

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

**I. PREAMBLE**

Novartis Corporation (Novartis) 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) and with the statutes, regulations, and written directives of the Food and Drug Administration (FDA requirements).

OIG and Novartis Pharmaceuticals Corporation (NPC) previously entered into a CIA effective September 29, 2010 (hereafter “2010 CIA”). Pursuant to Section XI.C of the 2010 CIA, the 2010 CIA could be modified only with written consent of both NPC and OIG. Effective November 19, 2015, NPC entered an Addendum to the 2010 CIA (CIA Addendum). The CIA Addendum extended the term of the 2010 CIA by five years from the effective date of the CIA Addendum. References to the 2010 CIA in this CIA shall refer to the 2010 CIA as subsequently modified by the CIA Addendum.

This CIA shall supersede and replace the 2010 CIA. Contemporaneously with this CIA, NPC is entering into a Settlement Agreement with the United States.

**II. TERM AND SCOPE OF THE CIA**

A. With the exception of those items specified below, the period of the compliance obligations assumed by Novartis 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. The first Reporting Period shall be the period between the Effective Date and December 31, 2020; the following three Reporting Periods shall align to each subsequent calendar year; and the fifth and final Reporting Period shall be the period between January 1, 2024, and the expiration of the CIA on the fifth anniversary of the Effective Date.

The compliance obligations relating to Specialty Pharmacy Related Functions (as defined below) shall expire five years after the effective date of the CIA Addendum in accordance with the terms of Section II of the 2010 CIA. The provisions that will expire shall include the provisions outlined in Sections II.C.5-7, III.B.2.s, III.E.3, III.P, V.B.22-23, V.C.2.c-d and X.A.1.r of this CIA relating to Specialty Pharmacy Related Functions and the provisions in Appendices B and D. In addition, as of that date, Product Related Functions (as defined in Section II.C.4) will no longer include the preparation of materials provided to or created by Specialty Pharmacies, Specialty Pharmacy Related Functions will no longer be within the scope of Covered Functions (as defined in Section II.C.9), and the list of Certifying Employees, as defined in Section III.A.4, will be adjusted accordingly.

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

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

1. For purposes of this CIA, the term "Covered Persons" includes:
  - (a) all owners of Novartis 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 Novartis;
  - (b) all employees of Novartis who are engaged in or who supervise personnel who are engaged in Covered Functions (as defined below in Section II.C.9); and
  - (c) all contractors, subcontractors, agents, and other persons who perform any of the Covered Functions on behalf of Novartis and who, in the course of performing Covered Functions, either (i) interact directly with health care professionals (HCPs), health care institutions (HCIs), or consumers; or (ii) perform activities, provide services, or create materials relating to the Covered Functions and those activities, services, or materials are not reviewed or supervised by a Novartis employee who is a Covered Person prior to execution or dissemination.

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 Novartis more than 160 hours per year, except that any such individual shall become a “Covered Person” at the point when they work more than 160 hours on a Covered Function for Novartis during the calendar year.

2. “Government Reimbursed Products” refers to all Novartis products that are: (a) marketed or sold by Novartis 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 Novartis’ review and approval processes for promotional materials and any applicable review committee(s).

4. The term “Product Related Functions” includes: (a) the preparation or external dissemination of non-promotional materials that are governed by Federal healthcare program and/or FDA requirements and distributed to Healthcare Professionals (HCPs), Healthcare Institutions (HCIs), and payors about Government Reimbursed Products and any materials about Government Reimbursed Products that are provided by NPC to Specialty Pharmacies or created by Specialty Pharmacies at the direction of NPC for use in connection with a Fee-For-Service Arrangement (as defined below), including those functions relating to any applicable review committees and those functions relating to Novartis’ Medical Affairs Department (Medical Affairs); (b) contracting with HCPs licensed in the United States or with HCIs to conduct post-marketing clinical trials, Investigator-Sponsored Studies (ISSs), and any other types of post-marketing studies relating to Government Reimbursed Products; (c) authorship, publication, and disclosure of articles or study results relating to Government Reimbursed Products; and (d) activities related to the submission of information about Government Reimbursed Products to Compendia (such as Drugdex or other compendia of information about Government Reimbursed Products).

5. The term “Arrangements” shall mean every arrangement or transaction that: involves, directly or indirectly, the offer, payment, solicitation, or receipt

of anything of value; and is between NPC and any Specialty Pharmacy and is related to the dispensing of a Government Reimbursed Product by the Specialty Pharmacy. Arrangements involving NPC's payment to a Specialty Pharmacy for services provided shall be referred to as "Fee-for-Service (or FFS) Arrangements." Those Arrangements under which NPC provides a pricing term (such as a discount) to the Specialty Pharmacy shall be referred to as "Discount Arrangements."

6. The term "Specialty Pharmacy Related Functions" includes the development, approval, review, management, implementation and operation of Arrangements.

7. The term "Specialty Pharmacies" shall mean pharmacies located in the United States and licensed and regulated by one or more state pharmacy board(s) that dispense specialty prescription drugs (those pharmaceuticals that typically require special handling, administration, or inventory management), primarily by mail or third party delivery service; to patients with chronic conditions, acute events, or complex or high-cost therapies; and that provide services including patient education, support, and/or coordination with patients and prescribers.

8. 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 Novartis or any entity acting on behalf of Novartis to any independent third-party patient assistance program (Independent Charity PAP); and (b) the operation of, or participation in, any patient assistance program by Novartis or any entity acting on behalf of Novartis that provides free drugs to patients, including Federal health care program beneficiaries, or programs to provide financial assistance to patients in the form of cost-sharing assistance (i.e., co-pay coupons or co-pay cards) (programs described under this Section II.C.8(b) shall be collectively referred to as "Novartis PAPs").

9. The term "Covered Functions" refers to "Promotional Functions," "Product Related Functions," "Specialty Pharmacy Related Functions" and "Contribution and Assistance Related Functions" collectively.

10. The term "Third Party Educational Activity" shall mean any scientific, educational, or professional program, meeting, or event for HCPs conducted by a third party and supported by Novartis, including but not limited to, continuing medical education (CME), disease awareness, or sponsorship of symposia at medical conferences.

11. The term “Third Party Personnel” shall mean personnel who perform Promotional Functions or Product Related Functions who are employees of entities with which Novartis has or may in the future (during the term of this CIA) enter into agreements to co-promote a Government Reimbursed Product in the United States or to engage in joint promotional activities in the United States relating to such a product. Novartis has represented that: (a) Third Party Personnel are employed by entities other than Novartis; (b) Novartis does not control the Third Party Personnel; and (c) it would be commercially impracticable to compel the compliance of Third Party Personnel with the requirements set forth in this CIA. Novartis agrees to promote compliance by Third Party Personnel with Federal health care program and FDA requirements by complying with the provisions set forth below in Sections III.B.1. Provided that Novartis complies with the requirements of Sections III.B.1, Novartis shall not be required to fulfill the other CIA obligations that would otherwise apply to Third Party Personnel who meet the definition of Covered Persons.

12. “Novartis Affiliate” shall mean any entity that is owned or controlled, directly or indirectly, by Novartis Corporation and engages in Covered Functions other than Sandoz, Inc. and any of its direct or indirect wholly owned subsidiaries. Advanced Accelerator Applications USA, Inc. (AAA) is also included within the definition of Novartis Affiliate if, and to the extent that, it engages in Covered Functions. Obligations set forth in Section III below shall apply to the Covered Persons and Covered Functions of the Novartis Affiliates in the same manner as they apply to Novartis, except as noted. All references to “Novartis” in the defined terms set forth in this Section II shall mean Novartis and Novartis Affiliate(s). In addition, the requirements of Section VI, VII, VIII, and X shall apply to both Novartis and any Novartis Affiliate(s).

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

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

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

1. *Chief Compliance Officer.* Within 90 days after the Effective Date, Novartis shall appoint a Chief Compliance Officer and shall maintain a Chief Compliance Officer for the term of the CIA. The Chief Compliance Officer shall be an employee and a member of senior management of Novartis; shall report directly to the

President of Novartis; and shall not be, or be subordinate to, the General Counsel or Chief Financial Officer of Novartis or any Novartis Affiliate or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for Novartis or any Novartis Affiliate. The Chief Compliance Officer shall be responsible for, without limitation:

- a. developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program and FDA requirements;
- b. making periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Novartis and shall be authorized to report on such matters to the Board of Directors at any time. Written documentation of the Chief Compliance Officer's reports to the Board of Directors shall be made available to OIG upon request; and
- c. monitoring the day-to-day compliance activities engaged in by Novartis as well as any reporting obligations created under this CIA.

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

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

2. *Compliance Committee.* Within 90 days after the Effective Date, Novartis shall appoint a Country Compliance Committee with compliance responsibility for all U.S. Novartis entities that are covered by the CIA. The Country Compliance Committee shall, at a minimum, include the Chief Compliance Officer and other members of senior management from Novartis and Novartis Affiliates necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as sales, marketing, legal, Medical Affairs, regulatory affairs, human resources, finance, and operations). The Chief Compliance Officer shall chair the Country Compliance Committee and the Country Compliance Committee shall support the Chief Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of Novartis'

risk areas and shall oversee monitoring of internal and external audits and investigations). The Country Compliance Committee shall meet at least quarterly. The minutes of the Country Compliance Committee meetings shall be made available to OIG upon request.

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

3. *Board of Directors Compliance Obligations.* The Board of Directors (or a committee of the Board) of Novartis (Board) shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA. The Board must include an independent (*i.e.*, non-employee and non-executive) member, whom shall have expertise in compliance.

Novartis 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.

- a. Board Oversight Responsibilities. The Board shall, at a minimum, be responsible for the following:
  - i. meeting at least quarterly to review and oversee Novartis' Compliance Program, including but not limited to the performance of the Chief Compliance Officer and Country Compliance Committee;
  - ii. 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;
  - iii. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board, summarizing its review and oversight of Novartis' compliance with Federal health care program

requirements, FDA requirements, and the obligations of this CIA; and

- iv. 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 FDA requirements (Compliance Expert) to perform a review of the effectiveness of Novartis' Compliance Program (Compliance Program Review). The Compliance Expert shall create a work plan for the Compliance Program Review and 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 Novartis' compliance program. The Board shall review the Compliance Program Review Report as part of its review and oversight of Novartis' compliance program. A copy of the Compliance Program Review report shall be provided to OIG in the Annual Reports submitted by Novartis for the second and fourth Reporting Periods. 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 of Directors has made a reasonable inquiry into the operations of Novartis' Compliance Program including the performance of the Chief Compliance Officer and the Country Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, Novartis has implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements, and the obligations of the CIA.”

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



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

- b. Engagement of Compliance Expert. For the second and fourth Reporting Periods of the CIA, the Board shall engage a Compliance Expert with the background and qualifications necessary to assist the Board in fulfilling the responsibilities described in Section III.A.3.
  - i. Novartis shall provide the following information to OIG within 30 days of the engagement of the Compliance Expert: (a) the identity, address, and phone number of the Compliance Expert; (b) a copy of the engagement letter between the Board and the Compliance Expert; (c) information regarding the Compliance Expert's background and qualifications relating to compliance with Federal health care program and FDA requirements; and (d) a certification from the Compliance Expert that neither he or she nor his or her firm has an engagement with the Board, Novartis, or any Novartis officer that would cause a reasonable person to question the Compliance Expert's objectivity, including a summary of any current engagement between the Compliance Expert and Novartis, the Board or any Novartis officer.
  - ii. Within 30 days of receiving the above information, or any additional information submitted by Novartis in response to a request by OIG, whichever is later, OIG shall notify Novartis if the Compliance Expert is unacceptable. Absent notification from OIG that the Compliance Expert is unacceptable, the Board may continue to engage the Compliance Expert.
  - iii. If a new Compliance Expert is engaged, Novartis shall submit the above-specified information to OIG within 30 days of engagement of the Compliance Expert. Within 30 days after receiving this information, or any additional information submitted by Novartis at the

request of OIG, whichever is later, OIG shall notify Novartis if the Compliance Expert is unacceptable. Absent notification from the OIG that the Compliance Expert is unacceptable, the Board may continue to engage the Compliance Expert.

4. *Management Certifications.* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Novartis and Novartis Affiliate employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable Novartis business unit is in compliance with applicable Federal health care program and FDA requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: Head, Novartis Pharma USA (NPC); Executive Vice President, US Novartis Oncology (NPC); Executive Director, Patient Assistance Programs (Novartis); US Head, Business Planning & Analysis (Novartis); US NBS Country Lead (Novartis Services, Inc.); SVP, Chief Business Officer (AveXis); SVP, Chief Medical Officer (AveXis); SVP, Chief Regulatory Officer (AveXis); SVP, Chief Financial Officer (AveXis); and AAA General Manager, USA (AAA).

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

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

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

Within 120 days after the Effective Date, Novartis 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. Third Party Personnel. Within 120 days after the Effective Date, and annually thereafter by the anniversary of the Effective Date, Novartis shall send, electronically or in hard copy format, a letter to each entity employing Third Party Personnel. The letter shall outline Novartis' obligations under the CIA and its commitment to full compliance with all Federal health care program and FDA requirements. The letter shall include a description of Novartis' Compliance Program. Novartis shall include with the letter a copy of its Code of Conduct and shall request the entity employing Third Party Personnel to either: (a) make a description of Novartis' Compliance Program available to its Third Party Personnel; or (b) represent to Novartis that it has and enforces a substantively comparable compliance program for its Third Party Personnel.

