps it is taking to implement an effective Compliance Program at ABC.

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

4. *Management Certifications:* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain ABC employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable ABC business unit is in compliance with applicable Federal health care program and with FDA and DEA requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: Executive Vice President (EVP) and Group President, Pharmaceutical Distribution and Strategic Sourcing; President, Community & Specialty Pharmacy; Senior Vice President (SVP), Corporate Partnership; EVP & Group CFO; SVP, Distribution Services; SVP and President, Clinical Product Solutions; President, Strategic Global Sourcing; SVP and President, Health Systems & Specialty Services; SVP and President, Specialty Physician Services; SVP, Market Economics; Executive Vice President (EVP) and Group President, Commercialization and Animal Health; SVP, Commercialization Solutions; SVP, Business Integration; SVP, Finance; President, Lash.

For each Reporting Period, each Certifying Employee shall sign a certification that states:

“I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department], an area under my supervision. My job responsibilities include ensuring compliance with regard to the \_\_\_\_\_ [insert name of the department] with all applicable Federal health care program requirements, FDA requirements, DEA requirements, obligations of the Corporate Integrity Agreement, and ABC policies, and I have taken steps to promote such compliance. To the best of my knowledge, the \_\_\_\_\_ [insert name of department] of ABC is in compliance with all applicable Federal health care program requirements, FDA requirements, DEA requirements, and the obligations of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States.”

If any Certifying Employee is unable to provide such a certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above.

Within 120 days after the Effective Date, ABC shall develop and implement a written process for Certifying Employees to follow for the purpose of completing the certification required by this section (e.g., reports that must be reviewed, assessments that must be completed, sub-certifications that must be obtained, etc. prior to the Certifying Employee making the required certification).

B. Written Standards

Within 120 days after the Effective Date, ABC shall develop and implement written policies and procedures regarding the operation of its compliance program in the United States, including the compliance program requirements outlined in this CIA and ABC's compliance with Federal health care program, FDA, and DEA requirements (Policies and Procedures). Throughout the term of this CIA, ABC shall enforce its Policies and Procedures and shall make compliance with its Policies and Procedures an element of evaluating the performance of all employees. The Policies and Procedures shall be made available to all Covered Persons.

At a minimum, the Policies and Procedures shall address appropriate ways to conduct each of the individual Covered Functions in compliance with any and all applicable Federal health care program requirements, FDA requirements, and DEA requirements. The Policies and Procedures shall also address disciplinary policies and procedures for violations of ABC's Policies and Procedures, including policies relating to any and all applicable Federal health care program, FDA, and DEA requirements.

At least annually (and more frequently, if appropriate), ABC shall assess and update, as necessary, the Policies and Procedures. Any new or revised Policies and Procedures shall be made available to all Covered Persons.

All Policies and Procedures shall be made available to OIG upon request.

C. Training and Education

1. *Covered Persons Training.* Within 90 days after the Effective Date, ABC shall develop a written plan (Training Plan) that outlines the steps ABC will take to ensure that: (a) all Covered Persons receive at least annual training regarding ABC's CIA requirements and compliance program, and (b) all Covered Persons who engage in Covered Functions receive at least annual training regarding: (i) all applicable Federal health care program, FDA, and DEA requirements relating to the Covered Function(s) engaged in or supervised by that Covered Person and (ii) all ABC Policies and Procedures and other requirements applicable to the Covered Function(s) engaged in or supervised by that Covered Person. The Training Plan shall include information regarding the following: training topics, categories of Covered Persons and required to attend each training session, length of the training session(s), schedule for training, and format of the training. ABC shall furnish training to its Covered Persons pursuant to the Training Plan during each Reporting Period.

2. *Board Member Training.* Within 90 days after the Effective Date, each member of the Board of Directors shall receive at least two hours of training. This training shall address the corporate governance responsibilities of board members, and the responsibilities of board members with respect to review and oversight of the Compliance Program. Specifically, the training shall address the unique responsibilities of health care Board members, including the risks, oversight areas, and strategic approaches to conducting oversight of a health care entity. This training may be conducted by an outside compliance expert hired by the Board and should include a discussion of OIG's guidance on Board member responsibilities.

New members of the Board of Directors shall receive the Board Member Training described above within 30 days after becoming a member or within 90 days after the Effective Date, whichever is later.

3. *Training Records.* ABC shall make available to OIG, upon request, training materials and records verifying that Covered Persons and Board members have timely received the training required under this section.

D. Risk Assessment and Internal Review Process

Within 120 days after the Effective Date, ABC shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with each of the Covered Functions as they apply to Government Reimbursed Products. The risk assessment and internal review process shall

require compliance, legal, and department leaders, at least annually, to: (1) identify and prioritize risks, (2) develop internal audit work plans related to the identified risk areas, (3) implement the internal audit work plans, (4) develop corrective action plans in response to the results of any internal audits performed, and (5) track the implementation of the corrective action plans in order to assess the effectiveness of such plans. Manufacturer shall maintain the risk assessment and internal review process for the term of the CIA.

E. Review Procedures

1. *General Description.*

- a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, ABC shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform the reviews listed in this Section III.E. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.
- b. *Retention of Records.* The IRO and ABC shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and ABC) related to the reviews.
- c. *Access to Records and Personnel.* ABC shall ensure the IRO has access to all records and personnel necessary to complete the reviews listed in this Section III.E., and that all records furnished to the IRO are accurate and complete.

2. *System, Transaction, and Additional Items Reviews.* As set forth more fully in Appendix B, the IRO reviews shall consist of three components: Systems Reviews and Transactions Reviews relating to the Covered Functions and an Additional Items Review.

- a. *Systems Review.* The Systems Reviews shall assess ABC’s systems, processes, policies, and procedures relating to the

Covered Functions. If there are no material changes in ABC's relevant systems, processes, policies, and procedures, the Systems Reviews shall be performed for the first and fourth Reporting Periods. If ABC materially changes its relevant systems, processes, policies, and procedures, the IRO shall perform a Systems Review for the Reporting Period in which such changes were made in addition to conducting the Systems Review for the first and fourth Reporting Periods, as set forth more fully in Appendix B.

- b. *Transactions Review.* The Transactions Reviews shall be performed for the second through fifth Reporting Periods. The IRO(s) shall perform all components of each annual Transaction Review. As set forth more fully in Appendix B, the Transactions Review shall include several components.
- c. *Additional Items Review.* The IRO review for the third and fifth Reporting Periods may also include a review of one additional areas or practices of ABC identified by OIG in its discretion (hereafter "Additional Item"). For purposes of identifying the Additional Item to be included in the IRO review for a particular Reporting Period, OIG will consult with ABC and may consider internal audit and monitoring work conducted by ABC, the Government Reimbursed Product portfolio, the nature and scope of ABC's business practices, and other information known to it.

3. *IRO Review Reports.* The IRO shall prepare a report based upon each IRO review performed (IRO Review Report). Information to be included in the IRO Review Report is described in Appendix B.

4. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to ABC a certification that the IRO has: (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.E; and (b) concluded that it is, in fact, independent and objective in accordance with the requirements specified in Appendix A to this CIA. The IRO's certification shall include a summary of current and prior engagements between ABC and IRO.

