

BUSINESS ETHICS & COMPLIANCE PROGRAM

SEPTEMBER 2023



The
Assistance
Fund

Letter From the CEO and Chairman of the Board

FELLOW TAF ASSOCIATES,

TAF's updated "Business Ethics and Compliance Plan" reflects our continued commitment to a culture of business ethics and compliance. To promote business ethics and compliance, we have formally incorporated compliance responsibilities throughout the organization — for our Board and all levels of staff. TAF has an engaged Board of Directors Compliance Committee and Executive Compliance Committee. And TAF developed a Compliance Champions Team with members from every department who provide input on the Business Ethics and Compliance Program and act as a valuable compliance resource to employees. TAF continues to successfully navigate industry changes by evolving our Business Ethics and Compliance Program and implementing best practices every step of the way.

“Operational excellence must be accompanied by personal and organizational integrity.”

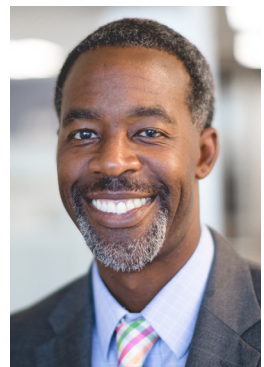
This Business Ethics and Compliance Program guides the conduct of TAF's Executive Leadership, directors, employees, contractors, and other persons engaged in patient assistance-related functions ("TAF Stakeholders"). It provides information on how TAF's Stakeholders may ask and resolve questions about potential regulatory or ethical issues and includes the various ways to internally report possible violations. Finally, it emphasizes TAF's non-retaliation policy related to reporting compliance issues.

As part of a highly regulated industry, our work is impacted by legislative and regulatory enforcement activities. In the coming years, we will vigilantly monitor new risks and vulnerabilities. Each of us at TAF—from the Board, Executive Leadership, employees, and others acting on behalf of TAF—is responsible for knowing and understanding the Business Ethics and Compliance Program and related policies that govern our work.

Thank you for your continued dedication and commitment to TAF!



Danielle Vizcaino
DANIELLE VIZCAINO
President & CEO



Lawrence Hatch
LAWRENCE HATCH
Chair, Board of Directors

Mission

To provide underinsured people living with life-threatening, chronic, and rare diseases access to critical treatment through financial assistance, education, and advocacy.

Vision

The Assistance Fund envisions the day when no one goes without treatment because of an inability to pay.

Values





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Introduction

ABOUT THE ASSISTANCE FUND

The Assistance Fund (TAF) is an independent charitable patient assistance organization that helps patients and families facing high medical out-of-pocket costs by providing financial assistance for their copayments, coinsurance, deductibles, and other health-related expenses.

TAF manages nearly 90 funds referred to as disease programs (“Programs”), each of which covers the FDA-approved treatment for a specific disease. After patients receive a diagnosis of a life-threatening, chronic, or rare disease, they may contact TAF to apply for assistance with the costs of their treatment or other health-related services. Patients receive an eligibility determination within minutes of applying. Once a patient is enrolled in one of our disease programs, their coverage lasts the entire calendar year. Since 2009, TAF has helped nearly 180,000 people access critical treatment for life-threatening, chronic, and rare diseases.

As an independent charitable patient assistance organization, TAF operates under an Advisory Opinion issued by the U.S. Department of Health and Human Services (“HHS”) Office of Inspector General (“OIG”). Additionally, TAF is subject to numerous laws and regulations including, but not limited to, the federal Anti-Kickback Statute, the federal Beneficiary Inducement Law, the False Claims Act, Exclusion Statute, and the Internal Revenue Service Code (“IRS”).

TAF’S BUSINESS ETHICS AND CORPORATE COMPLIANCE PROGRAM

Independent charitable patient assistance organizations operate in an increasingly complex legal and regulatory environment. TAF is fully committed to conducting all activities in full compliance with those laws and regulations and with the highest level of ethics and integrity. TAF prioritizes transparency, is accountable and open in all its business practices, and depends on employees and TAF Stakeholders to report any questionable activity.

“TAF is committed to conducting all activities in full compliance with the highest level of ethics and integrity.”



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Accordingly, TAF's Board of Directors ("Board") has implemented a Business Ethics and Compliance Program ("TAF Compliance Program"). This program is consistently evolving to ensure TAF's culture of compliance is implemented at every level of the organization.

“The TAF Board oversees TAF's Compliance Program to ensure our commitment to our patients and our work, and our compliance with the numerous laws, regulations, and policies that govern all TAF activities.”

TAF's Board provides oversight to TAF's Compliance Program to ensure our commitment to our patients and our work, and our compliance with the numerous laws, regulations, and policies that govern all TAF activities. The Board receives regular reports directly from TAF's Compliance Officer to ensure TAF continues to meet our ethical, legal, and regulatory requirements.

TAF created a Business Ethics and Compliance Program that strives to be: 1) well designed; 2) adequately resourced and empowered to function effectively; and 3) able to work in practice. Specifically, TAF's program incorporates the elements of an effective corporate compliance program defined in the U.S. Department of Justice's (DOJ's) 2023 updated guidance.

This Plan provides a high-level overview of our program. TAF provides detailed guidance in our policies and procedures, all of which are accessible to employees. In addition, TAF provides contractors and people engaged in patient-assistance-related functions with relevant policies and procedures.



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All TAF Stakeholders are individually responsible for understanding and complying with the applicable laws, government guidance, and TAF protocols that impact their daily activities or duties.

