

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
MALLINCKRODT PLC**

I. PREAMBLE

Mallinckrodt plc (Mallinckrodt) 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, Mallinckrodt is entering into a Settlement Agreement with the United States.

Mallinckrodt is also entering into settlement agreements with various states (State Settlement Agreements) and Mallinckrodt's agreement to this CIA is a condition precedent to those agreements.

On October 12, 2020, Mallinckrodt filed a voluntary petition for bankruptcy under chapter 11 of the Bankruptcy Code in the United States Bankruptcy Court for the District of Delaware (Case No. 20-12522) (hereinafter "Chapter 11 Case"). In connection with the Chapter 11 Case, Mallinckrodt agreed to an operating injunction that applies to its specialty generics business (Operating Injunction). Unless otherwise specified in the Operating Injunction, the terms of the Operating Injunction apply for eight years following the filing of Mallinckrodt's Chapter 11 Case, as described in that document. Among other things, the Operating Injunction requires Mallinckrodt to retain an outside, independent Monitor to evaluate, monitor, and submit periodic reports about its compliance with the Operating Injunction.

In addition to the Chapter 11 Case referenced above, Mallinckrodt is also subject to an examinership proceeding under the laws of Ireland (Examinership Proceeding). Mallinckrodt represents that the Chapter 11 Case and the Examinership

Proceeding will not be concluded, and the company will not emerge from bankruptcy, until likely at least four to five months after the Effective Date.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Mallinckrodt 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) Mallinckrodt’s final Annual Report; or (2) any additional materials submitted by Mallinckrodt pursuant to OIG’s request, whichever is later.

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

1. “Covered Persons” includes:
 - a. all owners of Mallinckrodt 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) and all officers and directors of Mallinckrodt;
 - b. with the exception of employees who are subject to the Operating Injunction, all U.S. employees of Mallinckrodt who engage in or supervise personnel who are engaged in Covered Functions (as defined below in Section II.C.6); and
 - c. all U.S. contractors, subcontractors, agents, and other persons who perform any of the Covered Functions on behalf of Mallinckrodt.

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 perform a Covered Function for Mallinckrodt more than 160 hours per year, except that any such individuals shall become a Covered Person at the point when they work more than 160 hours on a Covered Function for Mallinckrodt

during the calendar year.

2. “Government Reimbursed Products” refers to all Mallinckrodt products, with the exception of the products subject to the Operating Injunction, that are: (a) marketed or sold by Mallinckrodt in the United States (or pursuant to contracts with the United States) and (b) reimbursed by Federal health care programs.

3. The term “Promotional Functions” includes: (a) the selling, detailing, marketing, advertising, promoting, or branding of Government Reimbursed Products; and (b) the preparation or external dissemination of promotional materials or information about, or the provision of promotional services relating to, Government Reimbursed Products, including those functions relating to Mallinckrodt’s review and approval processes for promotional materials and any applicable review committee(s).

4. The term “Contribution and Assistance Related Functions” includes: all activities, systems, processes, and procedures relating to the following: (a) any grants, charitable contributions, or donations (in cash or in kind) provided by Mallinckrodt or any entity acting on behalf of Mallinckrodt to any independent third-party patient assistance program (Independent Charity PAP) relating to Government Reimbursed Products; and (b) the operation of, or participation in, any patient assistance program (PAP) by Mallinckrodt or any entity acting on behalf of Mallinckrodt that provides free Government Reimbursed Products to patients, including Federal health care program beneficiaries, or programs to provide financial assistance to patients for Government Reimbursed Products in the form of cost-sharing assistance (i.e., co-pay coupons or co-pay cards).

5. The term “Government Pricing Functions” includes 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) and the 340B Drug Pricing Program (codified at 42 U.S.C. § 256b) (the 340B Program), decision-making relating to the Medicare Program, the Medicaid Drug Rebate Program and the 340B Program, and the payment of rebates in connection with the Medicaid Drug Rebate Program. Persons engaged in these functions include individuals whose job responsibilities include the calculation and reporting of Average Sales Price (ASP), Average Manufacturer Price (AMP), Best Price, the 340B Program ceiling price, Average Wholesale Price (AWP), and all other information reported by Mallinckrodt and used in connection with the programs specified in this Paragraph.

6. The term “Covered Functions” refers to “Promotional Functions,” “Contribution and Assistance Related Functions,” and “Government Pricing Functions” collectively.

7. The term “Mallinckrodt Affiliate” shall mean any entity, including Mallinckrodt ARD LLC, that is owned or controlled directly or indirectly, by Mallinckrodt and whose employees or contractors perform any Covered Functions related to Government Reimbursed Products. All obligations set forth in Section III below shall apply to the Covered Functions performed by any Mallinckrodt Affiliate and all references to “Mallinckrodt” in the defined terms set forth in this Section II shall mean Mallinckrodt and any Mallinckrodt Affiliate. In addition, the notice requirements in Section IV and the certification obligations set forth in Section V.C. below shall apply to both Mallinckrodt and any Mallinckrodt Affiliate.

III. CORPORATE INTEGRITY OBLIGATIONS

Mallinckrodt shall establish and maintain a Compliance Program that includes the following elements:

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

1. *Compliance Officer.* Within 90 days after the Effective Date, Mallinckrodt 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 Mallinckrodt; shall report directly to the Chief Executive Officer of Mallinckrodt; 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 Mallinckrodt. 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 requirements;
- b. making periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Mallinckrodt (Board) and shall be authorized to report on such matters to the Board of

Directors at any time. Written documentation of the 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 Mallinckrodt and any reporting obligations 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.

Mallinckrodt 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 obligations in this CIA, within five business days after such a change.

2. *Compliance Committee.* Within 90 days after the Effective Date, Mallinckrodt 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 Mallinckrodt'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.

Mallinckrodt 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 Mallinckrodt (or a committee of the Board) shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements and the obligations of this CIA. The Board must include independent (i.e., non-employee and non-executive) members.

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

- a. meeting at least quarterly to review and oversee Mallinckrodt's Compliance Program, including but not limited to the performance of the Compliance Officer and Compliance Committee;
- b. submitting to 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;
- c. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board, summarizing its review and oversight of Mallinckrodt's compliance with Federal health care program requirements and the obligations of this CIA; and
- d. for the second and fourth Reporting Periods of the CIA, the Board shall retain an individual or entity with expertise in compliance with Federal health care program and Food and Drug Administration (FDA) requirements (Compliance Expert) to perform a review of the effectiveness of Mallinckrodt's Compliance Program (Compliance Program Review). The Compliance Expert shall prepare a written report about the Compliance Program Review. The written report (Compliance Program Review Report) shall include a description of the Compliance Program Review and any recommendations with respect to Mallinckrodt's compliance program. The Board shall review the Compliance Program Review Report as part of its review and oversight of Mallinckrodt's compliance program. A copy of the Compliance Program Review report shall be provided to OIG in each applicable Annual Report submitted by Mallinckrodt. In addition, copies of any materials provided to the Board by

the Compliance Expert, along with minutes of any meetings between the Compliance Expert and the Board, shall be made available to OIG upon request.

At minimum, the resolution shall include the following language:

“The Board has made a reasonable inquiry into the operations of Mallinckrodt’s Compliance Program including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, Mallinckrodt has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the Corporate Integrity Agreement.”

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 Mallinckrodt.

Mallinckrodt 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 business days after such a change.

4. *Management Certifications:* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Mallinckrodt employees (Certifying Employees) are expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable Mallinckrodt division or business unit is in compliance with applicable Federal health care program requirements and the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: Executive Vice President & Chief Financial Officer; Vice President, Government Affairs & Patient Advocacy; Senior Director, Patient Services and Reimbursement; Executive Vice-President and Chief Commercial & Operations Officer; Executive Vice President and Chief Scientific Officer. 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 or functional area], an area under my supervision. My job responsibilities include ensuring compliance with regard to the _____ [insert name of the department or functional area] with all applicable Federal health care program requirements, obligations of the Corporate Integrity Agreement, and Mallinckrodt policies, and I have taken steps to promote such compliance. To the best of my knowledge, the [insert name of department or functional area] of Mallinckrodt is in compliance with all applicable Federal health care program 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 90 days after the Effective Date, Mallinckrodt 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

1. *Policies and Procedures.* Within 150 days after the Effective Date, Mallinckrodt 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 Mallinckrodt’s compliance with Federal health care program requirements and applicable FDA requirements (Policies and Procedures). Throughout the term of this CIA, Mallinckrodt shall enforce its Policies and Procedures and shall make compliance with its Policies and Procedures an element in evaluating the performance of all Covered Persons. The Policies and Procedures shall be made available to all Covered Persons.

At a minimum, the Policies and Procedures shall address the following:

- a. appropriate ways to conduct Contribution and Assistance Related Functions in compliance with all applicable Federal health care program requirements, including but not limited to, the Federal Anti-Kickback Statute (codified at 42 U.S.C. § 1320a-7b(b)) and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733);
- b. to the extent that Mallinckrodt makes monetary donations to Independent Charity PAPs, arrangements and interactions with (including donations to and sponsorship of) Independent Charity PAPs. These Policies and Procedures shall be designed to ensure that Mallinckrodt's arrangements and interactions comply with all applicable Federal health care program requirements. The Policies and Procedures shall also be designed to ensure that Mallinckrodt's arrangements and interactions (including donations and sponsorship) comply with all guidance issued by OIG relating to the support and funding of patient assistance programs, including but not limited to, the OIG's Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623 (Nov. 22, 2005) and OIG's Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31120 (May 30, 2014);
- c. the operation of, or participation in, any patient assistance program by Mallinckrodt or any entity acting on behalf of Mallinckrodt. These Policies and Procedures shall be designed to ensure that Mallinckrodt's operation of or participation in such programs complies with all applicable Federal health care program requirements. The Policies and Procedures shall also be designed to ensure that Mallinckrodt's operation of or participation in any such patient assistance program complies with all guidance issued by OIG relating to assistance provided to patients by pharmaceutical manufacturers to reduce or eliminate the cost of copayments for drugs, including but not limited to, the OIG's Special Advisory Bulletin on Pharmaceutical Manufacturer Copayment Coupons (Sept. 2014);

- d. the materials and information that may be distributed by appropriate Mallinckrodt personnel about Independent Charity PAPs or Contribution and Assistance Related Functions and the manner in, and circumstances under, which appropriate Mallinckrodt personnel may respond to requests for information about Independent Charity PAPs or Contribution and Assistance Related Functions;
- e. appropriate ways to conduct Promotional Functions in compliance with all: (i) applicable Federal healthcare program requirements, including but not limited to, the Federal Anti-Kickback Statute and the False Claims Act, and (ii) applicable FDA requirements;
- f. appropriate ways to conduct Government Pricing Functions in compliance with all applicable Federal health care program requirements. This includes: (a) gathering, calculating, verifying and reporting data and information in connection with the Medicaid Drug Rebate Program, the Medicare program, and the 340B Program, and as otherwise required by Federal or state government requirements and directives relating to government drug pricing; (b) decision-making relating to the Medicaid Drug Rebate Program, the Medicare Program, and the 340B Program; and (c) payment of appropriate rebate amounts in connection with the Medicaid Drug Rebate Program; and
- g. disciplinary policies and procedures for violations of Mallinckrodt's Policies and Procedures, including policies relating to Federal health care program and applicable FDA requirements.

