

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

Contemporaneously with this CIA, Amgen is entering into a Settlement Agreement with the United States. Amgen will also enter into settlement agreements with various States (State Settlement Agreement) and Amgen's agreement to this CIA is a condition precedent to those agreements.

Prior to the Effective Date of this CIA (as defined below), Amgen established a voluntary compliance program applicable to all Amgen directors, officers, managers, and employees (Compliance Program). Amgen's Compliance Program includes, among other features, a Chief Compliance Officer, an executive-level compliance committee and a compliance committee of the Board of Directors; a code of conduct and written policies and procedures; educational and training initiatives; an investigations function and a disclosure program; and separate Healthcare Compliance Internal Audit and Healthcare Compliance Monitoring functions responsible for conducting audits of key risk areas and both transactional and field-based monitoring activities according to results of annual risk assessments.

Amgen shall continue its Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. Amgen may modify its

Compliance Program as appropriate, but, at a minimum, Amgen shall ensure that during the term of this CIA, it shall comply with the obligations set forth herein.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Amgen under this CIA shall be five years from the effective date of this CIA, unless otherwise specified. The “Effective Date” shall be the date on which Amgen is obligated to pay the Settlement Amount as set forth in the Settlement Agreement between Amgen and the United States. 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 and Amgen USA 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); all officers of Amgen and Amgen USA who: (i) reside within the United States or (ii) are engaged in or have job responsibilities relating to any of the Covered Functions (as defined below in Section II.C.8); and all directors of Amgen and Amgen USA;

b. all employees of Amgen and Amgen USA who are engaged in or have responsibilities relating to any of the Covered Functions (as defined below in Section II.C.8); and

c. all contractors, subcontractors, agents, and other persons who perform any of the Covered Functions on behalf of Amgen or Amgen USA, and in that capacity either: (i) interact directly with healthcare professionals (HCPs), healthcare institutions (HCIs), Payors (as defined below in Section II.C.7), or consumers; or (ii)

perform activities, provide services, or create materials relating to the Covered Functions and those activities, services, or materials are not reviewed or supervised by an Amgen or Amgen USA 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 work more than 160 hours per year, except that any such individuals shall become “Covered Persons” at the point when they work more than 160 hours during the calendar year.

2. “Relevant Covered Persons” includes all Covered Persons who engage in any of the Covered Functions and all individuals who supervise Covered Persons who engage in any of the Covered Functions.
3. “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.
4. 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 Material Approval and Compliance (MAC) process and any applicable review committee for promotional materials.
5. The term “Product Related Functions” includes: (a) the preparation or external dissemination of non-promotional materials that are governed by Federal healthcare program and/or FDA requirements and distributed to HCPs, HCIs, and Payors about Government Reimbursed Products, including those functions relating to any applicable review committees and those functions involved in scientific exchange (such as Medical Information or other components of Scientific Affairs and the Global Development organization); (b) contracting with HCPs licensed in the United States to conduct post-marketing clinical trials, Investigator-

Sponsored Studies (ISSs), and any other types of post-marketing studies relating to Government Reimbursed Products; (c) authorship, publication, and disclosure of articles or study results relating to Government Reimbursed Products; and (d) activities related to the submission of information about Government Reimbursed Products to compendia (such as Drugdex or other compendia of information about Government Reimbursed Products).

6. The term “Government Pricing Functions” refers to the collection, calculation, verification, or reporting of information for purposes of the Medicaid Drug Rebate Program (codified at 42 U.S.C. § 1396r-8), the Medicare Program (42 U.S.C. §§ 1395-1395hhh), and other government programs (including the 340B Drug Pricing Program, codified at 42 U.S.C. § 256b (the 340B Program)). Persons engaged in these functions include individuals whose job responsibilities include the calculation and reporting of Average Sales Price (ASP), Average Manufacturer Price (AMP), Best Price, the 340B Program ceiling price, Average Wholesale Price (AWP) (if applicable), and all other information calculated and reported by Amgen and used in connection with Federal health care programs.
7. The term “Payor Related Functions” refers to Promotional Functions and Product Related Functions as they relate to interactions (including contracting functions) between Amgen and entities that provide a drug health benefit program for Government Reimbursed Products, including but not limited to government payors (e.g., Medicaid and Medicare) or individuals or entities under contract with or acting on behalf of government payors and commercial health plans (collectively referred to as “Payors”). Payor Related Functions also includes interactions with Payors related to formulary placement, supplemental rebate agreements, and other types of rebate agreements.
8. The term “Covered Functions” refers to “Promotional Functions,” “Product Related Functions,” “Government Pricing Functions” and “Payor Related Functions” collectively.
9. The term “Independent Medical Education” shall mean, as defined in Amgen’s policies, professional education given by accredited medical

education providers who design and implement programs totally independent of any Amgen influence, in accordance with applicable independence standards established by the government or industry groups referenced in Amgen's policies.

10. The term "Third Party Personnel" shall mean personnel who perform Promotional Functions or Product Related Functions who are employees of entities with whom Amgen has or may in the future (during the term of this CIA) enter into agreements to co-promote a Government Reimbursed Product in the United States or to engage in joint promotional activities in the United States relating to such a product. Amgen has represented that: (a) Third Party Personnel are employed by entities other than Amgen; (b) Amgen does not control the Third Party Personnel; and (c) it would be commercially impracticable to compel the compliance of Third Party Personnel with the requirements set forth in this CIA. Amgen agrees to promote compliance by Third Party Personnel with Federal health care program and FDA requirements by complying with the provisions set forth below in Sections III.B.2, V.A.8, and V.B.4. Provided that Amgen complies with the requirements of Sections III.B.2, V.A.8, and V.B.4, 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 Responsibilities of Certain Amgen Employees and the Board of Directors.

1. *Compliance Officer.* Prior to the Effective Date, Amgen appointed an individual to serve as its Chief Compliance Officer (CCO) and Amgen shall maintain a CCO for the term of the CIA. The CCO is, and shall continue to be, responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program and FDA requirements. The CCO is, and shall continue to be, a member of senior management of Amgen; reports, and shall continue to report, directly to the

President and Chief Executive Officer of Amgen; makes and shall continue to make, periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Amgen or CRCC (as defined in Section III.A.3) of the Board; and is, and shall continue to be, authorized to report on such matters to the Board of Directors at any time. The CCO is not, and shall not be, or be subordinate to, the General Counsel or Chief Financial Officer. The CCO shall be responsible for monitoring the day-to-day compliance activities engaged in by Amgen as well as for any reporting obligations created under this CIA. Any job responsibilities of the CCO unrelated to compliance shall be limited and must not interfere with the CCO's ability to perform the duties outlined in this CIA.

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

2. *Compliance Committee.* Prior to the Effective Date, Amgen appointed a Compliance Committee which, in conjunction with the CCO assists in the implementation and enhancement of the Compliance Program. Amgen shall continue the Compliance Committee during the term of this CIA. The Compliance Committee shall, at a minimum, include the President and Chief Executive Officer, the CCO and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as research and development (which includes regulatory affairs), the commercial organization (which includes sales and marketing), manufacturing, human resources, and finance (which includes corporate internal audit)). The President and Chief Executive Officer of Amgen shall chair the Compliance Committee. To the extent that the President and Chief Executive Officer of Amgen elects not to chair the Compliance Committee, the CCO shall serve as chairperson. The Compliance Committee shall support the CCO 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.

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

3. *Corporate Responsibility and Compliance Committee of the Board of Directors.* Prior to the Effective Date, Amgen formed the Corporate Responsibility and Compliance Committee of the Board of Directors (CRCC), which has ultimate oversight responsibility for the Compliance Program. The CRCC shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA. The CRCC shall, at a minimum, be responsible for the following:

a. The CRCC shall meet at least quarterly to review and oversee Amgen's Compliance Program, including but not limited to the performance of the CCO. The CRCC shall evaluate the effectiveness of the Compliance Program, including, at a minimum, by receiving updates about the activities of the CCO and other compliance personnel and updates about the adoption and implementation of policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with applicable Federal health care program and FDA requirements.

b. For each Reporting Period of the CIA, the CRCC shall adopt a resolution, signed by each individual member of the CRCC, summarizing its review and oversight of Amgen's compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA.

At minimum, the resolution shall include the following language:

“The Corporate Responsibility and Compliance Committee (CRCC) of the Board of Directors has made a reasonable inquiry into the operations of Amgen's Compliance Program during the preceding twelve-month period, which included, among other things, receiving updates and reports by the Chief Compliance Officer about the activities of the Chief Compliance Officer and the Compliance Program. 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, FDA 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 Accountability and Certifications:* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Amgen officers or employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable Amgen business unit is compliant with applicable Federal health care program and FDA requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: Executive Vice President, Global Commercial Operations; Executive Vice President, Research & Development; Senior Vice President, U.S. Commercial Operations; Senior Vice President, Global Marketing & Commercial Development; Senior Vice President & Chief Medical Officer, Global Development; Senior Vice President, Global Value & Access; Senior Vice President, Global Regulatory Affairs & Safety; Vice President, Scientific Affairs; the general managers of Amgen U.S. commercial business units; and, to the extent that an Amgen business unit performs Covered Functions and is not covered by the certifications of one of the above-listed individuals, such other Amgen executives, vice-presidents, or leaders of business units as would be necessary to ensure that there is a Certifying Employee from each such business unit engaged in Covered Functions.

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, FDA 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, except as otherwise described herein, the _____ [insert name of department or functional area] of Amgen is in compliance with all applicable Federal health care program requirements, FDA requirements, and the obligations of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States.”

If any Certifying Employee is unable to provide such a conclusion in the certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above and the steps being taken to address the issue(s) identified in the certification.

B. Written Standards.

1. *Code of Conduct.* Prior to the Effective Date, Amgen developed, implemented, and distributed a written Code of Conduct to all Covered Persons. Amgen makes, and shall continue to make, the performance of job responsibilities in a manner consistent with the Code of Conduct an element in evaluating the performance of all employees who are Covered Persons. The Code of Conduct includes, or within 120 days after the Effective Date, shall be revised to include, the following:

- a. Amgen's commitment to full compliance with all Federal health care program requirements and FDA requirements, including its commitment to comply with all requirements relating to the Covered Functions;
- b. Amgen's requirement that all of its Covered Persons shall be expected to comply with all applicable Federal health care program requirements, FDA requirements, and with Amgen's own Policies and Procedures;
- c. Amgen's requirement that all Covered Persons shall be expected to report to the CCO, or other appropriate individual designated by Amgen, suspected violations of any Federal health care program requirements, FDA requirements, or of Amgen's own Policies and Procedures;
- d. the personal obligations of each Covered Person to comply with Federal health care program requirements, FDA requirements, and Amgen's Policies and Procedures; and
- e. the right of all individuals to use the Disclosure Program described in Section III.F, and Amgen's commitment to non-retaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

During and after May 2012, Amgen provided training explaining Amgen's Compliance Program, including its Code of Conduct, to Covered Persons and obtained certifications from all employees that they had received, read and understood the Code of Conduct. To the extent not already accomplished during the period beginning May 2012 through the Effective Date, within 120 days after the Effective Date, each Covered Person shall certify, in writing or by electronic acknowledgement, that he or she has received, read, understood, and shall abide by Amgen's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later.

Amgen shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code of Conduct shall be distributed within 30 days after any revisions are finalized. Each Covered Person shall certify, in writing or by electronic acknowledgement, that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.

2. *Third Party Personnel.* Within 120 days after the Effective Date, and annually thereafter by the anniversary of the Effective Date, Amgen shall send, electronically or in hard copy format, a letter 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 and FDA requirements. The letter shall include a description of Amgen's Compliance Program. Amgen shall include with the letter a copy of its Code of Conduct and shall request the entity employing Third Party Personnel to either: (a) make a copy of Amgen's Code of Conduct and a description of Amgen's Compliance Program available to its Third Party Personnel; or (b) represent to Amgen that it has and enforces a substantively comparable code of conduct and compliance program for its Third Party Personnel.

3. *Policies and Procedures.* Prior to the Effective Date, Amgen implemented written policies and procedures regarding the operation of the Compliance Program and Amgen's compliance with Federal health care program and FDA requirements (Policies and Procedures). Amgen has represented that the Policies and Procedures address, and the Policies and Procedures shall continue to address, at a minimum, the following:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1;
- b. appropriate ways to conduct Promotional Functions in compliance with all applicable Federal healthcare program requirements, including, but not limited to the Federal Anti-Kickback Statute (codified at 42 U.S.C. § 1320a-7b(b)) and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733), and in compliance with all applicable FDA requirements;
- c. appropriate ways to conduct Product Related Functions in compliance with all applicable Federal healthcare program requirements, including, but not limited to the Federal Anti-Kickback Statute (codified at 42 U.S.C. § 1320a-7b(b)) and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733), and in compliance with all applicable FDA requirements;
- d. appropriate ways to conduct Government Pricing Functions in compliance with all applicable Federal health care program and FDA requirements. This includes gathering, calculating, verifying, and reporting the data and information reported to the Centers for Medicare & Medicaid Services (CMS) and/or the State Medicaid programs in connection with the Medicaid Drug Rebate program, the Medicare program, and as otherwise required by Federal or state government directives. These Policies and Procedures shall require, among other things, that Amgen properly account for all price concessions and all service, administrative, or other fees (including those paid to group purchasing organizations, wholesalers, and distributors) in its calculation of prices and information reported to CMS and/or to State Medicaid programs;
- e. appropriate ways to conduct Payor Related Functions in compliance with all: (i) 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); (ii) applicable FDA requirements; and (iii) applicable state laws;

- f. the materials and information that may be distributed by Amgen sales representatives about Government Reimbursed Products and the manner in which Amgen sales representatives respond to requests for information about non-FDA approved (or “off-label”) uses of Government Reimbursed Products. These Policies and Procedures shall require that sales representatives: (i) not engage in off-label promotion of Government Reimbursed Products (i.e., sales representatives shall not promote the products for usages, dosages, length of treatment, or patient populations other than those in, or consistent with, the FDA-approved label); (ii) use only materials that have been approved by Amgen and approved through the MAC process or a substantively equivalent process; and (iii) refer all requests for information about off-label uses of Government Reimbursed Products to the Medical Information department;
- g. the materials and information that may be distributed by Medical Information and the mechanisms through, and manner in which, Medical Information receives and responds to requests for information from an HCP or another individual or entity about off-label uses of Government Reimbursed Products; the form and content of information disseminated by Amgen in response to such requests; and the internal review process for the information disseminated.

