



# Avanir's Commitment to Compliance and Ethics

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# A Message From the CEO and CCO

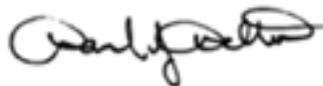
At Avanir, we recognize that our employees and those who work on our behalf (“Avanir Colleagues”) play an important role in supporting our commitment to conducting business with the highest standards of ethical conduct and integrity.

To support our Avanir Colleagues, we have developed this Guide, which includes the Avanir Code of Conduct and additional information that outlines Avanir’s commitment to CARE values. This Guide outlines the minimum requirements that Avanir Colleagues shall comply with when conducting business with, and on behalf of, Avanir.

Our reputation is integral to our success and is one of our most important assets. Ensuring that our ethical business standards are consistently adhered to and never compromised is a priority at Avanir Pharmaceuticals. Our Code of Business Conduct and Ethics (“Code of Conduct”) represents who we are as a company and the high standards we follow. It enables us to fulfill our commitments to our stakeholders, including our customers, patients, suppliers, business partners, regulators and each other. Our shared commitment to serving our stakeholders must be accompanied by a shared commitment to act in compliance with all applicable laws and with integrity.

If a specific activity is not addressed in this Guide, Avanir Colleagues are encouraged to use good judgment, common sense and integrity to guide their conduct. In addition, if questions should arise, Avanir management, members of the Compliance department, the Legal department, Human Resources or any other relevant Avanir department should be contacted. A list of departments and phone numbers can be found in the Contact Information section of this Guide.

Integrity is a cornerstone of Avanir and the foundation of our business practice. Thank you for helping us maintain the highest ethical standards in all that we do.



Dan Dalton, Sr. Vice President, Chief Compliance Officer



Wa'el Hashad, Chief Executive Officer

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# Introduction

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# Introduction

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# Avanir's Expectations of Those Who Work on Our Behalf

The business standards that follow apply to all our Avanir Colleagues. Avanir Colleagues are responsible for ensuring that they understand and comply with these standards; and where appropriate, undertake appropriate due diligence measures with their own business partners to maintain the standards outlined below.

Avanir Colleagues are required to:

## **FOLLOW THE RULES**

Know and comply with the laws, regulations and Company policies that apply when conducting business with, and on behalf of, Avanir. If local laws or policies are more restrictive than those outlined in this Guide or in any of Avanir's policies and procedures, follow the more restrictive requirements.

## **EXERCISE GOOD JUDGMENT**

Always conduct business with honesty and integrity and in a manner that protects Avanir's reputation.

## **ASK QUESTIONS**

If you are unsure about any of the laws, regulations or policies that apply when conducting business with, and on behalf of, Avanir, talk to management or another Avanir resource.

## **RAISE CONCERNS**

Promptly raise any concerns you may have about potential violations of this Guide. If a concern is not resolved to your satisfaction, escalate to another Avanir resource.

# Avanir's Commitment to Compliance and Ethics

The Avanir Commitment to Compliance and Ethics embodies the fundamental principles that guide the Company. It is our promise to conduct business ethically, compliantly and in a manner that reflects our underlying values.

## **OUR COMMITMENT TO PATIENTS AND CUSTOMERS**

We believe that patients and health care professionals have the right to decide the most appropriate treatment options available to them based on truthful, accurate and balanced information. When acting in a promotional capacity, we are committed to providing a balanced presentation of our products, including relevant safety information. Our products are only marketed for the purposes for which they have been approved.

We never solicit or prompt health care professionals or others to ask questions about investigational products or unapproved uses of approved products. Only members of our Medical team (acting in a non-promotional capacity) respond to unsolicited requests for off-label information. These legitimate scientific exchanges and materials are always truthful, accurate, balanced, not misleading, and supported by scientific evidence. We never use these discussions or materials to improperly promote our products.

We prohibit anyone working on our behalf from offering payments or other forms of rewards to health care professionals with the intention of inducing them to purchase, prescribe or recommend our products.

If we receive a report of an adverse event we report it immediately. Reports must be made, regardless of the severity of the event or whether or not the event is considered related to the use of an Avanir product, within the first business day of becoming aware of the event.

If we receive a complaint about any Avanir product from any source, we are committed to promptly and thoroughly following up on the complaint and to taking corrective actions if required.

## **OUR COMMITMENT TO DO BUSINESS THE RIGHT WAY**

We only offer business courtesies or other benefits if they are legal, modest in value, infrequent, or part of commonly accepted business or cultural practices. In providing any item of value we always comply with relevant Company policies and industry codes and, if we are in any doubt about the legality of our actions, we consult our managers and/or the Human Resources, Legal and Compliance departments.

# Avanir's Commitment to Compliance and Ethics

continued

When we do business we put the interests of our patients, customers and other stakeholders first. In order to avoid any conflict between our personal interests and those of the Company, we are proactive in disclosing and addressing potential conflicts before they interfere, or appear to interfere, with the Company's interests.

