

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

I. PREAMBLE

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

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

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Amgen under this CIA shall be five years from the effective date of this CIA. The “Effective Date” shall be the date on which the final signatory of this CIA executes this CIA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a “Reporting Period.”

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

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

1. "Covered Persons" includes:

- a. all owners of Amgen who are natural persons (other than shareholders who: (i) have an ownership interest of less than 5% and (ii) acquired the ownership interest through public trading);
- b. all executive officers and directors of Amgen;
- c. all U.S. employees of Amgen who engage in or supervise personnel who are engaged in Covered Functions (as defined below in Section II.C.5); and
- d. all U.S. contractors, subcontractors, agents, and other persons (including contract sales personnel) who perform any of the Covered Functions on behalf of Amgen and in that capacity either: (i) interact directly with healthcare professionals (HCPs), healthcare institutions (HCIs), consumers or independent third-party patient assistance programs; 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 Amgen 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 Amgen 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 Amgen during the calendar year.

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

4. The term “Patient Assistance Related Functions” includes: all activities, systems, processes, and procedures relating to the following: (a) any grants, charitable contributions, or cash or in kind donations provided by Amgen or any entity acting on behalf of Amgen to any independent third-party patient assistance program (Independent Charity PAP) (“Independent Charity PAP Related Functions”); and (b) the operation of, or participation in, any patient assistance program by Amgen or any entity acting on behalf of Amgen that provides free drugs to patients, including Federal health care program beneficiaries (*i.e.*, Amgen’s internal free drug program) 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.4.b shall be collectively referred to as “Amgen PAPs”).

5. The term “Covered Functions” refers to “Promotional Functions,” and “Patient Assistance Related Functions,” collectively.

6. The term “Third Party Personnel” refers to personnel who engage in Promotional Functions who are employees of entities with which Amgen has entered or may in the future (during the term of this CIA) enter into agreements to promote or co-promote a Government Reimbursed Product or to engage in joint promotional activities relating to such a product. Amgen represents that: (1) Third Party Personnel are employed by entities other than and independent of Amgen; (2) Amgen does not control Third Party Personnel; and (3) it would be commercially impractical to compel the compliance of Third Party Personnel with the requirements set forth in this CIA. Amgen agrees to promote compliance by Third Party Personnel with Federal health care program requirements by complying with the provisions set forth below in Sections III.C.4, V.A.7, and V.B.6. Provided that Amgen complies with the requirements of Sections III.C.4, V.A.7, and V.B.6, Amgen 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.

III. CORPORATE INTEGRITY OBLIGATIONS

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

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

1. *Compliance Officer.* Within 90 days after the Effective Date, Amgen 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 Amgen; shall report directly to the Chief Executive Officer of Amgen; and shall not be, or be subordinate to, the General Counsel or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for Amgen. 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 requirements;
- b. making periodic (at least quarterly) reports regarding compliance matters directly to the Corporate Responsibility and Compliance Committee of the Board of Directors of Amgen (CRCC) and shall be authorized to report on such matters to the CRCC at any time. Written documentation of the Chief Compliance Officer's reports to the CRCC shall be made available to OIG upon request; and
- c. monitoring the day-to-day compliance activities engaged in by Amgen and 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.

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

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

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

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

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

- a. meeting at least quarterly to review and oversee Amgen's Compliance Program, including but not limited to the performance of the Chief Compliance Officer and Compliance Committee;
- b. submitting to OIG a description of the documents and other materials it reviewed, as well as any additional steps taken, such as the engagement of an independent advisor or other third party resources, in its oversight of the compliance

program and in support of making the resolution below during each Reporting Period; and

- c. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the CRCC, summarizing its review and oversight of Amgen's compliance with Federal health care program requirements and the obligations of this CIA.

At minimum, the resolution shall include the following language:

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

If the CRCC is unable to provide such a conclusion in the resolution, the CRCC 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 Amgen.

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

4. *Management Certifications:* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Amgen employees (Certifying Employees) are expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable Amgen division or business unit is in compliance with applicable Federal health care program requirements and the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: Executive Vice President (EVP), Global Commercial Operations; Senior Vice President (SVP), Corporate Affairs; SVP, Global Strategy, Commercialization, and Innovation; SVP, General Manager (GM), U.S. General Medicine; Vice President (VP), GM, U.S. Oncology Business Unit; VP, GM, U.S. Inflammation and Nephrology Business Unit; VP, GM, Neurology Business Unit; VP, GM Bone and Cardiovascular Business Unit;

and VP, Value & Access. For each Reporting Period, each Certifying Employee shall sign a certification that states:

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

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

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

B. Written Standards.

Within 120 days after the Effective Date, Amgen 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 Amgen’s compliance with Federal health care program requirements (Policies and Procedures). Throughout the term of this CIA, Amgen shall enforce its Policies and Procedures and shall make compliance with its Policies and Procedures an element in evaluating the

performance of all Covered Persons. The Policies and Procedures shall be made available to all Covered Persons.