At least annually (and more frequently, if appropriate), Mallinckrodt 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, Mallinckrodt shall develop a written plan (Training Plan) that outlines the steps Mallinckrodt will take to ensure that: (a) all Covered Persons receive at least annual training regarding Mallinckrodt'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 and FDA requirements relating to the Covered Functions in which they engage and (ii) all Mallinckrodt Policies and Procedures and other requirements applicable to the Covered Functions in which they engage. The Training Plan shall include information regarding the following: training topics, categories of Covered Persons required to attend each training session, length of the training session(s), schedule for training, and format of the training. Mallinckrodt shall furnish training to its Covered Persons pursuant to the Training Plan during each Reporting Period.

2. *Board Member Training.* In addition to the training described in Section III.C.1, within 150 days after the Effective Date, each member of the Board 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 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 Board member or within 150 days after the Effective Date, whichever is later.

3. *Training Records.* Mallinckrodt 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. Risk Assessment and Mitigation Process

Within 150 days after the Effective Date, Mallinckrodt shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with each of its Government Reimbursed Products and with applicable Federal health care program requirements (including the requirements of the Federal Anti-Kickback Statute), including risks associated with the sales, marketing, and promotion of such products; the collection, calculation, verification and reporting of information for such products for purposes of the Medicaid Drug Rebate Program, the Medicare Program and the 340B Drug Pricing Program and the payment of rebates to the Medicaid Drug Rebate Program for such products; and risks associated with Mallinckrodt's operation of any PAP and the company's arrangements and interactions with any Independent Charity PAPs. 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 annually and shall require Mallinckrodt 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. Mallinckrodt 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, Mallinckrodt 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 Mallinckrodt shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports

(those exchanged between the IRO and Mallinckrodt) related to the reviews.

- c. *Access to Records and Personnel.* Mallinckrodt 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. *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 Review shall assess Mallinckrodt's systems, processes, policies, and procedures relating to the Covered Functions. If there are no material changes in Mallinckrodt's relevant systems, processes, policies, and procedures, the Systems Review shall be performed for the first and fourth Reporting Periods. If Mallinckrodt 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 Review shall be performed annually and shall cover each of the five 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.* For each Reporting Period, OIG, in its discretion, may identify up to three additional areas or practices of Mallinckrodt for the IRO to include in its Transaction Review (hereinafter "Additional Items"). For purposes of identifying the Additional Items to be included in

the Transactions Review for a particular Reporting Period, OIG will consult with Mallinckrodt and may consider internal audit and monitoring work conducted by Mallinckrodt, the Government Reimbursed Product portfolio, the nature and scope of Mallinckrodt's promotional practices and arrangements with health care professionals and health care institutions, and other information known to it.

3. *IRO Review Report.* 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 Mallinckrodt 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. The IRO's certification shall include a summary of current and prior engagements between Mallinckrodt and the IRO.

F. Disclosure Program

Within 90 days after the Effective Date, Mallinckrodt 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 Mallinckrodt's policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. Mallinckrodt 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 Mallinckrodt's Covered Persons shall be expected to report suspected violations of any Federal health care program requirements to the Compliance Officer or other appropriate individual designated by Mallinckrodt. 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, Mallinckrodt 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 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.

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 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.* Mallinckrodt shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

- a. Mallinckrodt 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. Mallinckrodt shall screen all current Covered Persons against the Exclusion List within 90 days after the Effective Date and on a quarterly basis thereafter.
- c. Mallinckrodt shall implement a policy requiring all Covered Persons to disclose immediately if they become an Ineligible Person.

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

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

1. *Employee and Executive Incentive Compensation Restriction Program.* Within 150 days after the Effective Date, Mallinckrodt shall develop and maintain throughout the term of the CIA an Employee and Executive Incentive Compensation Restriction Program consistent with the requirements described in Appendix C to this CIA. The Employee and Executive Incentive Compensation Program shall require Mallinckrodt to make certain disclosures about executive incentive compensation as described in further detail in Section III.L below.

2. *Executive Financial Recoupment Program.* Within 150 days after the Effective Date, Mallinckrodt shall establish and maintain throughout the term of this CIA an Executive Financial Recoupment Program consistent with the terms and conditions described in Appendix C to this CIA.

I. Notification of Government Investigation or Legal Proceeding.

Within 30 days after discovery, Mallinckrodt shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Mallinckrodt conducted or brought by a governmental entity or its agents involving an allegation that Mallinckrodt 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. Mallinckrodt also shall 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. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or
- c. the filing of a bankruptcy petition by Mallinckrodt.

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

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

3. *Reportable Events under Section III.J.1.a.* For Reportable Events under Section III.J.1.a, 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 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; and
- d. a description of Mallinckrodt's actions taken to correct the Reportable Event and prevent it from recurring.

4. *Reportable Events under Section III.J.1.b.* For Reportable Events under Section III.J.1.b, 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 Mallinckrodt 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.J.1.c.* For Reportable Events under Section III.J.1.c, the report to OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program requirements implicated.

K. Independent Charity Patient Assistance Program Activities

To the extent that Mallinckrodt makes monetary donations to Independent Charity PAPs, it shall implement the policies, procedures, and practices set forth in this Section III.K within 150 days after the Effective Date or upon deciding to make donations to an Independent Charity PAP, whichever is later. Mallinckrodt shall develop Independent Charity PAP policies, procedures, and practices as described below prior to making its first donation to an Independent Charity PAP and will continue such Independent Charity PAP policies, procedures, and practices throughout the term of the CIA.

1. *Independent Charity Group.* Mallinckrodt shall vest sole responsibility and authority for budgeting and all other activities relating to Independent Charity PAPs in a department or group within Mallinckrodt known as the "Independent Charity Group" that has the following roles and responsibilities:

- a. The Independent Charity Group shall be separate and independent from Mallinckrodt's commercial organization.
- b. The Independent Charity Group shall operate independently from Mallinckrodt's commercial organization and Mallinckrodt's commercial organization shall have no involvement in, or influence over, the review, approval, or implementation of any budget or other decisions or activities relating to Independent Charity PAPs.
- c. Mallinckrodt shall vest in the Independent Charity Group sole responsibility and authority for communicating with Independent Charity PAPs regarding Mallinckrodt's donations to such PAPs and Mallinckrodt's commercial organization shall not communicate with, influence, or be involved in any communications with, or receive information from the Independent Charity PAPs.
- d. Mallinckrodt's Independent Charity Group shall gather information about Independent Charity PAPs and their disease funds in a manner that does not exert or attempt to exert any direct or indirect control over the entity operating the PAP or over its assistance program.
- e. For purposes of this CIA, the "commercial organization" shall be defined to include the sales, marketing, and similar commercial business units of Mallinckrodt.

2. *Budgeting Process.* Mallinckrodt's Independent Charity Group shall establish a budget process to be followed for Mallinckrodt's donations to Independent Charity PAPs that meets the following requirements:

- a. The Independent Charity Group shall develop an annual budget for donations to Independent Charity PAPs based on objective criteria in accordance with general guidelines approved by the legal department with input from the compliance department.

- b. Mallinckrodt shall approve the annual budget for donations to Independent Charity PAPs at a level within the organization above the commercial organization (e.g., at the executive level).
- c. The Independent Charity Group shall have sole responsibility for allocating the approved budget across donations to Independent Charity PAPs and to any disease state fund established by the Independent Charity PAP.
- d. The Independent Charity Group shall have sole responsibility for assessing requests for additional or supplemental funding from Independent Charity PAPs outside of the annual budget using standardized, objective criteria established by the Independent Charity Group. Any such requests also shall be subject to legal and compliance personnel review and approval, to ensure that any supplemental funding to the Independent Charity PAP is provided in accordance with applicable Federal health care program requirements, OIG guidance, and Mallinckrodt Policies and Procedures.
- e. The commercial organization shall have no involvement in the Independent Charity PAP budget process, and the budget to be used for donations to Independent Charity PAPs shall not be based on monies allocated to the Independent Charity Group from the commercial organization.