To provide better, more effective products for patients, we regularly engage health care professionals as partners to provide various bona-fide services in support of our business. Because many of our health care professional partners are also our customers, there is the risk that patients and others might perceive potential conflicts of interest, even if none exist. So, to avoid even the suggestion of a conflict of interest, we conduct all interactions with health care professionals with the utmost integrity, scrupulously adhering to government and industry regulations, as well as enforcing our own strict internal guidelines.

## **OUR COMMITMENT TO EACH OTHER**

We respect the human rights of all people working for, or on behalf of, the Company. We comply with the labor standards set out by the International Labor Organization, as well as applicable labor and employment laws, wherever we operate.

We value the unique perspectives and insights that come from having a diverse mix of talented people. We prohibit discrimination based on personal characteristics including but not limited to race, color, ethnicity, creed, ancestry, religion, sex, sexual orientation, age, gender identity or gender expression, the presence of a mental or physical disability, or veteran status.

We foster a culture of openness, where everyone is encouraged to share their thoughts and ideas. We actively listen to our colleagues and make sure all voices are heard.

We ask questions whenever choices or actions related to our work are unclear. If we have concerns about misconduct, we speak up and promptly raise these concerns.

We believe it is never acceptable to retaliate against anyone who raises a genuine concern, reports misconduct, or participates in any review of such concerns.

We recognize that safety and health rely not only on effective policies and procedures, but also on a commitment from everyone at the Company to include health and safety considerations in their work practices. We work together to build and maintain a safe, respectful, and productive work environment.

# Avanir's Commitment to Compliance and Ethics

continued

## **OUR COMMITMENT TO THE PEOPLE WE PARTNER WITH**

We select Avanir Colleagues based on clear and objective criteria including, but not limited to, price and quality of goods or services, capability, reputation and past performance. We also have an expectation that they will act consistently with our compliance and ethics requirements. We expect our suppliers that provide materials that are incorporated into our products to comply with all applicable laws, which include laws prohibiting the use of child, involuntary or slave labor. We condemn the use of forced labor and human trafficking as well as all kinds of discrimination. We endeavor to select material suppliers who share our standards.

We never solicit gifts, hospitality or other benefits from our current or potential Avanir Colleagues. We only accept business courtesies if they are legal, modest in value, infrequent, or part of commonly accepted business or cultural practices. We accept no item of value that is intended, or likely to be perceived by others to be intended, to improperly influence our business decisions. We only accept business courtesies in circumstances that are consistent with relevant Company policies and industry codes.

We recognize that any misconduct by our Avanir employees and those who work on behalf of Avanir could be attributed to the Company itself. We do not direct, authorize or condone any illegal act by our Avanir employees and those who work on behalf of Avanir. If we become aware of any compliance issue relating to a business partner, we report the incident to the Human Resources, Legal or Compliance departments or the Avanir AlertLine.

## **OUR COMMITMENT TO INVESTORS AND OTHER STAKEHOLDERS**

During the course of business, we generate, and are entrusted with, a great deal of information that is both confidential and proprietary. Often this information is the product of many years of work and is of considerable value to the Company and to others. We are committed to safeguarding and preventing inappropriate or unauthorized access to, or disclosure of, this information.

We respect the privacy of those who share their personal information with us, including, but not limited to, patients, clinical trial participants, health care professionals and organizations, stakeholders, business contacts and Avanir Colleagues. We apply the same high standards to the personal information we handle as we do to confidential information, but in the case of personal information we also comply with additional requirements under applicable privacy laws and Company policies governing the collection and use of that information.

# Avanir's Commitment to Compliance and Ethics

continued

Our customers, partners, suppliers and the general public all rely on the information we have to make decisions to purchase our products, so we keep accurate and timely business records in sufficient detail in order to capture and reflect underlying events and the true nature of our business transactions. We also ensure that our records are free from any intentionally false or misleading entries.

During the course of normal business, we sometimes encounter market-sensitive information about other companies before that information is made known to the public. As employees of Avanir, we agree to never use this information to buy or sell securities, nor to disclose this information to others — inside or outside the Company — without a legitimate business reason and proper authorization.

We regard information as a critical Company asset that is vital to the success of our business and to maintaining public confidence in Avanir. We are committed to ensuring the security and proper use of our information systems and devices, and to preventing the loss, alteration, misuse or unauthorized access or disclosure of our data.

Every day, conversations take place online about Avanir and our products. We recognize that social media, like Facebook and Twitter, provide us with a powerful tool for engaging with our customers, colleagues, partners and the general public. Because we all have an important role to play in protecting the Company's reputation, we commit to using social media in a careful and responsible manner.

## **OUR COMMITMENT TO THE COMMUNITIES IN WHICH WE LIVE AND WORK**

We strive to not only protect and preserve the environment but also to improve it. We do this by constantly looking at ways to conserve our resources, recycle our waste, and reduce our energy usage.

We support charitable organizations and patient groups that benefit society, especially those that run closest to our clinical and scientific goals. We support and commend colleagues who donate their time and effort to community development initiatives and civic causes.