TAF's Business Ethics and Compliance Program embodies many interwoven activities that together form our compliance best practices.



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Overview of Code of Business Ethics

TAF adheres to the highest legal and ethical standards applicable to our organization as reflected in this Business Ethics and Compliance Plan. The standards and guidelines set forth throughout this Plan support TAF's standards of business conduct. This section guides TAF's business practices and principles and provides an overview of the standard for conducting all business activities with the highest degree of ethics and integrity. The integrity of each TAF Stakeholder is of the utmost importance. If there is any doubt about whether an activity is legal or proper, the individual should contact TAF's Compliance Officer.

1.1 COMPLIANCE WITH LAWS, REGULATIONS, AND CONTRACTS

TAF is committed to conducting all its activities in compliance with both the letter and spirit of applicable laws, regulations, Advisory Opinions, guidelines, and contractual obligations and requires all persons working for or on behalf of TAF to conduct themselves in accordance with this commitment.



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1.2 PROFESSIONAL ETHICS

TAF fairly and accurately represents itself in all business relationships and does not engage in any activity or scheme intended to defraud. All persons working for or on behalf of TAF conduct TAF-related activities in accordance with the highest level of business ethics and integrity and in a manner that TAF's reputation will not be impugned if the details of their dealings should become a matter of public discussion. TAF does not promote or market any of its Donors' products. TAF only promotes TAF's disease programs.

1.3 HARASSMENT AND RETALIATION

TAF prohibits its Stakeholders from engaging in harassment or retaliation against an individual for reporting an ethics or compliance violation or for any other unlawful reason.

1.4 FRAUD, WASTE, AND ABUSE

TAF prohibits its Stakeholders from engaging in fraudulent activity. More specifically, TAF prohibits them from receiving payments or other remuneration in exchange for making a decision or taking an action on TAF's behalf. They may not offer, pay, solicit, or receive anything of value to induce, or in exchange for the ordering or purchase, or the recommending or arranging for the order or purchase, of items or services paid for, in whole or in part, by a federal healthcare program.

1.5 CONFIDENTIALITY AND INTELLECTUAL PROPERTY

In addition to patient privacy, TAF recognizes the importance of confidentiality concerning TAF's business and financial records and Donor information. Therefore, TAF does not share Donor information with any other Donor, recipient, or third party unless legally obligated to do so. Also, TAF controls the dissemination of TAF's proprietary information. People with access to confidential information must not disclose to any outside party non-public business, financial, personnel, commercial or technological information, or plans or data acquired unless they are authorized by management and in accordance with TAF's policies.

Additionally, TAF Stakeholders are responsible for ensuring they do not unlawfully copy documents or computer programs in violation of applicable copyright laws or licensing agreements or use confidential business information obtained from competitors, including patient lists, contracts, or other information in a manner likely to provide an unfair competitive advantage to TAF.



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1.6 CONFLICTS OF INTEREST

TAF Stakeholders must: (1) conduct their activities in a way that avoids actual or perceived conflicts of interest; (2) never use their position with the organization, or any of its patients or Donors, for private gain, to advance personal interests or to obtain favors or benefits for themselves, members of their families or any other individuals, corporations, or business entities; (3) conduct their personal affairs such that their duties and responsibilities to the organization are not jeopardized and/or legal questions do not arise with respect to their association or work with the organization; and (4) immediately disclose, in accordance with TAF's conflict of interest policies, if they believe that a course of conduct or action may involve a conflict of interest.

A conflict of interest arises when an individual's interests influence or appear to influence their decisions regarding TAF. TAF considers it a potential conflict of interest if an employee knows personally any patient enrolled in a TAF disease program. TAF does not prohibit family members or other individuals personally known to TAF employees from enrolling in a TAF program; however, such relations must be disclosed immediately. Additionally, TAF considers any form of compensation from a Donor to an employee, or any ongoing relationship with a Donor, both as impermissible conflicts of interest.

1.7 SANCTIONED INDIVIDUALS

TAF does not knowingly employ or engage in a business relationship with anyone who is currently under sanction or exclusion by the OIG. TAF shall remove individuals or contractors under pending criminal charges related to healthcare or proposed exclusion sanction by the OIG, who are listed by a federal or state agency as debarred, excluded, or are otherwise ineligible for participation in a government-funded healthcare program. Upon hire and monthly thereafter, TAF routinely checks the Office of Inspector General's List of Excluded Individuals/Entities, and System for Award Management (EPLS/SAM) to ensure that potential and existing employees, providers, contractors, and consultants have not been excluded from participating in federal programs. TAF has a strict policy that prohibits employing individuals or engaging with any person or entity who has been subject to exclusion. If TAF discovers that an individual or company that TAF does business with becomes excluded while employed or contracted with TAF, TAF will immediately terminate the employee and/or contract.

1.8 GIFTS, ENTERTAINMENT, AND GRATUITIES

TAF is committed to maintaining fair and honest business relationships with third parties. TAF Stakeholders may not accept entertainment, gifts, gratuities, or preferable treatment from a person or entity that could influence, or appear to influence, TAF's business decisions or actions. Gifts, which include entertainment and gratuities, may be anything of value, such as discounts, cash, loans, favorable terms on any product or service, services, prizes,



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transportation, use of vehicles or vacation facilities, home improvements, tickets to events, and gift certificates. Gifts are acceptable only if the activities comply with applicable law, have a legitimate business purpose, and are consistent with TAF's policies. Receiving or giving gifts of cash or cash equivalents is never allowed.