## F. Disclosure Program

Within 90 days after the Effective Date, ABC shall establish a Disclosure Program that includes a mechanism (e.g., a toll free compliance telephone line) to enable individuals to disclose, to the Chief Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with ABC's policies, conduct, practices, or procedures with respect to a Federal health care program, FDA, or DEA requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. ABC shall appropriately publicize the existence of the Disclosure Program and the disclosure mechanism (e.g., via periodic e-mails to employees, or by posting the information in prominent common areas).

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. The Disclosure Program also shall include a requirement that all of ABC's Covered Persons shall be expected to report suspected violations of any Federal health care program, FDA, or DEA requirements to the Chief Compliance Officer or other appropriate individual designated by ABC. Upon receipt of a disclosure, the Chief Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Chief 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 appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, ABC shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Chief Compliance Officer (or designee) shall maintain a disclosure log and shall record each disclosure in the disclosure log within two business days of receipt of the disclosure. The disclosure log shall include a summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews.

## G. Ineligible Persons

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

- a. an “Ineligible Person” shall include an individual or entity who:
  - i. is currently excluded from participation in the Federal health care programs; or
  - ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded.
- b. “Exclusion List” means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at <http://www.oig.hhs.gov>).

2. *Screening Requirements.* ABC shall ensure that all prospective and current Covered Persons are not Ineligible Persons by implementing the following screening requirements.

- a. ABC shall screen all prospective Covered Persons against the Exclusion List prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.
- b. ABC shall screen all current Covered Persons against the Exclusion List within 90 days after the Effective Date and on a monthly basis thereafter.
- c. ABC shall maintain a policy requiring all Covered Persons to disclose immediately if they become an Ineligible Person.

Nothing in this Section III.G affects ABC’s responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by an excluded person. ABC understands that items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and that ABC may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether ABC meets the requirements of Section III.G.

3. *Removal Requirement.* If ABC has actual notice that a Covered Person has become an Ineligible Person, ABC shall remove such Covered Person from responsibility for, or involvement with, ABC's business operations related to the Federal health care program(s) from which such Covered Person has been excluded and shall remove such Covered Person from any position for which the Covered Person's compensation is paid in whole or part, directly or indirectly, by any Federal health care program(s) from which the Covered Person has been excluded at least until such time as the Covered Person is reinstated into participation in such Federal health care program(s).

4. *Pending Charges and Proposed Exclusions.* If ABC has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term, ABC shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary, or the accuracy of any claims submitted to any Federal health care program.

#### H. Incentive Compensation Restriction and Financial Recoupment Programs

1. *Employee and Executive Incentive Compensation Restriction Program.* ABC agrees to develop and maintain throughout the term of the CIA policies and procedures that shall: (1) be designed to ensure that financial incentives do not motivate Covered Persons to engage in improper activities with respect to any of the Covered Functions (Employee and Executive Incentive Compensation Program). The specific terms and conditions of the Employee and Executive Incentive Compensation Program are described in Appendix C to this CIA.

2. *Executive Financial Recoupment Program.* ABC agrees to establish and maintain throughout the term of this CIA a financial recoupment program that puts at risk of forfeiture and recoupment an amount equivalent to up to 3 years of annual performance pay for an executive who is discovered to have been involved in any significant misconduct (Executive Financial Recoupment Program). The specific terms and conditions of the Executive Financial Recoupment Program are described in Appendix C to this CIA.

#### I. Notification of Government Investigation or Legal Proceeding

Within 30 days after discovery, ABC shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to ABC conducted or brought by a governmental entity or its agents involving an allegation that ABC has committed a crime or has engaged in fraudulent activities. 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. ABC also shall provide written notice to OIG within 30 days after the resolution of the matter and describe the findings and/or results of the investigation or proceeding, if any.

J. Overpayments

1. *Scope.* This Section III.J shall apply only to those Business Units performing Covered Functions that receive funds directly from Federal health care programs.

2. *Definition of Overpayments.* For purposes of this CIA, an “Overpayment” means any funds that ABC receives or retains under any Federal health care program to which ABC, after applicable reconciliation, is not entitled under such Federal health care program.

3. *Repayment of Overpayments.* If, at any time, ABC identifies any Overpayment, ABC shall repay the Overpayment to the appropriate payer (e.g., Medicare contractor) in accordance with the requirements of the Centers for Medicare and Medicaid Services (CMS) overpayment statute and regulations, 42 U.S.C. § 1320a-7k(d) and 42 C.F.R. §§ 401.301-305, and any applicable CMS guidance. ABC should follow the payer’s policies regarding the form of notification and the repayment process for any Overpayment refunds. Any questions regarding the repayment process should be directed to the payer.

K. Reportable Events

1. *Definition of Reportable Event.* For purposes of this CIA, a “Reportable Event” means anything that involves:

- a. a substantial Overpayment;
- b. 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;

- c. a matter that a reasonable person would consider a probable violation of FDA requirements relating to a Covered Function unless otherwise reported to the FDA in accordance with Section III.L below;
- d. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or
- e. the filing of a bankruptcy petition by ABC.

A Reportable Event may be the result of an isolated event or a series of occurrences.

If the Reportable Event involves an Overpayment, within 60 days of identification of the Overpayment, ABC shall repay the Overpayment, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and 42 C.F.R. §§ 401.301-305 (and any applicable CMS guidance) and provide OIG with a copy of the notification and repayment.

2. *Reporting of Reportable Events.* If ABC determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, ABC shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Sections III.K.1.a through III.K.1.c.* For Reportable Events under Sections III.K.1.a through c, the report to OIG shall include:

- a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims (if applicable), transactions or other conduct giving rise to the Reportable Event, the period during which the conduct occurred, and the names of individuals and entities believed to be implicated, including an explanation of their roles in the Reportable Event;

- b. a statement of the Federal criminal, civil or administrative laws that are probably violated by the Reportable Event, if any;
- c. the Federal health care programs affected by the Reportable Event, if any;
- d. a statement of the FDA requirements probably violated by the Reportable Event, if any;
- e. a description of the steps taken by ABC to identify and quantify any Overpayments; and
- g. a description of ABC's actions taken to correct the Reportable Event and prevent it from recurring.

4. *Reportable Events under Section III.K.1.d.* For Reportable Events under Section III.K.1.d, the report to OIG shall include:

- a. the identity of the Ineligible Person and the job duties performed by that individual;
- b. the dates of the Ineligible Person's employment or contractual relationship;
- c. a description of the Exclusion List screening that ABC completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the screening process that led to the hiring or contracting with the Ineligible Person;
- d. a description of how the Ineligible Person was identified; and
- e. a description of any corrective action implemented to prevent future employment or contracting with an Ineligible Person.

5. *Reportable Events under Section III.K.1.e.* For Reportable Events under Section III.K.1.e, the report to OIG shall include documentation of the bankruptcy

filing and a description of any Federal health care program and/or FDA requirements implicated.