2. Policies and Procedures. Within 120 days after the Effective Date, Novartis 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 Novartis' compliance with Federal health care program and FDA requirements (Policies and Procedures). Throughout the term of this CIA, Novartis shall enforce its Policies and Procedures and shall make compliance with its Policies and Procedures an element of 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 Promotional Functions in compliance with all: (i) applicable Federal healthcare 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); and (ii) all applicable FDA requirements;
- b. appropriate ways to conduct Product Related Functions in compliance with: (i) all applicable Federal healthcare 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); and (ii) all applicable FDA requirements;

- c. the materials and information that may be distributed by Novartis sales representatives (including any contract sales force) about Government Reimbursed Products and the manner in which Novartis sales representatives respond to requests for information about non-FDA approved (or “off-label”) uses of Government Reimbursed Products;
- d. the materials and information that may be distributed by Medical Information and Communications (MIC) and the mechanisms through, and manner in which, MIC receives and responds to requests for information from an HCP or another individual or entity about off-label uses of Government Reimbursed Products; the form and content of information disseminated by Novartis in response to such requests; and the internal review process for the information disseminated;
- e. the manner and circumstances under which medical personnel interact with or participate in meetings or events with HCPs, HCIs, or payors (either alone or with Novartis sales representatives) and the role of the medical personnel at such meetings or events, as well as how they handle responses to requests for information about off-label uses of Government Reimbursed Products;
- f. the materials and information that may be distributed or made available by Novartis through social media and/or direct-to-consumer advertising;
- g. the development, implementation, and review of call plans for sales representatives (including any contract sales force) and other Novartis representatives who promote and sell Government Reimbursed Products;
- h. the development, implementation, and review of all plans for the distribution of samples of, or coupons or vouchers for, Government Reimbursed Products (Sample Distribution

Plans). This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive samples, coupons, or vouchers from Novartis (including, separately, from sales representatives, from Medical Information, or through other channels);

- i. arrangements involving, and circumstances under which, HCPs serve as presenters on behalf of Novartis, including at independent third-party scientific or medical conferences, or participate in speaker training programs (such arrangements are referred to as “Speaker Programs”). Novartis employees who are HCPs who present at Speaker Programs shall be referred to collectively as “Internal Speakers” and the events shall be referred to collectively as “Internal Speaker Programs.” The Policies and Procedures regarding Speaker Programs shall specify that such events may not take place in restaurant venues and that alcohol may not be served or available for purchase at such events. Non-Novartis employee HCPs who are engaged by Novartis to present at Speaker Programs shall be referred to collectively as “External Speakers” and the events shall be referred to collectively as “External Speaker Programs.” The Policies and Procedures relating to External Speaker Programs shall specify that Novartis may only provide remuneration (whether direct or indirect) to an External Speaker under the following circumstances:
  - a. The External Speaker Programs shall be conducted in a virtual format meaning that the External Speakers shall be remote and shall not be in the same location as any audience member.
  - b. The External Speaker Programs may occur only within 18 months of the FDA approval of a new Government Reimbursed Product or a new indication for a Government Reimbursed Product previously approved by the FDA. Such programs may include the opportunity for the real-time discussion of questions

and answers between the External Speaker and any audience member. Novartis may record External Speaker Programs (including the question and answer exchanges) and make such recordings available during and following the expiration of the 18-month period referenced above.

- c. For each newly-approved Government Reimbursed Product or new indication for a Government Reimbursed Product, Novartis may provide no more than a maximum of \$100,000 in total remuneration (whether direct or indirect) to all External Speakers for External Speaker Programs for such product or indication and each External Speaker shall receive no more than a maximum of \$10,000 in total remuneration associated with serving as an External Speaker for such product or indication. The above-referenced monetary limits shall include remuneration for speaking and for speaker training, but shall not include any direct payment by Novartis for travel and travel-related expenses (e.g., hotels, rental cars, etc.)
  
- j. consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including but not limited to arrangements for the following types of activities: presentations, appearances in Novartis-sponsored communications and materials, consultant task force meetings, advisory boards, ad hoc advisory activities, and any other financial engagement or arrangement with an HCP or HCI) and all events and expenses relating to such engagements or arrangements;
  
- k. programs by HCPs to educate sales representatives, including but not limited to presentations by HCPs at sales meetings, preceptorships, tutorials, and experience-based learning activities;
  
- l. sponsorship or funding of grants (including educational grants) or charitable contributions;

- m. funding of, or participation in, any Third Party Educational Activity as defined in Section II.C.10 above;
- n. review of promotional, reimbursement, and disease state materials and information intended to be disseminated outside Novartis by appropriate qualified personnel (such as regulatory, medical, and/or legal personnel) in a manner designed to ensure that legal, regulatory, and medical concerns are properly addressed during Novartis' review and approval process and are elevated when appropriate;
- o. compensation (including through salaries, bonuses, or other means) for Covered Persons engaged in Promotional Functions;
- p. the submission of information about any Government Reimbursed Product to any compendia such as Drugdex or other published source of information used in connection with the determination of coverage by a Federal health care program for the product (hereafter "Compendia"). This includes any initial submission of information to any Compendia and the submission of any additional, updated, supplemental, or changed information (including any changes based on Novartis' discovery of erroneous or scientifically unsound information or data associated with the information in the Compendia and the publication of new study results);
- q. sponsorship or other support of post-marketing clinical trials and all other post-marketing studies of Government Reimbursed Products and support of ISSs (collectively, "Research"), including the decision to provide financial or other support for such Research; the manner in which Research support is provided; the publication of information about the Research (including the publication of information about the Research results and trial outcomes); and uses made of publications relating to Research;

- r. authorship of journal articles or other publications about Government Reimbursed Products or about therapeutic areas or disease states that may be treated with Government Reimbursed Products, including, but not limited to, the disclosure of any and all financial relationships between the author and Novartis or other potential conflicts of interest that might bias the author's work; the identification of all authors or contributors (including professional writers) associated with a given publication; and the scope and breadth of research results made available to each author or contributor;
- s. Specialty Pharmacy Related Functions as defined in Section II.C.6 and Arrangements as defined in Section II.C.5. These Policies and Procedures shall be designed to ensure that NPC's Arrangements with Specialty Pharmacies are used for legitimate and lawful purposes in accordance with the federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b(b)) and other applicable Federal health care program and FDA requirements.

The Policies and Procedures shall include a requirement that all Arrangements be subject to a written review and approval process. With regard to FFS Arrangements, the Policies and Procedures shall include requirements about the business need for the Arrangements, the services provided under the Arrangements, and the amount of compensation provided under the Arrangements (including that the amount of compensation is fair market value for the service). For FFS Arrangements, including those that include a medication therapy management program, the Policies and Procedures shall require that: 1) the services be provided in a manner that would not reasonably be expected to undermine or otherwise interfere with the clinical judgment of the patients' prescribing health care professionals; and 2) NPC not direct or encourage a Specialty Pharmacy to cause or encourage health care professionals to prescribe, or patients to ask their health care professionals to prescribe, a Government Reimbursed Product over any other medically-appropriate product. The Policies and Procedures shall also require that



the terms of FFS Arrangements prohibit the offering of any financial inducement by a Specialty Pharmacy to any health care professional to prescribe or switch patients to a Government Reimbursed Product;

- t. appropriate ways to conduct Contribution and Assistance Related Functions in compliance with: (i) all applicable Federal healthcare 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;
- u. arrangements and interactions with (including donations to and sponsorship of) Independent Charity PAPs. These Policies and Procedures shall be designed to ensure that Novartis' arrangements and interactions comply with all applicable Federal health care program requirements. The Policies and Procedures shall also be designed to ensure that Novartis' 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);
- v. the operation of, or participation in, any Novartis PAP. These Policies and Procedures shall be designed to ensure that Novartis' 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 Novartis' operation of or participation in any such Novartis PAP 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);

- w. the materials and information that may be distributed by appropriate Novartis personnel about Independent Charity PAPs or Contribution and Assistance Related Functions and the manner in, and circumstances under, which appropriate Novartis personnel may respond to requests for information about Independent Charity PAPs or Contribution and Assistance Related Functions; and
- x. disciplinary policies and procedures for violations of Novartis' Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

At least annually (and more frequently, if appropriate), Novartis 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, Novartis shall develop a written plan (Training Plan) that outlines the steps Novartis will take to ensure that: (a) all Covered Persons receive at least annual training regarding Novartis' 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 Novartis Policies and Procedures and other requirements applicable to Covered Functions. The Training Plan shall include information regarding the following: training topics, categories of Covered Persons and required to attend each training session, length of the training session(s), schedule for training, and format of the training. Novartis 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 120 days after the Effective Date, each member of the Board of Directors 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 member or within 120 days after the Effective Date, whichever is later.

3. *Training Records.* Novartis 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 Internal Review Process

Within 120 days after the Effective Date, Novartis shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with each Government Reimbursed Product, including risks associated with the sales, marketing, and promotion of such products, risks associated with Novartis' operation of any Novartis PAP, and risks associated with its arrangements and interactions with any Independent Charity PAP. The Country Compliance Committee shall be responsible for implementation and oversight of the risk assessment and internal review process. The risk assessment and internal review process shall be conducted at least annually and shall require Novartis 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. Novartis 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, Novartis 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 Appendices A and B to this CIA, which are incorporated by reference.

- b. *Retention of Records.* The IRO and Novartis shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Novartis) related to the reviews.
- c. *Responsibilities and Liabilities.* Nothing in this Section III.E. affects Novartis' responsibilities or liabilities under any criminal, civil, or administrative laws or regulations applicable to any Federal health care program including, but not limited to, the Anti-Kickback Statute.
- d. *Access to Records and Personnel.* Novartis shall ensure the IRO has access to all records and personnel necessary to complete the reviews listed in this Section III.E., and that all records furnished to the IRO are accurate and complete.

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

- a. *Systems Review.* The Systems Reviews shall assess Novartis' systems, processes, policies, and procedures relating to the Covered Functions. If there are no material changes in Novartis' relevant systems, processes, policies, and procedures, the Systems Reviews shall be performed for the second and fourth Reporting Periods. If Novartis 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 second and fourth Reporting Periods, as set forth more fully in Appendix C.

- b. *Transactions Review.* As further detailed in Appendix C, the Transactions Reviews 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 C, the Transactions Review shall include several components.
- c. *Additional Items Review.* Each IRO review shall also include a review of up to three additional areas or practices of Novartis identified by OIG in its discretion (hereafter “Additional Items”). For purposes of identifying the Additional Items to be included in the IRO review for a particular Reporting Period, OIG will consult with Novartis and may consider internal audit and monitoring work conducted by Novartis, the Government Reimbursed Product portfolio, the nature and scope of Novartis’ promotional practices and arrangements with HCPs and HCIs, and other information known to it.

3. *Arrangements Review.* As set forth more fully in Appendix D, the IRO Arrangements Review shall consist of two components: Systems Review and Transactions Review.

- a. *Systems Review.* The Systems Review shall assess NPC’s systems, processes, policies, and procedures relating to Arrangements. If there are no material changes in NPC’s relevant systems, processes, policies, and procedures, then NPC will have completed its Arrangements Systems Review pursuant to the CIA Addendum. If NPC materially changes its relevant Arrangements systems, processes, policies, and procedures during the first Reporting Period, the IRO shall perform an Arrangements Systems Review for that Reporting Period, as set forth more fully in Appendix D.
- b. *Arrangements Transaction Review.* The Arrangements Transactions Review shall be performed annually and shall cover the first Reporting Period. The IRO(s) shall perform all components of each annual Arrangements Transaction Review. As set forth more fully in Appendix D, the

Arrangements Transactions Review shall include several components.

4. *IRO Review Reports.* The IRO shall prepare a report based upon each IRO review performed (IRO Review Report). Information to be included in the IRO Review Report is described in Appendices C and D.

5. *Independence and Objectivity Certification.* Each IRO shall include in its report(s) to Novartis 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 Appendices A and B to this CIA. The IRO's certification(s) shall include a summary of current and prior engagements between Novartis and IRO.

F. Disclosure Program

Within 90 days after the Effective Date, Novartis shall establish a Disclosure Program that includes a mechanism (e.g., a toll free compliance telephone line) to enable individuals to disclose, to the Chief Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Novartis' policies, conduct, practices, or procedures with respect to a Federal health care program or an FDA requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. Novartis shall appropriately publicize the existence of the Disclosure Program and the disclosure mechanism 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 Novartis' Covered Persons shall be expected to report suspected violations of any Federal health care program or FDA requirements to the Chief Compliance Officer or other appropriate individual designated by Novartis. Upon receipt of a disclosure, the Chief Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Chief Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the

appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Novartis shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Chief Compliance Officer (or designee) shall maintain a disclosure log and shall record all disclosures, whether or not related to a potential violation of criminal, civil or administrative law related to the Federal health care programs or FDA requirements, in the disclosure log within two business days of receipt of the disclosure. The disclosure log shall include a summary of each disclosure received (whether anonymous or not), the individual or department responsible for reviewing the disclosure, the status of the internal 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 the Federal health care programs; or
  - ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded.
- b. “Exclusion List” means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at <http://www.oig.hhs.gov>).

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

- a. Novartis 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. Novartis shall screen all current Covered Persons against the Exclusion List within 120 days after the Effective Date and on an annual basis thereafter.
- c. Novartis shall maintain a policy requiring all Covered Persons to disclose immediately if they become an Ineligible Person.

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

3. *Removal Requirement.* If Novartis has actual notice that a Covered Person has become an Ineligible Person, Novartis shall remove such Covered Person from responsibility for, or involvement with, Novartis' 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 Novartis 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, Novartis shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary, or the accuracy of any claims submitted to any Federal health care program.

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



1. *Employee and Executive Incentive Compensation Restriction Program.* Novartis agrees to develop and maintain throughout the term of the CIA policies and procedures that shall: (1) be designed to ensure that financial incentives do not improperly motivate sales representatives or their direct managers to engage in improper promotion, sales and marketing of Government Reimbursed Products; and (2) include mechanisms, where appropriate, to exclude from incentive compensation any sales that may indicate off-label promotion of Government Reimbursed Products (Employee and Executive Incentive Compensation Program). The specific terms and conditions of the Employee and Executive Incentive Compensation Program are described in Appendix E to this CIA.

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

I. Notification of Government Investigation or Legal Proceeding

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

J. Reportable Events

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

- a. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;

- b. a matter that a reasonable person would consider a probable violation of FDA requirements relating to the promotion of Government Reimbursed Products, unless otherwise reported to the FDA in accordance with Section III.K below;
- c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or
- d. the filing of a bankruptcy petition by Novartis.

