CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
CARDINAL HEALTH 108, LLC

I. PREAMBLE

Cardinal Health 108, LLC d/b/a Specialty Pharmaceutical Distribution (SPD) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this CIA, Cardinal Health Inc. is entering into a Settlement Agreement with the United States.

SPD represents that, prior to the Effective Date (as defined below), as a subsidiary of Cardinal Health Inc., SPD participated in the compliance program maintained by Cardinal Health Inc., which addresses all seven elements of an effective compliance program and is designed to address compliance with Federal health care program and other requirements ("the Compliance Program"). SPD shall continue to participate in Cardinal Health Inc.'s Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. The Compliance Program may be modified as appropriate but, at a minimum, SPD shall ensure that during the term of this CIA, it shall comply with the obligations set forth herein.

II. TERM AND SCOPE OF THE CIA

A. The Effective Date of this CIA shall be the date on which the final signatory of this CIA executes this CIA. The term of this CIA shall be five years from the Effective Date. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

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

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

1. "Arrangements" shall mean:

a. every arrangement or transaction that involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and is between SPD and any actual or potential source of health care business or referrals to SPD or any actual or potential recipient of health care business or referrals from SPD.

2. The term "source of health care business or referrals" shall mean any individual or entity that refers, recommends, arranges for, orders, leases, or purchases from SPD any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program.

3. The term "recipient of health care business or referrals" shall mean any individual or entity (a) to whom SPD refers an individual for the furnishing or arranging for the furnishing of any item or service, or (b) from whom SPD purchases, leases or orders or arranges for or recommends the purchasing, leasing, or ordering of any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program.

4. "Focus Arrangements" means every Arrangement that:

a. is between SPD and any actual source or recipient of health care business or referrals and involves, directly or indirectly, the offer, payment, or provision of anything of value.

5. "Covered Persons" includes:

(a) all owners who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5% and (2)

acquired the ownership interest through public trading), officers, and directors of SPD;

(b) all U.S. employees;

(c) all U.S. contractors, subcontractors, agents, and other persons who are involved in Arrangements, including but not limited to persons who perform marketing, billing, collections, or sales functions on behalf of SPD.

Notwithstanding the above, the term "Covered Persons" does not include SPD employees who work in SPD's distribution centers to the extent such employees do not perform any marketing, billing, collections or sales functions and do not interact with actual or potential customers. The term "Covered Persons" also does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work for SPD more than 160 hours per year, except that any such individual shall become a "Covered Person" at the point when they work more than 160 hours for SPD during the calendar year.

5. "Arrangements Covered Persons" includes each Covered Person at SPD and SPD Affiliates who is involved with the development, approval, management, negotiation, or review of SPD's Arrangements.

6. "Government Reimbursed Products" refers to all products that are: (a) distributed or sold by SPD in the United States (or pursuant to contracts with the United States) and (b) reimbursed by Federal health care programs.

7. The term "SPD Affiliate" shall mean any entity that is owned or controlled, directly or indirectly, by Cardinal Health Inc. and whose employees or contractors are involved with the development, approval, management, negotiation, or review of SPD's Arrangements. All obligations set forth in Section III below shall apply to any SPD Affiliate employee or contractor who is involved with the development, approval, management, negotiation, or review of SPD's Arrangements.

III. COMPLIANCE PROGRAM REQUIREMENTS

SPD shall establish and maintain a compliance program that includes the following elements:

A. Compliance Officer, Compliance Committee, Board of Directors Oversight, and Management Certifications

1. *Compliance Officer*. Within 90 days after the Effective Date, SPD shall appoint a Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be an employee and a member of senior management of SPD, shall report directly to the President of SPD, and shall not be or be subordinate to the General Counsel or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for SPD. The 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 requirements;

b. making periodic (at least quarterly) reports regarding compliance matters in person to the Risk Oversight Committee of Cardinal Health Inc.'s Board of Directors (Risk Oversight Committee) and shall be authorized to report on such matters to the Risk Oversight Committee at any time. Written documentation of the Compliance Officer's reports to the Risk Oversight Committee shall be made available to OIG upon request; and

c. monitoring the day-to-day compliance activities engaged in by SPD as well as any reporting requirements created under this CIA.

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

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

2. *Compliance Committee*. Within 90 days after the Effective Date, SPD shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as sales, marketing, legal, medical affairs/medical information, regulatory affairs, research and development, human resources, audit, finance, manufacturing, and operations). The Compliance Officer shall chair the Compliance Committee and the Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of SPD's risk areas and shall oversee monitoring of internal and external audits 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.

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

3. *Board of Directors Oversight.* The Risk Oversight Committee shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements and the requirements of this CIA. The Risk Oversight Committee must include independent (i.e., non-employee and non-executive) members.

The Risk Oversight Committee shall, at a minimum, be responsible for the following:

a. meeting at least quarterly to review and oversee SPD's compliance program, including but not limited to the performance of the Compliance Officer and Compliance Committee;

b. submitting to the OIG 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 Risk Oversight Committee summarizing its review and oversight of SPD's compliance with Federal health care program requirements, FDA requirements, and the requirements of this CIA.