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# Avanir's Compliance Program

The Avanir Compliance Program is an important resource to assist the Company in complying with various laws and regulations to maintain high ethical standards.

The Compliance Program has two primary goals:

- To promote and encourage a strong culture of ethics and compliance; and
- To prevent, detect and correct violations of law and Company policy.

Like other effective compliance programs, Avanir's Compliance Program consists of seven key elements.

## **STRONG LEADERSHIP**

The first element of an effective ethics and compliance program is strong leadership. Avanir's Chief Compliance Officer (CCO), who reports directly to Avanir's Board of Directors and CEO, is responsible for the management and operations of the Compliance department. Supporting the CCO is the Compliance Committee, which is comprised of senior executives who meet periodically to review and assess how current developments in compliance impact our business.

## **WRITTEN STANDARDS**

While the Code of Business Conduct and Ethics is Avanir's overarching written standard, it is reinforced by:

- Policies, which provide more specific requirements based on laws, regulations, industry standards and best practices; and
- Procedures, which operationalize these policies and provide guidance in our day-to-day activities.

Avanir's policies and procedures encompass relevant laws and regulations, including food and drug laws, and laws relating to government health care programs. As such, they are updated regularly to incorporate changes to the law, industry codes, and best practices. For example, the Company has specific procedures for speaker programs, consultancy, grants and donations, scientific research, publications, etc.

## **EFFECTIVE LINES OF COMMUNICATION**

Avanir has put in place a system to ask questions and report concerns. As an Avanir Colleague, it is your obligation to speak up and report any concerns you may have about potential unethical business conduct or potential violations of the Company's Code and policies.

# Avanir's Compliance Program

continued

Avanir management, the Compliance department, Human Resources, and the Legal department are all trusted resources. All reports will be taken seriously to determine whether an investigation is required.

## **TRAINING**

As part of our Compliance Program, Avanir colleagues receive training on many compliance-related topics, including product promotion and product-related activities. Once certified, Avanir holds our Avanir Colleagues responsible for both knowing which policies and procedures directly impact their job role and for following them.

## **ENFORCEMENT OF STANDARDS**

Avanir's Compliance department has an obligation to enforce the standards we set out through well-publicized disciplinary guidelines. And our Avanir Colleagues have an obligation to follow those standards. When they don't, they are held accountable.

## **MONITORING AND AUDITING**

Avanir's Compliance department partners with other corporate functions to continually assess our program. This assessment is important because it helps us to verify compliance with policies and procedures and identify areas of potential concern.

If we become aware of a concern, we investigate. Experts with the right knowledge and objectivity are assigned to confirm the facts and to determine if any law, regulation, policy or procedure has been violated.

Avanir colleagues are required to cooperate with these investigations. Withholding information or providing false or misleading information is not only a serious violation of Avanir's Code, it could also result in us failing to take the necessary actions to protect others.

## **CORRECTIVE ACTION**

Corrective action is important because it provides Avanir with an opportunity to not only correct situations, but to prevent future occurrences and make improvements in our processes.



# Avanir's Standards of Business Conduct

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# Avanir's Standards of Business Conduct

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# Promotional Discussions and Presentations

There are numerous laws and regulations that govern the way pharmaceutical companies are permitted to promote their products. Because of this, companies are required to closely review their promotional materials to ensure that they accurately and fairly reflect the content of their approved product labels.

## **OUR STANDARD**

Once promotional materials are approved, Avanir employees and those who work on behalf of Avanir involved in selling or marketing Avanir products are required to use these materials and only these materials in exactly the same form in which they were provided to them and only in the manner that the materials have been approved for.

## **WHAT TO DO**

When acting in a promotional capacity, Avanir employees and those who work on behalf of Avanir are required to:

- Use only materials approved by Headquarters for promotional use, without alteration of any kind.
- Give a balanced presentation of the product, including relevant safety information.
- Stay on label.
- Refer unsolicited questions regarding unapproved or off-label drug use to Avanir's Medical team.
- Follow Avanir's guidelines on careful email and written communications.

## **WHAT TO WATCH OUT FOR**

Do not engage in promotional activities when Avanir's Medical team is present.

Never solicit or encourage off-label questions from health care professionals (HCPs).

Be careful not to alter Avanir-approved materials by writing on, highlighting or placing stickers on them.

Do not use materials that have not been approved for promotion, including props.

# Off-Label Information and Unapproved Uses

A drug product is approved for use only as stated in its label. Any other use is considered off label. This includes information regarding disease state, dosing, patient populations, use of concomitant medications, duration of therapy, etc. While health care professionals (HCPs) may prescribe products off label in the exercise of their professional judgment, it is illegal for pharmaceutical companies to promote unapproved uses of a product. It is also illegal to promote a product before it is approved by the FDA.

## **OUR STANDARD**

At Avanir, only members of our Medical team (acting in a non-promotional capacity) may provide scientific information about unapproved products or uses upon receiving an unsolicited request for information from an HCP. Such requests and responses must be properly documented.

