Amgen BlueBook

U.S. Healthcare Compliance Requirements

AMGEN®

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1. PURPOSE AND SCOPE

Preserving Amgen's reputation and integrity requires all Amgen Staff members, temporary and other external workers (e.g., Staff augmentation, project-based workers, and outsourced service providers), secondees, consultants and vendors to follow the principles and requirements set forth in this document.

Although temporary and other external workers, secondees, and consultants are required to follow the contents of this document when conducting business on behalf of Amgen, they are not Amgen employees and nothing in this document should be construed to the contrary.

Certain capitalized terms are defined in the Healthcare Compliance Glossary.

2. U.S. HEALTHCARE COMPLIANCE

Expectations of Amgen Staff, Contractors, and Vendors

As a participant in the U.S. Healthcare industry, Amgen is required to follow complex legal, regulatory, and other industry requirements. Please refer to relevant training materials that provide background on these legal requirements. As a general matter, these laws are all designed to mitigate in whole or in part:

- **Corruption of Choice**: Avoiding prescription decision-making due to payments made to influence the choice.
- **Patient Harm**: Avoiding prescribing of Products or one Product over another that may not be the most beneficial for a Patient due to improper promotion or improper payments to influence decisions.
- **Overutilization of Products**: Avoiding unnecessary use of prescription drugs that may be influenced by improper promotion or improper payments.
- **Harm to either Federal, State or Private Payor Healthcare Programs**: Avoiding unnecessary costs to the healthcare programs due to improper promotion or improper payments.

The principles and requirements set forth in this document are designed to ensure that relevant Amgen Staff and contractors who engage in activities on behalf of Amgen understand the basis for the policies that govern our daily activities.

It is the obligation of every Amgen Staff member, contractor, vendor, or other person working on behalf of Amgen to fully comply with each of these requirements. To help Amgen Staff meet these requirements, Amgen's Worldwide Compliance & Business Ethics office has developed a robust program based on the seven elements of effective compliance programs as described in the Office of Inspector General (OIG) Compliance Program Guidance. These seven elements are designed to help ensure that Amgen and its employees, contractors and vendors engage in activities consistent with our policies and to detect instances where Amgen policies may not necessarily have been followed. These elements are:

1. Designation of a compliance officer and compliance committee
2. Development of compliance policies and procedures, including standards of conduct
3. Developing open lines of communication
4. Appropriate training and education
5. Internal monitoring and auditing
6. Response to detected deficiencies
7. Enforcement of disciplinary standards

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Amgen Compliance Leadership

The Amgen compliance organization is led by a Chief Compliance Officer (CCO) who reports directly to the Chief Executive Officer (CEO) and the Board of Directors. In this capacity, the CCO is responsible for ensuring Amgen has implemented requirements to support Amgen Staff in fulfilling their responsibility to operate with integrity and ethics. The CCO is responsible for providing periodic reports to the CEO and Board of Directors regarding the state of Amgen compliance obligations and leads the Compliance Council that consists of a selection of cross-functional leaders at Amgen who meet regularly, and address identified compliance risks.

Written Policies and Procedures

Amgen has established a three-tiered approach to capturing Amgen's expectations regarding requirements. First, Global Corporate Compliance Policies (GCCPs), which can be accessed on the WC&BE function page on MyAmgen, set out basic expectations and principles for how Amgen will conduct business in a complex healthcare ecosystem. Second, the U.S. Healthcare Compliance requirements (this document), will provide you with the "must do's" for your activity. The U.S. Healthcare Compliance requirements are collectively referred to as the "Amgen BlueBook" and contain compliance requirements that are designed to mitigate risk to Amgen. Third, the Standard Operating Procedures (SOPs) are produced at a function or organization level and inform on "how to do" your activity, or in other words, the process steps. The SOPs contain the procedures or process steps you need to follow in order to compliantly engage in a business-related activity.

The U.S. Healthcare Compliance Requirements in this document are contained across six chapters, each focused on similar activities or related concepts:

1. Introduction to U.S. Healthcare Compliance
2. Interactions with Members of the Healthcare Community
3. Funding
4. Internal Business Strategy and Planning
5. Interactions Related to Government Officials, Employees, and Political Activities
6. Patient Interactions, Programs, and Business Compliance Requirements

All written policies, requirements, and procedures are developed under the direction and supervision of the CCO and are communicated to affected Staff and suppliers. Amgen Staff and representatives are required to follow Amgen policies, requirements, and procedures.

Open Communication

You are required to promptly report all known or suspected violations of law, the Code of Conduct, or company policies as specified in Amgen's Compliance Reporting and Non-Retaliation Policy. Amgen policy permits reporting on a confidential and anonymous basis. If someone asks you or pressures you to do something that might be a violation, you should report that as well. Also, report any action you interpret as retaliation against anyone for making a report. Amgen maintains a strict Non-retaliation Policy, so concerns that are raised in good faith can be reported without fear of retribution or reprisal. Amgen's Non-retaliation Policy strictly prohibits intimidation or retaliation against Staff members who report a compliance concern in good faith or participate in good faith in any investigation or other proceeding. Amgen makes available various resources to you should you need to report a suspected violation of Amgen's policies and procedures include the Business Conduct Hotline, Human Resources, Amgen's Ombudsperson, or a member of the Compliance Council.

Amgen's Business Conduct Hotline operates globally 24 hours a day, 7 days a week, 365 days a year. You can contact the Business Conduct Hotline either by telephone at 1-888-376-5574 or via a

secured webform at https://amgenbch.ethicspoint.com. Both options offer anonymous reporting where allowed by local law.

Amgen's Ombudsperson assists Staff with work-related issues, including matters concerning a Staff member's employment, or ethical or legal issues related to the way the company conducts business. To contact the Ombudsperson, dial 8-447-8200 from within Amgen, or 1-805-447-8200 outside of Amgen. The toll-free North America number for Amgen's Ombudsperson is 1-866-511-6787.

Training and Education

All Amgen Staff must be trained in their roles and responsibilities under the Amgen compliance program. Amgen Staff may: (i) be assigned specifically required training based on their role or responsibility, (ii) receive training as part of their regular team meetings and activities, (iii) access on-demand training as needed for engaging in specific activities or tasks, or (iv) request specific training for unfamiliar activities or responsibilities. Amgen Staff are required to follow all aspects of training received.

Responding to Detected Deficiencies

The Amgen compliance investigations organization is responsible for evaluating potential misconduct or incidences of non-compliance by Amgen Staff. As part of this process, the Amgen investigators may conduct interviews, review documents, evaluate internal communications or pursue other tactics that will help identify facts and circumstances. Amgen Staff that are asked to meet with investigators are required to cooperate fully and honestly. Failure to cooperate fully and honestly will subject Amgen Staff to discipline.

Enforcement of Disciplinary Standards

To protect Amgen's integrity, Amgen Staff that fail to comply with Amgen policies, standards, procedures, and requirements will be subject to discipline. This discipline will follow standards established by Amgen Human Resources with input from the Amgen Compliance organization. Such discipline may include additional support for Amgen Staff such as receiving additional training or coaching or may take the form of consequences such as impact to Compensation, documentation in personnel file, or even termination of employment.

Commitment to Ethical Behavior

In addition to any requirements found in Amgen's GCCPs or Amgen Compliance requirements or procedures, Amgen Staff are required to always strive to be ethical in every action taken, show respect at all times to individuals inside and outside of Amgen, follow all applicable laws and regulations, and always protect the integrity and reputation of Amgen. This includes situations where making the ethical choice may run contrary to Amgen's immediate or perceived financial interests. Amgen Staff must always adhere to the following principles:

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In addition to the applicable principles in our Global Corporate Compliance Policies and the processes outlined in Standard Operating Procedures:

- Follow all laws, regulations, and applicable industry guidelines, reporting and disclosure requirements, and local and Country Specific Requirements for conducting Amgen activities.
- Know the guardrails and requirements for all Amgen activities you engage in.
- Do not offer or provide any Agreements, services, or funding to a member of the Healthcare Community to directly or indirectly, influence or encourage the member of the Healthcare Community to purchase, prescribe, refer, sell, arrange for the purchase or sale, reimburse or recommend formulary placement of any Amgen Product or to reward past, present, or future business.
- Follow the appropriate review and approval process for all materials used externally.
- Be truthful, balanced, and scientifically rigorous in materials and discussions.
- Use venues that are appropriate and reasonable when conducting Amgen business.
- Maintain accountability as a Responsible Amgen Employee (RAE) for your Amgen activities, regardless of who conducts them.
- Ensure Amgen activities support legitimate business or scientific needs.
- Engage only with parties qualified to provide their services.
- Pay expenses only to parties with whom we are in an Agreement.
- Document Agreements and applicable consents in writing and fully execute them prior to any services, goods or confidential data being provided.
- Ensure services are provided only during the active term of an executed Agreement.
- Ensure that performance of any compliance requirement activities by a third party are authorized by written approval from Healthcare Compliance and Law.
- Do not provide Gifts or Entertainment to those with whom we conduct business.
- Do not use personal funds to conduct Amgen business.
- Do not engage with any parties on any Exclusion Lists, including those hired by third parties.
- Do not allow inappropriate uninvited guests to participate or attend Amgen activities.
- All compliance requirements apply regardless of whether the interaction is in-person or virtual.

3. ADDITIONAL CONSIDERATIONS

Exceptions to U.S. Healthcare Compliance Requirements

In rare circumstances, Exceptions to U.S. Healthcare Compliance rules may be granted via a corporate approval process. However, approval of Exceptions to our rules does not permit violation of laws, regulations, or our commitment to compliance and ethical behavior. More detailed, procedural information can be found in the SOP: Exceptions from U.S. Healthcare Compliance requirements.

Exclusion List Self-Reporting

You must immediately disclose to the Business Conduct Hotline if you are currently on an Exclusion List or otherwise ineligible to participate in the federal healthcare programs or in federal procurement or non-procurement programs or have been convicted of a criminal offense that would lead to you being on an Exclusion List (i.e., a criminal offense under 42 U.S.C. § 1320-7(a)).

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4. REPORTING AND DISCIPLINE

Questions/Assistance

To report a concern or ask a question, contact the Business Conduct Hotline. Other resources are your Compliance Leads, Human Resources, or your manager.

Reporting

If you are aware of a situation that you believe may be violating any U.S. Healthcare Compliance requirement or may be otherwise unlawful or unethical, contact (888) 376-5574 or via the internet at https://amgenbch.ethicspoint.com at any time of day or night. Reports can be made anonymously, except where limited by law. Amgen maintains a strict Non-retaliation Policy, so concerns that are raised in good faith can be reported without fear of retribution or reprisal.

Discipline

If Amgen determines that any Amgen Staff member has violated these Compliance requirements, applicable laws or regulations, appropriate disciplinary measures will be taken.

The following is a non-exhaustive list of possible disciplinary measures to which Amgen Staff members may be subject: oral or written warning; suspension; removal of job duties/responsibilities or demotion; reduction in Compensation; and termination of employment.

Amgen reserves the right to take whatever disciplinary measures it determines in its sole discretion to be appropriate in any particular situation, including disclosure of the wrongdoing to governmental authorities. Nothing in any U.S. Healthcare Compliance requirement changes the at-will nature of employment at Amgen, its affiliates or subsidiaries, where applicable.

CHAPTER 2: INTERACTIONS WITH MEMBERS OF THE HEALTHCARE COMMUNITY

1. COMPLIANCE REQUIREMENTS

As you engage with Healthcare Professionals (HCPs) and other members of the Healthcare Community, it is important that you adhere to the following Compliance requirements:

1. Any promotional communications regarding Amgen Products must follow approved messages and use only approved materials, even if you have heard a different message from other sources such as a Patient, a Healthcare Provider, or an Amgen leader. All information or discussions must be truthful, balanced, accurate and non-misleading.
2. It is important and necessary to work with cross-functional colleagues when meeting the needs of HCPs or otherwise pursuing Amgen priorities. However, you may not use another function, for example Commercial, Development, or Medical, to accomplish a tactic or objective that is inappropriate for your own function to pursue.
3. All payments to HCPs must be pursuant to legitimate business or scientific needs, be consistent with Fair Market Value, and not intended to induce or influence any activity or decisions.

During our everyday business activities, we may directly or indirectly interact with HCPs in a variety of ways. Some examples of these interactions include, but are not limited to the following:

- Communications with HCPs regarding Amgen Products and relevant disease-states.
- Communications addressing reimbursement or coverage of our Products.
- Interactions to solicit advice or obtain consulting services from HCPs.
- Arrangements with HCPs to speak on Amgen's behalf.

This Chapter provides the minimum Compliance requirements for compliantly executing a variety of such interactions with the Healthcare Community.

CHAPTER 2: INTERACTIONS WITH MEMBERS OF THE HEALTHCARE COMMUNITY

In addition to the applicable principles in our Global Corporate Compliance Policies and the processes outlined in Standard Operating Procedures:

- Follow all laws, regulations, and applicable industry guidelines, reporting and disclosure requirements, and local and Country Specific Requirements for conducting Amgen activities.
- Know the guardrails and requirements for all Amgen activities you engage in.
- Do not offer or provide any Agreements, services, or funding to a member of the Healthcare Community to directly or indirectly, influence or encourage the member of the Healthcare Community to purchase, prescribe, refer, sell, arrange for the purchase or sale, reimburse or recommend formulary placement of any Amgen Product or to reward past, present, or future business.
- Follow the appropriate review and approval process for all materials used externally.
- Be truthful, balanced, and scientifically rigorous in materials and discussions.
- Use venues that are appropriate and reasonable when conducting Amgen business.
- Maintain accountability as a Responsible Amgen Employee (RAE) for your Amgen activities, regardless of who conducts them.
- Ensure Amgen activities support legitimate business or scientific needs.
- Engage only with parties qualified to provide their services.
- Pay expenses only to parties with whom we are in an Agreement.
- Document Agreements and applicable consents in writing and fully execute them prior to any services, goods or confidential data being provided.
- Ensure services are provided only during the active term of an executed Agreement.
- Ensure that performance of any compliance requirement activities by a third party are authorized by written approval from Healthcare Compliance and Law.
- Do not provide Gifts or Entertainment to those with whom we conduct business.
- Do not use personal funds to conduct Amgen business.
- Do not engage with any parties on any Exclusion Lists, including those hired by third parties.
- Do not allow inappropriate uninvited guests to participate or attend Amgen activities.
- All compliance requirements apply regardless of whether the interaction is in-person or virtual.

Capitalized terms are defined in the Healthcare Compliance Glossary.

2. PRODUCT DISCUSSIONS WITH HEALTHCARE PROFESSIONALS (HCPs)

PRODUCT PROMOTION - APPLIES TO COMMERCIAL AND MEDICAL THERAPEUTIC AREA STAFF (THAT ENGAGE EXTERNALLY)

All promotional materials need to be consistent with the U.S. FDA-approved labeling, fair balanced in their presentation of risks and benefits, fully and accurately describe relevant safety information, and must be approved by Material Approval and Compliance (MAC). More detailed, procedural information can be found in the SOP: Promotional and Non-Promotional Material Review.

Promotional Information provided to the Healthcare Community regarding Amgen Products needs to be complete, accurate, and non-misleading. All promotional materials will be consistent with the U.S. FDA-approved labeling, fair balanced in their presentation of risks and benefits, describe safety information fully and accurately, and approved by the appropriate Amgen review process prior to use. Note, even if you internally received background information for educational or informational purposes from your manager or other Amgen colleague, never use these materials or information contained therein externally for promotion unless officially approved for external use by an appropriate Amgen review process. For all proactive promotional calls, follow MAC guidance regarding distribution of the U.S. FDA-approved labeling.

CHAPTER 2: INTERACTIONS WITH MEMBERS OF THE HEALTHCARE COMMUNITY

Off-label Promotion of Amgen's Products is strictly prohibited under all circumstances.

Proactive Product discussions must be factual, accurate, balanced, and consistent with U.S. FDA-approved labeling.

Following every proactive and reactive discussion with a member of the Healthcare Community, Commercial Field-based Staff and Medical Field-based Staff must document the following into the appropriate system of record:

- All field interactions, and
- All materials left behind.

Medical Therapeutic Area Staff (that engage externally)

The Scientific Engagement Plan (SEP) is an annual plan that outlines the engagement plan of HCPs by Medical Science Liaisons (MSLs) and Health Outcomes and Pharmacoeconomic Specialists (HOPE Specialists). Appropriate scientific engagement includes but is not limited to clinical trial support, educational activities, and scientific congress support. The Scientific Engagement Steering Committee (SESC) will review the SEPs and provide oversight. The SEPs will be stored in the appropriate system of record.

The SESC is composed of leadership from the following organizations: Medical, Healthcare Compliance, Regulatory Promotion, Law, and Medical Capabilities.

U.S./Global Medical Therapeutic Area Staff, including MSLs/HOPE Specialists, may engage in limited proactive Product discussions as follows:

- With formulary committees or members of formulary committees.
- With other members of the Healthcare Community as follows:
    - Updates regarding substantial safety updates based on a determination by the Executive Safety Committee that a risk is a Level 1 Risk,
    - Providing clinical trial support, or
    - As otherwise directed by the SESC, such as a new Product launch or a label update.
- The time period for such interaction must be approved by the SESC and will be limited to that time necessary to adequately convey the necessary information to the relevant HCP population.
- If MSLs are asked for unsolicited, Off-label Information during an interaction, MSLs must collect the signature of the HCP attesting to the unsolicited nature of the question, prior to responding. Such attestation shall be stored in the appropriate system of record. Responses to the question asked must be narrowly tailored, truthful, balanced, and non-misleading. See "Responding to Unsolicited Questions or Requests" for additional guidance.
    - Only information that is consistent with the U.S. FDA-approved labeling of a marketed Product and/or in materials that are currently approved by the appropriate review and approval process for that use, may be shared proactively.
    - When discussing Amgen Products, you must ensure discussions are fair balanced by providing information about both the risks and benefits associated with the Product.
    - The U.S. FDA-approved labeling must be offered.
    - U.S./Global Medical Therapeutic Area Staff, including MSLs/HOPE Specialists need to record/report interactions with U.S. HCPs. You must record the following in the appropriate system of record:
        - All field interactions with members of the Healthcare Community, and
        - All materials left behind during field interactions with members of the Healthcare Community.

CHAPTER 2: INTERACTIONS WITH MEMBERS OF THE HEALTHCARE COMMUNITY

DISCUSSIONS ON PIPELINE PRODUCTS OR NEW INTENDED USES OF AN APPROVED AMGEN PRODUCT

Pipeline Products or New Intended Uses of an Approved Amgen Product

To abide by the FDA Payor Communications Guidance, Staff that engage externally may proactively provide the following information related to Pipeline Products as well as new potential indications to already marketed Products to Payors, formulary decision makers, and similar entities. These presentations must be reviewed, and MAC approved.

- Pipeline Product or new potential indication information, as appropriate, e.g., drug class, device description and features.
- Information on indication sought, such as clinical study endpoints and Patient population studied, e.g., number, eligibility criteria, demographics.
- Peer-reviewed publications of results from clinical or preclinical studies, i.e., no characterizations or conclusions regarding safety or efficacy, including material aspects of the study design, methodology, and applicable limitations of the study design, methodology and results (this factual information must not be selectively presented).
- Anticipated FDA approval/clearance timeline.
- Product pricing information.
- Patient utilization projections, e.g., epidemiological data projection on incidence and prevalence.
- Product-related programs or services, e.g., Patient Support Programs.

All such information must be unbiased, factual, accurate, non-misleading, and non-promotional in nature. The following should be made clear:

- The Product and/or use is under investigation and has not yet been approved, and the safety and effectiveness has not been established.
- The Development stage of Product or use, such as the phase of clinical trial, and whether a marketing application submitted to FDA or when it is planned to be submitted.

Communications about unapproved uses of approved/cleared/licensed Products should include a prominent statement disclosing the indications for which the FDA has approved, cleared, or licensed the Product and a copy of the U.S. FDA-approved labeling.

If information has been provided regarding a new Product or use, Amgen must provide follow-up information to all recipients, if such information materially changes, e.g., subsequent phase 3 data changing the character of the information previously provided or change in review status.

HEALTHCARE ECONOMIC INFORMATION (HCEI) BASED ON COMPETENT AND RELIABLE SCIENTIFIC EVIDENCE (CARSE)

HCEI materials must:

- Be related to an approved indication,
- Be neither false nor misleading,
- Be based on Competent and Reliable Scientific Evidence,
- Contain an analysis of the economic consequences such as the dollar costs to providers or Patients of health outcomes associated with using one drug compared to using another drug, another healthcare intervention, or no intervention, and
- Contain an analysis of economic consequences related to the drug's approved indication.

HCEI materials are considered promotional and are thus reviewed and approved through the MAC process.

CHAPTER 2: INTERACTIONS WITH MEMBERS OF THE HEALTHCARE COMMUNITY

The below materials are not subject to these Compliance requirements:

- Materials developed by Medical Information are not covered by these Compliance requirements. Refer to the Medical Information SOP.
- U.S. Health Technology Assessment (HTA) submissions and American Managed Care Pharmacy (AMCP)-format formulary dossiers are not covered by these Compliance requirements. Refer to the appropriate process.

Staff Who May Share HCEI

Amgen Staff with the requisite economic and scientific competency and training may share HCEI, utilizing MAC-approved materials. Generally, this includes Amgen Staff such as the HOPE Specialists, MSLs, Market Access Representatives, Value & Access Leadership, Reimbursement Value & Access Leads, or others with similar accountabilities. HCEI can be proactively provided to:

- Any Payor, Formulary Committee or entity similar to those described in the FDA Payor Communications Guidance that has knowledge and expertise in the area of healthcare economic analysis carrying out its responsibilities through a deliberative process for the selection of drugs for coverage or reimbursement.
- Healthcare Professionals acting in the capacity as a participant in a deliberative process, e.g., at a Payor, Healthcare organization, or other multidisciplinary entity that reviews scientific and technology assessments to make drug selection, formulary management, and/or coverage and reimbursement decisions on a population basis for healthcare organizations.
- Others that may be deemed an appropriate audience to receive HCEI with the requisite expertise that are engaged, retained, or relied upon in the deliberative process of an entity to inform its population-based decision-making process, such as:
    - A third-party vendor or consultant, e.g., New Century Health, in the business of healthcare economic analysis.
    - An independent assessment body, e.g., the Institute for Clinical and Economic Review.
    - A committee assessing value within a professional society, e.g., American Society of Clinical Oncology (ASCO), National Comprehensive Cancer Center (NCCN), American College of Cardiology (ACC) and the American Heart Association (AHA).
- The scope of a deliberative process includes the component elements of the process such as sub-committees or other functional groups within an entity involved in the selection of drugs for coverage or reimbursement.
- HCEI cannot be proactively provided to:
    - Other audiences such as HCPs who are acting in their capacity as prescribers, i.e., making individual Patient prescribing decisions.
    - Non-professional individuals or organization, e.g., Patient Advocacy organizations.