At minimum, the resolution shall include the following language:

> "The Risk Oversight Committee has made a reasonable inquiry into the operations of SPD's compliance program including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Risk Oversight Committee has concluded that, to the best of its knowledge, SPD has implemented an effective compliance program to meet Federal health care program requirements, FDA requirements, and the requirements of the CIA."

If the Risk Oversight Committee is unable to provide such a conclusion in the resolution, the Risk Oversight Committee 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 SPD.

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

4. *Management Certifications.* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain SPD employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable SPD department is in compliance with applicable Federal health care program and FDA requirements and with the requirements of this CIA. These Certifying Employees shall include, at a minimum, the following: Vice President, Direct Sales Management; Senior Vice President, General Manager

Acute Distribution & Services; Vice President, Financial Planning & Analysis; Vice President, Revenue Management; Vice President, Global Finance Shared Services; and Vice President, Account Management National Markets. 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 department] with all applicable Federal health care program requirements, FDA requirements, requirements of the Corporate Integrity Agreement, and SPD policies, and I have taken steps to promote such compliance. To the best of my knowledge, the [insert name of department] of SPD is in compliance with all applicable Federal health care program requirements and the requirements 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 90 days after the Effective Date, SPD 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 90 days after the Effective Date, SPD shall develop and implement written policies and procedures regarding the operation of its compliance program, including the compliance program requirements outlined in this CIA and SPD's compliance with Federal health care program requirements (Policies and Procedures). The Policies and Procedures also shall address:

a. 42 U.S.C. § 1320a-7b(b) (Anti-Kickback Statute) and the regulations and other guidance documents related to that statute, and business or financial arrangements or contracts

that generate unlawful Federal health care program business in violation of the Anti-Kickback Statute;

b. the requirements set forth in Section III.D (Compliance with the Anti-Kickback Statute); and

c. that SPD does not offer or enter arrangements with upfront rebates based on the term of the arrangement and that SPD terminated or modified all remaining arrangements with such a rebate to comply with the Anti-Kickback Statute within 90 days after the Effective Date.

The Policies and Procedures shall be made available to all Covered Persons. Throughout the term of this CIA, SPD shall enforce its Policies and Procedures and shall make compliance with its Policies and Procedures an element of evaluating the performance of all employees.

At least annually (and more frequently, if appropriate), SPD shall assess and update, as necessary, the Policies and Procedures. Any revised or new 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, SPD shall develop a written plan (Training Plan) that outlines the steps SPD will take to ensure that all Covered Persons receive at least annual training regarding SPD's CIA requirements and compliance program and the applicable Federal health care program and FDA requirements, including the requirements of the Anti-Kickback Statute; and that all Arrangements Covered Persons receive at least annual training regarding: (a) Arrangements that potentially implicate the Anti-Kickback Statute, as well as the regulations and other guidance documents related to that statute; (b) SPD's policies, procedures, and other requirements relating to Arrangements and Focus Arrangements, including but not limited to the Focus Arrangements Tracking System, the internal review and approval process, and the tracking of remuneration to and from sources of health care business or referrals required by Section III.D of the CIA; (c) the personal obligation of each individual involved in the development, approval, management, or review of SPD's Arrangements to know the applicable legal requirements and SPD's

policies and procedures; (d) the legal sanctions under the Anti-Kickback Statute; and (e) examples of violations of the Anti-Kickback Statute.

The Training Plan shall include information regarding the following: training topics, identification of Covered Persons and Arrangements Covered Persons required to attend each training session, length of the training sessions(s), schedule for training, and format of the training. SPD shall furnish training to its Covered Persons and Arrangements Covered Persons pursuant to the Training Plan during each Reporting Period.

2. *Board Training*. In addition to the training described in Section III.C.1, within 90 days after the Effective Date, each member of the Board of Cardinal Health Inc. shall receive training regarding 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 the OIG's guidance on Board member responsibilities.

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

3. *Training Records.* SPD shall make available to OIG, upon request, training materials and records verifying that the training described in Sections III.C.1 and III.C.2 has been provided as required.

D. Compliance with the Anti-Kickback Statute

1. *Focus Arrangements Procedures*. Within 90 days after the Effective Date, SPD shall create procedures reasonably designed to ensure that each existing and new or renewed Focus Arrangement does not violate the Anti-Kickback Statute or the regulations and guidance related to that statute (Focus Arrangements Procedures). These procedures shall include the following:

a. creating and maintaining a centralized tracking system for all existing and new or renewed Focus Arrangements and the

information specified in Sections III.D.1.b-f below for each existing and new or renewed Focus Arrangement (Focus Arrangements Tracking System);

b. documenting the names and positions of the Arrangements Covered Person(s) involved in the negotiation, review, and approval of all Focus Arrangements;

c. tracking all remuneration to and from all parties to Focus Arrangements to ensure that the parties are complying with the financial terms of the Focus Arrangements and that the Focus Arrangements are commercially reasonable;

d. documenting all fair market value determination(s) for any Focus Arrangement, including the fair market value amount or range and corresponding time period(s), the date(s) of completion of the fair market valuation(s), the individuals or entities that determined the fair market value amount or range, and the names and positions of the Covered Person(s) who received and/or were otherwise involved with the fair market value determination(s);

