

# Corporate Compliance Plan



**The  
Assistance  
Fund**

## I. INTRODUCTION

The Assistance Fund, Inc. (“TAF”) is a 501(c)3 nonprofit organization created to make access to medications a reality for patients who are critically or chronically ill. TAF’s vision is to ensure that no person goes without medication due to an inability to pay. Applicants may participate in the assistance programs available through TAF if they meet certain eligibility criteria. The criteria vary by program.

We commit to our patients and our work, and to our compliance with the numerous laws, regulations and policies that govern our conduct in all of TAF’s activities. A failure to comply with our legal or ethical obligations, even if inadvertent, can lead to civil or criminal liability on the part of TAF and donors to our disease funds.

Accordingly, TAF’s Board of Directors (the “Board”) has reviewed and approved this Compliance Plan, which is intended as a guide for the conduct of TAF and associated “Covered Persons”. Covered Persons includes all officers, directors and employees of TAF, as well as all contractors, agents and other 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. The term "Patient Assistance Related Functions" includes: all activities, systems, processes, and procedures relating to TAF's provision of financial assistance to any patient. This includes any grant, co-payment assistance, premium assistance or any other financial assistance that TAF may provide to patients.

This Compliance Plan defines the conduct expected of TAF and associated Covered Persons in connection with regulatory requirements and guidance issued to TAF by the U.S. Department of Health and Human Services Office of Inspector General (OIG). This Compliance Plan also provides guidance on how to resolve questions regarding legal and ethical issues and establishes a mechanism for reporting possible violations of law or ethical principles within TAF.

The TAF Compliance Plan is comprised of the following components:

- All Covered Persons must comply with the OIG Advisory Opinions issued to TAF, which are discussed in detail below. Each Covered Person is required to read, understand and comply fully with the OIG Advisory Opinions.
- Periodic educational training programs on the specific areas of compliance discussed in this Compliance Plan. These programs will be provided to all Covered Persons.
- Open channels of communication, including a TAF compliance hotline through which those affiliated with TAF may report any suspected or potential violations of law or deviation from compliance standards. Confidentiality will be maintained to the fullest extent possible. Anyone reporting misconduct in good faith will be fully protected against any form of retaliation. The Compliance Officer, in consultation with the Compliance

Committee, will investigate all communications and ensure that proper follow-up actions are taken.

- Enforcement of disciplinary action against employees who violate the Compliance Plan and non-employment or retention of excluded individuals or entities.
- Policies and procedures with respect to investigations of identified systemic problems including responses to detected offenses.

Maintaining compliance and reporting non-compliance is an essential part of all TAF employees' job functions and the duties of all TAF Directors. Compliance and reporting non-compliance are non-delegable duties. Any and all questions regarding the Compliance Plan, its meaning, or its applicability are to be directed promptly to the Compliance Officer or the Board member designated as the Compliance Committee Chair listed in **Attachment 1** .

TAF's Compliance Plan contains detailed descriptions of many of the fraud and abuse laws governing our operations. These descriptions, however, will not dispense with the need of each Covered Person to familiarize him or herself with the applicable laws, government guidance and TAF protocols impacting upon his or her job or duties.

## **Key Compliance Areas**

TAF is subject to numerous federal, state and local laws. We have summarized below a number of the general obligations arising in key areas of our operations. Individuals found in violation of applicable law not only will be subject to employment-related sanctions such as suspension or termination, but they also can be exposed to civil money damages for certain violations, to potential criminal sanctions, including imprisonment.

The key areas discussed below are:

1. Health Care Fraud and Abuse
  - a. Federal Anti-kickback Statute
  - b. Federal Beneficiary Inducement Law
  - c. Federal Civil False Claims Act
2. Confidentiality
3. Governance
4. Investigations
5. Government Program Exclusion Screening
6. Improper Influence on Conduct of Audits
7. Complaint Process

## **1. Health Care Fraud and Abuse**

### **a. General Compliance**

TAF does not offer or accept bribes, kickbacks or other payments designed to influence or compromise the conduct of the recipient; and no employee of TAF may accept any funds or other tangible or intangible benefits (including those provided as preferential treatment to the employee for fulfilling their responsibilities), for assisting in obtaining business or for securing special concessions from TAF. This means that TAF does not accept payments to influence the decisions of prescribers or patients and TAF does not make payments to any party to influence such decisions.