1.9 ACCURATE RECORDS

Every employee is responsible for ensuring that all financial reports, accounting records, research reports, expense accounts, timesheets, and other documents are accurate and clearly represent the relevant facts or the true nature of a transaction. Employees should never make false or misleading entries in reports or other records. TAF keeps business records in an accurate, true, and complete manner. To secure the accuracy and reliability of financial records and reports, TAF has internal control standards and procedures. Accurate business records are essential for TAF's legal, financial, and other reporting obligations. Fraudulent accounting or documentation violates TAF's policies and applicable laws.

1.10 DUTY TO REPORT

TAF Stakeholders have an affirmative duty to report any concerns or issues relating to potential non-compliance with applicable laws, regulations, policies, or procedures. Those who, in good faith, report a possible violation of law, regulation, policy, or procedure are not subject to retaliation, retribution, or harassment per TAF policies.

1.11 COMMUNICATIONS WITH THE PUBLIC

When communicating publicly on matters that involve TAF, Stakeholders should not represent or give the impression that they are speaking on behalf of TAF unless they are authorized, and the views they express reflect TAF's position.



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Business Ethics & Compliance Program Elements

Organizations build effective business ethics and compliance programs around various elements. For years, TAF and other organizations have referenced the “7 Elements of an Effective Compliance Program.” The compliance industry has recognized these seven elements as the foundation of an effective compliance program. However, recent Department of Justice guidance that serves to evaluate compliance programs provides organizations additional elements to support effectiveness. Accordingly, TAF has expanded its elements to 11 to reflect this updated guidance. Below is a detailed discussion of the 11 Elements of An Effective Compliance Program.

Why is an effective business ethics and compliance program important? An effective business ethics and compliance program helps ensure TAF and its employees understand, embrace, and follow the rules and policies that support a culture of business ethics and compliance. Additionally, it reduces the risks of compliance violations and mitigates penalties in the event of a violation. For example, if a regulator or law enforcement body found that TAF violated a regulation or law, they would evaluate the effectiveness of TAF’s Business Ethics and Compliance Program to determine penalties. If they found that TAF had a strong Business Ethics and Compliance Program, the fines and penalties would likely be less than if TAF did not have what they define as an effective program.



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In its recent guidance, the Department of Justice indicated it would evaluate the compliance program to assess penalties by asking three fundamental questions:

1. Is the corporation's compliance program well designed?
2. Is the program being applied earnestly and in good faith? In other words, is the program adequately resourced and empowered to function effectively?
3. Does the corporation's compliance program work in practice?

2.1 RISK ASSESSMENT

Risk identification is integral to TAF's Compliance Program. It is critical for TAF to carry out regular risk assessments of functional areas, especially in an era of changing regulatory standards. The Compliance Department, in collaboration with the functional areas, identifies high-risk areas and allocates more resources to monitor those areas. The risk assessment requires continuous access to operational data and informs policies and procedures and controls updates. Finally, the Compliance Department tracks and incorporates lessons learned from TAF's prior issues or those of other independent charitable patient assistance organizations into its periodic risk assessments.

2.2 POLICIES AND PROCEDURES



Detailed compliance policies and procedures supporting the operations of TAF's Compliance Program are accessible to all employees through a shared file system. In addition, TAF makes available relevant policies and procedures to other TAF Stakeholders. They address program requirements including, but not limited to, applicable federal healthcare program requirements; interactions with Donors and other third parties; independent charitable patient assistance organization activities; conflicts of interest; codes of conduct; and other program elements. These policies and procedures also require employees to report concerns and establish internal controls to contain identified compliance risk areas.

“Detailed compliance policies and procedures supporting the operations of TAF's Business Ethics and Compliance Program are accessible to all employees through a shared file system. In addition, TAF makes available relevant policies and procedures to all officers, consultants, and subcontractors.”



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2.3 TRAINING AND COMMUNICATION

2.3.1 Training



The purpose of compliance training is to communicate standards and procedures in a meaningful and effective manner that explain the requirements of the Business Ethics and Compliance Program, applicable laws, and how they impact our daily operations. TAF's employees and Board of Directors participate in training that explains these important features, as well as relevant regulations and guidelines. TAF offers a variety of education sessions using various modalities, including online, micro, role-specific, and face-to-face formats. These sessions are targeted and include both practical advice and case studies to address real-life scenarios, and guidance on how to obtain business ethics and compliance advice on a case-by-case basis.

Orientation

All newly hired employees must complete an intensive business ethics and compliance education course as part of TAF's new-hire orientation program. Topics focus on the details of TAF's Business Ethics and Compliance Program, independent charitable patient assistance organization-specific requirements under TAF's Advisory Opinion, and cybersecurity education that provides an overview on protecting patient health information.

All new Board members also receive education relevant to their corporate governance responsibilities and Business Ethics and Compliance Program oversight.

Quarterly Training

In prior years, all employees were required to participate in an annual online compliance training. In 2023, TAF changed the annual training to required quarterly online trainings. And we offer a series of face-to-face department micro-education sessions facilitated by the Compliance Department and Compliance Champions.

Specialty Training

Additional operational compliance training sessions are targeted at specific departments. Employees receive training specific to their job responsibilities and their obligations under the Business Ethics and Compliance Program. Specialty training is proactive and highlights lessons learned and risks identified by TAF.