3. *Criteria Relating to Donations to Independent Charity PAPs.* The Independent Charity Group (with input from the legal and compliance departments) shall establish standardized, objective written criteria that govern donations to Independent Charity PAPs and any specific disease state funds of such PAPs, designed to ensure that the Independent Charity PAP does not function as a conduit for payments or other benefits from Mallinckrodt to patients and does not impermissibly influence patients' drug choices. In addition, Mallinckrodt agrees that it will donate to an Independent Charity PAP only if the following criteria are satisfied:

- a. Mallinckrodt does not and shall not exert (directly or through any affiliate) any influence or control over the identification, delineation, establishment, or modification of any specific disease funds operated by the Independent Charity PAP. Among other things, Mallinckrodt has not made and shall not make (directly or through any affiliate) suggestions or requests to the Independent Charity PAP about the identification, delineation, establishment, or modification of disease state funds.
- b. Mallinckrodt does not and shall not exert (directly or through any affiliate) any direct or indirect influence or control over the Independent Charity PAP's process or criteria for determining eligibility of patients who qualify for its assistance program.
- c. Mallinckrodt does not and shall not solicit or receive (directly or indirectly through third parties) any data or information from the Independent Charity PAP that would enable it to correlate the amount or frequency of its donations with support for Mallinckrodt's products or services.
- d. Mallinckrodt does not and shall not provide donations for a disease state fund that covers only a single product or that covers only Mallinckrodt's products.
- e. Personnel from Mallinckrodt's legal and compliance departments shall review all proposed donations and arrangements between Mallinckrodt and any Independent Charity PAP prior to such donations being made or arrangements being entered into by Mallinckrodt.

L. Transparency and Reporting of Price-Related Information

1. At least 7 days prior to the implementation of any increase in the list price of Acthar or another non-generic Government Reimbursed Product that is separately reimbursable under Medicare or Medicaid (hereinafter collectively

“Reportable Products”), Mallinckrodt shall post on its website a notice about the planned price increase that includes the following information:

- a. the applicable Reportable Product, the proposed new list price, the percentage amount of the proposed price increase over the then-current list price, and the effective date of the proposed price increase; and
- b. the reason(s) for the proposed price increase.

Mallinckrodt shall place the notice in a prominent place on the main page of the company’s website.

2. At the same time that Mallinckrodt posts the information described in Section III.L.1 above on its website, Mallinckrodt shall also submit the same information in writing to OIG, along with a description of any expected changes in any patient assistance provided by Mallinckrodt for the applicable Reportable Product (e.g., through expansion of any internally operated PAP, any expansion of the company’s free drug program, any increased payments to third-party foundations operating PAP funds that cover Mallinckrodt products, etc.) following the price increase.

3. Mallinckrodt shall maintain the notice of proposed price increase information described in Section III.L.1 above on its website during the term of the CIA and, for each proposed price increase that becomes effective, shall update the notice to indicate the date on which such proposed price increase became effective. Mallinckrodt shall update the notice within three business days of the price increase effective date, and at the same time shall submit written notice of the price increase effective date to OIG.

4. Mallinckrodt shall post a link to the executive officer compensation section of its annual Proxy Statement in a prominent place on the same web page that includes the notice of proposed price increases described in Section III.L.1 above. Mallinckrodt shall update the link within three business days of the issuance of a new Proxy Statement and at the same time shall notify OIG that an updated link has been posted.

5. If Mallinckrodt is required, pursuant to any state or federal law, to submit to any government agency, or otherwise make public, information about prices or

any increase in the price of any Government Reimbursed Product(s) (including any justification for any price increase), Mallinckrodt shall at the same time provide to OIG a list of such reports submitted or made public by Mallinckrodt. The list shall include the following information: (a) the nature of, and relevant time period for, the pricing or price increase information, (b) the applicable law under which Mallinckrodt was required to submit or make public the information, and (c) the government agency to which and/or the means by which the information was submitted or made public. Copies of the reports shall be made available to OIG upon request

IV. SUCCESSOR LIABILITY

In the event that, after the Effective Date, Mallinckrodt 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 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. Mallinckrodt 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, Mallinckrodt 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, Mallinckrodt 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 180 days after the Effective Date, Mallinckrodt shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A.1, 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.2;
3. the names of the Board members who are responsible for satisfying the 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 written copy of the process to be followed by Certifying Employees in connection with completing the required certifications;
5. a list of the Policies and Procedures required by Section III.B.1;
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 Mallinckrodt that includes a summary of all current and prior engagements between Mallinckrodt and the IRO;
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 from the Compliance Officer that an Employee and Executive Incentive Compensation Restriction Program and an Executive Financial

Recoupment Program consistent with the requirements of Sections III.H and III.L of the CIA and Appendix C have been established and implemented;

12. a description of the Independent Charity PAP policies, procedures, and practices required by Section III.K, if applicable;

13. a list of all of Mallinckrodt's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers, and the location's Medicare and state Medicaid program provider and/or supplier numbers (if any);

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

15. the certifications required by Section V.C.

B. Annual Reports.

Mallinckrodt 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. (a) any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer; (b) a current list of the Compliance Committee members; (c) a current list of the Board members who are responsible for satisfying the Board compliance obligations; and (d) a current list of the Certifying Employees and (e) a description of any changes made during the Reporting Period to the Compliance Committee, Board of Directors, 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 Board (written documentation of such reports shall be made available to OIG upon request);

4. 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;
5. for each applicable Reporting Period, a copy of the Compliance Review Report prepared by the Compliance Expert required by Section III.A.3;
6. a list of any new or revised Policies and Procedures required by Section III.B.1 developed during the Reporting Period;
7. a description of any changes to Mallinckrodt's Training Plan developed pursuant to Section III.C and a summary of any Board training provided during the Reporting Period;
8. a description of any changes to the risk assessment and internal review process required by Section III.D, including the reasons for such changes;
9. 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;
10. a complete copy of all reports prepared pursuant to Section III.E and Mallinckrodt's response to the reports, along with corrective action plan(s) related to any issues raised by the reports;
11. a certification from the IRO regarding its professional independence and objectivity with respect to Mallinckrodt, including a summary of all current and prior engagements between Mallinckrodt and the IRO;
12. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs 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;

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

14. a description of any changes to the Employee and Executive Incentive Compensation Restriction Program and/or the Executive Financial Recoupment Program during the Reporting Period, and the reasons for the changes, and the annual reports to OIG required under Section E of Appendix C;

15. 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;

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

17. a description of any changes to the Independent Charity PAP policies, procedures, and practices outlined in section III.K including the reasons for such changes;

18. a summary of the Price-Related Information described in Section III.L that was posted on Mallinckrodt's website or submitted to OIG in accordance with Section III.L during the Reporting Period;

19. a description of all changes to the most recently provided list of Mallinckrodt's locations (including addresses) as required by Section V.A.13;

20. a description of any changes to Mallinckrodt's corporate structure, including any parent and sister companies, subsidiaries, and their respective lines of business; and

21. 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, Mallinckrodt shall include the certifications of Certifying Employees required by Section III.A.4;

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

- a. to the best of his or her knowledge, except as otherwise described in the report, Mallinckrodt is in compliance with all of the 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. he or she understands that the certification is being provided to and relied upon by the United States;
- d. for each disease fund of an Independent Charity PAP to which Mallinckrodt made a donation during the Reporting Period, the facts and circumstances relating to the donation were reviewed by competent legal counsel and were found to be in compliance with all applicable Federal health care program requirements, OIG guidance, and Mallinckrodt policies and procedures (including those outlined in Section III.K);
- e. for each patient assistance program for Government Reimbursed Products that Mallinckrodt or any entity acting on behalf of Mallinckrodt operates or participates in (e.g., through cash or in-kind donations), the facts and circumstances relating to the program were reviewed by competent legal counsel and were found to be in compliance with all applicable Federal health care program requirements, OIG guidance, and Mallinckrodt policies and procedures; and
- f. Mallinckrodt complied with the transparency and reporting

requirements outlined in Section III.L.

3. *Medicaid Drug Rebate Certification.* As part of the Implementation Report and each Annual Report, the Chief Financial Officer shall provide the Medicaid Drug Rebate certification set forth in Appendix D.

D. Submission of Information Relating to Operating Injunction.

Mallinckrodt shall submit to OIG any final Monitor Report (as defined in the Operating Injunction) produced by the Monitor pursuant to the Operating Injunction within five days of Mallinckrodt receiving such final Monitor Report. Any written responses or documentation Mallinckrodt submits to the Monitor pursuant to the Operating Injunction that is not otherwise appended to the final Monitor Report shall be made available to OIG upon request.

E. Designation of Information.

Mallinckrodt 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. Mallinckrodt 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

Mallinckrodt:

Kassie Harrold
Senior Vice President and Chief Compliance Officer
Mallinckrodt Pharmaceuticals
675 McDonnell Blvd.
Hazelwood, MO 63042
Telephone: 314.619.9008
Email: Kassie.Harrold@mnk.com

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, Mallinckrodt may be required to provide OIG with an additional copy of each notification or report required by this CIA in the 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 Mallinckrodt's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Mallinckrodt's locations for the purpose of verifying and evaluating: (a) Mallinckrodt's compliance with the terms of this CIA and (b) Mallinckrodt's compliance with the requirements of Federal health care programs. The documentation described above shall be made available by Mallinckrodt 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 Mallinckrodt's 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. Mallinckrodt shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Mallinckrodt's owners, employees, contractors and directors may elect to be interviewed with or without a representative of Mallinckrodt present.

VIII. DOCUMENT AND RECORD RETENTION

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

X. BREACH AND DEFAULT PROVISIONS

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

- a. a 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 Incentive Compensation Restriction and Financial Recoupment Programs required by Section III.H and Appendix C;
- k. notification of Government investigations or legal proceedings;
- l. reporting of Reportable Events;
- m. the Independent Charity PAP policies, procedures, and practices required by Section III.K; and
- n. the transparency and reporting of price-related information required by Section III.L.

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 Mallinckrodt fails to engage and use an IRO as required by Section III.E and Appendix A.

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Mallinckrodt fails to submit (a) a complete Implementation Report or Annual Report, (b) a certification to OIG in accordance with the requirements of Section V, or (c) a complete response to any request for information from OIG.

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

6. A Stipulated Penalty of \$50,000 for each false certification submitted by or on behalf of Mallinckrodt 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 Mallinckrodt fails to grant the IRO access to all records and personnel necessary to complete the reviews listed in Section III.E, and for each day Mallinckrodt fails to furnish accurate and complete records to the IRO, as required by Section III.E and Appendix A.