## **WHAT TO DO**

Avanir employees and those who work on behalf of Avanir acting in promotional capacity are responsible for learning and understanding what is included in the FDA-approved label of the drug(s) they are promoting.

In response to an unsolicited request for off-label information, you must:

- Explain to the requestor that the question concerns an unapproved use that you are not permitted to discuss; and
- Refer the requestor to a member of Avanir's Medical team.

## **WHAT TO WATCH OUT FOR**

Be careful not to solicit or prompt HCPs to ask questions about unapproved uses or off-label information.

Never discuss off-label information provided to HCPs by a member of Avanir's Medical team.

# Patient Privacy and Data Protection

Personal Information is any information that relates to, describes, identifies, or could reasonably be linked to a particular individual, including information supplied to Avanir by third parties, such as customers, contractors and vendors. In most countries in which Avanir conducts business there are laws and regulations in place designed to protect Personal Information.

## **OUR STANDARD**

Avanir requires its employees and those who work on behalf of Avanir to adhere to all applicable data protection requirements.

## **WHAT TO DO**

Only obtain personal data fairly and lawfully, and in a transparent manner.

Always give individuals an opportunity to say “yes” or “no” to the collection and use of their personal information.

Only use Personal Information for the specific purposes for which it was collected.

Always store and dispose of Personal Information in a manner consistent with Avanir’s data management, retention and disposal requirements.

Always provide individuals with the right to obtain, correct, amend or request deletion of their Personal Information.

Always take reasonable measures to ensure the Personal Information that is retained is accurate, complete and current.

Always use reasonable and appropriate measures to protect Personal Information.

## **WHAT TO WATCH OUT FOR**

Never share Personal Information with third parties without prior consent of Avanir’s Legal department.

# Accuracy and Integrity of Books and Records

Complete and accurate books and records are not only a legal requirement, they are also essential to operating a successful business.

## **OUR STANDARD**

Avanir employees and those who work on behalf of Avanir are responsible for ensuring that all books, records and accounts relating to Avanir business accurately reflect the content and nature of the subjects and transactions that are recorded.

## **WHAT TO DO**

Always track and report complete, accurate and timely data relating to transfers of value or payments to health care professionals (HCPs) and health care organizations (HCOs).

## **WHAT TO WATCH OUT FOR**

Never make a payment on Avanir's behalf with the intention or understanding that any part of the payment will be used for any purpose other than that described in the document supporting the payment.

Never omit or delete meaningful study results from a report.

Never include false information on an expense report.

# Adverse Event Reporting

An adverse event is any undesirable event occurring in a patient using or exposed to a drug, whether or not the event is considered to be related to the use of the drug.

## **OUR STANDARD**

Any Avanir Colleague who learns about an adverse event or potential adverse event must report it within 24 hours.

## **WHAT TO DO**

Report all adverse events you learn of, regardless of:

- How you found out about the event;
- Whether or not the event is considered to be related to the use of the drug;
- Whether the event is listed in the package insert as a potential adverse event.

Make all reports as soon as you become aware of them or within 24 hours.

## **WHAT TO WATCH OUT FOR**

Report any adverse event you become aware of, even if you have doubts about its relationship to the use of our drug.

# Antibribery and Anticorruption

Bribery and corruption occur whenever Avanir, or someone acting on Avanir's behalf, offers, promises, gives or receives anything of value for personal gain or to improperly influence business.

## **OUR STANDARD**

Avanir has zero tolerance for bribery and any form of corruption. Our expectation is that Avanir employees and those who work on behalf of Avanir comply with all applicable local and international laws and regulations governing bribery and corruption.

## **WHAT TO DO**

If offered a bribe or requested to make a bribe in your work for Avanir, immediately report the incident to Avanir's AlertLine.

Be cautious when faced with any form of commission payment and ensure that fees or any other payments for services are reasonable, proportionate, and paid through bona fide channels.

## **WHAT TO WATCH OUT FOR**

Never give or accept bribes directly or indirectly.

Never make a facilitation payment to secure or expedite the performance of a routine or necessary action.

# Conflicts of Interest

A conflict of interest exists whenever a Business Colleague's private interests interfere, or appear to interfere, with Avanir's interests. Having a conflict of interest is not necessarily illegal. However, it can become a problem or a legal matter if a Business Colleague or someone acting on Avanir's behalf tries to influence the outcome of business dealings for direct or indirect personal benefit.

## **OUR STANDARD**

Avanir's policy on conflicts of interest requires that decisions made by Avanir Colleagues are based solely on the best interest of Avanir without regard to personal, family or other considerations. Avanir expects our Avanir Colleagues to be proactive in managing conflicts of interest in collaboration with Avanir. Avanir employees and those who work on behalf of Avanir must be aware that even the appearance of conflicts of interest can be a violation of Avanir policy.

## **WHAT TO DO**

Always inform Avanir about all financial or personal interests that may present a conflict of interest.

Use good judgment when making business decisions and avoid situations that interfere with your ability to make an objective decision and act in the best interest of Avanir.