The Compliance Officer, in conjunction with other TAF employees and outside experts, periodically updates TAF's training procedures to ensure all sessions and materials reflect the most recent developments, including new and modified OIG Advisory Opinions and legal decisions. All TAF Stakeholders required to take TAF training will certify their participation in TAF's training programs. Employees who refuse or otherwise fail to participate in TAF training programs will be subject to disciplinary action.



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2.3.2 Communication



TAF's compliance success depends on our ability to recognize potential risks, take individual responsibility to avoid risks, and our collective effort to identify and remedy existing problems.

Maintaining compliance and reporting potential non-compliance is an essential part of all TAF employees' job functions and the duties of all TAF Executive Leadership, supervisors, managers, Board of Directors, and other Stakeholders. Duties like compliance and reporting non-compliance cannot be delegated, meaning it is their individual responsibility to speak up.

TAF Compliance Champion Team

To encourage open communication, TAF established a Compliance Champion Team. This team is a diverse group of trusted, proactive, and approachable employee volunteers ("Compliance Champions") from each department. The Compliance Champions' responsibilities are to:

- serve as a liaison between their department and the Compliance Office;
- strengthen compliance awareness and identify knowledge gaps;
- provide feedback to the Compliance Department;
- support mandatory training development and completion; and
- serve as a confidential channel for speaking up.

2.4 CONFIDENTIAL REPORTING STRUCTURE AND INVESTIGATION PROCESS

2.4.1 Channels to Voice Concerns

TAF makes transparency a priority and is accountable and open in all our business practices. We depend on all TAF Stakeholders to recognize potential compliance problems and speak up. TAF will not retaliate against anyone who reports a compliance concern in good faith.

If any TAF Stakeholders become aware of an issue or concern they can:

- speak to a Compliance Champion, their supervisor, or a member of the Executive Leadership team;
- report their concern to Linda Howard, Compliance Officer, at Linda.Howard@tafcares.org or (407) 801-6963; or
- report their concern to the independent third-party Compliance Hotline (ReportIt) by calling (877) 778-5463 or going to **www.reportit.net** (username: TAFcares; password: Assistance).



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“Maintaining compliance and reporting potential non-compliance is an essential part of all TAF employees’ job functions and the duties of all TAF supervisors, managers, and directors.”

Both confidential helpline resources are available 365 days a year, seven days a week, and 24 hours a day, and the individual can choose to be anonymous.

Below are important things to consider when reporting a concern:

- The person reporting it need not be certain that a violation has occurred before making a report; reasonable belief that a violation may have occurred is sufficient.
- Reporting enables TAF to investigate potential problems quickly and to take prompt action to address them.
- TAF will not retaliate against any person who reports a compliance concern in good faith.

2.4.2 Investigation



TAF is committed to conducting thorough, fair, and impartial internal investigations of reported and perceived errors, abuses, and violations. Internal investigations related to compliance will be conducted by TAF’s Compliance Officer, or his or her designee, in a professional and expeditious manner, maintaining confidentiality to the extent practicable under the circumstances. All TAF Stakeholders must fully cooperate with internal investigations. When TAF completes an internal investigation, TAF will—to the extent appropriate—inform the person reporting the alleged violation of the results of the investigation and of TAF’s determination.



Retaliation against any TAF Stakeholder, who in good faith seeks advice, raises a concern, reports misconduct, or provides information in an investigation is strictly prohibited. Examples of prohibited retaliation include denial of benefits, termination, demotion, suspension, threats, harassment, or discrimination. If any individual, regardless of their position at TAF, retaliates against an individual who has truthfully and in good faith reported a potential violation, TAF will take appropriate action. If the reporting individual believes that they have been retaliated against for seeking advice, raising a concern, reporting misconduct, or providing information in an investigation, they should contact the Compliance Officer immediately. They may also use the Compliance Helpline.

AND

It is the duty of each employee to report compliance concerns. Failure to report erroneous/fraudulent behavior is a violation of the Business Ethics and Compliance Program.



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2.5 THIRD-PARTY MANAGEMENT

Before entering third-party relationships, TAF should understand the business rationale for needing the third party in the transaction and the risks posed by third-party partners, including the third-party partners' reputations. The Compliance Department works together with other relevant departments to ensure that third-party risk management is in place that addresses, among other things, vendor onboarding/offboarding, due diligence, the RFP process, legal obligations, contract requirements, compliance requirements, performance requirements, and continuous monitoring.

2.6 MERGERS AND ACQUISITIONS

The DOJ recommends that if an organization contemplates any mergers or acquisitions, it should conduct comprehensive due diligence on any acquisition targets and ensure that there is a process for timely and orderly integration of the acquired entity into existing Business Ethics and Compliance Program structures and internal controls.

TAF does not anticipate any mergers or acquisitions, but should one occur in the future, TAF will conduct a comprehensive due diligence and put a plan in place for integration into TAF's Business Ethics and Compliance Program.

Is the Program Adequately Resourced and Empowered to Function Effectively?

2.7 COMMITMENT BY SENIOR AND MIDDLE MANAGEMENT

TAF continues to create and foster a culture of business ethics and compliance with the law at all levels of the organization, evidenced by a high-level commitment by Executive Leadership to implement a culture of compliance from the middle and the top. The Business Ethics and Compliance Program continues to support TAF's Executive Leadership in its communication to foster a culture of compliance.



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2.7.1 Board of Directors (“Board”)



As the organization’s governing body, the Board has oversight responsibility for TAF’s compliance with federal, state, and local laws and regulations, as well as ethical obligations. In conjunction with the appointed Compliance Officer, the Board reviews Business Ethics and Compliance Program functions, regulatory risks, and methods for achieving organization-wide accountability to achieve compliance goals and effectiveness. Additionally, the Board has chartered a Board-level Compliance Committee to work closely with the Compliance Officer to further support the management and administration of the Program.