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

Mallinckrodt 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 Mallinckrodt 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 Mallinckrodt 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 Mallinckrodt 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 Mallinckrodt of: (a) Mallinckrodt's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Mallinckrodt 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 Mallinckrodt elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Mallinckrodt 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 Mallinckrodt 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 Mallinckrodt to report a Reportable Event and take corrective action as required in Section III.J;
- 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 Mallinckrodt constitutes an independent basis for Mallinckrodt'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 Mallinckrodt has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Mallinckrodt of: (a) Mallinckrodt's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")

3. *Opportunity to Cure.* Mallinckrodt 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) Mallinckrodt has begun to take action to cure the material breach; (ii) Mallinckrodt is pursuing such action with due diligence; and (iii) Mallinckrodt has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Mallinckrodt fails to satisfy the requirements of Section X.D.3, OIG may exclude Mallinckrodt from participation in the Federal health care programs. OIG shall notify Mallinckrodt in writing of its determination to exclude Mallinckrodt. (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 Mallinckrodt’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, Mallinckrodt 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 Mallinckrodt 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, Mallinckrodt 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 Mallinckrodt was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Mallinckrodt 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 Mallinckrodt to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Mallinckrodt 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 Mallinckrodt was in material breach of this CIA and, if so, whether:

- a. Mallinckrodt 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 Mallinckrodt's receipt of the Notice of Material Breach: (i) Mallinckrodt had begun to take action to cure the material breach within that period; (ii) Mallinckrodt pursued such action with due diligence; and (iii) Mallinckrodt 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 Mallinckrodt, only after a DAB decision in favor of OIG. Mallinckrodt's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Mallinckrodt 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 Mallinckrodt 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. Mallinckrodt 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 Mallinckrodt, Mallinckrodt 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

Mallinckrodt 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) Mallinckrodt'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.

D. The undersigned Mallinckrodt 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.

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

ON BEHALF OF MALLINCKRODT PLC

/Mark Casey/

March 3, 2022

MARK CASEY
Executive Vice President and Chief Legal Officer
Mallinckrodt plc

DATE

/Avia M. Dunn/

March 3, 2022

AVIA M. DUNN
JENNIFER L. BRAGG
Skadden, Arps, Slate, Meagher & Flom LLP
Counsel for Mallinckrodt plc

DATE

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

/Lisa M. Re/

02/07/2022

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

DATE

/Mary E. Riordan/

3/3/2022

MARY E. RIORDAN
MADELINE E. BAINER
Senior Counsel
Office of Counsel to the Inspector General
Office of Inspector General

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. Mallinckrodt 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 E. Within 30 days after OIG receives the information identified in Section V.A.8 of the CIA or any additional information submitted by Mallinckrodt in response to a request by OIG, whichever is later, OIG will notify Mallinckrodt if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Mallinckrodt may continue to engage the IRO.

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

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the IRO Reviews who have expertise in the pharmaceutical industry and in all applicable Federal health care program and FDA requirements relating to the Covered Functions, including but not limited to expertise relating to marketing and promotional activities associated with pharmaceutical products and the Federal Anti-Kickback Statute and False Claims Act and relating to the collection, calculation, verification and reporting of information for such products for purposes of the Medicaid Drug Rebate Program, the Medicare Program and the 340B Drug Pricing Program;

2. assign individuals to design and select the samples for the IRO 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 and FDA requirements in making assessments in the IRO Reviews;

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

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

D. Mallinckrodt Responsibilities

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

E. IRO Independence and Objectivity

The IRO must perform each component of the IRO Reviews 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. *Mallinckrodt and IRO.* If Mallinckrodt terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Mallinckrodt 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. Mallinckrodt must engage a new IRO in accordance with Paragraph A of this Appendix 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 E or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify Mallinckrodt in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. Mallinckrodt 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 Mallinckrodt regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify Mallinckrodt in writing that Mallinckrodt shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. Mallinckrodt 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 Mallinckrodt to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

INDEPENDENT REVIEW ORGANIZATION REVIEWS

I. Covered Functions Review, General Description

As specified more fully below, Mallinckrodt shall retain an Independent Review Organization (IRO) (or IROs) to perform reviews (IRO Reviews) to assist Mallinckrodt in assessing and evaluating certain systems, processes, policies, procedures, and practices. The IRO Review shall consist of two components - a systems review (Systems Review) and a transactions review (Transactions Review) as described more fully below. Mallinckrodt may engage, at its discretion, a single IRO 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 the applicable systems, processes, policies, and procedures of Mallinckrodt, the IRO shall perform the Systems Review for the first and fourth Reporting Periods. If Mallinckrodt materially changes applicable systems, processes, policies, and procedures, the IRO shall perform a Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Systems Review for the first and fourth Reporting Periods. 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 each Reporting Period of the CIA.

II. Systems Review

A. Government Pricing Functions Systems Review

The Government Pricing Functions Systems Review shall be a review of Mallinckrodt's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to Government Pricing Functions for Government Reimbursed Products. More specifically, the IRO shall review shall include an assessment of the following:

1. The systems, processes, policies and practices used to determine Average Manufacturer Price (AMP)¹ for Government Reimbursed Products including, but not limited to, issues involving: (a) which Mallinckrodt customers and classes of trade are included or excluded for purposes of determining AMP; (b) whether and which particular transactions (e.g., sales, prices, discounts, rebates) are included in or excluded from AMP; and (c) the determination of AMP for Government Reimbursed Products that are authorized generic drugs;

2. The systems, processes, policies and practices used to determine Best Price for Government Reimbursed Products, including but not limited to, issues involving: (a) which Mallinckrodt customers and classes of trade are included or excluded for purposes of determining Best Price; (b) whether and which particular transactions (e.g., sales, prices, discounts, rebates) are included in or excluded from Best Price; and (c) the determination of Best Price for Government Reimbursed Products that are authorized generic drugs;

3. The systems, processes, policies, and practices used to identify Government Reimbursed Products that are 5i drugs including as they relate to the determination of whether a product is not generally dispensed through a retail community pharmacy;

4. The systems, processes, policies and practices used in connection with the calculation and payment of rebates due under the Medicaid Drug Rebate Program, including but not limited to: (a) rebate amounts due under 42 U.S.C. § 1396r-8(c)(1) and (c)(3)(A) and applicable regulations and guidance; (b) additional rebate amounts due under 42 U.S.C. §§ 1396r-8(c)(2) and (c)(3)(C) and applicable regulations and guidance (collectively hereafter “Additional Rebate Amounts”), including the systems, processes, policies, and practices used to determine base date AMP as used for purposes of determining Additional Rebate Amounts, and (c) rebate amounts due in connection with new formulations of Government Reimbursed Products;

5. The systems, processes, policies, and practices used by Mallinckrodt to classify its Government Reimbursed Products as Single Source Drugs, Innovator Multiple Source Drugs, or Non-Innovator Multiple Source Drugs for purposes of the Medicaid Drug Rebate Program;

¹ For purposes of this Appendix B, references to AMP includes AMP for 5i drugs (i.e., inhalation, infusion, instilled, implanted, and injectable drugs) as referenced in 42 C.F.R. § 447.507.

6. The systems, processes, policies and practices relating to the flow of data and information by which price, contract terms (including discounts and rebates), and transactions with Mallinckrodt's customers are accumulated from the source systems and entered and tracked in Mallinckrodt's information systems for purposes of calculating AMP and determining Best Price;

7. The controls and processes in place to examine and address Mallinckrodt internal system reports of variations, exceptions, or outliers, including a review of the bases upon which variations, exceptions, and outliers are identified and the follow-up activities undertaken to identify the cause of any variations;

8. A review of Mallinckrodt's methodology for determining AMP and Best Price; and

9. A review of any Mallinckrodt inquiries to or communication with CMS, including requests for interpretation or guidance, regarding: (a) AMP calculations and reporting requirements pursuant to the Medicaid Drug Rebate Program; (b) Additional Rebate Amounts and base date AMP; (c) Best Price determinations and reporting requirements pursuant to the Medicaid Drug Rebate Program; (d) the classification of a drug as a Single Source Drug, Innovator Multiple Source Drug, or Non-Innovator Multiple Source Drug; and (e) any reporting obligations under the Medicaid Drug Rebate Program, including reporting of any product information (e.g., NDC information or baseline information about a product); and (f) a review of any responses from CMS to any such inquiries or communications.

B. Contribution and Assistance Related Functions Systems Review

The Contribution and Assistance Related Functions Systems Review shall be a review of Mallinckrodt's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to Contribution and Assistance Related Functions. Where practical, Mallinckrodt 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 Mallinckrodt in accordance with the preceding sentence.

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

1. Mallinckrodt's systems, policies, processes, and procedures relating to arrangements and interactions with (including donations to and sponsorship of) independent third-party patient assistance programs (Independent Charity PAPs). This review shall include an assessment of the following:

- a. Mallinckrodt's organizational structure as it relates to arrangements and interactions with Independent Charity PAPs, including:
 - i. the identification of all those individuals, departments, or groups within Mallinckrodt (including, but not limited to, Mallinckrodt's Compliance Officer, Legal, and Medical Affairs) that have responsibility for, or involvement with, such arrangements and interactions;
 - ii. the respective scope and nature of the responsibilities of each individual, department, or group with responsibility for, or involvement with, arrangements and interactions with Independent Charity PAPs;
 - iii. the identification of those individuals, departments, or groups within Mallinckrodt (e.g., the commercial organization) that are precluded from involvement with arrangements and interactions with Independent Charity PAPs; and
 - iv. the manner by which the separation of Independent Charity PAP-related responsibilities from the commercial organization is enforced.
- b. Mallinckrodt's written policies and procedures as they relate to arrangements and interactions with Independent Charity PAPs, including:
 - i. the criteria governing whether and under what circumstances Mallinckrodt would donate to an Independent Charity PAP or any specific disease state fund of such a PAP;

- ii. communications (including any limitations on such communications) between any representatives of Mallinckrodt and any Independent Charity PAP (including the identity of individuals authorized to engage in such communications, the circumstances of such communications, and the subject matter of such communications including the exchange of any data);
 - iii. communications (including any limitations on such communications) between those individuals, departments, or groups within Mallinckrodt with responsibility for Independent Charity PAPs and the commercial organization of Mallinckrodt (including the identity of individuals authorized to engage in such communications, the circumstances of such communications, and the subject matter of such communications); and
 - iv. communications (including any limitations on such communications) between representatives of Mallinckrodt and health care providers or patients regarding assistance available through any Independent Charity PAP.
- c. Mallinckrodt's policies and practices as they relate to the budgeting process applicable to donations to Independent Charity PAPs as outlined in Section III.K of the CIA, including as it relates to initial or annual donation amounts and any supplemental amounts;
 - d. Mallinckrodt's policies and practices as they relate to the process by which decisions about the following are made and approved: (i) whether to donate (or continue to donate) to an Independent Charity PAP; and (ii) the amount of the donation (including any initial or annual amount and any supplemental amount);

- e. Mallinckrodt’s criteria, policies, and practices as they relate to donations made by Mallinckrodt to any Independent Charity PAPs as referenced in Section III.K.3, including the internal review process followed in connection with any donations to Independent Charity PAPs; and
- f. Mallinckrodt’s policies and practices as they relate to information provided, directly or indirectly, to the public about the availability of patient assistance for Mallinckrodt’s products.