INTERACTING WITH GUIDELINE DEVELOPING BODIES (GDBs)

A GDB is any entity that issues Clinical Practice Guidelines. Guidelines might be issued by a Professional Association/Society, such as, ASCO, NCCN and ACC, or a particular Healthcare Institution or Healthcare organization. Sometimes Clinical Practice Guidelines are meant to be advisory in nature regarding a particular approach to care while in other settings they may be mandatory.

GDBs are considered to be formulary decision makers. Amgen Staff may not attempt to exert any influence or control over any member of the Healthcare Community who is a member of a GDB. The independence of a GDB and their members must be respected and upheld (e.g., their medical judgment, policies, and activities).

CHAPTER 2: INTERACTIONS WITH MEMBERS OF THE HEALTHCARE COMMUNITY

You may not write, draft, edit, develop, update, advise on, create content, or program the content of Clinical Practice Guidelines or assist a member of the Healthcare Community to do the same.

You may not share one institution's Clinical Practice Guidelines with another member of the Healthcare Community. However, with permission from the institution, you may reactively share the name and contact information of an institution that has developed a Clinical Practice Guideline with a member of the Healthcare Community.

You may not engage in Off-label Information discussions in violation of applicable policies, Compliance requirements, SOPs, and training.

Amgen Staff cannot serve as an intermediary between two practices to share information that may include Off-label Information regarding uses of our Products.

You may not make copies of or distribute Clinical Practice Guidelines to members of the Healthcare Community that are not MAC approved.

Written contracts with HCPs that are GDB members may require the HCP to disclose to the GDB the existence and nature of the relationship with Amgen in accordance with applicable laws, regulations, industry standards and guidelines (e.g., Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals (PhRMA Code)).

You may inquire whether the HCP or GDB member is considering the development or implementation of a Clinical Practice Guideline; and if so, offer them the opportunity to receive additional clinical or HCEI data in accordance with applicable policies, Compliance requirements, SOPs, and training.

Medical Therapeutic Area Staff (that engage externally)

You may call on members of the Healthcare Community who serve on a GDB consistent with all policies, Compliance requirements, SOPs, and training.

You must follow all Scientific Exchange requirements and any provisions directly related to GDBs, as set forth in applicable policies, Compliance requirements, SOPs, and training.

Commercial Field-based Staff

You may call on members of the Healthcare Community who serve on a GDB consistent with all policies, Compliance requirements, SOPs, and training.

Proactive Product discussions must be factual, accurate, balanced, and consistent with the U.S. FDA-approved labeling. Any interaction must be in accordance with all applicable policies, Compliance requirements, SOPs, and training.

You may provide materials or data related to the specific work of the GDB committee member on a Clinical Practice Guideline that is consistent with the U.S. FDA-approved labeling and follows the approved class designation for use of the materials, as applicable.

Upon an unsolicited question, or request for information about unapproved uses of an Amgen Product, the request must be referred to Medical Information or handled through the MIR/eMIR process.

Healthcare Economic Information (HCEI) Communications

Only designated Staff having the requisite economic and scientific competency and training may be approved to deliver HCEI to a GDB. Such individuals may proactively provide HCEI to GDBs provided such bodies have knowledge and expertise in the area of healthcare economic analysis and carry out its responsibilities through a deliberative process to inform its population-based, decision-making process.

The HCEI disseminated must: (1) be neither false or misleading; (2) relate to an approved indication and contain an analysis of economic consequences related to the drug's approved indication and (3) be based on competent and reliable scientific evidence. For such interactions, follow all applicable policies and SOPs.

Submissions to Open Invitations from GDBs

This section does not apply to interactions with recognized compendium publishers.

Only Staff designated as having the requisite scientific competency and training in the area where information is being requested (the RAE) may reactively respond to an open invitation from a GDB.

The RAE is responsible for: (1) deciding whether to prepare materials for submission to an open invitation from a GDB; (2) developing materials for the submission in accordance with applicable local materials review and record-keeping processes; and (3) ensuring the submission is consistent with the Scientific Exchange requirements as outlined in applicable SOPs, policies and training on interactions with Healthcare Professionals and other members of the Healthcare Community.

PRODUCT, CONTRACT, AND REIMBURSEMENT DISCUSSIONS

Product Discussions

Commercial Field-based Staff

All discussions must be truthful, not be misleading, contain a balanced presentation of the risks and benefits, and always be consistent with the U.S. FDA-approved labeling. Off-label Promotion and Pre-approval Promotion are strictly prohibited.

When you engage in Product, contract, and reimbursement discussions of marketed Products, you must ensure that such materials are consistent with U.S. FDA-approved labeling and comply with all applicable Compliance requirements. An explanation for any interaction with an HCP outside of your call list, or specialty, is required in the appropriate system of record.

You must not proactively engage in discussions or interactions that solicit or could reasonably be expected to lead to a question or discussions about Off-label Information regarding uses of Amgen Products or pre-approval information.

Purchase Contract Discussions

Commercial Field-based Staff

You are permitted to offer Amgen Product purchase contracts to members of the Healthcare Community if you have been authorized to do so by the General Manager of your business unit or if doing so is consistent with your MAC-approved Plan of Action (POA).

You are prohibited from changing contract terms or signing Agreements.

You must not offer anything of value to members of the Healthcare Community in connection with entering into a purchase contract.

Reimbursement Discussions

Commercial Field-based Staff

We support accurate and responsible billing for our Products to Medicare and other public and private Payors by providing members of the Healthcare Community who purchase our Products with coverage, coding and billing information regarding such Products or related services.

Consistent with the general rules for Product promotion, you are only permitted to engage in discussion of reimbursement topics if the discussion utilizes MAC-approved messaging consistent

with the U.S. FDA-approved labeling and consistent with your POA. You are only permitted to use materials approved for reimbursement discussions.

Reimbursement discussions conducted by you must be narrowly tailored to address a particular topic. All reimbursement discussions must include a reminder to members of the Healthcare Community that they should confirm reimbursement information with the appropriate Payor.

Commercial Field-based Staff must never discuss how much money a member of the Healthcare Community can make or the difference between the acquisition cost and reimbursement from Medicare or other third-party Payors (e.g., "spread," "profit," "return-to-practice" or other similar concept). Specifically, Commercial Field-based Staff must not (1) advocate the "spread," "profit," or "return" as a reason to purchase an Amgen Product; (2) compare the "spread," "profit," or "return" of Amgen Products to competitor Products; or (3) guarantee a certain "profit," "spread," or "return" with an Amgen Product in exchange for purchase of the Product. Limited exceptions to these rules for Amgen biosimilar products are provided below.

If a question is presented that cannot be answered using MAC-approved materials or messaging, refer the HCP to the applicable reimbursement Product support program.

Do Not Combine Contract and Reimbursement Discussions

Commercial Field-based Staff

You are permitted to discuss a customer's net cost of purchasing our Products and the application of a customer's contract terms to purchases.

You are also permitted to discuss, in a separate meeting, how reimbursement works under government programs or private contracts.

Except as provided below, you are prohibited from discussing contracting (including rebates) and reimbursement issues during the same call or linking both subjects even if they are discussed in separate meetings.

In the context of financial discussions about an Amgen biosimilar product, you are permitted to inform customers about cost, pricing, contract terms, and reimbursement methodology in the same call or material subject to the guidelines below.

For Amgen biosimilar products, discussion points or content approved through this Exception may include information such as cost, pricing, a customer's net cost of purchasing our Products, the application of a customer's contract terms to purchases, and reimbursement methodologies applicable to Amgen biosimilar products. Further, such discussions may include calculating the difference between a customer's acquisition cost and reimbursement amount and advocating that difference as a reason to purchase the Amgen biosimilar product. All material developed for Amgen biosimilar products must be approved through the MAC process and must be accompanied by appropriate training to ensure compliance with Amgen standards and applicable laws and regulations.

RESPONDING TO UNSOLICITED QUESTIONS OR REQUESTS

Unsolicited Questions or Requests for Information

Medical Therapeutic Area Staff (that engage externally)

We are committed to Scientific Exchange that is truthful, non-misleading and non-promotional in its nature and intent. Scientific Exchange refers to 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 from a member of the Healthcare Community.

CHAPTER 2: INTERACTIONS WITH MEMBERS OF THE HEALTHCARE COMMUNITY

Only Medical Therapeutic Area Staff that engage externally may engage in Scientific Exchange with HCPs. Scientific Exchange must be consistent with all the following principles:

- **Scientifically Rigorous**: Scientific Exchange must be objective, current, and contain important safety-related data as appropriate.
- **Balanced**: Scientific Exchange must be unbiased. Positive and negative information, including safety-related data, must be presented when it is relevant as part of a balanced communication.
- **Appropriate Conclusions**: Specific study results or other scientific information may be communicated as part of Scientific Exchange. Results from a specific study may not be generalized to make broad claims about the safety and efficacy of an unapproved Product or indication.
- **Narrowly Tailored**: Written and verbal responses to unsolicited questions or requests for information on unapproved uses will be appropriately tailored, and not overly broad, to provide only that specific information needed to respond to the unsolicited questions or requests.
- **Conducted Independent of Promotional Activities**: Scientific Exchange will be conducted in a non-promotional context.
- **Appropriately Referenced**: Materials utilized in Scientific Exchange will contain appropriate references to relevant source materials supporting the Scientific Exchange.

You may respond to unsolicited requests for Off-label Information in accordance with the following:

- Answers/information must be narrowly tailored to respond to the question.
- Answers may be provided directly to the Requestor or redirected to Amgen Medical Information for fulfillment.
- Medical Information Requests (MIRs) and Electronic Medical Information Requests (eMIRs) must follow the requirements in the Medical Information SOP.
- You must document completion of each MIR/eMIR in the system of record.
- You may respond to an unsolicited request or question that Medical Information or other Development Staff receives from a member of the Healthcare Community, e.g., a request that is determined to require an in-person response.
- You may deliver presentations about molecules in Amgen's pipeline in response to specific unsolicited requests for such presentations. Generally, presentations about molecules in Amgen's pipeline should be delivered outside of the presence of Commercial Field-based Staff.

In the event that an unsolicited request or question cannot be adequately addressed with existing Company-approved materials, you may reference the peer-reviewed literature and/or perform literature searches.

- You must ensure that all responses are fair balanced and scientifically rigorous consistent with Compliance requirements addressing responses to unsolicited requests or questions. If more than one article addresses the unsolicited request or question, the breadth of the literature should be cited.
- The reprints or literature search results may be shown but cannot be left behind.
- If the member of the Healthcare Community requests a copy of the reprint or literature search, they may be referred to Medical Information, or you may submit a request to Medical Information on behalf of the member of the Healthcare Community.

Commercial Field-based Staff

Commercial Field-based Staff are permitted to respond to questions from members of the Healthcare Community about the safety and efficacy of Amgen Products only if the answers are consistent with the U.S. FDA-approved labeling and the responses use MAC-approved materials that have been approved for the purpose of answering the specific unsolicited questions asked.

You must not respond to unsolicited requests from members of the Healthcare Community for Off-label Information or pre-approval information.

You must not engage in discussion of Off-label Information or pre-approval information.

At the request of the member of the Healthcare Community, you may submit the question to Medical Information for tracking and fulfillment in one of the following ways:

- By submitting a MIR or eMIR, or
- By forwarding an email received from the member of the Healthcare Community and copying the member of the Healthcare Community on the forwarded email to Medical Information.

All unsolicited requests must contain the physical signature, electronic signature, or email address of the member of the Healthcare Community who made the unsolicited request.

Medical Information reviews each MIR, eMIR or email and determines if Medical Information will fulfill the request or will forward the request to an MSL. If MSL support is requested in a MIR, an eMIR, or an email, Medical Information will forward the MIR, eMIR, or email to an MSL.

If you request MSL support or if Medical Information forwards the request to an MSL, the MSL determines whether they will fulfill the request or return the request to Medical Information for fulfillment.

The inside sales organization may directly inform Medical Information of any unsolicited requests for information.

3. DISEASE-STATE DISCUSSIONS

The following applies to Commercial Field-based Staff and Medical Therapeutic Area Staff that engage externally.

Disease-State Discussions

Disease-state discussions are permitted on a proactive or reactive basis, pursuant to the following requirements:

- Discussions do not mention, suggest, or imply the use of Amgen pipeline or marketed Products.
- Discussions include only appropriately approved messages and materials.
- You are permitted to proactively or reactively engage in a Product discussion during the same call as a disease-state discussion provided that: (1) the Product is not used to treat Patients suffering from the disease-state or related to the disease-state that was discussed; and (2) you conclude the disease-state discussion before beginning any Product discussion.

Responding to Unsolicited Product Questions During Disease-State Discussions

Medical Therapeutic Area Staff (that engage externally)

If a question regarding an Amgen Product is raised during a disease-state discussion, you should explain that the conversation was intended to provide disease education and was not intended to discuss any particular Product.

However, you may respond to an unsolicited Amgen Product question that you receive, or you may redirect the request or question to Medical Information for fulfillment.

In response to an unsolicited request or question, you can provide answers if the request is specific, and the content of the response is narrowly tailored and responsive to the question.

All interactions resulting from unsolicited requests or questions shall be documented in the system of record for documenting interactions with members of the Healthcare Community.

Commercial Field-based Staff

If a question regarding an Amgen Product is raised during a disease-state discussion, you should explain that the conversation was intended to provide disease education and was not intended to discuss any particular Product.

If the question seeks information that is consistent with the Product's U.S. FDA-approved labeling, then you should ask the member of the Healthcare Community to arrange another visit or call to discuss his or her Product question. To the extent possible, you should continue with the disease-state discussion.

Commercial Field-based Staff may not answer specific Product questions during disease-state discussions unless MAC-approved materials have been provided that are specifically designed/created to use when responding to these specific Product questions. If such materials have been provided, then you may use the materials to respond to the specific Product question within the disease-state being discussed, consistent with the MAC-approved instructions.

Commercial Field-based Staff are permitted to proactively or reactively engage in a Product discussion during the same call as a disease-state discussion provided that: (1) the Product is not used to treat Patients suffering from the disease-state or related to the disease-state that was discussed; and (2) you conclude the disease-state discussion before beginning any Product discussion.

If the question seeks Off-label Information or seeks pre-approval information, you must follow the procedures on responding to unsolicited questions or requests. Questions about coverage or reimbursement of Amgen Products must be referred to the applicable reimbursement Product support program.

All interactions resulting from unsolicited requests or questions shall be documented in the system of record for documenting interactions with members of the Healthcare Community.

4. GATHERING INSIGHTS

PIPELINE/LIFECYCLE MANAGEMENT

Pipeline/Lifecycle Management includes long-term planning for the commercialization of Amgen Pipeline Product and Amgen marketed Products that focuses on the development and implementation of strategies designed to maximize the potential to reach all appropriate Patients through the Products' lifecycles.

CHAPTER 2: INTERACTIONS WITH MEMBERS OF THE HEALTHCARE COMMUNITY

Select Commercial Staff may engage in certain Product discussions with members of the Healthcare Community with the purpose to gain feedback, guidance or other information that is then used to inform an internal Amgen Product lifecycle management strategy. Such discussions are not promotional and must not be used to provide Product messages, encourage utilization or describe a Product's use.

- Pipeline/Lifecycle Management Commercial Staff include the following:
  - Directors and above within the Global Marketing & Commercial Development organization,
  - Directors and above within the Biosimilars organization, and
  - Executive Directors and above within the U.S. Commercial Operations organization, excluding all Commercial Field-based Staff.

Product/Lifecycle Management Discussions engaged by Amgen Staff below the Executive Director level, must be done under the direction and approval of the Amgen Staff member's supervisor.

No Compensation is provided to the member of the Healthcare Community for their advice.

Questions asked by Commercial Staff relating to Amgen Products must be kept to a minimum.

Questions from Pipeline/Lifecycle Management Commercial Staff should be limited to understanding evolving trends and unmet needs in the disease-state, therapeutic area, and the Payor environment; informing opportunity assessment; or understanding the overall competitive landscape.

Discussions cannot be promotional. It is impermissible to make a promotional claim concerning the safety or efficacy of a Pipeline Product or a new use of an existing Amgen Product prior to FDA approval.

You may not implicitly or explicitly discuss Amgen Products.

You may not inform the member of the Healthcare Community of the benefits and/or risks of a Pipeline Product or new use or presentation of an existing Amgen Product, proactively discuss Product data, or try to change opinions that the member of the Healthcare Community may provide regarding any Product.

If during an information gathering discussion, you are asked specific or limited Product data questions, you may provide a limited response if providing the response is necessary to obtain the feedback, guidance or information sought from the member of the Healthcare Community. However, you may not enter into an in-depth discussion concerning Product data. In-depth inquiries must be referred to appropriate Medical Staff.

- Limited response: Responses must be appropriately tailored, not overly broad, and provide only that specific information needed to respond to the question.

Prior to the discussion, you should consult Law concerning appropriate confidential treatment of any Amgen Confidential or Proprietary Information that could be discussed.

ADVISORY BOARDS AND SIMILAR ACTIVITIES

The information that follows provides only the U.S. Healthcare Compliance requirements for Advisory Boards. More detailed procedural information can be found in the SOP: Advisory Boards.

Advisory Boards must serve a legitimate business or scientific purpose that aligns to Amgen's strategic priorities. Amgen will not initiate, arrange, or hold an Advisory Board:

- To promote or as an inducement to use Amgen's pipeline or marketed Products,
- As an award for the use of Amgen's pipeline or marketed Products,

- To educate or train or advocate for Amgen's Products, pipeline, company beyond what is necessary to solicit the advice sought,
- To recruit potential investigators to participate in Amgen research projects, or
- Build relationships or gain exposure to advisors.

All Advisory Boards must have a Responsible Amgen Employee (RAE). Only Amgen Staff who reasonably require the advice of an Advisory Board may serve as the RAE for that Advisory Board.

- For Commercial Advisory Boards, the RAE is a Commercial Staff member.
- For Scientific Advisory Boards, the RAE is a Medical Staff member.

A third-party supplier, consultant, contract worker or temporary Staff member may be used to assist with an activity in connection with an Advisory Board; however, the RAE remains accountable for approving and attesting to the compliance approval documentation and for approving any supporting materials prior to their submission and finalization.

Please use the decision questions and information in the tables below to determine whether these Compliance requirements apply to your Advisory Board or similar activity.

In-Person Advisory Boards

Responsible Amgen Employee (RAE)	**U.S. RAE**				**Outside U.S. RAE (including Intercontinental RAEs)**			
Where is the Ad Board being conducted?	Ad Board in U.S.		Ad Board Outside U.S.		Ad Board in U.S.		Ad Board Outside U.S.	
Are U.S. advisors attending?	YES	NO	YES	NO	YES	NO	YES	NO
Follow this guidance?	YES	NO*	YES	NO*	YES	NO*		

*Please follow the Fee for Service Compliance requirements for the Region in which the Advisory Board is being conducted. These can be found in the Country Requirements Overview. **Note:** If you are unsure whether your meeting constitutes an Advisory Board, please consult with your Compliance Lead and Law.

Virtual Advisory Boards

Responsible Amgen Employee (RAE)	**U.S. RAE**		**Outside U.S. RAE (including Intercontinental RAEs)**
Are U.S. advisors attending?	YES	NO	This guidance is not applicable to virtual Advisory Boards initiated by OUS RAEs
Follow this guidance?	YES	NO*	

*Please follow the Fee for Service Compliance requirements for the Region in which the Advisory Board is being conducted. These can be found in the Country Requirements Overview. **Note:** If you are unsure whether your meeting constitutes an Advisory Board, please consult with your Compliance Lead and Law.

When an Advisory Board is initiated pursuant to contractual Agreements including, but not limited to co-development or co-promotional Agreements, you must consult with your Compliance Lead and the Law group responsible for reviewing the Advisory Board concept.

CHAPTER 2: INTERACTIONS WITH MEMBERS OF THE HEALTHCARE COMMUNITY

Receive Appropriate Review and Approvals for Advisory Board Concepts

Advisory Board concepts must be approved by your management and reviewed by Law. However, no concept review or meeting material review is required for Scientific Advisory Boards that only involve investigational, non-approved molecules that have yet to reach the end of phase 2 portal (Pre-EOP2 Scientific Advisory Boards). Reach out to your Product Team (PT) Lead if there is confusion regarding the phase of the compound for which the Advisory Board is being conducted.

Advisory Board Concept Review and Approval

	Commercial Advisory Boards*	**Scientific Advisory Boards**		
Product Phase	All Phases	Pre-End of Phase 2 (EOP2) Portal	Post-EOP2 Portal but Pre "Commit to File"	Post- "Commit to File"
Advisory Board Concept	Your management & GCO Law to review and approve	No DROC Law review or approval required	Your management & DROC Law to review and approve	Your management & GCO Law to review and approve
Advisory Board Concept Material Change Requests**	Your management & GCO Law to review and approve	No DROC Law review or approval required	Your management & DROC Law to review and approve	Your management & GCO Law to review and approve

*If there is confusion whether your Advisory Board fits into the Commercial Category, please consult with your Development, Regulatory, Operations and Contracting (DROC) Law attorney or Global Commercial Operations (GCO) Law attorney.

**Material change in this context means any changes to the objective or business need of the advisory board.

Meeting Material Approval

	Commercial Advisory Boards*	**Scientific Advisory Boards**		
Product Phase	All Phases	Pre-End of Phase 2 (EOP2) Portal	Post-EOP2 Portal, but pre-"Commit to File"	Post-"Commit to File"
Materials Review	Post-EOP2 Advisory Board materials are sent for review through MAC. GCO Law and Medical must review advisory board materials. **Note**: Pre-EOP2 Commercial Advisory Board materials are not reviewed in MAC. They are reviewed by GCO Law and Medical offline.	No DROC Law review or approval required.	Advisory Board materials are sent for review through Scientific Material Review Process (SMRP).	
			DROC Law may opt-out of review of Advisory Board materials.	GCO Law and Medical review Advisory Board materials.