Work with Avanir to resolve conflicts and avoid any impact to Avanir's business.

## **WHAT TO WATCH OUT FOR**

Remove yourself from any decision-making process where there may be a conflict.

# Confidentiality and Intellectual Property

Avanir's intellectual property and confidentiality are valuable assets. The disclosure of this information, whether intentional or accidental, can adversely affect the financial stability and competitive position of Avanir.

## **OUR STANDARD**

Avanir requires Avanir Colleagues to carefully protect the intellectual property and confidential information of Avanir and others. Avanir will not use third-party intellectual property or confidential information unless this is according to an agreement or occurs with prior approval from the owner.

## **WHAT TO DO**

Protect and respect the intellectual property and confidential information of Avanir, as well as that of third parties.

Ensure that intellectual property of Avanir is used for the allowed purpose and in accordance with Avanir's instruction.

Ensure that the intellectual property of third parties is used only with specific permission from the owner and only for the allowed purpose.

Ensure that confidential information of Avanir's, as well as third parties, is kept in strict confidence and is disclosed only in accordance with the consent of the owners.

## **WHAT TO WATCH OUT FOR**

Do not share Avanir's intellectual property or confidential information with third parties, unless with Avanir's consent.



# Laws & Regulations That Impact Avanir's Interactions with HCPs and Others

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# Laws & Regulations That Impact Avanir's Interactions with HCPs and Others

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# Laws & Regulations

continued

This is a summary of some important laws, regulations, codes and guidelines that govern how Avanir conducts activities with health care professionals (HCPs) and others. It is important that Avanir employees and those who work on behalf of Avanir understand how these laws and regulations apply to our activities, what we at Avanir are doing to comply with them, and what to do if activities raise potential concerns that need to be brought to the Company's attention.

## **ANTI-KICKBACK STATUTE**

The Anti-Kickback Statute is aimed at protecting federal health care programs and their patients from improper influence on the health care decisions made by health care providers. It prohibits payments or other forms of rewards from a pharmaceutical company that are intended to induce someone to buy, lease, order or recommend any goods or services paid for by a government health care program.

It is important to note that a kickback does not have to be in the form of money. In fact, a kickback could be anything of value — including discounts, rebates, grants, gifts, items sold below market value, free product, credit deals and other non-cash incentives that have a monetary value.

Penalties for violating the Anti- Kickback Statute can include severe criminal and administrative sanctions. Violations are considered felonies and can result in a fine of up to \$50,000 per instance, plus damages of up to three times the amount of unnecessary payments made by the government as a result of the kickback.

## **FALSE CLAIMS ACT**

The False Claims Act (FCA) is a powerful tool used by the federal government to combat health care fraud and abuse. The FCA prohibits anyone from knowingly filing — or causing someone else to file — a false claim for payment to any federal health care program or other government agency. The FCA has been applied very broadly to any entity that provides information related to a claim submitted to the government for reimbursement.

Marketing or promoting a product for any use other than its approved use can also become a false claim. If promotion is outside the approved indication, the product is considered “misbranded.” Any sale or distribution of a “misbranded” product violates the Food, Drug and Cosmetic Act and can result in a criminal conviction of a person or a company.

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# Laws & Regulations

continued

## **FDA LAWS AND REGULATIONS**

The Food, Drug and Cosmetic Act applies to the development of a pharmaceutical product, from clinical testing through promotion, and is enforced by the Food and Drug Administration or FDA.

As part of its authority, the FDA regulates product promotion. Before the FDA approves a drug for use, it first determines that the drug's label is truthful and that it doesn't omit any information required for the safe and effective prescribing of the drug. Once approved, a pharmaceutical company is responsible for ensuring that its drug is promoted on the basis of that information. When a drug is marketed for any use outside the approved prescribing information in the label, the promotion is considered "off-label."

Off-label promotion includes both:

- Discussing a product or indication of use not approved by the FDA; as well as
- Discussing information that is not consistent with the prescribing information.

It is illegal for pharmaceutical companies to promote unapproved uses of a product. It is also illegal to promote a product before it is approved by the FDA.

## **PRESCRIPTION DRUG MARKETING ACT (PDMA)**

The Prescription Drug Marketing Act of 1987 is a federal law governing the distribution of drug samples. One purpose of PDMA is to protect overall public health and to protect the public from the harm caused by the consumption of counterfeit, adulterated, misbranded, sub- potent or expired sample products by establishing procedures, requirements and minimum standards for the distribution of drug samples.

PDMA prohibits the sale, purchase or trade of drug samples, or an offer to sell, purchase or trade drug samples. PDMA also requires extensive documentation of many aspects of sampling transactions and falsification of any required documentation is a serious PDMA violation.

PDMA violations can result in monetary fines and criminal penalties for the company and for the individual employee. Violations can also result in the revocation of the company's sampling privileges.

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# Laws & Regulations

continued

## **PRIVACY AND DATA PROTECTION**

The U.S. system of privacy protection is like a patchwork quilt, made up of different laws and regulations created and enforced at federal, state and local levels of government. For example, the federal Health Insurance Portability and Accountability Act (HIPAA) governs the use of patients' medical and health information.