2. Mallinckrodt’s systems, policies, processes, and procedures relating to any patient assistance program that was formed or is funded, controlled, or operated (directly or indirectly) by Mallinckrodt or any person or entity acting on behalf of (or affiliated with) Mallinckrodt (including, but not limited to, its employees, agents, vendors, officers, shareholders, or contractors) involving Government Reimbursed Products. This shall include any programs designed to provide free product or to provide other assistance (e.g., coupons or vouchers) to patients to reduce or eliminate the cost of copayments for drugs. These programs shall be collectively referred to as “Mallinckrodt PAPs.” This review shall include an assessment of the following:

- a. Mallinckrodt’s organizational structure as it relates to Mallinckrodt PAPs, including:
 - i. the identification of those individuals, departments, or groups within Mallinckrodt that have responsibility for, or involvement with Mallinckrodt PAPs; and
 - ii. the respective scope and nature of the responsibilities of each individual, department, or group with responsibility for, or involvement with, Mallinckrodt PAPs.
- b. Mallinckrodt’s written policies and procedures as they relate to Mallinckrodt PAPs, including:
 - i. the nature and amounts (or value) of the assistance provided to patients under each of the Mallinckrodt PAPs;

- ii. the eligibility criteria governing whether and under what circumstances Mallinckrodt provides assistance to patients under each of the Mallinckrodt PAPs;
 - iii. Mallinckrodt's external communications about the Mallinckrodt PAPs;
 - iv. the maintenance of records regarding free product and other assistance provided to or through Mallinckrodt PAPs;
 - v. ensuring effective communication between Mallinckrodt, Mallinckrodt PAPs, or both, and Medicare Part D plans; and
 - vi. billing for free product provided to or through Mallinckrodt PAPs.
- c. Mallinckrodt's policies and practices as they relate to the budgeting process for financial or in-kind assistance provided under any Mallinckrodt PAPs, including as they relate to initial or annual donation amounts and any supplemental amounts;
- d. Mallinckrodt's policies and practices as they relate to the process by which decisions about the following are made and approved: (i) whether to provide (or continue to provide) assistance through any Mallinckrodt PAP; and (ii) the amount (or value) of the assistance to be provided through each program (including any initial or annual amount and any supplemental amount);
- e. Mallinckrodt's policies and practices as they relate to any contracts or arrangements entered between Mallinckrodt and outside entities relating to any Mallinckrodt PAPs or the distribution of free product, including the individuals, groups, or departments involved in the negotiation process, the requirements and terms of the contracts or arrangements, and the review and approval of such contracts or arrangements.

C. IRO Systems Review Report

The IRO shall prepare a report based upon each Systems Review. For each of the Reviewed Policies and Procedures identified in Sections II.A and II.B above, the report shall include the following items:

1. A description of the systems, processes, policies, and practices used to track, gather, and account for price terms, contract terms and transactions that are relevant to the calculation and reporting of AMP (including base date AMP), Best Price, and the calculation of rebate amounts (including Additional Rebate Amounts), including but not limited to:
 - a. The computer, software, applications, or other relevant systems (including the source systems and any other information systems, as applicable) used to track data for and to calculate and report AMP and Best Price;
 - b. The information input into Mallinckrodt's relevant computer or other systems used to calculate AMP and used to determine Best Price;
 - c. The system logic or decisional rationale used to determine which customers and classes of trade are included or excluded for purposes of calculating AMP and for purposes of determining Best Price;
 - d. The system logic or decisional rationale used to determine whether price and contract terms, discounts, rebates, and other relevant transactions are included or excluded when calculating AMP and when determining Best Price;
 - e. The systems, processes, policies, and practices (including those relating to transfer prices) relevant to the determination of AMP and Best Prices for Government Reimbursed Products that are authorized generic drugs;
 - f. The systems, processes, policies and practices used in connection with the determination of base date AMP and the calculation and payment of rebate amounts (including Additional Rebate Amounts); and

- d. Mallinckrodt's systems and practices for reporting any adjustments or additional information related to its AMP and/or Best Price submissions.
5. Findings and supporting rationale regarding any weaknesses in Medicaid Drug Rebate Program-related systems, processes, policies, and practices referenced above in Section II.A;
6. Recommendations to improve any of the systems, processes, policies, and practices referenced in Section II.A;
7. A description of the documentation (including policies) reviewed and any personnel interviewed relating to the Contribution and Assistance Related Functions Systems Review;
8. A detailed description of systems, policies, processes, and procedures relating to the items identified in Section II.B. above, including a general description of the control and accountability systems (e.g., documentation and approval requirements, and tracking mechanisms) and written policies regarding the Reviewed Policies and Procedures;
9. A description of the manner in which the control and accountability systems and the written policies relating to the items identified in Section II.B above are made known or disseminated within Mallinckrodt;
10. A detailed description of any system(s) used to track requests for donations or other assistance from any Independent Charity PAP;
11. A detailed description of any system(s) used to track donations or other assistance provided in response to requests from Independent Charity PAPs;
12. A detailed description of any system(s) used to track requests for donations or other assistance from or through any Mallinckrodt PAP;
13. A detailed description of any system(s) used to track donations or other assistance provided in response to requests from or through any Mallinckrodt PAP;

14. Findings and supporting rationale regarding any weaknesses in the systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures identified above in Section II.B, if any; and

15. Recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures identified above in Section II.B, if any.

III. Transactions Review

As described more fully below, the Transactions Review shall include: (1) an AMP Transactions Review; (2) a Best Price Transactions Review; (3) an Additional Rebates Review; (4) a review of Mallinckrodt's arrangements with selected Independent Charity PAPs; and (5) a review of up to three additional items identified by the OIG in accordance with Section III.E.2.c of the CIA (hereafter "Additional Items"). The IRO shall report on all aspects of its reviews in the Transactions Review Reports.

A. AMP Transactions Review.

1. For each Reporting Period, the IRO shall randomly select a quarter during the Reporting Period. The IRO then shall identify the NDCs for Government Reimbursed Products (at the NDC-9 level) for which AMP was reported during the selected quarter and, as described below, review a sample of the transactions that were taken into account in the AMP calculation. More specifically, the IRO shall review (i) all NDCs for Government Reimbursed Products that are Single Source Drugs or Innovator Multiple Source Drugs; and (ii) any NDCs for Government Reimbursed Products that are Non-Innovator Multiple Source Drugs.

The NDCs associated with the drugs referenced above shall be referred to hereafter as the "Selected AMP NDCs". The IRO shall review the Selected AMP NDCs to test whether Mallinckrodt calculated and reported AMP in accordance with the Medicaid Drug Rebate Statute, regulations, and CMS guidance (collectively, "Medicaid Drug Rebate Program Requirements").

2. For purposes of the AMP Transactions Review, the following definitions shall be used:

- (a) "Finalized Transaction Types" are defined as those transactions that are finalized at the time of the sale.

- (b) “Estimated Transaction Types” are defined as those transaction types that are sales, adjustments, and/or rebates that are available on a lagged basis.

3. The IRO shall review transactions underlying the AMP calculation for each Selected AMP NDC to test whether Mallinckrodt calculated and reported AMP in accordance with Medicaid Drug Rebate Program Requirements.

- (a) The IRO shall select and review all AMP Finalized Transactions for each Selected AMP NDC and determine whether: (a) the Finalized Transactions are supported by source documents; and (b) the Finalized Transactions were included in or excluded from the AMP calculation for each Selected AMP NDC in accordance with Medicaid Drug Rebate Program Requirements.
- (b) The IRO shall select and review a sample of 100 AMP Estimated Transactions for each Selected AMP NDC and determine whether: (a) the Estimated Transaction amounts were calculated in accordance with Medicaid Drug Rebate Program Requirements and were supported by relevant source documents; and (b) the Estimated Transactions were included in or excluded from the AMP calculation for the Selected AMP NDCs in accordance with Medicaid Drug Rebate Program Requirements.

4. If the IRO identifies any Finalized Transactions or Estimated Transactions that are not supported by relevant source documents or that were not included or excluded from Mallinckrodt’s AMP calculation(s) in accordance with Medicaid Drug Rebate Program Requirements, Mallinckrodt shall be required to (1) adjust the applicable AMP calculation(s), resubmit the adjusted AMP to CMS, and pay any additional Medicaid rebate amounts that may be owed; and (2) perform a root cause analysis to determine the cause of each error identified by the IRO, and provide the findings of such root cause analysis to OIG, within 30 days following Mallinckrodt’s receipt of the Government Pricing Transactions Review Report.