TAF employees should conduct their business affairs in such a manner that TAF's reputation will not be impugned if the details of their dealings should become a matter of public discussion. It is imperative that TAF employees, particularly its disease fund development staff, understand that TAF does not promote or market any of its donors' products. TAF only promotes TAF's patient assistance programs. Further, TAF does not attempt to influence patients' or prescribers' decision-making. For example, TAF does not suggest specific health care providers or products to patients.

The following conduct is expressly prohibited:

- (i) Exerting or allowing donors to exert any direct or indirect control or influence on the clinical decision-making of prescribers;
- (ii) Exerting or allowing donors to exert any direct or indirect control or influence on the patient's choice of provider or products;
- (iii) Permitting donors to control or influence, directly or indirectly, financial eligibility determinations of applicants;
- (iv) Making financial eligibility determinations for grant assistance based upon any donor's interests;
- (v) Making financial eligibility determinations for grant assistance based upon the applicant's choice in provider, practitioner, supplier, test or product;
- (vi) 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
- (vii) Permitting donors to control or influence the identification of disease funds.

Any employee found to be receiving, accepting or condoning a bribe, kickback, or other unlawful payment, or attempting to initiate such activities, will be subject to termination and possible criminal proceedings. Any employee found to be attempting fraud or engaging in fraud

will be liable to termination and possible criminal proceedings. All employees have a responsibility to report any actual or attempted bribery, kickback, fraud, waste or abuse to TAF.

## **b. Applicable Law**

Covered Persons must understand the laws and codes that apply to our healthcare business, the most important of which are (a) the Federal Anti-kickback Statute; (b) the Federal Beneficiary Inducement CMPs; and (c) the Federal Civil False Claims Act.

### **(i) Federal Anti-kickback Statute**

The federal Anti-kickback Statute, 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 health care programs (i.e., to induce physicians to prescribe particular medications). Examples covered by the Anti-kickback Statute include (i) 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.

The requirements of this Compliance Plan are based upon guidance issued to TAF and the independent charity patient assistance program industry by the OIG. 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 of OIG Advisory Opinion No. 10-07 in 2011 upon TAF's request to address TAF's desire to add new disease funds to its assistance program and expand the assistance program to include assistance with health insurance premiums.

In 2014, an OIG Special Advisory Bulletin for independent charity patient assistance programs was published, which expanded on the guidance issued under 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 funds for which only one drug exists. As a result of this guidance, the OIG issued a Notice of Modification of OIG Advisory Opinion No. 10-07, as modified, in which the OIG retracted its approval of certain features of TAF's programs that it had previously approved and required TAF to modify its programs accordingly. In 2019, TAF entered into an Integrity Agreement with the OIG which contractually defines TAF's compliance and reporting obligations.

The major areas of compliance outlined in the OIG Advisory Opinions and the Integrity Agreement are summarized in detail below and reflected throughout this Compliance Plan and TAF Policies & Procedures. Additionally, the OIG Advisory Opinions, Special Advisory Bulletin

and Integrity Agreement documents are located on the TAF website at: [www.tafcares.org/compliance/](http://www.tafcares.org/compliance/).

Each Covered Person is required to understand and be familiar with the contents of the OIG Advisory Opinions and Integrity Agreement and report any instances of non-compliance in accordance with the procedures set forth in this Compliance Plan.