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

2. *Reporting of Reportable Events.* If Novartis determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Novartis shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. Novartis shall not be required to report as a Reportable Event a matter that is the subject of an ongoing investigation or legal proceeding by a government entity or its agents if disclosed under Section III.1 above.

3. *Reportable Events under Sections III.J.1.a and III.J.1.b.* For Reportable Events under Sections III.J.1.a and b, the report to OIG shall include:

- a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event, the period during which the conduct occurred, and the names of individuals and entities believed to be implicated, including an explanation of their roles in the Reportable Event;
- b. a statement of the Federal criminal, civil or administrative laws that are probably violated by the Reportable Event, if any;
- c. the Federal health care programs affected by the Reportable Event, if any;

- d. a statement of the FDA requirements probably violated by the Reportable Event, if any; and
- e. a description of Novartis' actions taken to correct the Reportable Event and prevent it from recurring.

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

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

5. *Reportable Events under Section III.J.1.d.* For Reportable Events under Section III.J.1.d, the report to OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program and/or FDA requirements implicated.

K. Notification of Communications with FDA

Within 30 days after the date of any written report, correspondence, or communication between Novartis and the FDA that materially discusses Novartis' or a Covered Person's actual or potential non-compliance with any FDA requirements relating to the development, approval, marketing, promotion or sale of Novartis' products, Novartis shall provide a copy of the report, correspondence, or communication to OIG. Novartis shall also provide written notice to OIG within 30 days after the resolution of

any such disclosed matter, and shall provide OIG with a description of the findings and/or results of the matter, if any. The notification requirements in this Section shall not apply to any correspondence with the FDA regarding manufacturing.

L. Monitoring of Promotional Activities

Within 120 days after the Effective Date, Novartis shall establish a comprehensive monitoring program designed to evaluate and monitor promotional activities including Speaker Program activities and the activities of field sales personnel (hereafter, “Promotional Monitoring Program” or “PMP”). The PMP shall be a formalized process designed to directly and indirectly observe and monitor Speaker Program activities and the activities of field sales personnel. As described in more detail below, the PMP shall include: (1) controls around and monitoring of External Speaker Programs; (2) controls around and review of Internal Speaker Programs; (3) direct field observations (Observations) of sales personnel; and (4) the monitoring and review of other records relating to sales personnel’s interactions with HCPs and HCIs (Records Reviews).

1. *External Speaker Program Activities.*

- a. Within 120 days after the Effective Date, Novartis shall establish a process for planning, reviewing, approving, and implementing External Speaker Programs (as defined in Section III.B.2.i). Novartis shall identify the business needs for External Speaker Programs. Novartis compliance personnel shall be involved in the review and approval process for all External Speaker Programs. The External Speaker Programs shall be implemented in a manner consistent with the Policies and Procedures outlined in Section III.B.2.i, including that such programs may occur only within 18 months of the FDA approval of a new Government Reimbursed Product or a new indication for a previously-approved Government Reimbursed Product and shall be subject to the monetary caps outlined in Section III.B.2.i.
- b. External Speakers shall be selected based on objective, standardized criteria without any involvement by field sales representatives. Field sales representatives may not nominate or recommend any individual to serve as an External Speaker.

- c. Novartis shall ensure that External Speakers are paid according to centrally managed, pre-established rate structure that is based on an independent fair-market analysis.
- d. Novartis and the Novartis Affiliates shall establish centralized systems to track all remuneration and expenses (including speaker fees, travel, and other expenses) paid to each External Speaker and the total remuneration paid in connection with all External Speaker Programs associated with each Government Reimbursed Product.
- e. Novartis shall require all External Speakers to complete training and enter written agreements that describe the scope of work to be performed, the speaker fees to be paid, and compliance obligations for the speakers (including requirements regarding the use of Novartis approved materials and requirements that External Speakers may not directly or indirectly promote the product for off-label uses).
- f. Consistent with Section III.B.2.i, all External Speaker Programs shall be in a virtual format, meaning that the External Speaker shall not be in the same location as any audience member. Novartis shall not organize or facilitate a group gathering of HCPs outside of an individual HCP's institution or office setting for purposes of participating in or viewing any External Speaker Program.
- g. Novartis shall institute an External Speaker Monitoring Program under which Novartis compliance or other appropriately trained Novartis personnel who are independent from the functional area being monitored or third party consultants appropriately trained by Novartis and under the supervision of Novartis (Monitoring Personnel) shall review four External Speaker Programs for each newly-approved Government Reimbursed Product or each newly-approved indication for any Government Reimbursed Product (External Speaker Program Audits). Monitoring Personnel shall assess

whether the External Speaker Programs were conducted in a manner consistent with Novartis' Policies and Procedures.

2. *Internal Speaker Program Activities.*

- a. Within 120 days after the Effective Date, Novartis shall establish a process for planning, reviewing, approving, and implementing Internal Speaker Programs (as defined in Section III.B.2.i). As part of the process, Novartis shall identify the business needs for Internal Speaker Programs. Novartis compliance personnel shall be involved in the review and approval process for any Internal Speaker Programs planned in connection with a Government Reimbursed Product, including any subsequent modification of the planned programs. Internal Speaker Programs shall be implemented in a manner consistent with the Policies and Procedures outlined in Section III.B.2.i.
- b. Novartis shall maintain records relating to all Internal Speaker Programs, including records of the attendees at such Programs. Consistent with Section III.B.2.i, Internal Speaker Programs shall not take place in a restaurant venue and alcohol may not be provided or available for purchase.
- c. Novartis shall provide appropriate training to all Novartis employees who are Internal Speakers. The training shall address compliance obligations associated with the programs (including requirements regarding the use of Novartis approved materials and requirements that speakers may not directly or indirectly promote the product for off-label uses).
- d. Novartis shall require certifications from the Internal Speakers or other Novartis personnel that each Internal Speaker Program complied with Novartis requirements. In the event of non-compliance, Novartis shall require the identification of the policy violation and ensure appropriate follow up activity to address the violation.

Novartis shall maintain the controls around External and Internal Speaker Programs as described above and shall conduct its External Speaker Program Audits as described above throughout the term of the CIA.

3. *Observations.* As a component of the PMP, Monitoring Personnel shall conduct observations of field sales representatives (including any contract sales personnel) to assess whether the interactions between field sales representatives and HCPs and HCIs are consistent with applicable legal requirements and with Novartis' Policies and Procedures. These observations shall be full day ride-alongs with field sales representatives (Observations), and each Observation shall consist of directly observing all meetings between a sales representative and HCPs and HCIs during the workday. The Observations shall be scheduled throughout the year, judgmentally selected by Monitoring Personnel, include a review of each therapeutic area and actively promoted Government Reimbursed Product, and be conducted across the United States.

At the completion of each Observation, Monitoring Personnel shall prepare a report which includes:

- 1) the identity of the sales representative;
- 2) the identity of the Monitoring Personnel who conducted the Observation;
- 3) the date and duration of the Observation;
- 4) the product(s) promoted during the Observation;
- 5) an overall assessment of compliance with Novartis Policies and Procedures; and
- 6) the identification of any potential off-label promotional activity or other improper conduct by the field sales representative.

Monitoring Personnel shall conduct at least 60 Observations during each Reporting Period. Monitoring Personnel shall have access to all relevant records and information necessary to assess field representatives' interactions with HCPs and HCIs and to identify potential or actual compliance violations.

4. *Records Reviews.* As a component of the PMP, Novartis shall also review various types of records to assess field representatives' interactions with HCPs and HCIs and to identify potential or actual compliance violations.

- a. For each Reporting Period, Novartis shall develop and implement a plan for conducting Records Reviews associated

with at least five Government Reimbursed Products. The Records Reviews shall include a review of records relating to the activities of sales representatives using either a risk-based targeting approach or a random sampling approach.

- b. The Records Reviews shall include the monitoring and review of:
  - (i) records and systems associated with field sales representatives' interactions with HCPs and HCIs (including records relating to promotional activities, samples, travel and entertainment, expense reports, any payments to HCPs or HCIs, and sales communications from managers);
  - (ii) message recall studies or other similar records (such as Verbatims) purporting to reflect the details of field sales representatives interactions with HCPs and HCIs;
  - (iii) records relating to requests inquiries or requests for medical information about the Government Reimbursed Products under review;
  - (iv) field sales representative call notes;
  - (v) field sales representatives' e-mails and other electronic records; and
  - (vi) recorded results of the Observations of field sales force representatives, coaching guides, and district manager notes.

5. *Reporting and Follow-up.* Results from the PMP shall be compiled and reported to the Compliance Officer for review and remediation as appropriate. If any potential compliance issue is identified during any portion of the PMP, Novartis shall investigate the incident consistent with established Policies and Procedures for the handling of investigations. As part of the investigative procedures, findings shall be made and all necessary and appropriate responsive action (including disciplinary action) and corrective action shall be taken, including the disclosure of Reportable Events



pursuant to Section III.J above, as applicable. Any compliance issues identified during the PMP and any corrective action shall be recorded in the files of the Compliance Officer.

M. Monitoring of Non-Promotional Activities

Within 120 days after the Effective Date, Novartis shall develop and implement a monitoring program for consultant arrangement activities and medical education grants. This program shall be referred to as the Non-Promotional Monitoring Program (NPMP).

1. *Consulting Arrangement Activities.* To the extent that Novartis engages HCPs who are not Novartis employees for services other than for External Speaker Programs, such HCPs shall be referred to herein as “Consultants”.
  - a. Novartis shall require all Consultants to enter written agreements describing the scope of work to be performed, the consultant fees to be paid, and compliance obligations for the Consultants. Consultants shall be paid according to a centrally managed, pre-set rate structure that is determined based on an independent fair-market value analysis.
  - b. Within 120 days after the Effective Date, Novartis shall establish a process to develop an annual budgeting plan that identifies the business needs for, and the estimated numbers of, the various Consultant engagements and activities to occur during the following year. The annual Consultant budgeting plan shall also identify the budgeted amounts to be spent on Consultant-related activities. Novartis compliance personnel shall be involved in the review and approval of such plans, including any subsequent modification of an approved plan. The purpose of this review shall be to ensure that Consultant arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements and Novartis Policies and Procedures.
  - c. Within 120 days after the Effective Date, Novartis shall establish a process to ensure that a needs assessment has been completed to justify the retention of a Consultant prior to the

retention of the Consultant. The needs assessment shall identify the business need for the retention of the Consultant and provide specific details about the consulting arrangement (e.g., information about the numbers and qualifications of the HCPs to be engaged, the agenda for the proposed meeting, and a description of the proposed work to be done and the type of work product to be generated). Any deviations from the Consultant budgeting plans shall be documented in the needs assessment form and shall be subject to review and approval by Novartis compliance personnel.

- d. Novartis shall require that Consultants be selected with no involvement by field sales representatives. Field sales representatives may not nominate or recommend any individual to serve as a Consultant. Consultants shall be selected based on objective, standardized criteria for the particular consulting activity.
- e. Novartis and the Novartis Affiliates shall establish centralized systems to track all services provided by Consultants and the remuneration and expenses (including travel and other expenses) paid to each Consultant. Novartis shall ensure that each Consultant performed the work for which the Consultant was engaged and that, as applicable, Novartis received the work product generated by the Consultant.
- f. Within 120 days after the Effective Date, Novartis shall establish a Consultant Monitoring Program through which it shall conduct audits (Consultant Program Audits) of at least 60 Consultant engagements with HCPs during each Reporting Period. Of this number, at least 30 ad hoc consulting arrangements, at least seven advisory board arrangements, at least seven arrangements relating to marketing and sales meetings, and arrangements relating to at least eight medical events shall be reviewed. The Consultant Monitoring Program shall select Consultant arrangements for review using either a risk-based targeting approach or a random sampling approach. Monitoring Personnel shall review needs assessment documents, Consultant contracts, and materials

relating to the program or work of the Consultant (including work product resulting from any program or event), in order to assess whether the programs and arrangements were conducted in a manner consistent with Novartis' Policies and Procedures. Results from the Consultant Program Audits, including the identification of potential violations of Novartis policies, shall be compiled and reported to the Chief Compliance Officer (or compliance personnel designee) for review and follow up as appropriate.

2. *Medical Education Grant Activities.* Within 120 days after the Effective Date, Novartis and the Novartis Affiliates shall establish grants management systems which shall be the exclusive mechanism through which requestors may request or be awarded grants for independent medical education grants, other grant activities, and non-patient assistance program charitable contributions supported by Novartis. Novartis' sales and marketing personnel shall have no involvement in, or influence over, the review and approval of medical education grants or charitable contribution requests. Grant and charitable contribution requests shall be submitted through the centralized grants management systems and processed in accordance with standardized, objective criteria developed by Novartis (such as based upon the qualifications of the requestor, or the quality of the program funded by the grant.) In addition, the grants or charitable contributions shall be provided only pursuant to a written agreement with the funding recipient, and if payments to the funding recipient are consistent with the written agreement. Novartis shall continue the grant and charitable contribution process described above (or an equivalent process) throughout the term of the CIA, and shall notify OIG in writing at least 60 days prior to the implementation of any new system subsequent to the Effective Date.

Within 120 days after the Effective Date, Novartis shall establish a Grants Monitoring Program through which it shall conduct audits for each Reporting Period of at least 30 medical education grants. The Grants Monitoring Program shall select grants for review both on either a risk-based targeting approach or a random sampling approach. Monitoring Personnel shall review proposal documents (including grant requests), approval documents, contracts, payments and materials relating to the grant management system's review of the requests, and documents and materials relating to the grants and any events or activities funded through the grants in order to assess whether the activities were conducted in a manner consistent with Novartis' Policies and Procedures. Results from the Grants Monitoring Programs, including the identification of potential violations

of policies, shall be compiled and reported to the Chief Compliance Officer (or compliance personnel designee) for review and follow-up as appropriate.

3. *Follow Up Reviews and Reporting.* In the event that a potential violation of Novartis' Policies and Procedures or of legal or compliance requirements, including but not limited to potential improper promotion, are identified during any aspect of the NPMP, Novartis shall investigate the incident consistent with established policies and procedures for the handling of investigations and shall take all necessary and appropriate responsive action (including disciplinary action) and corrective action, including the disclosure of Reportable Events pursuant to Section III.J above, if applicable.