B. Best Price Transactions Review. For each Reporting Period, the IRO shall perform a review to test whether Mallinckrodt determined and reported

Best Price for Government Reimbursed Products in accordance with Medicaid Drug Rebate Program Requirements. The Best Price Transactions Review shall consist of two parts:

1. Part One of the Best Price Transactions Review.
 - a. For all of its Government Reimbursed Products that are Single Source Drugs and Innovator Multiple Source Drugs Mallinckrodt shall provide the IRO with a list of all Mallinckrodt customers who purchased or contracted for those products during the Reporting Period (Selected Customers).
 - b. For each Selected Customer, the IRO shall identify all contracts with Mallinckrodt, any non-contract pricing terms offered by Mallinckrodt to the Selected Customer, and all corresponding Selected BP NDCs. The IRO shall determine whether all contract prices and any non-contract pricing terms for each Selected BP NDC were appropriately considered for purposes of determining Best Price in accordance with Medicaid Drug Rebate Program Requirements. To the extent that Mallinckrodt made available multiple price concessions in connection with the sale of a Selected BP NDC to a Selected Customer, the IRO shall determine whether the price concessions were appropriately considered for purposes of determining Best Price.
 - c. Mallinckrodt also shall provide the IRO with information and documentation about all non-price-related arrangements or relationships initiated or in effect during the Reporting Period between Mallinckrodt and Selected Customers (“Other Arrangements”). These Other Arrangements could include, for example, grants provided to the Mallinckrodt customer or data or service fee arrangements entered into with the Mallinckrodt customer. The IRO shall review documentation and information about the Other Arrangements sufficient to identify the nature of the Other Arrangements, describe the terms of the Other Arrangements (including any amounts paid or other benefits conferred by Mallinckrodt in connection with the Other Arrangements and the time period of the Other Arrangements), and identify any NDCs that were associated with the Other

Arrangements. The IRO shall assess whether the Other Arrangements were appropriately considered for purposes of determining Best Prices for any NDCs associated with the Other Arrangements.

2. Part Two of the Best Price Transactions Review.

- a. For all of its Single Source Drugs and Innovator Multiple Source Drugs that are Government Reimbursed Products, Mallinckrodt shall provide the IRO with a listing of the Medicaid rebate eligible NDCs (at the NDC-9 level) for which Mallinckrodt paid Medicaid rebates during the Reporting Period.
- b. For each of the NDCs identified in paragraph B.2.a, Mallinckrodt shall provide the IRO with a listing of all unique prices paid to Mallinckrodt for the product that were lower than the reported Best Price for the product.
- c. For each unique price that was lower than the reported Best Price (“Unique Lower Price”), the IRO shall review all the transactions associated with each of these Unique Lower Prices to determine whether each transaction was properly excluded from the determination of Best Price for the NDC in accordance with Medicaid Drug Rebate Program Requirements.

3. If the IRO’s Best Price Transactions Review identifies: (1) for any Selected Customers, any contract prices or non-contract terms that were not appropriately considered by Mallinckrodt for purposes of determining Best Price for the associated Selected BP NDCs; (2) any Other Arrangements with Selected Customers that were not appropriately considered for purposes of determining Best Price; or (3) any transactions associated with Unique Lower Prices paid to Mallinckrodt that were not appropriately excluded from the determination of Best Price for a Medicaid rebate eligible NDC, then Mallinckrodt shall be required to (1) adjust the applicable Best Price determination(s), resubmit the adjusted Best Price to CMS, and pay any additional Medicaid rebate amounts that may be owed; and (2) perform a root cause analysis to determine the cause of each error identified by the IRO, and provide the findings of such root cause analysis to OIG, within 30 days following Mallinckrodt’s receipt of the Government Pricing Transactions Review Report

C. Additional Rebate Review.

1. For each Reporting Period, the IRO shall identify the NDCs at the NDC-9 level for all Government Reimbursed Products and shall review Mallinckrodt's practices regarding Additional Rebate Amounts due for the NDCs (Additional Rebate Review).
2. For each NDC included in the Additional Rebate Review, the IRO shall evaluate whether the Base Date AMP and/or market date information reported by Mallinckrodt to CMS for the NDC was determined correctly in accordance with the Medicaid Drug Rebate Requirements.
3. For each NDC included in the Additional Rebate Review, the IRO shall assess whether the Additional Rebate Amount due was calculated correctly in accordance with Medicaid Drug Rebate Program Requirements.
4. If the IRO's Additional Rebate Review identifies: (1) any Base Date AMP and/or market date information that was not calculated or reported in accordance with Medicaid Drug Rebate Requirements, Mallinckrodt shall be required to adjust the applicable Base Date AMP and/or market date information, resubmit the adjusted Base Date AMP to CMS and pay any supplemental Additional Rebate Amounts that may be owed; or (2) any Additional Rebate Amount due that was not calculated correctly, Mallinckrodt shall be required to adjust the applicable Additional Rebate Amount calculation and/or pay any supplemental Additional Rebate Amounts that may be owed. Mallinckrodt shall perform a root cause analysis to determine the cause of each error identified by the IRO and provide the findings of such root cause analysis to OIG, within 30 days following Mallinckrodt's receipt of the Government Pricing Transactions Review Report.

D. Review of Arrangements with Independent Charity PAPs. If Mallinckrodt makes monetary donations to Independent Charity PAPs during a Reporting Period, the IRO shall conduct a review and assessment of Mallinckrodt's compliance with the Independent Charity PAP processes, policies, and procedures outlined in Section III.K of the CIA. More specifically, the IRO shall review the arrangements and interactions with all Independent Charity PAPs or disease state funds with which Mallinckrodt entered

charitable donation arrangements during the Reporting Period for which the IRO is conducting the review.

1. For purposes of this IRO review, the term “Reviewed Materials” shall include the following for each Independent Charity PAP reviewed: (a) all budget-related documents; (b) all documents relating to any decision to provide donations to the Independent Charity PAP; (c) any agreements between Mallinckrodt and the Independent Charity PAP; (d) all email, correspondence and other documents reflecting communications and interactions between Mallinckrodt and the Independent Charity PAP; (e) all email, correspondence and other documents reflecting communications and interactions within Mallinckrodt (or between Mallinckrodt and any entity acting on its behalf) relating to the arrangement with the Independent Charity PAP; and (f) other available information relating to the arrangements and interactions between Mallinckrodt and the selected Independent Charity PAP. In addition to reviewing documents and written materials, the IRO shall also interview individuals at Mallinckrodt who have responsibility for arrangements and interactions with Independent Charity PAPs.

2. For each Independent Charity PAP arrangement or interaction reviewed, the IRO shall assess the Reviewed Materials and conduct interviews to evaluate whether the Independent Charity PAP-related activities were conducted in a manner consistent with Mallinckrodt’s policies and procedures including those described in Section III.K and with OIG guidance. More specifically, the IRO Review shall evaluate and identify:

- a. Whether activities relating to arrangements and interactions with the Independent Charity PAP were undertaken by the appropriate individuals, departments, or groups within Mallinckrodt in accordance with Mallinckrodt’s policies and procedures including those outlined in Section III.K;
- b. Whether Mallinckrodt’s commercial organization (as defined in Section III.K) played a role in any arrangement or interaction with the Independent Charity PAP in violation of Mallinckrodt’s policies and procedures or OIG guidance;
- c. Whether Mallinckrodt followed the budgeting policies and practices outlined in Section III.K.2 regarding any initial or annual donation amounts to the Independent Charity PAP and any supplemental amounts;

- d. Whether Mallinckrodt followed the decision-making and approval process outlined in Section III.K of the CIA with regard to any decisions: (i) whether to donate (or continue to donate) to the Independent Charity PAP; (ii) the amount of the donation (including any initial or annual amount and any supplemental amount); and (iii) the criteria governing whether Mallinckrodt would donate to the Independent Charity PAP or any specific disease state fund of such a PAP;
- e. Whether Mallinckrodt followed the criteria, policies, and practices outlined in Section III.K.3 of the CIA in connection with all donations made by Mallinckrodt to any Independent Charity PAP, including as they pertain to the internal review of potential donations and the adherence to the criteria specified in Section III.K.3;
- f. Any communications that occurred between any representatives of Mallinckrodt and the Independent Charity PAP (including the identity of individuals authorized to engage in such communications, the circumstances of such communications, and the subject matter of such communications (including the exchange of any data)) and whether any such communications complied with Mallinckrodt's policies and procedures and OIG guidance;
- g. Any communications that occurred between the groups or departments within Mallinckrodt responsible for Independent Charity PAP functions and the commercial organization and whether any such communications complied with Mallinckrodt's policies and procedures;
- h. Any communications that occurred between any representatives of Mallinckrodt and health care providers or patients relating to assistance available through the Independent Charity PAP and whether any such communications complied with Mallinckrodt's policies and procedures;

- i. Whether, for each donation from Mallinckrodt to any Independent Charity PAP, Mallinckrodt complied with the requirements outlined in Section III.K.3; and
- j. Whether, based on its review, the IRO found that Mallinckrodt exerted influence or control over the Independent Charity PAP in violation of Mallinckrodt's policies and procedures, including those outlined in Section III.K.3.

E. IRO Review of Additional Items. As set forth in Section III.E.2.c of the CIA, for each Reporting Period, the OIG at its discretion may identify up to three additional items for the IRO to review (hereafter "Additional Items").

1. No later than 120 days prior to the end of the applicable Reporting Period, the OIG shall notify Mallinckrodt of the nature and scope of the IRO review to be conducted for each of the Additional Items. Prior to undertaking the review of the Additional Items, the IRO and/or Mallinckrodt shall submit an audit work plan to the OIG for its review. If the OIG does not object to the audit work plan, then the IRO shall conduct the review of the Additional Items based on the work plan. The IRO shall include information about its review of each Additional Item in the Transactions Review Report (including a description of the review conducted for each Additional Item; the IRO's findings based on its review for each Additional Item; and the IRO's recommendations for any changes in Mallinckrodt's systems, processes, policies, and procedures based on its review of each Additional Item).

2. Mallinckrodt may propose to the OIG that its internal audit(s) be substituted, subject to the Verification Review requirements set forth below, for one or more of the Additional Items that would otherwise be reviewed by the IRO for the applicable Reporting Period. The OIG retains sole discretion over whether, and in what manner, to allow Mallinckrodt's internal audit work to be substituted for a portion of the Additional Items review conducted by the IRO.