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

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

reduce or eliminate the cost of copayments for drugs, including but not limited to, the OIG's Special Advisory Bulletin on Pharmaceutical Manufacturer Copayment Coupons (Sept. 2014);

- d. the materials and information that may be distributed by appropriate Amgen personnel about Independent Charity PAPs or Patient Assistance Related Functions and the manner in, and circumstances under, which appropriate Amgen personnel may respond to requests for information about Independent Charity PAPs or Patient Assistance Related Functions; and
- e. appropriate ways to conduct Promotional Functions in compliance with all: (i) applicable Federal healthcare program requirements, including but not limited to, the Federal Anti-Kickback Statute and the False Claims Act, and (ii) applicable Federal Food and Drug Administration (FDA) requirements.

At least annually (and more frequently, if appropriate), Amgen 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, Amgen shall develop a written plan (Training Plan) that outlines the steps Amgen will take to ensure that: (a) all Covered Persons receive at least annual training regarding Amgen's CIA requirements and compliance program, and (b) all Covered Persons who engage in Covered Functions receive at least annual training regarding: (i) all applicable Federal health care program and FDA requirements relating to Covered Functions and (ii) all Amgen 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 required to attend each training session, length of the training session(s), schedule for training, and format of the training. Amgen shall

furnish training to its Covered Persons pursuant to the Training Plan during each Reporting Period.

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

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

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

4. *Third Party Personnel.* Within 90 days after the Effective Date, and annually thereafter by the anniversary of the Effective Date, Amgen shall send a letter, either in hard copy or electronic form, to each entity employing Third Party Personnel. The letter shall outline Amgen's obligations under the CIA and its commitment to full compliance with all Federal health care program requirements. The letter shall include a description of the Amgen Compliance Program. Amgen shall request the entity employing Third Party Personnel to either: (a) make a description of the Amgen Compliance Program available to its Third Party Personnel; or (b) represent to Amgen that it has and enforces a substantially comparable compliance program for its Third Party Personnel.

D. Risk Assessment Process.

Within 120 days after the Effective Date, Amgen shall develop and implement a centralized annual Risk Assessment Process to identify and address risks associated with each of Amgen's Government Reimbursed Products and with applicable Federal health care program requirements. The Risk Assessment Process shall require compliance,

legal, and department leaders, at least annually, to: (1) identify and prioritize risks related to the sales, marketing, and promotion of Government Reimbursed Products, and risks associated with Amgen's operation of any Patient Assistance Related Function and the company's arrangements and interactions with any Independent Charity PAPs, (2) develop mitigation plans in response to the results of risk assessments performed, and (3) track the implementation of the mitigation plans in order to assess the implementation, status, or effectiveness of such plans. Amgen shall maintain the Risk Assessment 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, Amgen shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform the reviews listed in this Section III.E. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.
- b. *Retention of Records.* The IRO and Amgen shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Amgen) related to the reviews.
- c. *Access to Records and Personnel.* Amgen shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in this Section III.E and that all records furnished to the IRO are accurate and complete.

2. *System, Transaction, and Additional Items Reviews.* As set forth more fully in Appendix B, the IRO Reviews shall consist of two components: Systems Review and Transactions Review. The Systems Review shall assess Amgen's systems, processes, policies, and procedures relating to the Covered Functions.

If there are no material changes in Amgen’s relevant systems, processes, policies, and procedures relating to Independent Charity PAP Related Functions or the Independent Charity PAP Review Program, the IRO shall perform the Systems Review for Independent Charity PAP Related Functions and the Independent Charity PAP Review Program for first and fourth Reporting Periods.

If there are no material change in Amgen’s systems, processes, policies, and procedures relating to Amgen PAPs, the IRO shall perform the Systems Review relating to Amgen PAPs for the second and fourth Reporting Periods.

If Amgen materially changes its relevant systems, processes, policies, and procedures, the IRO shall perform a Systems Review for the Reporting Period in which such changes were made in addition to conducting the Systems Review for the first and fourth or second and fourth Reporting Periods, as set forth more fully in Appendix B.

The Transactions Review shall be performed for the second through fifth Reporting Periods. The IRO(s) shall perform all components of each annual Transaction Review.

As set forth more fully in Appendix B, the Transactions Review shall include several components. In addition to the items specifically identified in Appendix B, each Transactions Review shall also include a review of up to three additional areas or practices of Amgen identified by OIG in its discretion (hereafter “Additional Items”).

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

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

F. Disclosure Program.

Within 90 days after the Effective Date, Amgen 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 Amgen's policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. Amgen shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees, or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. The Disclosure Program also shall include a requirement that all of Amgen's Covered Persons shall be expected to report suspected violations of any Federal health care program requirements to the Chief Compliance Officer or other appropriate individual designated by Amgen. 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, Amgen shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

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

G. Ineligible Persons.

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

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

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

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

Nothing in this Section III.G affects Amgen’s responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by excluded persons. Amgen understands that items or services furnished, ordered, or prescribed by an excluded person are not payable by Federal health care programs and that Amgen may be liable for overpayments and/or criminal, civil, and

administrative sanctions for employing or contracting with an excluded person regardless of whether Amgen meets the requirements of Section III.G.