*If there is confusion whether your Advisory Board fits into the Commercial Category, please consult with your Development, Regulatory, Operations and Contracting (DROC) Law attorney or Global Commercial Operations (GCO) Law attorney.

CHAPTER 2: INTERACTIONS WITH MEMBERS OF THE HEALTHCARE COMMUNITY

Do Not Select Advisors to Influence

Amgen will not select any advisor with the intent of, directly or indirectly, influencing or encouraging the advisor to purchase, prescribe, refer, sell, arrange for the purchase or sale, reimburse or recommend formulary placement of any Amgen Product.

In addition, Amgen will not select Patient advisors for the purposes of influencing their selection of particular Healthcare Providers, practitioners, suppliers, or for the purposes of their recommendation or endorsement of Products.

Selecting Qualified Advisors

The number of advisors must not be greater than the number that is reasonably necessary to meet the identified business need.

Advisors should not routinely be expected to act in capacities other than as participants at Advisory Boards.

Medical Therapeutic Area Staff

- Will select advisors for Scientific Advisory Boards.
- Recommend advisors to Commercial Advisory Boards and may participate in their ultimate selection.

Commercial Staff

- May recommend advisors to Scientific Advisory Boards but may not participate in their ultimate selection.

Patient Advisory Boards should follow the same business rules.

Secure Written Agreement Prior to Start of Advisory Board

Unless there is written authorization from Healthcare Compliance, fully executed advisor Agreements must be secured from Healthcare Compliance at least three (3) business days prior to the start of the Advisory Board. In addition, participants of a Patient Advisory Board must execute a privacy notice and Patient authorization in a form approved by Amgen's Global Privacy Office.

Note: It is the responsibility of the RAE to appropriately plan ahead and ensure that a fully executed Agreement is secured by Healthcare Compliance prior to any transfers of value being made to the advisors. For example, no advisor should fly (with the expectation of expensing the flight to Amgen) to the city in which the Advisory Board is taking place unless Healthcare Compliance has secured the signed Advisory Board Agreement prior to the start of the Advisory Board.

The written authorization will be housed in the Healthcare Compliance appropriate system of record.

Allow Appropriate Amgen Attendees

In-person Amgen Staff attendance at Advisory Boards should be limited to:

- Those having a clearly defined role and/or a clear business need to attend.
- Ensure that attendance does not impede the conduct and execution of the Advisory Board.
- Commercial Staff Attendance at Scientific Advisory Boards:
    - Commercial Staff may attend a Scientific Advisory Board provided there exists a legitimate business need; the RAE will provide justification on the Advisory Board Concept Approval Request Form (ABCARF).
    - The number of Commercial Staff attending a Scientific Advisory Board must be less than the number of Medical Staff in attendance.
    - Commercial Staff attending a Scientific Advisory Boards may only observe.
    - No Commercial Field-Based Staff may attend Scientific Advisory Boards.

The RAE will be responsible for ensuring that attendance of in-person Amgen Staff at an Advisory Board does not exceed the number approved to attend, and for ensuring that only those individuals identified may be in attendance in person.

Amgen Compliance or Law Staff attendance for auditing or monitoring purposes are not counted as in-person Amgen Staff.

Utilize Feedback and Outcomes

You must complete and submit within 45 days after the conclusion of an Advisory Board, an Advisory Board Summary Report that summarizes the significant advice or information obtained and provides an explanation of how Amgen has or plans to use the information. Healthcare Compliance will retain the Advisory Board Summary Report in the appropriate system of record.

MARKET AND CUSTOMER RESEARCH

The information that follows provides only the U.S. Healthcare Compliance requirements for Market and Customer Research. More detailed procedural information can be found in the SOP: Market and Customer Research.

Only Specific Amgen Groups May Conduct Market and Customer Research

All Market and Customer Research will be conducted only by qualified persons who are in authorized departments and following successful completion of requisite training that have been granted permission by the Business Process Owner (BPO) of the Master List. To access the list of authorized departments and identify the BPO, click here.

Any person outside of an authorized department that has a legitimate business need for conducting Market and Customer Research must consult with the BPO. If permission is granted by the BPO, the person will be provisioned access to the Master List following successful completion of requisite training. The BPO will communicate these Exceptions to Compliance, Regulatory, and Human Resource partners to ensure awareness, and, if applicable, update the list of authorized departments noted above. The Sales organization is prohibited from conducting Market and Customer Research.

Maintain Master List of Market and Customer Research

In order to avoid duplication of activities and interactions, the Master List of completed Market and Customer Research will be maintained by the BPO of the Master List, as designated by Market and Customer Research Leadership.

Comply with Quality, Standards, and Ethics Codes

Amgen requires all Market and Customer Research to be conducted in accordance with the quality control procedures and codes of standards and ethics for Market Research set forth in the Council of American Survey Research Organizations (CASRO), European World Association of Opinion and Marketing Research Professionals (ESOMAR), European Pharmaceutical Market Research Association (EphMRA), and other applicable foreign country codes of conduct.

Potential Publication of Market and Customer Research Results

If there is interest in potentially publishing the results of Development-Driven Market Research (DDMR), please consult the slide deck here and follow the Observational Research Review Group (ORRG) review process.

If there is interest in potentially publishing the results of market research that is not DDMR, prior to conducting the research, consult with the Global Commercial Operations (GCO) Law attorney (for U.S.) or local Law attorney and the Regulatory Promotion Lead (for U.S.) or local lead on the

promotional review process for the relevant Products or therapeutic areas, as well as with R&D Compliance.

Do Not Contact or Identify Specific Individuals for Recruitment

Amgen will not contact or identify specific individuals to recruit for Market and Customer Research. It is permissible for Amgen to provide a listing (e.g., prescriber target list) of prospective participants if there is sufficient ability to recruit without knowing or being able to reasonably infer the specific identity of the final participants.

Note: The provision of Patient lists to vendors and suppliers for projects that would otherwise have been considered syndicated research shall be deemed Market and Customer Research and are subject to the application of the Market and Customer Research SOP.

Conduct Market and Customer Research with Sponsor Blinded

Market and Customer Research should generally be conducted with the participants blinded to the sponsor of the Market and Customer Research. If Amgen is identified as the sponsor, an appropriate basis for such non-blinding must be documented in the Master List. The Project Manager is responsible for ensuring that Unblinded Market and Customer Research is conducted only when necessary. The supplier should not identify Amgen as the sponsor of Market and Customer Research unless directed or otherwise instructed by Amgen.

Act Appropriately During Market and Customer Research

In the case of Market and Customer Research in which you or others are present, you may not know the identity of individual participants or other participant-identifying information.

Amgen Staff must not disclose the identity of individual participants or other participant-identifying information to anyone who was not present during the Market and Customer Research.

When Amgen Staff are present, they may not participate with, engage with, or otherwise interact in any way with participants. However, Amgen Staff may present material or messages as stimuli, e.g., a mock core visual aid demonstration, but may not be involved in the questioning of any participants.

Do Not Conduct Customer and Market Research Return on Investment

Amgen will not conduct, or engage a supplier to conduct, any “return on investment” analysis that measures commercial outcomes in the prescribing patterns of Healthcare Professionals as related to their participation in Market and Customer Research.

Paying HCPs for recruiting Market and Customer Research Participants is prohibited, except (a) in the case of Market and Customer Research required by law, e.g., REMS; (b) when HCPs are acting in the capacity of a clinical trial investigator for DDMR.

Allow Only Appropriate Attendees

No Commercial Field-based Staff or their immediate manager shall attend in-person, any Market and Customer Research activities.

Travel Expenses

Travel expenses for participants or Caregivers will not be paid, nor reimbursed, for Customer and Market Research activities.

Project Delivery and Final Report/Deliverables

Project Manager will develop a final report/deliverable of the Market and Customer Research which addresses the business objectives and submit the final report/deliverables to the Project Sponsor.

CHAPTER 2: INTERACTIONS WITH MEMBERS OF THE HEALTHCARE COMMUNITY

5. SPEAKER BUREAUS AND SPEAKER PROGRAMS

The information that follows provides only the U.S. Healthcare Compliance requirements for Speaker Programs and Speaker Bureaus. More detailed procedural information can be found in the SOP: Speaker Programs and Speaker Bureaus.

As part of appropriate Product marketing and education practices, Amgen may choose to engage select HCPs to speak to the Healthcare Community on our behalf. All Amgen Staff who engage in Amgen Speaker Program activities must be familiar with these risks and follow the requirements below.

MANAGING SPEAKER BUREAUS

Selection of Appropriate Speakers

Speakers must only be selected based on appropriate qualifications such as; (i) Product knowledge, (ii) speaking and communication skills, (iii) professional experience, reputation, (iv) willingness to adhere to Amgen requirements, and (v) other attributes that are necessary to deliver the approved messages and materials. Speakers may not be selected based on (i) their prescribing history, (ii) expectations of future prescribing practices, or (iii) any impact that being a Speaker for Amgen might have on their clinical judgment.

All decisions regarding whether or not a particular HCP will be offered a position on a particular Speaker Bureau must be made exclusively by the Responsible Amgen Employee (RAE) located in Amgen's home office and who does not have any field or Call Plan responsibilities ("Speaker Bureau RAE"). The Speaker Bureau RAE may obtain feedback and nominations from Commercial Field-based Staff.

Commercial Field-based Staff

- May communicate unsolicited stated interests from a member of the Healthcare Community to the applicable Regional Sales Director (RSD). Only an RSD or equivalent may make specific suggestions to the Speaker Program RAE.
- May not discuss Speaker nominations with members of the Healthcare Community.
- Are permitted to nominate Speakers; however, they are not allowed to participate in the evaluation or decision-making process related to the nomination, nor are they allowed to engage in any follow up discussions with the Healthcare Professionals (HCPs) they've nominated.

The Speaker Bureau RAE, in consultation with Medical, will make the final selection of Speakers.

The Speaker Bureau RAE will annually review and assess the need for a Speaker Bureau and assess the Speaker's utilization. They will retain the documentation of such need in the appropriate system of record, which may include the brand plan or other documents evidencing a legitimate business need for a Speaker Bureau.

Speakers who are on an excluded specialty list for a specific Amgen Product, cannot participate in the Speaker Bureau for that Amgen Product, disease-state, or reimbursement program.

Types of Bureaus/Programs

Effective January 1, 2022, alcohol must not be provided at any Speaker Programs.

Amgen may conduct promotional, disease-state, or reimbursement Speaker Programs.

Promotional Speaker Programs discuss Amgen marketed Products and must present information that is consistent with the U.S. FDA-approved labeling of the Amgen marketed Product as well as the important safety information or applicable risk information and be MAC approved.

Disease-state Programs discuss a particular disease or health condition but do not mention any specific drug or make any representation or suggestion concerning a particular drug. If an Amgen Product is proactively discussed in the course of a disease-state discussion, the Speaker Program will be considered a promotional event and must comply with the requirements for a promotional Speaker Program including the presentation of risk information and offering the U.S. FDA-approved labeling.

Reimbursement Speaker Programs discuss business topics that are directly related to Amgen Products, e.g., coverage and coding issues related to Amgen Products. If an Amgen Product is proactively discussed in the course of a reimbursement discussion, the Speaker Program will be considered a promotional event and must comply with the requirements for a promotional Speaker Program.

Before any HCP can conduct any of the Speaker Programs described above, the HCP must be first trained as a Speaker. Speaker training meetings must be conducted solely for the purpose of training Speakers to serve as a member of an Amgen Speaker Bureau and to participate in Amgen Speaker Programs. Speaker training meetings must not be conducted for the purpose of promoting Amgen marketed or Pipeline Products. The Speaker Bureau RAE must document the legitimate business need and training objectives for the Speaker training in the Speaker Training Request Form (STRF). The applicable Executive Director must approve the STRF.

All Speakers must be trained on the U.S. FDA-approved labeling for promotional and reimbursement Speaker Programs and must receive Amgen's training on (1) Amgen's rules governing Speakers; (2) applicable FDA regulatory requirements, including answering questions from participants; and (3) the use of approved presentation materials, including slide kits.

Speaker training, including communications and notifications, should be conducted periodically, in order to maintain a qualified Speaker Bureau.

Speakers may answer unsolicited questions posed by the audience during a Speaker Program, only in accordance with the Amgen Speaker rules.

Venue, Location, and Travel

When a Speaker training meeting is conducted before or after a medical convention, it is appropriate to pay an honorarium and to reimburse only for the additional lodging expenses incurred as a result of attending the Speaker training meeting.

Attendance for Speaker Training

The target audience and any Amgen Staff in attendance for each Speaker training meeting must be documented by the Speaker Bureau RAE in the STRF. Active members should only attend if there is a demonstrated need for additional training as documented by the Speaker Bureau RAE in the STRF.

Generally, Speakers should be trained in a formal group setting. If a Speaker is unable to attend a group training session, or if it is not feasible for Amgen to conduct group training, individual Speakers may be trained by appropriate Amgen Staff members.

Speakers who request one-on-one training in lieu of attending the group Speaker training session, will not be compensated for the training time.

Qualified outside experts, e.g., opinion leaders, professional facilitators, may be used as faculty at Speaker training meetings.

Medical Therapeutic Area Staff (that engage externally)

U.S. Medical Directors (USMDs) and Medical Science Liaisons (MSLs) may help facilitate national Speaker training programs to train Speaker candidates on clinical content. On a limited basis, working together with Healthcare Compliance and the Marketing RAE, USMDs or MSLs may provide clinical training to an individual Speaker who was not able to attend the national Speaker training program.

Commercial Field-based Staff

Clinical specialists may also train nurse Speakers and/or other allied Healthcare Professional Speakers; no other Commercial Staff members may conduct Amgen Speaker deck training.

Commercial Field-based Staff and their immediate managers are prohibited from attending Speaker training sessions. This rule applies whether the training occurs at a formal meeting or a one-on-one training session. For non-clinical content, e.g., welcomes/introductions, logistics issues, and access/reimbursement issues, appropriate Amgen Staff members may include Commercial Staff as well as vendors.

Post-Training Requirements for RAE

Upon completion of the Speaker training meeting, the Speaker Bureau RAE must submit names of Speakers who attended the Speaker training in the appropriate system of record.

CONDUCTING SPEAKER PROGRAMS

Speaker Program RAE

The Speaker Program RAE must be an Amgen Staff member.

Invites and Materials

Speaker Programs must use only MAC-approved materials.

If written invitations are used, the invitation or invitation template must be MAC approved.

Attendance

Only those with a bona fide educational need for the information should be invited.

Repeat attendance at a Speaker program on the same or substantially the same topic is generally not appropriate unless the attendee has a bona fide educational need to receive the information presented. Attendance by Speakers as participants at programs after speaking on the same or substantially the same topic is generally not appropriate.

Amgen attendees must have specific, clearly defined roles.

The Speaker Program RAE must be present at live and virtual Speaker Programs during the Speaker presentation.

Speaker Engagements

Speaker engagements may never be used as an inducement or reward for prescribing a particular medicine or course of Treatment, or potential to generate future business.

Medical Therapeutic Area Staff (that engage externally)

USMDs and MSLs are permitted to attend Speaker Programs in a quality evaluation and observational capacity to assess the Speaker's skills, performance, and substantive knowledge of the content.

Commercial Field-based Staff

It is appropriate for a local Commercial Field-based Staff member to attend a Speaker Program for purposes of assisting the Speaker with logistics, helping to ensure that the content of the presentation is the Amgen-approved content, and for training purposes.

Speaker Program Venue

For Speaker Programs at third-party venues, the third-party venue selected by the company should not be extravagant or the main attraction of the event or perceived as such. Luxury resorts, high-end restaurants, and Entertainment, sporting, or other recreational venues or events are not appropriate.

Speaker Programs

Speaker Programs will only be conducted when there is a reasonable expectation that at least four appropriate members of the Healthcare Community will attend.

Speaker Programs may not be conducted where a Speaker speaks only to their own Staff.

A Speaker's own Staff do not satisfy the requirement that at least four appropriate members of the Healthcare Community attend.

Behavior and Contingencies

If the Speaker is unable to attend the event, the Speaker Program RAE must work through approved channels to compliantly conduct the Speaker Program.

Medical Therapeutic Area Staff (that engage externally)

USMDs and MSLs may not act in the capacity of a Speaker at any Speaker Programs.

Commercial Field-based Staff

Commercial Field-based Staff may not act in the capacity of a Speaker at any Speaker Programs.

Amgen Staff members must refrain from proactively engaging in discussions during the presentation portion of Speaker Programs.

In the limited and rare circumstance when a Speaker is not able to answer a question that is consistent with the U.S. FDA-approved labeling during a promotional or reimbursement presentation, the Speaker may ask you to answer that question. This question should be addressed with information consistent with the U.S. FDA-approved labeling and Amgen-approved messaging. If Off-label Information is required to appropriately address the question, you must refer the Speaker Program attendees to Medical Information.

If the Speaker requests that you answer a participant question about a disease-state during a disease-state presentation, you may answer. If the question concerns an Amgen Product, you must respond that this is a disease-state presentation, and it is not appropriate to discuss any Amgen Products. If the questioner persists, you should speak separately with the questioner after the presentation. After briefly answering the question, you should direct the questioner to Medical Information or the Product website for current U.S. FDA-approved labeling.

Post-Requirements

Speakers may not be paid more than $75,000 total Compensation per calendar year, not including expenses, for participation in Speaker Bureaus.

The Speaker Bureau RAE will have the responsibility for efforts to measure effectiveness of a Speaker training meeting. No Amgen Staff, including the Speaker Bureau RAE, may conduct any "return on investment" analysis that measures commercial outcomes, such as changes in the prescribing patterns of Speakers with respect to a Speaker training meetings.

Speaker Program Vendor Requirements and RAE Checks

Each third-party vendor that manages Speaker Programs for Amgen shall perform a monthly quality assurance check to ensure that its invoices to Amgen accurately reflect the services provided. The third-party vendor shall provide the results of those quality assurance checks to the Amgen Speaker Program RAE upon request.

Amgen Sales and Marketing Operations shall perform a periodic, sample-based review of payments to a third-party vendor that manages Speaker Programs prior to paying an invoice from that vendor in the appropriate system of record.

SPEAKING AT NON-PROMOTIONAL EVENTS

USMDs and MSLs

You may speak at non-promotional events either:

- As directed by Amgen Corporate Headquarters, e.g., Scientific Advisory Boards, scientific congresses.
- At the request of a member of the Healthcare Community, e.g., Staff in-services, fellows' training, or at a professional society.

You must use Company-approved materials. Please refer to the Independent Medical Education (IME) Compliance requirements should you be asked to speak at an Independent Medical Education event.

- Our USMD and MSL Staff may speak at non-Amgen funded IME programs when all of the following conditions are met:
  - The IME provider has made an unsolicited and independently crafted, written request for the Amgen Staff member to speak. The request must also contain the rationale for the Amgen Staff member to serve as a Speaker.
  - Our Staff member is qualified to deliver the presentation on the specific topic.
  - Activity must be approved by the Speaker's supervisor.
  - The presentation must be approved through the applicable corporate review and approval process, e.g., MAC, Scientific Materials Review Process (SMRP), Final Publications Review (FPR), to safeguard Amgen proprietary information.

6. INTERACTIONS WITH GROUP PURCHASING ORGANIZATIONS (GPOS)

The information that follows provides only the U.S. Healthcare Compliance requirements for Interactions with Group Purchasing Organizations. More detailed procedural information can be found in the SOP: Interactions with Group Purchasing Organizations.

Interactions with GPOs

Many segments of the Healthcare Community, including Healthcare Professionals and Healthcare Institutions, join GPOs in order to obtain favorable pricing and other terms for the purchase of healthcare Products and services and in order to achieve efficiencies in purchasing. Generally, GPOs do not directly purchase Products. Instead, the pricing and other terms available to GPO Members, including applicable Discounts and Rebates, are included in the GPO Product Agreement between the GPO and Amgen.

CHAPTER 2: INTERACTIONS WITH MEMBERS OF THE HEALTHCARE COMMUNITY

Although a GPO will have its own independent and legitimate reasons for promoting Amgen's Products to its GPO Members, this alignment of interests between Amgen and the GPO does not allow you to become involved in the promotional efforts of the GPO. Amgen Staff are prohibited from taking any action to facilitate, arrange for, or be involved in GPO activities that could be attributable to Amgen and that we could not perform directly or indirectly.

GPO Product Agreements

Amgen's GPO Product Agreements outlining the terms and conditions of Agreements with GPOs for the purchase of Products must comply with all applicable laws and Amgen's policies relating to Discounts and Rebates. The U.S. Value and Access (U.S. V&A) group within U.S. Business Operations (USBO) will ensure that GPO Product Agreements, based on Law-approved templates, include language requiring GPOs to notify their GPO Members to comply with any obligation to report Discounts and Rebates in accordance with the requirements of the federal Anti-kickback law and regulations and relevant state laws.

Separate from the pricing (including Discounts and Rebates) provided to GPO Members, GPOs themselves receive GPO Administrative Fees from vendors like Amgen pursuant to a safe harbor to the federal Anti-kickback law that permits GPOs to receive GPO Administrative Fees from vendors. GPO Administrative Fees generally are based on a percentage of the value of purchases by GPO Members. The U.S. V&A group will ensure that GPO Product Agreements contain language requiring individual GPOs to represent and warrant that it complies with all applicable laws and the GPO safe harbor.

GPO Administrative Fees are paid to the GPO itself and are not intended to serve as additional Discounts or Rebates to GPO Members. Amgen does not direct or suggest how GPOs use GPO Administrative Fees.

An Agreement to obtain services or data from a GPO may not be offered in connection with discussions or negotiations with the GPO relating to its GPO Product Agreement. It is not appropriate to enter into an Agreement in order to assist the GPO to recruit GPO Members, to induce GPO Members or potential GPO Members to purchase or recommend Amgen Products, or to perform activities that Amgen is prohibited from performing directly or indirectly. A service Agreement may not be offered with the intent of directly or indirectly influencing or encouraging the GPO to enter into or continue with a GPO Product Agreement with Amgen or in order to influence the terms of any such GPO Product Agreement.

Law-approved contract templates will contain language requiring the GPO to disclose its relationship with Amgen and that such services are being performed on behalf of Amgen and not for its own benefit. Such language will also make it clear that the GPO may not promote GPO services or membership when acting on behalf of Amgen.

