

1. Scope

This Policy applies to all Amgen staff members, consultants, contract workers, secondees and temporary staff worldwide who engage in Advocacy Relations Activities (“Covered Persons”). Patient Assistance Programs are outside the scope of this SOP and are instead governed by other regional or country-level SOPs, as applicable. Although consultants, contract workers, secondees and temporary staff are required to follow this Policy when conducting business on behalf of Amgen, they are not Amgen employees and nothing in this Policy should be construed to the contrary. For the avoidance of doubt, the activities performed by any third-party service provider engaged by a Covered Person to perform Advocacy Relations Activities on Amgen’s behalf shall comply with this Policy.

This Policy should be read in conjunction with all applicable policies and SOPs relating to engagements with members of the healthcare community (including Government Officials), and if applicable, any local SOPs that relate specifically to Sponsorships or Donations. In the case of any conflict between these policies, the most restrictive policy shall control.

2. Policy

This Policy sets forth the general guidelines applicable to Advocacy Relations Activities throughout the world.

Definitions:

Term	Definition
Advocacy Relations Activity	The practice of interacting with Third-Party Advocacy Organizations with the aim of establishing common, mutually beneficial goals intended to ensure that patients can gain access to care and/or improve their health outcomes. For the avoidance of doubt, the marketing or promotion of Amgen Products is not considered an Advocacy Relations Activity for purposes of this Policy.
Donation	Contribution, grant, or payment in cash or in kind, made by Amgen to a not-for-profit and/or tax-exempt organization without expectation of something in return other than customary donor recognition of incidental value.
Government Official	Any officer or employee of a government or any department, agency, or instrumentality thereof (e.g., government owned or supported hospitals), or of a public international organization (e.g., World Health Organization, United Nations, etc.) or any person acting in an official capacity for or on behalf of any such government or department agency or for or on behalf of any such public international organization. This includes any political party or candidate for political office and their representatives.

Term	Definition
Patient Assistance Program (PAP)	A nonprofit foundation that provides product or financial support to uninsured or underinsured patients with limited financial resources. These foundations are strictly for the benefit of patients who qualify for each program. PAPs include: (i) The Safety Net Foundation; and (ii) any independent third-party co-payment assistance foundations which assist qualifying patients with co-payments and/or other cost-sharing obligations under their public and private insurance plans and programs.
Responsible Amgen Employee (RAE)	The Amgen staff member designated to have primary responsibility for the activity with a Third-Party Advocacy Organization and for compliance with all applicable Amgen policies and procedures pertaining to engagements with Third Party Advocacy Organizations (e.g., SOPs on Sponsorships or Donations).
Sponsorships	A funding opportunity offered by a for-profit or not-for-profit entity that provides a Tangible Benefit to Amgen.
Tangible Benefit	A benefit to the business interests of Amgen or its products/brands that is more than tenuous or incidental. This could include a promotional or branded public relations opportunity for Amgen. General recognition of Amgen's support or incidental goodwill alone is not sufficient to be a Tangible Benefit. Examples of Tangible Benefits: (1) Marketing or advertising of a brand or distribution of brand-related materials; (2) Marketing or advertisement of Amgen's general business interests such as recruitment, disease state/awareness; and (3) Distribution of Amgen scientific materials at research & development booths at scientific congresses. Examples of Incidental (not Tangible) Benefits: (1) Incidental acknowledgement of Amgen support with placement of an Amgen logo at an event; (2) Honorable mentions and announcement of thanks, written or verbal; and (3) unused table(s) and/or tickets to an event.
Third-Party Advocacy Organizations	Any patient or professional organization that advocates for and advances the interests of patients, health care professionals, or caregivers with respect to one or more therapeutic areas or disease state[s]. Such organizations can be for profit or not-for-profit.

Amgen desires to create long-term relationships with Third-Party Advocacy Organizations that share in its commitment to advocate for, and advance the interests of patients, health care professionals, and caregivers with respect to a therapeutic area or disease state.

In pursuit of those objectives, relationships with Third-Party Advocacy Organizations must comply with the following requirements:

General Principles

All Covered Persons engaged in Advocacy Relations Activities shall respect the independence of the Third-Party Advocacy Organization in terms of its political judgment, policies and activities.

Advocacy Relations Activities should be conducted in a manner that avoids the creation of a conflict of interest.

Engagement

All Advocacy Relations Activities must have oversight and the appropriate involvement by the Amgen staff member designated as the RAE.

Engagements with Third-Party Advocacy Organizations that involve disclosable transfers of value will be reported and disclosed in accordance with applicable laws, regulations, industry standards and guidelines (e.g., Pharmaceutical Research and Manufacturers of America Code on Interactions with Health Care Professionals (PhRMA Code) and the European Federation of Pharmaceutical Industries and Associations (EFPIA) Disclosure Code) governing Amgen's conduct, and company policies.