Novartis shall include a summary of the NPMP and the results of the NPMP as part of each Annual Report. As part of each Annual Report, Novartis also shall provide OIG with descriptions of any instances identified through the NPMP in which it was determined that improper promotion of Government Reimbursed Products occurred or the activities violated Novartis' Policies and Procedures, and a description of the action(s) that Novartis took as a result of such determinations. Novartis shall make the documents relating to the NPMP available to OIG upon request.

N. Notice to Health Care Providers and Entities

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

As you may be aware, Novartis Pharmaceuticals Corporation recently entered into a civil and administrative settlement with the United States and the State of New York in connection with Novartis' promotion of several of its cardiovascular and other products. This letter provides you with additional information about the global settlement, explains Novartis' commitments going forward, and provides you with access to information about those commitments.

In general terms, the government alleged that Novartis Pharmaceuticals Corporation violated the Federal Anti-kickback statute and caused the submission of false claims to Federal health care programs through its speaker programs and other interactions with health care practitioners

during which the company promoted certain of its cardiovascular and other drugs. To resolve its liability for remuneration Novartis agreed to enter a civil settlement agreement and pay \$678 million. More information about this settlement may be found at the following: **[Novartis shall include a link to the USAO, OCL, and its own websites in the letter.]**

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

Please call Novartis at [insert toll free number] or visit us at [insert web link] if you have questions about the settlement referenced above. Please call Novartis at [insert toll free number] or visit us at [insert web address] to report any instances in which you believe that a Novartis representative inappropriately promoted a product or engaged in other questionable conduct. Alternatively, you may report any improper conduct associated with prescription drug marketing committed by a Novartis Representative to the FDA's Office of Prescription Drug Promotion at 301-796-1200. You should direct medical questions or concerns about Novartis products to [insert toll free number].

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

O. Reporting of Payments to Covered Recipients

1. *Reporting of Payment Information.* Within 90 days after the Effective Date, Novartis shall post on its website a description of the types of Payments it makes to Covered Recipients and include a link to CMS's Open Payments Data website ([www.openpaymentsdata.cms.gov](http://www.openpaymentsdata.cms.gov)). Novartis also shall include on its website instructions regarding how to utilize the CMS Open Payments Data search tool to search for information regarding Payments provided to Covered Recipients from Novartis.

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

P. Specialty Pharmacy Related Functions

NPC shall develop and implement the following procedures and requirements specifically designed to ensure that its relationships with Specialty Pharmacies comply with the Anti-Kickback Statute.

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

- a. creating and/or maintaining a centralized tracking system for all existing and new or renewed Arrangements (Arrangements Tracking System);
- b. tracking remuneration to and from all parties to Arrangements;
- c. tracking service and activity logs to ensure that parties to the Arrangement are performing the services required under the applicable Arrangement(s) (if applicable);
- d. establishing and implementing a written review and approval process for all Arrangements, the purpose of which is to ensure that all new and existing or renewed Arrangements do not violate the Anti-Kickback Statute and that includes at least the following: (i) a legal review of all Arrangements by

counsel with expertise in the Anti-Kickback Statute, (ii) for FFS Arrangements, a process for specifying the business need or business rationale for each service provided under the FFS Arrangement and determining and documenting the fair market value of the remuneration specified in the FFS Arrangement;

- e. requiring the Chief Compliance Officer (or designee) to review the Arrangements Tracking System, internal review and approval process, and other Arrangements Procedures on at least an annual basis and requiring the Chief Compliance Officer to provide a report on the results of such review to the Country Compliance Committee; and
- f. implementing effective responses when suspected violations of the Anti-Kickback Statute are discovered, including disclosing Reportable Events.

2. *New or Renewed Arrangements.* Prior to entering into new Arrangements or renewing existing Arrangements, in addition to complying with the Arrangements Procedures set forth above, NPC shall comply with the following requirements (Arrangements Requirements):

- a. ensure that each Arrangement is set forth in writing and signed by NPC and the other parties to the Arrangement;
- b. NPC shall provide each party to the Arrangement with a copy of its Code of Conduct and relevant Policies and Procedures relating to the Anti-Kickback Statute;
- c. include in the written agreement a certification by the parties to the Arrangement that the parties shall not violate the Anti-Kickback Statute with respect to the performance of the Arrangement; and
- d. maintain on file a certification by the Vice President of Patient Access and Health Policy, the Vice President of Managed Markets and Market Access, the Vice President of Managed Markets Finance, and an appropriate manager with

responsibility for the Arrangement, with respect to each Arrangement and provided at or about the time the Arrangement was first entered into and again upon or about each anniversary of the date such Arrangement was first entered into, that the written agreement for such Arrangement sets forth all material terms of the Arrangement.

3. *Arrangements Tracking System Verification and Certification.* For each Reporting Period, the Chief Compliance Officer shall review the entries in NPC's Arrangements Tracking System and certify in writing to OIG that, to the best of his or her knowledge, the Arrangements Tracking System is complete and accurate, except for any discrepancies identified. The Chief Compliance Officer shall provide an explanation for: (1) any Arrangements found to have been missing from the Arrangements Tracking System; and (2) any entries in the Arrangements Tracking System found to have been incomplete or inaccurate.

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

Q. Independent Charity Patient Assistance Program Activities

To the extent that Novartis makes monetary donations to Independent Charity PAPs, it shall implement the policies, procedures, and practices set forth in this Section III.Q within 120 days after the Effective Date. Novartis shall continue the Independent Charity PAP policies, procedures, and practices described below (or equivalent processes) throughout the term of the CIA, and shall notify OIG in writing at least 60 days prior to the implementation of any modifications to such policies, procedures, and practices.

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

- a. The ICCF Executive Committee shall be separate and independent from Novartis' commercial organization.



- b. The ICCF Executive Committee shall operate independently from Novartis' commercial organization and Novartis' 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. Novartis shall vest in the ICCF Executive Committee sole responsibility and authority for communicating with Independent Charity PAPs regarding Novartis' donations to such PAPs and Novartis' commercial organization shall not communicate with, influence, or be involved in any communications with, or receive information from the Independent Charity PAPs.
- d. Novartis' ICCF Executive Committee 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 Novartis.

2. *Budgeting Process.* Novartis' ICCF Executive Committee shall establish a budget process to be followed for Novartis' donations to Independent Charity PAPs that meets the following requirements:

- a. The ICCF Executive Committee 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. Novartis 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 ICCF Executive Committee 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 ICCF Executive Committee 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 ICCF Executive Committee. 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 Novartis Policies and Procedures.
- e. The commercial organization shall have no involvement in the budget process, and the budget to be used for donations to Independent Charity PAPs shall not be based on monies allocated to the ICCF Executive Committee from the commercial organization.

3. *Criteria Relating to Donations to Independent Charity PAPs.* The ICCF Executive Committee (with input from the legal department 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. The criteria shall be designed to ensure that the Independent Charity PAP does not function as a conduit for payments or other benefits from Novartis to patients and does not impermissibly influence patients' drug choices. In addition, Novartis agrees that it will donate to an Independent Charity PAP only if the following criteria are satisfied:

- a. Novartis 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, Novartis 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. Novartis 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. Novartis does not and shall not solicit or receive (directly or indirectly through third parties including hubs or pharmacies) any data or information from or about the Independent Charity PAP that would enable it to correlate the amount or frequency of its donations with support for Novartis' products or services.
- d. Novartis does not and shall not provide donations for a disease state fund that covers only a single product or that covers only Novartis' products.
- e. Personnel from Novartis' legal and compliance departments shall review all proposed donations and arrangements between Novartis and any Independent Charity PAP prior to such donations being made or arrangements being entered into by Novartis.

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

In the event that, after the Effective Date, Novartis proposes to (a) sell any or all of its business, business units or locations (whether through a sale of assets, sale of stock or other type of transaction) that are subject to this CIA; or (b) purchases or establishes a new business, business unit or location related to or engaged in any of the Covered Functions, the CIA shall be binding on the purchaser of any business, business unit or location. Any such new business, business unit or location (and all Covered Persons at each new business, business unit or location) shall be subject to the applicable requirements of this CIA, unless otherwise determined and agreed to in writing by OIG. Novartis 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, Novartis 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, Novartis must notify OIG in writing of the proposed sale or purchase at least 30 days in advance. This notification shall include a description of the business, business unit, or location to be sold or purchased, a brief description of the terms of the transaction and, in the case of a proposed sale, the name and contact information of the prospective purchaser.

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

### **A. Implementation Report**

Within 150 days after the Effective Date, Novartis shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Chief Compliance Officer required by Section III.A.1, and a summary of other noncompliance job responsibilities the Chief Compliance Officer may have;
2. the names and positions of the members of the Country Compliance Committee required by Section III.A.2;
3. the names of the Board members who are responsible for satisfying the Board of Directors compliance obligations described in Section III.A.3;
4. the names and positions of the Certifying Employees required by Section III.A.4 and a copy of the written process to be followed by Certifying Employees in connection with completing the certification required by Section III.A.4;
5. a copy of the letter (including all attachments) required by Sections II.C.11 and III.B.1 sent to each party employing Third Party Personnel; a list of all existing co-promotion and other applicable agreements with the party employing the Third Party Personnel; and a description of the entities' responses to Novartis' letter;
6. a list of the Policies and Procedures required by Section III.B.2;

7. 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);
8. a description of the risk assessment and internal review process required by Section III.D;
9. 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 Appendices A and B to this CIA; and (d) a certification from the IRO regarding its professional independence and objectivity with respect to Novartis that includes a summary of all current and prior engagements between Novartis and the IRO;
10. a description of the Disclosure Program required by Section III.F;
11. a description of the Ineligible Persons screening and removal process required by Section III.G;
12. a certification by the Chief Compliance Officer that the notice required by Section III.N was posted in the manner required by Section III.N and a summary of the calls or messages received in response to the notice;
13. a certification from the Chief Compliance Officer that information regarding Payments has been posted on Novartis' website as required by Section III.O;
14. a description of the Independent Charity PAP policies, procedures, and practices required by Section III.Q;
15. a list of all of Novartis' locations (including locations and mailing addresses); the corresponding name under which each location is doing business; and the locations' Medicare and state Medicaid provider number and/or supplier number(s) if any;
16. a description of Novartis' corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and
17. the certifications required by Section V.C.

B. Annual Reports

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

1. any change in the identity, position description, or other noncompliance job responsibilities of the Chief Compliance Officer; a current list of the Country Compliance Committee members; a current list of the Board members who are responsible for satisfying the Board of Directors compliance obligations; and a current list of the Certifying Employees, along with the identification of any changes made during the Reporting Period to the Country Compliance Committee, Board of Directors, and Certifying Employees; and a description of any changes to the written process to be followed by Certifying Employees in order to complete the certification required by Section III.A., including the reasons for the changes;
2. the dates of each report made by the Chief Compliance Officer to the Board (written documentation of such reports shall be made available to OIG upon request);
3. the Board resolution required by Section III.A.3 and a description of the documents and other materials reviewed by the Board, as well as any additional steps taken, in its oversight of the compliance program and in support of making the resolution;
4. for the second and fourth Reporting Periods, a copy of the Compliance Review Report prepared by the Compliance Expert for the Board and a copy of any changes to the information about the Compliance Expert required by Section III.A.3;
5. a copy of the letter (including all attachments) required by Sections II.C.11 and III.B.1 sent to each party employing Third Party Personnel; a list of all existing co-promotion and other applicable agreements with the party employing the Third Party Personnel; and a description of the entities' responses to Novartis' letter;
6. a list of any new or revised Policies and Procedures required by Section III.B developed during the Reporting Period;

7. a description of any changes to Novartis' Training Plan developed pursuant to Section III.C and a summary of any Board of Directors 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 Novartis' 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 Novartis, including a summary of all current and prior engagements between Novartis 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, FDA requirements, or Government Reimbursed Products, including at least the following information: (a) a description of the disclosure, (b) the date the disclosure was received, (c) the resolution of the disclosure, and (d) the date the disclosure was resolved (if applicable). The complete disclosure log shall be made available to OIG upon request;

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 the Incentive Compensation Restriction and Financial Recoupment programs required by Section III.H including any changes to the programs during the Reporting Period and the reasons for the changes;

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

18. a summary of the PMP and the results of the PMP required by Section III.L, including copies of the Observations for any instances in which it was determined that improper promotion occurred and a description of the action (s) that Novartis took as a result of such determinations;

19. a summary of the NPMP and the results of the program described in Section III.M, including detailed description of any identified instances in which it was determined that the activities violated Novartis' policies or that improper promotion of Government Reimbursed Products occurred and a description of the action(s) Novartis took as a result of such determinations;

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

21. a certification from the Chief Compliance Officer that information regarding Payments has been posted on NPC's website as required by Section III.O;

22. a description of any changes to the Arrangements Tracking System required by Section III.P.1.a; any changes to the internal review and approval process required by Section III.P.1.d; and any changes to the tracking and monitoring procedures and other Arrangements Procedures required by Section III.P.1;

23. the certification regarding the completeness and accuracy of the Arrangements Tracking System required by Section III.P.3, as well as an explanation of: any Arrangements found to have been missing from the Arrangements Tracking System; and any entries in the Arrangements Tracking System found to have been incomplete or inaccurate;

24. a description of any changes to the Independent Charity PAP processes, policies, and procedures outlined in Section III.Q;



25. a description of all changes to the most recently provided list of Novartis' locations (including addresses) as required by Section V.A.15;

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

27. a list of all Government Reimbursed Products approved by the FDA during the Reporting Period and all Government Reimbursed Products for which the FDA approved a new indication during the Reporting Period, including the name of each newly-approved Government Reimbursed Product, a brief description of any newly-approved indication, and the date of the applicable approval;

28. a report of all External Speaker Programs held during the Reporting Period, including the date, title/topic of the program (including the identification of the Government Reimbursed Product), program format, name of the External Speaker, and the amount of remuneration provided to the External Speaker;

29. for each Government Reimbursed Product and/or new indication approved by the FDA, the total amount of remuneration expended by Novartis relating to External Speaker Programs during the Reporting Period;

30. a report of all Internal Speaker Programs held during the Reporting Period, including the date, title/topic (including the Government Reimbursed Product), program venue/format, and the name of the Internal Speaker; and

31. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 120 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, Novartis shall include the certifications of Certifying Employees as required by Section III.A.4;

2. *Chief Compliance Officer and President of Novartis.* The

Implementation Report and each Annual Report shall include a certification by the Chief Compliance Officer and President that:

- a. to the best of his or her knowledge, except as otherwise described in the report, Novartis has implemented and is in compliance with all requirements of this CIA;
- b. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful;
- c. to the best of his or her knowledge, NPC has implemented procedures reasonably designed to ensure that all Arrangements do not violate the Anti-Kickback Statute, including the Arrangements Procedures required in Section III.P.1.a of the CIA;
- d. to the best of his or her knowledge, NPC has fulfilled the requirements for New and Renewed Arrangements under Section III.P.2 of the CIA;
- e. for each disease fund of an Independent Charity PAP to which Novartis 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 Novartis' policies and procedures (including those outlined in Section III.Q);
- f. for each Novartis PAP, 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 Novartis' policies and procedures; and
- g. he or she understands that the certification is being provided to and relied upon by the United States.