**(a) Disease Funds.** In developing its disease funds, TAF must ensure that its interactions with donors and prescribers comply with TAF's OIG Advisory Opinion, as modified. As such, TAF cannot function as a conduit for payments or other benefits from a donor to patients and must not impermissibly influence beneficiaries' drug or health care provider choices. To this end, TAF employees shall adhere to the following safeguards in developing disease funds, as required by the OIG Advisory Opinions and Integrity Agreement:

- (1) Donors (including their affiliates) to TAF's disease funds shall not be permitted to exert any direct or indirect influence or control over TAF.
- (2) Donors (or their affiliates) to TAF's disease funds shall not be permitted to influence the identification of any disease fund, and TAF shall not solicit suggestions from any donor regarding the identification, delineation or modification of any funds.
- (3) Disease funds shall not be defined by reference to specific symptoms, severity of symptoms, or the method of administration of drugs. TAF conducts an independent assessment and utilizes a Medical Advisory Board to determine disease state definitions and covered drugs.
- (4) Any additional disease funds will be defined by TAF's Board based upon such independent assessment of whether a new fund arrangement would serve patient needs.
- (5) Disease state funds shall not be defined by reference to the stages of a particular disease, the type of drug treatment, and any other ways of narrowing the definition of widely recognized disease states. Excepted from this prohibition are disease funds for metastatic stages of cancer, as approved by the 2016 OIG Notice of Modification of Advisory Option No. 10-07.
- (6) Disease funds shall not be defined such to limit assistance to high-cost or specialty drugs. Funds will make assistance available for all prescription medications, including generic or bioequivalent drugs approved by the FDA for treatment of the disease state(s) covered by the fund.

- (7) In the event that a disease state fund is defined by reference to multiple disease states, donors may earmark their donations to any disease fund, but TAF will not permit donors to earmark donations for any specific drug or disease state within the fund.
  - (8) Disease state funds shall not be defined in a manner that intentionally results in the coverage of medications exclusively or primarily manufactured or distributed by donors.
  - (9) Disease state funds shall not be defined such that assistance is limited to a subset of available products, rather than all products approved by the FDA for treatment of the disease state(s) covered by the fund or reimbursed by relevant federal healthcare programs when prescribed for the treatment of the disease state(s). For example, funds will not be limited covering patients' cost-sharing obligations related to only expensive or specialty drugs. Disease funds shall include coverage of all prescription medication, including generic or bioequivalent drugs, approved by the FDA for treatment of the disease state covered by the fund.
  - (10) TAF shall not maintain any disease fund that provides copayment assistance for only one drug, or only the drugs made or marketed by one pharmaceutical manufacturer or its affiliates.
  - (11) With respect to funds for a disease for which the FDA has approved only one drug or only the drugs made or marketed by one manufacturer or its affiliates, 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, including all prescription medications for an FDA-approved indication related to managing the disease, including, but not limited to, prescription medications to treat symptoms of the disease and side effects of treatments.
  - (12) TAF may provide forms of assistance in addition to co-payment, premium assistance or other cost-sharing assistance associated with the medications the patient receives to treat the disease state (for example, cost-sharing assistance for related physician office visits, home visits, medical devices, and other tests, as well as incidental expenses related to receiving such treatment such as child care, travel/transportation, lodging and meals). Such assistance will be awarded by TAF upon the request of the eligible patient, on a case-by-case basis.
- (b) **Eligible Recipients.** TAF must determine eligibility

according to a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner. Some criteria for determining financial need described in the federal guidance for independent charity patient assistance programs are as follows:

- (1) TAF will employ a process for screening all applicants for compliance with the disease fund's designated financial eligibility criteria prior to enrolling the applicants in a fund. Such process shall be uniformly applied across all funds and shall include verifying each participant's financial resources through information provided by a third-party service and collecting documentation of financial need from the applicant.
  - (2) Applications for assistance will be considered on a first come, first served basis, to the extent of available funding.
  - (3) Applicants will be required to have already selected his or her health care providers, practitioners, suppliers, and products, and will already have a treatment regimen in place. However, all patients will remain free to change their health care providers, practitioners, suppliers, and products while receiving assistance from TAF.
  - (4) TAF shall not make eligibility determinations based in whole or in part on (i) the interest of any donor or donor's affiliate who contributes to TAF 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.
  - (5) Eligibility can be determined based upon poverty guidelines which take into account family size.
  - (6) Other variables beyond income can be considered, such as local cost of living or the scope and extent of a patient's total medical bills.
  - (7) Eligibility cannot solely be based upon the cost of the particular drug for which the patient is applying for assistance.
  - (8) TAF may establish funds that serve only Federal health care program beneficiaries, provided that such funds are subject to all other safeguards required by the OIG Advisory Opinions.
- (c) **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 drug or health care provider. The following safeguards apply:

- (1) TAF will not refer applicants to, recommend, or arrange for the use of any particular medication, test, practitioner, provider or supplier.
- (2) TAF will not inform patients or donors of the donations made to TAF by donors or others.
- (3) TAF shall not implement any system that will result in patients paying more for an inexpensive drug than they would for a high-cost drug; however, TAF may require a minimum claim amount for accumulated claims in order to avoid the administrative burden and cost of reimbursing multiple small claims.
- (4) For recipients who are receiving assistance with health insurance premiums through a TAF disease fund, TAF will provide the premium system grants directly to the insurance company or shall make grants payable to the recipient upon proof that the recipient incurred such cost.

**(d) Interaction with Donors.**

- (1) Donors (or their affiliates) shall not be eligible to serve on TAF's Board of Directors.
- (2) 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 aid recipients who use its products or services, or the volume of those products supported by TAF. As such, 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 fund during that reporting period.
- (3) TAF shall not request specific donation amounts from any Donor for a fund. TAF shall provide Donors only with information about the total estimated amount needed for each fund. TAF shall not permit Donors to earmark for any drug or disease state within a given fund.
- (4) TAF shall not convey any individual patient information to any donor.

- (5) TAF shall document and maintain records reflecting all internal and external communications (including all written communications and all substantive oral communications) about any and all decisions relating to the [Disease Fund Process] for each disease or other fund that it establishes, modifies, or maintains.

**(ii) Federal Beneficiary Inducement Law**

Many of the products that are covered by our programs are ultimately reimbursed under Medicaid, Medicare or other federal or state health care programs. The Beneficiary Inducements CMP provides for the imposition of civil monetary penalties (CMPs) against any person that offers or transfers remuneration 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. OIG may initiate administrative proceedings to seek such CMPs and exclude such person from the Federal health care programs. A subsidy for cost-sharing obligations provided by a patient assistance program may implicate the Beneficiary Inducements CMP, if the subsidy is likely to influence a Medicare or Medicaid beneficiary's selection of a particular provider, practitioner, or supplier, such as by making eligibility dependent on the patient's use of certain prescribing physicians or certain pharmacies to dispense the drugs.

**(iii) Federal Civil False Claims Act**

Many of our patients are seeking financial assistance to purchase products that are ultimately reimbursed under Medicaid, Medicare or other federal or state health care 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 of three times the amount of the actual claim, plus civil penalties of up to \$11,000 per claim and reasonable attorney's fees and costs. A third party, like TAF, may have liability under the False Claims Act if it causes a prescriber to submit false claims (for example, by steering patients to particular drugs in violation of the Anti-Kickback Statute).

**2. Confidentiality**

TAF recognizes the importance of confidentiality in the provision of its services, and it is TAF's policy to keep all information and records pertaining to its recipients as confidential in accordance with applicable laws and regulations, including laws and regulations relating to the confidentiality of protected health information. TAF does not share any assistance recipients' or donor's confidential information with other donors or recipients, or any third parties, unless obligated to do so under law. All Covered Persons with access to confidential information must

adhere to TAF's policies in this regard. If you become aware of unauthorized or inappropriate disclosure by TAF personnel of confidential information, you should immediately contact your supervisor, the Compliance Officer or Compliance Committee Chair.