2.7.2 Compliance Officer

The Compliance Officer is responsible for the day-to-day management and administration of this Plan. The Compliance Officer is primarily responsible for overseeing compliance within the organization and ensuring adherence to applicable laws, regulatory requirements, policies, and procedures. The Compliance Officer functions as an independent and objective professional who reports to the President and CEO and the Board.

2.7.3 Executive Compliance Committee (“ECC”)

The ECC is a senior-level leadership committee representing various areas of TAF’s operations. Its members have been charged by the Board with the responsibility to: (1) contribute to the Business Ethics and Compliance Program’s effectiveness, and (2) assist the Compliance Officer in the administration of the Plan. Committee responsibilities include, among other things: (1) reviewing the policies and procedures and training at least annually, and (2) implementation and oversight of the risk assessment and internal review process.

The ECC is chaired by the Compliance Officer who is responsible for reporting the compliance activities of the organization, maintaining the minutes of the meetings, and ensuring that decisions are implemented in a timely fashion.

2.8 AUTONOMY AND RESOURCES

The Compliance Department has the autonomy and deploys the resources necessary to accomplish its mandates. The Compliance Officer assesses and ensures the Compliance Program’s structure meets TAF’s compliance objectives. TAF invests in continual education of compliance personnel and other employees responsible for implementing or overseeing controls that TAF puts in place to minimize business ethics and compliance risks.

The Compliance Department ensures that processes are in place for it to have access to the information and metrics necessary to help detect compliance misconduct and addresses any impediments that limits the Compliance Department’s access to relevant sources of data. The Compliance Department uses this information and these metrics to inform TAF’s Business Ethics and Compliance Program.



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2.9 COMPENSATION STRUCTURES AND CONSEQUENCE MANAGEMENT



TAF is committed to encouraging compliance with and enforcing its compliance plan policies and procedures and standards of ethical conduct. Executive Leadership, managers, supervisors, and other employees are all held accountable for failing to comply. TAF's response to compliance violations is proportional to the conduct and depends on a variety of factors, such as:

- the nature and severity of the conduct
- whether the employee intentionally, recklessly, negligently, or accidentally committed the conduct
- whether the employee had previously engaged in misconduct
- whether the violation is part of a pattern or practice of noncompliance
- whether the employee self-reported their error or misconduct
- the extent to which the employee cooperated with any investigation

Appropriate actions can range from additional training for errors to termination for intentional misconduct. TAF implements its responses to compliance violations consistently across the organization per TAF's HR progressive disciplinary action policies and procedures.

To create a culture of compliance that starts at the top, TAF is committed to deterring bad behavior and encouraging ethical practices in its Executive Leadership team. The Department of Justice's new guidelines recommend tying executive compensation structures to compliance. The DOJ emphasizes that imposing financial penalties for executive misconduct can deter risky behavior and foster a culture of compliance. At the same time, the DOJ encourages organizations to use positive rewards for all their employees who demonstrate ethical leadership



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Does the Corporation's/Organization's Compliance Program Work in Practice?

2.10 CONTINUOUS IMPROVEMENT, PERIODIC TESTING, AND REVIEW

An ongoing process to evaluate effectiveness is critical to determining if a compliance program is effective in practice. TAF's Business Ethics and Compliance Program assesses effectiveness through a variety of processes, including: (1) internal monitoring; (2) external independent audits to assess levels of compliance and opportunities to improve current systems, processes, policies, and procedures; and (3) employee surveys to gauge the compliance culture and evaluate the strength of controls.

If an audit identifies compliance risks, TAF proactively mitigates those risks and implements corrective action as appropriate.

2.11 INVESTIGATION, ANALYSIS, AND REMEDIATION PROCESS

TAF places importance on having a well-functioning and appropriately funded mechanism for the timely and thorough investigation of any allegations or suspicions of misconduct by TAF Stakeholders. TAF has an established means of documenting TAF's response, including any disciplinary or remediation measures taken.

2.11.1 *Response and Prevention*

TAF ensures all compliance investigations finding irregular behavior will include a mitigation plan including, if applicable, corrective action (e.g., disciplinary action and notice to the government). When investigations show no irregularity but present potential areas of risk, TAF will develop proactive solutions. These include, but are not limited to, education, training, and policy and/or operational changes. Lastly, TAF conducts a thoughtful root cause analysis of misconduct and timely and appropriately remediates to address the root causes.

2.11.2 *Self-reporting to Government Agencies*

Under certain specific circumstances, the President and CEO, Compliance Officer, and the Board of Directors may consider voluntary disclosures to governmental agencies. All decisions regarding self-reporting will be reviewed by legal counsel prior to any voluntary disclosure.



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Federal Laws, Regulations, Guidance, and Internal Protocols

TAF provides charitable assistance in accordance with all applicable federal, state, and local laws and regulations. This section provides a summary of the key applicable laws and regulatory documents that guide TAF—through its systems, practices, policies, and procedures—to advance compliant and ethical business decisions and activities. Individuals found in violation of applicable laws and regulatory documents not only will be subject to contract termination and employment-related sanctions, such as suspension or termination, they may also be responsible for civil money damages and potential criminal sanctions, including imprisonment.