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

4. *Pending Charges and Proposed Exclusions.* If Amgen 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, Amgen 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. Notification of Government Investigation or Legal Proceeding.

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

I. Reportable Events.

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

- a. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable

to any Federal health care program for which penalties or exclusion may be authorized;

- b. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or
- c. the filing of a bankruptcy petition by Amgen.

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

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

3. *Reportable Events under Section III.I.1.a.* For Reportable Events under Section III.I.1.a, the report to OIG shall include:

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

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

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

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

J. Independent Charity Patient Assistance Program Activities

To the extent that Amgen makes monetary donations to Independent Charity PAPs, it shall implement the policies, procedures, and practices set forth in this Section III.J within 120 days after the Effective Date. Amgen 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. *PAP Governance Committee.* Amgen shall vest sole responsibility and authority for budgeting and all other activities relating to Independent Charity PAPs

in a department or group within Amgen known as the “PAP Governance Committee” that has the following roles and responsibilities:

- a. The PAP Governance Committee shall be separate and independent from Amgen’s commercial organization.
- b. The PAP Governance Committee shall operate independently from Amgen’s commercial organization and Amgen’s commercial organization shall have no involvement in, or influence over, the review, approval, or implementation of any budget or other decisions or activities relating to Independent Charity PAPs.
- c. Amgen shall vest in the PAP Governance Committee sole responsibility and authority for communicating with Independent Charity PAPs regarding Amgen’s donations to such PAPs and Amgen’s commercial organization shall not communicate with, influence, or be involved in any communications with, or receive information from the Independent Charity PAPs.
- d. Amgen’s PAP Governance 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.
- d. For purposes of this CIA, the “commercial organization” shall be defined to include the sales, marketing, and similar commercial business units of Amgen.

2. *Budgeting Process.* Amgen’s PAP Governance Committee shall establish a budget process to be followed for Amgen’s donations to Independent Charity PAPs that meets the following requirements:

- a. The PAP Governance 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. Amgen shall approve the annual budget for donations to Independent Charity PAPs through a process or organization that does not include, nor is influenced by, the commercial organization (e.g., the Amgen Finance Department).
- c. The PAP Governance 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 PAP Governance 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 PAP Governance 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 Amgen 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 PAP Governance Committee from the commercial organization.

3. *Criteria Relating to Donations to Independent Charity PAPs.* The PAP Governance 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 Amgen to patients and does not

impermissibly influence patients' drug choices. In addition, Amgen agrees that it will donate to an Independent Charity PAP only if the following criteria are satisfied:

- a. Amgen 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, Amgen 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. Amgen 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. Amgen 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 Amgen's products or services.
- d. Amgen does not and shall not provide donations for a disease state fund that covers only a single product or that covers only Amgen's products.
- e. Personnel from Amgen's legal and compliance departments shall review all proposed donations and arrangements between Amgen and any Independent Charity PAP prior to such donations being made or arrangements being entered into by Amgen.

4. *Independent Charity PAP Review Program.* Within 120 days after the Effective Date, Amgen shall establish an Independent Charity PAP Review Program (Independent Charity PAP Review Program) through which members of the compliance

department or other appropriate personnel (either Amgen employees or outside resources) (Monitoring Personnel) shall conduct annual monitoring of ten (10) or fifty percent (50%) (whichever is a greater number) of Amgen's donations to disease state funds of Independent Charity PAPs. The Independent Charity PAP Review Program shall select donations for review through both a risk-based targeting approach and a random sampling approach.

With respect to the donations subject to monitoring, Monitoring Personnel shall review: (a) budget documents; (b) documents relating to the decision to provide donations to a particular Independent Charity PAP; (c) any written agreements in place between Amgen and the Independent Charity PAPs; (d) correspondence, emails, and other documents reflecting communications and interactions between Amgen and the Independent Charity PAPs; and (e) other available information relating to the arrangements and interactions between Amgen and the Independent Charity PAPs. The purpose of the Independent Charity PAP Review Program shall be to assess whether the activities were conducted in a manner consistent with Amgen's policies and procedures described above and with OIG guidance.

In the event that a compliance issue, including but not limited to any potential improper conduct or noncompliance with Amgen's policies and procedures or legal or compliance requirements, is identified during any portion of the Independent Charity PAP Review Program, Amgen shall address the incident consistent with established policies and procedures for the handling of compliance issues. 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.I above, as applicable. Results from the Independent Charity PAP Review Program, including the identification of potential violations of policies and procedures, shall be compiled and reported to the Chief Compliance Officer for review and follow-up as appropriate. Any compliance issues identified during the PAP Review Program and any corrective action shall be recorded in the files of the Chief Compliance Officer.