e. tracking service and activity logs to ensure that parties to the Focus Arrangement are performing the services required under the applicable Focus Arrangement(s) (if applicable);

f. monitoring the use of leased space, medical supplies, medical devices, equipment, or other patient care items to ensure that such use is consistent with the terms of the applicable Focus Arrangement(s) (if applicable);

g. establishing and implementing a written review and approval process for Focus Arrangements, the purpose of which is to ensure that all new and existing or renewed Focus Arrangements do not violate the Anti-Kickback Statute and that includes at least the following: (i) a legal review of all Focus Arrangements by counsel with expertise in the Anti-Kickback Statute, (ii) a process for specifying and

documenting the business need or business rationale for all Focus Arrangements, and (iii) a process for determining and documenting the fair market value of the remuneration specified in the Focus Arrangement;

h. ensuring that all existing Focus Arrangements are subject to the review and approval process described in Section III.D.1.g above;

i. requiring the Compliance Officer to review the Focus Arrangements Tracking System, internal review and approval process, and other Focus Arrangements Procedures on at least an annual basis and to provide a report on the results of such review to the Compliance Committee; and

j. implementing effective responses when suspected violations of the Anti-Kickback Statute are discovered, including disclosing Reportable Events.

2. *New or Renewed Focus Arrangements*. No later than 90 days after the Effective Date, and prior to entering into new Focus Arrangements or renewing existing Focus Arrangements, in addition to complying with the Focus Arrangements Procedures set forth above, SPD shall comply with the following requirements (Focus Arrangements Requirements):

a. Ensure that all written Focus Arrangements are signed by SPD and the other party(ies) to the Focus Arrangement prior to the payment or receipt of any remuneration pursuant to the Focus Arrangement;

b. Ensure that all Focus Arrangements have been subject to the written review and approval process described in Section III.D.1.g prior to the payment or receipt of any remuneration pursuant to the Focus Arrangement, and that SPD maintains appropriate documentation of the review and approval of such Focus Arrangement; and

c. Include in any written agreement a certification by the parties to the Focus Arrangement that the parties shall not violate the Anti-Kickback Statute with respect to the performance of the Arrangement.

3. *Records Retention and Access*. SPD shall retain and make available to OIG, upon request, the Focus Arrangements Tracking System and all supporting documentation of the Focus Arrangements subject to this Section and, to the extent available, all non-privileged communications related to the Focus Arrangements and the actual performance of the duties under the Focus Arrangements.

E. Review Procedures

1. *General Description*.

a. *Engagement of Independent Review Organization*. Within 90 days after the Effective Date, SPD shall engage a law or consulting firm, or lawyer (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 SPD shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and SPD) related to the reviews.

c. *Responsibilities and Liabilities*. Nothing in this Section III.E affects SPD's responsibilities or liabilities under any criminal, civil, or administrative laws or regulations applicable to any Federal health care program including, but not limited to, the Anti-Kickback Statute.

d. *Access to Records and Personnel.* SPD shall ensure that 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. *Arrangements Review*. The IRO shall perform an Arrangements Review and prepare an Arrangements Review Report as outlined in Appendix B to this CIA, which is incorporated by reference.

3. *Certification Regarding Prohibited Relationships*. The IRO shall include in its report(s) to SPD a certification that the IRO (a) does not currently represent or is not currently employed or engaged by SPD and (b) does not have a current or prior relationship to SPD or its owners, officers, or directors that would cause a reasonable person to question the IRO's objectivity in performing the reviews required by Section III.E. The IRO's certification shall include a summary of any current and prior relationships between SPD or its owners, officers, or directors and the IRO.

F. Risk Assessment and Internal Review Process

Within 90 days after the Effective Date, SPD shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with Arrangements (as defined in Section II.C.1 above). The Compliance Committee shall be responsible for implementation and oversight of the risk assessment and internal review process. The risk assessment and internal review process shall be conducted at least annually and shall require SPD 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. SPD shall maintain the risk assessment and internal review process for the term of the CIA.

G. Disclosure Program

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

existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

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 SPD's Covered Persons shall be expected to report suspected violations of any Federal health care program or FDA requirements to the Compliance Officer or other appropriate individual designated by SPD. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, SPD shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a disclosure log and shall record all disclosures (whether or not related to a potential violation of criminal, civil, or administrative law related to the Federal health care programs or FDA requirements) 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 individual or department responsible for reviewing the disclosure, the status of the review, and any corrective action taken in response to the review.

H. 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 any Federal health care program; 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.* SPD shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

a. SPD 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. SPD shall screen all current Covered Persons against the Exclusion List within 90 days after the Effective Date and on a monthly basis thereafter.

c. SPD shall implement a policy requiring all Covered Persons to disclose immediately if they become an Ineligible Person.

Nothing in this Section III.H affects SPD'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. SPD understands that items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and that SPD may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether SPD meets the requirements of Section III.H.