While TAF is not subject to HIPAA, TAF has prioritized the confidentiality of patient information. Generally, documents containing sensitive data, including information concerning prescribers, recipients or donors must not be left in public view, or in an unsecured location. You also must pay particular attention to the manner in which you enter, secure and store computer data; given the nature of our business, the potential for a breach of security exists, and must be taken into account, at all times. If you observe individuals whom you do not recognize using computers or other TAF technology, immediately report this to your supervisor, the Compliance Officer or Compliance Committee Chair.

These issues are further addressed in various privacy and security policies adopted by TAF as best practices to which all workforce is bound which covers the confidentiality of information that TAF may and have access to. These policies and procedures are available in the TAF SharePoint document management system and TAF's website at [www.tafcares.org/compliance/](http://www.tafcares.org/compliance/)

### **3. Governance**

The Governing Board of TAF is responsible for ensuring compliance with all federal, state, and local laws and regulations, as well as ethical obligations. In conjunction with the appointed Compliance Officer, the Board has oversight responsibility for implementing and maintaining policies, practices, and procedures for ongoing evaluation of adherence to this Compliance Plan and any other TAF policies. The CEO and members of the Board are fully cognizant of their responsibilities and will ensure that the Compliance Program functions effectively.

### **4. Government Program Exclusion Screening**

TAF does not employ individuals or engage with any Covered Persons excluded from participation in Medicare, Medicaid or any other federal healthcare program. Therefore, prior to hire and or contract and periodically thereafter TAF must perform a check to confirm that employees, contractors and other Covered Persons are not excluded to participate in these federally funded healthcare programs according to the Office of Inspector General (OIG).

All employment application forms will require applicants for employment to indicate whether they have been excluded from participation in Medicare, Medicaid or any other government health care program. Job applicants will certify on such forms that the information they have provided regarding such exclusions is accurate and complete.

While a prior exclusion that is not in effect at the time of the application does not automatically bar an applicant from employment by TAF, no offer of employment may be made to such an applicant without the approval of the Compliance Officer.

Contracts with Covered Persons shall include assurance that the Covered Person has not been excluded from participation in Medicare, Medicaid or any other government health care program.

The Director of Human Resources or his or her designee will screen all final candidates for employment as well as other Covered Persons against the OIG List of Excluded Individuals/Entities (LEIE). TAF is prohibited from offering employment to any individual or entity who is included on the LEIE.

The Director of Human Resources or his or her designee will further screen all existing Covered Persons against the LEIE on a monthly basis. Any Covered Person who is included on the LEIE list will be subject to immediate termination.

Upon receipt of notification from the U.S. Department of Health and Human Services Office of Inspector General or any state Medicaid program that a Covered Person has been excluded from a state or federal health care program, TAF will promptly terminate the employee's employment or engagement. If any Covered Person obtains information indicating that another Covered Person is subject to such exclusion, the Covered Person who obtained such information will promptly notify the Compliance Officer or the Compliance Committee Chair, who will be responsible for investigating the matter.

## **5. Investigations**

From time to time, federal, state or local officials may request information from TAF regarding the company's business activities, or the activities of its employees, donors, recipients, prescribers or other Covered Persons. It is the company's policy to cooperate with these government investigations. To ensure that we do so in an orderly manner, and in a way that does not improperly disclose confidential information, such as protected health information, that may not fall within the scope of the government's inquiry, we ask that you immediately notify your supervisor, the Compliance Officer, or Compliance Committee Chair if you are contacted by a government investigator and are asked to provide information related to your activities at TAF.

Of course, if you are contacted individually by a government investigator, the decision of whether to cooperate with their inquiry and provide requested information is up to you alone, and you will not be disciplined, punished, or otherwise retaliated against if you decide to do so. However, if you decide to speak with government investigators, it is important that you are accurate and truthful in all of your responses to their questions. You must never lie or make false or misleading statements to any government investigator.