Amgen shall include a summary of the Independent Charity PAP process and the PAP Review Program outlined in this section III.J in the Implementation Report. In addition, Amgen shall include a description of any changes to the Independent Charity PAP process and the results of the PAP Review Program as part of each Annual Report.

IV. SUCCESSOR LIABILITY

In the event that, after the Effective Date, Amgen proposes to (a) sell any or all of its business, business units or locations (whether through a sale of assets, sale of stock or other type of transaction) that are subject to this CIA; or (b) purchases or establishes a new business, business unit or location related to or engaged in any of the Covered Functions, the CIA shall be binding on the purchaser of any business, business unit or location. Any new business, business unit or location (and all Covered Persons at each new business, business unit or location) shall be subject to the applicable requirements of this CIA, unless otherwise determined and agreed to in writing by OIG. Amgen 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, Amgen 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, Amgen 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, Amgen 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 Compliance Officer may have;
2. the names and positions of the members of the Compliance Committee required by Section III.A.2;

3. the names of the CRCC members who are responsible for satisfying the compliance obligations described in Section III.A.3;
4. the names and positions of the Certifying Employees required by Section III.A.4 and a written copy of the process to be followed by Certifying Employees in connection with completing the required certifications;
5. a list of the Policies and Procedures required by Section III.B.3;
6. the Training Plan required by Section III.C.1 and a description of the Board of Directors training required by Section III.C.2 (including a summary of the topics covered, the length of the training and when the training was provided);
7. (a) a copy of the letter (including all attachments) required by Section III.C.4 sent to each party employing Third Party Personnel; (b) a list of all existing co-promotion and other applicable agreements with the party employing the Third Party Personnel; and (c) a description of the entities' response to Amgen's letter;
8. a description of the Risk Assessment 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 Appendix A; and (d) a certification from the IRO regarding its professional independence and objectivity with respect to Amgen;
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 description of the Independent Charity PAP policies, procedures, and practices required by Section III.J including the Independent Charity PAP Review Program;
13. a list of all of Amgen's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the

corresponding phone numbers and fax numbers, and the location's Medicare and state Medicaid program provider and/or supplier numbers (if any);

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

15. the certifications required by Section V.C.

B. Annual Reports.

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

1. (a) any change in the identity, position description, or other noncompliance job responsibilities of the Chief Compliance Officer; (b) a current list of the Compliance Committee members; (c) a current list of the CRCC members who are responsible for satisfying the Board of Directors compliance obligations; (d) a current list of the Certifying Employees, along with any changes made during the Reporting Period to the Compliance Committee, CRCC, and Certifying Employees; and (e) a description of any changes to the process to be followed by Certifying Employees 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 CRCC resolution required by Section III.A.3 and a description of the documents and other materials reviewed by the Board, as well as any additional steps taken, in its oversight of the compliance program and in support of making the resolution;

4. a list of any new or revised Policies and Procedures developed during the Reporting Period under Section III.B;

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

6. (a) a copy of the letter (including all attachments) required by III.C.4 sent to each party employing Third Party Personnel; (b) a list of all entities employing Third Party Personnel with whom Amgen has entered into such co-promotion and other similar agreements; and (c) a description of the entities' response to Amgen's letter;

7. a description of any changes to the Risk Assessment Process required by Section III.D, including the reasons for such changes;

8. a summary of the following components of the Risk Assessment Process during the Reporting Period: (a) mitigation plans developed; and (b) steps taken to track the implementation, status, and effectiveness of the mitigation plans. Copies of any mitigation plans, and documents relating to the implementation, status and effectiveness of the mitigation plans shall be made available to OIG upon request;

9. a complete copy of all reports prepared pursuant to Section III.E and Appendix B and Amgen's response to the reports, along with corrective action plan(s) related to any issues raised by the reports;

10. a certification from the IRO regarding its professional independence and objectivity with respect to Amgen;

11. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs or Government Reimbursed Products, including at least the following information: (a) a description of the disclosure; (b) the date the disclosure was received; (c) the resolution of the disclosure; and (d) the date the disclosure was resolved (if applicable). The complete disclosure log shall be made available to OIG upon request;

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

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

14. a summary of Reportable Events (as defined in Section III.I)

identified during the Reporting Period;

15. a description of any changes to the Independent Charity PAP policies, procedures, and practices outlined in section III.J (including the reasons for such changes) and a summary of the results of the PAP Review Program including a description of any instances in which it was determined that improper conduct or policy violations occurred and a description of the action(s) that Amgen took as a result of such determinations;

16. a description of all changes to the most recently provided list of Amgen's locations as required by Section V.A.13;

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

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

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

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

3. *Compliance Officer and Chief Executive Officer.* Each Annual Report shall include a certification by the Chief Compliance Officer and Chief Executive Officer that:

- a. to the best of his or her knowledge, except as otherwise described in the report, Amgen is in compliance with the requirements of this CIA;
- b. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful;
- c. for each disease fund of an Independent Charity PAP to which Amgen 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 Amgen's policies and procedures (including those outlined in Section III.J); and
- d. for each Amgen PAP (as defined in Section II.C.4.b above), the facts and circumstances relating to each 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 Amgen's policies and procedures.