Types of Approved Service Arrangements

Unless otherwise specified in these Compliance requirements, a GPO may perform a number of bona fide services for Amgen, but only if in compliance with all applicable Compliance requirements, policies, and guidelines. Examples of such service arrangements include, but are not limited to:

- Exhibit Space
    - Amgen may purchase Exhibit Space at qualifying GPO meetings in compliance with Exhibit Space requirements. More detailed, procedural information can be found in the SOP: Exhibit Space.
- Speaker Programs
    - Amgen may conduct a Speaker Program targeted at GPO Members in compliance with the Speaker Program and Speaker Bureaus Compliance requirements. It must

be clear to attendees that the Speaker Program is an Amgen program and not a GPO program.
    - If the Speaker Program is conducted in connection with a prescheduled GPO meeting, Amgen may not pay the GPO to organize the Speaker Program, nor may Amgen provide or pay for a Meal in connection with the program/GPO meeting.
    - Amgen may engage a GPO to organize a stand-alone Speaker Program in accordance with Compliance requirements.

- Data Purchase Agreements
    - We may purchase data from GPOs in accordance with Compliance requirements.
- Purchase of Advertising Space
    - Amgen may purchase advertising space from GPOs, either in print or electronically, e.g., web banner ads, in accordance with Compliance requirements.

Prohibited Arrangements

- A GPO may not be paid or retained, retained to plan, or otherwise organize an Advisory Board on behalf of Amgen.

Transparency of GPO Relationships

- When a GPO performs services for us, the respective roles of Amgen and the GPO must be explicitly disclosed to GPO Members or potential GPO Members, e.g., disclosing relationships of the parties at Speaker Programs.
- A GPO may not promote GPO services or membership when acting on behalf of Amgen.

Commercial Operations

The U.S. V&A group may serve as a contact for communication with Commercial Field-based Staff relating to Discount and Rebate terms, amendments, and contract administration issues. Nothing in these Compliance requirements are intended to restrict Commercial Field-based Staff from discussing Discount and Rebate terms and contract administration issues with individual GPO Members.

- Group Purchasing Organization Liaisons may proactively contact GPO representatives. USBO Staff who are not designated as GPO Liaisons may not proactively engage with a GPO representative. If a GPO representative contacts an USBO Staff member who is not designated as a GPO Liaison, e.g., whether about a Product, a contract term, or service, the USBO Staff member should refer the GPO representative to either a GPO Liaison or, in the case of a question of a clinical nature, Medical Information.
- In order to maintain independence and to avoid the appearance of impropriety, Commercial Field-based Staff may not engage with GPO Liaisons in joint calls to GPO Members or potential GPO Members. In the event of a contract dispute with a GPO where coordinated interaction is deemed critical by the GPO Liaison, a Commercial Field-based Staff member and/or a person within the U.S. V&A group may participate in a joint call with the GPO Liaison.
- On a reactive basis only, and if MAC approved, Commercial Field-based Staff may provide GPO Members and potential GPO Members with a list of GPOs that have GPO Product Agreements with Amgen but may not provide a comparison or rating of GPOs to potential GPO Members, discuss GPO business practices with potential GPO Members, or share data relating to potential GPO Members with any GPO. The U.S. V&A group shall maintain the list of GPOs with GPO Product Agreements.

CHAPTER 2: INTERACTIONS WITH MEMBERS OF THE HEALTHCARE COMMUNITY

7. INTERACTIONS WITH COMPENDIA

The information that follows provides only the U.S. Healthcare Compliance requirements for Compendia. More detailed procedural information can be found in the SOP: Compendia.

Submissions to Compendia

Medical

- Medical will maintain a list of Centers for Medicare and Medicaid Services (CMS)-recognized Compendia.
- Amgen submits both positive and negative material information concerning Amgen Products to CMS-recognized Compendia.
- Amgen submits information about our Products to CMS-recognized Compendia for the purpose of updating the CMS-recognized Compendia on new or important scientific data, or for the purposes of correcting material errors.
- When considering whether to submit new data to a CMS-recognized Compendia, we must not take into consideration whether or not the new data supports the continued or increased use of the Product.
- Amgen does not submit scientific information to CMS-recognized Compendia with the intention to promote or encourage the off-label use of a Product.
- All materials submitted to CMS-recognized Compendia must be objective, balanced, current, scientifically rigorous, and appropriately referenced.
- Except for the provision of pricing information regarding Amgen Products, Commercial Staff may not influence or participate in the decision to provide a CMS-recognized Compendia submission, the content of any submissions or financial support to a CMS-recognized Compendia.
- All interactions with CMS-recognized Compendia must be managed by Medical who serves as the RAE. No Amgen Staff member other than Medical are allowed to interact with the CMS-recognized Compendia for the purpose of providing clinical information related to drug monographs except with the prior approval of Medical.
- Submissions are prepared by individuals with appropriate scientific/medical training, experience and responsibilities within Amgen.
- All materials submitted to CMS-recognized Compendia must be reviewed and approved per applicable Compliance requirements prior to submission.
- Medical will retain copies of all submission correspondence and follow-up documentation in the appropriate system of record.

Review Content Annually

Medical Therapeutic Area Staff (that engage externally)

Medical will maintain a list of CMS-recognized Compendia to which we submit information.

On at least an annual basis, Medical reviews the current list of CMS-recognized Compendia to determine whether the list Amgen maintains needs to be updated. Medical will maintain a record of the review in the appropriate system of record.

On at least an annual basis, Medical will review our Product listing and monographs within each of the CMS-recognized Compendia to identify errors or inaccuracies. Medical will document the annual review in the appropriate system of record.

If Medical detects errors or inaccuracies relating to our Products, Medical will make a preliminary assessment of whether the error or inaccuracy should be raised to the U.S. Medical Leader (USML).

Initiate Interaction

Medical Therapeutic Area Staff (that engage externally)

Medical determines whether to initiate interactions with CMS-recognized Compendia based on the following events:

- Package Insert (PI) updates and/or safety communications,
- Correction of material error,
- Request for content review,
- Request for PI and references within the PI, or
- Availability of new clinically significant data.

Law

Law will review and approve submission packets prior to submission to CMS-recognized Compendia.

Law may request Regulatory Promotions to review submission packets.

Regulatory Promotions

Regulatory Promotions will review submission packets upon request from Law.

Review Financials Annually

Medical Therapeutic Area Staff (that engage externally)

Medical will conduct an annual review of all arrangements, processing fees, or other payments or financial support, if any, provided by us to any CMS-recognized Compendia. Medical will include Law or U.S. Healthcare Compliance in the review. Medical documents the annual review of financial support in the appropriate system of record. Any identified issues will be escalated consistent with Amgen policy.

8. OTHER INTERACTIONS

JOINT VISITS

Joint Visits with the Healthcare Community

A Joint Visit is an interaction with a member of the Healthcare Community that includes Amgen Staff members from both the Commercial and Medical functions. Joint Visits are not intended to be promotional.

Joint Visits can be an efficient and effective way of conducting important Amgen business and responding to customer needs. However, when not executed properly, Joint Visits can be seen as an attempt to engage in inappropriate marketing or promotional activity. The following rules regarding Joint Visits must be followed to ensure that Joint Visit activities are not perceived as an effort to engage in impermissible promotional activities.

You are responsible for protecting Amgen's integrity and should only engage in Joint Visits when necessary to further legitimate Amgen interests.

Joint Visits may occur if:

- There is a legitimate Amgen business purpose for the meeting, and
- It is a type of Joint Visit that is permitted.

CHAPTER 2: INTERACTIONS WITH MEMBERS OF THE HEALTHCARE COMMUNITY

Types of Permitted Joint Visits

- Joint Visits that do not include any Commercial Field-based or Medical Field-based Staff.
- Joint Visits that include Commercial Field-based and/or Medical Field-based Staff and the purpose of the Joint Visit is for one of the following reasons:
  - Introductory Visits that are intended to simply introduce one Field-based Staff member to a member of the Healthcare Community by a Field-based Staff member of the other function.
  - Payor/Formulary Visits with Payors, Formulary Committees or similar entities that are intended to discuss matters related to, and timely with a coverage determination, and in situations where separate visits are not practical.
- Other Joint Visits that have been approved in advance by U.S. Healthcare Compliance and the functional leadership of the Staff members proposing to engage in the Joint Visit. Requests for Other Joint Visits must be submitted at least ten (10) business days before the date of the meeting.

Introductions are Required

At the beginning of each Joint Visit, all Staff members must introduce themselves and their role with Amgen, to clarify who represents Medical, who represents Commercial, and any other functions present, for the members of the Healthcare Community.

Appropriate Engagement

You cannot use a Joint Visit to directly or indirectly engage in any activity in which you are otherwise prohibited from engaging. Engaging in a Joint Visit does not change the rules or boundaries of the conversations you can have with customers.

Determine if Joint Visit is Warranted

Consider whether you can meet your call objective without having your counterpart (i.e., Commercial or Medical) present in the meeting. If you can, then a Joint Visit should not occur. Joint Visits should only occur in the rare circumstance that both Commercial and Medical are required to be present to meet the call objective.

Recording and Conduct for Joint Visits

Medical Therapeutic Area Staff that engage externally need to record/report interactions with U.S. HCPs. All Joint Visits must be captured in the appropriate system of record and include all the following information:

- The members of the Healthcare Community present,
- Amgen Staff in attendance, and
- Description of the topics discussed.

Appropriate Subject Matter for Discussion

It is the responsibility of each Amgen Staff member participating in any Joint Visit to ensure that only appropriate subject matter is discussed during the Joint Visit.

For all Joint Visit types other than Payor/Formulary Joint Visits, appropriate subject matter includes any materials or topics that are approved for use by all Amgen Staff members participating in the Joint Visit.

For Payor/Formulary Joint Visits only, appropriate subject matter includes any materials or topics that are approved for proactive use by at least one Amgen Staff member participating in the Joint Visit. At Joint Visits where subject matter includes materials or topics that are not approved for

proactive use by all participants in the Joint Visit, only those Amgen Staff members for whom materials or topics are approved may participate in the discussion regarding that subject matter.

If a question is received during the Joint Visit that would require the discussion of inappropriate subject matter, but Amgen SOPs and requirements would permit at least one Joint Visit participant to respond to the question, the question may be answered if the answer is brief and does not alter the original purpose of the Joint Visit. While the question is answered, Amgen Staff members that are not approved to discuss the subject matter must not participate in the discussion. If the question requires a lengthy or detailed response, the answer must be deferred to the end of the meeting or must be addressed at a future meeting when only approved Amgen Staff members are present.

Materials for Joint Visits

You may only use materials approved through an applicable Company-approved process, e.g., MAC, SMRP, during a Joint Visit.

Responding to Unsolicited Requests for Information

Commercial Field-based Staff may not respond to questions or engage in discussions regarding Off-label Information about Amgen Products with members of the Healthcare Community. Off-label questions that arise in the context of a Joint Visit may be submitted to Medical Information for tracking and fulfillment in one of the following ways:

- By submitting a MIR or eMIR, or
- By forwarding an email received from the member of the Healthcare Community and copying the member of the Healthcare Community on the forwarded email to Medical Information.

For Joint Visits that Include Non-Field-based Staff

If the member of the Healthcare Community asks an unsolicited question that may only be addressed by providing Off-label Information, the Staff members must follow one of the approaches outlined below:

- If the question can be answered without changing the overall purpose of the discussion, the Medical Therapeutic Area Staff that engage externally may answer the question and the Commercial Staff member may remain present but must not engage in the response to the question. The response must be narrowly tailored to respond to the question asked. Upon providing the answer to the unsolicited question, the conversation must return to the original purpose of the interaction. Commercial Staff may not reference the conversation in subsequent meetings with the member of the Healthcare Community who were present at that Joint Visit.
- If the question cannot be answered without changing the overall purpose of the discussion, the Medical Therapeutic Area Staff that engage externally may (i) schedule a follow-up visit without Commercial Staff present to fully address the question, or (ii) terminate the current discussion, dismiss the Commercial Staff member, and repurpose the meeting to address the unsolicited question.

Joint Visits at Medical Congresses and Similar Events

Commercial Field-based Staff and Medical Field-based Staff may participate in Joint Visits taking place at medical congresses only in an introductory capacity. At medical congresses only, if during the introductory Joint Visit, an unsolicited question instigates an Off-label Information Product discussion, Commercial Field-based Staff who just served in an introductory capacity, may stay during that Product discussion.

Commercial Field-based Staff may not participate in an Off-label Information conversation, nor may they reference the conversation in subsequent meetings with the member of the Healthcare Community who were present at that Joint Visit.

Joint Visits that take place at a medical congress must be recorded in the appropriate system of record. However, a single document that captures all related Joint Visits that took place at the medical congress may be produced and housed in the appropriate system of record.

MEALS, GIFTS, EDUCATIONAL ITEMS, TRAVEL, AND HOSPITALITY

The information that follows provides only the U.S. Healthcare Compliance requirements for Meals, Gifts, Educational Items, Travel, and Hospitality. More detailed procedural information can be found in the SOP: Meals, Gifts, Educational Items, Travel, and Hospitality.

Government Employees

Meals provided to Government Employees should follow the U.S. Government Affairs & Policy SOP: Gifts to Government Employees.

Former Amgen Staff Retained to Provide Post-Employment Services

Meals, Travel, and Hospitality benefits with former Amgen Staff who have been retained to provide post-employment services relating to their vacated position at Amgen, should not exceed those that are available to other Amgen Staff in the former position.

Amgen Board Members

The Meal restrictions in this section do not apply to Meals with Amgen Board members who are acting in the capacity of an Amgen Board member.

Plans of Action and Scientific Engagement Plans

Staff members who have Plans of Action (POAs) or Scientific Engagement Plans (SEPs), who provide Meals, Light Refreshments, or Educational Items to members of the Healthcare Community must do so consistently with their POAs and SEPs.

Do Not Provide Meals, Gifts, Educational Items, Travel, or Hospitality to Unduly Influence Prescribing of Amgen Products

We do not provide Meals, Gifts, Educational Items, Travel, or Hospitality with the intent of, directly or indirectly, influencing or encouraging members of the Healthcare Community to purchase, prescribe, refer, sell, arrange for the purchase or sale, reimburse or recommend formulary placement of any Amgen Product, or as a reward for any such past behavior. Amgen does not provide Gifts or Entertainment to members of the Healthcare Community.

Do Not Aide or Assist with Completion of Forms

Amgen Staff are not allowed to complete forms on behalf of the HCP or the Patient. Examples include completion of prior authorization forms or reimbursement appeals.

Transfers of Value, e.g., Gifts, Meals, Educational Items

Amgen Staff are strictly prohibited from providing Gifts or Entertainment to any HCP, Healthcare Institution, Member of the Scientific Community, Purchaser, Professional Society and Trade Association or Payor.

Such restricted items include, but are not limited to:

- Items that have independent value to an HCP outside of his or her professional responsibilities, e.g., floral arrangements or tickets to a sporting event, even if the items could also be used to provide education to Patients, e.g., DVD or CD players.
- Items for the personal benefit of an HCP or a member of the HCP's family, e.g., clothing or golf balls, irrespective of whether they bear a company or Product logo.
- Cash or cash equivalents.
- Samples of Amgen Product provided for an HCP's personal or family use (as opposed to Patient use in accordance with the Prescription Drug Marketing Act).

The following items may be provided to Patients and shall not be considered Gifts under these Compliance requirements only if they are reviewed and approved in advance by GCO Law and your Compliance Lead:

- Co-payment assistance support provided through an approved program.
- Amgen-approved Patient support items such as sharps containers and Patient starter kits, or other items that are intended for the Patient's own use.
- Items that are provided directly to Patients to further Patient education.
- Other items of nominal value that are not intended to encourage improper Product utilization.

Following approval, partner with your Compliance Lead to create an execution plan that identifies the specific requirements for implementation of the approved Patient program. Submit the execution plan to Healthcare Compliance for document retention or store in the appropriate system of record.

Meals and Educational Items Annual Spend Limit

Meals and Educational Items, other than Meals provided to consultants, must be within the Amgen Annual Spend Limit for an individual member of the Healthcare Community in a single year. The Annual Spend Limit is posted on Amgen's external website. This does not apply to U.S. Government Affairs and Policy (U.S. GA&P) interactions with the U.S. Congress, as governed by the applicable U.S. GA&P policies and procedures.

Meals, Educational Items, and Hospitality Must Satisfy a Legitimate Business Need

Meals or Light Refreshments may only be provided to members of the Healthcare Community in connection with a legitimate business or scientific purpose, including but not limited to:

- Providing information about the benefits and risks associated with our Products.
- Providing scientific and educational information related to the clinical areas in which we have ongoing business or scientific interests.
- Obtaining legitimate and valuable feedback and information relating to areas in which we have business or scientific interests.
- Negotiating contracts and sale terms.
- Performing work under a bona fide service Agreement with Amgen or clinical trial Agreement, i.e., Consulting Meals.

Speaker Programs

Effective January 1, 2022, alcohol must not be provided at any Speaker Programs.

Incidental Meals furnished to attendees must be modest as judged by local standards, as well as subordinate in focus to the educational presentation.

CHAPTER 2: INTERACTIONS WITH MEMBERS OF THE HEALTHCARE COMMUNITY

General Meal Compliance Requirements

- Modest non-alcoholic beverages and modest small snacks, e.g., cookies and coffee, provided at congresses, meetings and headquarters-driven exhibit booths are not considered Meals and do not need to be recorded and tracked unless more restrictive federal or state restrictions apply. See here for guidance.
- Exhibit booths which have Commercial Field-based Staff as the RAE may not provide modest small snacks. More detailed procedural information can be found in the SOP: Exhibit Space.
- No alcohol may be provided during in-office or in-hospital Meals.
- No cash or cash equivalents, e.g., Gift cards can be given to Healthcare Professionals in lieu of paying for a Meal.
- At least one Amgen Staff member must actively participate when a Meal is provided and be present the entire duration of the Meal.
- Incidental Meals can be provided only where there is a reasonable expectation, and reasonable steps are taken to confirm, that each attendee has a substantive interaction or discussion with the Amgen Staff member.
- All Meals, Educational Items, Travel, and Hospitality expenses or reimbursements provided to members of the Healthcare Community must be recorded accurately in the appropriate system of record.
- Amgen will not pay for or reimburse any costs or expenses incurred by an uninvited person. The invited person is responsible for any costs incurred by the uninvited person.
- Reimbursement for a Caregiver, essential to an invited participant's care, is assessed on a case-by-case basis.

Only Provide Modest and Occasional Meals and Abide by Per-Meal Cost Limits

In connection with presentations or discussions, it is appropriate for occasional incidental Meals to be offered as a business courtesy to Healthcare Professionals, as well as members of their Staff attending presentations, so long as the presentations provide scientific or educational value, and the Meals provided are: (a) modest as judged by local standards; (b) not part of an Entertainment or recreational event; and (c) provided in a manner conducive to informational communication.

We are responsible for ensuring that Meals, which includes drinks, tax, and tip, are within per-Meal cost limits as follows:

Type	Breakfast/Lunch Meal Limit	Dinner
Out-of-Office/Hospital Meal	$50 per person	$150 per person
In-Office/Hospital Meal	$35 per person	$50 per person
Combination Breakfast/Lunch/Snack Out-of-Office Meetings, i.e., Advisory Boards	$150 per person (including snacks)	$150 per person

Commercial Field-based Staff Cannot Provide Out-of-Office Meals

Commercial Field-based Staff below the level of Regional Sales Director may not provide Out-of-Office Meals to a member of the Healthcare Community. This restriction does not apply to:

- Amgen Staff members with Account Management Roles having Meals with Payors or with individuals who primarily serve in institutional management, business, or administrative roles, e.g., medical directors, pharmacy directors, business executives.
- Speaker Programs

Only Provide Occasional Educational Items

Only items with the primary purpose of education of Patients of HCPs, e.g., an anatomical model for use in an examination room, may be offered to members of the Healthcare Community. You are strictly prohibited from providing items primarily designed for Patient Treatment, rather than for Patient or HCP education, e.g., stethoscopes or other medical equipment.

Educational Items must be reviewed, and MAC approved.

Only Educational Items offered as part of a headquarters-approved program and made available on a designated ordering system may be offered to members of the Healthcare Community.

Educational Items must have a retail value of less than $100 (excluding shipping and all taxes).

Educational Items offered to federal Government Employees cannot be valued at more than $20 (excluding shipping and all taxes), including subscriptions to scientific journals.

Educational Items may be provided in connection with informational presentations by Commercial Field-based Staff or by certain Medical Therapeutic Area Staff that engage externally in the context of disease or Treatment education of Healthcare Professionals or their Patients.

Educational Items may not be provided in the following settings:

- To attendees at an Amgen-supported Independent Medical Education (IME) event.
- In connection with contract negotiations relating to the purchase of Amgen Products or in connection with discussions relating to formulary placement of Amgen Products.

No more than two textbooks may be provided to any one Healthcare Professional per year.

Field-based Staff may not distribute textbooks directly to a Healthcare Professional.

Any transfer of value must be recorded in the appropriate system of record.

SCIENTIFIC RESEARCH

We may sponsor, fund, or otherwise support Scientific Research activities with the Healthcare Community that fill legitimate research needs on the part of Amgen.

All Scientific Research must contribute to Amgen's understanding of a Product, Product candidate, disease, therapeutic area, or Treatment alternative. All Scientific Research must be (1) funded, and (2) conducted or overseen by the R&D organization.

Scientific Research activities, discussions about clinical studies/trials, opportunity to participate in Amgen clinical trials or investigator-sponsored clinical studies will in no way be used as a tool for promoting Amgen Products or to solicit questions about Off-label Information.

All Scientific Research under these Compliance requirements must be reviewed and approved by an appropriate review body within Medical.

Medical Therapeutic Area Staff (that engage externally)

- Medical Therapeutic Area Staff that engage externally are responsible for all steps of the design and conduct of Scientific Research.
- Medical Therapeutic Area Staff that engage externally are responsible for the selection of investigators and institutions for Amgen Scientific Research.

- USMDs and MSLs may provide research support for Amgen-sponsored research and Investigator Sponsored Studies (ISSs) as requested by Medical.