In addition to federal laws, U.S. states have their own privacy laws, including laws that relate to notification of certain data breaches. For example, California recently passed the California Consumer Privacy Act (CCPA). CCPA gives California residents certain rights in relation to their Personal Information, including:

- **Right to Notice:** Covered businesses must inform individuals what information is collected about them, and how it will be used.
- **Right to Opt-Out:** Individuals have the right to opt-out of the disclosure of their Personal Information to third parties.
- **Right to Deletion:** Individuals can request that their Personal Information be deleted.
- **Right to Equal Service and Price:** Businesses cannot discriminate by charging a different price, or by providing lower-quality goods or services.

## **MEDICAID REBATE STATUTE**

The Medicaid Drug Rebate Statute, administered by the Centers for Medicare and Medicaid Services (CMS), requires manufacturers to enter into an agreement with the Secretary of the Department of Health and Human Services (HHS) to provide rebates for their covered outpatient drugs, to help offset government drug spending. Avanir must accurately report prices and pay rebates as required by the Medicaid Drug Rebate Statute to Medicaid. The affected programs include Medicaid, Medicare, TRICARE, the Veterans Administration Federal Supply Schedule, Section 340B drug pricing programs, the Federal Employee Health Benefit Plans, and Indian health clinics, among others.

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# Laws & Regulations

continued

## **U.S. OPEN PAYMENTS AND TRANSPARENCY LAWS**

U.S. Open Payments and other transparency laws are intended to provide more transparency in the relationships between pharmaceutical manufacturers and health care providers, by requiring manufacturers to report payments and other “transfers of value” to physicians and U.S. teaching hospitals on an ongoing basis.

These laws are important because they:

- Encourage transparency about financial ties;
- Provide information about the nature and extent of these financial relationships;
- Help to curb wasteful health care spending; and
- Help prevent inappropriate influence on research, education and clinical decision-making.

Avanir complies with transparency laws by collecting and reporting on payments and other transfers of values to health care professionals and other covered recipients.

## **FOREIGN CORRUPT PRACTICES ACT (FCPA)**

The U.S. Foreign Corrupt Practices Act (FCPA), which is essentially an anti-bribery statute, applies to U.S.-based companies as well as subsidiaries and agents under their control, whether or not they are in the United States. The FCPA prohibits giving, offering, promising, or paying money or anything of value, directly or indirectly by an intermediary or third-party agent, to a foreign official for the purpose of obtaining or retaining business or obtaining an improper advantage. The term “foreign officials” under the FCPA is broad. Any question regarding compliance with the FCPA or related standards may be referred to Avanir’s Legal or Compliance departments.

## **PHYSICIAN DATA RESTRICTION PROGRAM (PDRP)**

The American Medical Association developed the Prescription Data Restriction Program (PDRP) to empower all physicians to make their own choice to “opt out” of having their prescribing data released to pharmaceutical companies.

Pharmaceutical companies are required to check the opt out list quarterly, at a minimum.

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# Laws & Regulations

continued

At Avanir, opt out prescribers' prescription activity are excluded from all sales reports. All reports that contain prescriber data have a disclaimer that all data and information is not for distribution, display or promotion with customers and is for authorized Avanir personnel only.

## **OIG GUIDANCE TO PHARMACEUTICAL MANUFACTURERS**

The Compliance Program Guidance for Pharmaceutical Manufacturers was released by the Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS) in 2003. The document sets out seven elements upon which an effective compliance program may be built. Its aim is to assist companies in developing and implementing internal controls and procedures that promote adherence to federal health care rules, regulations and requirements.

## **PHRMA CODE ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS**

The Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Health Care Professionals addresses pharmaceutical manufacturers' relationships with health care professionals and establishes guidance concerning several practices.

Avanir's policies and practices have been developed to be consistent with the OIG guidance and the PhRMA code, as well as to comply fully with all relevant laws and regulations. By following Avanir's policies and Avanir standards, you can promote the integrity of Avanir and avoid behavior that can be costly to you and to Avanir.

## **PHRMA PRINCIPLES ON CONDUCT OF CLINICAL TRIALS**

The PhRMA Principles on Conduct of Clinical Trials address key issues including protecting research participants, conduct of clinical trials, ensuring objectivity in research and disclosure of study results. These principles focus on assuring the safety of research participants through the appropriate conduct of clinical trials and maintaining objectivity and transparency when reporting study results.



# Avanir's CIA & DPA

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# Avanir's CIA & DPA

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# Avanir's Corporate Integrity Agreement

Avanir's commitment to excellence takes many forms — excellence in our research and development; excellence in our products; and excellence in our corporate integrity and business ethics.

Avanir has entered into a five-year Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services. The Company has agreed to undertake certain integrity obligations designed to promote compliance with applicable Federal health care program and FDA requirements. The term of the agreement is five years.