Section 3.1 provides the main points of four primary federal laws—categorized as fraud and abuse statutes— that apply to TAF: the Anti-Kickback Statute; the Beneficiary Inducement Law; the Civil False Claims Act; and the Exclusion Statute.

Section 3.2 outlines key regulatory documents under which TAF operates.

Section 3.3 describes how applicable laws and guidance govern TAF's operations.

Section 3.4 describes TAF's privacy practices.



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3.1 FRAUD AND ABUSE STATUTES

Many of the products that are covered by TAF Programs are ultimately reimbursed under Medicare, Medicaid, or other federal or state healthcare programs. As such, TAF is subject to several federal fraud and abuse laws. The four most important federal fraud and abuse laws that apply to TAF are the Anti-Kickback Statute (AKS), federal Beneficiary Inducement Law, the False Claims Act (FCA), and the Exclusion Statute. Government agencies, including the Department of Justice, the Department of Health & Human Services Office of Inspector General (OIG), and the Centers for Medicare & Medicaid Services (CMS), are charged with enforcing these laws.

3.1.1 *TAF Advisory Opinion No. 10-07, as modified* (42 USC 1320a-7b)

The federal Anti-Kickback Statute (“AKS”) makes it a crime punishable by monetary fines and/or imprisonment to knowingly and willfully solicit, receive, pay, offer to pay, or provide anything of value (e.g., cash, services, gifts, entertainment, favors, etc.) in order to influence any person’s recommendation, prescription, or purchase of services or supplies that may be reimbursable by federal healthcare programs.

Examples covered by the Anti-Kickback Statute include (a) receiving a gift from a Donor in exchange for influencing prescribers’ or patients’ choice of medications; (ii) offering or providing a gift or payment (including any free goods or services) to a physician or other prescriber to influence the prescribing, dispensing, or recommending of particular prescription products; and (iii) offering or providing goods or services at below market value for the purpose of inducing prescriber’s referrals.

3.1.2 *Federal Beneficiary Inducement Law* (42 USC 1320a-7a(a)(5))

The Beneficiary Inducement Law imposes civil monetary penalties (“CMPs”) against any person who offers or transfers remuneration (i.e., anything of value) to a Medicare or Medicaid beneficiary that the benefactor knows or should know is likely to influence the beneficiary to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, by Medicare or Medicaid. For example, making eligibility requirements for a disease program dependent on a patient’s use of a certain physician or pharmacy is a violation of the Beneficiary Inducement Law.

3.1.3 *Federal Civil False Claims Act* (31 USC 3729-3733)

Many of our patients are seeking financial assistance to purchase products that are ultimately reimbursed under Medicaid, Medicare, or other federal or state healthcare programs.

Federal and state false claims acts prohibit individuals and entities from submitting, or causing others to submit, a false claim for reimbursement from the federal or state governments, including from Medicare or Medicaid. False claims are not only claims for payment which the payee knows are unwarranted, but also those the payee submits with reckless disregard for, or in deliberate ignorance of, their accuracy. False claims can result in damages three



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times the amount of the actual claim, plus civil penalties of up to \$11,000 per claim and reasonable attorney's fees and costs. TAF can be liable under the False Claims Act if it causes a prescriber to submit false claims or steers a patient to particular drugs in exchange for something of value in violation of the Anti-Kickback Statute.

3.1.4 **Exclusion Statute** (42 USC 1320a-7)

The OIG is legally required to exclude from participation in all federal healthcare programs those individuals and entities convicted of certain crimes including Medicare or Medicaid fraud; patient abuse or neglect; felony convictions for other healthcare-related fraud, theft, or misconduct; and felony convictions for unlawful manufacture, distribution, prescription, or dispensing of controlled substances. The OIG may also exclude participation on several other grounds including misdemeanor convictions including, but not limited to, unlawful kickback arrangements and defaulting on health education loan obligations.

3.2 OIG ADVISORY OPINIONS AND SPECIAL ADVISORY BULLETINS

An advisory opinion is a legal opinion issued by the OIG to one or more requesting parties about the application of the OIG's fraud and abuse authorities to the party's existing or proposed business arrangement. It is legally binding on the requested party. A party that receives a favorable advisory opinion is protected against OIG administrative sanctions, so long as the arrangement is conducted in accordance with the facts contained in the advisory opinion. TAF's Business Ethics and Compliance Program requirements are also based on the OIG Advisory Opinions and Special Advisory Bulletins issued to TAF and the independent charitable patient assistance program industry.

TAF Stakeholders are required to understand and be familiar with the contents of the TAF OIG Advisory Opinion No. 10-07, as modified, and Special Advisory Bulletins summarized below and reflected throughout this Business Ethics and Compliance Program Plan Summary and TAF's policies and procedures.

The OIG issued Advisory Opinion No.10-07 in 2010, which set forth a favorable opinion on TAF's then-proposed activities in connection with providing cost-sharing assistance for specialty medications to patients diagnosed with one of three specific disease states. The OIG issued a Notice of Modification to OIG Advisory Opinion No. 10-07 in 2011 upon TAF's request to add new disease programs and include assistance with health insurance premiums.

In 2014, the OIG published a Special Advisory Bulletin for all independent charitable patient assistance programs that expanded on the guidance from the previous OIG advisory opinions issued to TAF and other established guidance. Specifically, the Special Advisory Bulletin advised against providing assistance only for expensive specialty drugs and provided safeguards for narrowly defined disease programs for which only one drug exists. As a result of this guidance, the OIG issued another Notice of Modification of OIG Advisory Opinion No. 10-07, in which the OIG retracted its approval of certain TAF disease program features that it had previously approved and required TAF to modify its disease programs accordingly.