3. *Removal Requirement.* If SPD has actual notice that a Covered Person has become an Ineligible Person, SPD shall remove such Covered Person from responsibility for, or involvement with, SPD'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 SPD 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, SPD 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.

I. Notification of Government Investigation or Legal Proceeding

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

J. Reportable Events

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

a. 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;

b. a matter that a reasonable person would consider a probable violation of FDA requirements relating to the distribution or sale of Government Reimbursed Products, unless otherwise reported to the FDA in accordance with Section III.L below;

c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.H.1.a; or

d. the filing of a bankruptcy petition by SPD.

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

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

3. *Reportable Events under Section III.K.1.a.and III.K.1.b.* For Reportable Events under Section III.K.1.a and b, 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, transactions, or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of entities and individuals 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; and

d. a description of SPD's actions taken to correct the Reportable Event and prevent it from recurring.

4. *Reportable Events under Section III.K.1.c.* For Reportable Events under Section III.K.1.c, 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 SPD completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the Ineligible Persons 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.d*. For Reportable Events under Section III.K.1.d, the report to the OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program authorities implicated.

K. Notification of Communications with FDA

Within 30 days after the date of any written report, correspondence, or communication between SPD and the FDA that materially discusses SPD's or a Covered Person's actual or potential unlawful or improper distribution or sale of Government Reimbursed Products, SPD shall provide a copy of the report, correspondence, or communication to OIG. SPD shall also provide written notice to OIG within 30 days after the resolution of any such disclosed matter, and shall provide OIG with a description of the findings and/or results of the matter, if any.

L. Reporting of Physician Payments

1. *Reporting of Payment Information.* Within 90 days after the Effective Date, SPD shall post on Cardinal Health Inc.'s website a description of the types of Payments it makes to Covered Recipients and include a link to CMS's Open Payments Data website (www.openpaymentsdata.cms.gov). SPD also shall include on Cardinal Health Inc.'s website instructions regarding how to utilize the CMS Open

Payments Data search tool to search for information regarding Payments provided to Covered Recipients from SPD.

2. *Definitions.* For purposes of this Section III.N, the terms "Payments" and "Covered Recipient" are defined as specified in 42 U.S.C. § 1320a-7h and the related regulations and guidance (including FAQs) published by CMS.

IV. SUCCESSOR LIABILITY

In the event that, after the Effective Date, SPD 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) relating to the furnishing of items or services that may be reimbursed by a Federal health care program, or (b) purchase or establish a new business, business unit, or location relating to the furnishing of items or services that may be reimbursed by a Federal health care program, the CIA shall be binding on the purchaser of any business, business unit, or location and any 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. SPD 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 proposed purchase, SPD 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, SPD 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 120 days after the Effective Date, SPD 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, business address, business phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;

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

3. the names of the Risk Oversight Committee members who are responsible for satisfying the Board compliance requirements 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 for Certifying Employees to follow in order to complete the certification required by Section III.A.4;

5. a list of all Policies and Procedures required by Section III.B;

6. the Training Plan required by Section III.C.1 and a description of the Board 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 (a) the Focus Arrangements Tracking System required by Section III.D.1.a, (b) the internal review and approval process required by Section III.D.1.g; and (c) the tracking and monitoring procedures and other Focus Arrangements Procedures required by Section III.D.1;

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 that it does not have a prohibited relationship with SPD as set forth in Section III.E.3 that includes a summary of any current and prior relationships between SPD or its owners, officers, or directors and the IRO;

9. a description of the risk assessment and internal review process required by Section III.F;

10. a description of the Disclosure Program required by Section III.G;

11. a description of the Ineligible Persons screening and removal process required by Section III.H;

12. a certification from the Compliance Officer that information regarding Payments has been posted on Cardinal Health Inc.'s website as required by Section III.L;

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

14. a list of all of SPD's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, and each location's Medicare and state Medicaid program provider number(s) and/or supplier number(s) as applicable; and

15. the certifications required by Section V.C.

B. Annual Reports

SPD shall submit to OIG a written report 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 Compliance Officer; a current list of the Compliance Committee members, a current list of the Risk Oversight Committee members who are responsible for satisfying the Board compliance requirements, and a current list of the Certifying Employees, along with the identification of any changes made during the Reporting Period to the Compliance Committee, Risk Oversight Committee, and Certifying Employees;

2. a description of any changes to the written process for Certifying Employees to follow in order to complete the certification required by Section III.A.4;

3. the dates of each report made by the Compliance Officer to the Risk Oversight Committee (written documentation of such reports shall be made available to OIG upon request);

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

5. a list of any new or revised Policies and Procedures developed during the Reporting Period;

6. a description of any changes to SPD's Training Plan developed pursuant to Section III.C, and a summary of any Board training provided during the Reporting Period;

7. a description of (a) any changes to the Focus Arrangements Tracking System required by Section III.D.1.a; (b) any changes to the internal review and approval process required by Section III.D.1.g; and (c) any changes to the tracking and monitoring procedures and other Arrangements Procedures required by Section III.D.1;

8. a complete copy of all reports prepared pursuant to Section III.E and SPD'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 that it does not have a prohibited relationship with SPD, as described in Section III.E.3 above, including a summary of any current and prior relationships between SPD or its owners, officers, or directors and the IRO;