L. Notification of Communications with FDA

Within 30 days after the date of any written report, correspondence, or communication between ABC and the FDA that materially discusses ABC's or a Covered Person's unlawful or improper activity relating to a Covered Function, ABC shall provide a copy of the report, correspondence, or communication to OIG. ABC shall also provide written notice to OIG within 30 days after the resolution of any matter reported to OIG under this Section III.L, and shall provide OIG with a description of the findings and/or results of the matter, if any.

With regard to PharMEDium Healthcare, ABC shall provide to OIG a copy of the following types of communications between ABC and FDA: (i) any Form FDA 483s; (ii) any FDA Untitled Letters; (iii) any FDA Warning Letters; (iv) any recall classification letters; and (v) any formal written communications between FDA and PharMEDium (or ABC) relating to such Form 483s, FDA Untitled Letters, FDA Warning Letters and recall classification letters. ABC shall provide copies of any such PharMEDium-related communication within 30 days after the date of the communication. ABC shall also provide written notice to OIG within 30 days after the resolution of any PharMEDium-related matter reported to OIG under this Section III.L, and shall provide OIG with a description of the findings and/or results of the matter, if any.

M. Notice to Health Care Providers

Within 30 days after the Effective Date, ABC shall post in a prominent place on the main page of the health care professional section of its company website (or other placement agreed to in advance by OIG), a copy of a letter signed by ABC's Chief Executive Officer containing the language set forth below:

As you may be aware, ABC recently entered into criminal and civil resolutions with the United States and individual states in connection with ABC's conduct relating to the preparation and distribution of syringes that were pre-filled with oncology supportive care drugs. This letter provides you with additional information about the settlements, explains ABC's commitments going forward, and provides you with access to information about those commitments.

The Government alleges that ABC engaged in several types of unlawful and improper conduct relating to a pre-filled syringe program based at a Dothan, Alabama facility. More specifically, the United States contends that ABC and its subsidiaries, through the pre-filled syringe program, caused the submission of numerous false claims to Federal health care programs.

To address criminal liability associated with the pre-filled syringe program, a subsidiary of ABC pled guilty to violating the Federal Food Drug, and Cosmetic Act and agreed to pay \$260 million in criminal penalties. In addition, the federal government and several individual states alleged that ABC's conduct violated the Federal False Claims Act and equivalent state statutes. To resolve those allegations, ABC entered into a separate civil False Claims Act settlement in which ABC agreed to pay the United States and participating states \$625 million. More information about the criminal plea and civil settlement may be found at the following: **[The letter should include links to the DOJ press announcements about the criminal plea and the federal False Claims Act settlement and to ABC's corresponding press announcements.]**

As part of the settlement, ABC also entered into a five-year corporate integrity agreement with the Office of Inspector General of the U.S. Department of Health and Human Services. The corporate integrity agreement is available at <http://oig.hhs.gov/fraud/cia/index.html>. Under this agreement, ABC agreed to maintain and undertake certain obligations designed to promote compliance with Federal health care program, FDA, and DEA requirements. We also agreed to notify healthcare providers about the settlement and inform them that they can report any questionable practices by ABC's representatives to ABC's Compliance organization or the FDA using the information set out below.

Please call ABC at (833) 247-2760 or email us at [OOC@amerisourcebergen.com](mailto:OOC@amerisourcebergen.com) if you have questions about the settlement referenced above. Please call ABC at (833) 247-2760 or email us at [OOC@amerisourcebergen.com](mailto:OOC@amerisourcebergen.com) to report any instances in which you believe that a ABC representative engaged in questionable conduct. If you wish to remain anonymous, please call (800) 570-4810 or report online at

<http://www.tnwgrc.com/Amerisourcebergen>. Alternatively, you may report any improper conduct associated with prescription drug marketing to the FDA's Office of Prescription Drug Promotion at 301-796-1200.

The notice shall remain posted for a period of at least 180 days. The Chief Compliance Officer (or a designee) shall maintain a log of all calls and messages received in response to the notice. The log shall include a record and summary of each call and message received (whether anonymous or not), the status of the call or message, and any corrective action taken in response to the call or message. The log of all calls and messages received in response to the notice shall be made available to OIG upon request. As part of the Implementation Report and each Annual Report, ABC shall provide to OIG a summary of the calls and messages received.

#### **IV. SUCCESSOR LIABILITY**

In the event that, after the Effective Date, ABC proposes to (a) sell any or all of its business, business units or locations (whether through a sale of assets, sale of stock or other type of transaction) that are subject to this CIA; or (b) purchases or establishes a new business, business unit or location related to or engaged in any of the Covered Functions, the CIA shall be binding on the purchaser of any business, business unit or location. Any such new business, business unit or location (and all Covered Persons at each new business, business unit or location) shall be subject to the applicable requirements of this CIA, unless otherwise determined and agreed to in writing by OIG. ABC shall give notice of such sale or purchase to OIG within 30 days following the closing of the transaction.

If, in advance of a proposed sale or a proposed purchase as described above, ABC wishes to obtain a determination by OIG that the proposed purchaser or the proposed acquisition will not be subject to the requirements of the CIA, ABC must notify OIG in writing of the proposed sale or purchase at least 30 days in advance. This notification shall include a description of the business, business unit, or location to be sold or purchased, a brief description of the terms of the transaction and, in the case of a proposed sale, the name and contact information of the prospective purchaser.

#### **V. IMPLEMENTATION AND ANNUAL REPORTS**

##### **A. Implementation Report**

Within 150 days after the Effective Date, ABC 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 Chief Compliance Officer required by Section III.A.1, and a summary of other noncompliance job responsibilities the Chief Compliance Officer may have;
2. the names and positions of the members of the Compliance Committee required by Section III.A.2;
3. the names of the Board members who are responsible for satisfying the Board of Directors compliance obligations described in Section III.A.3;
4. the names and positions of the Certifying Employees required by Section III.A.4 and a copy of the written process followed for purposes of completing the certifications required by Section III.A.4;
5. a list of the Policies and Procedures required by Section III.B;
6. the Training Plan required by Section III.C.1 and a description of the Board of Directors training required by Section III.C.2 (including a summary of the topics covered, the length of the training and when the training was provided);
7. a description of the risk assessment and internal review process required by Section III.D;
8. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this CIA; and (d) a certification from the IRO regarding its professional independence and objectivity with respect to ABC;
9. a description of the Disclosure Program required by Section III.F;
10. a description of the Ineligible Persons screening and removal process required by Section III.G;

11. a certification by the Chief Compliance Officer that the notice required by Section III.M was posted in the manner required by Section III.M and a summary of the calls or messages received in response to the notice;

12. a list of all of ABC's locations that engage in Covered Functions (including locations and mailing addresses); the corresponding name under which each location is doing business; and the locations' Medicare and state Medicaid provider number and/or supplier number(s) if any;

13. a description of the corporate structure of ABC entities that engage in Covered Functions, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

14. the certifications required by Section V.C.