Commercial Staff

- Commercial cannot fund Scientific Research.
- Commercial Staff cannot participate in the ISS decision process, or the selection of investigator or sites for Amgen-sponsored research activities. Commercial Staff can; however, recommend investigators and institutions for Scientific Research.
- If a member of the Healthcare Community informs you that he or she desires to participate in an Amgen-sponsored clinical trial or to apply for funding for an ISS, then you must refer the member of the Healthcare Community to the appropriate MSL. You must not discuss current or proposed Amgen clinical trials or ISSs with members of the Healthcare Community.
- You must not state or imply that a member of the Healthcare Community will, or will likely, be selected as a clinical trial investigator or provided funding for an Investigator Sponsored Study.

Investigator Meetings

Investigator Meetings may be conducted by appropriate Medical Therapeutic Area Staff that engage externally to convey or exchange information with investigators, sub-investigators, and other research site Staff to support the effective conduct or close-out of an Amgen-sponsored study. Investigator Meetings must not be held or used to promote Amgen pipeline or marketed Products, to induce meeting invitees to use or reward meeting invitees for using Amgen Products, or to recruit potential investigator or sites to participate in an Amgen study.

CHAPTER 3: FUNDING

1. COMPLIANCE REQUIREMENTS

During the normal course of business, we may enter into Agreements that involve providing funds, Compensation, or resources (collectively termed *funding*) to external parties, who are members of the Healthcare Community. Some examples of funding include, but are not limited to:

- Hiring a doctor to provide a service or advice,
- Purchasing data that is important for strategic planning,
- Donating lab equipment to an educational institution,
- Providing financial support to an organization that is engaging in activities that Amgen supports, or
- Making a charitable Donation for disaster relief.

When entering financial arrangements with members of the Healthcare Community, all Amgen Staff must adhere to the following Compliance requirements:

- All financial arrangements must be pursuant to a legitimate Amgen business or scientific need.
- No Amgen Staff may enter into a financial arrangement with a member of the Healthcare Community with the intent of influencing any prescribing, coverage or other decisions or positions.
- Financial arrangements may not be used to build favor or further relationships with recipients.
- All financial arrangements must be prudent, based on arm's length transactions and represent appropriate use of Amgen resources. The terminology used by a third party to describe the funding opportunity is not determinative. Amgen determines acceptable criteria for funding based on the nature of the funding opportunity.

Any funding to members of the Healthcare Community must follow applicable Healthcare Compliance review and approval processes.

All Research Collaboration Agreements with U.S. Covered Individuals and Entities, and certain U.S. non-Covered Individuals and Entities as determined by Healthcare Compliance on a case-by-case basis, must follow the applicable compliance rules in the U.S. Compliance requirements. However, the procedures for their initiation, approval and execution are owned by Research and Development (R&D). This Chapter provides the minimum Compliance requirements for compliantly executing a variety of such funding and applies to those who receive, review, approve, create, or process funding requests.

CHAPTER 3: FUNDING

In addition to the applicable principles in our Global Corporate Compliance Policies and the processes outlined in Standard Operating Procedures:

- Follow all laws, regulations, and applicable industry guidelines, reporting and disclosure requirements, and local and Country Specific Requirements for conducting Amgen activities.
- Know the guardrails and requirements for all Amgen activities you engage in.
- Do not offer or provide any Agreements, services, or funding to a member of the Healthcare Community to directly or indirectly, influence or encourage the member of the Healthcare Community to purchase, prescribe, refer, sell, arrange for the purchase or sale, reimburse or recommend formulary placement of any Amgen Product or to reward past, present, or future business.
- Follow the appropriate review and approval process for all materials used externally.
- Be truthful, balanced, and scientifically rigorous in materials and discussions.
- Use venues that are appropriate and reasonable when conducting Amgen business.
- Maintain accountability as a Responsible Amgen Employee (RAE) for your Amgen activities, regardless of who conducts them.
- Ensure Amgen activities support legitimate business or scientific needs.
- Engage only with parties qualified to provide their services.
- Pay expenses only to parties with whom we are in an Agreement.
- Document Agreements and applicable consents in writing and fully execute them prior to any services, goods or confidential data being provided.
- Ensure services are provided only during the active term of an executed Agreement.
- Ensure that performance of any compliance requirement activities by a third party are authorized by written approval from Healthcare Compliance and Law.
- Do not provide Gifts or Entertainment to those with whom we conduct business.
- Do not use personal funds to conduct Amgen business.
- Do not engage with any parties on any Exclusion Lists, including those hired by third parties.
- Do not allow inappropriate uninvited guests to participate or attend Amgen activities.
- All compliance requirements apply regardless of whether the interaction is in-person or virtual.

Certain capitalized terms are defined in the Healthcare Compliance Glossary.

The information that follows provides only the U.S. Healthcare Compliance requirements for Agreements with Covered Individuals/Entities and Agreements with Patients. More detailed procedural information can be found in the SOPs: Agreements with Covered Individuals and Entities; and Agreements with Patients.

2. GENERAL REQUIREMENTS FOR FUNDING

The Compliance requirements outlined below apply to all financial arrangements with members of the Healthcare Community unless otherwise noted:

- Unless approved by headquarters, never actively promote the availability of Amgen funding opportunities, or directly or indirectly make any promises, representations, or guarantees for funding prior to approval.
- Funding may not be used to further otherwise inappropriate activity, or to circumvent our policies, Compliance requirements, and any other guideline, including government laws and guidelines.
- All funding including Advocacy Relations Activities and Government Affairs should be conducted in a manner that avoids the creation of a conflict of interest.

- All covered persons engaged in Advocacy Relations activities shall respect the independence of the third-party Advocacy organization in terms of its political judgement, policies, and activities.
- We will not engage in any funding which results in any Gifts being given to any recipient, this includes items with Amgen's company or Product logos, e.g., pens, tote bags, tee shirts, etc. This does not include funding related to sporting events such as fundraisers like walks, cycling, runs, etc. where the sponsor's logos which may also include the Amgen logo appearing on apparel designed for all event participants and/or for the Staff of the event. At such events, where giveaways are provided, the RAE must ensure that a sign is posted informing Healthcare Professionals (HCPs) that pursuant to the Pharmaceutical Research and Manufacturers of America (PhRMA) Code, the HCP may not take any such giveaway items.
- We will not fund activities intended to provide data, messages, other information, or any other activities that we are not permitted to do ourselves.
- If you are a Staff member who serves as a board member or are in similar position of authority, or perform administrative or management duties, or have some other significant affiliation with an organization that will receive our funding, you must not be involved in decisions related to the funding provided to that organization.
- All funding approvals must be obtained from an individual with the appropriate Signature Authority, per Global Finance Policy Commitment and Expenditure Signature Authorization.
- The only funding that Regional Sales Directors and below may provide, would be for Exhibit Space. More detailed, procedural information can be found in the SOP: Exhibit Space.
- You may not submit funding requests on behalf of anyone who is prohibited from doing so.
- You must never enter into any Agreement if doing so is not within your role and responsibilities.
- No funding may be provided in order to satisfy or be perceived to satisfy a quid pro quo.
- Funding to an entity must never directly or indirectly benefit any specific individual that may have a close relationship or control over the entity.
- Any changes to funding Agreements must be treated as a new Agreement. That is, it must be appropriately re-reviewed and re-approved.
- All costs, fees, Compensation, etc., related to funding should reflect Fair Market Value (FMV) if applicable, and/or be in line with industry standards.
    - Only legitimate and reasonable expenses for travel, accommodation and related expenses incurred by contracted parties will be reimbursed, unless prohibited by other Amgen policies, Amgen Compliance requirements, or applicable laws, regulations, or guidance.
    - If you are an Amgen Field-based Staff member, you are not allowed to negotiate, agree to, or adjust any costs and fees, e.g., room fees, associated with any funding, compensation, or payment.
- In consulting arrangements with former Amgen Staff who have been retained to provide post-employment services relating to their vacated position at Amgen, Compensation and travel benefits should not exceed those that are available to other Amgen Staff in the former position.
- There must exist in an appropriate system of record, documentation that goods, services, or data etc., have been rendered pursuant to the funding paid, or contract terms, as applicable.
- Recipients of our funding will be open and transparent, and where appropriate and/or required, disclose that they have received funding from Amgen. This includes any disclosure requirements that the recipient may be obligated to follow depending on the recipient's employer, affiliation, association, etc.
- All Agreements and Payments must be processed through Amgen in the appropriate system of record.

- All payments must:
    - Be consistent with the terms of the Agreement,
    - Provided only after an Agreement is fully executed,
    - Be paid following receipt of any benefits or services, as applicable, consistent with the terms of the funding Agreement,
    - Be paid directly to the contracted party,
    - Be paid through Amgen's financial system of record, and
    - Be tracked and reported appropriately.

Discussions about Funding

Amgen Role	Permitted Discussions about Funding
Sales organization: District Sales Manager (DSM) level and below	May not engage in discussions about a proposed Agreement. However, may provide other Amgen Staff with information about a member of the Healthcare Community's qualifications or interest in providing services, goods, or data to Amgen.
Sales organization: Above DSM level	May hold discussions with members of the Healthcare Community in connection with the development of a proposed Agreement but may not make any commitments regarding the scope of the Agreement or Compensation.
All Other Staff	May hold discussions with members of the Healthcare Community in connection with the development of a proposed Agreement but may not make any commitments regarding the scope of the Agreement or Compensation.

Members of the Healthcare Community can learn how to submit a Donation request through the external Amgen website www.amgen.com.

DONATION REQUESTS AND INQUIRIES BY INTERNAL AMGEN STAFF

R&D Staff

Amgen Staff in the R&D organization may submit Donation requests on behalf of members of the Healthcare Community through R&D Operations. R&D Staff may not submit Donations request on behalf of Amgen clinical investigators or follow up regarding submitted requests on behalf of clinical investigators.

Commercial Staff

Amgen Staff in U.S. Business Operations (USBO) may not submit Donations requests on behalf of members of the Healthcare Community and may not follow up on submitted requests on behalf of members of the Healthcare Community. Direct inquirers to the Amgen website Donations portal.

- No Amgen Staff member who is otherwise eligible to submit Donation requests directly to the Medical organization may submit a request on behalf of, or at the request of Amgen Staff in USBO who are otherwise ineligible to submit requests.
- Senior Leadership (i.e., Executive Staff, General Managers and above and the head of Global Marketing within USBO) are not subject to the limitation immediately above and may submit requests directly to the Medical organization.

Other Staff

Amgen Staff in Advocacy Relations or Government Affairs may submit Donation requests on behalf of members of the Healthcare Community.

Amgen Staff in Corporate Philanthropy, including Site Communicators, may submit Donation requests on behalf of members of the Healthcare Community.

Any inquiries by a Requestor regarding the status of a pending request should be referred to the Medical organization for further handling.

CHAPTER 3: FUNDING

3. DONATIONS

The information that follows provides only the U.S. Healthcare Compliance requirements for Donations. More detailed procedural information can be found in the SOP: Donations.

Charitable Donations

The Amgen Foundation may provide financial or Product support to members of the Healthcare Community to support charitable purposes such as disaster relief, research support, Donation of equipment or other purposes that are consistent with the Amgen Foundation charter and mission pursuant to the following requirements:

- Other than members of the Amgen Operating Team, members of U.S. Business Operations (USBO) may not be involved in any Donations made by the Amgen Foundation.
- No return on investment or similar analyses may be performed that connect the Donation to utilization of Amgen Products.
- Recipient must be a certified not-for-profit or non-profit organization.

Amgen may only make Donations to members of the Healthcare Community for the following purposes:

- The support of science, technology, medicine, healthcare, or education.
- Education of the public on disease-states, medical conditions, science, or technology.
- In furtherance of other genuine philanthropic and charitable purposes that are consistent with Amgen's scientific and disease-state interests.

Types of Donations provided to Qualified Recipients may include only the following:

- Support for educational activities, including, but not limited to, fellowship programs (excluding those programs that include internships/externships with Amgen), endowed professorships, scholarships, and public education programs (excluding Independent Medical Education).
- Patient Advocacy programs.
- Other giving or funding to members of the Healthcare Community to support programs and initiatives consistent with the stated purposes above, including charitable Donations such as payments for fundraising events that provide only incidental benefits to Amgen, consistent with customary donor recognition practices.

Donation Requirements

- Donations must never (i) be offered or provided with any intent (actual or perceived) to induce, reward, or influence the purchasing, prescribing, or use of Amgen Products or to influence regulatory, pricing, formulary, or reimbursement decision, (ii) be conditioned on the value or volume of Amgen's sales made or anticipated to the requesting organization; or (iii) be provided or otherwise intended for promoting Amgen Products or gaining access to Amgen's customers.
- Donations must not be (i) linked, directly or indirectly, to an Agreement to use, prescribe, recommend, or refer Amgen Products or (ii) used to reward past business.
- The Donation must not be for the purpose of benefitting any Amgen Staff or Board member.
- Donations must never be made contingent on the performance of services or in lieu of payment for a fee-for-service activity.
- The Donation must be given directly to the Qualified Recipient and must be unrestricted.
- If an activity is funded by a Donation, the activity must be wholly independent from Amgen's control.

- No Donations may be made to buy or maintain credibility or relationships, or other similar purposes.
- The Amgen organization making the Donation must own the budget from which the Donation is made.
- No Donations may be made to support Product-related activities or events.
- No return on investment or similar analysis may be performed that connects the Donation to utilization of Amgen Products.
- When possible, Amgen must require the recipient to disclose financial support from Amgen.
- Amgen Staff in USBO may not be involved in the review, approval, or decision-making process for any individual Donation request from members of the Healthcare Community.

Donation Review and Approval

All requests for Donations to the members of the Healthcare Community must be processed in the Medical organization's system of record.

All requests will be reviewed and either approved or rejected by a designated representative of either Advocacy Relations, Government Affairs, Corporate Philanthropy (including Site Communicators), or R&D.

Donations made by Advocacy Relations or Government Affairs

Advocacy Relations and Government Affairs may consult and seek input from R&D and Commercial in order to ensure a consistent Amgen strategy and approach to interactions with Advocacy organizations. However, Advocacy Relations and Government Affairs shall develop specific tactics independently based on a legitimate Advocacy interest only. R&D and Commercial (Marketing, Sales) may not direct Advocacy Relations or Government Affairs tactics or resource allocation decisions.

Amgen may provide financial support to a non-profit Patient or professional Advocacy entity in order to support that entity's overall mission pursuant to the following requirements:

- RAE must be from the Amgen Advocacy organization or the Amgen Government Affairs organization.
- Advocacy Relations Donations must be for genuine and bona fide charitable or healthcare related purposes.
- The recipient organization must be a bona fide charitable organization recognized by the Internal Revenue Service (IRS) as tax exempt under section 501(c)(3), 501(c)(4), and 501(c)(6) of the IRS code. Other entities may qualify on a case-by-case basis.
- Recipient may not be a provider, an entity owned by a provider, or similar institution.
- Amgen support is generally limited to 35% of the overall event/initiative budget or fundraising goal. Amgen support may exceed that percentage on a case-by-case basis with appropriate justification and Compliance approval.
- On an annual basis, the total amount of Amgen funds provided to the recipient organization must not exceed 49% of the entity's prior year income.

Donations made by Corporate Philanthropy and R&D

Amgen may make Donations to Qualified Recipients that are one of the following:

- Hospitals, universities, Patient groups, or other organizations exempt from federal income tax under Internal Revenue Code Sections 501(c)(3) (charitable organizations), 501(c)(4) (social welfare organizations), and 501(c)(6) (trade and professional associations).
- Other not-for-profit entities that Amgen determines will use the funding in furtherance of the purposes set forth below:
    - The support of science, technology, medicine, healthcare, or education.
    - Education of the public on disease-states, medical conditions, science, or technology.

- In furtherance of other genuine philanthropic and charitable purposes that are consistent with Amgen's scientific and disease-state interests.

Patient Assistance Program Donations

- Amgen may provide Donations to independent charitable Patient Assistance Programs that provide financial support to financially needy Patients. For more information about requirements for Donations to independent charitable Patient Assistance Programs, please see Chapter 6: Interactions with Patients and Related Support Programs.

INDEPENDENT MEDICAL EDUCATION (IME)

The information that follows provides only the U.S. Healthcare Compliance requirements for Independent Medical Education. More detailed procedural information can be found in the SOP: Independent Medical Education.

Amgen may provide financial support to medical education providers to support Independent Medical Education.

General Rules Governing IMEs

- Any Amgen Staff member receiving a request for IME funding will direct the Requestor to the external Amgen website, www.amgen.com.
- We do not issue request for proposals (RFPs) to solicit IME funding requests. However, the Medical organization is permitted to communicate areas of interest to medical education providers.
- Amgen Staff will not assist members of the Healthcare Community with the IME funding request process, e.g., by advising the members on completion of the request, completing and/or submitting a request on behalf of a member, or attempting to advocate funding for a request. Medical may provide general information about requirements for completion of the request.
- Amgen will fund IME based on the following objective criteria: the quality of the proposed IME program; the alignment of the proposed IME program to established educational goals (which focus on unmet clinical, educational or professional practice needs in therapeutic areas of interest to Amgen); and the completeness of the IME funding request.
- IME funding decisions will not take into account the current or potential customer status of the IME Requestor.
- Commercial Staff are not involved in decisions to fund IME programs.
- The Medical organization shall have sole responsibility for funding IME.
- If a member of the Healthcare Community has questions about a rejected request or has questions or seeks an update on the status of a pending IME request, the Amgen Staff member receiving the inquiry must direct the Requestor to contact Medical Operations via email at hccime@amgen.com.
- All communications regarding IME funding decisions will come from Medical Operations.
- Healthcare Professional attendees should not be offered Compensation for time spent participating in the IME event.
- Financial support for IME will not be provided for Meals at the event or for the costs of travel, lodging, or other personal expenses of non-faculty HCPs attending the event, either directly to the individuals participating in the event or indirectly to the event's provider.
- An educational conference organizer may offer financial assistance for scholarships or other educational funds to permit medical students, residents, fellows, and other Healthcare Professionals in training to attend educational conferences so long as the selection of individuals who will receive the funds is made by the academic or training institution.

- If an IME program occurs as a part of a broader activity involving members of the Healthcare Community, such as an IME program at a professional society meeting, Amgen may separately sponsor activities, purchase Exhibit Space or purchase advertising space in materials unrelated to the IME program as permitted by other applicable SOPs, e.g., Exhibit Space; Corporate Sponsorships and Corporate Memberships.
- The IME provider must be instructed to disclose Amgen funding at the activity, and if applicable, Speakers, faculty or organizers must also disclose Amgen funding to their respective companies/employers.

Independence of IMEs

IME programs will be developed and implemented without any Amgen Staff involvement. The content, organization, and operation of the IME activity must be independent of Amgen's control and influence. In order to preserve the integrity and independence of Amgen IME support, Amgen Staff may not:

- Assist the Requestor with the application process.
- Offer any assistance to the IME provider nor respond to any requests for assistance from the IME provider concerning the IME program (e.g., planning for an IME program; suggestions for education topics, invitees, or faculty members; providing materials; assisting with content development; or providing a technical review of IME content).
- Perform a return on investment or other analysis that measures commercial outcomes with Amgen-funded IME events.
- Proactively promote the availability of IME funding and/or solicit IME program submissions from Amgen to members of the Healthcare Community for any reason, e.g., as a means to obtain access to those members.
- Suggest or imply to any member of the Healthcare Community that they have any influence on the IME funding process.
- Purchase advertising in IME programs funded by Amgen.
- Promote or distribute an IME program funded by Amgen, e.g., through distribution of invitations or otherwise.
- Be faculty members at an Amgen-supported IME programs.

Approval of IME Requests

The Medical organization owns the budget and reviews and approves IME funding requests.

At least on an annual basis, the appropriate governing body reviews and approves areas of interest goals and funding allocation and retains documentation of its decisions.

Educational goals will be reviewed by GCO Law.

Staff Attendance at IMEs

Amgen Staff may attend Amgen-supported IME activities as silent observers to stay current on scientific, clinical, and unmet educational needs associated with relevant therapeutic areas and to evaluate the quality of the program. All attendees must comply with medical conference rules on company participation and the Accreditation Council for Continuing Medical Education (ACCME) standards for commercial support. Amgen Staff attending such events must not:

- Engage in Product discussions.
- Ask questions or request someone else to ask questions of Speakers or presenters.
- Participate in any promotional activities including providing Meals, Entertainment, or promotional materials.

Staff may speak at non-Amgen funded IME programs when all of the following conditions are met:

- The IME provider has made an unsolicited and independently crafted, written request for the Amgen Staff member to speak. The request must also contain the rationale for the Amgen Staff member to serve as a Speaker.
- The selection of an Amgen Staff member as a Speaker must be made independently by the IME provider. Amgen Staff must not play a role in drafting the written request submitted by the IME provider.
- Our Staff member is qualified to deliver the presentation on the specific topic.
- Activity must be approved by the Speaker's supervisor.
- Medical or other functions within R&D shall review and approve or deny the request. The presentation must be approved through the applicable review and approval process (e.g., Materials Approval Compliance (MAC), Scientific Materials Review Process (SMRP), Final Publication Review (FPR), to safeguard Amgen proprietary information).

If you learn of any Product or safety related inaccuracies or misrepresentations of U.S. FDA-approved labeling during an Amgen funded IME event, you must report the misinformation to the Medical organization.

Review of IMEs

The Medical organization will regularly evaluate IME programs to assess the quality of the program and conduct a reconciliation of the program costs.

4. SPONSORSHIPS

The information that follows provides only the U.S. Healthcare Compliance requirements for Corporate Sponsorships and Corporate Memberships. More detailed procedural information can be found in the SOP: Corporate Sponsorships and Corporate Memberships.

Sponsorship activities should be developed and operated independently from Amgen.

Amgen may provide financial support to covered entities to support activities where Amgen receives a Tangible Benefit. Amgen must receive a Tangible Benefit that goes beyond simple recognition of support. Examples may include:

- Participation in a round table discussion,
- Access to data or other information, or
- Ability to conduct targeted advertising.

We will not approve Sponsorships that provide financial support or free goods to Patients.

You must upload proof of receipt of Tangible Benefits and evidence demonstrating use of Corporate Memberships into the Healthcare Compliance system of record.