The Policies and Procedures shall include a requirement that Amgen develop a database for use by Medical Information (Inquiries Database) to track all requests for information about Government Reimbursed Products made to Medical Information. The Inquiries Database shall include the following items of information for each unique inquiry (Inquiry) received for information about Government Reimbursed Products: (i) date of Inquiry; (ii) form of Inquiry (e.g., fax, phone, etc.); (iii) name of the requesting HCP, HCI, or other individual or entity; (iv) nature and topic of request (including exact language of the Inquiry if made in writing); (v) an evaluation of whether the Inquiry relates to information about an off-label use for the product; (vi) nature/form of the response from Amgen (including a record of

the materials provided to the HCP or HCI in response to the request); and (vii) the name of the Amgen representative who called on or interacted with the HCP, customer, or HCI, if known;

- h. the manner and circumstances under which Regional Medical Liaisons (RMLs) and other medical personnel within Scientific Affairs and the Global Development Organization interact with or participate in meetings or events with HCPs, HCIs, or Payors (either alone or with Amgen sales representatives) and the role of the medical personnel at such meetings or events, as well as how they handle responses to requests for information about off-label uses of Government Reimbursed Products. These Policies and Procedures shall require that RMLs and other medical personnel not engage in the off-label promotion of Government Reimbursed Products;
- i. the development, implementation, and review of call plans (e.g. Amgen Plans of Action and specialty target lists) for sales representatives and other Amgen representatives who promote and sell Government Reimbursed Products. For each Government Reimbursed Product, the Policies and Procedures shall require that Amgen review the call plans for the product and the bases upon, and circumstances under which HCPs and HCIs belonging to specified medical specialties or types of clinical practice are included in, or excluded from, the call plans. The Policies and Procedures shall also require that Amgen modify the call plans as necessary to ensure that Amgen is promoting Government Reimbursed Products in a manner that complies with all applicable Federal health care program and FDA requirements. The call plan reviews shall occur at least annually and shall also occur each time when the FDA approves a new or additional indication for a Government Reimbursed Product;
- j. the development, implementation, and review of plans for the distribution of samples of Government Reimbursed Products (Sample Distribution Plans). This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs

belonging to specified medical specialties or types of clinical practice may receive samples from Amgen. The Policies and Procedures shall also require that Amgen modify the Sample Distribution Plans as necessary to ensure that Amgen is promoting Government Reimbursed Products in a manner that complies with all applicable Federal health care program and FDA requirements;

- k. consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including but not limited to, to the extent they are conducted, speaker programs, speaker training programs, presentations, consultant task force meetings, advisory boards, and ad hoc advisory activities, and any other financial engagement or arrangement with an HCP or HCI) and all events and expenses relating to such engagements or arrangements. These Policies and Procedures shall be designed to ensure that the arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements. The Policies and Procedures shall include requirements about the content and circumstances of such arrangements and events;
- l. to the extent they are conducted, programs by HCPs to educate sales representatives, including but not limited to presentations by HCPs at sales meetings, preceptorships, tutorials, and experience-based learning activities, if any. These Policies and Procedures shall be designed to ensure that the programs are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements. The Policies and Procedures shall include requirements about the content and circumstances of such arrangements and events;
- m. contributions, grants, payments, or sponsorship in cash or in kind, to any not-for-profit or tax-exempt organization that is a member of the health care community (collectively “Donations”). These Policies and Procedures shall be designed to ensure that Amgen’s funding and/or charitable donations complies with all applicable Federal health care program and FDA requirements;

- n. funding of, or participation in, any Independent Medical Education activity as defined in Section II.C.9 above. These Policies and Procedures shall be designed to ensure that Amgen's funding and/or sponsorship of such programs satisfies all applicable Federal health care program and FDA requirements;

The Policies and Procedures shall require that: (i) all Independent Medical Education activity funding requests are reviewed, tracked, and evaluated by the centralized Healthcare Compliance Operations organization to ensure that the request meets compliance criteria; (ii) funding decisions are based on objective criteria such as the qualifications of the requestor, the quality of the Independent Medical Education activity program, and pre-established educational goals; (iii) Independent Medical Education activity funding is provided only pursuant to a written agreement with the funding recipient, and payments to the Independent Medical Education activity funding recipient are consistent with the written agreement; and (iv) Independent Medical Education activity programs funded by Amgen are developed and implemented independently of Amgen staff involvement;

- o. review of promotional, reimbursement, and disease state materials and information intended to be disseminated outside Amgen by appropriate qualified personnel (such as regulatory, medical, and/or legal personnel) in a manner designed to ensure that legal, regulatory, and medical concerns are properly addressed during Amgen's review and approval process and are elevated when appropriate. The Policies and Procedures shall be designed to ensure that such materials and information comply with all applicable Federal health care program and FDA requirements and shall continue to incorporate Amgen's MAC process or a substantively equivalent process. Among other things, the Policies and Procedures shall continue to require that: (i) applicable review committees review all promotional materials prior to the distribution or use of such materials; and (ii) deviations from the standard review committee practices and

protocols (including timetables for the submission of materials for review) shall be documented and referred for appropriate follow-up;

- p. participation in funding opportunities offered by a for-profit or not-for-profit entity that provides a tangible economic benefit to the business interests of Amgen or its products (collectively “Sponsorships”). These Policies and Procedures shall be designed to ensure that Amgen’s participation in such Sponsorships complies with all applicable Federal health care program and FDA requirements;
- q. compensation (including through salaries, bonuses, or other means) for Relevant Covered Persons. These Policies and Procedures shall: (i) be designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in improper promotion, sales, and marketing of Amgen’s Government Reimbursed Products; and (ii) include mechanisms, where appropriate, to exclude from incentive compensation sales that may indicate off-label promotion of Government Reimbursed Products;
- r. the submission of information about any Government Reimbursed Product to any CMS-recognized Compendia, as defined in Amgen’s Policies and Procedures, such as Drugdex or other published source of information used in connection with the determination of coverage by a Federal health care program for the product (hereafter “Compendia”). This includes any initial submission of information to any Compendia and the submission of any additional, updated, supplemental, or changed information (including any changes based on Amgen’s discovery of erroneous or scientifically unsound information or data associated with the information in the Compendia and the publication of new study results). The Policies and Procedures shall include a requirement that Amgen conduct: (i) a review at the time of submission of information to Compendia, to verify that the information submitted to the Compendia (including information about clinical studies and other Research) is complete and accurate; (ii) an

annual review of Amgen product listings and monographs within the Compendia designed to identify errors or inaccuracies; and (iii) an annual review of all arrangements, processing fees, or other payments or financial support (if any) provided by Amgen to any Compendia. Amgen's legal or compliance personnel shall be involved in this review;

- s. sponsorship or support by Amgen of post-marketing research involving consented human subjects and Government Reimbursed Products that is conducted by HCPs licensed to practice medicine in the U.S. This includes post-marketing clinical trials and other post-marketing studies sponsored by Amgen (Amgen-Sponsored Research) and support by Amgen of ISSs (Amgen-Sponsored Research and ISSs supported by Amgen are collectively referred to as "Research" for purposes of this CIA), including the decision to provide financial or other support for such Research; the manner in which Research support is provided; the publication of information about the Research, including the publication of information about the Research results and trial outcomes; and uses made of publications relating to Research;

Policies/Procedures regarding Research:

Amgen represents that it requires that all Research sponsored or funded by Amgen address a legitimate scientific question or need, and be reviewed and approved by the relevant governance body within its research and development organization. Research and Development (R&D) personnel are responsible for all steps of the design, conduct, and/or publication of Research. Commercial personnel do not participate in the approval of the publication of Research results. The Global Health Economics organization has a dual reporting line to R&D and commercial, and Research conducted by Global Health Economics is subject to oversight by the R&D organization. The Biosimilars organization also has a dual reporting line to R&D and commercial, and Research conducted by the Biosimilars organization is subject to oversight by the R&D organization.

Registration of Studies and Publication of Study Results:

Amgen represents that it registers Amgen-Sponsored Research that involves clinical trials and reports results of such clinical trials on the National Institutes of Health (NIH) sponsored website (www.clinicaltrials.gov) in accordance with Amgen's Policies and Procedures governing clinical trial disclosure, which shall at minimum require registration consistent with all Federal requirements. Amgen shall continue to comply with Federal requirements or other applicable requirements relating to the registration and results reporting of such Amgen-Sponsored Research throughout the term of this CIA. In addition, if there is a change in Federal requirements or other applicable requirements relating to registration and results reporting of information about Amgen-Sponsored Research, Amgen shall fully comply with such requirements.

Amgen represents that it has established policies, procedures and practices with respect to prematurely discontinued Amgen-Sponsored Research, which require timely notification of the relevant institutional review board or ethics committee about the decision and reasons for premature discontinuation. As specified in Amgen's Policies and Procedures governing clinical trial disclosure, Amgen posts status updates with respect to Amgen-Sponsored Research (including discontinued studies) to the NIH sponsored website (www.clinicaltrials.gov).

Amgen represents that it has established policies, systems and practices to ensure that adverse event information regarding its products is collected, processed, analyzed, communicated and reported to FDA. Amgen requires sponsors of ISSs to agree to provide Amgen with safety reports as a condition to providing support for ISSs, and during the study, Amgen assesses the sponsor's compliance with safety reporting requirements per contractual agreements.

While recognizing the decision-making role of the authors and journals, respectively, Amgen represents that it makes good faith efforts to publish Amgen-Sponsored Research results in peer-reviewed journals and includes specified timeframes for the submission of manuscripts following completion of an Amgen-Sponsored Research study in the global publication plan for each Government Reimbursed Product. Amgen's Policies and Procedures govern the publication of results from Amgen-Sponsored Research. Amgen further represents that its written agreements pertaining to ISSs require the investigator to exercise best efforts to publish the results of the ISS.

The standards, policies, and practices described above shall hereafter be referred to collectively as the "Research and Publication Practices." Amgen shall maintain its Research and Publication Practices (or standards and practices substantively equivalent to those set forth above) for Research initiated, supported, or completed after the Effective Date for the term of the CIA. To the extent that Amgen intends to materially change these Research and Publication Practices, it shall notify the OIG about the change 30 days in advance of the effective date of the change;

- t. authorship of journal articles or other publications about Government Reimbursed Products or about therapeutic areas or disease states that may be treated with Government Reimbursed Products, including, but not limited to, the disclosure of any and all financial relationships between the author and Amgen or other potential conflicts of interest that might bias the author's work to the journal or congress, as required by the pertinent journal or congress, the identification of all authors or contributors (including professional writers) associated with a given publication, and the scope and breadth of research results made available to each author or contributor.

Authorship Requirements: Amgen represents that it requires all authors of journal articles about Amgen-Sponsored Research to adhere to International Committee of Medical Journal Editors

(ICMJE) requirements regarding authorship. In addition, Amgen requires all authors of articles about Research to disclose any Amgen financial support for the study and any financial relationship with Amgen (including any financial interest the author may have in Amgen or an Amgen product) to the journal or congress, as required by the pertinent journal or congress. In addition, Amgen represents that individuals may be considered an “author” on a publication about Amgen-Sponsored Research only if the individual has made substantial contributions to the study and has given final approval to the version of the publication ultimately published. Amgen’s policies and procedures strictly prohibit guest/honorary/gift authorship, ghostwriting, and plagiarism.

The standards, policies and practices described above shall be referred to collectively as “Authorship-Related Practices”; and

- u. disciplinary policies and procedures for violations of Amgen’s Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

To the extent not already accomplished, within 120 days after the Effective Date, the Policies and Procedures shall be made available to all Covered Persons. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), Amgen shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, any such revised Policies and Procedures shall be made available to all Covered Persons.

C. Training and Education.

1. *General Training.* Except as limited below, within 120 days after the Effective Date, Amgen shall provide at least one hour of General Training to each Covered Person. This training, at a minimum, shall explain Amgen’s:

- a. CIA requirements; and
- b. Compliance Program (including the Code of Conduct).

During and after May 2012, Amgen provided training explaining Amgen's Compliance Program, including its Code of Conduct, to Covered Persons. Within 120 days after the Effective Date, Covered Persons who received Code of Conduct training during the period beginning May 2012 through the Effective Date of this CIA shall receive at least thirty minutes of training on the CIA requirements, as described in Section III.C.1.a, but are not required to receive the Compliance Program training referenced in Section III.C.1.b.

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. *Specific Training.* Amgen shall provide annual training to each Relevant Covered Person relating to his or her specific job responsibilities. This training shall be known as Specific Training.

Amgen represents that all Relevant Covered Persons who engage in or supervise Covered Persons who engage in Payor Related Functions also are, and will continue to be throughout the term of this CIA: (i) Relevant Covered Persons who engage in or supervise Covered Persons who engage in Promotional Functions; or (ii) Relevant Covered Persons who engage in or supervise Covered Persons who engage in Product Related Functions. Amgen further represents that Specific Training for Promotional Functions and Product Related Functions will address, throughout the term of this CIA, requirements for Payor Related Functions.

Within 120 days after the Effective Date, each Relevant Covered Person engaged in Promotional Functions, Product Related Functions, or Payor Related Functions shall receive at least three hours of Specific Training in addition to the General Training required above.

This Specific Training shall include a discussion of:

- a. all applicable Federal health care program requirements relating to Promotional Functions, Product Related Functions, and Payor Related Functions;

- b. all applicable FDA requirements relating to Promotional Functions, Product Related Functions, and Payor Related Functions;
- c. all Amgen Policies and Procedures and other requirements applicable to Promotional Functions, Product Related Functions, and Payor Related Functions;
- d. Amgen's systems and processes applicable to Payor Related Functions;
- e. the personal obligation of each individual involved in Promotional Functions, Product Related Functions, and Payor Related Functions to comply with all applicable Federal health care program and FDA requirements and all other applicable legal requirements;
- f. the personal obligation of each individual involved in Payor Related Functions to ensure that all information provided or reported to Payors is complete, accurate, and not misleading;
- g. the legal sanctions for violations of the applicable Federal health care program and FDA requirements; and
- h. examples of proper and improper practices related Promotional Functions, Product Related Functions, and Payor Related Functions.

Within 120 days after the Effective Date, each Relevant Covered Person engaged in Government Pricing Functions shall receive at least three hours of Specific Training in addition to the General Training required above.

This Specific Training shall include a discussion of:

- i. Amgen's systems and processes relating to Government Pricing Functions;

- j. all applicable Federal health care program requirements relating to Government Pricing Functions;
- k. Amgen's systems for gathering relevant data and calculating, verifying, and reporting information to CMS and/or the State Medicaid Programs for purposes of the Medicaid Drug Rebate Program, the Medicare Program, or any other Federal or state government price reporting requirement;
- l. the personal obligation of each individual involved in Government Pricing Functions to ensure that all reported pricing and other information is accurate;
- m. the legal sanction for violations of Federal health care program requirements; and
- n. examples of proper and improper practices related to Government Pricing Functions.

New Relevant Covered Persons shall receive their Specific Training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 120 days after the Effective Date, whichever is later. A Covered Person who has completed the Specific Training shall review the work of a new Relevant Covered Person, to the extent that the work relates to any of the Covered Functions, until such time as the new Relevant Covered Person completes his or her Specific Training.

After receiving the initial Specific Training described in this Section, each Relevant Covered Person shall receive at least three hours of Specific Training in each subsequent Reporting Period.

3. *Board Member Training.* Within 120 days after the Effective Date, Amgen shall provide at least two hours of training to each member of the Board of Directors, in addition to the General Training. This training shall address the responsibilities of board members and corporate governance.

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 120 days after the Effective Date, whichever is later.

To the extent that Amgen provides the training described in this Section III.C.3 to members of the Board of Directors on or after December 1, 2012, such training will satisfy the requirements of this Section III.C.3 even if such training is conducted prior to the Effective Date.

4. *Certification.* Each Covered Person who is required to complete training shall certify, in writing or in electronic form, that he or she has received such training. The certification shall specify the type of training received and the date received. The CCO (or designee) shall retain these certifications, along with all course materials. These shall be made available to OIG, upon request.

5. *Qualifications of Trainer.* Persons responsible for providing training shall be knowledgeable about the subject area of the training, including about applicable Federal health care program and FDA requirements.

6. *Update of Training.* Amgen shall review its training annually, and, where appropriate, shall update the training to reflect changes in Federal health care program requirements, FDA requirements, any issues discovered during internal audits or the IRO Reviews, and any other relevant information.

7. *Training Methods.* The training and education required under this Section III.C may be provided in one or more training module(s) over one or more day(s), by supervisory employees, knowledgeable staff, Amgen trainers, or outside consultant trainers selected by Amgen.

8. *Computer-based Training.* Amgen may provide the training required under this CIA through appropriate computer-based training approaches. If Amgen chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

D. Risk Assessment and Mitigation Process. Amgen represents that prior to the Effective Date, it implemented a standardized annual risk assessment process that focuses on activities governed by Amgen's Policies and Procedures (hereafter the "Activity-Based Risk Assessment"). The Activity-Based Risk Assessment is intended, among other objectives, to inform Healthcare Compliance Internal Audit and Healthcare Compliance Monitoring annual priorities. Furthermore, in 2012, Amgen initiated a pilot project to

implement a standardized annual compliance process which is referred to herein as “Ra3” (Risk - Assess, Align, Address) which would allow Amgen compliance, regulatory and other personnel to identify and assess risk on a product-specific basis beginning in 2013.

Ra3, which is described more fully in Appendix C, will assess information associated with safety, advertising, marketing and promotion of Government Reimbursed Products. The outcomes of Ra3 will be coordinated with outcomes of the Activity-Based Risk Assessment. Additionally, based on the outcomes of Ra3 and the Activity-Based Risk Assessment, Amgen will annually develop and implement specific plans and oversight activities designed to mitigate or reduce the identified risk, which plans may include additional auditing, monitoring, training, compliance support, legal oversight, issuance of new policies or procedures or the implementation of new or enhanced compliance controls.

In addition to general categories of information described above, the Ra3 process shall, at a minimum, include a review of annual financial and budget-type information. For example, the Ra3 process shall include a review of information about prior year expenditures and proposed financial and strategic plans for engaging HCPs for advisory boards, speaker training and speaker programs, consultant meetings, and Research as well as prior year and proposed financial and strategic plans for Publications relating to Government Reimbursed Products. The Ra3 process shall also include a review of past and projected financial and strategic plans for Independent Medical Education activities and Donations. Amgen shall maintain the Ra3 process or a substantively equivalent process for all Government Reimbursed Products throughout the term of the CIA.

E. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 120 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 reviews to assist Amgen in assessing and evaluating its Covered Functions and the Ra3 process. More specifically, the IRO(s) shall conduct reviews that assess Amgen’s systems, processes, policies, procedures, and practices relating to the Covered Functions (including Research and Publication Activities and

Authorship-Related Practices) and to Amgen's Ra3 process (IRO Reviews).

The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference. Each IRO engaged by Amgen shall have expertise in applicable Federal health care program and FDA requirements as may be appropriate to the IRO Review for which the IRO is retained. Each IRO shall assess, along with Amgen, whether it can perform the engagement in a professionally independent and objective fashion, as appropriate to the nature of the IRO Review, taking into account any other business relationships or other engagements that may exist.

b. Frequency and Brief Description of Reviews.

System, Transaction, and Additional Items Reviews. As set forth more fully in Appendices B and C, the IRO Reviews shall consist of two components: Systems Reviews and Transactions Reviews relating to the Covered Functions and to the Ra3 process. The Systems Reviews shall assess Amgen's systems, processes, policies, and procedures relating to the Covered Functions and to the Ra3 process. If there are no material changes in Amgen's relevant systems, processes, policies, and procedures, the Systems Reviews shall be performed 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 second and fourth Reporting Periods, as set forth more fully in Appendices B and C.

The Transactions Reviews shall be performed annually and shall cover each of the five Reporting Periods. The IRO(s) shall perform all components of each annual Transaction Review. As set forth more fully in Appendices B and C, the Transactions Review shall include several components.

In addition, as set forth in Appendix B, each Transactions Review relating to Covered Functions shall also include a review of up to

three additional areas or practices of Amgen identified by the OIG in its discretion (hereafter “Additional Items”). For purposes of identifying the Additional Items to be included in the Transactions Review for a particular Reporting Period, the OIG will consult with Amgen and may consider internal audit and monitoring work conducted by Amgen, the Government Reimbursed Product portfolio, the nature and scope of Amgen’s promotional practices and arrangements with HCPs and HCIs, and other information known to it.

As set forth more fully in Appendix B, Amgen may propose to the OIG that its Healthcare Compliance Internal Audit(s) and Healthcare Compliance Monitoring activities be substituted, in whole or in part as may be appropriate under the circumstances, for one or more of the Additional Items that would otherwise be reviewed by the IRO as part of the Transactions Review. The OIG retains sole discretion over whether, and in what manner, to allow Amgen’s internal audit and monitoring work to be substituted for any portion of the Additional Items review conducted by the IRO.

The OIG shall notify Amgen of the nature and scope of the IRO review for each of the Additional Items not later than 150 days prior to the end of each Reporting Period. Prior to undertaking the review of the Additional Items, the IRO and/or Amgen shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG.

c. 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 IRO Reviews.

2. IRO Review Reports. The IRO shall prepare a report based upon each IRO Review performed (IRO Review Report). Information to be included in the IRO Review Report is described in Appendices A-C.

3. *Validation Review.* In the event OIG has reason to believe that: (a) any of Amgen's IRO Reviews fails to conform to the requirements of this CIA; or (b) the IRO's findings or Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the applicable IRO Review complied with the requirements of the CIA and/or the findings or Review results are inaccurate (Validation Review). Amgen shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of Amgen's final Annual Report shall be initiated no later than one year after Amgen's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Amgen of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, Amgen may request a meeting with OIG to: (a) discuss the results of any IRO Review submissions or findings; (b) present any additional information to clarify the results of the IRO Review or to correct the inaccuracy of the IRO Review; and/or (c) propose alternatives to the proposed Validation Review. Amgen agrees to provide any additional information as may be requested by OIG under this Section III.E.3 in an expedited manner. OIG will attempt in good faith to resolve any IRO Review issues with Amgen prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

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 conducted 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.

F. Disclosure Program.

Prior to the Amgen Effective Date, Amgen established a Disclosure Program that includes a mechanism (the toll free Business Conduct Hotline) to enable individuals to disclose, to the CCO 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 or an FDA requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. Amgen publicizes, and shall continue to appropriately publicize, the existence of the Disclosure Program and the Business Conduct Hotline (e.g., via periodic

e-mails to employees, by posting the information in prominent common areas, or through references in the Code of Conduct and during training).

The Disclosure Program emphasizes, and shall continue to emphasize, a non-retribution, non-retaliation policy and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the CCO (or designee) shall gather all relevant information from the disclosing individual. The CCO (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that it obtains all necessary information 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.

Amgen shall maintain, a disclosure log, which includes a record and 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. This disclosure log shall be made available to OIG upon request.

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, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or non-procurement programs; or
 - ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.
- b. “Exclusion Lists” include:
 - i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.oig.hhs.gov>); and

ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://www.epls.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. as part of the hiring or contracting process, Amgen shall require all prospective and current Covered Persons to disclose whether they are Ineligible Persons and shall screen potential Covered Persons against the Exclusion Lists prior to engaging their services.
- b. Amgen shall screen all Covered Persons against the Exclusion Lists within 120 days after the Effective Date and on an annual basis thereafter.
- c. Amgen shall maintain a policy requiring all Covered Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person 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 by excluded persons 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 programs and shall remove such Covered Person from any position for which the Covered Person's compensation or the items or services furnished, ordered, or prescribed by the Covered Person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the Covered Person is reinstated into participation in the Federal health care programs.

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, patient, or resident, or the accuracy of any claims submitted to any Federal health care program.

H. Notification of Government Investigation or Legal Proceedings.

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.-based 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 shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, 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. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any FDA requirements relating to the promotion of Government Reimbursed Products (including an FDA Warning Letter issued to Amgen);
- c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or

d. the filing of a bankruptcy petition by 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.

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

- a. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program or FDA authorities implicated;
- b. a description of Amgen's actions taken to correct the Reportable Event; and
- c. any further steps Amgen plans to take to address the Reportable Event and prevent it from recurring.

Amgen shall not be required to report as a Reportable Event a matter which is the subject of an ongoing investigation or legal proceeding by a government entity or its agents previously disclosed under Section III.H above.

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

J. Notification of Communications with FDA. Within 30 days after the date of any written report, correspondence, or communication between Amgen and the FDA that materially discusses Amgen's or a Covered Person's actual or potential unlawful or improper promotion of Amgen's products (including any improper dissemination of information about off-label indications), Amgen shall provide a copy of the report,

correspondence, or communication to the OIG. Amgen shall also provide written notice to the OIG within 30 days after the resolution of any such disclosed off-label matter, and shall provide the OIG with a description of the findings and/or results of the matter, if any.

K. Implementation of Controls, Monitoring and Auditing.

1. *Controls.* Prior to the Effective Date, Amgen developed and implemented internal compliance controls and processes to ensure that Amgen's business activities are conducted in accordance with Federal health care program and FDA requirements (Compliance Controls). Amgen represents that these Compliance Controls are based on requirements set forth in Amgen's Policies and Procedures and function as oversight and risk mitigation mechanisms designed to ensure that the Compliance Program operates effectively and that compliance concerns are detected and remedied in a systematic manner. Amgen further represents that through a combination of: (i) the Ra3 process (as described in Section III.D), (ii) transaction-specific Compliance Controls (as described in this Section III.K.1) and (iii) the Healthcare Compliance Monitoring program (as described in Section III.K.2 below), the Compliance Program reviews fair market value payments and needs assessments for Consultant arrangements, Researcher arrangements and Publications activities, among other activities, to ensure that these arrangements or activities fulfill legitimate Amgen business or scientific needs.

Amgen reviews, and throughout the term of this CIA shall continue to review, the Compliance Controls on a routine and ongoing basis. As part of its review of the Compliance Controls, except as expressly set forth below, Amgen will revise the Compliance Controls based on the results of the Activity-Based Risk Assessment and the Ra3 process described in Section III.D of this CIA. Amgen will summarize any revisions to Compliance Controls in Annual Reports submitted to OIG pursuant to Section V.B of this CIA.

a. *Speaker Program Controls.* Amgen implemented prior to the Effective Date, and shall continue to maintain throughout the term of this CIA, Compliance Controls for speaker programs. Amgen represents that these controls ensure, among other factors, that: (i) all speakers enter into written agreements describing the scope of work to be performed, the fees to be paid and the compliance obligations of the speakers (including requirements that speakers may only use Amgen approved materials and may not directly or indirectly promote the product for off-label uses); (ii) only eligible and qualified speakers (who have completed required training) participate in

speaker programs; (iii) amounts paid to speakers are consistent with fair market value and tracked in connection with speaker programs conducted during each Reporting Period; (iv) appropriate venues are selected for speaker training and speaker programs; and (v) there is a legitimate need for the speaker program (collectively, the “Speaker Program Controls”). Amgen shall require that a designated Amgen staff member manage each speaker program to ensure that the Speaker Program Controls are operating effectively and that speaker programs are conducted in accordance with Amgen Policies and Procedures, and to promptly report any instances of non-compliance.

b. *Consultant Arrangements Controls.* To the extent that Amgen enters into contracts, agreements, or other arrangements with HCPs or HCIs that involve the provision of goods, data, or services that relate to Promotional Functions or to Product Related Functions (e.g. as a member of an advisory board or to attend consultant meetings) other than for speaker programs, Research, or Publication activities (as defined below), such HCPs or HCIs shall be referred to herein as “Consultants”. Amgen implemented prior to the Effective Date, and shall continue to maintain throughout the term of this CIA, Compliance Controls for Consultant arrangements. Amgen represents that these controls ensure, among other factors, that: (i) prior to retention of the Consultant, Amgen defines the scope of the proposed services to be performed by the Consultant, confirms that the Consultant is appropriately qualified to provide these proposed services and verifies that there is a legitimate business need for the Consultant’s retention; (ii) amounts paid to Consultants are fair market value and for services rendered; (iii) all Consultants enter into written agreements describing the scope of work to be performed, the fees to be paid and the compliance obligations of the Consultants; and (iv) to the extent applicable, Amgen received the work product generated by the Consultant (collectively, the “Consultant Arrangements Controls”).

c. *Independent Medical Education Activities Controls, Donations Controls, and Sponsorships Controls.* Amgen implemented prior to the Effective Date, and shall continue to maintain throughout the term of this CIA, Compliance Controls for Independent Medical Education (as defined in Section II.C.9) activities. Amgen represents that these controls ensure, among other factors, that: (i) all Independent Medical Education activity funding requests are reviewed, tracked, and evaluated by the Compliance organization to ensure that the requests meet compliance criteria; (ii) funding decisions are based on objective criteria such as: the qualifications of the requestor, the quality of the Independent Medical Education activity program, and Amgen’s pre-established educational goals; (iii) Independent Medical Education activity funding is provided only pursuant to a written agreement with the funding recipient and payments

made to the Independent Medical Education activity funding recipient comply with the express terms of the written agreement; and (iv) Amgen staff are not involved in the development or implementation of Independent Medical Education activity programs funded by Amgen (collectively, the “Independent Medical Education Activity Controls”).

Amgen implemented prior to the Effective Date, and shall continue to maintain throughout the term of this CIA, Compliance Controls for Donations to ensure that Amgen’s Donations comply with all applicable Federal health care program and FDA requirements (Donations Controls). Amgen represents that the Donations Controls ensure, among other factors, that: (i) Donations are provided to a qualified recipient which is a tax-exempt or not-for-profit entity; (ii) Donations are not linked, directly or indirectly, to any agreement to use Amgen’s products or to reward past business; (iii) Amgen does not fund any Donations request until the request is approved and an executed agreement is in place; and (iv) Donations payments are made consistent with the approval letter and written agreement.

In addition, Amgen implemented prior to the Effective Date, and shall continue to maintain throughout the term of this CIA, Compliance Controls for Sponsorships to ensure that Amgen’s Sponsorships comply with all applicable Federal health care program and FDA requirements (Sponsorships Controls). Amgen represents that the Sponsorships Controls ensure, among other factors, that: (i) a legitimate business purpose for the Sponsorship exists; (ii) a tangible benefit for the Sponsorship exists; (iii) proposed costs and fees are reasonable; and (iv) prior to the Sponsorship being provided and paid, there is a fully executed agreement in place which sets forth the Sponsorship to be provided.

d. *Publication Controls.* To the extent that Amgen engages HCPs or HCIs as authors for articles or other publications relating to Research involving Government Reimbursed Products (Publications), such HCPs or HCIs shall be referred to as “Authors”. Amgen implemented prior to the Effective Date, and shall continue to maintain throughout the term of this CIA, Compliance Controls for Publications. Amgen represents that these controls ensure, among other factors, that: (i) prior to beginning the drafting of a Publication manuscript, Authors confirm in writing that they will participate in a manner consistent with Amgen’s requirements for Authors; (ii) during the Final Publication Approval process, Publications are reviewed and approved by non-commercial Amgen personnel with relevant expertise prior to submission to a journal or congress; (iii) Publications are developed in a transparent and collaborative manner in accordance with principles of scientific exchange; (iv) with certain limited exceptions, no

compensation is paid to Authors for their time spent drafting or revising Publications; and (v) Authors confirm that they satisfy International Committee of Medical Journal Editors (ICMJE) authorship criteria, including providing final approval of the version of the Publication to be published (collectively, the “Publication Controls”).

e. *Research Controls.* To the extent that Amgen engages or provides support to HCPs or HCIs to conduct Research, such HCPs and HCIs will be referred to herein as “Researchers”. Amgen implemented prior to the Effective Date, and shall continue to maintain throughout the term of this CIA, Compliance Controls for Research. Amgen represents that these controls ensure, among other factors, that: (i) all Researchers enter into written agreements describing the scope of work to be performed, the fees to be paid and the compliance obligations of the Researchers; (ii) if payment or funding is provided, that amounts paid are fair market value for services rendered; and (iii) prior to retention of the Researcher, Amgen defines the scope of the proposed Research, confirms that Researchers are appropriately qualified to perform the Research, and verifies that there is a legitimate business or scientific need for the Research (collectively, the “Research Controls”).

2. *Healthcare Compliance Monitoring.* Prior to the Effective Date, Amgen established a comprehensive Healthcare Compliance Monitoring program. The Healthcare Compliance Monitoring program is a formalized and ongoing process in which appropriately trained Amgen personnel from the Compliance organization or Law, R&D, or other Amgen organizations at the direction of the Compliance organization who are independent from the activity area being monitored (collectively “Monitoring Personnel”) check and measure healthcare compliance-related performance pertaining to a specific function or department to ensure achievement of operational and/or compliance objectives. To the extent not already accomplished, within 120 days after the Effective Date, Amgen shall extend its Healthcare Compliance Monitoring program and/or Healthcare Compliance Internal Audit program to all business areas within Amgen that perform Covered Functions under this CIA.

As described in more detail below, the Healthcare Compliance Monitoring program includes, and shall continue to include: 1) the development and execution of an annual plan that is based on an assessment of compliance risks and that identifies the types and volume of monitoring activities to be performed for each year (Monitoring Plan); 2) activities that evaluate compliance through a focus on processes, procedures, and documentation for various activities that are initiated and handled internally from Amgen headquarters (Transactional Activities); and 3) activities that evaluate compliance through attendance at the site of a business activity, such as speaker programs and

Corporate Integrity Agreement
Amgen Inc.

observations of sales representatives (Field-Based Activities). Amgen implemented prior to the Effective Date, and shall continue to maintain throughout the term of this CIA, written policies and procedures regarding the operation of the Healthcare Compliance Monitoring program and reporting and follow-up for any potential or suspected non-compliance with Amgen's Policies and Procedures or legal requirements.

a. *Annual Monitoring Plan.* Prior to the Effective Date, Amgen developed, and shall continue to maintain throughout the term of this CIA, annual Monitoring Plans based on relative assessment of risk in each calendar year, using the results of the Activity-Based Risk Assessment and Ra3, with consideration of external factors (e.g., regulatory changes, IRO findings) and internal factors (e.g., past monitoring results, management feedback). Pursuant to the applicable Monitoring Plan(s), during each year, Amgen shall select Transactional Activities and Field-Based Activities for review and assessment, using both a risk-based targeting and sampling approach.