D. Designation of Information

Novartis 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. Novartis 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

Novartis:

Bryant Aaron  
Vice President and Chief Compliance Officer, NPC  
U.S. Country Head, Ethics, Risk & Compliance  
One Health Plaza  
East Hanover, NJ 07936-1080  
Telephone: 862.778.8300

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, Novartis may be required to provide OIG with an additional copy of each notification or report required by this CIA in OIG's requested format (electronic or paper).

## **VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS**

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may conduct interviews, examine and/or request copies of or copy Novartis' books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Novartis' locations for the purpose of verifying and evaluating: (a) Novartis' compliance with the terms of this CIA and (b) Novartis' compliance with Federal health care program requirements and with all applicable FDA requirements. The documentation described above shall be made available by Novartis 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 Novartis' 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. Novartis shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Novartis' owners, employees, contractors and directors may elect to be interviewed with or without a representative of Novartis present.

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

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

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

Novartis 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, Novartis 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) per obligation for each day Novartis fails to establish, implement or comply with any of the following obligations as described in Section III:

- a. a Chief Compliance Officer;
- b. a Country 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;

- k. notification of Government investigations or legal proceedings;
- l. reporting of Reportable Events;
- m. notification of written communications with FDA;
- n. the PMP;
- o. the NPMP;
- p. notification to HCPs and HCIs;
- q. posting of any Payment-related information;
- r. the Specialty Pharmacy requirements, including the Arrangements Procedures and the Arrangements Tracking System Certification and Verification set forth in Section III.P; and
- s. the Independent Charity PAP processes, policies, and procedures required by Section III.Q.

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 Novartis fails to engage and use a Compliance Expert as required in Section III.A.3 or an IRO as required by Section III.E and Appendices A or B.

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

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

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

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

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

C. Payment of Stipulated Penalties

1. *Demand Letter.* Upon a finding that Novartis 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 Novartis of: (a) Novartis' failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 business days after the receipt of the Demand Letter, Novartis 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 Novartis elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Novartis 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 Novartis 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 Novartis 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 Appendices C or D;
- d. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- e. a failure by Novartis to develop and implement measures relating to External and Internal Speaker Programs as required by Section III.B.2.i.

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

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

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, Novartis fails to satisfy the requirements of Section X.D.3, OIG may exclude Novartis from participation in the Federal health care programs. OIG shall notify Novartis in writing of

its determination to exclude Novartis (this letter shall be referred to hereinafter as the “Exclusion Letter”). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Novartis’ 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, Novartis 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 Novartis 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, Novartis 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 Novartis was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Novartis 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 Novartis to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Novartis 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 Novartis was in material breach of this CIA and, if so, whether:

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

Novartis and OIG agree as follows:

*Novartis Corporate Integrity Agreement*

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) Novartis' responsibility to follow all applicable Federal health care program and FDA requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable Federal health care program or FDA requirements.

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

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

**ON BEHALF OF NOVARTIS CORPORATION**

          /Thomas N. Kendris/            
THOMAS N. KENDRIS  
President, Novartis Corporation  
U.S. Country President

          June 30, 2020            
DATE

          /Bryant Aaron/            
BRYANT AARON  
Vice President & Chief Compliance Officer,  
Novartis Pharmaceuticals Corporation  
U.S. Country Head, Ethics, Risk & Compliance

          6-30-20            
DATE

          /Sarah Franklin/            
SARAH FRANKLIN, Esq.  
MATTHEW J. O’CONNOR, Esq.  
Covington & Burling LLP  
Counsel for Novartis Pharmaceuticals Corporation

          6/30/20            
DATE

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

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

6/30/2020  
DATE

/Mary E. Riordan/  
MARY E. RIORDAN, SENIOR COUNSEL  
MADELINE BAINER, ASSOCIATE COUNSEL  
Office of Inspector General  
U.S. Department of Health and Human Services

6/30/2020  
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. Novartis 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.9 of the CIA or any additional information submitted by Novartis in response to a request by OIG, whichever is later, OIG will notify Novartis if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Novartis may continue to engage the IRO.

2. If Novartis 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, Novartis shall submit the information identified in Section V.A.9 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 Novartis at the request of OIG, whichever is later, OIG will notify Novartis if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Novartis 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.

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 inquiries in a prompt, objective, and factual manner; and
4. prepare timely, clear, well-written reports that include all the information required by Appendix C to the CIA.

D. Novartis Responsibilities

Novartis shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in III.E of the 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. *Novartis and IRO.* If Novartis terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Novartis 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. Novartis must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. *OIG Removal of IRO.* In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph E or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify Novartis in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. Novartis 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 Novartis regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify Novartis in writing that Novartis shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. Novartis 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 Novartis to engage a new IRO shall be made at the sole discretion of OIG.

## APPENDIX B

### INDEPENDENT REVIEW ORGANIZATION FOR ARRANGEMENTS REVIEW

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

#### A. IRO Engagement

1. Novartis or, as applicable, NPC (hereafter in this Appendix B, “Novartis”) shall engage an IRO that possesses the qualifications set forth in Section B, below, to perform the responsibilities in Section C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Section E, below. Within 30 days after OIG receives the information identified in Section V.A.9 or any additional information submitted by Novartis in response to a request by OIG, whichever is later, OIG will notify Novartis if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Novartis may continue to engage the IRO.

2. If Novartis engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Novartis shall submit the information identified in Section V.A.9 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 Novartis at the request of OIG, whichever is later, OIG will notify Novartis if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Novartis may continue to engage the IRO.

#### B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Arrangements Review who are knowledgeable in the requirements of the Anti-Kickback Statute and the regulations, directives, and other guidance documents related to this statute;
2. possess expertise in fair market valuation issues or have the ability to associate with a valuation firm to assist in conducting the transactions review component of the Arrangements Review;
3. assign or retain individuals to conduct the Arrangements Review

who are knowledgeable in the requirements of the Anti-Kickback Statute and the regulations and other guidance documents related to this statute. These individuals shall have the expertise and qualifications necessary to perform legal analyses as required in connection with the Arrangements Review including specifically as it relates to items C.7 and C.11 of the Arrangements Transactions Review described in Appendix D and the legal analysis described in Section D.2 of Appendix D (Arrangements Transactions Review Report); and

4. have sufficient staff and resources to conduct the Arrangements Review required by the CIA on a timely basis.

C. IRO Responsibilities

The IRO shall:

1. perform each Arrangements Review in accordance with the specific requirements of the CIA;
2. respond to all OIG inquiries in a prompt, objective, and factual manner; and
3. prepare timely, clear, well-written reports that include all the information required by Section III.E of the CIA and Appendix D to the CIA.

D. Novartis Responsibilities

Novartis shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in III.E.3 of the CIA and that all records furnished to the IRO are accurate and complete.

E. IRO Independence and Objectivity

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

F. Assertions of Privilege

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

G. IRO Removal/Termination

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

2. *OIG Removal of IRO.* In the event OIG has reason to believe that the IRO does not possess the qualifications described in Section B, is not independent and objective as set forth in Paragraph E, or has failed to carry out its responsibilities as described in Section C, OIG shall notify Novartis in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. OIG may, at its sole discretion, require Novartis to engage a new IRO in accordance with Section A of this Appendix. Novartis must engage a new IRO within 60 days of its receipt of OIG's written notice.

Prior to requiring Novartis to engage a new IRO, OIG shall notify Novartis of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, Novartis may present additional information regarding the IRO's qualifications, independence, or performance of its responsibilities. OIG will attempt in good faith to resolve any differences regarding the IRO with Novartis prior to requiring Novartis to terminate the IRO. However, the final determination as to whether or not to require Novartis to engage a new IRO shall be made at the sole discretion of OIG.

## APPENDIX C

### INDEPENDENT REVIEW ORGANIZATION REVIEWS

#### I. Covered Functions Review, General Description

As specified more fully below, Novartis shall retain an Independent Review Organization (IRO) (or IROs) to perform reviews (IRO Reviews) to assist Novartis 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. Novartis 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 Novartis relating to reviewed Policies and Procedures described below, the IRO shall perform the Systems Review for the second and fourth Reporting Periods. If Novartis 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 Review for the second 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. Promotional and Product Related Functions Systems Review

The Promotional and Product Related Functions Systems Review shall be a review of systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) of Novartis relating to Promotional Functions, Product Related Functions, and other systems as described below. Where practical, Novartis 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 Novartis in accordance with the preceding sentence.

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

1. Novartis’ systems (including any centralized electronic systems), processes, policies, and procedures relating to External Speaker Programs as defined and described in Sections III.B.2.i and Section III.L.1 including but not limited to systems, processes, policies and procedures relating to the identification, selection, and approval of External Speakers, the timing and implementation of External Speaker Programs, the amounts paid to External Speakers, the expenses incurred or amounts paid by Novartis for travel and travel-related expenses in connection with External Speaker Programs, the tracking of amounts paid to External Speakers and the amounts spent on travel and travel-related expenses, and the External Speaker Monitoring Program;

2. Novartis’ systems (including any centralized electronic systems), processes, policies, and procedures relating to Internal Speaker Programs as defined and described in Sections III.B.2.i and Section III.L.2 including but not limited to systems, processes, policies, and procedures relating to decisions to hold Internal Speaker Programs, the identification of Internal Speakers, and the implementation of Internal Speaker Programs (including the venue of such programs);

3. Novartis’ systems, processes, policies, and procedures relating to the engagement of HCPs or HCIs to serve as consultants or for other fee-for-service arrangements (including, but not limited to, presentations, appearances in Novartis-sponsored communications and materials, consultant task force meetings, advisory boards, preceptorships, mentorships, and ad hoc advisory activities, and any other financial engagement) and all events and expenses associated with such activities;

4. Novartis’ systems, policies, processes and procedures applicable to the manner in which sales representatives and personnel from Medical Information and Communications (MIC) handle requests or inquiries relating to information about the uses of Government Reimbursed Products (including non-FDA-approved (*i.e.*, off-label) uses of Government Reimbursed Products) and the dissemination of materials relating to the uses of Government Reimbursed Products. This review shall include: (a) the manner in which Novartis sales representatives handle requests for information about off-label uses of Government Reimbursed Products, (b) the manner in which MIC personnel, including those at Novartis’ headquarters, handle and respond to requests for information

about off-label uses of Government Reimbursed Products; (c) the form and content of information and materials related to Government Reimbursed Products disseminated to HCPs, HCIs, payors, and formulary decision-makers by Novartis; (d) the systems, processes, policies, and procedures to track requests to MIC for information about off-label uses of Government Reimbursed Products and responses to those requests; (e) the manner in which Novartis collects and supports information reported in any systems used to track and respond to requests to MIC for Government Reimbursed Product information; (f) the processes and procedures by which MIC or other appropriate individuals within Novartis identify situations in which it appears that off-label or other improper promotion may have occurred; and (g) Novartis' processes and procedures for investigating, documenting, resolving, and taking appropriate disciplinary action for potential situations involving improper promotion;

5. Novartis' systems, policies, processes, and procedures applicable to the manner and circumstances under which Novartis' medical personnel participate in meetings or events with HCPs or HCIs (either alone or with sales representatives) regarding Government Reimbursed Products, and the role of the medical personnel at such meetings or events;

6. Novartis' systems, policies, processes, and procedures applicable to Novartis' internal review of promotional materials related to Government Reimbursed Products that are disseminated in the United States to HCPs, HCIs, and payors or individuals or entities (e.g., PBMs) acting on behalf of HCPs, HCIs or payors;

7. Novartis' systems, policies, processes, and procedures applicable to Novartis' internal review of non-promotional materials related to Government Reimbursed Products (e.g., disease state awareness materials, information on social media platforms, etc.) disseminated to HCPs, HCIs, payors, patients, or other individuals or entities;

8. Novartis' systems, policies, processes, and procedures applicable to patient outreach efforts and materials used in connection with such efforts, including direct-to-consumer advertising, patient education, and the dissemination of materials/information through social media;

9. Novartis' systems, policies, processes, and procedures applicable to the development and review of Novartis processes relating to incentive compensation for Covered Persons who are prescriber-facing sales representatives and their direct managers, with regard to whether the systems, policies, processes, and procedures are

designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in the improper promotion, sales, and marketing of Government Reimbursed Products. To the extent that Novartis establishes different methods of compensation for different Government Reimbursed Products, the IRO shall review each type of compensation arrangement separately;

10. Novartis' systems, policies, processes, and procedures applicable to the development and review of Novartis' call plans for Government Reimbursed Products. This shall include a review of the bases upon which HCPs and HCIs belonging to specified medical specialties are included in, or excluded from, the call plans based on expected utilization of Government Reimbursed Products for FDA-approved uses or non-FDA-approved uses;

11. Novartis' systems, processes, policies, and procedures of Novartis' funding, directly or indirectly, of Third Party Educational Activities (as defined in Section II.C.10 of the CIA) and all events and expenses relating to such activities;

12. Novartis' systems, processes, policies, and procedures applicable to Research (as defined in Section III.B.2.q of the CIA), including the decision to provide financial or other support for Research; the manner in which Research support is provided; the publication of information about the Research, including the publication of information about the Research results and trial outcomes; and uses made of publications relating to such Research;

13. Novartis' systems, policies, processes, and procedures relating to the structure and operation of the Country Compliance Program at Novartis Corporation and the Novartis Affiliates, as defined in Section II.C.12 of the CIA, and within business units including the organization, reporting structure, and coordination about compliance issues concerning Government Reimbursed Products between and among Novartis and the Novartis Affiliates and business units (including US Pharma and US Oncology); and

14. Novartis' systems, processes, policies, and procedures relating to its risk assessment and internal review process outlined in Section III.D of the CIA. This review shall assess whether the risk assessment and internal review process identifies and addresses relevant and appropriate risks associated with each Government Reimbursed Product, including risks associated with the sales, marketing, and promotion of such products.