D. Designation of Information.

Amgen 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. Amgen 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

Amgen:

Chief Compliance Officer
Amgen
One Amgen Center Drive
Thousand Oaks, CA 91320
Telephone: 805.447.1000

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

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may conduct interviews, examine and/or request copies of or copy Amgen's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Amgen's locations for the purpose of verifying and evaluating: (a) Amgen's compliance with the terms of this CIA and (b)

Amgen's compliance with the requirements of Federal health care programs. The documentation described above shall be made available by Amgen 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 Amgen's owners, employees, contractors and directors who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Amgen shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Amgen's owners, employees, contractors and directors may elect to be interviewed with or without a representative of Amgen present.

VIII. DOCUMENT AND RECORD RETENTION

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

X. BREACH AND DEFAULT PROVISIONS

Amgen 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, Amgen and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the

day after the date the obligation became due) for each day Amgen fails to establish, implement or comply with any of the following obligations as described in Section III:

- a. a Chief Compliance Officer;
- b. a Compliance Committee;
- c. the CRCC compliance obligations;
- d. the management certification obligations;
- 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 Process;
- h. a Disclosure Program;
- i. Ineligible Persons screening and removal requirements;
- j. notification of Government investigations or legal proceedings;
- k. reporting of Reportable Events; and
- l. the Independent Charity PAP policies, procedures, and practices and the Independent Charity PAP Review Program required by Section III.J.

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 Amgen fails to engage and use an IRO as required by Section III.E, Appendix A, or Appendix B.

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Amgen fails to submit a

complete Implementation Report, Annual Report or any certification to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Amgen fails to submit any IRO Review report in accordance with the requirements of Section III.E and Appendix B.

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

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

8. A Stipulated Penalty of \$1,000 for each day Amgen fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Amgen stating the specific grounds for its determination that Amgen has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Amgen shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the date Amgen 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. Amgen 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 Amgen fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or

file the notification or report shall not begin to accrue until three days after Amgen receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

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

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Amgen 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 Amgen elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Amgen 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 Amgen 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 Amgen to report a Reportable Event and take corrective action as required in Section III.I;
- c. a failure to engage and use an IRO in accordance with Section III.E, Appendix A, or Appendix B; or
- d. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Amgen constitutes an independent basis for Amgen's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in OIG's discretion, but not more than five years per material breach. Upon a determination by OIG that Amgen has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Amgen of: (a) Amgen's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")

3. *Opportunity to Cure.* Amgen shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate 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) Amgen has begun to take action to cure the material breach; (ii) Amgen is pursuing such action with due diligence; and (iii) Amgen has provided to OIG a reasonable timetable for curing the material breach.

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

its determination to exclude Amgen. (This letter shall be referred to as the “Exclusion Letter.”) Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Amgen’s receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, Amgen 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 Amgen 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, Amgen 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 Amgen was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Amgen 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 Amgen to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Amgen 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 Amgen was in material breach of this CIA and, if so, whether:

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

Amgen and OIG agree as follows:

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

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

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

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

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

ON BEHALF OF AMGEN INC.

/Cynthia M. Patton/
CYNTHIA PATTON
Chief Compliance Officer
Amgen Inc.

4/23/2019
DATE

/John Rah/
JOHN RAH
DLA Piper
Counsel for Amgen Inc.

4/23/2019
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

04/24/2019
DATE

/Mary E. Riordan/
MARY E. RIORDAN
Senior Counsel

4/24/2019
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. Amgen Inc. (Amgen) 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 Amgen in response to a request by OIG, whichever is later, OIG will notify Amgen if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Amgen may continue to engage the IRO.

2. If Amgen 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, Amgen 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 Amgen at the request of OIG, whichever is later, OIG will notify Amgen if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Amgen 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 any 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 B to the CIA.

D. Amgen Responsibilities

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

E. IRO Independence and Objectivity

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

F. IRO Removal/Termination

1. *Amgen and IRO.* If Amgen terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Amgen 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. Amgen 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 Amgen in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. Amgen 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 Amgen regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify Amgen in writing that Amgen shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. Amgen 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 Amgen to engage a new IRO shall be made at the sole discretion of OIG.

CIA with Amgen Inc. Appendix B

I. IRO Engagement, General Description

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

If there are no material changes in Amgen's systems, processes, policies, and procedures relating to Independent Charity PAP Related Functions or the Independent Charity PAP Review Program, the IRO shall perform the Systems Review outlined in Sections II.A.1 and II.B below (relating to Independent Charity PAP Related Functions and the Independent Charity PAP Review Program, respectively) for the first and fourth Reporting Periods.