If required by an applicable SOP, such as the SOP governing Sponsorships, the objectives and scope of any engagement shall be transparent and documented in a written agreement. Financial and nonfinancial support provided by Amgen shall always be recorded in the applicable system of record and clearly acknowledged on related Third-Party Advocacy Organization materials. To the extent required by local law or regulation, the nature of support provided shall be made publicly available. Payments may only be made consistent with the terms of such written agreement between Amgen and the Third-Party Advocacy Organization.

Any funding provided to a Third-Party Advocacy Organization must be processed with appropriate involvement and oversight by the RAE and in accordance with the applicable Amgen SOP(s).

The venue and circumstance of any meeting with a Third-Party Advocacy Organization must be conducive to the purpose of the meeting. Resorts, casinos and other similar locations are not appropriate venues. Amgen will not provide support that goes toward, nor helps the Third-Party Advocacy Organization provide recreational or entertainment events in conjunction with the meeting.

Covered Persons engaged in Advocacy Relations Activities are strictly prohibited from engaging in off-label promotion, including but not limited to:

- soliciting or prompting inquiries about Amgen products that require the provision of off-label information;

- promoting a product prior to grant of its marketing authorization by the relevant regulatory authorities; or
- promoting a product outside its licensed indications.

Moreover, Scientific Exchange (i.e., the bona fide exchange of medical and scientific information or data (a) through scientific dialogue that is conducted in non-promotional contexts or (b) in response to an unsolicited question or request for information on unapproved uses of an Amgen product) must be consistent with the applicable provisions of other regional policies and SOPs governing Scientific Exchange.

Amgen may request the correction of any factual inaccuracies in any Third-Party Advocacy Organization produced materials.

As part of an Advocacy Relations Activity, Amgen shall not request a Third-Party Advocacy Organization to undertake the marketing of any Amgen product.

All arrangements with Third-Party Advocacy Organizations shall comply with applicable anti-bribery and anti-corruption laws and regulations. Covered Persons must not offer, promise or give – directly or indirectly – any payment (whether cash or non-cash) or any other advantage or thing of value (e.g. including an offer of employment) to any Government Official or any other party as an improper inducement for such person to take any action, or refrain from taking any action, that benefits Amgen businesses. Arrangements with Third-Party Advocacy Organizations shall never be conditioned on any, or in any way linked, directly or indirectly to an agreement to provide an improper business advantage to Amgen, including to approve, use, purchase, prescribe, recommend or refer Amgen products, or be used to reward past or future business. Covered Persons must also not accept – directly or indirectly -- any financial or other advantage from any Government Official or any other person for performing, agreeing to perform, refraining or agreeing to refrain from taking any improper action that benefits Amgen businesses.

3. Additional Information

Every Covered Person is required to follow and employ reasonable steps in preventing violations of (1) the Amgen Code of Conduct, (2) laws and regulations applicable in the relevant jurisdictions (including those requiring the participants in Advocacy Relations Activities to be registered), and (3) Amgen policies and other governance documents applicable to him or her. Covered Persons are also required to report any conduct that may violate such laws, regulations, the Amgen Code of Conduct, and Amgen policies and other governance documents. Covered Persons must refer to the governance documents in effect for the geographic area in which they work, or for which they are responsible, or request guidance from their manager or compliance representative with responsibility for that geographic area. The term “governance documents” in this Policy means Amgen’s written policies, standards, procedures, business practices, and manuals.

Amgen expects its managers to (1) be familiar with (or take appropriate steps to become familiar with) applicable laws and regulations, (2) know the Amgen Code of Conduct, and Amgen policies and other governance documents applicable to the activities they manage or supervise, (3) ensure their direct reports have appropriate training on compliance requirements to perform their job functions, and (4) supervise their direct reports with respect to compliance requirements and activities.

If Amgen determines that any Covered Person has violated this Policy, related standards, procedures or controls, applicable laws or regulations, or any governance documents, appropriate disciplinary measures will be taken, up to and including immediate termination of employment, to the extent permitted by applicable laws. The following is a non-exhaustive list of possible disciplinary measures to which Covered Persons may be subject (subject to applicable law): oral or written warning, suspension, removal of job duties/responsibilities, demotion, reduction in compensation, and/or termination of employment.

Subject to applicable laws, Amgen reserves the right to take whatever disciplinary or other measure(s) it determines in its sole discretion to be appropriate in any particular situation, including disclosure of wrongdoing to governmental authorities. Nothing in this Policy changes the at-will nature of employment at Amgen, its affiliates or subsidiaries, where applicable. Amgen may also terminate the services or work engagement of non-employee Covered Persons for violation of this Policy.