10. a description of any changes to the risk assessment and internal review process required by Section III.F, including the reasons for such changes;

11. a summary of the following components of the risk assessment and internal review process during the Reporting Period: work plans developed, internal audits performed, corrective action plans developed in response to internal audits, and steps taken to track the implementation of the corrective action plans. Copies of any work plans, internal audit reports, and corrective actions plans shall be made available to OIG upon request;

12. a summary of the disclosures in the disclosure log required by Section III.G that: (a) relate to Federal health care programs; or (b) involve allegations of

conduct that may involve illegal remuneration or inappropriate referrals in violation of the Anti-Kickback Statute (the complete disclosure log shall be made available to OIG upon request);

13. a description of any changes to the Ineligible Persons screening and removal process required by Section III.H, including the reasons for such changes;

14. 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;

15. a summary of Reportable Events (as defined in Section III.J) identified during the Reporting Period;

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

17. a description of all changes to the most recently provided list of SPD's locations (including addresses) as required by Section V.A.14;

18. a description of any changes to SPD's corporate structure, 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, SPD shall include the certifications of Certifying Employees as required by Section III.A.4;

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

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

b. to the best of his or her knowledge, SPD has implemented procedures reasonably designed to ensure that all Focus Arrangements do not violate the Anti-Kickback Statute, including the Focus Arrangements Procedures required in Section III.D of the CIA;

c. to the best of his or her knowledge, SPD has fulfilled the requirements for New and Renewed Focus Arrangements under Section III.D.2 of the CIA;

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

e. he or she understands that the certification is being provided to and relied upon by the United States.

D. Designation of Information

SPD 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. SPD 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

SPD:

Keith Seaton
Vice President, Ethics & Compliance
Specialty Pharmaceutical Distribution
7000 Cardinal Place
Dublin, OH 43017
Telephone: 847.887.6299
Email Address: Keith.Seaton@cardinalhealth.com

Unless otherwise specified, all notifications and reports required by this CIA shall be made by overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. Upon request by OIG, SPD 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 SPD's books, records, and other documents and supporting materials, and conduct on-site reviews of any of SPD's locations for the purpose of verifying and evaluating: (a) SPD's compliance with the terms of this CIA; and (b) SPD's compliance with the requirements of the Federal health care programs. The documentation described

above shall be made available by SPD 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 SPD's owners (as defined in II.C.4.a), 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. SPD shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. SPD's owners (as defined in II.C.4.a), employees, contractors, and directors may elect to be interviewed with or without a representative of SPD present.

VIII. DOCUMENT AND RECORD RETENTION

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

X. BREACH AND DEFAULT PROVISIONS

A. Stipulated Penalties

OIG may assess:

1. A Stipulated Penalty of up to $2,500 for each day SPD fails to comply with Section III.A;

2. A Stipulated Penalty of up to $2,500 for each day SPD fails to comply with Section III.B;

3. A Stipulated Penalty of up to $2,500 for each day SPD fails to comply with Section III.C;

4. A Stipulated Penalty of up to $2,500 for each day SPD fails to comply with Section III.D;

5. A Stipulated Penalty of up to $2,500 for each day SPD fails to comply with Section III.E;

6. A Stipulated Penalty of up to $2,500 for each day SPD fails to comply with Section III.F;

7. A Stipulated Penalty of up to $2,500 for each day SPD fails to comply with Section III.G;

8. A Stipulated Penalty of up to $2,500 for each day SPD fails to comply with Section III.H;

9. A Stipulated Penalty of up to $2,500 for each day SPD fails to comply with Section III.I;

10. A Stipulated Penalty of up to $2,500 for each day SPD fails to comply with Section III.J;

11. A Stipulated Penalty of up to $2,500 for each day SPD fails to comply with Section III.K;

12. A Stipulated Penalty of up to $2,500 for each day SPD fails to comply with Section III.L;

13. A Stipulated Penalty of up to $2,500 for each day SPD fails to comply with Section IV;

14. A Stipulated Penalty of up to $2,500 for each day SPD fails to comply with Section V;

15. A Stipulated Penalty of up to $2,500 for each day SPD fails to comply with Section VII;

16. A Stipulated Penalty of up to $2,500 for each day SPD fails to comply with Section VIII; or

17. A Stipulated Penalty of up to $50,000 for each false certification or false statement made to OIG by or on behalf of SPD under this CIA.

B. Timely Written Requests for Extensions

SPD 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. 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 SPD fails to meet the revised deadline set by OIG. If OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after SPD receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties

1. *Demand Letter*. If OIG determines that a basis for Stipulated Penalties under Section X.A exists, OIG shall notify SPD of: (a) SPD's failure to comply; and (b) OIG's demand for payment of Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter.* Within 15 business days after the date of the Demand Letter, SPD shall either: (a) 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.

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.