If there are no material changes in Amgen's systems, processes, policies, and procedures relating to Amgen PAPs (as defined in Section II.C.4.b of the CIA), the IRO shall perform the Systems Review outlined in Section II.A.2 below (relating to Amgen PAPs) for the second and fourth Reporting Periods.

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

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

II. IRO Systems Review

The Systems Review shall be a review of Amgen's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures)

relating to Patient Assistance Related Functions and the Independent Charity PAP Review Program. Where practical, Amgen 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 Amgen pursuant to the preceding sentence.

More specifically, the IRO shall review Amgen’s systems, processes, policies, and procedures associated with the following (hereafter “Reviewed Policies and Procedures”):

A. Patient Assistance Related Functions

- 1) Amgen’s systems, policies, processes, and procedures relating to arrangements and interactions with (including donations to and sponsorship of) Independent Charity PAPs.

This review shall include an assessment of the following:

- a. Amgen’s organizational structure as it relates to arrangements and interactions with Independent Charity PAPs, including:
 - i. the identification of those individuals, departments, or groups within Amgen (e.g., the PAP Governance Committee, legal, compliance) 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 Amgen (e.g., the commercial business units) that are precluded from involvement with arrangements and interactions with Independent Charity PAPs; and
 - iv. methods that Amgen uses to separate Independent Charity PAP-related responsibilities from the commercial business units.
- b. Amgen’s written policies and procedures as they relate to arrangements and interactions with Independent Charity PAPs, including:

- i. the criteria governing whether and under what circumstances Amgen 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 Amgen 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 Amgen with responsibility for Independent Charity PAPs and the commercial business units of Amgen (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 Amgen and health care providers or patients regarding assistance available through any Independent Charity PAP.
- c. Amgen's policies and practices as they relate to the budgeting process applicable to donations to Independent Charity PAPs as outlined in Section III.J.2 of the CIA, including as it relates to initial or annual donation amounts and any supplemental amounts;
- d. Amgen's policies and practices as they relate to the process by which decisions about the following are made and approved: i) whether to donate (or continue to donate) to a particular Independent Charity PAP; and ii) the amount of the donation (including any initial or annual amount and any supplemental amount);
- e. Amgen's policies and practices as they relate to donations made by Amgen to any Independent Charity PAPs as referenced in Section III.J.3, including the internal review process followed in connection with any donations to Independent Charity PAPs; and
- f. Amgen's policies and practices as they relate to information provided, directly or indirectly, to the public about the availability of patient assistance for Amgen's products.

- 2) Amgen's systems, policies, processes, and procedures relating to any Amgen PAPs.

This review shall include an assessment of the following:

- a. The general elements of Amgen PAPs, including: i) the types of assistance that are made available through Amgen 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; and iv) the controls used to implement the eligibility criteria (*i.e.*, controls employed to ensure that appropriate patients receive the various types of assistance).
- b. Amgen's policies and practices as they relate to the process by which decisions about the following are made and approved: i) whether to provide (or continue to provide) the various types of assistance through any Amgen 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
- c. Amgen's policies and practices as they relate to any contracts or agreements entered between Amgen and outside entities relating to any Amgen 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 agreements, and the review and approval of such contracts or agreements.

B. Independent Charity PAP Review Program

- 1) Amgen's systems, policies, processes, and procedures related to its Independent Charity PAP Review Program.

This review shall include a review to understand the following:

- a. Amgen's systems, processes, policies and procedures related to Amgen's Independent Charity PAP Review Program required by Section III.J.4 that are designed to identify and manage relevant risks arising under Federal health care program requirements associated with donations by pharmaceutical manufacturers to Independent Charity PAPs;
- b. The process or factors that Amgen uses to identify the following:

- i. which donation arrangements with Independent Charity PAPs will be reviewed for the particular Reporting Period;
 - i. the relevant Amgen colleague roles that Amgen will include in the Independent Charity PAP Review Program for a particular Reporting Period; and
 - ii. the relevant records, documents or other information that Amgen will include as part of its Independent Charity PAP Review Program for a particular Reporting Period;
- c. The frequency or timing of when Amgen conducts the Independent Charity PAP Review Program;
- d. The experience and background of individuals who are engaged in the Independent Charity PAP Review Program and a review of any relevant training or other guidance provided to these individuals; and
- e. The systems, policies, processes and procedures to review initial results of the Independent Charity PAP Review Program that are related to donations to Independent Charity PAPs and to remediate any issues identified as a part of the Independent Charity PAP Review Program.

III. IRO Systems Review Report

The IRO shall prepare a report based upon each Systems Review.