Amgen represents that the Monitoring Plan for the period January 1, 2013 through December 31, 2013 includes each of the types of Transactional Activities and Field Based Activities described in Sections III.K.2.b and III.K.2.c below (i.e., monitoring activities for Consultant arrangements, Researcher arrangements, Publication activities, Independent Medical Education activities, Donations, Records Review, speaker programs and Observations (hereafter, "CIA-required Monitoring Activities")). Amgen further represents that the Monitoring Plan for the period January 1, 2013 through December 31, 2013 requires Amgen to conduct, at minimum, the numbers of CIA-required Monitoring Activities described in Sections III.K.2.b and III.K.2.c below.

On or before November 1, 2013, Amgen shall submit to OIG the Monitoring Plan for the period January 1, 2014 to December 31, 2014 (Monitoring Plan). The Monitoring Plan shall include, at minimum, the types of CIA-required Monitoring Activities described in Sections III.K.2.b and III.K.2.c below. Thereafter, no later than November 1 of each calendar year beginning in 2014 through the end of the term of the CIA, Amgen shall submit to OIG a summary and an explanation of: (i) any reductions in the number of CIA-required Monitoring Activities to be conducted in the upcoming calendar year, compared to the prior year's Monitoring Plan and (ii) any material modifications to the types of CIA-required Monitoring Activities to be conducted in the upcoming calendar year, compared to the prior year's Monitoring Plan. OIG shall have the right to object to each annual Monitoring Plan in the event it does not comply with requirements of Sections III.K.2.b and III.K.2.c, and OIG shall have the right to object to any proposed reductions or modifications with respect to CIA-required Monitoring Activities for

upcoming and subsequent years. In the event OIG does not notify Amgen of any objection to the applicable Monitoring Plan and/or proposed reductions or modifications submitted to the OIG from time to time, Amgen may proceed to implement the Monitoring Plan and/or the proposed reductions and modifications submitted to OIG, as of January 1 of the following calendar year. In addition to the notifications to OIG under this Section III.K.1.a, Amgen shall provide information regarding each year's Monitoring Plan to OIG as part of the Annual Reports in accordance with Section V.B.17 below.

Subject to the limitations of this Section III.K.2 the number of Transactional Activities and/or Field-Based Activities conducted by Amgen each year may be increased or decreased from time to time based on the applicable Monitoring Plan as informed by the Activity-Based Risk Assessment and Ra3. Furthermore, to the extent that the subject matter of a Transactional Activity (e.g., speaker programs, Donations) is subject to an Audit (as defined in Section III.K.3), and with the approval of the OIG, Amgen may, subject to the limitations of this Section III.K.2, modify the types of monitoring activities it conducts to avoid duplication of Healthcare Compliance Monitoring and Healthcare Compliance Internal Audit efforts.

b. *Transactional Activities.* Prior to the Effective Date, Amgen developed, and shall continue to maintain throughout the term of this CIA, a process for monitoring Transactional Activities through which Monitoring Personnel review certain activities and complete monitoring activity documents (Monitoring Worksheets). Monitoring Worksheets describe the risk area being examined, identify the Compliance Controls that form the basis of the Transactional Activity and ask a series of questions designed to verify whether the Transactional Activity that was reviewed complied with Amgen's Policies and Procedures. Monitoring Worksheets shall account for Compliance Controls based on requirements set forth in Amgen's Policies and Procedures and shall ensure that Monitoring Personnel review all documentation available for the Transactional Activity to assess whether the activities being monitored were conducted in a manner consistent with Amgen's Policies and Procedures.

During the term of this CIA, except as otherwise set forth in this Section III.K.2, Amgen, through Monitoring Personnel, shall conduct reviews of, and complete Monitoring Worksheets for, the following Transactional Activities:

(i) *Consultant Arrangement Activities.* To the extent that Amgen engages Consultants during the term of the CIA, Amgen created, and shall maintain throughout the term of this CIA, Monitoring Worksheets that assess compliance with the

Consultant Arrangements Controls consistent with Amgen's Policies and Procedures. In the period January 1, 2013 to December 31, 2013, Monitoring Personnel shall review, and complete Monitoring Worksheets for, at least 75 Consultant arrangements with HCPs or HCIs. Beginning January 1, 2014, and for each subsequent calendar year in the remainder of the term of the CIA, Monitoring Personnel shall review, and complete Monitoring Worksheets for, at least the number of Consultant arrangements with HCPs or HCIs selected in accordance with the applicable year's Monitoring Plan and as approved by the OIG in accordance with Section III.K.2.a.

(ii) *Researcher Arrangement Activities.* To the extent that Amgen engages Researchers during the term of the CIA, Amgen created, and shall continue to maintain throughout the term of this CIA, Monitoring Worksheets that assess compliance with the Research Controls consistent with Amgen's Policies and Procedures. In the period January 1, 2013 to December 31, 2013, Monitoring Personnel shall review, and complete Monitoring Worksheets, for at least 20 Researcher arrangements with HCPs or HCIs. Beginning January 1, 2014, and for each subsequent calendar year in the remainder of the term of the CIA, Monitoring Personnel shall review, and complete Monitoring Worksheets for, at least the number of Researcher arrangements with HCPs or HCIs selected in accordance with the applicable year's Monitoring Plan and as approved by OIG in accordance with Section III.K.2.a.

(iii) *Publication Activities.* To the extent that Amgen engages Authors for Publication activities, Amgen created, and shall continue to maintain throughout the term of this CIA, Monitoring Worksheets that assess compliance with the Publication Controls consistent with Amgen's Policies and Procedures. In the period January 1, 2013 through December 31, 2013, Monitoring Personnel shall review, and complete Monitoring Worksheets for, at least 25 Publication activities. Beginning January 1, 2014, and for each subsequent calendar year in the remainder of the term of the CIA, Monitoring Personnel shall review, and complete Monitoring Worksheets for, at least the number of Publication activities selected in accordance with the applicable Monitoring Plan and as approved by OIG in accordance with Section III.K.2.a.

(iv) *Independent Medical Education Activities and Donations Activities.* To the extent that Amgen provides funding for Independent Medical Education activities or provides Donations to HCPs or HCIs, Amgen created, and shall continue to maintain throughout the term of this CIA, Monitoring Worksheets that assess compliance with the Independent Medical Education Activity Controls and Donations Controls governing the process through which requesters may seek or be awarded funding

for Independent Medical Education activities or Donations from Amgen. In the period January 1, 2013 through December 31, 2013, Monitoring Personnel shall review, and complete Monitoring Worksheets for, at least 30 Independent Medical Education activities (i.e., Independent Medical Education requests) and at least 25 Donations activities. Beginning January 1, 2014, and for each subsequent calendar year in the remainder of the term of the CIA, Monitoring Personnel shall review, and complete Monitoring Worksheets for, at least the number of Independent Medical Education activities and Donations selected in accordance with the applicable Monitoring Plan and as approved by OIG in accordance with Section III.K.2.a.

(v) *Records Review.* As a component of its monitoring of Transactional Activities, Amgen shall also review various types of records to assess sales representatives' interactions with HCPs and HCIs in order to identify actual or potential compliance violations (Records Reviews). Amgen created, and shall maintain throughout the term of this CIA, Monitoring Worksheets that assess compliance with Amgen's Policies and Procedures governing interactions between sales representatives and HCPs and HCIs. For each Reporting Period, Amgen shall complete Monitoring Worksheets based on Records Reviews for at least three Government Reimbursed Products in accordance with that year's Monitoring Plan, which shall result in Monitoring Personnel conducting a Records Review of sales representatives from across Amgen's business units and United States geographic regions.

In the period January 1, 2013 through December 31, 2013, the Records Reviews shall include, at a minimum, a review of: (1) Amgen's required system of records for field sales personnel (which includes call notes); (2) requests for medical information; and (3) field contact reports describing field ride-alongs conducted by a field manager with a sales representative. Beginning January 1, 2014, through the Monitoring Plan as informed by the Activity-Based Risk Assessment and Ra3 and subject to OIG approval of any reductions or modifications as referenced in Section III.K.2.a above, Amgen shall determine the types of documentation completed by sales representatives in connection with their interactions with HCPs or HCIs that will permit Amgen to assess most effectively the compliance of sales representatives with Policies and Procedures governing interactions with HCPs and HCIs in that Reporting Period. Following this determination, and as documented in the Monitoring Plan, Monitoring Personnel will review such documentation in order to complete the required Monitoring Worksheets.

In connection with the development of the Monitoring Plan for each calendar year, the OIG shall have the discretion to identify the Government Reimbursed Products to be

reviewed for each applicable Reporting Period. The OIG will select the products based on information about Amgen's products provided by Amgen, upon request by the OIG no later than 60 days prior to the beginning of the Reporting Period, and other information known to the OIG. If the OIG does not identify the Government Reimbursed Products to be reviewed within the first 30 days of the Reporting Period, Amgen shall select the products to be reviewed based on the Monitoring Plan.

c. *Field-Based Activities.* Prior to the Effective Date, Amgen developed, and shall continue to maintain throughout the term of this CIA, a process for monitoring Field-Based Activities through which Monitoring Personnel complete Monitoring Worksheets based on direct or indirect observations of sales representatives made at the site of a business activity and the documentation associated with such observations. As with Transactional Activities, Monitoring Personnel shall review, and complete Monitoring Worksheets for, Field-Based Activities that account for the Compliance Controls based on requirements set forth in Amgen's Policies and Procedures, guide Monitoring Personnel in making the necessary direct and indirect observations during the Field-Based Activity, and ensure that Monitoring Personnel review all documentation needed to assess whether the Field-Based Activity was conducted in a manner consistent with Amgen's Policies and Procedures.

During the term of this CIA, except as otherwise set forth in this Section III.K.2, Amgen, through Monitoring Personnel, shall review, and complete Monitoring Worksheets for, the following Field-Based Activities:

(i) *Speaker Programs Activities.* Prior to the Effective Date, Amgen conducted, and shall continue to conduct throughout the term of this CIA, monitoring of Field-Based Activities that require Monitoring Personnel to attend speaker programs (Speaker Monitoring Program). For each speaker program selected for the Speaker Monitoring Program, the relevant Monitoring Personnel shall complete a Monitoring Worksheet that requires the review of slides and other materials used as part of the speaker program, speaker statements made during the program, and Amgen representative activities during the program to assess whether the programs were conducted in a manner consistent with Amgen's Policies and Procedures.

In the period January 1, 2013 through December 31, 2013, Monitoring Personnel shall attend and review at least 150 speaker programs. Beginning January 1, 2014, and for each subsequent calendar year in the remainder of the term of the CIA, Monitoring Personnel shall attend and review at least the number of speaker programs selected-in

accordance with the applicable Monitoring Plan and as approved by OIG in accordance with Section III.K.2.a.

(ii) *Observations.* Prior to the Effective Date, Amgen conducted, and shall continue to conduct throughout the term of this CIA, observations of sales representatives to assess whether the messages delivered and materials distributed to HCPs are consistent with applicable legal requirements and with Amgen's Policies and Procedures. These observations shall be full day ride-alongs with sales representatives (Observations) by Monitoring Personnel, and each Observation shall consist of the relevant Monitoring Personnel observing all meetings between a sales representative and HCPs during the workday. In the period January 1, 2013 through December 31, 2013, Amgen shall conduct at least 50 Observations, which shall result in Monitoring Personnel conducting Observations of sales representatives across Amgen's business units and United States geographic regions. Beginning January 1, 2014, and for each subsequent calendar year in the remainder of the term of the CIA, Monitoring Personnel shall conduct at least the number of Observations selected in accordance with the applicable Monitoring Plan and as approved by OIG in accordance with Section III.K.2.a, which shall result in Monitoring Personnel conducting Observations of sales representatives across Amgen's business units and United States geographic regions.

At the completion of each Observation, Monitoring Personnel shall complete a Monitoring Worksheet that includes at a minimum:

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

d. *Reporting and Follow-Up.* Completed Monitoring Worksheets documenting the results from monitoring of Transactional Activities and Field-Based Activities shall be compiled, retained, and reported to the Compliance organization and other appropriate organizations within Amgen for review and follow-up as appropriate. In the event that a Monitoring Worksheet indicates that an activity has raised one or more potential compliance concerns or issues for follow-up, a member of the

Compliance organization shall review and assess the significance of the finding. If the finding is determined by the Compliance organization to present a potential significant compliance issue, the finding shall be reported to the CCO. The finding shall also be referred to the appropriate department within the Compliance organization or Amgen, including but not limited to, the Compliance organization's Internal Investigations program to respond to the finding consistent with established policies and procedures for the triage and handling of potential noncompliance and to ensure all necessary and appropriate responsive (including disciplinary) and corrective actions are taken, including the disclosure of Reportable Events pursuant to Section III.I, if applicable. Completed Monitoring Worksheets, and any corrective action taken as a result of the findings identified in the course of the monitoring of Transactional Activities or Field-Based Activities, shall be recorded in the files of the Compliance organization. Amgen shall include in each Annual Report a summary of the Healthcare Compliance Monitoring program and the results of the monitoring activities conducted for Transactional Activities and Field-Based Activities. Amgen shall make documents relating to its monitoring of Transactional Activities and Field-Based Activities available to the OIG upon request.

3. *Auditing.* Prior to the Effective Date, Amgen established a comprehensive Healthcare Compliance Internal Audit program, which is separate and distinct from the Healthcare Compliance Monitoring program. Amgen represents that while the Healthcare Compliance Monitoring program shall act as an ongoing process for checking and measuring healthcare compliance-related performance related to specific functions or departments to ensure early detection and resolution of potential or suspected non-compliance, the Healthcare Compliance Internal Audit program shall serve to systematically and thoroughly review the compliance aspects of individual business activity areas on a regular, scheduled basis by conducting deeper reviews (Audits) into certain processes to confirm that the sampled business activities were conducted in compliance with Amgen's Policies and Procedures. Although they are separate programs, Amgen represents that the Healthcare Compliance Internal Audit and the Healthcare Compliance Monitoring programs shall serve similar collaborative oversight mechanisms to ensure that Compliance Controls based on requirements set forth in Amgen's Policies and Procedures are operating effectively and are mitigating the occurrence of potential compliance issues or concerns.

To the extent not already accomplished, within 120 days after the Effective Date, Amgen shall extend its Healthcare Compliance Internal Audit program and/or its Healthcare Compliance Monitoring program to address (*i.e.*, assess risk and audit, as

applicable, in accordance with the risk assessment) all business areas within Amgen that perform Covered Functions, which may include delegating specific audit activities to Audit Personnel that reside in the R&D organization. As described in more detail below, the Healthcare Compliance Internal Audit program includes, and shall continue to include: 1) an annual plan that lists the Audits to be performed for each Reporting Period that is risk-based and developed based on assessment of risk (Audit Plan); 2) audits performed by trained and qualified Healthcare Compliance Internal Audit personnel, R&D compliance audit personnel, or through qualified external advisors (collectively “Audit Personnel”) pursuant to specific and standardized Audit process requirements; and 3) oversight of corrective action pertaining to non-routine Audit findings and tracking and documentation of corrective action by Audit Personnel. Amgen represents that it implemented prior to the Effective Date, and shall maintain throughout the term of this CIA, written policies and procedures regarding the operation of the Healthcare Compliance Internal Audit program and that implement the requirements of this CIA regarding reporting and follow-up for any potential or suspected non-compliance with Amgen’s Policies and Procedures or legal requirements.

a. *Annual Audit Plan.* Amgen shall develop an Audit Plan based on relative assessment of risk for each Reporting Period, using the results of the Activity-Based Risk Assessment and Ra3, with consideration of external factors (e.g., legislative and regulatory enactments and changes, IRO findings) and internal factors (e.g., date since last Audit, past Audit results, management feedback). Pursuant to the Audit Plan and the requirements of this CIA, Amgen will select business or activity areas for Audit during each Reporting Period, prioritizing areas of higher relative risk identified in the risk assessment process. The business or activity areas evaluated for inclusion in the Audit Plan (or in partnership with the Research & Development compliance audit program) will include, at minimum, those areas in which Amgen is required to maintain Compliance Controls pursuant to Section III.K.1 of this CIA.

b. *Audit Personnel and Audit Process.* Amgen requires, and shall continue to require, that all Audits be performed by trained and qualified Audit Personnel. Amgen further requires, and shall continue to require, that Audit Personnel conduct Audits, assign criticality to Audit findings, and report results of Audits in accordance with standardized procedures set forth in written policies and procedures for the Healthcare Compliance Internal Audit program. The written policies and procedures for the Healthcare Compliance Internal Audit program shall require Audit Personnel to notify immediately the head of Healthcare Compliance Internal Audit of any serious noncompliance issue, including the failure of a Compliance Control.

c. *Oversight of Corrective Action.* Amgen requires, and shall continue to require, that departments and individuals subject to an Audit prepare written corrective action plans identifying the actions that will be undertaken to address Healthcare Compliance Internal Audit findings. The corrective action plans shall set forth a date for completion of corrective action, which date shall be determined with reference to the assigned criticality of the finding. Each corrective action plan shall be reviewed by Audit Personnel. Audit Personnel shall be responsible for tracking all corrective actions to conclusion prior to closure of an Audit, which process shall be tracked and appropriately documented.

d. *Reporting and Follow-Up.* Completed Audit reports documenting the results of Audits, including the identification of potential deviations from Amgen's Policies and Procedures and/or violations of legal requirements, shall be compiled, retained and reported to the Compliance organization for review and follow-up as appropriate. In the event that a potential deviation from Amgen's Policies and Procedures or potential violation of legal or compliance requirements, including but not limited to potential off-label promotion, is identified during an Audit, Amgen shall review and assess the significance of the finding. If the finding is determined by Audit Personnel to present a potential significant compliance issue, the finding shall be reported to the CCO. The finding shall also be referred to the appropriate group within the Compliance organization or within Amgen, including but not limited to the Compliance organization's Internal Investigations program, to respond to the finding consistent with established policies and procedures for the triage and handling of potential noncompliance and to ensure all necessary and appropriate responsive action (including disciplinary action) and corrective action is taken, including the disclosure of Reportable Events pursuant to Section III.I above, if applicable. Audit reports, and any corrective action taken as a result of the findings identified in the course of Audits, shall be retained in the files of the Compliance organization. Amgen shall include in its Annual Reports a summary of the Healthcare Compliance Internal Audit program and the results of Audit activities.