Sponsorships with Enduring Materials

In addition to the above, sponsorships for activities that will result in enduring materials must also adhere to the following requirements:

- If enduring materials will discuss Amgen Products, funding may only be provided to activities that will only discuss uses of Amgen Products that are consistent with the U.S. FDA-approved labeling.
- If Amgen is the sole sponsor of the activity resulting in Enduring Materials, Amgen must retain the right to review materials prior to dissemination.
- Amgen review shall only address the clinical accuracy of the material and shall not be used to further an Amgen Product message.
- If the enduring material is Product or disease-state related, GCO Law and Regulatory Promotions should review.

Corporate Memberships

Amgen may purchase memberships to multi-party organizations pursuant to the following requirement:

- Upon renewal of membership, the RAE must be able to document use of membership benefits.

5. PURCHASING GOODS AND SERVICES

Amgen may purchase goods or services from members of the Healthcare Community pursuant to the following requirements:

- The RAE must demonstrate that the good or service is connected to a legitimate Amgen business or scientific interest.
- The amount paid to the member of the Healthcare Community represents the Fair Market Value for such goods or services in the open market and pursuant to an “arm’s length” transaction.

Data Purchase Arrangements or Subscriptions

Must follow the processes and procedures established by the Commercial Data and Analytics organization.

May not be used to purchase data that Amgen already owns or has access to or is otherwise unnecessary or unusable.

Renewal of data subscriptions must include an explanation of how the data has been used at Amgen.

Collaborations

Collaborations are an Agreement between Amgen and a member of the Healthcare Community to develop science, information, data, or insights, to better inform and potentially improve both the clinical outcome and experience of Patients. An example of a collaboration is a value-based partnership where two or more organizations share a mutually beneficial endeavor to deliver the highest value to the healthcare system and society by focusing on improving Patient outcomes (e.g., clinical outcomes, quality metrics and Patient satisfaction) in the context of system and societal total costs.

- All Amgen contributions must directly benefit the collaboration.
- Never enter a collaboration to perform an entity’s core function.
- Amgen and other entities in the collaboration have joint decision-making authority.
- Must involve mutual contribution and benefit that is reasonably related to the value in the ownership of the output of the collaboration.
- All parties to the collaboration must be aligned on the time frame of the overall partnership as well as metrics, milestones, and phases that are to be completed as part of the collaboration.

Coalition Building Initiated by Advocacy

If there is a legitimate need, Amgen may catalyze the bringing together of individuals and/or organizations that share common goals to create a new coalition or Advocacy group. Creation of such a coalition or Advocacy group must be based on a legitimate Amgen business need and aligned with the U.S. Advocacy Relations group’s strategic goals.

The creation of a new coalition or Advocacy group must respect the independence of the newly created entity (including the independence of its political judgment, policies and activities). This means the newly created entity must be set up as a non-profit that operates independently from Amgen.

CHAPTER 3: FUNDING

Amgen may enter an arrangement with an entity or multiple entities that may be members of the Healthcare Community that provides financial, administrative, or organizational support to create a coalition that would not exist without Amgen support. Such a coalition may not be established to encourage or influence further utilization of Amgen Products. In addition, the following requirements must be followed:

- RAE must be an Advocacy Relations Director.
- A vendor may be used to establish the newly formed entity.
- RAE must engage with Law and Healthcare Compliance before engaging in any such activities.
- An engagement plan must be developed that includes descriptions of:
  - Legitimate need for Amgen to participate/fund the coalition/Advocacy group,
  - Amgen's role/ongoing role in the newly formed entity,
  - Proposed structure/governance/membership seeking plan/activities,
  - A defined timetable to establish an independent structure and governance, as well as recruit multiple active members, and
  - Funding and gated plan with milestones.
- The engagement plan must also include an exit plan with a reasonable timetable that describes how Amgen will exit from the coalition or group as needed.
- Amgen may fund up to 100% of the seed funding:
  - Seed funding must be interim, and
  - Newly formed entity must find alternate forms of funding within a defined timeframe.
- Amgen involvement/funding must be appropriately disclosed in materials and activities.
- Newly created entity (coalition) must be:
  - Independent of Amgen, and
  - A non-profit organization.
- No promotional interactions or engagements permitted between Amgen and the Coalition.

CHAPTER 4: INTERNAL BUSINESS STRATEGY AND PLANNING

1. COMPLIANCE REQUIREMENTS

Our success as a business is reflected by the way we serve Patients and satisfy our shareholders. Setting appropriate strategy and internal business planning is a key to achieving success. As we develop business plans and strategies, we must remember that while we are comprised of multiple and distinct functions, we form one Amgen with a single mission to serve Patients.

As we embrace our approach to serving Patients, we must also recognize that we are a company made up of distinct functions with differing governing requirements, expectations, and measures of success. Therefore, business planning and strategy development activities should adhere to the following Compliance requirements:

- Our business strategy should reflect legitimate and appropriate business objectives.
- Cross-functional planning activities should never create the appearance that one function is seeking to control another function or its resources.
- All cross-functional planning documents and materials should reflect the overall Amgen strategy but should avoid combining individual, function-specific tactics and objectives.

This Chapter outlines the compliance requirements necessary to appropriately conduct certain activities related to internal business planning and strategy and applies to those involved or participating in such activities.

In addition to the applicable principles in our Global Corporate Compliance Policies and the processes outlined in Standard Operating Procedures:

- Follow all laws, regulations, and applicable industry guidelines, reporting and disclosure requirements, and local and Country Specific Requirements for conducting Amgen activities.
- Know the guardrails and requirements for all Amgen activities you engage in.
- Do not offer or provide any Agreements, services, or funding to a member of the Healthcare Community to directly or indirectly, influence or encourage the member of the Healthcare Community to purchase, prescribe, refer, sell, arrange for the purchase or sale, reimburse or recommend formulary placement of any Amgen Product or to reward past, present, or future business.
- Follow the appropriate review and approval process for all materials used externally.
- Be truthful, balanced, and scientifically rigorous in materials and discussions.
- Use venues that are appropriate and reasonable when conducting Amgen business.
- Maintain accountability as a Responsible Amgen Employee (RAE) for your Amgen activities, regardless of who conducts them.
- Ensure Amgen activities support legitimate business or scientific needs.
- Engage only with parties qualified to provide their services.
- Pay expenses only to parties with whom we are in an Agreement.
- Document Agreements and applicable consents in writing and fully execute them prior to any services, goods or confidential data being provided.
- Ensure services are provided only during the active term of an executed Agreement.
- Ensure that performance of any compliance requirement activities by a third party are authorized by written approval from Healthcare Compliance and Law.
- Do not provide Gifts or Entertainment to those with whom we conduct business.
- Do not use personal funds to conduct Amgen business.
- Do not engage with any parties on any Exclusion Lists, including those hired by third parties.
- Do not allow inappropriate uninvited guests to participate or attend Amgen activities.
- All compliance requirements apply regardless of whether the interaction is in-person or virtual.

Certain capitalized terms are defined in the Healthcare Compliance Glossary.

CHAPTER 4: INTERNAL BUSINESS STRATEGY AND PLANNING

2. GENERAL REQUIREMENTS FOR INTERNAL BUSINESS PLANNING & STRATEGY-RELATED ACTIVITIES

The Compliance requirements outlined in this section apply to all internal business planning and strategy-related activities. Specifically, these general Compliance requirements must be followed for all activities in addition to any Compliance requirements for specific activities outlined in the sections below.

Internal Business Planning and Strategies

All internal business planning and strategies must:

- Be based on and consistent with the U.S. FDA-approved labeling and appropriate uses for Amgen marketed Products; or be intended for the appropriate uses for Pipeline Products.
- Never encourage anti-competitive behavior or generate an unfair business advantage.
- Not be discussed or used to coordinate with competitors or such accounts to avoid creating a risk of violating any antitrust and/or competition laws.

3. INTERNAL CROSS-FUNCTIONAL STRATEGIC PLANNING

In order for our company to perform at its best to serve the needs of Patients and shareholders, different functions may need to interact with one another. These interactions may sometimes involve sharing information, gaining alignment, coordination, or collaboration, to name a few.

Meaningful Coordination

Meaningful coordination between the Medical and Commercial organizations is not only appropriate but expected. However, these functions have unique purposes and are governed by different sets of legal, regulatory and Compliance requirements.

Separate Medical and Commercial Organizations

Government agencies, such as the Office of Inspector General (OIG) for the U.S. Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA), have provided written guidance regarding the importance for pharmaceutical companies to separate their Medical and Commercial organizations. Therefore, there is a critical need to maintain the independence of our Medical and Commercial organizations.

Amgen Staff

Our Medical Staff are responsible for the development, education, and communication of scientific information. They perform non-promotional activities that enhance Patient care and the practice of medicine. Medical Staff are not incentivized based on individual sales performance.

Our Commercial Staff are directly or indirectly responsible for promotional activities. Many Commercial colleagues are involved in promoting the use, purchase, prescription or recommendation of our Products. Others are responsible for marketing or reimbursement, which are indirect promotional activities.

COMPLIANCE REQUIREMENTS FOR INTERNAL CROSS-FUNCTIONAL INTERACTIONS

The Compliance requirements below don't address all aspects or details of every internal cross-functional interaction. If you are not sure whether you are permitted to, or how best to interact with another organization, contact your Compliance Lead for assistance.

CHAPTER 4: INTERNAL BUSINESS STRATEGY AND PLANNING

Have Clear and Distinct Roles, Responsibilities, Objectives, and Activities

The roles, responsibilities, and objectives of Commercial and Medical functions must be clear, separate, and distinct from each other. Interactions between Medical and Commercial functions must satisfy each function's separate and independent legitimate business need.

Function-specific activities, tactics, and goals must always be driven by the individual function's priorities and objectives. That is, Commercial activities and planning must be separate from Medical activities and planning.

Do Not Direct One Another

The Commercial or the Medical organization must never directly, indirectly, dictate or direct, or be perceived to dictate or direct the other's activities.

Planning, Strategy, and Information Sharing

Medical and Commercial may interact at a strategic level, but their function-specific tactics must be developed and executed separately.

General information, such as organizational plans, results, etc. may be shared between Medical and Commercial if the intent is to inform the other group on a strategic level.

Functions should seek to share meaningful and useful information, data, and insights cross-functionally in order to assist one another in reaching function-specific priorities.

Information related to specific customers which may help with access, i.e., logistics, names of assistants, etc. may be shared between Medical and Commercial colleagues. However, information that can be perceived as being more directive for the other organization, i.e., prescription data, notes on specific interactions which can be perceived to drive conversations, etc. should not be shared between Medical and Commercial.

TRAINING-RELATED COMPLIANCE REQUIREMENTS

There may be circumstances where internal Staff are trained by other internal Staff. Below are key Compliance requirements that you must be aware of for such instances.

Provision of Training to Commercial Field-based Staff

Appropriately trained Medical Staff may conduct scientific training to Commercial Field-based Staff.

Medical Staff leadership may review and approve, if appropriate, written training requests submitted by the Sales District Managers or Sales Training for one-on-one Commercial Field-based Staff training that is consistent with the U.S. FDA-approved labeling.

The approval of these one-on-one trainings must be granted prior to their taking place. The request must include a description of the legitimate need for the interaction and the approved materials to be used.

Any request for training to Commercial Field-based Staff that includes Off-label Information must be approved in advance by Medical Staff leadership and Material Approval Compliance (MAC). To obtain approval, the request must include documentation of legitimate training needs and the materials to be used. The approvals for training are stored in the appropriate system of record.

All training materials to Commercial Field-based Staff must be appropriately approved.

Commercial Field-based Staff Access to Training or Other Informational Materials

If you are a Commercial Field-based Staff member:

- You are only permitted to have access to our internal training or educational materials relating to Amgen Products if those materials have been MAC approved for such use.
- You are not permitted to access or utilize Research and Development (R&D) materials, Staff, or support systems, e.g., Medical Information, to request or obtain Off-label Information or pre-approval information, even if the stated purpose is solely for informational or educational purposes for the Commercial Field-based Staff.

Materials for Internal Training Purposes to MSLs and USMDs

The following internal Product or disease-state education materials must be reviewed by qualified R&D Staff:

- Therapeutic training curriculum,
- Materials specifically developed and created for USMD or MSL training containing scientific and/or clinical content, and
- Slide decks developed by external consultants.

The following internal Product or disease-state education materials do not need review:

- Non-therapeutic materials, and
- Non-modified articles from the literature.

4. INCENTIVE COMPENSATION (IC) & CALL PLANS FOR COMMERCIAL STAFF

The information that follows provides only the U.S. Healthcare Compliance requirements for Incentive Compensation and Call Plans. More detailed procedural information can be found in the SOP: Incentive Compensation and Call Plans.

Consistent with the U.S. FDA-approved Labeling

Diligent measures must be taken to develop IC plans that are reasonably attainable based on sales that are consistent with the U.S. FDA-approved labeling, reward promotion that is consistent with the U.S. FDA-approved labeling, and do not encourage or reward Off-label Promotion of any Products.

Support Appropriate Competitive Behavior

We don't design IC Plans to drive anti-competitive behavior. An IC Plan must not encourage activities that result in gaining an improper business advantage in the marketplace.

The factors to consider in assessing appropriate competitive behavior include, but are not limited to, competitive entrants and current market dynamics.

Target Appropriate Specialties

Where feasible and appropriate, IC Plans must either:

- Target a pre-approved list of approved specialties.
- Exclude specialties that are unlikely to treat Patients for conditions indicated in the U.S. FDA-approved labeling for the Product.

Qualifications for Incentive Compensation

In order to be eligible for the IC Plan, you must be designated as a Sales Incentive employee in Human Resources (HR) or treated as a Participant in some or all of the Amgen Sales Incentive Compensation program documents as determined by and at the sole discretion of Amgen management.

CHAPTER 4: INTERNAL BUSINESS STRATEGY AND PLANNING

In order to be eligible to benefit from all elements of the IC Plan including awards and contests, you must have completed all required Worldwide Compliance & Business Ethics (WC&BE) assigned training during the time period on which the IC awards are based.

Your eligibility to receive Non-base Incentive Awards is at the sole discretion of Amgen, and Amgen may, at its discretion, cease to provide non-base incentives.

Commercial Field-based Staff without Account Management Roles may be compensated based on sales data from approved specialty lists and appropriate customer types.

Commercial Field-based Staff with Account Management Roles may be compensated based on sales data from approved customer types and may include sales data from approved specialty lists to recognize pull-through sales credit.

Some Commercial Field-based Staff have Account Management Roles in which they engage in discussions with Healthcare Professionals (HCPs) who are performing duties other than individual prescribing decisions for the clinical Treatment of Patients. In these discussions, the HCP is not acting as a prescriber, but rather as a representative of a larger organization or accountant, e.g., Pharmacy & Therapeutics (P&T) committee member or practice administrator/director, etc., and may in some circumstances have a specialty that is outside the approved specialty list, and it is okay to meet with that HCP in that capacity.

IC Plans Mandatory Inclusions

IC Plans must include the applicable IC Plan and associated Call Plan for Commercial Field-based Staff including those with Account Management Roles must include the following statement: Amgen Staff are expected to abide by all U.S. Healthcare Compliance Policies, Compliance requirements and procedures. In order to participate in or benefit from any element of Amgen’s Incentive Compensation Program, including Incentive Compensation and Awards, a Participant may only engage in discussions with accounts or customers included on an approved customer type list and must conduct all Product promotion in a manner consistent with the U.S. FDA-approved labeling and appropriate competitive behavior.

IC Plans must include a section dedicated to Sales Credit Rules (SCRs). These rules identify the type of sales that will be credited to Commercial Field-based Staff for IC purposes. If a co-commercialization arrangement exists for a particular Amgen Product, the Business Unit (BU) IC Team will verify with Law the appropriate engagement and sharing of the IC Plan with the external party. The BU IC Team must document Law's opinion via email and forward a copy of the email containing the opinion to the Compliance Lead. If engagement with the external party is required, the BU IC Team will document such engagement in the appropriate system of record and provide documentation to the Compliance Lead.

Assess and Mitigate Business and Compliance Risk

The appropriate functions who have the review and signature responsibility in the table below will collectively take sufficient measures to analyze and mitigate risk by developing and periodically reviewing a written risk assessment that identifies business and compliance risk. The written risk assessment will be attached to the IC Plan and retained in the appropriate system of record.

Sales Operations Responsibilities

Sales Operations will provide the U.S. Healthcare Monitoring group with monthly reports of interactions with specialties requiring explanations. Sales Operations will also provide reports on an ad-hoc basis if requested by the U.S. Healthcare Monitoring group.

Sales Operations must maintain written procedures in its system of record outlining the specifics of Sales Operations roles and responsibilities and call activity management oversight.

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IC Plan Review and Approval

The following must review and sign off on the proposed IC Plan and risk assessment for BU Vice President (VP)/General Manager (GM) consideration: the applicable Director, Sales Operations, the National Sales Lead, VP, or Executive Director, relevant attorney within Law, Finance, Human Resources (HR), Compliance Lead, and Commercial Strategy and Analytics (CS&A), according to the following table:

Role	Responsibilities

Director, Sales Operations	• The IC Plan is in compliance with the Compliance requirements on incentive Compensation.
	• Appropriate steps have been taken to exclude off-label sales and encourage appropriate competitive behavior, including:
	  ○ The IC Plan includes a section devoted to SCR, which identify the type of sales that will be credited towards incentive Compensation,
	  ○ All communications regarding the IC Plan explicitly prohibit the Off-label Promotion of Amgen Products and the IC Plan has been designed to not encourage or require off-label sales promotion or behavior that is anti-competitive, and
	  ○ The anticipated Compensation associated with the IC Plan (budget and payout curves) has been approved.
	• The IC Plan is consistent with the Relevant Brand Strategy and Plan.
	• The IC Plan takes reasonable steps to mitigate identified risks.

National Sales Lead, VP, or Executive Director	• The IC Plan is in compliance with the Compliance requirements on incentive Compensation.
	• Appropriate steps have been taken to exclude off-label sales and encourage appropriate competitive behavior, where feasible, from sales measures, specifically:
	  ○ The IC Plan includes a section devoted to SCRs, which identify the type of sales that will be credited towards incentive Compensation.
	  ○ All communications regarding the IC Plan explicitly prohibit the Off-label Promotion of Amgen Products and the IC Plan has been designed to not encourage or require off-label sales promotion or behavior that is anti-competitive.
	  ○ The anticipated Compensation associated with the IC Plan (budget and payout curves) has been approved.
	• The IC Plan is consistent with the Relevant Brand Strategy and Plan.
	• The IC Plan takes reasonable steps to mitigate identified risks.

Employment Law	• Review proposed changes to a current IC Plan.
Commercial Law	• Participate in the review and approval of customer types and specialty lists. Evaluate the IC Plan for compliance with applicable laws relating to healthcare compliance issues, including FDA Product promotion, Anti-kickback laws and regulations and supporting appropriate competitive behavior. • The IC Plan takes reasonable steps to mitigate identified risks.

Role	Responsibilities
Finance	• Ensure that the growth rates or sales goals in the plan are in line with the rates or goals provided by Finance. • Review the anticipated Compensation and payout curves to align to the IC budget. • Analyze available data and acknowledge that the growth rates contained in the IC Plan are reasonably attainable by the relevant Field-based Sales Staff through promotional efforts that are consistent with the U.S. FDA-approved labeling and appropriate competitive behavior. • The IC Plan takes reasonable steps to mitigate identified risks.
Commercial Strategy & Analytics	• The IC Plan Expected Sales Measures are reasonably attainable through promotion efforts consistent with the U.S. FDA-approved labeling and is not a sales measure that would encourage or drive inappropriate or anti-competitive sales behavior. ○ The IC Plan takes reasonable steps to mitigate identified risks.
Human Resources	• Ensure IC Plan aligns to established IC philosophy/guiding principles. Review plan for effectiveness in driving talent motivation, providing equity in IC practices across BU plans, and delivering clear employee communication. Validate Staff eligibility for awards. • The IC Plan takes reasonable steps to mitigate identified risks.

Compliance Lead	• The IC Plan is in compliance with the General Business Rules on incentive Compensation and consistent with other applicable Amgen SOPs.
	• Appropriate steps have been taken to exclude off-label sales, where feasible, from sales measures, specifically:
	  ○ The communications within the IC Plan explicitly prohibit the Off-label Promotion of all Products.
	  ○ The specialties that sales reps call on are appropriate for consistent with the U.S. FDA-approved labeling sales.
	• The IC Plan takes reasonable steps to mitigate identified risks.

The BU VP/General Manager is the approval authority for the proposed IC Plan.

The Director, Sales Operations must retain the approved final IC Plan in the appropriate system of record.

The IC Plan must not be communicated to appropriate Commercial Field-based Staff prior to BU VP/General Manager approval.

If a proposed change to an approved IC Plan further restricts or expands applicable criteria, eligibility, or awards, the IC Plan must be re-reviewed and re-approved by the BU VP/GM.

IC Plan Execution

Group	Responsibilities
BU IC Team	• Communicates approved IC Plans to their appropriate Commercial Field-based Staff, and all Commercial Field-based Staff in that BU must acknowledge receipt of the plan within a deadline determined by the BU IC team. • Provides the IC Operations team with the criteria for configuring the Compensation system in order to execute the plan. • Determines if Sales Credit adjustments are required based on sales operations adjustment criteria. Will also document and retain the approval of any adjustments submitted to the IC Operations team. • Determines whether National Level Adjustments are desired based on variance to the sales goal/expected IC Plan measures, or as appropriate for compliance reasons. These adjustments must be re-reviewed and approved per the IC Plan review and approval process, with the U.S. Business Operations Senior Vice President (SVP) is added as the final approver. • Determines whether True-up adjustments or Payout changes are desired based on variance to the sales goal/expected IC Plan measures, or as appropriate for compliance reasons. These adjustments require approval in writing via email from the BU VP or Sales, Executive Director, and the IC Director. • Conducts a periodic review of at least two IC Plans annually based upon that plan's risk assessment. The results of the periodic reviews will be stored in the IC Team's system of record.
IC Operations Team	• Implements and executes IC Plans with direction from the BU IC Team. • Implements any adjustments which are required. • Disseminates, on a regular basis, executive and incentive summary workbooks to the BU IC team, Finance, and the BU VP/GM.