B. Annual Reports

ABC shall submit a written report to OIG on its compliance with the CIA requirements for each of the five Reporting Periods (Annual Report). Each Annual Report shall include, at a minimum, the following information:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Chief Compliance Officer; a current list of the Compliance Committee members; a current list of the Board members who are responsible for satisfying the Board of Directors compliance obligations; a current list of the Certifying Employees, along with the identification of any changes made during the Reporting Period to the Compliance Committee, Board of Directors, and Certifying Employees; and a description of any changes to the process followed in connection with certifications by Certifying Employees and an explanation of the reasons for the changes;

2. the dates of each report made by the Chief Compliance Officer to the Board (written documentation of such reports shall be made available to OIG upon request);

3. the Board resolution required by Section III.A.3 and a description of the documents and other materials reviewed by the Board, as well as any additional steps taken, in its oversight of the compliance program and in support of making the resolution;

4. a list of any new or revised Policies and Procedures required by Section III.B developed during the Reporting Period;
5. a description of any changes to ABC's Training Plan developed pursuant to Section III.C and a summary of any Board of Directors training provided during the Reporting Period;
6. a description of any changes to the risk assessment and internal review process required by Section III.D, including the reasons for such changes;
7. a summary of the following components of the risk assessment and internal review process during the Reporting Period: (a) work plans developed; (b) internal audits performed; (c) corrective action plans developed in response to internal audits; and (d) steps taken to track the implementation of the corrective action plans. Copies of any work plans, internal audit reports, and corrective action plans shall be made available to OIG upon request;
8. a complete copy of all reports prepared pursuant to Section III.E and ABC's response to the reports, along with corrective action plan(s) related to any issues raised by the reports;
9. a certification from the IRO regarding its professional independence and objectivity with respect to ABC;
10. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs, FDA requirements, or Government Reimbursed Products, including at least the following information: (a) a description of the disclosure, (b) the date the disclosure was received, (c) the resolution of the disclosure, and (d) the date the disclosure was resolved (if applicable). The complete disclosure log shall be made available to OIG upon request;
11. a description of any changes to the Ineligible Persons screening and removal process required by Section III.G, including the reasons for such changes;
12. a description of the Incentive Compensation Restriction and Financial Recoupment Programs required by Section III.H;
13. a summary describing any ongoing investigation or legal proceeding

required to have been reported pursuant to Section III.I. 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 summary of Reportable Events (as defined in Section III.K) identified during the Reporting Period;

15. a summary describing any written communication with the FDA required to have been reported pursuant to Section III.L. This summary shall include a description of each matter and the status of each matter;

16. a summary of the calls and messages received in response to the notice required by Section III.M and the disposition of those calls and messages;

17. a description of all changes to the most recently provided list of ABC's locations (including addresses) as required by Section V.A.12;

18. a description of any changes to the corporate structure of ABC entities that engage in Covered Functions, including any parent and sister companies, subsidiaries, and their respective lines of business; and

19. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 60 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

1. *Certifying Employees.* In each Annual Report, ABC shall include the certifications of Certifying Employees as required by Section III.A.4;

2. *Chief Compliance Officer and Chief Executive Officer.* The Implementation Report and each Annual Report shall include a certification by the Chief Compliance Officer and Chief Executive Officer that:

- a. to the best of his or her knowledge, except as otherwise described in the report, ABC has implemented and is in compliance with all requirements of this CIA;

- b. 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;
- c. except as otherwise agreed with OIG, every ABC subsidiary has been included in ABC's Compliance Program and has been subject to all applicable requirements (including training, policies and procedures, and auditing monitoring) and every subsidiary has been included in ABC's risk assessment and internal review process developed pursuant to Section III.D; and
- d. he or she understands that the certification is being provided to and relied upon by the United States.

D. Designation of Information

ABC 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. ABC 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

ABC:

Chris Zimmerman  
Senior Vice President and Chief Compliance Officer  
Corporate Security & Regulatory Affairs  
AmerisourceBergen Corporation  
1300 Morris Drive  
Chesterbrook, PA 19087  
Telephone: 610.727.7444

Unless otherwise specified, all notifications and reports required by this CIA may be made by electronic mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. Upon request by OIG, ABC may be required to provide OIG with an additional copy of each notification or report required by this CIA in OIG's requested format (electronic or paper).

## **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 conduct interviews, examine and/or request copies of or copy ABC books, records, and other documents and supporting materials and/or conduct on-site reviews of any of ABC locations for the purpose of verifying and evaluating: (a) ABC's compliance with the terms of this CIA and (b) ABC's compliance with Federal health care program requirements and with all applicable FDA and DEA requirements. The documentation described above shall be made available by ABC to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of ABC owners, employees, contractors and directors 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. ABC shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. ABC owners, employees, contractors and directors may elect to be

interviewed with or without a representative of ABC present.

## **VIII. DOCUMENT AND RECORD RETENTION**

ABC shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this CIA for six years (or longer if otherwise required by law) from the Effective Date.

## **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 ABC prior to any release by OIG of information submitted by ABC pursuant to its obligations under this CIA and identified upon submission by ABC as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, ABC shall have the rights set forth at 45 C.F.R. § 5.42 (a).

## **X. BREACH AND DEFAULT PROVISIONS**

ABC 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, ABC 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 ABC fails to establish, implement or comply with any of the following obligations as described in Section III:

- a. a Chief Compliance Officer;
- b. a Compliance Committee;
- c. the Board of Directors compliance obligations and the engagement of a Compliance Expert, the performance of a

Compliance Program Review, and the preparation of a Compliance Program Review Report, as required by Section III.A.3.;

- d. the management certification obligations and the development and implementation of a written process for Certifying Employees, as required by Section III.A.4.;
- e. written Policies and Procedures;
- f. the development of a written training plan and the training and education of Covered Persons and Board Members;
- g. a risk assessment and internal review process;
- h. a Disclosure Program;
- i. Ineligible Persons screening and removal requirements;
- j. the establishment of Incentive Compensation Restriction and Financial Recoupment Programs;
- k. notification of Government investigations or legal proceedings;
- l. policies and procedures regarding the repayment of Overpayments;
- m. reporting of Reportable Events;
- n. notification of written communications with FDA; and
- o. notification to health care providers.

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 ABC fails to engage and use an IRO as required by Section III.E and Appendix B.

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 ABC fails to submit a complete Implementation Report, Annual Report or any certification 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 ABC fails to submit any IRO Review report in accordance with the requirements of Section III.E and Appendix B.

5. A Stipulated Penalty of \$1,500 for each day ABC fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date ABC fails to grant access.)

6. A Stipulated Penalty of \$50,000 for each false certification submitted by or on behalf of ABC as part of its Implementation Report, any Annual Report, additional documentation to a report (as requested by OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of \$2,500 for each day ABC fails to grant the IRO access to all records and personnel necessary to complete the reviews required by Section III.E and for each day ABC fails to furnish accurate and complete records to the IRO, as required by Section III.E and Appendix A; and

8. A Stipulated Penalty of \$1,000 for each day ABC fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to ABC stating the specific grounds for its determination that ABC has failed to comply fully and adequately with the CIA obligation(s) at issue and steps ABC shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the date ABC 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- 7 of this Section.

#### B. Timely Written Requests for Extensions

ABC 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 ABC 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 days after ABC 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 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 ABC 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 ABC of: (a) ABC'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").