B. Contribution and Assistance Related Functions Systems Review



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

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

1. Novartis’ systems, policies, processes, and procedures relating to arrangements and interactions with (including donations to and sponsorship of) Independent Charity PAPs as defined in Section II.C.8 of the CIA. This review shall include an assessment of the following:
  - a. Novartis’ 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 Novartis (e.g., the ICCF Executive Committee) 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 Novartis (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. Novartis' 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 Novartis 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 Novartis 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 Novartis with responsibility for Independent Charity PAPs and the commercial organization of Novartis (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 Novartis and health care providers or patients regarding assistance available through any Independent Charity PAP.
  - c. Novartis' policies and practices as they relate to the budgeting process applicable to donations to Independent Charity PAPs

as outlined in Section III.Q.2 of the CIA, including as it relates to initial or annual donation amounts and any supplemental amounts;

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

2. Novartis' systems, policies, processes, and procedures relating to any Novartis PAPs, as defined in Section II.C.8 of the CIA. This review shall include an assessment of the following:

- a. The general elements of Novartis PAPs, including:
  - i. the types of assistance that are made available through Novartis PAPs;
  - ii. the types of patients to whom each type of assistance is made available;
  - iii. the eligibility criteria for the various types of assistance provided;
  - iv. the controls used to implement the eligibility criteria (i.e., controls employed to ensure that appropriate patients receive the various types of assistance);

- v. the maintenance of records regarding free product and other assistance provided to or through Novartis PAPs; and
  - vi. Novartis' external communications about Novartis PAPs, including communication between Novartis and/or Novartis PAPs, and Medicare Part D Plans.
- b. Novartis' policies and practices as they relate to the budgeting process for financial or in-kind assistance provided under any Novartis PAP, including as they relate to initial or annual donation amounts and any supplemental amounts;
  - c. Novartis' 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 Novartis 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); and
  - d. Novartis' policies and practices as they relate to any contracts or arrangements entered between Novartis and outside entities relating to any Novartis 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 documentation (including policies) reviewed and any personnel interviewed;
- 2. a detailed description of systems, policies, processes, and procedures relating to the items identified in Sections II.A and 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;

3. a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Sections II.A and II.B above are made known or disseminated within the Novartis;

4. a detailed description of any system(s) used to track and respond to requests for information about Government Reimbursed Products;

5. a detailed description of the incentive compensation system for Covered Persons who are prescriber-facing sales representatives and their direct managers, including a description of the bases upon which compensation is determined. To the extent that Novartis may establish compensation differently for individual products, the IRO shall report separately on each such type of compensation arrangement;

6. a description of the structure and operation of Novartis' Compliance Program and findings about the coordination about compliance issues concerning Government Reimbursed Products between and among Novartis and the Novartis Affiliates and business units;

7. findings relating to whether the risk assessment and internal review processes identify and address relevant and appropriate risks for each Government Reimbursed Product;

8. findings relating to whether the risk assessment and internal review processes result in the implementation of appropriate corrective action plans and appropriate tracking and monitoring of such corrective action plans;

9. a detailed description of any system(s) used to track requests for donations or other assistance from any Independent Charity PAP;

10. a detailed description of any system(s) used to track donations or other assistance provided in response to requests from Independent Charity PAPs;

11. a detailed description of any system(s) used to track requests for and assistance provided through any Novartis PAP;

12. a detailed description of any system(s) and processes used to track the amounts paid to External Speakers and expenses incurred or amounts paid for travel or travel-related expenses and to ensure that External Speaker Programs are conducted only during the time frames required by Section III.B.2.i.b of the CIA and are subject to the monetary caps described in Section III.B.2.i.c of the CIA;

13. findings and supporting rationale regarding any weaknesses in the systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures identified in Sections II.A and II.B above, if any; and

14. recommendations to improve any of the systems, policies, processes, or procedures relating to any of the Reviewed Policies and Procedures identified in Sections II.A and II.B above, if any.

### III. Transactions Review

As described more fully below, the Transactions Review shall include: (1) a review of External Speaker Programs (as defined in Section III.B.2.i); (2) a review of Internal Speaker Programs (as defined in Section III.B.2.i); (3) a review of Consulting Activities; (4) a review of selected internal reviews; (5) a review of Novartis' arrangements with selected Independent Charity PAPs; and (6) 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. IRO Review of External Speaker Programs.

1. *Review of External Speaker Program Activities.* The term "External Speaker Program Activities" shall refer to all activities referenced in Sections III.B.2.i and III.L.1.

2. *Selection of Sample.* For the first Reporting Period, the IRO shall review activities associated with all External Speaker Programs held during the Reporting Period. For the second and subsequent Reporting Periods, at least 30 days prior to the end of the applicable Reporting Period, Novartis shall provide the OIG with the number of External Speakers retained by Novartis to date during the Reporting Period and the OIG shall have 15 days to notify Novartis or its IRO regarding the number of External Speaker Programs to be reviewed for the applicable Reporting Period.

3. *Materials and Information to be Reviewed:* For purposes of conducting its review of External Speaker Programs, the IRO shall have access to all records and personnel necessary to complete the review described below. This shall include access to recordings of the External Speaker Programs.

4. *Scope of Review for External Speaker Programs.* For each External Speaker Program reviewed the IRO shall determine whether:

- a. the program was conducted in a virtual format (meaning that the External Speaker was remote and not in the same location as any audience member);
- b. the program occurred within the 18-month timeframe outlined in Section III.B.2.i;
- c. Novartis complied with the total aggregate spending limitations for External Speaker Programs associated with each newly approved Government Reimbursed Product or new indication for a Government Reimbursed Product as outlined in Section III.B.2.i;
- d. for each newly-approved Government Reimbursed Product or new indication for a Government Reimbursed Product, Novartis complied with the spending caps for each External Speaker as outlined in Section III.B.2.i;
- e. a needs assessment identifying the business need for the External Speaker Program and providing details about the program was completed prior to the initiation of the External Speaker Program, and Novartis compliance personnel were involved in the review and approval of the business need for External Speaker Program;
- f. Novartis complied with the requirements for the selection of the External Speaker as set forth in Section III.L.1.b. The IRO's review shall include an evaluation of the process by which each External Speaker was selected, the identification of Novartis personnel involved in the speaker identification

and selection process, and the criteria that formed the basis for the selection of the External Speaker;

- g. the remuneration paid to the External Speaker was determined in accordance with a centrally managed, pre-established rate based on an independent fair-market value analysis;
- h. each External Speaker received training prior to speaking on behalf of Novartis; and
- i. a written agreement was in place for each External Speaker describing the scope of work to be performed, the remuneration to be paid to each External Speaker, and the compliance obligations of the External Speaker.

In addition, for each External Speaker, Novartis shall provide the IRO with information about the expenses Novartis incurred and/or the amounts Novartis paid for travel and travel-related expenses in connection with the External Speaker programs. Novartis shall also provide the IRO with information about whether the External Speaker received other Payments (as defined in Section III.O.2 of the CIA) in connection with other activities on behalf of Novartis (including but not limited to Payments in connection with Consulting Activities as defined below in Section III.C). If the External Speaker received such Payments, Novartis shall provide information about the total amount of Payments paid to the External Speaker, the nature/purpose of each Payment, and the date of each Payment. The IRO shall assess whether Novartis paid the External Speaker an amount that exceeded the annual cap(s) on compensation to non-employee HCPs established in accordance with Novartis' Policies and Procedures.

#### B. IRO Review of Internal Speaker Programs.

1. *Review of Internal Speaker Program Activities.* The term "Internal Speaker Programs Activities" shall refer to all activities referenced in Section III.B.2.i and in Section III.L.2.

2. *Selection of Sample.* For each Reporting Period, at least 30 days prior to the end of the applicable Reporting Period, Novartis shall provide the OIG with the number of Internal Speaker Programs that occurred to date during the Reporting



Period and the OIG shall have 15 days to notify Novartis or its IRO regarding the number of Internal Speaker Programs to be reviewed for the applicable Reporting Period.

3. *Scope of Review for Internal Speaker Programs.* For each Internal Speaker Program reviewed the IRO shall determine whether:

- a. the program was conducted in a non-restaurant venue and alcohol was not served or available for purchase as specified in Section III.B.2.i;
- b. a needs assessment identifying the business need for the Internal Speaker Program and providing details about the program was completed prior to the initiation of the Internal Speaker Program and Novartis compliance personnel were involved in the review and approval of the business need for Internal Speaker Programs;
- c. Novartis provided appropriate training to each Internal Speaker as set forth in Section III.L.2.c; and
- d. Novartis obtained certifications of compliance relating to each Internal Speaker Program and took appropriate steps in the event of non-compliance as set forth in Section III.L.2.d.

C. IRO Review of Consulting Activities.

1. *Consulting Activities.* For purposes of this Appendix C, the term “Consulting Activities” shall include all consulting and other fee for service arrangements entered with HCIs or HCPs who are not Novartis employees, except External Speaker Programs reviewed above under Section III.A. This shall include, but not be limited to, advisory boards, research and development meetings, product training and education sessions, presentations, appearances in Novartis-sponsored communications and materials, ad hoc advisory activities, research and any other financial engagement or arrangement and all related expenses.

2. *Selection of Sample.* For the first Reporting Period, the IRO shall select and review a sample of 60 of the Consulting Activities that Novartis entered into with HCPs or HCIs and all related expenses. Of this number, at least 30 ad hoc consulting arrangements (15 each with HCPs and HCIs) shall be reviewed. The IRO

shall select 15 of the remaining Consulting Activities from among the two other types of Consulting Activities with HCPs for which Novartis had the highest numbers of activities in 2019. The IRO shall select the 15 remaining Consulting Activities from among the two other types of Consulting Activities with HCIs for which Novartis had the highest numbers of activities in 2019.

For the second and subsequent Reporting Periods, at least 60 days prior to the end of the applicable Reporting Period, Novartis shall provide the following information to the OIG: (a) a description of each type of Consulting Activity undertaken during the Reporting Period and a description of the services to be provided under each Consulting Activity; (b) the number of each type of Consulting Activity undertaken during the Reporting Period; and (c) the overall budgeted amount to be spent in connection with each type of Consulting Activity during the Reporting Period. For the second and subsequent Reporting Periods, the IRO shall select and review a total of 50 Consulting Activities which shall include a review of specified numbers of each type of Consulting Activities as determined by the OIG.

3. *Scope of Review.* For each Consulting Activity reviewed the IRO shall determine whether:

- a. a written agreement was in place for each Consulting Activity that describes the scope of work to be performed, the fees and related expenses to be paid for the Consulting Activity, and the compliance obligations for the Consultant;
- b. the compensation paid for the Consulting Activity was determined in accordance with a centrally managed, pre-set rate structure established by Novartis;
- c. the rate structure referenced in Section III.B.2.b was established based on an independent fair market value analysis;
- d. the Consulting Activity was identified in the annual Consultant budgeting plan developed by Novartis;
- e. a needs assessment that identifies the business need for the Consulting Activity and provides details about the Consulting

Activity was completed prior to the initiation of the Consulting Activity;

- f. the Consulting Activity was reviewed and approved in accordance with Novartis Policies and Procedures, including whether the HCP or HCI was selected for the Consulting Activity in accordance with Novartis' policies relating to the identification, selection, and approval of a Consultant;
- g. Novartis collected and retained a record of the specific activity performed by the HCP or HCI and, if applicable, a copy of the work product generated by the HCP or HCI in connection with the Consulting Activity; and
- h. the activity undertaken by the Consultant and/or the work product generated by the HCP or HCI was used by Novartis in a manner consistent with the needs assessment that was completed prior to the initiation of the Consulting Activity.

In addition, for each Consulting Activity selected for review, Novartis shall provide the IRO with information about the total aggregate annual Payments (as defined in Section III.O.2 of the CIA) by Novartis to the associated HCP or HCI (including, e.g., Payments made to External Speakers.) The IRO shall assess whether Novartis paid the HCP or HCI an amount that exceeded the annual cap(s) on compensation established in accordance with Novartis' Policies and Procedures.

D. IRO Review of Select Internal Reviews. Each year, Novartis conducts Risk Assessment and Internal Review Processes as described in Section III.D of the CIA. As part of the annual risk assessment process, the Ethics, Risk & Compliance function evaluates annual risk assessment results and, depending on the specific risks identified, incorporates those risks into a risk-based audit and monitoring plan. Novartis may decide to mitigate certain potential risks prior to, or separate from, conducting any auditing or monitoring. The Ethics, Risk & Compliance function executes the annual audit and monitoring plan, including the auditing and monitoring of those issues identified for inclusion in the plan through the annual risk assessment process.

For the second through fifth Reporting Periods, Novartis shall provide the IRO and OIG with: i) the report containing the results from Novartis' prior annual risk assessment and ii) Novartis' Ethics, Risk & Compliance auditing and monitoring plan

relating to identified risk areas. The OIG will select for review by the IRO two of the Novartis reviews conducted at Novartis or Novartis Affiliates performing Covered Functions and identified in the auditing and monitoring plan (“Selected Internal Reviews”).