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The full text of the *OIG Advisory Opinions and Special Advisory Bulletins* documents are located on the TAF website at: <https://tafcares.org/compliance/compliance-documents/>.

3.3 PROGRAM MANAGEMENT POLICIES AND PROCEDURES: PROHIBITED AND PERMISSIBLE ACTIVITIES

TAF prohibits the activities below to ensure compliance with federal laws, regulations, and guidance.

TAF will terminate the employment or relationship with any TAF Stakeholders who receive, accept, or condone a bribe, kickback, or other unlawful payment, or attempts to initiate such activities. In addition, such individuals may be subject to criminal proceedings. All TAF Stakeholders have a responsibility to report any actual or attempted bribery, kickback, fraud, waste, or abuse to TAF.



TAF expressly prohibits:

- exerting or allowing Donors to exert any direct or indirect control or influence on the clinical decision-making of prescribers;
- exerting or allowing Donors to exert any direct or indirect control or influence on the patient's choice of provider or products;
- permitting Donors to control or influence, directly or indirectly, financial eligibility determinations of applicants;
- making eligibility determinations for financial assistance based on any Donor's interests;
- making eligibility determinations for financial assistance based on the applicant's choice in provider, practitioner, supplier, test, or product; and
- providing Donors with any data that would facilitate a Donor in correlating the amount or frequency of its donations with the amount or frequency of the use of its products; and permitting Donors to control or influence the identification of disease programs.

3.3.1 *Disease Programs*

In developing its disease programs, TAF must ensure that its interactions with Donors and prescribers comply with TAF's *OIG Advisory Opinion*, as modified. TAF cannot function as a conduit for payments or other benefits from a Donor to patients and must not impermissibly influence beneficiaries' treatment or healthcare provider choices.

“Donors to TAF's disease programs cannot exert any direct or indirect influence or control over TAF.”



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TAF Program Management policies outline in detail the safeguards for developing disease programs. Below is a summary of those safeguards for developing disease programs to which TAF employees must adhere:

TAF cannot:

- solicit suggestions from any Donor regarding disease programs and cannot allow Donors to exert any influence or control over TAF or influence how TAF identifies disease programs.
- define disease programs by reference to specific symptoms, the severity of symptoms, the method or type of treatment, the stages of a disease, or in a manner that intentionally results in the coverage of medications exclusively or primarily manufactured or distributed by Donors.
- limit assistance to high-cost or specialty drugs or a subset of available products. Disease programs must provide assistance for all FDA-approved prescription medication intended to treat the disease states covered by the disease program, including generic or bioequivalent drugs.
- maintain any disease program that provides copayment assistance for only one drug, or only the drugs made or marketed by one pharmaceutical manufacturer or its affiliates.

If the FDA has approved only one drug or only the drugs made or marketed by one manufacturer or its affiliates for a disease, TAF will provide support for other medical needs of the patient in addition to cost-sharing support for the FDA-approved treatment of the disease.

TAF may provide forms of assistance in addition to copayment, premium assistance, or other cost-sharing assistance associated with the medications the patient receives to treat the disease state (e.g., physician office visits, home visits, medical devices, other tests, childcare, travel/transportation, lodging, and meals).

TAF's Board will define additional disease programs after an independent assessment of patient needs.

TAF's Program Management Policies addressing disease programs are located on the TAF SharePoint site at: theassistancefund.sharepoint.com.

3.3.2 Eligible Recipients

TAF must determine whether a patient is eligible for financial assistance according to a reasonable, verifiable, and uniform measure of financial need that is applied consistently. TAF Program Management policies outline in detail guidelines for determining recipient eligibility as described in the federal guidance for independent charitable patient assistance programs. Below is a summary of the criteria for determining financial need described in accordance with TAF's policies:

- TAF will screen all applicants, on a first-come, first-served basis, to determine financial eligibility prior to enrolling the applicants in a disease program in accordance with our policies. Eligibility can be determined based on poverty guidelines (household size and household income) and local cost of living or the scope and extent of a patient's total medical bills. However, eligibility cannot be based solely on the cost of the treatment for which the patient is applying for assistance.

“TAF must determine whether a patient is eligible for financial assistance according to a reasonable, verifiable, and uniform measure of financial need that is applied consistently.”

- If funding is not available, TAF shall offer the applicant the option of being placed on a waitlist to receive notification if funds become available.

“Applications for assistance will be considered on a first-come, first-served basis.”

- TAF cannot make eligibility determinations based in whole or in part on (if) the interest of any Donor or Donor's affiliate who contributes to TAF disease programs; (ii) the applicant's choice of provider, practitioner, insurer, insurance plan, supplier, test, or product; (iii) the identity of the referring person or organization (including whether the referring person is a Donor); or (iv) the amount of any contributions made by a Donor whose services or products are used or may be used by the applicant.
- TAF may establish disease programs that serve only federal healthcare program beneficiaries, provided that the disease programs are subject to all other safeguards required by the OIG Advisory Opinions.

TAF's Program Management Policies addressing recipient eligibility are located on the TAF SharePoint site at: theassistancefund.sharepoint.com.

3.3.3 *Interaction with Patients*

TAF must not engage with patients in a way that interferes with patient choice or results in steering patients to a particular treatment or healthcare provider. TAF Program Management policies outline in detail the safeguards for interaction with patients. Below is a summary of those safeguards for interaction with patients to which TAF employees must adhere:

“TAF must not engage with patients in a way that interferes with patient choice.”