Staff Relations	• Reviews the list of Staff members being considered for Non-base Incentive Awards to evaluate their eligibility to receive them based on the following considerations:
	  ○ Disciplinary action received for performance issues, non-compliance, or other misconduct.
	  ○ Time in field during the relevant reward period.
	  ○ Maximizing Amgen's Performance (MAP) rating.
	• Will receive a list of Staff members considered ineligible for a Non-base Incentive Award for each relevant period from WC&BE Investigations and will not approve these awards for those WC&BE-determined ineligible Staff without written approval from a WC&BE VP or SVP.

5. FAIR MARKET VALUE (FMV) RATE CARDS

The information that follows provides only the U.S. Healthcare Compliance requirements for Fair Market Value. More detailed procedural information can be found in the SOP: Fair Market Value.

On a regular basis, FMV Rate Cards must be reviewed by a Policy Director or above on the Global Policy, Training, and Programmatic Improvements team within WC&BE. If that review results in a determination to retire, introduce, or modify any rates in the Amgen FMV Rate Cards, then the VP of Compliance within WC&BE must approve the revised rate cards before they become effective. Global Policy, Training and Programmatic Improvements is responsible for retaining the VP's approval in the appropriate system of record.

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6. PRESCRIBING DATA

In the normal course of doing business, we may purchase data from Health Information Organizations (HIO) relating to specific Healthcare Professionals' (HCP) prescribing practices, which we refer to as Prescribing Data. The lawful collection and use of Prescribing Data are important to our business activities and we respect the confidentiality of the HCPs who are the subject of this data. We use this Prescribing Data for legitimate purposes, including to:

- Facilitate the efficient flow of information to HCPs.
- Convey to HCPs important safety and risk information related to Amgen's Products.
- Conduct research.
- Track adverse events and comply with FDA-mandated risk management programs requiring Amgen to identify and interact with HCPs who prescribe particular Amgen Products.
- Provide direct marketing and clinical information to those HCPs who would most likely benefit from information about a particular Amgen Product.

The Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals (PhRMA Code) requires PhRMA-member companies to implement certain safeguards to ensure the responsible use of Prescribing Data and respect HCP requests to restrict access to their Prescribing Data from appropriate Commercial Field-based Staff. It is our policy to respect such HCP requests and comply with the PhRMA Code.

We consider prescriber personal data (prescriber data) as personal information which is subject to protections under Amgen's Global Corporate Compliance Policy: Protection of Personal Information.

Purchase Only Prescribing Data We Need

Only purchase Prescribing Data relevant to a legitimate business need.

Safeguard the Use of Prescribing Data

Any function or business units engaged in the collection, handling, use and dissemination of Prescribing Data are responsible for:

- Collecting, processing, using, and transferring Prescribing Data in accordance with the PhRMA Code and all applicable laws and regulations.
- Complying with specific protocols or Agreements we may undertake with respect to handling of the Prescribing Data.
- Implementing appropriate measures to protect Prescribing Data against unauthorized or improper disclosure, use or access.
- Taking the necessary steps to respond to any incident involving a potential disclosure of Prescribing Data, when required by law; and excluding restricted data elements from appropriate Commercial Field-based Staffs' reports, including:
    - Percent or any indicators of prescribing pattern changes including color coding, up or down arrows, or directional indicators such as alerts.
    - Aggregated or segmented data that reveals actual prescription volume of HCP or indicates an increase or decrease in HCP prescribing activity.

Opt-Out of Appropriate Commercial Field-based Staffs' Use of Prescribing Data

We recognize that individual HCPs may not wish to have their Prescribing Data shared with our appropriate Commercial Field-based Staff. We have implemented the American Medical Association's (AMA's) Physician Data Restriction Program (PDRP), which allows physicians to prohibit their physician-identifiable Prescribing Data from being made available to Commercial

Field-based Staff. This means that those physicians have opted out. Regarding the HCPs who have opted out, appropriate Commercial Field-based Staff may receive the following data:

- Decile at the market and/or therapeutic class level.
- Segmented data categorized so it does not reveal actual prescription volume or an indication of an increase or decrease in prescribing activity by an individual provider.
- HCPs who have opted out may be included in aggregated territory level reports so long as the data contained in such reports is not calculated or associated with any restricted Prescribing Information enabling the connection between the restricted Prescribing Information and HCP.
- Data for Products ordered by HCPs.

Monitoring the Opt-Out List

The HIO HCP opt-out list must be reviewed on a monthly basis and must comply with all opt-out requests within thirty (30) days from which date the monthly opt-out list is received.

Inquiries Relating to the Use of Prescribing Data

Inquiries relating to the use of Prescribing Data should be directed to the Chief Privacy Officer at (805) 313-5151, via email at privacy@amgen.com, or at the WC&BE function page on MyAmgen.

7. PRICE SETTING AND PRICE REPORTING

Amgen is legally obligated to report timely, accurate and complete pricing information to governmental authorities or risk both legal and business consequences.

Amgen may be exposed to liability under the federal civil False Claims Act, certain criminal statutes prohibiting false claims, and/or analogous state false claims laws if we improperly report pricing data to the government, such as data relating to the average sales price, average manufacturer price, best price, non-federal average manufacturer price, or federal ceiling price. Failure to comply with these reporting requirements can lead to the termination of the related government Agreements, which in turn would result in no federal funding being available for Amgen's Products under Medicaid or Medicare Part B. In addition to any obligation to refund the government any overpayment, with interest, non-compliance also may be subject to various program-specific penalties.

U.S. Value & Access (U.S. V&A)

U.S. Value & Access is responsible for developing and approving pricing, contracting, and discounting recommendations as well as setting procedures for the same. Requirements and processes governing the U.S. Pricing Committee, which is responsible for setting and approving pricing strategy, and ensures appropriate governance over U.S. price actions and Product contracting and discounting decisions, can be found in the U.S. V&A governance documents. Please contact U.S. V&A for more information.

U.S. Government Price Reporting

Amgen follows all applicable laws and regulations related to U.S. Government price reporting calculations and reporting of price information for Amgen Products. In the U.S.:

- All government price calculations and data must be accurate and submitted in a timely fashion to the U.S. Government (or provided in the time allotted by extension, if applicable).
- Amgen's U.S. Government price reporting calculations and reporting policies must be maintained and updated, and appropriate training must be provided to relevant covered persons to ensure compliance with such policies and procedures.
- Amgen will refrain from any action that could potentially interfere with the ability of a buyer of an Amgen Product to meet its obligations to report a discount or Rebate.

Government Pricing Team

The Government Pricing team is responsible for:

- Following all of Amgen's policies, procedures and methodologies related to reporting each specific price type.
- Adequate and appropriate training of all Amgen Staff involved in government pricing activities.
- Maintaining proper systems, policies, Compliance requirements, procedures, and methodologies necessary to calculate and submit accurate government price information in accordance with applicable laws.

Law

Law must review our government price reporting methodologies.

8. PRICE CONCESSIONS

The Compliance requirements below must be followed when negotiating and contracting for Discounts, Rebates, Managed Care Organization (MCO) or Group Purchasing Organizations (GPO) Administrative Fees, provision of free goods, or other Price Concessions collectively, "Price Concessions" to Buyers, MCOs, Wholesalers, or GPOs collectively, "Buyers or their Agents".

Discussions and Negotiations of Price Concessions

All discussions of Price Concessions must comply with U.S. V&A requirements and processes. If the content of the discussions is outside of the approved pricing strategy, they would need to be approved by the U.S. Pricing Committee.

We do not enter into any Agreement that provides any Price Concession terms that are not in the approved Contract Platform or have not been approved by the U.S. Pricing Committee**.**

Do Not Discuss Additional Arrangements During Negotiations

We do not offer any other potential services or business Agreements with Buyers or their agents when negotiating the terms of the Product Agreement. For example, we don't discuss sponsorships, service Agreements, or other similar Agreements when negotiating terms of an Agreement for Price Concessions.

Terms for Price Concessions

Agreements with members of the Healthcare Community that provide Price Concessions must be approved consistent with the procedures set by U.S. V&A.

Discussing Price Concessions

Whether you are permitted to engage in discussions on the proposed structure of a Price Concession with a Buyer or its Agent depends on your organization and role as noted below:

Commercial Staff Role	Allowed
Commercial Field-based Staff Member – Director or below	No
U.S. Value & Access (U.S. V&A) Staff	Yes, only for Price Concessions in an approved pricing strategy.
Account Management Role	Yes, only for Price Concessions in an approved pricing strategy.
Vice Presidents or above	Yes, for Price Concessions in and not in an approved pricing strategy.

CHAPTER 4: INTERNAL BUSINESS STRATEGY AND PLANNING

Discussing Our Pricing Policies or Practices

To avoid creating a risk of violating any antitrust and/or competition laws, do not discuss our pricing policies or practices with competitors or accounts.

Government Price Reporting Methodologies Review

Law must review our government price reporting methodologies.

Review, Approval, Documentation and Reporting of Price Concessions

All Price Concessions must be documented in a Product Agreement with the Buyer or their agent.

All Price Concessions must comply with the Product pricing strategy approved by the Pricing Committee.

All Product Agreements, including Price Concession amounts, must be reviewed and approved by the U.S. V&A group.

All requests for material changes to a Product Agreement Template must be reviewed and approved by Law.

We must report any Price Concessions as applicable by law in accordance with U.S. V&A guidance documents.

We must include all Price Concessions, as appropriate, in government pricing calculations pursuant to U.S. V&A guidance documents.

All Product Agreements must include language advising Buyers or their agents of the Buyers' obligations to properly report any Price Concession and requiring the Buyers to comply with any obligation to report Price Concessions in accordance with the federal Anti-kickback Statute and regulations and relevant state laws.

We must never take any action that impedes the Buyer's ability to meet their Price Concessions reporting obligations.

In addition to the other Compliance requirements noted in this section, the Compliance requirements below must be followed when entering into GPO Product Agreements.

The terms and conditions of Agreements with GPOs for the purchase of Products must comply with all applicable laws and Amgen's policies relating to Discounts and Rebates. The U.S. V&A group will work with Law to set appropriate terms for Product Agreements with GPOs.

- GPO Administrative Fees:
    - Separate from the pricing, including Discounts and Rebates provided to GPO Members, GPOs themselves may receive GPO Administrative Fees from vendors like Amgen pursuant to a safe harbor to the federal Anti-kickback law that permits GPOs to receive GPO Administrative Fees from vendors. GPO Administrative Fees generally are based on a percentage of the value of purchases by GPO Members. The U.S. V&A group will ensure that GPO Product Agreements contain language requiring individual GPOs to represent and warrant that they comply with all applicable laws and the GPO safe harbor.
    - GPO Administrative Fees are paid to the GPO itself and are not intended to serve as additional Discounts or Rebates to GPO Members. Amgen does not direct or suggest how GPOs use GPO Administrative Fees.

An Agreement to obtain services or data from the GPO may not be offered in connection with discussions or negotiations with the GPO relating to its GPO Product Agreement.

CHAPTER 4: INTERNAL BUSINESS STRATEGY AND PLANNING

9. SAMPLES

The information that follows provides only the U.S. Healthcare Compliance requirements for Samples. More detailed procedural information can be found in the SOP: Samples.

We may provide Licensed Prescribers with Samples free of charge to give to Patients through an approved Brand Sample Program. Samples of certain Amgen Products may be provided to HCPs through either the "Direct Ship Sample Program" or the "Hand Carry Sample Program".

Amgen Staff must not provide Samples to Licensed Prescribers if they know or suspect that the Licensed Prescriber intends to:

- Use the Sample in a manner that is inconsistent with the specific prescription drug Product's U.S. FDA-approved labeling.
- Submit claims for reimbursement for the Sample.
- Sell or trade the Sample or offer the Sample for sale or trade.

COMPLIANCE REQUIREMENTS FOR ALL SAMPLE PROGRAMS

Amgen provides Samples to Licensed Prescribers in order to:

- Allow a Licensed Prescriber to gain experience with the Sample Product that is consistent with the U.S. FDA-approved labeling.
- Provide a trial period for the Patient.

Each Brand Sample Program:

- Must comply with the requirements of the Prescription Drug Marketing Act (PDMA), FDA regulations, and other applicable federal and state laws.
- Includes only FDA-approved prescription drugs owned or marketed by Amgen.
- Must have an associated Brand Sample Program RAE.

Samples must never be offered or provided with the intent of, direct or indirectly:

- Rewarding prescription drug use,
- Influencing formulary placement,
- Resolving customer complaints,
- Replacing lost or stolen drug Products, or
- Providing for indigent or underinsured Patients.

If you become aware of Sample use that does not conform to the Compliance requirements in this document, you must call the Business Conduct Hotline at 1-888-376-5574 or notify your manager and your Compliance Lead.

Samples Program Governance Structure

Committee Name	Representation and Responsibilities
Samples Steering Committee (SSC)*	• Law, Regulatory Affairs, WC&BE. • Provides oversight of the Samples Review Committee (SRC) and Samples Operations Committee (SOC). • Provides general oversight for Amgen's Samples activities. • Reviews and approves any deviation from the approved Sample Program Operating Criteria (SPOC). • Decides issues that cannot be resolved by the SRC and SOC.

Committee Name	Representation and Responsibilities

Samples Review Committee (SRC)*	• Law, Regulatory Affairs, WC&BE, Global Safety.
	• Initial and periodic review and approval of all Brand Sample Programs, including but not limited to:
	  ○ Evaluating the Brand Sample program for legitimate business need, and
	  ○ Ensuring documentation that any applicable external business partner has been consulted for any co-marketing Agreements associated with Amgen Products.
	• Establishes the SPOC for all approved Brand Sample Programs consistent with Samples Steering Committee (SSC) guidance.
	• Establishes a Samples reconciliation variance level for hand carry Samples programs.

Samples Operations Committee (SOC)*	• WC&BE, Global Strategic Sourcing, Trade Operations, Information Systems, Amgen Distribution Center. • Manages Samples operations, including management of processing and fulfilling Sample requests based on the approved SPOC, and Sample returns.

*All minutes must be recorded and maintained.

Sample Packaging

All Sample packaging must be appropriately reviewed, and MAC approved.

Role-Specific Compliance Requirements for Sample Compliance Training

Role	Compliance Requirements
Commercial Field-based Staff	• Must successfully complete the required Samples Prescription Drug Marketing Act (PDMA) Annual Certification Curriculum before participating in the Brand Sample Program. • Must annually renew the required Samples PDMA Annual Certification Curriculum in order to continue participation in Samples activities. • May provide Sample request forms to Licensed Prescribers pursuant to the approved SPOC only upon successful completion of the Samples PDMA Annual Certification Curriculum.
Brand Sample Program RAE	• Must successfully complete the required Samples PDMA Annual Certification Curriculum before participating in the Brand Sample Program. • Annually renew the required Samples PDMA Annual Certification Curriculum in order to continue participation in Samples activities.

Sample Falsification, Diversion, Theft, or Known Conviction of an Amgen Staff Member

If the Regulatory Affairs Samples Reporting Designee (RASRD):

- Has a reason to believe that a person has falsified any Sample-related documents, records, or is diverting Samples.
- Has become aware of a theft of any Sample.
- Has become aware of a conviction notice of any Amgen Staff member for a violation of section 503(c)(1) of the federal Food, Drug, and Cosmetic Act or any state law involving the sale, purchase, or trade of a Sample or the offer to sell, purchase, or trade Samples.

Then the RASRD must conduct the following activities under PDMA mandated timelines and any other applicable federal and state laws:

- Notify the appropriate federal and state agencies.
- Investigate the alleged violations with Compliance Investigations and Law.

- Report the falsification, diversion, theft, or conviction to the appropriate federal and state agencies.
- Ensure all correspondence with the required government agencies is retained in the appropriate system of record.

Direct Ship Sample Programs

All Sample Orders must be appropriately tracked, reconciled, and reported by WC&BE or its delegate.

WC&BE or its delegate will monitor for Sample Loss and document this activity through a Reconciliation Report accounting for any loss. This report will be submitted to the RASRD per the applicable Regulatory Affairs Guidelines.

Licensed Prescribers may be prohibited from obtaining any Samples from Amgen and placed on the Do Not Ship list based on tracking and reconciliation results.

Hand Carry Sample Programs

All Sample Orders must be appropriately tracked, reconciled, and reported by WC&BE or its delegate.

WC&BE or its delegate must:

- Maintain a record of all Samples distributed and report to federal and state agencies on Samples provided as required by federal and state Marketing laws.
- Monitor for Sample Loss and document this activity through a Reconciliation Report accounting for any loss. This report will be submitted to the Regulatory Affairs Samples reporting designee per the applicable Regulatory Affairs Guidelines.
- Audit Hand Carry Sample Programs annually, randomly, or for-cause:

Type of Audit	WC&BE or its delegate will:
Annual	Audit each Commercial Field-based Staff member who participates in the Hand Carry Sample Program. The annual audit will include a physical inventory count of Samples in the Staff member's possession and a check that Sample storage requirements are followed.
Random	Ensure that random audits of Commercial Field-based Staff members are conducted pursuant to a predetermined basis.
For-Cause	Perform for-cause audits as warranted and appropriate.

All variances in reconciliations, whether found during an audit or routine inventory checks, or by any other method that exceed the SRC-established Samples variance level must be reported to the FDA as a potential loss.

Commercial Field-based Staff

If you are a Commercial Field-based Staff member participating in a Hand Carry Sample Program, you must:

- Store Samples under conditions that will maintain the Product's stability, integrity, and effectiveness. The Samples must be stored in a locked container in a secure location and must be protected against contamination, deterioration, and adulteration.
- Perform a monthly physical inventory count of all Samples in possession.
- Assist WC&BE or its delegate with reconciliation activities on a quarterly basis.
- Ensure that quarterly reconciliations do not exceed the SRC established Samples variance.

CHAPTER 5: INTERACTIONS RELATED TO GOVERNMENT OFFICIALS, EMPLOYEES, AND POLITICAL ACTIVITIES

1. COMPLIANCE REQUIREMENTS

There may be times during the normal course of business when you engage with a Government Official or employee. Any interaction with such a person may be construed to be Political Activity, so you must be especially diligent that these interactions are appropriate and compliant.

In addition to the applicable principles in our Global Corporate Compliance Policies and the processes outlined in Standard Operating Procedures:

- Follow all laws, regulations, and applicable industry guidelines, reporting and disclosure requirements, and local and Country Specific Requirements for conducting Amgen activities.
- Know the guardrails and requirements for all Amgen activities you engage in.
- Do not offer or provide any Agreements, services, or funding to a member of the Healthcare Community to directly or indirectly, influence or encourage the member of the Healthcare Community to purchase, prescribe, refer, sell, arrange for the purchase or sale, reimburse or recommend formulary placement of any Amgen Product or to reward past, present, or future business.
- Follow the appropriate review and approval process for all materials used externally.
- Be truthful, balanced, and scientifically rigorous in materials and discussions.
- Use venues that are appropriate and reasonable when conducting Amgen business.
- Maintain accountability as a Responsible Amgen Employee (RAE) for your Amgen activities, regardless of who conducts them.
- Ensure Amgen activities support legitimate business or scientific needs.
- Engage only with parties qualified to provide their services.
- Pay expenses only to parties with whom we are in an Agreement.
- Document Agreements and applicable consents in writing and fully execute them prior to any services, goods or confidential data being provided.
- Ensure services are provided only during the active term of an executed Agreement.
- Ensure that performance of any compliance requirement activities by a third party are authorized by written approval from Healthcare Compliance and Law.
- Do not provide Gifts or Entertainment to those with whom we conduct business.
- Do not use personal funds to conduct Amgen business.
- Do not engage with any parties on any Exclusion Lists, including those hired by third parties.
- Do not allow inappropriate uninvited guests to participate or attend Amgen activities.
- All compliance requirements apply regardless of whether the interaction is in-person or virtual.

This Chapter contains Compliance requirements that you must follow for any interactions you may have with U.S. Government Officials or employees. Additionally, it also points you to appropriate Global Government Affairs & Policy (GGA&P) documents whose contents may also be applicable to your interactions with U.S. Government Officials or employees.

Certain capitalized terms are defined in the Healthcare Compliance Glossary.

CHAPTER 5: INTERACTIONS RELATED TO GOVERNMENT OFFICIALS, EMPLOYEES, AND POLITICAL ACTIVITIES

2. GENERAL REQUIREMENTS FOR INTERACTIONS WITH THE GOVERNMENT

The information that follows provides only the U.S. Healthcare Compliance requirements for Interactions with the Government. More detailed procedural information can be found in the SOPs: Lobbying Activities; Use of Corporate Resources for Political Activity; and Gifts to Government Employees.

We take interactions with Government Employees very seriously, and GGA&P is responsible for interactions with U.S. Government Officials and employees.

Interactions with U.S. Government Officials or employees requires you to follow the GGA&P requirements.

Interactions with U.S. Government Officials or employees who are also members of the Healthcare Community, requires you to consult with both U.S. Healthcare Compliance and GGA&P.

If you are unsure about any engagements, interactions, or requirements when dealing with U.S. Government Employees, please contact U.S. Healthcare Compliance and GGA&P for assistance.

3. LOBBYING

In general, only members of GGA&P may engage in Lobbying.

Under the laws of certain states, individuals who communicate with state Medicaid agencies regarding issues of drug coverage, formulary placement, and/or payment are required to register as lobbyists. To the extent that an Amgen Staff member's interaction with a state Medicaid agency or other government entity or official requires registration under these laws, that Amgen Staff member may register as a lobbyist and engage in Lobbying. The Amgen Staff member must notify the head of State Government Affairs (SGA) or his or her delegate prior to registration.

Only GGA&P Staff may retain an outside firm to engage in Lobbying.

For further information, please see Global Government Affairs SOP: Lobbying Activities. If you are uncertain whether your actions constitute Lobbying, please contact U.S. Healthcare Compliance and GGA&P for assistance.

4. FINANCIAL SUPPORT

Certain Reportable Contributions

Funding to charitable organizations must be examined with care if they originate with, honor, or relate to a political officeholder, political candidate, or political committee. All such funding opportunities must be approved in advance by GGA&P. If this funding involves a member of the Healthcare Community, you must also follow the Compliance requirements contained in U.S. Healthcare Compliance Requirements: Chapter 3 – Funding.

Use of Corporate Resources for Political Activity

Corporations, including Amgen, are strictly prohibited from making direct contributions to support candidates for federal elective office. Similarly, Amgen's corporate resources cannot be used by Staff to support candidates for elective office.