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, ABC 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 ABC elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until ABC 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 electronic funds transfer to an account specified by OIG in the Demand Letter.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.d, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that ABC 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. repeated violations or a flagrant violation of any of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- b. a failure by ABC to report a Reportable Event and take corrective action as required in Section III.K;
- c. a failure to engage and use an IRO in accordance with Section III.E and Appendix B; or
- d. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by ABC constitutes an independent basis for ABC's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in OIG's discretion, but not more than five years per material breach. Upon a determination by OIG that ABC has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify ABC of: (a) ABC'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.* ABC 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. the alleged material breach has been cured; or
- b. the alleged material breach cannot be cured within the 30 day period, but that: (i) ABC has begun to take action to cure the material breach; (ii) ABC is pursuing such action with due diligence; and (iii) ABC has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, ABC fails to satisfy the requirements of Section X.D.3, OIG may exclude ABC from participation in the Federal health care programs. OIG shall notify ABC in writing of its determination to exclude ABC (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 ABC’s receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, ABC 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 ABC 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, ABC 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. The procedures relating to the filing of a request for a hearing can be found at <http://www.hhs.gov/dab/divisions/civil/procedures/divisionprocedures.html>.

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 ABC was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. ABC 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 ABC to pay Stipulated Penalties, such Stipulated Penalties shall

become due and payable 20 days after the ALJ issues such a decision unless ABC 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 whether ABC was in material breach of this CIA and, if so, whether:

- a. ABC cured such breach within 30 days of its receipt of the Notice of Material Breach; or
- b. the alleged material breach could not have been cured within the 30 day period, but that, during the 30 day period following ABC's receipt of the Notice of Material Breach: (i) ABC had begun to take action to cure the material breach within that period; (ii) ABC pursued such action with due diligence; and (iii) ABC provided to OIG within that period a reasonable timetable for curing the material breach.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for ABC, only after a DAB decision in favor of OIG. ABC's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude ABC 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 ABC 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. ABC 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 ABC, ABC 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**

ABC and OIG agree as follows:

A. This CIA shall become final and binding on the date the final signature is obtained on the CIA.

B. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA.

C. All requirements and remedies set forth in this CIA are in addition to and do not affect (1) ABC's responsibility to follow all applicable Federal health care program, FDA, and DEA requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable Federal health care program, FDA, or DEA requirements.

D. The undersigned ABC signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacity and that they are authorized to execute this CIA.

E. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Electronically-transmitted signatures shall constitute acceptable, binding signatures for purposes of this CIA.

**ON BEHALF OF AMERISOURCEBERGEN CORPORATION**

/Steven H. Collis/  
Steven H. Collis  
Chairman, President  
and Chief Executive Officer  
AmerisourceBergen Corporation

9/27/18  
DATE

/Erik Sitarchuk/  
Erik W. Sitarchuk  
John J. Pease  
Ryan P. McCarthy  
Morgan, Lewis & Bockius, LLP  
Counsel for AmerisourceBergen Corporation

9/27/18  
DATE

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

/Lisa M. Re/

Lisa M. Re  
Assistant Inspector General for Legal Affairs  
Office of Inspector General  
U.S. Department of Health and Human Services

9/28/2018

DATE

/Mary E. Riordan/

Mary E. Riordan, Senior Counsel  
Madeline J. Bainer, Associate Counsel  
Office of Inspector General  
U.S. Department of Health and Human Services

9/28/2018

DATE

## APPENDIX A

### INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.E of the CIA.

#### A. IRO Engagement

1. AmerisourceBergen Corporation (ABC) 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 objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives the information identified in Section V.A.8 of the CIA or any additional information submitted by ABC in response to a request by OIG, whichever is later, OIG will notify ABC if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, ABC may continue to engage the IRO.

2. If ABC engages a new IRO during the term of the CIA, that IRO must also meet the requirements of this Appendix. If a new IRO is engaged, ABC 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 this information or any additional information submitted by ABC at the request of OIG, whichever is later, OIG will notify ABC if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, ABC may continue to engage the IRO.

#### B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the IRO Reviews who have expertise in Federal health care program, FDA, and DEA requirements applicable to the reviews being conducted;

2. assign individuals to design and select samples for the Transactions Reviews who are knowledgeable about the appropriate statistical sampling techniques; 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 component of the IRO Reviews in accordance with the specific requirements of the CIA;
2. follow all applicable Federal health care program, FDA, and DEA requirements in making assessments in the Transactions Reviews;
3. request clarification from the appropriate authority (e.g., Medicare contractor), if in doubt of the application of a particular Federal health care program, FDA, or DEA requirement, policy, or regulation;
4. respond to all OIG inquires in a prompt, objective, and factual manner; and
5. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. ABC Responsibilities

ABC shall ensure that the IRO has access to all records and personnel necessary to complete the reviews referenced in Section III.E and Appendix B and that all records furnished to the IRO are accurate and complete.

E. IRO Independence and Objectivity

The IRO must perform the IRO Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the U.S. Government Accountability Office.

F. IRO Removal/Termination

1. *ABC and IRO.* If ABC terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, ABC must submit a notice explaining (a) its reasons for termination of the IRO or (b) the IRO's reasons for its withdrawal to OIG, no later than 30 days after termination or withdrawal. ABC must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. *OIG Removal of IRO.* In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in

Paragraph C, OIG shall notify ABC in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. ABC shall have 30 days from the date of OIG's written notice to provide information regarding the IRO's qualifications, independence or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by ABC regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify ABC in writing that ABC shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. ABC must engage a new IRO within 60 days of its receipt of OIG's written notice. The final determination as to whether or not to require ABC to engage a new IRO shall be made at the sole discretion of OIG.

## **Appendix B**

### **IRO System and Transaction Reviews**

#### **I. IRO Engagement, General Description**

As specified more fully below, AmerisourceBergen Corporation (ABC) shall retain an Independent Review Organization (IRO) to perform engagements to assist ABC in assessing and evaluating its systems, processes, policies, and procedures related to aspects of ABC's Compliance Program and Covered Functions as defined in the CIA (collectively "IRO Reviews"). The IRO Reviews shall consist of two components - a systems review (Systems Review) and a transactions review (Transactions Review), as described more fully below. ABC may engage, at its discretion, a single entity to perform both components of the IRO Reviews provided that the entity has the necessary expertise and capabilities to perform both.

If there are no material changes in ABC's systems, processes, policies, and procedures relating to the Compliance Program or Covered Functions, the IRO shall perform the Systems Review outlined in Section II below for the first and fourth Reporting Periods of the CIA.

If ABC materially changes its systems, processes, policies, and procedures relating to the Compliance Program or Covered Functions, the IRO shall perform a Systems Review for the Reporting Period(s) in which such material changes were made in addition to conducting the Review as set forth above. The additional Systems Review(s) shall consist of: 1) an identification of the material changes; 2) an assessment of whether other systems, processes, policies, and procedures previously reported did not materially change; and 3) a review of the systems, processes, policies, and procedures that materially changed.

The IRO shall conduct the Transactions Review for the second through fifth Reporting Periods of the CIA.

#### **II. IRO Systems Review**

The Systems Review shall be a review of (1) the manner in which ABC's systems, processes, policies and procedures (including the controls on those systems, processes, policies, and procedures) relating to its Compliance Program are implemented at both the corporate and individual Business Unit level; (2) ABC's risk assessment and internal review process; and (3) ABC's processes, data, policies, and practices relating to its Annual Incentive Plan (AIP) as outlined below.