For each of the Selected Internal Reviews, Novartis shall provide the IRO with: i) the Internal Review work plan; ii) the Internal Review report; iii) documentation reviewed by Novartis in the Internal Review process, and iv) documentation of any corrective action taken by Novartis as a result of the Internal Review report results.

For each of the Selected Internal Reviews, the IRO shall: i) evaluate whether the Internal Review work plan was sufficient to address the identified risk areas; and ii) note any instances in which the Novartis Internal Review failed to follow its work plan, or failed appropriately to identify and address any compliance related concerns related to the identified risk areas. The IRO shall report on its findings from the reviews in the Transactions Review Report.

E. Review of Arrangements with Independent Charity PAPs. The IRO shall conduct a review and assessment of Novartis’ compliance with the Independent Charity PAP processes, policies, and procedures outlined in Section III.Q of the CIA. More specifically, the IRO shall review the arrangements and interactions with all Independent Charity PAPs or disease state funds with which Novartis 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 regarding donations to Independent Charity PAPs required by Novartis policy to evidence or document the review and approval of a decision to provide a donation to a particular Independent Charity PAP; (c) any donation agreements between Novartis and the Independent Charity PAP; (d) all email, correspondence and other documents reflecting communications and interactions between Novartis and the Independent Charity PAP relating to any donation arrangement with the Independent Charity PAP; and (e) all email, correspondence and other documents reflecting communications and interactions between the groups or departments within Novartis responsible for Independent Charity PAP functions and the commercial organization relating to the arrangement with the Independent Charity PAP. In addition to reviewing documents and written materials, the IRO may also interview individuals at Novartis who have responsibility for arrangements and interactions with Independent Charity PAPs.

2. For each Independent Charity PAP arrangement or interaction reviewed as part of the IRO review, the IRO shall assess the Reviewed Materials and any interviews conducted by the IRO to evaluate whether the Independent Charity PAP-related activities were conducted in a manner consistent with Novartis' policies and procedures including those described in Section III.Q 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 Novartis in accordance with the company's policies and procedures including those outlined in Section III.Q;
- b. Whether Novartis' commercial organization (as defined in Section III.Q) influenced or was involved in decisions to enter into any arrangement with the Independent Charity PAP in violation of Novartis' policies and procedures or OIG guidance;
- c. Whether Novartis followed the budgeting policies and practices outlined in Section III.Q.2 regarding any initial or annual donation amounts to the Independent Charity PAP and any supplemental amounts;
- d. Whether Novartis followed the decision-making and approval process outlined in Section III.Q 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 Novartis would donate to the Independent Charity PAP or any specific disease state fund of such a PAP;
- e. Whether Novartis followed the criteria, policies, and practices outlined in Section III.Q.3 of the CIA in connection with all donations made by Novartis 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.Q.3;

- f. Any communications that occurred between any representatives of Novartis 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 Novartis' policies and procedures and OIG guidance;
- g. Whether, for each donation from Novartis to any Independent Charity PAP, Novartis complied with the requirements outlined in Section III.Q.3; and
- h. Whether, based on its review, the IRO found that Novartis exerted influence or control over the Independent Charity PAP in violation of Novartis' policies and procedures, including those outlined in Section III.Q.3.

F. 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 150 days prior to the end of the applicable Reporting Period, the OIG shall notify Novartis 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 Novartis shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG. 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 Novartis' systems, processes, policies, and procedures based on its review of each Additional Item).

2. Novartis may propose to the OIG that its internal audit(s) and/or review(s) conducted as part of the Monitoring of Promotional Activities described in Section III.L or the monitoring of Non-Promotional Activities described in Section III.M

of the CIA and/or other reviews conducted by both internal and outside entities at Novartis' request 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 Novartis' internal audit work or monitoring and/or other reviews conducted by outside entities 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 Novartis' planned monitoring activities and audit work, the results of the Transactions Review(s) during prior Reporting Period(s), and Novartis' demonstrated audit capabilities to perform the proposed audit work internally. If the OIG denies Novartis' 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, Novartis shall engage the IRO to perform the Review as outlined in this Section III.E.

4. If the OIG agrees to permit certain of Novartis' monitoring, internal audit work, or other reviews for a given Reporting Period to be substituted for a portion of Additional Items review, such 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.

G. 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 Review of External Speaker Programs. In connection with the review of External Speaker Programs:

- i. A description of each External Speaker Program Reviewed, including the identity of the External Speaker, an identification of the Government Reimbursed Product associated with the program, the date of the program, and a description of the format of the program (e.g., whether the program occurred in a virtual format, whether the program included a question and answer session; whether the program was recorded, etc.);
- ii. For each Government Reimbursed Product and/or new indication approved by the FDA for which External Speaker Programs occurred, the total amount of remuneration expended by Novartis relating to External Speaker Programs;
- iii. For each External Speaker, the total amount of remuneration paid to the External Speaker in connection with External Speaker Programs for each Government Reimbursed Product and the total amount incurred or paid by Novartis for travel and travel-related expenses for the External Speaker;
- iv. For each External Speaker, a description of any other Payments provided by Novartis to the External Speaker. This description shall include the total amount of other Payments, the nature/purpose of each Payment, and the date of each such Payment;
- v. The IRO's findings and supporting rationale as to whether:



- a. Novartis complied with the requirements relating to the format of External Speaker Programs (including requirements that External Speaker Programs be conducted in a virtual format and requirements that Novartis not organize or facilitate group gatherings of HCPs outside of the individual HCP's office setting for purposes of participating in or viewing External Speaker Programs);
- b. Novartis complied with the requirement that External Speaker Programs be held within 18 months of the FDA approval of a new Government Reimbursed Product or a new indication for a Government Reimbursed Product previously approved by the FDA;
- c. Novartis complied with the spending limitations associated with External Speaker Programs. More specifically, the IRO shall assess whether Novartis complied with the \$100,000 cap on total remuneration to all External Speakers engaged in External Speaker Programs for each newly approved Government Reimbursed Product or new indication for a Government Reimbursed Product. The IRO also shall assess whether Novartis complied with the \$10,000 cap on the total remuneration provided to each individual External Speaker;
- d. a needs assessment identifying the business need for the External Speaker Program and providing details about the program was completed prior to the initiation of the External Speaker Program and Novartis compliance personnel were involved in the review and approval of the business need for the External Speaker Program;

- e. Novartis complied with the requirements for the selection of the External Speaker as set forth in Section III.L.1.b., including regarding the process by which each External Speaker was selected, whether field sales personnel played any role in the process, and the basis for the selection of the External Speaker;
- f. the remuneration paid to the External Speaker was determined in accordance with a centrally managed, pre-established rate based on an independent fair-market value analysis;
- g. each External Speaker received training prior to speaking on behalf of Novartis;
- h. a written agreement was in place for each External Speaker describing the scope of work to be performed, the remuneration to be paid to each External Speaker, and the compliance obligations for the External Speaker;
- i. the IRO identified any weaknesses in Novartis' systems, processes, policies, procedures and/or practices relating to External Speaker Programs; and
- j. the IRO has recommendations for improvements to Novartis' systems, processes, policies, procedures and/or practices relating to External Speaker Programs.

b. Relating to the Review of Internal Speaker Programs. In connection with the review of Internal Speaker Programs:

- i. A description of each Internal Speaker Program Reviewed, including the identity of the Internal Speaker, an identification of the Government Reimbursed Product associated with the program, the

date of the program, and a description of the location and format of the program);

- ii. The IRO's findings and supporting rationale as to whether:
  - a. the program was conducted in a non-restaurant venue and alcohol was not served or available for purchase as specified in Section III.B.2.i;
  - b. a needs assessment identifying the business need for the Internal Speaker Program and providing details about the program was completed prior to the initiation of the Internal Speaker Program and Novartis compliance personnel were involved in the review and approval of the business need for the Internal Speaker Programs;
  - c. Novartis provided appropriate training to all Internal Speakers as set forth in Section III.L.2.c;
  - d. Novartis obtained certifications of compliance relating to the Internal Speaker Programs and took appropriate steps in the event of non-compliance as set forth in Section III.L.2.d;
  - e. the IRO identified any weaknesses in Novartis' systems, processes, policies, procedures and/or practices relating to Internal Speaker Programs; and
  - f. the IRO has recommendations for improvements to Novartis' systems, processes, policies, procedures and/or practices relating to Internal Speaker Programs.

c. Relating to the Review of Consulting Activities. In connection with the review of Consulting Activities:

- i. A description of each type of Consulting Activity reviewed, including the number of each type of Consulting Activity reviewed and an identification of the types of documents and information reviewed for each Consulting Activity;
- ii. For each Consulting Activity, the aggregate annual Payments by Novartis to the associated HCP or HCI and the amount of each Payment;
- iii. The IRO's findings and supporting rationale as to whether:
  - a. a written agreement was in place for each Consulting Activity that describes the scope of work to be performed, the fees and expenses to be paid for each Consulting Activity, and the compliance obligations for the Consultant;
  - b. the compensation to be paid for the Consulting Activity was determined in accordance with a centrally managed, pre-set rate structure set by Novartis;
  - c. the rate structure was established based on an independent fair market value analysis;
  - d. the Consulting Activity was identified in the annual Consulting budgeting plan developed by Novartis;
  - e. a needs assessment that identifies the business need for the Consulting Activity and provides detail about the activity was prepared prior to the initiation of the Consulting Activity;

- f. the Consulting Activity was reviewed and approved in accordance with Novartis Policies and Procedures, including Policies and Procedures relating to the identification, selection and approval of a given HCP or HCI;
- g. Novartis collected and retained a record of the specific activity performed by the HCP and, if applicable, a copy of the work product generated in connection with the Consulting Activity;
- h. the activity undertaken by the Consultant and/or the work product generated was used by Novartis in a manner consistent with the needs assessment that was completed prior to the initiation of the Consulting Activity;
- i. the aggregate amount paid by Novartis to the HCP or HCI exceeded the applicable cap established under Novartis' Policies and Procedures;
- j. the IRO identified any weaknesses in Novartis' systems, processes, policies, procedures and/or practices relating to Consulting Activities; and
- k. the IRO has recommendations for improvements to Novartis' systems, processes, policies, procedures and/or practices relating to Consulting Activities.

d. Relating to IRO Review of Selected Internal Reviews

- i. A description of each Selected Audit reviewed by the IRO, including the documentation reviewed for each Selected Audit;

- ii. The IRO's findings and supporting rationale regarding whether:
  - a. Novartis' report from the Internal Review was consistent with the Novartis Internal Review work plan and documentation reviewed by Novartis in the Internal Review process;
  - b. the IRO agreed with the results in Novartis' Internal Review report or, if applicable, the basis for the IRO's disagreement;
  - c. the Internal Review work plan was sufficient to address the identified risk areas;
  - d. Novartis took appropriate corrective action in response to the Internal Review consistent with Novartis' risk assessment and, if applicable, the IRO's recommendations regarding any additional or alternative corrective action;
  - e. Novartis took appropriate follow-up steps to ensure that any corrective action was appropriately implemented and, if applicable, the IRO's recommendations regarding any additional or alternative follow-up steps; and
  - f. the Novartis audit appropriately identified and addressed compliance related concerns related to the identified risk areas consistent with Novartis' risk assessment and, if applicable, a description of any compliance related concerns that were not so appropriately identified and addressed.

e. Relating to the Review of Independent Charity PAP Arrangements

- i. a list of the Independent Charity PAPs with which Novartis entered donation arrangements 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 Novartis 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 Novartis' systems, processes, policies, procedures, and practices relating to its arrangements and interactions with Independent Charity PAPs; and
  - v. recommendations, if any, for changes in Novartis' systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to its arrangements and interactions with Independent Charity PAPs.
- f. 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 Novartis' 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 Novartis' systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the review.



## APPENDIX D

### ARRANGEMENTS REVIEW

The Arrangements Review shall consist of two components: a systems review and a transactions review. The IRO shall perform all components of each Arrangements Review. If there are no material changes to NPC' systems, processes, policies, and procedures relating to Arrangements, then NPC will have completed its Arrangements Systems Review pursuant to the CIA Addendum. If NPC materially changes the Arrangements systems, processes, policies, and procedures during the first Reporting Period, the IRO shall perform an Arrangements Systems Review of the material changes for that Reporting Period. The Arrangements Transactions Review shall be performed annually and shall cover the first Reporting Period. As set forth in Section II.A of the CIA, Appendix B and this Appendix D shall expire five years after the effective date of the CIA Addendum.