L. Notice to Health Care Providers and Entities. Within 90 days after the Effective Date, Amgen shall send, by first class mail, postage prepaid with delivery confirmation, a notice containing the language set forth below to all HCPs and HCIs that Amgen currently details. This notice shall be dated and shall be signed by Amgen's Chief Executive Officer. The body of the letter shall state the following:

As you may be aware, Amgen recently entered into a civil, criminal, and administrative settlement with the United States and individual states in connection with Amgen's promotion of several of its products. This letter provides you with additional information about the global settlement, explains Amgen's commitments going forward, and provides you with access to information about those commitments.

In general terms, the Government alleged that Amgen unlawfully promoted Aranesp® (darbepoetin alfa), Enbrel® (etanercept), and Neulasta® (pegfilgrastim) for uses not approved by the Food & Drug Administration (FDA) and that Amgen engaged in other improper conduct relating to these and other Amgen drugs, including EPOGEN® (epoetin alfa), NEUPOGEN® (filgrastim), and Sensipar® (cinacalcet), which constituted violations of the False Claims Act. To resolve these matters, Amgen pled guilty to one-count misdemeanor criminal violation of the Federal Food, Drug & Cosmetic Act (FDCA) relating to the promotion of Aranesp, and agreed to pay a combined criminal fine and forfeiture amount of \$150 million. In addition, Amgen and the Federal and State Governments entered into civil settlements to resolve False Claims Act allegations, pursuant to which Amgen agreed to pay approximately \$612.1 million to the Federal Government and State Medicaid programs. More information about this settlement may be found at the following: **[Amgen shall include a link to the USAO, OCL, and Amgen websites in the letter.]**

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

Please call Amgen at **XXXX** or visit us at **[insert name of web link]** if you

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

The CCO (or a designee) shall maintain a log of all calls and messages received in response to the notice. The log shall include a record and summary of each call and message received (whether anonymous or not), the status of the call or message, and any corrective action taken in response to the call or message. The log of all calls and messages received in response to the notice shall be made available to OIG upon request. As part of the Implementation Report and each Annual Report, Amgen shall provide to the OIG a summary of the calls and messages received.

M. Reporting of Physician Payments.

1. *Reporting of Payment Information.* Quarterly Reporting: On or before June 30, 2013, Amgen shall post in a prominent position on its website an easily accessible and readily searchable listing of all U.S.-based physicians and Related Entities who or which received Payments (as defined in Section III.M.2) directly or indirectly from Amgen during the first full calendar quarter following the Effective Date and the aggregate value of such Payments. Thereafter, 60 days after the end of each calendar quarter during the term of the CIA, Amgen shall post on its website a report of the cumulative value of the Payments provided to each physician and Related Entity during the preceding calendar quarter.

Annual Reporting: On or before March 31, 2014, and 90 days after the end of each subsequent calendar year during the term of the CIA, Amgen shall post on its website a report of the cumulative value of the Payments provided to all U.S.-based physicians and Related Entities directly or indirectly from Amgen during the prior applicable calendar year. Each quarterly and annual report shall be easily accessible and readily searchable.

Each listing made pursuant to this Section III.M shall include a complete list of all individual physicians or Related Entities to whom or which Amgen made Payments in the preceding quarter or year (as applicable). Each listing shall be arranged alphabetically

Corporate Integrity Agreement
Amgen Inc.

according to the physicians' last name or name of Related Entity. The Payment amounts in the lists shall be reported in the actual amount paid for all physicians or Related Entity on the listing. For each physician, the applicable listing shall include the following information: (i) physician's full name; (ii) name of any Related Entities (if applicable); (iii) city and state that the physician has provided to Amgen for contact purposes; and (iv) the aggregate value of the payment(s) in the preceding quarter or year (as applicable). If payments for multiple physicians have been made to one Related Entity, the aggregate value of all payments to the Related Entity will be the reported amount.

2. *Definitions and Miscellaneous Provisions.*

(i) Amgen shall continue to make each annual listing and the most recent quarterly listing of Payments available on its website during the term of the CIA. Amgen shall retain and make available to OIG, upon request, all supporting documentation, correspondence, and records related to all applicable Payments and to the annual and/or quarterly listings of Payments. Nothing in this Section III.M affects the responsibility of Amgen to comply with (or liability for noncompliance with) all applicable Federal health care program requirements and state laws as they relate to all applicable Payments made to physicians or Related Entity.

(ii) For purposes of Section III.M.1, "Payments" is defined to include all "payments or transfers of value" as that term is defined in §1128G(e)(10) under Section 6002 of the Patient Protection and Affordable Care Act (Public Law 111-148) (Affordable Care Act) and any regulations promulgated thereunder. The term Payments includes, by way of example, the types of payments or transfers of value enumerated in §1128G(a)(1)(A)(vi) of the Affordable Care Act. The term includes all payments or transfers of value made to Related Entities on behalf of, at the request of, for the benefit or use of, or under the name of a physician for whom Amgen would otherwise report a Payment if made directly to the physician. The term Payments also includes any payments or transfers of value made, directly by Amgen or by a vendor retained by Amgen to a physician or Related Entity in connection with, or under the auspices of, a co-promotion arrangement.

(iii) For purposes of its annual and quarterly website postings as described above, and only with regard to payments made pursuant to product research or development agreements and clinical investigations as set forth in § 1128G(c)(E) of the Affordable Care Act, Amgen may delay the inclusion of such payments on its website listings consistent with § 1128G(c)(E) of the Act and any subsequent regulations promulgated thereunder.

(iv) The term “Payments” does not include transfers of value or other items that are not included in or are excluded from the definition of “payment” as set forth in § 1128G(e)(10) under Section 6002 of the Affordable Care Act and any regulations promulgated thereunder.

(v) For purposes of this Section III.M, the term “Related Entity” is defined to be any entity by or in which any physician receiving Payments is employed, has tenure, or has an ownership interest.

N. Other Transparency/Disclosure Initiatives.

Amgen represents that, on a quarterly basis, it posts on its company website the following information with respect to all independent medical education grants and healthcare donations. The information posted on the company website includes: (i) the name of the recipient; (ii) the program name; and (iii) the amount of the grant or donation. Amgen shall continue to post (and provide updates to) the above-described information about grants and healthcare donations throughout the term of this CIA. Amgen shall notify the OIG in writing at least 60 days prior to any change in the substance of its policies regarding the funding of grants and healthcare donations or posting of the above-referenced information relating to such funding.

Amgen shall require all Consultants to fully comply with all applicable disclosure obligations relating to their relationship with Amgen that may be externally imposed on the Consultants based on their affiliation with formulary or Pharmacy & Therapeutics (P&T) committees or committees associated with the development of treatment protocols or standards or that are required by any HCI, medical committee, or other medical or scientific organization with which the Consultants are affiliated. Within 120 days after the Effective Date, Amgen shall, if necessary, amend its policies relating to Consultants to explicitly state that Amgen requires all Consultants to fully comply with all applicable disclosure obligations relating to their relationship with Amgen that may be externally imposed on the Consultants based on their affiliation with formulary, P&T committees, or committees associated with the development of treatment protocols or standards or that are required by any HCI, medical committee, or other medical or scientific organization with which the Consultants are affiliated. In addition, for any amendment to its contracts with Consultants and in any new contracts with Consultants entered into after 120 days following the Effective Date, Amgen shall include an explicit requirement that the Consultants fully comply with all applicable disclosure requirements, as referenced above in this paragraph. Amgen shall continue these disclosure requirements throughout the term of this CIA.

Corporate Integrity Agreement
Amgen Inc.

Amgen represents that it expects all Authors of biomedical manuscripts to fully comply with the International Committee of Medical Journal Editors (ICMJE) criteria regarding authorship and disclosure of their relationship with Amgen and to disclose any potential conflicts of interest, including any financial or personal relationships that might be perceived to bias their work. Within 120 days after the Effective Date, Amgen, if necessary, shall amend its Author confirmation letter to explicitly state Amgen's requirement about full disclosure by Authors consistent with the requirements of any HCI, medical committee or other medical or scientific organization with which the Authors are affiliated. In addition, for any amendments to its engagement letters with Authors and in any new engagement letters with Authors entered into after 120 days following the Effective Date, Amgen shall include an explicit requirement that Authors disclose in their manuscripts, journal submissions, and elsewhere as appropriate or required, any potential conflicts of interest, including their financial or personal relationship with Amgen, the names of any individuals who have provided editorial support for any manuscript or other publication, and all funding sources for the study or publication.

To the extent not already accomplished, within 120 days after the Effective Date, Amgen shall post or make available information on its company website about post-marketing commitments (PMCs). The Amgen website or links included therein shall provide access to general information about the PMC process, descriptions of ongoing Amgen studies, and information about the nature and status of FDA post-marketing commitments. Amgen shall continue to post or make available the above-described information about PMCs on its website or links included therein throughout the term of this CIA.

IV. CHANGES TO BUSINESS UNITS OR LOCATIONS

A. Change or Closure of Unit or Location. In the event that, after the Effective Date, Amgen changes locations or closes a business unit or location related to or engaged in any of the Covered Functions, Amgen shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change or closure of the location.

B. Purchase or Establishment of New Unit or Location. In the event that, after the Effective Date, Amgen purchases or establishes a new business unit or location related to or engaged in any of the Covered Functions, Amgen shall notify OIG no later than five business days after the date that the purchase or establishment of the new business unit or

location is publicly disclosed by Amgen. This notification shall include the address of the new business unit or location, phone number, fax number, the location's Federal health care program provider number and/or supplier number(s) (if applicable); and the name and address of each Federal health care program contractor to which Amgen currently submits claims (if applicable). Each new business unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements of this CIA.

C. Sale of Unit or Location. In the event that, after the Effective Date, Amgen proposes to sell any or all of its business units or locations that are subject to this CIA, Amgen shall notify OIG of the proposed sale at no later than five business days after the sale is publicly disclosed by Amgen. This notification shall include a description of the business unit or location to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This CIA shall be binding on the purchaser of such business unit or location, unless otherwise determined and agreed to in writing by the OIG.

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 CCO required by Section III.A.1, and a summary of other noncompliance job responsibilities the CCO 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 members of the CRCC of the Board of Directors referenced in Section III.A.3;
4. the names and positions of the Certifying Employees required by Section III.A.4;
5. a copy of Amgen's Code of Conduct required by Section III.B.1;

6. the number of Covered Persons required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

7. a summary of all Policies and Procedures required by Section III.B.3 (a copy of such Policies and Procedures shall be made available to OIG upon request);

8. (a) a copy of the letter (including all attachments) required by Sections II.C.10 and III.B.2 sent to each party employing Third Party Personnel; (b) a list of all existing co-promotions and other applicable agreements with the party employing the Third Party Personnel; and (c) a description of the entities' responses to Amgen's letter;

9. the following information regarding each type of training required by Section III.C:

a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and

b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

10. 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; (d) a summary and description of any and all current and prior engagements and agreements between Amgen and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to Amgen;

11. a description of the Disclosure Program required by Section III.F;

12. a description of the process by which Amgen fulfills the requirements of Section III.G regarding Ineligible Persons;

13. a certification by the CCO that the notice required by Section III.L was mailed to each HCP and HCI, the number of HCPs and HCIs to whom the notice was mailed, a sample copy of the notice required by Section III.L, and a summary of the calls or messages received in response to the notice;

14. a certification from the CCO that, if required under Section III.M and to the best of his/her knowledge, information regarding Payments has been posted on Amgen's website as required by Section III.M;

15. 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; each location's Federal health care program provider number and/or supplier number(s) (if applicable); and the name and address of any each Federal health care program contractor to which Amgen currently submits claims (if applicable);

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

17. the certifications required by Section V.C.

B. Annual Reports. Amgen shall submit to OIG annually a report with respect to the status of, and findings regarding, Amgen's compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the CCO and any change in the membership of the Compliance Committee, the CRCC of the Board of Directors, or the group of Certifying Employees described in Sections III.A.1-III.A.4;

2. a copy of the resolution by the CRCC required by Section III.A.3;

3. the number of individuals required to review Amgen's Code of Conduct and complete the certifications required by Section III.B.1, the percentage of individuals who have completed such certifications, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

Corporate Integrity Agreement
Amgen Inc.

4. (a) a copy of the letter (including all attachments) required by Sections II.C.10 and III.B.2 sent to each party employing Third Party Personnel; (b) a list of all existing co-promotions and other applicable agreements with the party employing the Third Party Personnel; and (c) a description of the entities' responses to Amgen's letter;

5. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in applicable requirements);

6. the following information regarding each type of training required by Section III.C:

a. a description of the initial and annual training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and

b. the number of individuals required to complete the initial and annual training, percentage of individuals who completed the training, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request;

7. a summary of any significant changes to the Ra3 process required by Section III.D;

8. a complete copy of all reports prepared pursuant to Section III.E along with a copy of the IRO's engagement letter;

9. Amgen's response to the reports prepared pursuant to the reviews outlined in Section III.E, along with corrective action plan(s) related to any issues raised by the reports;

10. a summary and description of any and all current and prior engagements and agreements between Amgen and the IRO (if different from what was submitted as part of the Implementation Report);

11. certifications from the IRO regarding its professional independence and

objectivity with respect to Amgen;

12. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs, FDA requirements, or Government Reimbursed Products;

13. any changes to the process by which Amgen fulfills the requirements of Section III.G regarding Ineligible Persons;

14. 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;

15. a summary of Reportable Events (as defined in Section III.I) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;

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

17. a summary of the Compliance Controls, monitoring, and auditing implemented and conducted in accordance with Section III.K, including a summary of the Healthcare Compliance Monitoring Program, the Healthcare Compliance Internal Auditing Program, and results of the monitoring and auditing activities;

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

19. a description of all changes to the most recently provided list of Amgen's locations (including addresses) as required by Section V.A.15; the corresponding name under which each location is doing business; and the corresponding phone numbers and fax numbers;

20. a description of: i) any additional, updated, supplemental or changed information submitted to any Compendia in accordance with Section III.B.3.r; ii) Amgen's review of information submitted to the Compendia and Amgen's conclusion as to whether information submitted to the Compendia and product listings and monographs

contained in the Compendia about Government Reimbursed Products are accurate and complete and do not contain any errors; and iii) all arrangements, processing fees, and other payments or financial support (if any) with or made to any Compendia evaluated during the annual review described in Section III.B.3.r; and

21. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 90 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 as required by Section III.A.4;

2. Chief Compliance Officer: In each Implementation Report and Annual Report, Amgen shall include the following individual certification by the CCO:

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. Amgen's: (i) Policies and Procedures as referenced in Section III.B.3 above; (ii) templates for standardized contracts and other similar documents; and (iii) the training materials used for purposes of Section III.C all have been reviewed by competent legal counsel and have been found to be in compliance with all applicable Federal health care program and FDA requirements. In addition, Amgen's promotional materials containing claims or information about Government Reimbursed Products and other materials and information intended to be disseminated outside Amgen have been reviewed by competent regulatory, medical, or, as appropriate, legal counsel in accordance with applicable Policies and Procedures to ensure that legal, medical, and regulatory concerns have been addressed by Amgen and brought to the attention of the appropriate individuals when required, and that, to the best of his or her knowledge, the materials and information when finally approved are in compliance with all applicable Federal health care program and FDA requirements. If the applicable legal requirements

have not changed, after the initial review of the documents listed above, only material changes to the documents must be reviewed by competent legal counsel. The certification shall include a description of the document(s) reviewed and approximately when the review was completed. The documentation supporting this certification shall be available to OIG, upon request; and

d. Amgen's call plans for Government Reimbursed Products (e.g. Amgen Plans of Action and specialty target lists) were reviewed at least once during the Reporting Period (consistent with Section III.B.3.i) and, for each product the call plans were found to be consistent with Amgen's policy objectives as referenced above in Section III.B.3.i.