3. In making its decision, the OIG agrees to consider, among other factors, the nature and scope of Mallinckrodt's planned internal audit work, the results of the Transactions Review(s) during prior Reporting Period(s), and Mallinckrodt's demonstrated audit capabilities to perform the proposed audit work internally. If the OIG denies Mallinckrodt's request to permit its internal audit work to be substituted for a portion of the IRO's review of Additional Items in a given Reporting Period,

Mallinckrodt shall engage the IRO to perform the Review as outlined in this Section III.E.

4. If the OIG agrees to permit certain of Mallinckrodt's internal audit work for a given Reporting Period to be substituted for a portion of Additional Items review, such internal work would be subject to verification by the IRO (Verification Review). In such an instance, the OIG would provide additional details about the scope of the Verification Review to be conducted by the IRO.

F. Transactions Review Report. For each Reporting Period, the IRO shall prepare a report based on its Transactions Review. 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 a description of the sampling unit and universe utilized in performing the procedures for each sample reviewed; 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 Transaction Review Report:

a. Relating to the AMP Transactions Review. In connection with the AMP Transactions Review:

- i. A detailed narrative description of the procedures performed and, where applicable, a description of the sampling unit and universe utilized in performing the procedures for each sample reviewed;

- ii. A full description of documentation and other information, if applicable, relied upon by the IRO in performing the AMP Transactions Review;
- iii. A description of Mallinckrodt's methodologies for calculating AMP (including for authorized generic drugs and for 5i drugs), including its methodologies for determining which customers, classes of trade, and types of transactions are included or excluded for purposes of calculating AMP;
- iv. A description of all Reasonable Assumptions relied on by Mallinckrodt in connection with its calculation of AMP for the Selected AMP NDCs;
- v. A description of the actions taken by Mallinckrodt in accordance with Section III.A.4 above; and
- vi. Any IRO recommendations for changes to Mallinckrodt's policies and procedures or methodologies to correct or address any weaknesses identified during the AMP Transactions Review.

b. Relating to the Best Price Transactions Review. In connection with the Best Price Transactions Review:

- i. A detailed narrative description of the procedures performed;
- ii. A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Best Price Transactions Review;
- iii. A description/identification of the following: (i) the Selected Customers included under Part One of the review; (ii) the number of contracts and a summary of the contract terms associated with each Selected Customer and the Selected BP NDCs, (iii) the Selected BP NDCs tested; (iv) the contract prices and non-

contract pricing terms for each Selected BP NDC tested; and (v) a description of any supporting documentation reviewed;

- iv. For each Selected Customer, a description of the steps taken to determine whether all contract prices and non-contract pricing terms were appropriately considered in Mallinckrodt's determination of the Best Prices for the Selected Best Price NDCs in accordance with Medicaid Drug Rebate Program Requirements;
- v. For any situations involving multiple price concessions in connection with the sale of a Selected BP NDC to a Selected Customer, a description of any instance in which the price concessions were not appropriately considered for purposes of determining Best Price;
- vi. For each Selected Customer, a list of any contract prices and/or non-contract pricing terms that were not properly included in or excluded from Mallinckrodt's Best Price determination for the applicable quarter during the Reporting Period;
- vii. For each Selected Customer, a description of the nature of all Other Arrangements in effect between Mallinckrodt and the customer, a description of the terms of all Other Arrangements (including any amounts paid or other benefits conferred by Mallinckrodt in connection with the Other Arrangements and the time periods of the arrangements), an identification of any NDCs that were associated with the Other Arrangements, a description of the documentation or information reviewed with regard to all Other Arrangements; and an identification of any Other Arrangements (and related NDCs) that were not appropriately considered for purposes of determining Best Price;

- viii. A list of: (a) the Medicaid rebate eligible NDCs identified under Section III.B.2.a; (b) the Best Price reported by Mallinckrodt to CMS for the Medicaid Drug Rebate Program for each of the NDCs under review, and (c) a description of the underlying documentation supporting the transactions associated with each Unique Lower Price;
- ix. A description of the steps and the supporting documentation reviewed to assess the Unique Lower Prices for each of the selected NDCs. If more than one transaction is associated with any of the Unique Lower Prices, the IRO shall also identify how many such transactions exist for each Unique Lower Price;
- x. A list of any Unique Lower Prices not properly excluded from Mallinckrodt's Best Price determination for any of the NDCs reviewed and the corresponding NDC for which the Unique Lower Price was not properly excluded;
- xi. A description of Mallinckrodt's methodologies for calculating Best Price for all Single Source and Innovator Multiple Source Drugs (including authorized generic drugs);
- xii. A description of all Reasonable Assumptions relied on by Mallinckrodt in connection with its calculation of Best Prices;
- xiii. A description of the actions taken by Mallinckrodt in accordance with Section III.B.3 above; and
- xiv. Any IRO recommendations for changes to Mallinckrodt's policies and procedures or methodologies relating to Best Price to correct or address any weaknesses identified during the review.

c. Relating to the Additional Rebate Review. In connection with the Additional Rebate Review:

- i. For each of the NDCs reviewed in the Additional Rebate Review, a listing of the Base Date AMP that Mallinckrodt reported to CMS for the NDC;
- ii. An identification of any NDC for which the IRO determined that an incorrect Base Date AMP and/or incorrect market date information was reported to CMS; an explanation of the IRO's rationale for such determination; an estimate of the financial impact of the incorrect Base Date AMP and/or incorrect market date information on the amount of Additional Rebate Amount due under the Medicaid Drug Rebate Program; and a description of the actions taken by Mallinckrodt in accordance with Section III.C.4 above;
- iii. For each of the NDCs included in the Additional Rebate Review, an assessment of whether the Additional Rebate Amount due was calculated correctly in accordance with Medicaid Drug Rebate Program Requirements. For any NDCs for which the IRO determined the Additional Rebate Amount was not correct, the IRO shall identify the correct Additional Rebate Amount and describe the actions taken by Mallinckrodt in accordance with Section III.C.4 above;
- iv. A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Additional Rebate Review;
- v. A description of Mallinckrodt's methodology for calculating the Additional Rebate Amounts; and
- vi. Any IRO recommendations for changes to Mallinckrodt's policies and procedures or

methodologies to correct or address any weaknesses identified during the Additional Rebate Review.

- d. Relating to the Review of Independent Charity PAP Arrangements (if applicable)
 - i. a list of the Independent Charity PAPs with which Mallinckrodt entered arrangements or had interactions during the Reporting Period;
 - ii. for each Independent Charity PAP for which the IRO reviewed arrangements or interactions during the Reporting Period: (a) a description of the review conducted by IRO; and (b) a summary of all instances in which it appears that Mallinckrodt failed to follow its policies and procedures and/or OIG guidance regarding its arrangements or interactions with an Independent Charity PAP;
 - iii. for each Independent Charity PAP reviewed by the IRO, findings regarding each element specified above in Section III.D above;
 - iv. the findings and supporting rationale regarding any overall weaknesses in Mallinckrodt's systems, processes, policies, procedures, and practices relating to its arrangements and interactions with Independent Charity PAPs; and
 - v. recommendations, if any, for changes in Mallinckrodt's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the review.

- e. Relating to the Review of Additional Items
 - i. for each Additional Item reviewed, a description of the review conducted;

- ii. for each Additional Item reviewed, the IRO's findings based on its review;
- iii. for each Additional Item reviewed, the findings and supporting rationale regarding any weaknesses in Mallinckrodt's systems, processes, policies, procedures, and practices relating to the Additional Item, if any; and
- iv. for each Additional Item reviewed, recommendations, if any, for changes in Mallinckrodt'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 Executive Financial Recoupment Program

Within 150 days after the Effective Date of the CIA, Mallinckrodt shall establish and maintain throughout the term of the CIA two programs relating to compensation for its employees and executives. The first shall be an Employee and Executive Incentive Compensation Restriction Program as described below in Section A. The second shall be an Executive Financial Recoupment Program as described below in Section B.

(A) Employee and Executive Incentive Compensation Restriction Program

Within 150 days after the Effective Date, Mallinckrodt shall develop and maintain throughout the term of the CIA an Employee and Executive Incentive Restriction Compensation Program (Incentive Compensation Program). Mallinckrodt's Incentive Compensation Policy (Policy) outlines the criteria that Mallinckrodt employees and executives must satisfy as a prerequisite to earning incentive compensation. To be eligible for any form of incentive, employees and executives must adhere to and comply with all applicable laws and with Mallinckrodt's rules and policies (including the Code of Conduct, other compliance requirements, and other applicable Mallinckrodt policies, procedures and guidelines.)

Among other things, incentive compensation shall be designed so that financial incentives do not inappropriately incentivize employees or executives to engage in or tolerate improper marketing, promoting, or selling of Mallinckrodt products (including promotion of products to inappropriate prescribers or for uses not approved by the FDA). Under the Policy, employees or executives may not be eligible or may have limited eligibility for incentive compensation where they have been found to have committed or directed significant or non-minor violations of company policies and procedures, have not completed compliance training, or have unsatisfactory job performance.

If an employee or executive (other than Covered Executives who are addressed below in Section (B)) is determined to have violated the law, Code of Conduct, or a significant or non-minor provision of any Company policy, the employee or executive shall be ineligible to receive future incentive payments for a two-year period from the date of such determination. In addition, if Mallinckrodt determines that the employee or executive engaged in Significant Misconduct (as defined below), incentive grants to the individual must be suspended for the current period and must be rescinded for any prior period in which such violations occurred or were discovered. To the extent such an incentive grant was already paid, the employee or executive must promptly repay any incentive already received or the company shall recoup it in accordance with the Policy.

In addition to the requirements outlined above, the Incentive Compensation Program shall require Mallinckrodt to post a link to the executive officer compensation section of its annual Proxy Statement as described in Section III.L.4 of the CIA.