A. Independent Charity PAP Related Functions

For each of the Reviewed Policies and Procedures identified in Section II.A.1 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 Amgen's systems, policies, processes, and procedures relating to the items identified in Section II.A.1 above, including a general

- description of Amgen's 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 Section II.A.1 above are made known or disseminated within Amgen;
 - 4) a detailed description of any system(s) used to track requests for donations or other assistance from any Independent Charity PAP and the donations or other assistance provided in response to such requests;
 - 5) findings and supporting rationale regarding any weaknesses in Amgen's systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and
 - 6) recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

B. Amgen PAPs

For each of the Reviewed Policies and Procedures identified in Section II.A.2 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 Amgen's systems, policies, processes, and procedures relating to the items identified in Section II.A.2 above, including a general description of Amgen's control and accountability systems (e.g., documentation and approval requirements, and tracking mechanisms) and any written policies;
- 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.2 above are made known or disseminated within Amgen;
- 4) a detailed description of any system(s) used to track requests for donations or other assistance from any Independent Charity PAP and the donations or other assistance provided in response to such requests;

- 5) a detailed description of any system(s) used to track donations or other assistance provided in response to requests through any Amgen PAP;
- 6) findings and supporting rationale regarding any weaknesses in Amgen's systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and
- 7) recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

C. Independent Charity PAP Review Program

For each of the systems, processes, policies and procedures reviewed pursuant to Section II.B above, the report shall include the following items:

- 1) A description of the documentation reviewed and personnel interviewed as part of the Independent Charity PAP Review Program Systems Review;
- 2) A description of the systems, processes, policies and procedures that Amgen uses to conduct the Independent Charity PAP Review Program and to remediate and escalate issues related to donations to Independent Charity PAPs;
- 3) A description of the background and experience of the individuals who perform the Independent Charity PAP Review Program;
- 4) Whether the Independent Charity PAP Review Program processes, policies and procedures related to the Independent Charity PAP Review Program are reasonably designed to identify, prioritize and manage relevant risks;
- 5) Whether the systems, processes, policies and procedures are reasonably designed to escalate identified issues and/or remediate such issues; and
- 6) Recommendations to improve any of the systems, policies, processes, or procedures relating to the Independent Charity PAP Review Program, if any.

IV. IRO Transactions Review

As described more fully below in Sections IV.A-C, the Transactions Review shall include: (1) a review of Amgen’s arrangements with selected Independent Charity PAPs; and (2) a review of up to three additional items identified by OIG (hereafter “Additional Items”). The IRO shall report on all aspects of its reviews in the Transactions Review Reports.

A. IRO Review of Arrangements with Independent Charity PAPs

The IRO shall conduct a review and assessment of Amgen’s compliance with the Independent Charity PAP processes, policies, and procedures outlined in Section III.J of the CIA. More specifically, the IRO shall review fifty percent (50%) of the donation arrangements that Amgen entered into with Independent Charity PAPs during the Reporting Period for which the IRO is conducting the Transactions Review.

Amgen has represented that, as a matter of practice, Amgen enters a separate agreement with an Independent Charity PAP for each disease state fund of the PAP to which Amgen makes a donation. Amgen shall provide the IRO with a list of all Independent Charity PAPs with which Amgen entered into a donation agreement during the Reporting Period under review (the “applicable Reporting Period”). The IRO will randomly select and review 50% of these donation arrangements for the applicable Reporting Period.

For purposes of the Independent Charity PAP Transactions Review, the term “Reviewed Materials” shall mean the following for each Independent Charity PAP arrangement reviewed:

- 1) the Annual Notice from Amgen to Independent Charity PAPs (which announces Amgen’s willingness to consider written requests for contributions and seeks information regarding: anticipated patient need for particular disease state funds; patient eligibility criteria used by the Independent Charity PAPs; and information about the Independent Charity PAPs);
- 2) responses from Independent Charity PAPs to the Annual Notice (which includes information on anticipated patient need for particular disease state funds; details regarding patient eligibility criteria used by the Independent Charity PAPs; and information about the Independent Charity PAPs (e.g., information about administrative fees, patient grant amounts, average processing time to assist patients, etc.));

- 3) patient needs assessment documentation related to a donation arrangement with an Independent Charity PAP (which includes information on the assessment of patient need in disease states based on non-patient-specific or drug-specific information from eligible Independent Charity PAPs, other publicly available information, and Amgen's internal free drug program);
- 4) allocation documentation that shows the objective criteria used to evaluate Independent Charity PAPs and the allocation of the approved budget across disease states and Independent Charity PAPs (e.g., patient needs assessment information for disease state funds, information about Amgen's historical donations; eligibility criteria of the Independent Charity PAPs; and other relevant information, as applicable);
- 5) documents required by Amgen policy to evidence or document the review and approval of a decision to provide a donation to a particular fund of an Independent Charity PAP (e.g., minutes from Amgen's PAP Governance Committee that memorialize donation decisions, including budget allocation across disease states and Independent Charity PAPs, and final determinations (approvals or rejections) on proposed donations to Independent Charity PAPs);
- 6) to the extent not covered by item 2 above, all correspondence between Amgen and an Independent Charity PAP relating to any donation arrangement with the Independent Charity PAP;
- 7) any donation agreement entered into between Amgen and an Independent Charity PAP during the applicable Reporting Period; and
- 8) payment documentation required by Amgen policy reflecting: the total amount of donations Amgen agreed to make to an Independent Charity PAP broken down by disease fund, if applicable; the schedule of such payments, if applicable; the actual payments made; and any decisions to change the initial donation amount agreed to by Amgen.