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: Cynthia M. Patton
Senior Vice President and Chief Compliance Officer
Amgen Inc.

One Amgen Center Drive
MS 38-4-A
Thousand Oaks, CA 91320-1799
Telephone: 805.447.6217
Facsimile: 805.480.9941

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt. Upon request by OIG, Amgen may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), either instead of or in addition to, a paper copy.

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 examine or request copies of 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 the Federal health care programs in which it participates and with all applicable FDA requirements. 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, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Amgen's employees, contractors, or agents 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 employees 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. § 5.65(d).

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 and implement any of the following obligations as described in Section III:

- a. a Chief Compliance Officer;
- b. a Compliance Committee;
- c. the CRCC's compliance obligations, including the resolution from the Board;
- d. the management accountability and certification obligations;
- e. a written Code of Conduct;
- f. written Policies and Procedures;
- g. the training of Covered Persons, Relevant Covered Persons, and Board Members;

- h. an Ra3 process, or substantively equivalent risk assessment and mitigation process;
- i. a Disclosure Program;
- j. Ineligible Persons screening and removal requirements;
- k. notification of Government investigations or legal proceedings;
- l. reporting of Reportable Events;
- m. notification of written communications with FDA as required by Section III.J;
- n. a program for Compliance Controls, monitoring, and auditing as required by Section III.K;
- p. notification to HCPs and HCIs as required by Section III.L; and
- q. posting of any Payments as required by Section III.M.

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 in Section III.E and Appendices A-C.

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 the Implementation Report or any Annual Reports 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 Appendices B-C.

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 \$5,000 for each false certification submitted by or on behalf of Amgen as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

7. 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 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- 6 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 business 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 business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter*. Upon a finding that 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 is 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. a repeated or flagrant violation 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 and Appendices A-C;
- d. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- e. a failure of the Board to issue a resolution in accordance with Section III.A.3.

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. 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 is hereinafter 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 to OIG's satisfaction that:

- a. Amgen is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;
- b. the alleged material breach has been cured; or
- c. 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 hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Amgen's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and non-procurement programs. Reinstatement to program participation is not automatic. After 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.

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:

- a. whether Amgen was in material breach of this CIA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Amgen had begun to take action to cure the material breach within that period; (ii) Amgen has pursued and is pursuing such action with due diligence; and (iii) Amgen provided to OIG within that period a reasonable timetable for

curing the material breach and Amgen has followed the timetable.

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 be binding on the successors, assigns, and transferees of Amgen;

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

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

D. The undersigned Amgen signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is 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. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

ON BEHALF OF AMGEN INC.

/Cynthia M. Patton/

12/12/12

CYNTHIA M. PATTON
Senior Vice President
& Chief Compliance Officer
Amgen Inc.

DATE

/Brien T. O'Connor/

12/10/12

BRIEN T. O'CONNOR
Ropes & Gray LLP
Counsel for Amgen Inc.

DATE

/Michele M. Garvin/

12/10/12

MICHELE M. GARVIN
Ropes & Gray LLP
Counsel for Amgen Inc.

DATE

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

/Robert K. DeConti/

12/14/12

ROBERT K. DECONTI
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

DATE

/Mary E. Riordan/

12/14/12

MARY E. RIORDAN
Senior Counsel
Office of Inspector General
U. S. Department of Health and Human Services

DATE

/Lisa G. Veigel/

12/14/12

LISA G. VEIGEL
Senior Counsel
Office of Inspector General
U. S. Department of Health and Human Services

DATE

Appendix A to CIA for Amgen Inc. 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.

Amgen shall engage an IRO (or IRO(s)) that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives the information identified in Section V.A.10 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.

If Amgen engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Amgen shall submit the information identified in Section V.A.10 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 have expertise in applicable Federal health care program and FDA requirements that relate to certain of the Covered Functions, including expertise relating to: i) marketing and promotional activities associated with pharmaceutical products; ii) research regarding such products; and iii) publication, authorship, and disclosure activities associated with such research. The assigned individuals shall also be experienced in risk identification and mitigation in relation to pharmaceutical product marketing and promotion. The assigned individuals also shall be knowledgeable about the general requirements of the Federal health care programs under which Amgen products are reimbursed;

2. assign individuals to design and select the samples for the IRO Transactions Reviews who are knowledgeable about 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 each IRO Review in accordance with the specific requirements of the CIA;

2. follow all applicable Federal health care program and FDA requirements in making assessments in each IRO Review;

3. if in doubt of the application of a particular Federal health care program or FDA requirement, request clarification from the appropriate authority (e.g., CMS or FDA);

4. respond to all OIG inquiries in a prompt, objective, and factual manner; and

5. prepare timely, clear, well-written reports that include all the information required by Appendices B and C to the CIA.

D. Independence and Objectivity.

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

E. IRO Removal/Termination.

1. *Amgen Termination of 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 its reasons for termination or the reason for 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 the termination or withdrawal of the IRO.

2. *OIG Removal of IRO.* In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and/or objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require Amgen to engage a

new IRO in accordance with Paragraph A of this Appendix. Amgen must engage a new IRO within 60 days of termination of the IRO.

Prior to requiring Amgen to engage a new IRO, OIG shall notify Amgen of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, Amgen may present additional information regarding the IRO's qualifications, independence, or performance of its responsibilities. OIG will attempt in good faith to resolve any differences regarding the IRO with Amgen prior to requiring Amgen to terminate the IRO. However, 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.

Appendix B to CIA for Amgen Inc. Independent Review Organization Reviews

I. Covered Functions Review, General Description

As specified more fully below, Amgen Inc. (Amgen) shall retain an Independent Review Organization (IRO) (or IROs) to perform reviews (IRO Reviews) to assist Amgen in assessing and evaluating its systems, processes, policies, procedures, and practices related to certain of Amgen's Covered Functions. 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 IRO to perform both components of the IRO Review 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 the relevant Covered Functions, the IRO shall perform the Systems Review for the second and fourth Reporting Periods. If Amgen materially changes its systems, processes, policies, and procedures relating to the relevant Covered Functions, the IRO shall perform a Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Review for the second and fourth Reporting Periods. The additional Systems Review(s) shall consist of: 1) an identification of the material changes; 2) a review of the systems, processes, policies, and procedures that materially changed; and 3) an assessment of whether other systems, processes, policies, and procedures previously reported materially changed. The IRO shall conduct the Transactions Review for each Reporting Period of the CIA.

II. IRO Systems Review

A. Description of Reviewed Policies and Procedures

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 certain of the Covered Functions. 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 in accordance with the preceding sentence.

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

1) the manner in which Amgen field personnel and personnel from the Medical Information department handle requests or inquiries relating to information about the uses of Government Reimbursed Products (including non-FDA-approved (i.e., off-label) uses of the products) and the dissemination of materials relating to the uses of the products. This review shall include:

- a) the manner in which Amgen commercial sales personnel handle requests for information about off-label uses of Government Reimbursed Products (i.e., by referring all such requests to Medical Information);
- b) the manner in which Medical Information personnel handle and respond to requests for information about off-label uses of Government Reimbursed Products (including tracking the requests and using pre-approved materials for purposes of responding to the requests);
- c) the form and content of information and materials related to Government Reimbursed Products disseminated to healthcare professionals (HCPs), healthcare institutions (HCIs), and Payors by Amgen;
- d) Amgen's systems, processes, policies, and procedures (including the Inquiries Database) to track requests to Medical Information for information about off-label uses of Amgen products and responses to those requests;
- e) the manner in which Amgen collects and supports information reported in any systems used to track and respond to requests to Medical Information for Government Reimbursed Product information, including its Inquiries Database;
- f) the processes and procedures by which Medical Information, the Chief Compliance Officer, or other appropriate individuals within Amgen identify situations in which it appears that off-label or other improper promotion may have occurred; and

- g) Amgen's processes and procedures for investigating, documenting, resolving, and taking appropriate disciplinary action for potential situations involving improper promotion;
- 2) the manner and circumstances under which Amgen's medical personnel (including those from Scientific Affairs and the Global Development Organization) participate in meetings or events with HCPs or HCIs (either alone or with sales representatives) regarding Government Reimbursed Products, the role of the medical personnel at such meetings or events, and the manner in which medical personnel handle requests for information about off-label uses of Government Reimbursed Products;
- 3) Amgen's internal review of promotional materials related to Government Reimbursed Products disseminated to HCPs, HCIs and Payors;
- 4) the development and review of call plans (e.g., Amgen plans of action and specialty target lists) as defined in Section III.B.3.i of the CIA for Government Reimbursed Products. This shall include a review of the bases upon which HCPs and HCIs belonging to specified medical specialties are included in, or excluded from, the call plans based on expected utilization of Government Reimbursed Products for FDA-approved uses or non-FDA-approved uses;
- 5) the development and review of Sample Distribution Plans (as defined in Section III.B.3.j of the CIA) for Government Reimbursed Products. This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive samples from Amgen (including, separately, from Amgen sales representatives and other Amgen personnel or components). It shall also include a review of whether samples of Government Reimbursed Products are distributed by Amgen through sales representatives or are distributed from a central location and the rationale for the manner of distribution;
- 6) speaker programs, speaker training programs, and all events and expenses relating to such engagements or arrangements;
- 7) non-speaker related consultant or other fee-for-service engagements Amgen enters into with HCPs or HCIs (including, but not limited to, consultant meetings, advisory boards, ad hoc advisory activities, and other

financial engagements with HCPs or HCIs) and all events and expenses associated with such activities;

8) Amgen’s funding, directly or indirectly, of Independent Medical Educational Activities (as defined in Section II.C.9 of the CIA) and all events and expenses relating to such activities;

9) the submission of information about any Government Reimbursed Product to any CMS-recognized Compendia (as defined in Amgen’s Policies and Procedures) such as Drugdex or other published source of information used in connection with the determination of coverage by a Federal health care program for the product (hereafter “Compendia”). This includes any initial submission of information to any Compendia and the submission of any additional, updated, supplemental, or changed information, (e.g., any changes based on Amgen's discovery of erroneous or scientifically unsound information or data associated with the information in the Compendia). The review shall also assess Amgen's processes relating to (i) the initial review of information submitted to the Compendia; (ii) Amgen’s annual review of Amgen product listings and monographs; and (iii) Amgen’s annual review of all arrangements, processing fees, or other payments or financial support (if any) provided to any Compendia as set forth in Section III.B.3.r of the CIA;

10) Research and Publication Practices (as defined in Section III.B.3.s of the CIA), including the decision to provide financial or other support for Research; the manner in which Research support is provided; the publication of information about the Research, including the publication of information about the Research results and trial outcomes; and uses made of publications relating to such Research;

11) Authorship-Related Practices (as defined in Section III.B.3.t of the CIA), including, but not limited to, the disclosure of any and all financial relationships between the author and Amgen, the identification of all authors or contributors (including professional writers, if any) associated with a given publication, and the scope and breadth of research results made available to each author or contributor;

12) the manner and circumstances under which Amgen personnel participate in meetings with Payors (as defined in Section II.C.7 of the CIA) regarding Government Reimbursed Products and the role of the Amgen personnel at such meetings; and

13) the form and content of information and materials disseminated by Amgen to Payors and Amgen's systems, policies, processes, and procedures relating to Amgen's internal review and approval of information and materials related to Government Reimbursed Products disseminated to Payors by Amgen.

B. IRO Systems Review Report

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

- 1) a description of the documentation (including policies) reviewed and any personnel interviewed;
- 2) a detailed description of Amgen's systems, policies, processes, and procedures relating to the items identified in Sections II.A.1-13 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 Sections II.A.1-13 above are made known or disseminated within Amgen;
- 4) a detailed description of any system(s) used to track and respond to requests for information about Government Reimbursed Products (including the Inquiries Database);
- 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.

III. IRO Transactions Review

As described more fully below in Sections III.A-F, the Transactions Reviews shall include: (1) a review of a sample of Inquiries reflected in the Inquiries Database; (2) a review of Amgen’s call plans (as defined in Section III.B.3.i of the CIA) and Amgen’s call plan review process; (3) a review of Sampling Events as defined below in Section III.C; (4) a review of records relating to a sample of the Payments that are reported by Amgen pursuant to Section III.M of the CIA; (5) a review of Research and Publication Practices and Authorship-Related Practices; and (6) a review of up to three additional items identified by the OIG in accordance with Section III.E.1.b of the CIA (hereafter “Additional Items”). The IRO shall report on all aspects of its reviews in the Transactions Review Reports.

A. Review of Inquiries and Inquiries Database

1) Description of Inquiries Database

As set forth in Section III.B.3.g of the CIA, Amgen shall establish a database to track information relating to requests for information received by Amgen about its Government Reimbursed Products (hereafter “Inquiries”). Specifically, Amgen shall document and record all Inquiries regarding Government Reimbursed Products in a database(s) (the “Inquiries Database”). Amgen shall record in the Inquiries Database the following information for each Inquiry received: (i) date of Inquiry; (ii) form of Inquiry (e.g., fax, phone, medical information request form); (iii) name of requesting HCP or HCI or other individual or entity; (iv) nature and topic of request (including exact language of the Inquiry if made in writing); (v) an evaluation of whether the Inquiry relates to information about an off-label use for the product; (vi) nature/form of the response from Amgen (including a record of any materials provided in response to the request); and (vii) the name of the Amgen representative who called upon or interacted with the HCP, HCI, or customer, if known.

2) Internal Review of Inquiries Database

On a semi-annual basis, the Chief Compliance Officer or designee shall review the Inquiries Database and related information, as appropriate, and shall generate a report summarizing the items of information outlined in Section III.A.1 above for each Inquiry received during the preceding two quarters (Inquiry Report). The Chief Compliance Officer or designee shall review the Inquiry Reports to assess whether the information contained in

the report suggests that improper off-label promotion may have occurred in connection with any Inquiry(ies). If the Chief Compliance Officer or designee, in consultation with other appropriate Amgen personnel, suspects that improper off-label promotion may have occurred in connection with any Inquiry, the Chief Compliance Officer or designee shall undertake a follow-up review of the Inquiry (Off-Label Review), make specific findings based on his/her Off-Label Review, and take all appropriate responsive action (including disciplinary action of the Covered Person and reporting of the conduct, including disclosing Reportable Events pursuant to Section III.I of the CIA, if applicable).

3) IRO Review of Inquiries Reflected in Inquiries Database

The IRO shall select and review a random sample of 50 Inquiries from among the Inquiries reflected in the Inquiries Database for each Reporting Period. Forty of the Inquiries reviewed by the IRO shall be Inquiries for which Amgen conducted an Off-Label Review, and the other ten shall be Inquiries for which Amgen did not conduct an Off-Label Review. For each Inquiry reviewed, the IRO shall determine:

- a) Whether each item of information listed above in Section III.A.1 is reflected in the Inquiries Database for each reviewed Inquiry; and
- b) For each Inquiry for which the Chief Compliance Officer or designee conducted an Off-Label Review, the basis for suspecting that improper off-label promotion may have occurred; the steps undertaken as part of the Off-Label Review; the findings of the Chief Compliance Officer or designee as a result of the Off-Label Review; and any follow-up actions taken by Amgen based on the Off-Label Review findings.