The CIA obligations broadly include, amongst other things, requirements regarding:

1. Governance
2. Written Standards
3. Training and Education
4. Risk Assessment and Mitigation
5. Retention of an Independent Review Organization to Conduct Annual Reviews of Systems and Transactions
6. Confidential Disclosure Program
7. Screening for "Ineligible Persons"
8. Notifying OIG Regarding Certain Investigations, Legal Proceedings, FDA Communications, and Reportable Events
9. Internal Field Force and Non-Promotional Monitoring
10. Providing Reports to OIG on the Status of Compliance Activities

Our CIA applies to Avanir and to certain activities conducted by employees, contractors, or agents. The "Covered Functions" under the CIA are "Promotional Functions" and "Product-Related Functions."

Promotional Functions include:

- Activities that involve the selling, detailing, marketing, advertising, promoting or branding of Avanir products that are marketed or sold by Avanir in the United States.
- The preparation or external dissemination of promotional materials or information about, or the provision of promotional services relating to, such products, including activities relating to Avanir's review and approval processes for promotional materials and any applicable review committee(s).

# Avanir's Corporate Integrity Agreement

continued

Product-Related Functions include:

- Preparing or disseminating non- promotional materials that are governed by Federal healthcare program and/or FDA requirements and distributed to healthcare providers, healthcare institutions, and / or payers about products that are marketed or sold by Avanir in the United States, including activities relating to any applicable review committees, medical affairs/medical information services, or functions involved in scientific exchange
- Contracting with healthcare practitioners licensed in the United States or with health care institutions to conduct post- marketing clinical trials and other post-marketing studies [such as investigator-initiated studies and post-marketing observational studies] with the products that we market or sell in the United States;
- Authorship, publication, and/or disclosure of articles or study results about the products that we market or sell in the United States; and
- Submitting information about our marketed pharmaceutical products to compendia.

If you are an employee, contractor, vendor, agent, etc. that works on the above activities, you may be a Covered Person under the CIA. Avanir's obligations related to Covered Persons include, amongst others:

- Covered Persons must complete mandatory training;
- Covered Persons must notify Compliance immediately of any debarment, exclusion, suspension, or conviction of a criminal offense that may impact your participation in Federal health care programs;
- Certain Policies & Procedures must be made available to all Covered Persons and compliance with these Policies & Procedures must be an element of performance evaluations for Covered Persons

Certain Avanir management must certify on annual basis that, to the best of their knowledge, Avanir is in compliance with the CIA and with applicable Federal health care program and FDA requirements. If Avanir is found to be non- compliant with the CIA, OIG may impose monetary penalties. In addition, a material breach of the CIA could result in exclusion from participation in Federal health care programs.

# Avanir's Deferred Prosecution Agreement

Avanir has also entered into a Deferred Prosecution Agreement with the Department of Justice (DOJ). The term of the DPA is three years. However, the Government may seek to extend the agreement if Avanir materially violates or fails to perform its obligations under the DPA. Under the DPA, Avanir has made several commitments, including that it will implement a compliance and ethics program designed to prevent and detect violations of the Food, Drug, and Cosmetic Act, the Anti-Kickback statute, and HIPAA, as well as health care fraud, false claims, conspiracy to defraud the United States, obstruction of justice, and false statements throughout its operations (including those of its subsidiaries, operationally controlled affiliates, agents, and joint ventures).

The Company also agrees to abide by the terms of the CIA entered separately between the Company and DOJ.

If during the term of the agreement the Company:

- Commits any felony under U.S. federal law;
- Provides in connection with this Agreement deliberately false, incomplete, or misleading information, including in connection with its disclosure of information about individual culpability;
- Fails to cooperate as set forth in the Agreement;
- Fails to implement a compliance program as required by the Agreement and the CIA entered into separately between the Company and the OIG; or
- Fails to completely perform or fulfill any other obligation under the Agreement

The Company shall be subject to prosecution for any federal criminal violation of which the Government has knowledge.



# Reporting Violations & Seeking Advice

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# Reporting Violations & Seeking Advice

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Reporting Violations and Seeking Advice

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# Reporting Violations & Seeking Advice

Avanir offers several channels for reporting violations and seeking advice. All information is handled discreetly, and reports may be made anonymously. Avanir employees and those who work on behalf of Avanir are encouraged to use the channel they feel most comfortable with.

## **OUR STANDARD**

Avanir Colleagues have an affirmative responsibility to report potential or actual violations of any law, regulation or Company policy. No Colleague will be retaliated against for reporting potential or actual violations in good faith. Avanir takes all claims of retaliation seriously. All allegations will be thoroughly investigated and, if substantiated, those responsible will be subject to disciplinary action.

## **WHAT TO DO**

If you reasonably believe a potential or actual violation has occurred, talk to:

- Management
- The Compliance Department
- The Legal Department
- Internal Audit
- Avanir's AlertLine: 1-855-809-3045

Only provide information that you genuinely believe is honest and accurate, even if you are later proven to be mistaken.

Report any retaliatory behavior observed.

Observe all instructions you receive concerning confidentiality and the importance of maintaining it.