Where practical, ABC personnel may compile documentation, schedule and organize interviews, and undertake other efforts to assist the IRO in performing the Systems

Review. The IRO is not required to undertake a de novo review of the information gathered or activities undertaken by ABC pursuant to the preceding sentence.

Specifically, the IRO shall review ABC's systems, processes, policies, and procedures associated with the following (hereafter "Reviewed Policies and Procedures"):

- A. IRO Systems Review. The Systems Review shall be a review of ABC's systems, processes, policies, and procedures relating to certain aspects of the ABC Compliance Program. Specifically, the IRO shall review the following:
  1. ABC's systems, policies, and procedures with respect to maintaining a Chief Compliance Officer and Compliance Committee at the corporate level and with respect to maintaining Group Compliance Officers (GCOs) at the business unit level;
  2. ABC's systems, policies, and procedures with respect to the establishment and maintenance of written policies and procedures regarding the operation of its Compliance Program at the corporate and business unit levels;
  3. ABC's systems, policies, and procedures with respect to Covered Persons training and Board Member training, including training at the corporate and business unit levels;
  4. ABC's systems, policies, and procedures with respect to its risk assessment and internal review process as applied at the corporate and business unit levels. This review shall assess whether the risk assessment and internal review process identifies and addresses relevant and appropriate risks relating to Covered Functions for each business unit and subsidiary;
  5. ABC's systems, policies, and procedures with respect to establishing the performance measures and goals used for purposes of ABC's AIP (including the financial data used to establish the performance measures and goals); and
  6. ABC's systems, policies, procedures, and practices with respect to determining whether to make downward adjustments to Awards for Covered Persons under the AIP in instances where ABC's policies and/or procedures or applicable laws, rules, or regulations have been violated (collectively, "Compliance Violation Situations").
  
- B. IRO Systems Review Report. The IRO shall prepare a report based upon each Systems Review performed. For each of the Reviewed Policies and Procedures identified in Section A above, the report shall include the following items:
  1. A description of the documentation (including policies) reviewed and any personnel interviewed;

2. A detailed description of ABC's systems, policies, processes, and procedures relating to each of the Reviewed Policies and Procedures;
3. Findings relating to whether every ABC subsidiary and business unit was included and integrated into ABC's Compliance Program;
4. Findings relating to whether ABC's risk assessment and internal review process identifies and addresses relevant and appropriate risks relating to Covered Functions at a corporate level and for each business unit and subsidiary;
5. Findings relating to whether the risk assessment and internal review processes result in appropriate tracking and monitoring of corrective action plans;
6. Findings relating to the manner in which ABC establishes performance measures and goals for purposes of making Awards to covered individuals under its AIP, including whether the performance measures and goals are designed to ensure that financial incentives do not motivate Covered Persons to engage in improper activities with respect to any of the Covered Functions;
7. Findings relating to the frequency and basis upon which ABC made downward adjustments to Awards for covered individuals in Compliance Violation Situations;
8. Findings and supporting rationale regarding any weaknesses in ABC's systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and
9. Recommendations to improve any of ABC's systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

### **III. IRO Transactions Review**

#### **A. IRO Review of Selected Audits**

Each year, ABC's Office of Compliance coordinates with other ABC departments as deemed appropriate by the ABC Office of Compliance to conduct a Risk Assessment of all of the ABC business units ("ABC Risk Assessment"). Based on the results of the ABC Risk Assessment, ABC's Office of Compliance develops an Audit Plan that identifies compliance issues that ABC's Office of Compliance will audit each year ("ABC Audit Plan"). The ABC Office of Compliance executes the ABC Audit Plan by conducting the audits of the issues identified in the ABC Audit Plan each year.

For the second through fifth Reporting Periods, ABC shall provide the IRO and OIG with: i) the ABC Risk Assessment report and ii) the ABC Audit Plan. The OIG will select for review by the IRO three of the ABC audits conducted at the ABC business units performing Covered Functions and identified in the Audit Plan ("Selected Audits"). The IRO shall report on its reviews in the Transactions Review Reports.

For each of the three Selected Audits, ABC shall provide the IRO with: i) the audit work plan; ii) the audit report; iii) documentation reviewed by ABC in the audit process, and iv) documentation of any corrective action taken by ABC as a result of the audit report findings. After consultation with the OIG, the IRO may engage in additional targeted sampling to further assess the issue identified by the ABC Audit Plan for auditing in the Selected Audit.

For each of the three Selected Audits, the IRO shall: i) evaluate whether the audit work plan was sufficient to address the identified risk areas; and ii) note any instances in which the ABC audit failed to follow its audit work plan, or failed appropriately to identify and address any compliance related concerns related to the identified risk areas.

#### B. Additional Item Reviews

As set forth in Section III.E of the CIA, for the third and fifth Reporting Periods, OIG at its discretion may identify one additional item for the IRO to review (hereafter “Additional Items”). No later than 90 days prior to the end of the applicable Reporting Period, OIG shall notify ABC of the nature and scope of the IRO review to be conducted for each Additional Item. Prior to undertaking the review of the Additional Item, the IRO and/or ABC shall submit an audit work plan to OIG for approval and the IRO shall conduct the review of the Additional Item based on a work plan approved by OIG. If an Additional Item Review is required for a Reporting Period, the IRO shall include information about its Additional Item Review in the Transactions Review Report as outlined below.

#### C. Transactions Review Report

For the second through fifth Reporting Periods, the IRO shall prepare a report based on its Transactions Reviews. The report shall include the following:

##### 1. General Elements to Be Included in Report:

- a) Review Objectives: A clear statement of the objectives intended to be achieved by each part of the review;
- b) Review Protocol: A detailed narrative description of the procedures performed; and
- c) Sources of Data: A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Transactions Review.

##### 2. Results to be Included in Report. The following results shall be included in each Transactions Review Report for each Selected Audit:

- a) A description of the review conducted by the IRO;
- b) A description of the documentation reviewed (including the policies and procedures reviewed) and an identification of any personnel interviewed in connection with the Transactions Review;
- c) A statement as to whether the ABC Audit Report is consistent with the ABC audit work plan and documentation reviewed by ABC in the audit process;
- d) A statement of whether the IRO agrees with the findings in ABC's Audit Report and, if not, the basis for the IRO's disagreement;
- e) A statement of whether the audit work plan was sufficient to address the identified risk areas;
- f) A statement of whether, in the IRO's view, ABC took appropriate corrective action in response to the audit findings and, if applicable, the IRO's recommendations regarding any additional or alternative corrective action;
- g) A statement of whether ABC took appropriate follow-up steps to ensure that any corrective action was appropriately implemented and, if applicable, the IRO's recommendations regarding any additional or alternative follow-up steps; and
- h) A statement as to whether the ABC audit appropriately identified and addressed any compliance related concerns related to the identified risk areas and, if applicable, a description of any compliance related concerns that were not appropriately identified and addressed.