B. IRO Review of Amgen's Call Plans and Call Plan Review Process

The IRO shall conduct a review and assessment of Amgen's review of its call plans as defined and set forth in Section III.B.3.i of the CIA. Amgen shall provide the IRO with: (i) a list of Government Reimbursed Products promoted by Amgen during the Reporting Period; (ii) information about the FDA-approved uses for each such product; and (iii) the call plans for each such product. Amgen shall also provide the IRO with information about the reviews of call plans that Amgen conducted during the Reporting Period and any modifications to the call plans made as a result of Amgen's reviews.

For each call plan, the IRO shall select a sample of 50 of the HCPs and HCIs included on the call plan. For each call plan, the IRO shall compare the sampled HCPs and HCIs against the criteria (e.g., medical specialty or practice area) used by Amgen in conducting its review and/or modifying the call plan. The IRO shall seek to determine whether Amgen followed its criteria and Policies and Procedures in reviewing and modifying the call plan.

The IRO shall note any instances in which it appears that the sampled HCPs or HCIs on a particular call plan are inconsistent with Amgen's criteria relating to the call plan and/or Amgen's Policies and Procedures. The IRO shall also note any instances in which it appears that Amgen failed to follow its criteria or Policies and Procedures.

C. IRO Review of the Distribution of Samples of Amgen Government Reimbursed Products

The IRO shall conduct a review and assessment of the distribution of samples of Government Reimbursed Products to HCPs and HCIs. Amgen shall provide the IRO with: (i) a list of Government Reimbursed Products for which Amgen distributed samples during the Reporting Period; (ii) information about the FDA-approved uses for each such product; and (iii) information about Amgen's policies and procedures relating to the distribution of samples of each type of product, including Amgen's Sample Distribution Plan showing which types of samples may not be distributed by sales personnel or other Amgen personnel to HCPs and HCIs of particular medical specialties or types of clinical practices. Amgen shall also provide the IRO with information about the reviews of Sample Distribution Plan that Amgen conducted during the Reporting Period as set forth in Section III.B.3.j of the CIA and any modifications to the Sample Distribution Plans made as a result of Amgen's reviews.

For each Government Reimbursed Product for which Amgen distributed samples during the Reporting Period, the IRO shall randomly select a sample of 50 separate instances in which Amgen provided samples of the product to HCPs or HCIs. Each such instance shall be known as a "Sampling Event."

For each Sampling Event, the IRO shall review all documents and information relating to the distribution of the sample to the HCP or HCI. The reviewed materials shall include materials about the following: 1) the quantity, dosage, and form of the Amgen product provided to the HCP or HCI; 2) the identity and type of medical specialty or clinical practice of the HCP or HCI; 3) which individual Amgen sales personnel or other Amgen personnel provided the sample to the HCP or HCI; and 4) the manner and mechanism through which the sample was requested (e.g., sample request form, letter, or call to Amgen).

For each Sampling Event, the IRO shall evaluate whether the sample was provided to an HCP or HCI whose medical specialty or clinical practice is consistent with the uses of the Government Reimbursed Product approved by the FDA and whether the sample was distributed by an Amgen representative in a manner consistent with Amgen's Sample Distribution Plan for the product(s) provided during the Sampling Event. To the extent that a sample was shipped to an HCP or HCI by an Amgen vendor, the IRO shall review the Proof of Receipt form signed by the HCP or HCI. If no Proof of Receipt form is available, or if the HCP or HCI was contacted by an Amgen representative other than a sales representative or an Amgen approved vendor, the IRO shall contact the HCP or HCI by letter. The letter shall request that the HCP or HCI: 1) verify that he/she/it received the quantity and type of samples identified by the IRO as the Sampling Event; 2) verify that he/she/it requested the samples provided during the Sampling Event; 3) explain or confirm its type of medical specialty or clinical practice; and 4) identify the basis for requesting the sample (e.g., conversations with a Amgen sales representative, conversation with a Amgen representative at headquarters, independent research, or knowledge of the HCP or HCI).

For each Sampling Event, the IRO shall compare the medical specialty and type of clinical practice of the HCPs and HCIs that received the sample with uses of the Government Reimbursed Product approved by the FDA. The IRO shall note any instances in which it appears that the medical specialty or clinical practice of the HCPs or HCIs that received a sample during a Sampling Event were not consistent with the uses of the Government Reimbursed Product approved by the FDA. For each such situation, the IRO shall note the process followed by Amgen in determining that it was appropriate to provide a sample to such HCP or HCI and the basis for such determination. The IRO shall also note any instances in which it appears that Amgen failed to follow its Sample Distribution Plan for the Government Reimbursed Product(s) provided during the Sampling Event.

D. IRO Review of Physician Payment Listings

1. Information Contained in Physician Payment Listings

For purposes of the IRO Review as set forth in this Section III.D, each annual listing of physicians and Related Entities who received Payments (as defined in Section III.M of the CIA) from Amgen shall be referred to as the "Physician Payment Listing" or "Listing." For each physician and Related Entity, each Physician Payment Listing shall include the following information: (i) physician's full name; (ii) name of Related Entity (if applicable); (iii) city and state of the physician's practice or the Related Entity; and (iv) the aggregate value of the Payment(s) in the preceding year(s).

For purposes of this IRO Review, the term “Control Documents” shall include all documents or electronic records associated with each Payment reflected in the Physician Payment Listing for a sampled physician and/or Related Entity. For example, the term “Control Documents” includes, but is not limited to, documents relating to the nature, purpose, and amount of all Payments reflected in the Listing; contracts relating to the Payment(s) reflected in the Listing; documents relating to the occurrence of Payment(s) reflected in the Listing; documents reflecting any work product generated in connection with the Payment(s); documents submitted by field personnel or headquarters personnel to request approval for the Payment(s); and business rationale or justification forms relating to the Payment(s).

2. Selection of Sample for Review

For each Reporting Period, the OIG shall have the discretion to identify up to 50 physicians or Related Entities from the applicable Physician Payment Listing that will be subject to the IRO review described below. If the OIG elects to exercise this discretion, it shall notify the IRO at least 90 days prior to the end of the Reporting Period, of the physicians and/or Related Entities subject to the IRO review. If the OIG elects not to exercise its discretion as described above, the IRO shall randomly select 50 physicians and/or Related Entities to be included in the review. For each selected physician and/or Related Entity, the IRO shall review the entry in the Physician Payment Listing and the Control Documents relating to Payments reflected in the Listing identified by the IRO as necessary and sufficient to validate the Payment information in the Listing.

3. IRO Review of Control Documents for Selected Physicians and/or Related Entities

For each physician and/or Related Entity selected as part of the sample, the IRO shall review the Control Documents identified by the IRO as necessary and sufficient to validate each Payment reflected in the Listing to evaluate the following:

- a) Whether Control Documents are available relating to each Payment reflected in the Listing for the sampled physician and/or Related Entity;
- b) Whether the Control Documents were completed and archived in accordance with the requirements set forth in Amgen’s policies;

- c) Whether the aggregate value of the Payment(s) as reflected in the Listing for the sampled Physician is consistent with the value of the Payments(s) reflected in the Control Documents; and
- d) Whether the Control Documents reflect that Amgen's policies were followed in connection with Payment(s) reflected in the Listing (e.g., all required written approvals for the activity were obtained in accordance with Amgen's policies).

4. Identification of Material Errors and Additional Review

A Material Error is defined as any of the following:

- a) A situation in which all required Control Documents relating to Payments reflected in the Listing for the sampled physician and/or Related Entity do not exist and:
 - i. no corrective action was initiated prior to the selection of the sampled physicians and/or Related Entities; or
 - ii. the IRO cannot confirm that Amgen otherwise followed its policies and procedures relating to the entry in the Listing for the sampled physician or Related Entity, including its policies and procedures relating to any Payment(s) reflected in the Listing; or
- b) Information or data is omitted from key fields in the Control Documents that prevents the IRO from assessing compliance with Amgen's policies and procedures, and the IRO cannot obtain this information or data from reviewing other Control Documents.

If a Control Document does not exist, but Amgen has initiated corrective action prior to the selection of the sampled physicians and/or Related Entities, or if a Control Document does not exist but the IRO can determine that Amgen otherwise followed its policies and procedures with regard to each entry in the Listing for a sampled physician or Related Entity, the IRO shall consider such a situation to be an exception (rather than a Material Error) and the IRO shall report the situation as such. Similarly, the IRO shall note as exceptions any Control Documents for which non-material information or data is omitted.

If the IRO identifies any Material Errors, the IRO shall conduct such Additional Review of the underlying Payment associated with the erroneous Control Documents as may be necessary to determine the root cause of the Material Errors. For example, the IRO may need to review additional documentation and/or conduct interviews with appropriate personnel to identify the root cause of the Material Error(s) discovered.

E. IRO Review of Research and Publications Practices and Authorship-Related Activities

The IRO shall conduct a review and assessment of Amgen's Research and Publications Practices and Authorship-Related activities as described in Sections III.B.3.s-t of the CIA.

Review of Research Activities: Amgen shall provide the IRO with a list of all Research activities (as defined in Section III.B.3.s of the CIA) that occurred during the Reporting Period. The IRO shall select a sample of 20 such activities, which sample shall include a review of each type of Research (*i.e.*, post-marketing clinical trials, other post-marketing studies, and post-marketing investigator-sponsored studies (ISSs)). The IRO shall review samples of each type of Research in proportion to the relative number of each type of Research that occurred during the reporting period. Amgen shall provide the IRO with documents relating to the Research activities sufficient for the IRO to conduct the reviews outlined below.

For each sampled Research activity, the IRO will review whether: (i) the activity was approved consistent with Amgen's standards, policies, procedures and processes regarding sponsorship or support of Research, including obtaining required approval for the Research and ensuring that Amgen funded the Research in order to address a legitimate scientific question or need; (ii) there is an executed written agreement with the Researcher that meets the requirements of Amgen's standards, policies and procedures and, among other things, requires the Researcher to disclose in any publication of Research, Amgen's support and any financial interest the researcher may have in Amgen; and (iii) Amgen's commercial personnel did not participate in the approval, design, conduct, or publication of the Research activity except as permitted under the limited exceptions in Amgen's policies and procedures.

In addition, if Amgen prematurely discontinues any clinical study for a Government Reimbursed Product during a Reporting Period, Amgen shall provide the IRO with copies of notifications that Amgen provided to the relevant institutional review board, ethics committee, and investigators about the discontinuation of the study. The IRO shall

review the notifications to determine whether Amgen notified the applicable entities and investigators in accordance with Amgen standards, policies, procedures, and processes.

Review of Publication Activities:

Amgen shall provide the IRO with a list of Publication activities (as defined in Section III.K.2.b of the CIA) that resulted in publication of data from Amgen-Sponsored Research published during the Reporting Period. The list will be broken down into two categories: (i) Amgen-Sponsored post-marketing clinical trials, and (ii) other Amgen-Sponsored post-marketing studies (e.g., observational studies, health outcomes research studies.) The IRO shall select a sample from each category for review, in proportion to the relative numbers in each category (collectively, “Reviewed Publication Activities”). The IRO shall review a total of 25 Reviewed Publication Activities. Amgen shall provide the IRO with copies of the publications and documents and information relating to each of the Reviewed Publication Activities sufficient for the IRO to conduct the reviews outlined below.

The IRO will assess each of the Reviewed Publication Activities to test whether the Reviewed Publication Activity was conducted in a manner consistent with Amgen’s standards, policies, procedures and processes, including those that require: i) registration and reporting of trial results from applicable Amgen-Sponsored clinical trials on the NIH sponsored website in compliance with Amgen’s policies and procedures; ii) publication (or attempted publication) of the results of Amgen-Sponsored Research studies in peer-reviewed journals within specified periods of times; and iii) compliance with Amgen’s policies and procedures regarding publications (including standards relating to appropriateness, accuracy, balance, and acknowledgement of Amgen’s role as the funding source for the Research).

Review of Authorship-Related Activities:

For each of the Reviewed Publication Activities, the IRO shall also assess the activity to test whether the activity was conducted in a manner consistent with Amgen’s standards, policies, procedures and processes relating to authorship, including those that require: i) authors of journal articles about Amgen-Sponsored Research to adhere to ICMJE authorship requirements; ii) authors of articles on Amgen-Sponsored Research to disclose any Amgen financial support for the study and any financial relationship with Amgen; and iii) authors of a publication about Amgen-Sponsored Research to make substantial contributions to the study and give final approval to the version of the publication ultimately published.

F. IRO Review of Additional Items

As set forth in Section III.E.1.b of the CIA, the OIG at its discretion may identify up to three additional items for the IRO to review (hereafter “Additional Items”). No later than 150 days prior to the end of the applicable Reporting Period, the 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 and/or Amgen shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG. The IRO shall include information about its review of each Additional Item in the Transactions Review Report (including a description of the review conducted for each Additional Item; the IRO’s findings based on its review for each Additional Item; and the IRO’s recommendations for any changes in Amgen’s systems, processes, policies, and procedures based on its review of each Additional Item).

Amgen may propose to the OIG that its Healthcare Compliance Internal Audits and Healthcare Compliance Monitoring activities be substituted, subject to the Verification Review requirements set forth below, for one or more of the Additional Items that would otherwise be reviewed by the IRO for the applicable Reporting Period. The OIG retains sole discretion over whether, and in what manner, to allow Amgen’s internal audit and monitoring work to be substituted for a portion of the Additional Items review conducted by the IRO.

In making its decision, the OIG agrees to consider, among other factors, the nature and scope of Amgen’s planned internal audit and monitoring work, the results of the Transactions Review(s) during prior Reporting Period(s), and Amgen’s demonstrated audit and monitoring capabilities to perform the proposed Additional Items review work internally. If the OIG denies Amgen’s request to permit its internal audit and monitoring work to be substituted for a portion of the IRO’s review of Additional Items in a given Reporting Period, Amgen shall engage the IRO to perform the Review as outlined in this Section III.F.

If the OIG agrees to permit certain of Amgen’s internal audit and monitoring work for a given Reporting Period to be substituted for a portion of Additional Items review, such internal work shall be subject to verification by the IRO (Verification Review). In such an instance, the OIG would provide additional details about the scope of the Verification Review to be conducted by the IRO. However, for purposes of any Verification Review, the IRO shall review at least 20% of the sampling units reviewed by Amgen in its internal audit and monitoring work.