## **WHAT TO WATCH OUT FOR**

Never intentionally make a report in bad faith.



# Appendix

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# Appendix

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# Contact Information

If you have questions or want to raise concerns, you should contact your manager. If circumstances prevent contact with your manager, you should use one of the following options:

- Contact the Compliance department;
- Contact Human Resources;
- Contact the Legal department;
- Call the Avanir AlertLine at 1-855-809-3045 [you may elect to remain anonymous];
- Submit a report online to the Avanir AlertLine at <http://www.avanir.alertline.com>

You can access policies and procedures on:

- The Avanir Intranet
- The Avanir Learning Management System

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# Glossary

**Adverse Event (AE)**

An AE is any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related.

**Anti-Kickback Statute**

The Anti-Kickback Statute prohibits payments or other forms of rewards by a pharmaceutical company to induce someone to prescribe or recommend the use of that company's products.

**Corporate Integrity Agreement (CIA)**

An agreement between the Office of the Inspector General of the Department of Health and Human Services and a health care provider or other entity as part of a settlement for alleged civil wrongdoing relating to U.S. federal health laws.

**Facilitation Payments**

Payments made to government officials directly or through third parties to secure or speed up government processes or actions. Avanir does not permit "facilitation payments" even if local laws permit such payments or payments are nominal in value.

**Fair Balance**

The presentation of an accurate and fair assessment of the risks as well as benefits of a drug.

**False Claims Act**

The False Claims Act imposes penalties on companies and individuals who either submit a false claim for payment or cause someone else to file a false claim for payment to the federal government.

**Food and Drug Administration (FDA)**

Established by the Food, Drug and Cosmetic Act (FDCA) to regulate the importation, manufacture, distribution and sale of drugs in the United States and is responsible for ensuring that all drugs approved for marketing are safe and effective. To accomplish its purpose, the FDA issues regulations directed at drug labeling and advertising by manufacturers, which also affects speech related to the sale of these drugs.

**Food, Drug & Cosmetic Act (FDCA)**

The federal statute governing the importation, manufacture, distribution, marketing and sale of drugs and foods in the United States.

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# Glossary

continued

## **Foreign Corrupt Practices Act (FCPA)**

Forbids corrupt payments to any foreign official for the purpose of obtaining business. “Foreign official” includes an officer or employee of a foreign government or agency, including state-owned hospitals or health care systems.

## **Health Insurance Portability and Accountability Act (HIPAA)**

Privacy rule created in 1996 to assure covered entities such as health plans and health care providers protect personal health information (PHI), while allowing the flow of health information necessary to promote and provide high-quality health care and to protect the public’s health.

## **Health Care Professional (HCP)**

Any person or entity in a position to prescribe or influence a purchasing decision for, any product or service including, without limitation, hospitals, physicians and other HCPs (e.g., nurses, pharmacists, etc.), research institutions, research foundations, medical associations, group purchasing organizations, managed care organizations (MCOs), pharmacy benefit managers (PBMs), health maintenance organizations (HMOs) and other health care coverage providers, and other similar or related entities.

## **Hold Order**

Directives issued by the Legal department to notify employees and Avanir employees and those who work on behalf of Avanir when Avanir is required to preserve documents because of pending litigation or investigation. They require all relevant parties not to discard, delete or destroy any document covered by the Hold Order.

## **Office of Inspector General (OIG)**

Investigative arm of the agency that oversees Medicare and Medicaid (Department of Health and Human Services (HHS) / the Center for Medicare and Medicaid Services (CMS)). The OIG is charged with protecting the integrity of these programs, as well as protecting the health and welfare of the beneficiaries of those programs.

## **Off-Label Information**

Information that has not been approved by FDA and, thus, is not contained in the prescribing information for a drug. It is illegal for pharmaceutical manufacturers or their agents to promote a drug off label.

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# Glossary

continued

**Package Insert/Prescribing Information (PI)**

Medically relevant information for which the manufacturer submitted data to the FDA and which the FDA approved. In approving a product, the FDA determines both that the content of the PI is entirely truthful, and that it does not omit any information that is pertinent to the safe and effective prescribing of the drug, based solely on the scientific data that has been submitted to the FDA. Once approved, the FDA has ongoing surveillance responsibilities.

**Prescription Drug Marketing Act (PDMA)**

The PDMA of 1987 prohibits the sale, purchase or trade of drug samples, or an offer to sell, purchase or trade drug samples. PDMA also requires extensive documentation of many aspects of sampling transactions and falsification of any required documentation is a serious PDMA violation.

**Personally Identifiable Information (PII)**

PII is any information that identifies or provides a reasonable basis to believe it can be used to identify an individual.

**Pharmaceutical Research and Manufacturers of America (PhRMA)**

Pharmaceutical Research and Manufacturers of America (PhRMA) is an industry trade group representing the pharmaceutical research and biotechnology companies in the United States.

**Retention Schedule**

Documents that identify how records are to be maintained and destroyed in accordance with all applicable legal, regulatory and business requirements.