3. Results to Be Included for any Additional Item Review:

- a) for each Additional Item reviewed, a description of the review conducted;
- b) for each Additional Item reviewed, the IRO's findings based on its review;
- c) for each Additional Item reviewed, the findings and supporting rationale regarding any weaknesses in ABC's systems, processes, policies, procedures, and practices relating to the Additional Item; and
- d) for each Additional Item reviewed, recommendations, if any, for changes in ABC's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the review.

## **Appendix C**

### **Incentive Compensation Restriction and Financial Recoupment Program**

To the extent not already accomplished, AmerisourceBergen Corporation (ABC) and the ABC Affiliates (as defined in Section II.C of the CIA) shall establish and maintain throughout the term of the CIA a financial recoupment program that puts at risk of forfeiture and recoupment an amount equivalent to up to 3 years of annual incentive compensation (including Cash Awards and Equity Awards as defined below) for any Eligible Individual (as defined below in Paragraph B(ii)) who is the subject of an Affirmative Recoupment Determination (as defined below in Paragraph D). The program shall be known as the “Financial Recoupment Program”. The Financial Recoupment Program shall apply to Eligible Individuals who are either current ABC or ABC Affiliate employees or who are former ABC or ABC Affiliate employees at the time of a Recoupment Determination.

**(A) Annual Incentive Plan.** ABC maintains an Annual Incentive Plan based on the attainment of annual corporate and individual performance goals on a fiscal year basis. All U.S. regular full-time and part-time non-sales employees at compensation levels stated in the plan are eligible to participate in the Annual Incentive Plan. Awards under the Annual Incentive Plan are at risk of a downward adjustment of 0% to 20% in cases where it is determined by senior management that company policies and/or procedures have been violated. In addition to, but separate from, the Financial Recoupment Program, which applies to Eligible Individuals, ABC shall maintain the downward adjustment portions of the Annual Incentive Plan throughout the term of the CIA with respect to all participants in the Annual Incentive Plan.

**(B) Financial Recoupment Program.** The forfeiture and recoupment provisions of the Financial Recoupment Program are set forth below.

**(i) Forfeiture of Unpaid and Unvested Awards.** To the extent not already accomplished, within 120 days after the Effective Date of the CIA, ABC and ABC Affiliates shall establish policies and procedures (and modify employment and other contracts as necessary) to provide that annual cash incentive awards, bonuses, and other similar awards (collectively, “Cash Awards”) for each Eligible Individual are at risk of forfeiture in the event of any potential Significant Misconduct that is discovered by ABC or the ABC Affiliates before the Cash Award is paid. In the event of any potential Significant Misconduct by any Eligible Individual, ABC and the ABC Affiliates shall also reserve the right and full discretion to void and forfeit any unvested stock options, unvested stock appreciation rights, unvested stock awards, unvested restricted stock unit

awards, unvested performance share awards, and any other unvested right to receive company common stock (collectively, “Equity Awards” referred to collectively with Cash Awards as “Awards”). If ABC or an ABC Affiliate discovers any potential Significant Misconduct that would implicate the forfeitures described in this Paragraph B(i) by an Eligible Individual, then the Recoupment Committee (as defined below) shall evaluate the situation and make a determination about whether any forfeiture shall be implemented and, if so, the terms of such forfeiture in accordance with the process for a Recoupment Determination (as defined below).

**(ii) Recoupment of Paid or Vested Awards.** In addition, to the extent not already accomplished, within 120 days after the Effective Date of the CIA, ABC and the ABC Affiliates shall modify and supplement their annual bonus plans applicable to an Eligible Individual (and any employment agreements, as appropriate) by imposing the following eligibility and repayment conditions set forth in Paragraphs B(ii)(a) and B(ii)(b) below on Cash Awards and Equity Awards made beginning in fiscal year 2019 and making the additional remedies discussed below in Paragraph B(iii) applicable to all eligible individuals who are included within ABC’s Executive Lead Team, Level 1, and Level 2 (collectively, “Eligible Individuals”). ABC and the ABC Affiliates shall implement policies and procedures and, as necessary, shall modify contracts with Eligible Individuals so that beginning in fiscal year 2019 the Cash Awards and Equity Awards may be recouped if an Affirmative Recoupment Determination is made. The forfeiture and recoupment rights described in Paragraph B shall apply prospectively to Equity Awards granted to Eligible Individuals on or after October 1, 2018 and Cash Awards paid or payable to Eligible Individuals with respect to performance periods beginning on or after October 1, 2018.

**(a) Cash Award Eligibility and Repayment Conditions.** ABC and ABC Affiliates shall implement an eligibility and repayment condition on annual Cash Awards that shall be designed to survive both the payment of the Cash Award and the separation of an Eligible Individual’s employment. This will allow ABC and the ABC Affiliates, as a consequence of a Triggering Event, to pursue repayment in accordance with Paragraph B(ii) from the Eligible Individual of all or a portion of the Cash Award paid to the Eligible Individual. To the extent permitted by controlling law, these Cash Award eligibility and repayment conditions shall survive the payment of the Eligible Individual’s Cash Award and the separation of the Eligible Individual’s employment for a period of 3 years from the payment of the Cash Award for the applicable plan year. If payment of any portion of a Cash Award is deferred on a mandatory or voluntary basis, the 3-year period shall be measured from the date the Cash Award would have been paid in the absence of deferral.

If an Affirmative Recoupment Determination is made, ABC and/or the applicable

ABC Affiliate shall endeavor to collect repayment of any Cash Award from the Eligible Individual through reasonable and appropriate means according to the terms of the incentive plan (or executive contract if applicable), and to the extent permitted by controlling law of the relevant jurisdiction. If necessary and appropriate to collect the repayment, ABC or the ABC Affiliate shall file suit against the Eligible Individual unless good cause exists not to do so. For purposes of the Financial Recoupment Program, good cause shall include, but not be limited to, a financial inability on the part of the Eligible Individual to repay any recoupment amount or ABC or the ABC Affiliates' inability to bring such a suit under the controlling law of the relevant jurisdiction.

**(b) Equity Award Eligibility and Repayment Conditions.** ABC and ABC Affiliates shall implement an eligibility and repayment condition on annual Equity Awards that shall be designed to survive the vesting or distribution of the Equity Award and the separation of an Eligible Individual's employment. This will allow ABC and the ABC Affiliates, as a consequence of a Triggering Event, to pursue repayment in accordance with Paragraph B(ii) from the Eligible Individual of all or a portion of the Equity Award. To the extent permitted by controlling law, these Equity Award eligibility and repayment conditions will survive the vesting or distribution of the Eligible Individual's Equity Award and the separation of the Eligible Individual's employment for a period of 3 years from the vesting or distribution of the Equity Award. If payment of any portion of an Equity Award is deferred on a mandatory or voluntary basis, the 3-year period shall be measured from the date the Equity Award would have been vested or distributed in the absence of deferral.

If an Affirmative Recoupment Determination is made, ABC and the ABC Affiliates shall endeavor to collect repayment of any Equity Awards from the Eligible Individual through reasonable and appropriate means according to the terms of the incentive plan (or executive contract if applicable), and to the extent permitted by controlling law of the relevant jurisdiction. If necessary and appropriate to collect the repayment, ABC or the ABC Affiliate shall file suit against the Eligible Individual unless good cause exists not to do so. For purposes of the Financial Recoupment Program, good cause shall include, but not be limited to, a financial inability on the part of the Eligible Individual to repay any recoupment amount or ABC or the ABC Affiliates' inability to bring such a suit under the controlling law of the relevant jurisdiction.