However, contributions or expenditures by the Amgen Political Action Committee (PAC) are permissible at the federal level and in many state and local jurisdictions. Staff who are part of Amgen's restricted class (typically GCF level 5 or above, and biopharmaceutical Sales

Representatives who are also green card holders or U.S. citizens) are eligible to voluntarily support the Amgen PAC. Through the PAC, these contributions are donated to the campaigns of candidates who share our mission to serve Patients. The Amgen PAC may make political contributions at the federal level and in some state and local jurisdictions, and only the Amgen PAC Treasurer or the Treasurer's delegate is authorized to make such contributions.

Amgen does not restrict the ability of Staff members to engage in personal Political Activity, including making financial contributions to candidates for elective office, provided that the Staff member does not use Amgen's name, corporate resources or its facilities in a manner inconsistent with the Global Government Affairs SOP: Use of Corporate Resources for Political Activity, or the Policy: Use of Company Systems and Internet Conduct.

For further information, please see Global Government Affairs SOP: Use of Corporate Resources for Political Activity. If you have any questions about the Amgen PAC or personal involvement in the election process, please contact U.S. Healthcare Compliance and GGA&P for assistance.

Gifts, Transportation, Meals, and Invitations

Please see the Global Government Affairs SOP: Gifts to Government Employees for specific requirements when engaging with U.S. Government Employees. If the U.S. Government Employee is a member of the Healthcare Community, you must also follow all applicable U.S. Healthcare Compliance requirements in SOP: Meals, Gifts, Educational Items, Travel, and Hospitality. If you are not certain whether a particular Gift to a U.S. state or local Government Employee is appropriate, contact State Government Affairs (SGA).

- **Gifts:** Certain non-SGA Staff who routinely interact with U.S. state and local officials, such as Commercial Field-based Staff with Account Management Roles, may give Gifts to U.S. state and local Government Employees, but only if such Gifts are permissible under applicable law and, if the U.S. state or local Government Employee is a member of the Healthcare Community, also complies with applicable U.S. Healthcare Compliance requirements in SOP: Meals, Gifts, Educational Items, Travel, and Hospitality. For further information, please see Global Government Affairs SOP: Gifts to Government Employees. If you have any questions regarding Gifts to Government Employees, please contact U.S. Healthcare Compliance and GGA&P for assistance.
- **Meals and Transportation:** Please note that there are specific Meals and transportation restrictions that apply to certain U.S. Government Officials and Employees. These restrictions are addressed in the GGA&P SOP.

CHAPTER 6: PATIENT INTERACTIONS AND PATIENT PROGRAMS

1. COMPLIANCE REQUIREMENTS

During our everyday business activities, Amgen and our vendors may interact with Patients in a variety of ways. Some examples of these interactions include:

- Educating Patients on Amgen's Products,
- Operating Co-pay and Other Access Programs, and
- Engaging Patients as Speakers (through a Patient contract).

This Chapter provides the minimum Compliance requirements for compliantly executing a variety of such interactions with the Patients.

In addition to the applicable principles in our Global Corporate Compliance Policies and the processes outlined in Standard Operating Procedures:

- Follow all laws, regulations, and applicable industry guidelines, reporting and disclosure requirements, and local and Country Specific Requirements for conducting Amgen activities.
- Know the guardrails and requirements for all Amgen activities you engage in.
- Do not offer or provide any Agreements, services, or funding to a member of the Healthcare Community to directly or indirectly, influence or encourage the member of the Healthcare Community to purchase, prescribe, refer, sell, arrange for the purchase or sale, reimburse or recommend formulary placement of any Amgen Product or to reward past, present, or future business.
- Follow the appropriate review and approval process for all materials used externally.
- Be truthful, balanced, and scientifically rigorous in materials and discussions.
- Use venues that are appropriate and reasonable when conducting Amgen business.
- Maintain accountability as a Responsible Amgen Employee (RAE) for your Amgen activities, regardless of who conducts them.
- Ensure Amgen activities support legitimate business or scientific needs.
- Engage only with parties qualified to provide their services.
- Pay expenses only to parties with whom we are in an Agreement.
- Document Agreements and applicable consents in writing and fully execute them prior to any services, goods or confidential data being provided.
- Ensure services are provided only during the active term of an executed Agreement.
- Ensure that performance of any compliance requirement activities by a third party are authorized by written approval from Healthcare Compliance and Law.
- Do not provide Gifts or Entertainment to those with whom we conduct business.
- Do not use personal funds to conduct Amgen business.
- Do not engage with any parties on any Exclusion Lists, including those hired by third parties.
- Do not allow inappropriate uninvited guests to participate or attend Amgen activities.
- All compliance requirements apply regardless of whether the interaction is in-person or virtual.

Since Patient organizations are considered a member of the Healthcare Community, please reference Chapter 2: Interactions with Members of the Healthcare Community for the appropriate Compliance requirements.

Certain capitalized terms are defined in the Healthcare Compliance Glossary.

CHAPTER 6: PATIENT INTERACTIONS AND PATIENT PROGRAMS

The information that follows provides only the U.S. Healthcare Compliance requirements for Interactions with Patients. More detailed procedural information regarding contracting with Patients can be found in the SOP: Agreements with Patients.

2. GENERAL REQUIREMENTS FOR INTERACTIONS WITH PATIENTS

Do Not Influence Patients

We never, and any third parties that act on our behalf must never, offer, require, or expect a Patient to receive services from any particular Healthcare Provider. A Patient's choice of Healthcare Provider is his/her sole decision and has nothing to do with an Agreement or payment a Patient may receive for his/her services.

Unless under an Agreement, Amgen will not engage with a Patient with the intent of, directly or indirectly, influencing or encouraging the Patient to communicate an Amgen message to any audience.

We are not allowed to influence any aspect of the Patient's medical care, provide medical advice, or make any medical referrals. Product information provided to Patients should represent fair balance and appropriately address both efficacy and safety information. It is never condoned to "downplay" side effect risks.

Do Not Select HCPs as Patients

Healthcare Professionals (HCPs) cannot be engaged as Patients.

Obtain Appropriate Consents

Prior to engaging in any substantive discussions with a Patient, you must obtain a Patient Privacy Notice and Consent Form, have it signed by the Patient, and retain it in the appropriate system of record. If a similar form addressing privacy and consent is required to be completed by the Patient, the similar form may be used in lieu of the Patient Privacy Notice and Consent Form, if permitted by the Compliance Lead and Privacy Office.

Communicating with Patients

Any discussion with Patients should be restricted to the approved use of Amgen's Product consistent with the U.S. FDA-approved labeling; however, Commercial Field-based Staff must not discuss Product information with Patients unless otherwise approved by MAC. This also means that we may not solicit or prompt inquiries from Patients that require the provision of Off-label Information.

Third-Party Vendor Involvement

Prior to outsourcing any initiatives with a third-party vendor, who will be interacting with Patients, you are required to consult with your Compliance Lead. Third-party vendors are required to follow applicable Healthcare Compliance requirements and use all associated Amgen Agreements and forms. Additionally, the use of a vendor does not relieve you from the obligations outlined in these Healthcare Compliance requirements. It is your responsibility to maintain oversight of the third-party vendor.

The RAE or the vendor must initiate and submit executed Amgen Agreements and forms in the Healthcare Compliance system of record.

CHAPTER 6: PATIENT INTERACTIONS AND PATIENT PROGRAMS

3. AMGEN STAFF INTERACTIONS WITH PATIENTS

Interactions That Require Human Factors Engineering (HFE) Input

HFE, also known as usability engineering, cognitive ergonomics, or user-centered design, is a marriage of psychology and engineering: the application of a scientific body of knowledge about human strengths and weaknesses to the design of technology. If a topic of engagement poses questions relating to the design or use of a medical device (e.g., physical device, combination Product, software device, packaging or instructional labeling, device rituals or routines), you must follow the process for collection of HFE input that involves devices. Any research that has the potential to trigger usability responses (e.g., questions about current experiences with potential improvements to a specific Amgen device, comparisons of new concepts to an Amgen device, etc.) must seek the input of HFE.

Advocacy and/or Lobbying Activities

For interactions and Agreements with Patients intended to engage in Advocacy and/or Lobbying activities, you must consult with Law as indicated here:

Development, Regulatory, Operations and Contracting (DROC) Law	For activities related to interactions with the U.S. Food and Drug Administration (FDA).
Global Commercial Operations (GCO) Law	For activities related to interactions with the Centers for Medicare and Medicaid Services (CMS), Payors, or commercial-related activities and issues.

Review of Appropriateness for Speaking Engagements (if applicable)

In order to ensure that resources are not expended on inappropriate Patients for speaking engagements, the RAE must consult with Law and Regulatory Promotions to determine whether the identified Patient is appropriate for the speaking engagement, e.g., the identified Patient is consistent with the U.S. FDA-approved labeling for a particular engagement, the identified Patient has an appropriate medical history for the particular engagement.

For Development-Driven Patient Speaking Engagements	For All Other Speaking Engagements
RAE must consult with: • Development, • Regulatory, • DROC Law, and • Regulatory Promotions	RAE must go through Material Approval and Compliance (e.g., MAC) concept review process to consult with: • GCO Law, and • Regulatory Promotions
RAE must provide to Law and Regulatory Promotions appropriate materials which would aid in review. At a minimum, the following materials should be provided: • A copy of the signed Patient Privacy Notice and Consent Form. • A description of the scientific/business need for the services to be provided by the Patient. • Relevant medical history. Materials provided for review of Patient appropriateness need to be stored in the appropriate system of record.	

Depending on the nature of the activity, RAEs should consult with their MAC partners on the level of evidence necessary to ensure the Patient is appropriate for the particular speaking engagement being considered. Information beyond the list above may be requested.

Provide Applicable Training Prior to Patient Speaking Engagements

After consultation with Law & Regulatory, you must ensure that any applicable guidelines and/or training are provided to and reviewed with the Patient prior to his/her provision of services related to a speaking engagement.

4. SOCIAL MEDIA INFLUENCERS (SMIs OR SM INFLUENCERS)

The information that follows provides only the U.S. Healthcare Compliance requirements for Social Media Influencers. More detailed procedural information can be found in the Amgen Social Media Influencer Engagement Guidelines.

Overview

Amgen engages SMIs or SM Influencers as credible, authentic voices to reach target audiences. Many SMIs are regularly read, visited, or followed by Amgen's audiences, and have become a source of information about various topics including healthcare, health, wellness, and living with chronic or acute medical conditions.

Social Media Influencers must comply with FDA regulations governing social media and follow all applicable FDA guidance and Amgen policies.

Endorsements made by a SMI must include disclosing their relationship with Amgen.

Independence

Amgen is responsible for the accuracy and completeness of all communications that arise out of SMI engagements with the Exception of third-party communications deemed to be truly independent of Amgen. A third party is only considered independent if:

- The content is not produced by or on behalf of Amgen, and
- The content is not prompted or influenced by Amgen.

Except for communications that are truly independent of Amgen, Amgen Staff engaging with SMIs have the obligation to ensure that any SMI content is reviewed for accuracy and completeness.

Selecting Social Media Influencers

When selecting SMIs to collaborate or engage with, the RAE should take into account the SMI's ability to uphold Amgen's reputation, successfully fulfill their contractual obligations, and adhere to Amgen's policies and FDA guidance.

RAE Responsibilities

The RAE must monitor and review all content produced and published by a SMI.

If the monitoring activities reveal any published or disseminated content that is either incomplete or inaccurate, the RAE must develop a corrective communication plan for the SMI and engage legal, regulatory and compliance advisors on providing an appropriate correction to the published content.

Contracts must go through Healthcare Compliance, using the Social Media Influencer Agreement. The RAE must work with Law and Regulatory on the specific contract language to ensure the project complies with Amgen's policies and FDA guidance.

CHAPTER 6: PATIENT INTERACTIONS AND PATIENT PROGRAMS

5. PATIENT ASSISTANCE PROGRAMS (PAPs)

The information that follows provides only the U.S. Healthcare Compliance requirements for Patient Assistance Program Donations. More detailed procedural information can be found in the SOP: Patient Assistance Program Donations.

Ensure Independence of Charity PAPs from Amgen

Independent charity PAPs are charitable foundations that assist Patients in financial need in meeting their Co-pay obligations. These foundations are independent of Amgen and while Amgen may donate to these organizations, Amgen may not attempt in any way to direct Amgen's Donations to Patients who are on Amgen Products. Therefore, all interactions of any kind with independent charity PAPs will be conducted in a manner to ensure Amgen does not exert or attempt to exert any direct or indirect control over the entity operating the independent charity PAP or over its assistance programs. This includes ensuring that all such interactions:

- Exert no influence or control over the identification, delineation, establishment, or modification of any specific disease funds operated by the independent charity PAP.
- Exert no influence or control over the independent charity PAP's process or criteria for determining eligibility of Patients who qualify for assistance.

Only the PAP Team is permitted to interact with independent charity PAPs regarding Donations and related issues.

The Amgen Safety Net Foundation is a non-profit Foundation sponsored by Amgen. The Foundation is a free drug program that provides Amgen medicines to qualifying Patients who demonstrate a financial need.

Independent charity PAPs and Amgen's Safety Net Foundation are collectively referred to as PAPs.

Input on Independent Charity PAP Decisions

The PAP Governance Committee and PAP Team may seek and receive information from other Amgen functions relevant to decisions concerning Amgen's support of independent charity PAPs.

Those other functions providing information may not make suggestions or recommendations regarding specific funding objectives or recipients and may not suggest specific disease criteria for charitable Donations.

The PAP Governance Committee and PAP Team may inform other Amgen functions of its funding decisions.

Annual Budget and Plan

Amgen will establish an annual PAP budget and giving plan that includes Donations to the Amgen Safety Net Foundation and independent charity PAPs.

The budget and plan will be developed by Amgen's PAP Team and approved by the PAP Governance Committee.

The PAP Governance Committee may approve additional PAP Donations not specified in the annual budget and giving plan.

Permissible Cash or Product Donations

Amgen may make cash or Product Donations to the Amgen Safety Net Foundation.

Amgen only makes cash Donations to qualified independent charity PAPs.

CHAPTER 6: PATIENT INTERACTIONS AND PATIENT PROGRAMS

An independent charity PAP is qualified if all interactions with Amgen meet specific requirements and characteristics as outlined in the Patient Assistance Program Donations SOP.

Price Reporting

A program assessment of the PAP must be conducted by Amgen's Government Price Reporting Team during the concept and/or development phase of any new Amgen program or proposal or change to existing Amgen programs or proposals (e.g., Amgen Safety Net Foundation program that will provide financial assistance and/or any free goods or discounts to Patients or any member of the Healthcare Community).

Patient-Specific PAP Inquiries

For all Patient-specific case inquiries regarding the Amgen Safety Net Foundation, direct the inquirer to contact the Amgen Safety Net Foundation for follow up.

For all Patient-specific case inquiries regarding independent charity PAPs, direct the inquirer to contact the appropriate independent charity PAP for information.

Referrals by Reimbursement Services Vendors

Patients may be referred to PAPs by Amgen's reimbursement services vendors. Reimbursement services vendors may provide approved information regarding the Amgen Safety Net Foundation, and independent charity PAPs, and may refer Healthcare Professionals, Patients, and their agents to these programs. When there are multiple independent charity PAPs with relevant support programs, such referrals must identify all independent charity PAPs with open support programs. Vendors may not collect data that allows the vendor or Amgen to correlate its Donations to its Products. See below regarding data from Independent Charity PAPs.

Information Provided to Healthcare Professionals

PAPs are strictly for the benefit of Patients who qualify. Amgen Staff members must not market these programs as a benefit or as a reason to prescribe Products. Amgen Staff members may only deliver company-approved PAP information to members of the Healthcare Community.

Data from the Amgen Safety Net Foundation

Amgen Staff members may not request or knowingly receive or use any data from the Amgen Safety Net Foundation that would allow correlation of free Product provided to Patients with sales of Amgen Product to customers. Amgen may only use data received from the Amgen Safety Net Foundation in a manner that furthers the charitable purposes of the respective foundation from which the data was received and may not use any such data in a manner that is intended to, or has the effect of, providing a commercial or other benefit to Amgen that is more than tenuous and other than incidental to its intended charitable use.

Data from Independent Charity PAPs

Amgen may not request, knowingly receive directly or indirectly, or use any data from independent charity PAPs that allow correlation of the amount or frequency of Amgen's PAP Donation with the amount or frequency of Amgen Products used by Patients receiving assistance from that foundation.

Amgen may not conduct any "return on investment" analysis that measures commercial outcomes, such as changes in the prescribing patterns or sales, as a result of any PAP Donation. The PAP Team can evaluate independent charity PAPs that are receiving the Donations, including but not limited to their charitable status, operations, program administration, and Patient and Healthcare Provider satisfaction, in order to verify that Donations are being made to appropriate organizations and used efficiently to support Patients in need.

Donations to Independent Charity PAPs

The PAP Team may only make Donations to independent charity PAPs that are approved to receive such Donations. Each independent charity PAP will be approved on an annual basis.

The PAP Team works with Healthcare Compliance to ensure that the independent charity PAP is not restricted from working with Amgen based upon any Exclusion Lists and retains documentation, in the appropriate system of record, that these exclusion checks have been performed.

Amgen will not fund any approved PAP Donation to an independent charity PAP unless an executed Donation Agreement between Amgen and the independent charity PAP is in place.

6. PATIENT SUPPORT PROGRAMS (PSPs)

Ensure Alignment on Foundational Principals Within Amgen and Across PSP Vendors

PSPs are for the benefit of the Patient, not the Healthcare Provider or other customer. PSPs must not act in the capacity of the Patient's Healthcare Provider.

Ensure Alignment of Legal Advice and PSP Operations

You must involve GCO Law early and often from inception to execution of PSPs. You will be designated and accountable for implementing any legal advice provided.

Ensure PSP Operations are Consistent with Amgen Approved Business Rules

Amgen and the PSP vendors must agree upon business rules and institute a plan for regular updates to ensure the business rules reflect reality and the evolving environment. Changes to Amgen business rules cannot be made unilaterally by the vendor and require Agreement between Amgen and the PSP vendor. GCO Law should be involved in drafting, reviewing and approving Amgen business rules for PSP vendors.

PSPs are Not Intended to Induce Prescribing of Amgen Products

PSPs are designed to remove barriers to Patient access, not to encourage HCPs to prescribe such Products; they are intended for use after an HCP has determined that an Amgen Product is clinically appropriate for the Patient. Therefore, PSPs must be designed, executed, and described consistent with that purpose. PSPs performance analyses should be conducted in a manner consistent with this purpose and after consultation with Law.

Training of Amgen Staff and PSP Staff

Everyone involved with PSPs must be trained on the business rules for each PSP they are involved with and any other governing procedures.

Ensure Amgen Approval of All PSP Training Documents

Documents prepared by a PSP vendor and distributed to its representatives must go through Amgen review and sign-off consistent with the contract terms unless expressly identified as being proprietary.

Inducements

Patient support offerings must not become a financial inducement and cannot be promoted as the reason to prescribe an Amgen Product.

Performance Incentives for Specialty Pharmacies

All interactions of any kind with specialty pharmacies will be conducted in a manner to ensure Amgen does not exert or attempt to exert any direct or indirect control over the pharmacies' provision of

Amgen Products. This is to say, no performance incentives will be created to encourage the inappropriate utilization of Amgen Products.

Vendors

Vendors acting on behalf of Amgen, whose role it is to provide the Patient with information on the approved use of Amgen's Products, must abide by all applicable Compliance requirements.

7. CO-PAY SUPPORT PROGRAMS

The information that follows provides only the U.S. Healthcare Compliance requirements for Co-pay Programs. More detailed procedural information can be found in the SOP: Co-pay Programs.

Co-pay Program Roles and Responsibilities

Responsible Party	Responsibility
Compliance Lead	• Reviewing that the Co-pay Program is reasonably designed and would not encourage or incentivize inappropriate behavior. • Reviewing the Co-pay Program to ensure reasonable eligibility criteria are in place. • Reviewing for conformance with OIG regulations. • Reviewing that the Co-pay Program is consistent with applicable Amgen Compliance requirements.
Law	• Identifying and evaluating legal risks associated with Co-pay programs, e.g., Anti-kickback law, False Claims Act, OIG guidance, interpreting federal and state laws and other guidance.
Responsible Amgen Employee (RAE)	• Ensuring the proposed Co-pay Program meets applicable Compliance requirements and, once approved and operational, continues to operate as intended. • Ensuring proper storage of materials documenting Co-pay Program approvals.
U.S. Value and Access (U.S. V&A), Executive Director or above	• Reviewing and approving new Co-pay Programs and material alterations to existing Co-pay Programs.

Co-pay Programs are Not Intended to Provide any Financial Assistance for Items paid for by any Federal, State, or Government-funded Healthcare Program

Co-pay Programs are not intended to provide any financial assistance for items paid for by any federal, state, or government-funded healthcare program, such as Medicare, Medicare Advantage, Medicare Part D, Medicaid, Medigap, Veterans Affairs (VA), the Department of Defense (DoD) or TRICARE® or where otherwise prohibited by law. Co-pay Programs will be designed and executed employing reasonable safeguards directed at preventing the use of financial assistance for items paid for in whole or part by government-funded healthcare programs.

Co-pay Programs are Not Intended to Induce Prescribing of Amgen Products

Co-pay Programs are designed to remove barriers to Patient access, not to encourage HCPs to prescribe such Products; they are intended for use after an HCP has determined that an Amgen

CHAPTER 6: PATIENT INTERACTIONS AND PATIENT PROGRAMS

Product is clinically appropriate for the Patient. Therefore, Co-pay Programs must be designed, executed, and described consistent with that purpose. Co-pay Program performance analyses should be conducted in a manner consistent with this purpose and after consultation with Law.

Patient Cost Sharing Responsibility and Program Caps

Co-pay Program limits and Patient out-of-pocket cost sharing will be carefully assessed to ensure program designs and rules are reasonable; RAEs will consult with Law to determine reasonableness. A Patient's primary insurance will be used prior to applying any benefits from Co-pay Program.

Co-pay Program Approval and Documentation

All new Co-pay Programs and any material changes to existing Co-pay Programs will receive formal review and approval and must use the U.S. Healthcare Compliance Co-Pay Program Review Form.

All documentation of approvals will be stored in the appropriate system of record.

Review of Co-Pay Program Materials Provided to the Healthcare Community

Materials describing Co-pay Programs that will be used with members of the Healthcare Community will be reviewed as determined by the Promotional and Non-Promotional Material Review SOP.

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