For each Independent Charity PAP donation arrangement selected as part of the IRO review, the IRO shall assess the Reviewed Materials to evaluate whether the Independent Charity PAP Related Functions were conducted in a manner consistent with Amgen's policies and procedures, including those described in Section III.J of the CIA, and with

OIG guidance. In addition, the IRO may interview members of Amgen's PAP Governance Committee regarding the Reviewed Materials and Amgen's policies and process relating to donations to Independent Charity PAPs.

Based upon the Reviewed Materials and any interviews of the PAP Governance Committee, the IRO shall evaluate and identify:

- 1) Whether activities relating to arrangements with the Independent Charity PAP were undertaken by the appropriate individuals, departments, or groups within Amgen in accordance with the company's policies and procedures including those outlined in Section III.J.1 of the CIA;
- 2) Whether Amgen's commercial business units influenced or were involved in the PAP Governance Committee's decisions to enter into an arrangement with an Independent Charity PAP in violation of Amgen's policies and procedures or OIG guidance;
- 3) Whether Amgen followed the budgeting policies and practices outlined in Section III.J.2 of the CIA with regard to any initial or annual donation amounts to the Independent Charity PAP and any supplemental amounts;
- 4) Whether Amgen followed the decision-making and approval process required by Amgen's policies and procedures and outlined in Section III.J 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 Amgen would donate to the Independent Charity PAP or any specific disease state fund of such a PAP;
- 5) Whether Amgen followed the policies and practices outlined in Section III.J.3 in connection with all donations made by Amgen to any Independent Charity PAP, including as they pertain to the internal review of potential donations and adherence to the criteria set forth in Section III.J.3;
- 6) Any communications that occurred between any representatives of Amgen 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 Amgen's policies and procedures and OIG guidance;

- 7) Whether for each donation made to the Independent Charity PAP, Amgen complied with the requirements outlined in Section III.J.3; and
- 8) Whether, based on its review, the IRO found that Amgen exerted influence or control over the Independent Charity PAP in violation of Amgen's policies and procedures, including those outlined in Section III.J.3.

B. IRO Review of Additional Items

As referenced in Section III.E.2 of the CIA, for the second through fifth Reporting Periods OIG at its discretion may identify up to three additional items for the IRO to review (hereafter "Additional Items"). Amgen has represented that, prior to the Effective Date of the CIA, Amgen established an annual external review process through which Amgen engages an outside entity to review and make findings regarding certain aspects of its operations (the "External Reviews"). For at least the second Reporting Period, OIG agrees to permit these External Reviews to be substituted for any Additional Items reviews by an IRO that would otherwise be required under this Section IV.B of Appendix B.

At least 60 days prior to the end of the second Reporting Period, Amgen shall provide to OIG a list of all External Reviews completed in that Reporting Period. OIG may select up to three of the External Reviews and shall notify Amgen of its selection at least 30 days prior to the end of the second Reporting Period. For each External Review selected by the OIG, Amgen shall include the following information in its Annual Report for the second Reporting Period: (1) complete copies of any written reports produced as a result of the External Review, including any findings and recommendations; and (2) Amgen's response and corrective action plan relating to any findings and recommendations set forth in the External Review report.

For subsequent Reporting Periods, OIG shall retain sole discretion over whether to continue to permit Amgen's External Reviews to be substituted for one or more of the Additional Item reviews that would otherwise be conducted by the IRO and to follow the process outlined above.

If OIG determines it will not permit such substitution then, no later than 120 days prior to the end of the applicable Reporting Period, OIG shall notify Amgen 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 shall submit an audit work plan to OIG for approval.

The IRO shall conduct the review of the Additional Items based on a work plan approved by 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 Amgen's systems, processes, policies, and procedures based on its review of each Additional Item).

C. Transactions Review Report

For each Reporting Period, the IRO shall prepare a report based on its Transactions Reviews. The report shall include the following:

1. General Elements to Be Included in Report

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

2. Results to be Included in Report

The following results shall be included in each Transactions Review Report:

(for the review of Independent Charity PAP arrangements)

- a) a list of the Independent Charity PAP funds to which Amgen made donations during the Reporting Period;
- b) for each Independent Charity PAP arrangement reviewed by the IRO, a description of the review conducted by the IRO;
- c) for each Independent Charity PAP arrangement reviewed by the IRO, findings regarding each element specified above in Sections IV.A.1-8;
- d) for each Independent Charity PAP arrangement reviewed by the IRO, a statement as to whether Amgen identified any compliance issues associated with the arrangement;

- e) the findings and supporting rationale regarding any overall weaknesses in Amgen's systems, processes, policies, procedures, and practices relating to its arrangements and interactions with Independent Charity PAPs; and
- f) recommendations, if any, for changes in Amgen's 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.

(Relating to the IRO Review of Additional Items (if required))

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