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

1. NPC' systems, policies, processes, and procedures with respect to creating and maintaining a centralized tracking system for all existing and new and renewed Arrangements (Arrangements Tracking System), including a detailed description of the information captured in the Arrangements Tracking System;
2. NPC' systems, policies, processes, and procedures for tracking remuneration to and from all parties to Arrangements;
3. NPC' systems, policies, processes, and procedures for tracking service and activity logs to ensure that parties to the Arrangement(s) are performing the services required under the applicable Arrangement(s) (if applicable);
4. NPC' systems, policies, processes, and procedures for the review and approval of materials provided by NPC to Specialty Pharmacies or created by Specialty Pharmacies at the direction of NPC for use in connection with a Fee-for-Service (FFS) Arrangement;
5. NPC' systems, policies, processes, and procedures for initiating, reviewing, and approving Arrangements, including those policies that identify the

individuals with authority to initiate an Arrangement and those policies that specify the business need or business rationale required to initiate an FFS Arrangement;

6. NPC' systems, policies, processes, and procedures relating to NPC' evaluation of services and activities in potential Arrangements and the classification of contract approach (*e.g.*, discount or fee-based contracts);

7. NPC' systems, policies, processes, and procedures designed to ensure that, to the extent that a Specialty Pharmacy provides services under a FFS Arrangement, including any FFS Arrangement with a medication therapy management program, the services be provided in a manner that would not reasonably be expected to undermine or otherwise interfere with the clinical judgment of patients' prescribing health care professionals;

8. NPC' systems, policies, processes, and procedures designed to ensure that, to the extent that a Specialty Pharmacy provides services under the terms of a FFS Arrangement, (a) NPC shall not direct or encourage a Specialty Pharmacy to cause or encourage a health care professional to prescribe, or patients to ask their health care professionals to prescribe, a NPC Government Reimbursed Product over any other medically-appropriate product; and (b) the terms of such Arrangements shall prohibit the offering of any financial inducement by the Specialty Pharmacy to any health care professional to prescribe or switch patients to a NPC Government Reimbursed Product;

9. NPC' systems, policies, processes, and procedures relating to any allocation of patients to specified Specialty Pharmacies in connection with an Arrangement (if applicable);

10. NPC' systems, policies, processes, and procedures for the internal review and approval of all Arrangements, including those policies that identify the individuals required to approve each type or category of Arrangement entered into by NPC, the internal controls designed to ensure that all required approvals are obtained, and the processes for ensuring that all Arrangements are subject to a legal review by counsel with expertise in the Anti-Kickback Statute;

11. the Chief Compliance Officer's (or designee's) annual review of and the Chief Compliance Officer's reporting to the Compliance Committee on the Arrangements Tracking System; NPC' internal review and approval process; and other Arrangements systems, policies, processes, and procedures;

12. NPC' systems, policies, processes, and procedures for implementing effective responses when suspected violations of the Anti-Kickback Statute are discovered, including disclosing Reportable Events;

13. NPC' systems, policies, processes, and procedures for ensuring that all new and renewed Arrangements comply with the Arrangements Requirements set forth in Section III.P.2 of the CIA;

14. NPC' systems, policies, processes, and procedures for auditing the performance of Specialty Pharmacies under the FFS Arrangements to ensure and assess compliance with the contractual terms of the Arrangements; and

15. NPC' systems, policies, processes, and procedures for ensuring that applicable NPC policies and guidelines are followed during the analysis, initiation, and implementation of Arrangements and that the policies and guidelines are compliant with applicable legal requirements (including the Anti-Kickback Statute).

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

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

2. a detailed description of NPC' systems, policies, processes, and procedures relating to the items identified in Section A.1–15, above;

3. findings and supporting rationale regarding weaknesses in NPC' systems, policies, processes, and procedures relating to Arrangements described in Section A.1–15, above; and

4. recommendations to improve NPC' systems, policies, processes, or procedures relating to Arrangements described in Section A.1–15, above.

C. Arrangements Transactions Review. For purposes of the Arrangements Transactions Review, the IRO shall review a total of 18 Arrangements which shall be divided between Discount Arrangements and FFS Arrangements as specified by the OIG. Prior to the determination of the number of each type of Arrangement to be reviewed Reporting Periods, NPC shall provide to the OIG the information specified below in the next paragraph within 60 days prior to the end of the applicable preceding Reporting Period.

The IRO shall select its sample of Arrangements for review in consultation with OIG after the provision of information about the Arrangements to the OIG. NPC shall provide information to the OIG about: 1) the number of Arrangements in place during the Reporting Period; 2) the identity of the parties to each Arrangement; 3) the type of each Arrangement (*e.g.*, discount or service fee Arrangement); 4) a description of the services to be provided under each Arrangement; 5) the duration and value of each Arrangement; and 6) the NPC Government Reimbursed Product to which each Arrangement relates.

The IRO's assessment with respect to each Arrangement that is subject to review (Reviewed Arrangement) shall include:

1. verifying that the Reviewed Arrangement is maintained in NPC's centralized tracking system in a manner that permits the IRO to identify the parties to the Arrangement and the relevant terms of the Arrangement (*i.e.*, the services/data to be provided, the amount of compensation, the products at issue, the effective date, the expiration date, etc.);
2. verifying that the Reviewed Arrangement was subject to the applicable internal review and approval process and obtained the necessary approvals and whether such review and approval was appropriately documented;
3. verifying that the services and activities in the Reviewed Arrangement were evaluated and the contract approach (*i.e.*, discount or fee-based contracts) classified according to NPC policies and procedures;
4. verifying that the remuneration (*e.g.*, discount or service fee) related to the Reviewed Arrangement is properly documented and that the amount of the compensation for services under a FFS Arrangement is supported by a sound fair market valuation methodology;
5. verifying that any Reviewed Arrangement which is a FFS Arrangement is supported by a valid and properly documented business need or business rationale;
6. verifying that: (a) the service and activity logs or other documents to be provided by a Specialty Pharmacy under a FFS Reviewed Arrangement reflecting activities and/or services provided by the Specialty Pharmacies are properly completed and are reviewed by NPC, and (b) based on a review of the documents and related information, it appears that the parties to the Reviewed Arrangement are performing the activities and/or services required under the applicable Arrangement (if applicable);

7. to the extent that a Reviewed Arrangement involves any allocation of patients to specified Specialty Pharmacies, an identification of the quantities (*e.g.*, percentage of patients) involved in any allocation, and a legal analysis of the basis for the allocation;

8. verifying that any materials provided by NPC to the Specialty Pharmacy or created by the Specialty Pharmacy at the direction of NPC for use in connection with a Reviewed FFS Arrangement were approved through NPC' material approval process (if applicable);

9. verifying that the Reviewed Arrangement satisfies the Arrangements Requirements of Section III.P.2 of the CIA;

10. to the extent that a Specialty Pharmacy provides services under the terms of a Reviewed FFS Arrangement, including an FFS Arrangement with a medication therapy management program, assessing (based on the information set forth in the Arrangements Tracking System, supporting documentation about the Arrangement, and the IRO's review of Items 1-9 above) whether the services were provided in a manner that would not reasonably be expected to undermine or otherwise interfere with the clinical judgment of the patients' prescribing health care professionals;

11. to the extent that a Specialty Pharmacy provides services under the terms of a Reviewed FFS Arrangement, a legal analysis of whether (based on the information set forth in the Arrangements Tracking System, supporting documentation about the Arrangement, and the IRO's review of Items 1-10 above): (a) the provision of services could reasonably be expected to encourage patients to use, or health care professionals to prescribe, a NPC Government Reimbursed product over any other medically-appropriate product or (b) the Arrangement appeared to involve the offering of a financial inducement by the Specialty Pharmacy to any health care professional to prescribe or switch patients to a NPC Government Reimbursed Product; and

12. to the extent a Reviewed Arrangement was subject to an internal audit or review by NPC, assessing the findings of NPC' review as to whether the performance of the Specialty Pharmacy complied with the contractual terms of the Arrangements. If the internal NPC review determined any instances of non-compliance, the IRO shall conduct an assessment of whether NPC took any action in response to the findings of non-compliance and, if so, whether such action addressed the non-compliance.

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

1. *Review Methodology*

- a. Review Protocol: A narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for the sample reviewed.
- b. Sources of Data: A full description of the documentation and other information, if applicable, relied upon by the IRO in performing the Arrangements Transactions Review.
- c. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Arrangements selected as part of the Arrangements Transactions Review and NPC shall furnish such documentation and materials to the IRO, prior to the IRO initiating its review of the Arrangements. If the IRO accepts any supplemental documentation or materials from NPC after the IRO has completed its initial review of the Arrangements (Supplemental Materials), the IRO shall identify in the Arrangements Transactions Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Arrangements Transactions Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

2. *Review Findings*. The Arrangements Transactions Review Report shall include the IRO's findings with respect to each of the items set forth in Section C.1–12, above. In addition, the IRO shall identify in the Arrangements Transactions Review Report any Reviewed Arrangement(s) that a reasonable person would consider a probable violation of the Anti-Kickback Statute, along with the IRO's basis for reaching that conclusion. If the IRO concludes that none of the

Reviewed Arrangements are probable violations, the IRO shall include a statement in the report reflecting this conclusion.

**Appendix E**  
**Incentive Compensation Restriction and**  
**Executive Financial Recoupment Program**

Within 120 days after the Effective Date of the CIA, Novartis Corporation (Novartis) 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**

Novartis' Incentive Eligibility Policy outlines the criteria that Novartis Associates must satisfy as a prerequisite to earning incentive payments. To be eligible for any form of incentive, Associates must adhere to and comply with all applicable laws and with Novartis rules and policies (including the Code of Conduct, other compliance requirements, and other applicable Novartis policies, procedures and guidelines.) If an Associate is determined to have violated the law, Code of Conduct, or any provision of any Company policy, the Associate shall be ineligible to receive future incentive payments for a period of up to two future selling cycles from the date the violation was discovered. In addition, if Novartis determines that the Associate engaged in a material violation, incentive grants to the Associate 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 Associate must promptly repay any incentive already received.

**(B) Executive Financial Recoupment Program**

Within 120 days after the Effective Date of the CIA, Novartis shall establish a financial recoupment program that puts at risk of forfeiture and recoupment an amount equivalent to up to 3 years of annual performance pay (including Cash and Equity Awards) for any Covered Executive who is the subject of an Affirmative Recoupment Determination. This program shall be known as the Executive Financial Recoupment Program. This recoupment program shall apply to Covered Executives, as defined below, who are either current Novartis employees or former Novartis employees at the time of a Recoupment Determination.

Within 120 days after the Effective Date of the CIA, Novartis shall establish policies and procedures (and modify employment and other contracts as necessary) to provide that incentive awards, bonuses, and other similar awards (collectively "Cash Awards") for each Covered Executive who is at risk of forfeiture in the event of Significant Misconduct (i.e., a violation of a law or regulation or a violation of a



significant Novartis policy) that is discovered by Novartis before the bonus is paid. In the event of Significant Misconduct by any Covered Executive, Novartis 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 Novartis 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 make a determination about whether any forfeiture, and the terms of such forfeiture, shall be implemented.

Within 120 days after the Effective Date of the CIA, Novartis shall modify and supplement the annual bonus plans applicable to Covered Executives (and any employment agreements, as appropriate) by imposing the eligibility and repayment conditions described below on future Cash and Equity Awards and making the additional remedies discussed below applicable to all Certifying Employees, as set forth in Section III.A.4 of the CIA, and all direct reports to the Certifying Employees who oversee business units that are engaged in Covered Functions, as defined in Section II.C.9 of the CIA (collectively, “Covered Executives”). Novartis shall implement policies and procedures and, as necessary, shall modify contracts with Covered Executives so that, beginning no later than calendar year 2021, Cash 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 2021 bonus plan and Equity Award years.

**(i) Cash Award Eligibility and Repayment Conditions.** Novartis shall implement an eligibility and repayment condition on Cash Awards that will allow Novartis, as a consequence of a Triggering Event, to pursue repayment from Covered Executives of all or any portion of Cash Awards paid to the individual in the three years prior to the Affirmative Recoupment Determination. To the extent permitted by controlling law, these eligibility and repayment 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 3-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, Novartis shall endeavor to collect repayment of 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 collect the repayment, Novartis 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 Novartis' inability to bring such a suit under the controlling law of the relevant jurisdiction.

**(ii) Equity Awards and Repayment Conditions.** Novartis shall implement an eligibility and repayment condition on Novartis' Equity Awards that will allow Novartis, as a consequence of a Triggering Event, to pursue repayment 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. To the extent permitted by controlling law, these eligibility and repayment 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, Novartis shall endeavor to collect repayment of all or a portion of the value of Equity Awards for the three years prior to an Affirmative Recoupment Determination from a Covered Executive through reasonable and appropriate means (including by means of filing suit against the executive, as may be appropriate) to the extent permitted by controlling law of the relevant jurisdiction.

**(iii) Additional Remedies.** To the extent permitting by controlling law, for the three years during which the Cash and Equity Award eligibility and repayment conditions exist, if Novartis reasonably anticipates that a Triggering Event has occurred, and Novartis has recoupment rights remaining under Paragraphs B(i)-(ii), Novartis 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, Novartis 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 repayment 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

violation of a significant Novartis policy) relating to Covered Functions, as defined in Section II.C.9 of the CIA, by the Covered Executive that, if discovered prior to payment, would have made the Covered Executive ineligible for a Cash or Equity Award in that plan year or subsequent plan years; or

- (ii) Significant Misconduct (as defined above) relating to Covered Functions, as defined in Section II.C.9 of the CIA, by subordinate employees in the business unit for which the Covered Executive had responsibility 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 or Equity Award in that plan year or subsequent plan years.

**(D) Administration of Recoupment Programs.** Novartis shall engage in a standardized, formal process to determine whether a Triggering Event has occurred, and, if so, the extent of the Cash and Equity Awards that will be subject to repayment or forfeiture by the Covered Executive, and the most appropriate method for securing recoupment of relevant monies previously paid to a Covered Executive. The findings and conclusions resulting from this process shall be referred to as the “Recoupment Determination.” A determination that Cash 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.** Novartis shall initiate the Recoupment Determination process upon: (1) discovery of potential Significant Misconduct that may rise to the level of a Triggering Event, or (2) written notification by a United States federal government agency to Novartis’ Chief Compliance Officer of a situation that may rise to the level of a Triggering Event and either occurred in the United States or gives rise to liability relating to Federal health care programs. This written notification shall either identify the Covered Executive(s) potentially at issue or provide information (e.g., a description of the alleged Significant Misconduct and the applicable time period) to allow Novartis to identify the Covered Executive.

**(ii) Recoupment Committee.** The Recoupment Determination shall be made by a committee of senior executives representing the Ethics, Risk & Compliance, People & Organization; Legal, and Finance and Internal Audit (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 individual is subject to a Recoupment Determination. If a Recoupment Determination involves an Executive Officer of Novartis, a Recoupment

Determination for such individual shall be subject to approval by the Board of Directors (or appropriate committee thereof) of Novartis.

**(iii) Recoupment Determination Process.** Novartis shall initiate the Recoupment Determination process within 30 days after discovery by Novartis, or notification pursuant to Paragraph D(i)(2), of a potential Triggering Event.

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 or Equity Awards (collectively “performance pay”) that will be subject to forfeiture and/or repayment by the Covered Executive, if any; 3) the means that will be followed to implement the forfeiture and/or secure the recoupment of performance pay from the Covered Executive; and 4) the timetables under which Novartis will implement the forfeiture and/or attempt to recoup the performance pay.

For purposes of this Paragraph, a “Delegate” shall refer to the Novartis 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 Novartis 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. Novartis shall provide OIG with additional information regarding any Recoupment Determination where a Triggering Event has occurred upon OIG's request.

Novartis 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.