D. Exclusion for Material Breach of this CIA

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

a. failure to comply with any of the requirements of this CIA for which OIG has previously issued a demand for Stipulated Penalties under X.C;

b. failure to comply with Section III.A.1;

c. failure to comply with Section III.D;

d. failure to comply with Section III.E;

e. failure to comply with Section III.J;

f. failure to comply with Section V;

g. failure to respond to a Demand Letter in accordance with Section X.C.;

h. failure to pay Stipulated Penalties within 20 days after an ALJ issues a decision ordering SPD to pay the Stipulated Penalties or within 20 days after the HHS Departmental Appeals Board (DAB) issues a decision upholding the determination of OIG; or

i. failure to come into compliance with a requirement for which the OIG has demanded Stipulated Penalties, pursuant to the deadlines listed in Section X.E.2.

2. *Notice of Material Breach and Intent to Exclude*. The parties agree that a material breach of this CIA by SPD constitutes an independent basis for SPD's exclusion from participation in the Federal health care programs. The length of the

exclusion shall be in the OIG's discretion, but not more than five years for each material breach. Upon a preliminary determination by OIG that SPD has materially breached this CIA, OIG shall notify SPD of: (a) SPD's material breach; and (b) OIG's intent to exclude SPD. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")

3. *Response to Notice*. SPD shall have 30 days from the date of the Notice of Material Breach and Intent to Exclude to submit any information and documentation for OIG to consider before it makes a final determination regarding exclusion.

4. *Exclusion Letter*. If OIG determines that exclusion is warranted, OIG shall notify SPD in writing of its determination to exclude SPD. (This letter shall be referred to 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 the Exclusion Letter. The exclusion shall have national effect. The effect of the exclusion shall be that no Federal health care program payment may be made for any items or services furnished, ordered, or prescribed by SPD, including administrative and management services, except as stated in regulations found at 42 C.F.R. 1001.1901(c). Reinstatement to program participation is not automatic. At the end of the period of exclusion, SPD 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 issuing a Demand Letter or Exclusion Letter to SPD, and as an agreed-upon remedy for the resolution of disputes arising under this CIA, SPD 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. 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 DAB, in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21, but only to the extent this CIA does not provide otherwise. Notwithstanding the language in 42 C.F.R. § 1005: (a) the request for a hearing involving Stipulated Penalties shall be made within 15 business days after the date of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after the date of the Exclusion Letter; and (b) no discovery shall be available to the parties. 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 SPD was in full and timely compliance with the requirements of this CIA for which OIG demands payment; and (b) the period of noncompliance. SPD shall have the burden of proving its full and timely compliance. If the ALJ upholds the OIG's determination that SPD has breached this CIA and orders SPD to pay Stipulated Penalties, SPD must (a) come into compliance with the requirement(s) of this CIA that resulted in the OIG imposing Stipulated Penalties and (b) pay the Stipulated Penalties within 20 days after the ALJ issues a decision, unless SPD properly and timely requests review of the ALJ decision by the DAB. If the ALJ decision is properly and timely appealed to the DAB and the DAB upholds the determination of OIG, SPD must (a) come into compliance with the requirement(s) that resulted in the OIG imposing Stipulated Penalties and (b) pay the Stipulated Penalties within 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 SPD was in material breach of this CIA. If the ALJ sustains the OIG's determination of material breach, the exclusion shall take effect 20 days after the ALJ issues the decision. 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. SPD shall waive its right to any notice by OIG of the exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of SPD, SPD shall be reinstated effective on the date of the 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. 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 and SPD agrees not to seek additional review of the DAB's decision (or the ALJ's decision if not appealed) in any judicial forum.

XI. EFFECTIVE AND BINDING AGREEMENT

SPD 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. OIG may agree to a suspension of SPD's requirements under this CIA based on a certification by SPD that it is no longer providing health care items or services that will be billed to any Federal health care program and it does not have any ownership or control interest, as defined in 42 U.S.C. §1320a-3, in any entity that bills any Federal health care program. If SPD is relieved of its CIA requirements, SPD shall be required to notify OIG in writing at least 30 days in advance if SPD plans to resume providing health care items or services that are billed to any Federal health care program or to obtain an ownership or control interest in any entity that bills any Federal health care program. At such time, OIG shall evaluate whether the CIA will be reactivated or modified.

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

E. The undersigned SPD 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 capacities and that they are authorized to execute this CIA.

F. 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 copies of Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

ON BEHALF OF CARDINAL HEALTH 108, LLC (SPD)

__/Heidi Hunter/_____ ___Jan 18, 2022_____
HEIDI HUNTER DATE
President
Cardinal Health 108, LLC

__/Stephen Sozio/_____ ___1/19/22_____
STEPHEN G. SOZIO DATE
JONES DAY
Counsel for Cardinal Health 108, LLC

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

/Lisa M. Re/ 01/21/2022

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

DATE

/Madeline J. Bainer/ 01/21/2022

MADELINE J. BAINER
Senior Counsel
Office of Counsel to the Inspector General
U.S. Department of Health and Human Services

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. SPD 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 not have a prohibited relationship to SPD as set forth in Paragraph E. Within 30 days after OIG receives the information identified in Section V.A.8 of the CIA or any additional information submitted by SPD in response to a request by OIG, whichever is later, OIG will notify SPD if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, SPD may continue to engage the IRO.