**(iii) Additional Remedies.** If, after expiration of the time period specified in Paragraphs B(ii)(a)-B(ii)(b) above, the Recoupment Committee in its sole discretion determines that a Triggering Event has occurred, ABC and ABC Affiliates shall make a determination as to whether to pursue available remedies (e.g., filing suit against the Eligible Individual) existing under statute or common law to the extent available.

**(C) Definition of Triggering Events.** The forfeiture and repayment conditions described above shall be triggered upon a Recoupment Determination that finds either of the following (each, a “Triggering Event”):

(i) significant violation of an ABC or ABC Affiliate policy or regulation or law (“Significant Misconduct”) relating to the Covered Functions (as defined in section II.C of the CIA) by the Eligible Individual that, if discovered prior to payment, would have made the Eligible Individual ineligible for a Cash or Equity Award in that plan year or subsequent plan years; or

(ii) Significant Misconduct relating to the Covered Functions (as defined in section II.C of the CIA) by subordinate employees in the business unit for which the Eligible Individual had responsibility that does not constitute an isolated occurrence and which the Eligible Individual knew or should have known was occurring that, if discovered prior to payment, would have made the Eligible Individual ineligible for a Cash or Equity Award in that plan year or subsequent plan years.

**(D) Administration of Financial Recoupment Program.** ABC and ABC Affiliates shall engage in a standardized, formal process to determine, in their sole discretion, whether a Triggering Event has occurred, and, if so, the extent of Cash Awards and/or Equity Awards that will be subject to repayment or forfeiture by the Eligible Individual, and the most appropriate method for securing recoupment of the relevant Awards. The findings and conclusions resulting from this process shall be referred to as the “Recoupment Determination.” A determination that Cash Award and/or Equity Award amounts shall be forfeited by or recouped from an Eligible Individual shall be referred to as an “Affirmative Recoupment Determination.”

(i) **Initiation.** ABC and/or any ABC Affiliate shall initiate the Recoupment Determination process upon: (1) discovery of potential Significant Misconduct that may rise to the level of a Triggering Event, or (2) written notification by a United States federal government agency to ABC’s or an ABC Affiliates’ compliance officer of a situation that may rise to the level of a Triggering Event and either occurred in the United States or gives rise to liability relating to Federal health care programs. This written notification shall either identify the Eligible Individual(s) potentially at issue or provide information (e.g., a description of the alleged Significant Misconduct and the applicable time period) to allow ABC and ABC Affiliates to identify the Eligible Individual.

(ii) **Recoupment Committee.** The Recoupment Determination shall be made by a committee of senior executives representing the business units engaged in

Covered Functions (as defined in section II.C of the CIA), Legal, and Compliance (the “Recoupment Committee”). The Recoupment Committee may also include members of other functional areas or business groups, as it deems necessary. An Eligible Individual shall not participate in the Recoupment Committee while that individual is subject to a Recoupment Determination. If a Recoupment Determination involves an Executive Officer of ABC, a Recoupment Determination for such individual shall be subject to approval by the Board of Directors (or appropriate committee thereof) of ABC. If an Executive Officer of ABC or other Eligible Individual is subject to a Recoupment Determination and is a member of the ABC Board of Directors, that individual shall not participate in the Board’s approval process. For purposes of this section, “Executive Officer” means any Executive Officer of the Registrant, as described in ABC’s Annual Report on Form 10-K filed with the Securities and Exchange Commission for its most recently completed fiscal year, the Corporate Controller of ABC, and such other executives of ABC subject to the reporting requirements of Section 16 of the Securities Exchange Act of 1934, as amended, as may be determined by the ABC Board of Directors.

**(iii) Recoupment Determination Process.** ABC or an ABC Affiliate shall initiate the Recoupment Determination process within 30 days after discovery by ABC or the ABC Affiliate, or notification pursuant to Paragraph D(i), of a potential Triggering Event. Absent extraordinary reasons, the Recoupment Committee shall reach a Recoupment Determination within 90 days after initiation of the determination process.

As part of the Recoupment Determination process, the Recoupment Committee or appropriate Delegate (as defined below) shall: i) undertake an appropriate and substantive review or investigation of the facts and circumstances associated with the potential Triggering Event or any written notifications about potential Triggering Events received pursuant to Paragraph D(i) above; ii) make written findings regarding the facts and circumstances associated with the potential Triggering Event and any written notifications about potential Triggering Events received pursuant to Paragraph D(i) above; and iii) set forth in writing its determinations (and the rationale for such determinations) about: 1) whether a Triggering Event occurred; 2) the extent of Cash Awards or Equity Awards that will be subject to forfeiture and/or repayment by the Eligible Individual, if any; 3) the means that will be followed to implement the forfeiture and/or secure the recoupment of Awards from the Eligible Individual; and 4) the timetables under which ABC and/or the applicable ABC Affiliate will implement the forfeiture and/or attempt to recoup the Awards.

For purposes of this Paragraph, a “Delegate” shall refer to the ABC or ABC Affiliate personnel to whom the Recoupment Committee has delegated one or more of its required tasks in furtherance of the Financial Recoupment Program.

**(E) Reporting.** The Recoupment Committee shall provide annual reports to the Board of Directors (or an appropriate committee thereof) of ABC about: i) the number and circumstances of any Triggering Events that occurred during the preceding fiscal year and any written notifications about potential Triggering Events received pursuant to Paragraph D(i)(2) above; ii) a description of any Recoupment Determinations where a Triggering Event occurred during the preceding year (including any decision to require or not require forfeiture/recoupment from any Eligible Individuals, the amount and type of any forfeiture/recoupment, the means for collecting any recoupment and the rationale for such decisions); and iii) a description of the status of any forfeitures and/or recoupments required under prior Affirmative Recoupment Determinations that were not fully completed in prior fiscal years. In addition, the Recoupment Committee shall provide similar annual reports to the Board(s) of Directors of any ABC Affiliate that employs/employed an Eligible Individual that is the subject of a Triggering Event.

The Recoupment Committee shall also provide annual reports to the OIG about: i) the number and circumstances of any Triggering Events that occurred during the preceding fiscal year and any written notifications about potential Triggering Events received pursuant to Paragraph D(i)(2) above; ii) a summary description of any Recoupment Determinations where a Triggering Event occurred during the preceding year (including any decision to require or not require forfeiture/recoupment from any Eligible Individuals, the amount and type of any forfeiture/recoupment, the method for collecting any recoupment, and the rationale for such decisions); and iii) a description of the status of any forfeitures and/or recoupments required under prior Affirmative Recoupment Determinations that were not fully completed in prior fiscal years. Upon request by OIG, ABC shall provide OIG with additional information regarding any Recoupment Determination for which a Triggering Event has occurred.

ABC and ABC Affiliates commit, to the extent permitted by controlling law, to maintaining all of the forfeiture and recoupment commitments set forth in Paragraphs A-E above for at least the duration of the CIA, absent agreement otherwise with the OIG.