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TAF will not:

- refer applicants to, recommend, or arrange for the use of any particular medication, test, practitioner, provider, or supplier;
- inform patients or Donors of the donations made to TAF by Donors or others; or
- implement any system that will result in patients paying more for an inexpensive drug than they would for a high-cost drug.

For patients who are receiving assistance with health insurance premiums through a TAF disease program, TAF provides the premium system grants directly to the insurance company or will make grants payable to the patient upon proof that he or she incurred such cost.

TAF's Program Management Policies addressing interaction with patients are located on the TAF SharePoint site at: theassistancefund.sharepoint.com.

3.3.4 *Interaction with Donors*

TAF must remain independent of Donors and cannot allow donors to influence TAF's operations, development of disease programs, or TAF's interactions with patients. TAF Program Management policies outline in detail the safeguards for interaction with Donors. Below is a summary of those safeguards for interaction with Donors to which TAF employees must adhere:

- TAF must operate independently from all Donors.
- Donors are ineligible to serve on TAF's Board of Directors.
- TAF will not provide a Donor with any information that would enable the Donor to correlate the amount or frequency of its donations with the number of patients who use its products or services, or the volume of those products supported by TAF. TAF will provide Donors only with reports including data such as the aggregate number of applicants for assistance, the aggregate number of patients qualifying for assistance, and the aggregate amount disbursed from the disease program during that reporting period.
- TAF cannot request specific donation amounts from any Donor for a disease program. TAF must provide Donors with information only about the total estimated amount needed for each disease program. TAF cannot permit Donors to earmark for any treatment or disease state within a given disease program.

“TAF must operate independently from all Donors.”



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- TAF cannot convey any individual patient information to any Donor.
- TAF must document and maintain written records reflecting all communications (oral or written) with Donors about donation offers or requests; requests for all data shared with Donors; and requests or suggestions from Donors relating to the identification, establishment, or delineation of a disease program and TAF's response.

TAF's Program Management Policies addressing interactions with Donors are located on the TAF SharePoint site at: theassistancefund.sharepoint.com.

3.4 PRIVACY

TAF Stakeholders must protect all confidential information they receive in a manner consistent with applicable legal and ethical standards and TAF's privacy and confidentiality policies. Specifically, they must follow established policies and procedures when using or disclosing information that the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") defines as Protected Health Information ("PHI").

While TAF is not formally subject to HIPAA, TAF may be subject to state privacy laws designed to protect health and other sensitive information. TAF recognizes the importance of confidentiality in providing its services, follows a best practice approach in securing confidential and health information, and has implemented systems and practices to ensure strict confidentiality of patient confidential and health information.

TAF does not share patient information with Donors or other patients, or unauthorized parties without the written consent of the patient or the patient's legal representative unless obligated to do so under law.

All TAF Stakeholders with access to patient information must adhere to TAF's policies and applicable contracts regarding patient information.

Workplace privacy and confidentiality are paramount in a hybrid work environment. Employees must refrain from sharing, discussing, texting, or otherwise revealing any patient or patient information to anyone other than a fellow employee who needs to know this information to perform their job responsibilities. To ensure patient information is secure, documents containing sensitive data, including information concerning prescribers, recipients, or donors, must not be left in public view or unsecured. People with access to TAF data must pay particular attention to how they enter, secure, and store electronic data. Given the nature of TAF's business, employees and other people with access to private or confidential information must always consider that the potential for a breach of security exists. Anyone with knowledge of unauthorized usage of TAF technology must immediately report it to a Compliance Champion, their supervisor, the Senior Vice President of Business Intelligence, or the Compliance Officer. Donors with information only about the total estimated amount needed for each disease program. TAF cannot permit Donors to earmark for any treatment or disease state within a given disease program.



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Conclusion

As TAF continues to evolve, I'm proud to be part of an organization with the level of integrity and commitment to corporate compliance that TAF's leadership, Board members, and employees exhibit. Our Business Ethics and Compliance Program will continue to evolve. As TAF grows, we will identify opportunities to improve how every employee upholds our core value of transparency. We will move forward with agility to ensure our Business Ethics and Compliance Program is as comprehensive and effective as possible.

All of us have an important role to ensure that public confidence remains strong. Together, we can fulfill our mission to provide underinsured people living with life-threatening, chronic, and rare diseases access to critical treatment through financial assistance, education, and advocacy.

Speak Up and Put Your Best Foot Forward!



LINDA HOWARD

Compliance
Officer



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Glossary



TAF Stakeholder shall mean any entity or persons engaged in Patient Assistance Related Functions (as defined below) on behalf of or in conjunction with TAF and in that capacity either (i) interact directly with Donors (as defined below), healthcare professionals, healthcare institutions, or patients; or (ii) perform activities, provide services, or create materials relating to the Patient Assistance Related Functions and those activities, services, or materials are not reviewed or supervised by a TAF employee prior to execution or dissemination.



Donor shall mean any pharmaceutical manufacturer of any affiliate, subsidiary, or other entity acting on its behalf which donates money to TAF for its disease programs. Donor includes both existing and prospective Donors of TAF and shall include all affiliates and agents of existing and prospective Donors. (Donor, as used throughout this Plan, is not meant to include individual patients or their families who donate to TAF).



Patient Assistance Related Functions include all activities, systems, processes, and procedures relating to TAF's provision of financial assistance to any patient. This includes any grant, copayment assistance, premium assistance, or any other financial assistance that TAF may provide to patients.



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