G. Transactions Review Report

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

- 1) General Elements to Be Included in Report
 - a) Review Objectives: A clear statement of the objectives intended to be achieved by each part of the review;
 - b) Review Protocol: A detailed narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for each sample reviewed; and
 - c) Sources of Data: A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Transactions Review.
- 2) Results to be Included in Report

Consistent with the scope of items reviewed by the IRO for the applicable Reporting Period, the following results shall be included in each Transaction Review Report:

(Relating to the Review of Inquiries)

- a) in connection with the review of Inquiries, a description of each type of sample unit reviewed, including the number of each type of sample units reviewed (e.g., the number of Inquiries) and an identification of the types of documents and information reviewed for the Inquiries;
- b) for each Inquiry sample unit, the IRO shall summarize the information about the Inquiry contained in the Inquiries Database;
- c) for each Inquiry sample unit, findings and supporting rationale as to whether: (i) each item of information listed in Section III.A.1 is reflected in the Inquiries Database; and (ii) for each Inquiry for which an Off-Label Review was conducted, a description of the basis for suspecting that improper off-label promotion may have

occurred; the steps undertaken as part of the Off-Label Review; the findings of the Chief Compliance Officer or designee as a result of the Off-Label Review; and any follow-up actions taken by Amgen as a result of the findings;

- d) the findings and supporting rationale regarding any weaknesses in Amgen's systems, processes, policies, procedures, and practices relating to the Inquiries and the Inquiries Database, if any;
- e) recommendations for improvement in Amgen's systems, processes, policies, procedures, and practices relating to the Inquiries and the Inquiries Database, if any;

(Relating to the Call Plan Reviews)

- f) a list of the Government Reimbursed Products promoted by Amgen during the Reporting Period and a summary of the FDA-approved uses for such products;
- g) for each Government Reimbursed Product promoted during the Reporting Period: (i) a description of the criteria used by Amgen in developing or reviewing the call plans and for including or excluding specified types of HCPs or HCIs from the call plans; (ii) a description of the review conducted by Amgen of the call plans and an indication of whether Amgen reviewed the call plans as required by Section III.B.3.i of the CIA; (iii) a description of all instances for each call plan in which it appears that the HCPs and HCIs included on the call plan are inconsistent with Amgen's criteria relating to the call plan and/or Amgen's Policies and Procedures; and (iv) a description of all instances in which it appears that Amgen failed to follow its criteria or Policies and Procedures relating to call plans or the review of the call plans;
- h) the findings and supporting rationale regarding any weaknesses in Amgen's systems, processes, policies, procedures, and practices relating to Amgen's call plans or the review of the call plans, if any;
- i) 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 call plans or the review of the call plans;

(Relating to the Sampling Event Reviews)

- j) for each Government Reimbursed Product distributed during the Reporting Period: (i) a description of Sample Distribution Policies and Procedures (including whether sales representatives may provide samples for the product and, if so, to HCPs or HCIs of which medical specialty or type of clinical practice sales representatives may provide samples); (ii) a detailed description of any instances in which it appears that the medical specialty or clinical practice of the HCPs or HCIs that received a sample during a Sampling Event was not consistent with the uses of the product approved by the FDA. This description shall include a description of the process followed by Amgen in determining that it was appropriate to provide a sample to such HCP or HCI and the basis for such determination; and (iii) a detailed description of any instances in which it appears that Amgen failed to follow its Sample Distribution Policies and Procedures for the Government Reimbursed Product(s) provided during the Sampling Event;
- k) the findings and supporting rationale regarding any weaknesses in Amgen's systems, processes, policies, procedures, and practices relating to Amgen's distribution of samples of Government Reimbursed Products, if any;
- l) 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 the distribution of samples;

(Relating to the Physician Payment Listing Reviews)

- m) a description of the entries in the Physician Payment Listing for each physician or Related Entity sampled and a description of Control Documents reviewed in connection with each selected physician or Related Entity;
- n) for each sampled physician or Related Entity, findings and supporting rationale as to whether: (i) all required Control

Documents exist; (ii) each Control Document was completed in accordance with all of the requirements set forth in the applicable Amgen policy; (iii) the aggregate value of the Payment(s) as reflected in the Listing for the sampled physician or entity is consistent with the value of the Payment(s) reflected in the Control Documents; (iv) each Control Document reflects that Amgen's policies were followed in connection with the underlying activity reflected in the document (e.g., all required approvals were obtained); and (v) disciplinary action was undertaken in those instances in which Amgen policies were not followed;

- o) for each sampled physician or Related Entity unit reviewed, an identification and description of all exceptions discovered. The report shall also describe those instances in which corrective action was initiated prior to the selection of the sampled physicians or Related Entities, including a description of the circumstances requiring corrective action and the nature of the corrective action;
- p) if any Material Errors are discovered in any sample unit reviewed, a description of the error, the Additional Review procedures performed and a statement of findings as to the root cause(s) of the Material Error;

(Relating to the Review of Research and Publication Practices and Authorship-Related Activities)

- q) a description of each sampled Research activity reviewed, including an identification of the types of documents and information reviewed in connection with each sampled Research activity;
- r) for each discontinued clinical study reviewed by the IRO (if any), a description of the discontinued study; and an assessment of whether Amgen notified the applicable institutions and investigators about the discontinuation in accordance with Amgen's standards, processes, and practices;
- s) an assessment of whether, for each sampled Research activity: (i) the activity was approved consistent with Amgen's standards, policies, procedures and processes regarding sponsorship or support of Research; (ii) there is an executed written agreement with the Researcher that meets the requirements of Amgen's standards,

policies and procedures; and (iii) Amgen's commercial personnel did not participate in the design, conduct, or publication of the Research activity except as permitted under Amgen's policies and procedures. If a sampled Research activity failed to meet Amgen standards, policies, procedures and processes, an explanation of the deficiency;

- t) a description of each Reviewed Publication Activity assessed by the IRO, including an identification of the types of documents and information reviewed in connection with each Reviewed Publication Activity;
- u) an assessment of whether for each Reviewed Publication Activity: i) authors of journal articles about Amgen-Sponsored Research adhered to ICMJE requirements; ii) authors of articles on Amgen-Sponsored Research disclosed any Amgen financial support for the study and any financial relationship with Amgen; and iii) authors of a publication about Amgen-Sponsored Research made substantial contributions to the study and gave final approval to the version of the publication ultimately published;
- v) if any Reviewed Publication Activity or Authorship-Related activity failed to meet Amgen standards, policies, procedures and processes, an explanation of the deficiency;
- w) the IRO's findings and supporting rationale regarding any weaknesses or deficiencies in Amgen's systems, processes, policies, procedures, and practices relating to Amgen's Research and Publications Practices and Authorship-Related activities, if any;
- x) 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 Transactions Review with respect to Research and Publications Practices and Authorship-Related activities;

(Relating to the Review of Additional Items)

- y) for each Additional Item reviewed, a description of the review conducted;

- z) for each Additional Item reviewed, the IRO's findings based on its review and its supporting rationale for such findings;
- aa) 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, if any; and
- bb) 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.

Appendix C to CIA for Amgen Inc. IRO Reviews of Amgen's Ra3 Process

I. General Description of the Ra3 Process

Amgen represents that, prior to the Effective Date, it initiated a pilot project to implement Ra3, a process to identify, evaluate, and mitigate health care compliance risk, including information associated with safety, advertising, marketing and promotion of Government Reimbursed Products. In addition to its ongoing Compliance Program activities, beginning in 2013, Amgen will implement Ra3 across all Amgen Government Reimbursed Products. Amgen represents that the outcomes of the Ra3 will be coordinated with outcomes of the Activity-Based Risk Assessment that Amgen conducts on an annual basis to assess risk associated with activities governed by Amgen's Policies and Procedures in order to develop annual Audit Plans and annual Monitoring Plans. The overall Ra3 process is overseen by a cross-functional steering committee including representatives from Amgen's Compliance organization, Regulatory, and business stakeholders (Steering Committee).

As described in more detail below, the Ra3 includes a risk identification and assessment phase (Assess), an alignment phase (Align), and a risk mitigation phase (Address).

A. Assess

As an initial step in the Ra3 process, designated individuals within the Compliance organization coordinate the collection of fact-based information, including information about each product, soliciting feedback from other groups within Amgen as appropriate, and record product information using standardized questionnaires (Product Profiles). Completed Product Profiles are used to inform the completion of risk assessment documents (Product Risk Matrices) that calibrate risk according to instructions in the Risk Matrices and using approved risk rating criteria. A separate Product Risk Matrix is completed for each Government Reimbursed Product. The Compliance organization reviews the Product Risk Matrix for each Government Reimbursed Product and identifies product-specific areas and activities for risk mitigation.

B. Align

Using completed Product Risk Matrices, the Compliance organization collaborates with business stakeholders and oversees the development of mitigation plans (Risk Mitigation Plans) to address the identified risks. Risk Mitigation Plans are coordinated with the annual Monitoring Plan and with the annual Audit Plan.

The Compliance organization also collaborates with business stakeholders and oversees the completion of a summary of the risk assessment for each Government Reimbursed Product (Summary Report), which includes at least the following components: (i) an identification and explanation of risk areas identified for mitigation; (ii) the risk mitigation activity or activities to address each risk area, including sufficient detail regarding scope and timing of mitigation activities; and (iii) a responsible individual for each mitigation activity. The Summary Reports are presented to the Steering Committee for review and, thereafter, to Amgen's Chief Compliance Officer (CCO) for approval.

C. Address

The responsible individuals for risk mitigation activities implement the Risk Mitigation Plans and ensure that risk mitigation activities are performed, tracked, and documented. Ra3 mitigation activities may include, among others, HCC Monitoring activities, HCC Internal Audit activities, training or job aids, written guidance, activities by designated Compliance personnel within Amgen business units (e.g., Compliance Leads), additional regulatory oversight, and/or additional business controls such as Compliance program approvals or certifications. Progress on Risk Mitigation Plans is reported on a regular basis to the Steering Committee and the CCO.

II. IRO Reviews of Ra3, General Description

A. As specified more fully below, Amgen shall retain an IRO to assist Amgen in assessing and evaluating its systems, processes, policies, procedures, and practices relating to the Ra3 program (Ra3 Review). The Ra3 Review 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 IRO to perform both components of the Ra3 Review provided that the entity has the necessary expertise and capabilities to perform both.

B. If there are no material changes in Amgen's systems, processes, policies, and procedures relating to Ra3, the IRO shall perform the Systems Review for the second and fourth Reporting Periods. If Amgen materially changes its systems, processes, policies, and procedures relating to Ra3, the IRO shall perform a Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Systems Review for the second and fourth Reporting Periods. The additional Systems Review(s) shall consist of: (i) an identification of the material changes; (ii) an assessment of whether other systems, processes, policies, and procedures previously reported did not materially change; and (iii) a review of the systems, processes, policies, and procedures that materially changed. The IRO shall conduct the Transactions Review for each Reporting Period.

III. Systems Reviews

A. Each Systems Review shall consist of the following:

1. A review of the standards and processes by which Amgen develops and evaluates Product Risk Matrices, the Summary Reports, and the Risk Mitigation Plans, including: (i) the sources of information (e.g., the individual personnel, departments or functional areas, and/or any systems involved) used to compile the Product Risk Matrices, Summary Reports, and Risk Mitigation Plans; (ii) the types of underlying data and information that are considered or evaluated during the development of the Product Risk Matrices, Summary Reports, and Risk Mitigation Plans; and (iii) the timing for development of the Product Risk Matrices, Summary Reports, and Risk Mitigation Plans (including modifications to the Product Risk Matrices, Summary Reports, and Risk Mitigation Plans in the event of significant new developments);
2. An assessment of whether, in developing the Product Risk Matrices, Summary Reports, and Risk Mitigation Plans: (i) additional or different sources of information should be utilized; (ii) additional or different types of data or information should be utilized; and (iii) additional or different timing cycles should be utilized;
3. A review of the experience and background of Amgen Compliance organization personnel responsible for the development of the Product Risk Matrices, Summary Reports, and Risk Mitigation Plans and an assessment of the completeness and appropriateness of the training, policies, procedures, standard operating procedures, and guidance each such individual receives regarding the development of the Product Risk Matrices, Summary Reports, and Risk Mitigation Plans;
4. An assessment of whether the risk monitoring and audit activities included in Risk Mitigation Plans are designed to: (i) adequately monitor all relevant identified risks; (ii) identify any actual problems that have occurred in connection with the identified potential risk; and/or (iii) prevent reoccurrence of any problems associated with an identified risk;
5. An assessment of whether risk monitoring and audit activities that may be included in Risk Mitigation Plans should be: (i) enhanced, revised, or refined; (ii) changed to include additional or different

mitigation/monitoring options to be considered based upon specific identified risks; and/or (iii) tracked and reviewed more frequently than prescribed by current policies to ensure that the options address all relevant risks for the specific products reviewed;

6. An assessment of whether risk mitigation action items (and options for such activities) included in Risk Mitigation Plans are designed to: (i) adequately address all relevant identified risks; (ii) identify any actual problems that have occurred in connection with the identified potential risk; and/or (iii) prevent reoccurrence of any problems associated with an identified risk;
7. An assessment of whether risk mitigation action items that may be included in Risk Mitigation Plans should be: (i) enhanced, revised, or refined; (ii) changed to include additional or different mitigation options to be considered based upon specific identified risks; and/or (iii) tracked and reviewed more frequently than prescribed by current policies to ensure that the options address all relevant risks for the specific products reviewed; and
8. A review of the systems, policies, procedures, and processes by which Amgen tracks and manages Risk Mitigation Plan activities and an assessment of whether the systems, policies, procedures and processes ensure that the Risk Mitigation Plans are appropriately tracked and implemented (including by identifying individuals responsible for the follow-up or action items).

B. The IRO shall prepare a report based upon each Systems Review performed (Systems Review Report). The Systems Review Report will include the IRO's findings, recommendations, observations, and comments on items 1-8 above and, to the extent not otherwise addressed, an assessment of the following: (i) whether the Product Risk Matrices, Summary Reports, and Risk Mitigation Plans identify and prioritize relevant risks; (ii) whether the risk monitoring and audit activities and the risk mitigation action items identified in the Risk Mitigation Plans address identified risks; (iii) whether sufficient controls exist to ensure that all monitoring and auditing activities and risk mitigation action items are tracked in accordance with the Risk Mitigation Plans; (iv) whether the options for risk monitoring and audit activities and the risk mitigation action items identified in the Risk Mitigation Plans address and potentially mitigate identified risks; and (v) whether sufficient controls exist to ensure that all agreed-upon risk monitoring and audit activities and risk mitigation action items are completed in accordance with the Risk Mitigation Plans.

IV. Transactions Review

A. At least thirty (30) days prior to the end of each Reporting Period, Amgen shall submit to OIG a list of all Amgen Government Reimbursed Products and shall notify OIG about the risks identified for each Government Reimbursed Product and the types of risk mitigation activities undertaken in connection with each Government Reimbursed Product. Prior to the end of the applicable Reporting Period, OIG shall select up to three Amgen Government Reimbursed Products (each a “Selected Product” and together the “Selected Products”) to be reviewed in connection with the Transactions Review.

B. For each Reporting Period and for each Selected Product, the IRO shall conduct a review of: (i) the applicable Product Profile, Product Risk Matrix, Summary Report, and Risk Mitigation Plans; (ii) documents and materials related to the development of the Risk Mitigation Plans for the Selected Product; and (iii) documents and materials relating to the implementation of the Risk Mitigation Plans applicable to the Selected Product. The IRO shall also interview the Amgen personnel responsible for the development of the Product Risk Matrix and Summary Report, and the Amgen Compliance organization personnel responsible for overseeing the development and implementation of the risk monitoring and auditing activities and risk mitigation action items specified in the Risk Mitigation Plans.

The objective of the IRO shall be to: (i) understand the standards and processes followed by Amgen in developing the applicable Risk Mitigation Plans for each Selected Product; (ii) determine whether, based on the information contained in the Product Risk Matrix and Summary Report for the Selected Product, appropriate Risk Mitigation Plans (including the included risk monitoring and auditing activities and risk mitigation action items) were developed for the Selected Product; and (iii) assess Amgen’s tracking and implementation of Risk Mitigation Plans applicable to the Selected Product.

C. The IRO will prepare a report based on each Transactions Review performed (Transactions Review Report). The Transactions Review Report shall include the following:

1. an identification of the Selected Products and a description of the documents and information reviewed in connection with each Selected Product;
2. for each Selected Product, a description of: (i) the standards and process followed in developing the applicable Product Risk Matrix; (ii) the standards and process used in developing the applicable Summary

Report and Risk Mitigation Plans; and (iii) the identified risk areas associated with the Selected Product;

3. for each Selected Product, an assessment of whether, based on the information contained in the applicable Product Risk Matrix and Summary Report, appropriate risk monitoring and auditing activities and risk mitigation activities were developed for the Selected Product;
4. for each Selected Product, a description of the expertise and backgrounds of Amgen personnel responsible for the development of the applicable Product Risk Matrix, Summary Reports, and Risk Mitigation Plans;
5. for each Selected Product, a description of the following items set forth in the Risk Mitigation Plan: (i) identification and explanation of the risk areas identified for mitigation; (ii) identification and explanation of the risk-based monitoring and auditing activities; (iii) identification and explanation of other risk mitigation activities; (iv) responsible individual(s); (v) expected date(s) of completion for each risk mitigation activity; and (vi) if the Risk Mitigation Plan did not specify each of the items set forth above, a description of any deficiencies;
6. for each Selected Product, a description of whether risk monitoring and auditing activities specified in the Risk Mitigation Plan were implemented and tracked in accordance with the Risk Mitigation Plan and Amgen's policies and procedures, and a description of any deficiencies;
7. for each Selected Product, a description of whether risk mitigation activities specified in the Risk Mitigation Plan were implemented and tracked in accordance with the Risk Mitigation Plan and Amgen's policies and procedures, and a description of any deficiencies;
8. for each Selected Product a description of: (i) any recommendations made by the IRO regarding any risk-based monitoring and auditing activities or other risk mitigation activities included in the Risk Mitigation Plan; (ii) whether, and in what manner, Amgen implemented the recommendations from the IRO; and (iii) if Amgen did not implement the IRO recommendations, a description of the rationale for Amgen's decision not to implement the recommendations; and

9. the IRO's findings and supporting rationale regarding any weaknesses or deficiencies in Amgen's systems, processes, policies, procedures, and practices relating to the Ra3 process, if any; and 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 the Ra3 process.