(B) Executive Financial Recoupment Program

Within 150 days after the Effective Date of the CIA, Mallinckrodt shall establish a financial recoupment program that puts at risk of forfeiture and recoupment an amount equivalent to up to three years of annual performance pay (including Cash and Equity Awards, as defined below) for any Covered Executive (as defined below) who is the subject of an Affirmative Recoupment Determination (as defined below). This program shall be known as the Executive Financial Recoupment Program. This recoupment program shall apply to Covered Executives who, at the time of a Recoupment Determination, are either current Mallinckrodt employees or became former Mallinckrodt employees at any time 150 days or more after the Effective Date of the CIA..

Within 150 days after the Effective Date of the CIA, Mallinckrodt shall establish policies and procedures (and modify employment and other contracts as necessary) to provide that incentive awards, bonuses, and other similar awards on an after tax/net basis (collectively “Cash Awards”) for each Covered Executive is at risk of forfeiture in the event of Significant Misconduct that is discovered by Mallinckrodt before the Cash Award is paid. In the event of Significant Misconduct by any Covered Executive, Mallinckrodt shall also reserve the right and full discretion to void and forfeit any unvested stock options, unvested stock appreciation rights, unvested deferred share units, and other unvested rights to receive company common stock (collectively, “Equity Awards”). If Mallinckrodt discovers any Significant Misconduct that would implicate the forfeitures described in this Paragraph by a Covered Executive, it shall evaluate the situation in accordance with the process outlined below and determine whether any forfeiture, and the terms of such forfeiture, shall be implemented.

Within 150 days after the Effective Date of the CIA, Mallinckrodt shall modify and supplement the annual bonus plans applicable to Covered Executives (and any employment agreements, as appropriate) by imposing the eligibility and recoupment conditions described below on future Cash Awards and Equity Awards and making the additional remedies discussed below applicable to all U.S.- based Executive Vice Presidents and the Chief Executive Officer (collectively, “Covered Executives”). Mallinckrodt shall implement policies and procedures and, as necessary, shall modify contracts with Covered Executives so that, beginning no later than calendar year 2022, Cash Awards and Equity Awards may be recouped if an Affirmative Recoupment Determination is made. The forfeiture and recoupment rights described in this Paragraph shall apply prospectively to Covered Executives beginning no later than the calendar year 2022 Cash Award and Equity Award years.

(i) Cash Award Eligibility and Recoupment Conditions. Within 150 days after the Effective Date of the CIA, Mallinckrodt shall implement an eligibility and recoupment condition on Cash Awards that will allow Mallinckrodt, as a consequence of a Triggering Event, to pursue recoupment from Covered Executives of all or any portion of Cash Awards paid to the Covered Executive in the three years prior to the Affirmative Recoupment Determination. These eligibility and recoupment conditions shall be designed to survive the payment of the Covered Executive's Cash Award and the separation of the Covered Executive's employment for a period of three years from the payment of the Cash Award. If payment of any portion of a Cash Award is deferred on a mandatory or voluntary basis, the three-year period shall be measured from the date the bonus would have been paid in the absence of deferral.

If an Affirmative Recoupment Determination is made, Mallinckrodt shall endeavor to recoup any Cash Award from the Covered Executive through reasonable and appropriate means according to the terms of its Cash Award plan (or executive contract if applicable), and to the extent permitted by controlling law of the relevant jurisdiction. If necessary and appropriate to recoup the Cash Award, Mallinckrodt shall file suit against the Covered Executive unless Good Cause exists not to do so. For purposes of the Executive Financial Recoupment Program, Good Cause shall include, but not be limited to, a financial inability on the part of the Covered Executive to repay any recoupment amount or Mallinckrodt's inability to bring such a suit under the controlling law of the relevant jurisdiction.

(ii) Equity Awards and Recoupment Conditions. Within 150 days after the Effective Date of the CIA, Mallinckrodt shall implement an eligibility and recoupment condition on Mallinckrodt's Equity Awards that will allow Mallinckrodt, as a consequence of a Triggering Event, to pursue recoupment from Covered Executives of all or a portion of the value of Equity Awards provided to the Covered Executive for the three years prior to the Affirmative Recoupment Determination Equity Awards. These eligibility and recoupment conditions shall be designed to survive the vesting or distribution of the Equity Award and the separation of a Covered Executive's employment for a period of three years from the vesting or distribution.

If an Affirmative Recoupment Determination is made, Mallinckrodt shall endeavor to recoup all or a portion of the realized value of Equity Awards for the three years prior to an Affirmative Recoupment Determination from the Covered Executive through reasonable and appropriate means according to the terms of its bonus plan (or executive contract if applicable), and to the extent permitted by controlling law of the relevant jurisdiction. If necessary and appropriate to recoup the value of the Equity Award, Mallinckrodt shall file suit against the Covered Executive unless Good Cause exists not to do so.

(iii) Additional Remedies. To the extent permitting by controlling law, for the three years during which the Cash Award and Equity Award eligibility and recoupment conditions exist, if Mallinckrodt reasonably anticipates that a Triggering Event has occurred, and Mallinckrodt has recoupment rights remaining under Paragraphs B(i)-(ii), Mallinckrodt shall have the right to notify the Covered Executive that those rights shall be tolled and thereby extended for an additional three years or until the Recoupment Committee determines that a Triggering Event has not occurred, whichever is earlier, to the extent permitted by controlling law of the relevant jurisdiction.

If, after expiration of the time period specified in Paragraphs B(i)-(ii) above, the Recoupment Committee determines that a Triggering Event has occurred, Mallinckrodt shall make a determination as to whether to pursue available remedies (e.g., filing suit against the Covered Executive) existing under statute or common law to the extent available.

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

- (i) Significant Misconduct (i.e., a violation of a law or regulation or a significant violation of a Mallinckrodt policy) relating to Covered Functions by the Covered Executive that, if discovered prior to payment, would have made the Covered Executive ineligible for a Cash Award or Equity Award in the applicable award plan year or subsequent award plan years; or
- (ii) Significant Misconduct (as defined above) relating to Covered Functions by subordinate employees in the business unit for which the Covered Executive had responsibility on or after 150 days after the Effective Date of the CIA that does not constitute an isolated occurrence and which the Covered Executive knew or should have known was occurring that, if discovered prior to payment, would have made the Covered Executive ineligible for a Cash Award or Equity Award in the applicable award plan year or subsequent award plan years.

(D) Administration of Recoupment Programs. Mallinckrodt shall engage in a standardized, formal process to determine whether a Triggering Event has occurred, and, if so, the extent of the Cash Awards and Equity Awards that will be subject to recoupment or forfeiture by the Covered Executive, and the most appropriate method for recouping Cash Awards or all or a portion of the value of any Equity Awards from a Covered Executive. 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 a Covered Executive shall be referred to as an “Affirmative Recoupment Determination.”

(i) Initiation. Mallinckrodt shall initiate the Recoupment Determination process within 30 days after: (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 Mallinckrodt’s 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 healthcare programs. This written notification shall either identify the Covered Executive(s) potentially at issue or provide information (e.g., a description of the alleged misconduct and the applicable time period) to allow Mallinckrodt to identify the Covered Executive.

(ii) Recoupment Committee. The Recoupment Determination shall be made by a committee of senior executives representing the Compliance, Legal, Internal Controls, Finance and Human Resources groups (Recoupment Committee). The Recoupment Committee may also include members of other functional areas or business groups, as it deems necessary. A Covered Executive shall not participate in the Recoupment Committee while that Covered Executive is subject to a Recoupment Determination. If a Recoupment Determination involves an executive officer (e.g., Chief Executive Officer, Chief Financial Officer, etc.) of Mallinckrodt, a Recoupment Determination for such individual shall be subject to approval by the Board of Directors (or appropriate committee thereof) of Mallinckrodt.

(iii) Recoupment 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 Triggering Event or any written notifications about potential Triggering Events received pursuant to Paragraph D(i)(2) above; ii) make written findings regarding the facts and circumstances associated with the Triggering Event and any written notifications about potential Triggering Events received pursuant to Paragraph D(i)(2) 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 recoupment by the Covered Executive, if any; 3) the means that will be followed to implement the forfeiture and/or secure the recoupment of Cash Awards or Equity Awards from the Covered Executive; and 4) the timetables under which Mallinckrodt will implement the forfeiture and/or attempt to recoup the Cash Award or Equity Award .

For purposes of this Paragraph, a “Delegate” shall refer to the Mallinckrodt personnel to whom the Recoupment Committee has delegated one or more of its required

tasks in furtherance of the Executive Financial Recoupment Program.

(E)Reporting. The Recoupment Committee shall provide annual reports to the Board of Directors (or an appropriate committee thereof) of Mallinckrodt about: i) the number and circumstances of any Triggering Events that occurred during the preceding 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 Covered Executives, 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 years.

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 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 Covered Executives, 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 years. Mallinckrodt shall provide OIG with additional information regarding any Recoupment Determination where a Triggering Event has occurred upon OIG's request.

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

APPENDIX D

MEDICAID DRUG REBATE CERTIFICATION

In accordance with the CIA entered into between Mallinckrodt and OIG, the undersigned Chief Financial Officer of Mallinckrodt plc hereby certifies the following to the best of my knowledge, information, and belief:

1. Mallinckrodt has in place policies and procedures describing in all material respects its methods for collecting, calculating, verifying and reporting the data and information reported to the Centers for Medicare and Medicaid Services (CMS) and/or the State Medicaid programs in connection with the Medicaid Drug Rebate Program (Medicaid Rebate Policies and Procedures);

2. the Medicaid Rebate Policies and Procedures have been designed to ensure compliance with Mallinckrodt's obligations under the Medicaid Drug Rebate Program;

3. Mallinckrodt's Medicaid Rebate Policies and Procedures were followed in all material respects in connection with the calculation and reporting of Average Manufacturer Price (AMP) (including Base Date AMP) and Best Price (BP) for Mallinckrodt's products for each of the following quarters and months:

4. the AMPs and BPs reported to CMS for the above-listed time periods were calculated accurately and reported appropriately, Mallinckrodt paid appropriate rebate amounts (including additional rebate amounts) for the above-listed time periods, and all information and statements made in connection with the submission of AMPs and BPs and in this certification are true, complete, current, and made in good faith.

Signature
Chief Financial Officer
Mallinckrodt plc

Printed Name

Date