2. If SPD 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, SPD 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 SPD at the request of OIG, whichever is later, OIG will notify SPD if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, SPD may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Arrangements Review who are knowledgeable in the requirements of the Anti-Kickback Statute and the Stark Law and the regulations and other guidance documents related to these statutes;

2. possess expertise in fair market valuation issues or have the ability to associate a valuation firm to assist in conducting the transactions review component of the Arrangements Review; 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 Arrangements Review in accordance with the specific requirements of the CIA;

2. respond to all OIG inquires in a prompt, objective, and factual manner; and

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

D. SPD Responsibilities

SPD shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in Section III.E of this CIA and that all records furnished to the IRO are accurate and complete.

E. IRO Relationship to SPD

The IRO shall not (1) currently represent or currently be employed or engaged by SPD or (2) have a current or prior relationship to SPD or its owners, officers, or directors that would cause a reasonable person to question the IRO's objectivity in performing the reviews required by Appendix B to this CIA.

F. Assertions of Privilege

SPD shall not assert claims of attorney-client privilege in order to avoid disclosing to OIG information related to or resulting from the IRO's engagement. SPD's engagement letter with the IRO shall include a provision stating that the IRO agrees not to assert claims of work product privilege in order to avoid disclosing to OIG information related to or resulting from its engagement.

G. IRO Removal/Termination

1. *SPD and IRO*. If SPD terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, SPD 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. SPD 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 that the IRO does not possess the qualifications described in Paragraph B, has a prohibited relationship

as set forth in Paragraph E, or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify SPD in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. SPD shall have 30 days from the date of OIG's written notice to provide information regarding the IRO's qualifications, relationship or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by SPD regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify SPD in writing that SPD shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. SPD 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 SPD to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

ARRANGEMENTS REVIEW

The Arrangements Review shall consist of two components: a systems review and a transactions review. The IRO shall perform all components of each Arrangements Review. If there are no material changes to SPD's systems, processes, policies, and procedures relating to Arrangements, the Arrangements Systems Review shall be performed for the first and fourth Reporting Periods. If SPD materially changes the Arrangements systems, processes, policies and procedures, the IRO shall perform an Arrangements 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. The Arrangements Transactions Review shall be performed annually and shall cover each of the five Reporting Periods.

A. Arrangements Systems Review. The Arrangements Systems Review shall be a review of SPD's systems, processes, policies, and procedures relating to the initiation, review, approval, and tracking of Arrangements. Specifically, the IRO shall review the following:

1. SPD's systems, policies, processes, and procedures with respect to creating and maintaining a centralized tracking system for all existing and new and renewed Focus Arrangements (Focus Arrangements Tracking System), including a detailed description of the information captured in the Focus Arrangements Tracking System;

2. SPD's systems, policies, processes, and procedures for documenting the names and positions of the Arrangements Covered Person(s) involved in the negotiation, review, and approval of all Focus Arrangements;

3. SPD's systems, policies, processes, and procedures for tracking all remuneration to and from all parties to Focus Arrangements to ensure that the parties are complying with the financial terms of the Focus Arrangements and that the Focus Arrangements are commercially reasonable;

4. SPD's systems, policies, processes and procedures for documenting all fair market value determination(s) for any Focus Arrangement, including the fair market value amount or range and corresponding time period(s), the date(s) of completion of the fair market valuation(s), the individuals or entities that determined the fair market value amount or range, and the names and positions of

the Arrangements Covered Person(s) who received or were otherwise involved with the fair market value determination(s);

5. SPD's systems, policies, processes, and procedures for tracking service and activity logs to ensure that parties to the Focus Arrangement are performing the services required under the applicable Focus Arrangement(s) (if applicable);

6. SPD's systems, policies, processes, and procedures for monitoring the use of leased space, medical supplies, medical devices, equipment, or other patient care items to ensure that such use is consistent with the terms of the applicable Focus Arrangement(s) (if applicable);

7. SPD's systems, policies, processes, and procedures for initiating Arrangements, including those policies that identify the individuals with authority to initiate an Arrangement and that specify the business need or business rationale required to initiate an Arrangement;

8. SPD's systems, policies, processes, and procedures for the internal review and approval of existing, new and renewed Focus Arrangements, including those policies that identify the individuals required to approve each type or category of Focus Arrangement entered into by SPD, the internal controls designed to ensure that all required approvals are obtained, the processes for determining and documenting the business need or business rationale for all Focus Arrangements, the processes for determining and documenting the fair market value of the remuneration specified in the Focus Arrangement, and the processes for ensuring that all Focus Arrangements are subject to a legal review by counsel with expertise in the Anti-Kickback Statute;

9. the Compliance Officer's annual review of and reporting to the Compliance Committee on the Focus Arrangements Tracking System, SPD's internal review and approval process, and other Focus Arrangements systems, process, policies, and procedures;

10. SPD's systems, policies, processes, and procedures for implementing effective responses when suspected violations of the Anti-Kickback Statute are discovered, including disclosing Reportable Events and quantifying and repaying Overpayments when appropriate; and

11. SPD's systems, policies, processes, and procedures for ensuring that all new and renewed Focus Arrangements comply with the Focus Arrangements Requirements set forth in Section III.D.2 of the CIA.

B. Arrangements Systems Review Report. The IRO shall prepare a report based upon each Arrangements Systems Review performed. The Arrangements Systems Review Report shall include the following information:

1. a description of the documentation (including policies) reviewed and personnel interviewed;

2. a detailed description of SPD's systems, policies, processes, and procedures relating to the items identified in Section A.1-11 above;

3. findings and supporting rationale regarding weaknesses in SPD's systems, processes, policies, and procedures relating to Arrangements described in Section A.1-11 above; and

4. recommendations to improve SPD's systems, policies, processes, or procedures relating to Arrangements described in Section A.1-11 above.

C. Arrangements Transactions Review. The Arrangements Transactions Review shall consist of a review by the IRO of 50 randomly selected Focus Arrangements that were entered into or renewed by SPD during the Reporting Period. The IRO shall assess whether SPD has complied with the Focus Arrangements Procedures and the Focus Arrangements Requirements described in Sections III.D.1 and III.D.2 of the CIA, with respect to the selected Focus Arrangements.

1. The IRO's assessment with respect to each Focus Arrangement that is subject to review shall include:

a. verifying that the Focus Arrangement is maintained in SPD's centralized tracking system in a manner that permits the IRO to identify: (i) the parties to the Focus Arrangement, (ii) the name(s) and position(s) of the Arrangements Covered Person(s) involved in the negotiation, review, and approval of the Focus Arrangement; (iii) the relevant terms of the Focus Arrangement (i.e., the items, services, equipment, or space to be provided, the amount of compensation, the effective date, the expiration date, etc.); and (iv) the parties' performance under the Focus Arrangement (i.e, items or services actually provided, equipment or space actually provided or leased, amount of payments, dates of payment, etc.);

b. verifying that the Focus Arrangement was subject to the internal review and approval process (including both a legal and business review)

and obtained the necessary approvals and that such review and approval is appropriately documented;

c. verifying that the remuneration related to the Focus Arrangement has been determined in accordance with SPD's policies and procedures for determining and documenting the fair market value of the remuneration, that the remuneration is properly tracked, and that the parties to the Focus Arrangement are complying with the financial terms of the Focus Arrangement;

d. verifying that the business need or business rationale for the Focus Arrangement is specified and is consistent with SPD's policies and procedures;

e. verifying that the service and activity logs are properly completed and reviewed (if applicable);

f. verifying that leased space, medical supplies, medical devices, and equipment, and other patient care items are properly monitored (if applicable); and

g. verifying that the Focus Arrangement satisfies the Focus Arrangements Requirements of Section III.D.2 of the CIA.

2. For any Focus Arrangement for which the IRO cannot verify compliance with each of the applicable requirements specified in Section C.1 above, the IRO shall identify and review the system(s) and process(es) that resulted in the identified non-compliance and recommend improvements to such system(s) and process(es). The IRO may need to review additional documentation and/or interview personnel to identify the system(s) and process(es) that resulted in the identified non-compliance.

3. If the IRO cannot verify compliance with each of the applicable requirements specified in Section C.1 above with respect to at least 90% of the Focus Arrangements subject to the Arrangements Transactions Review, then, at its discretion, within 60 days of receipt of the Arrangements Transactions Review Report, the OIG may require the IRO to select an additional sample of Focus Arrangements, not to exceed the number of Focus Arrangements initially reviewed by the IRO, that will be subject to the Arrangements Transactions Review (Additional Transactions Review) and complete and submit to SPD and OIG an Additional Transactions Review Report that includes the information specified in

Section D below, within 60 days of the date the OIG notifies SPD and its IRO that an Additional Transactions Review will be required.

D. Arrangements Transactions Review Report. The IRO shall prepare a report based on each Arrangements Transactions Review performed. The Arrangements Transaction Review Report shall include the following information:

1. *Review Methodology*.

a. Review Protocol. A description of the process used by the IRO to identify the Focus Arrangements subject to review in the Arrangements Transactions Review.

b. Sources of Data. A full description of the documentation and other information relied upon by the IRO in performing the Arrangements Transactions Review.

c. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Focus Arrangements selected as part of the Arrangements Transactions Review and SPD shall furnish such documentation and materials to the IRO prior to the IRO initiating its review of the Focus Arrangements. If the IRO accepts any supplemental documentation or materials from SPD after the IRO has completed its initial review of the Focus Arrangements (Supplemental Materials), the IRO shall identify in the Arrangements Transactions Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Arrangements Transactions Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

2. *Review Findings*. The IRO's findings with respect to whether SPD has complied with the Focus Arrangements Procedures and Focus Arrangements Requirements with respect to each of the randomly selected Focus Arrangements reviewed by the IRO, including findings for each item listed in Sections C.1.a-g above. In addition, as applicable, the Arrangements Transactions Review Report shall include the IRO's recommendations as required by Section C.2 above.

3. *Names and Credentials*. The names and credentials of the individuals who conducted the Arrangements Systems Review and the Arrangements Transactions Review.