Destruction of evidence in a governmental investigation is a serious crime. You must never destroy or alter any records or documents during, or in anticipation of, a government inquiry. No Covered Person is to destroy TAF records except in accordance with TAF's record retention and destruction policy. You must never, under any circumstance, lie to or intentionally mislead an investigator, or attempt to persuade any person to do so. Such behavior will result in termination from TAF, and can result in criminal sanctions, including imprisonment.

## **6. Improper Influence on Conduct of Audits**

No Covered Person, or any other person acting under the direction thereof, shall directly or indirectly take any action to coerce, manipulate, mislead or fraudulently influence any public or

certified public accountant engaged in the performance of an audit or review of the financial statements of TAF if that person knows or should know that such action, if successful, could result in rendering TAF's financial statements materially misleading. Any person who believes such improper influence is being exerted should contact the Compliance Officer or Compliance Committee Chair to report such action.

Types of conduct that could constitute improper influence include, but are not limited to, directly or indirectly:

- Offering or paying bribes or other financial incentives, including future employment or contracts for non-audit services;
- Providing an auditor with an inaccurate or misleading legal analysis;
- Threatening to cancel or canceling existing non-audit or audit engagements if the auditor objects to TAF's accounting;
- Seeking to have a partner removed from the audit engagement because the partner objects to TAF's accounting;
- Blackmailing; and
- Making physical threats.

## **7. Complaint Process**

We recognize that our ability to achieve uniform compliance depends upon our ability to recognize potential problems, our individual decisions to avoid those problems, and our collective effort to identify and remedy existing problems. Our compliance, therefore, depends not only upon a choice to "follow the rules," but also our obligation to TAF, and to each other, to assist fellow employees, donors, recipients, prescribers and others who interact with TAF in any capacity to comply with the laws, and to bring all issues of potential concern to the attention of the TAF Compliance Officer or the Compliance Committee Chair or other member of the Compliance Committee, as described below. In return, you have our commitment that the issues you raise will be promptly and properly reviewed, and that appropriate corrective action will be taken. Importantly from your personal perspective, you will not in any way be subjected to any adverse consequences for making such good faith reports; to the contrary, we view a failure to bring appropriate concerns to our attention to be a serious breach of your obligations to TAF and to the TAF community.

### **(a) Discharging Your Obligations**

We recognize that there may be instances where you come across, or learn of, practices at TAF that may be of concern to you. There are numerous different ways for you to address those concerns, and your choice will likely depend upon your relationship with the particular Covered

Person involved, and upon the relationship you (or those Covered Persons) have with your supervisors. For instance, you may elect to inquire directly about the questionable conduct with the relevant employees, donors, or others, or you may choose to bring the situation to your supervisor's attention. However, we wish to assure you that the TAF Compliance Officer and Compliance Committee exist to help you when you are unable, for any reason, to assure yourself that the conduct in question is in fact appropriate, or if you believe that the problem has not been effectively remedied. In those instances, we fully expect that you will bring the issue promptly to the TAF Compliance Officer, Compliance Committee Chair or other a member of the Compliance Committee.

Employees will also be required to complete an annual certification, attached hereto as **Attachment 2**, stating that you have reported any such issues that you are aware of, as described in section 2 below. The Compliance Officer and Compliance Committee is comprised of senior TAF employees and officers who, together with TAF's counsel, are committed to ensuring full compliance with all existing laws, rules, regulations, protocols and policies governing TAF.

(b) The Process

All TAF employees and other Covered Persons are required to bring any and all concerns to the attention of the Compliance Officer or Compliance Committee Chair, either directly and immediately upon learning of the potential problem, or upon determining through their dealings with their co-employees or supervisors that their concerns have not been satisfactorily and completely addressed. A Covered Person need not be absolutely 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 deal with them. These reports may be made in person, in writing or over the telephone, at the addresses and numbers designated in **Attachment 1**. Correspondence and any written communications, relating to these issues should be marked "CONFIDENTIAL." Confidentiality will be maintained to the fullest extent possible. In some instances, however, it may not be possible to keep your identity confidential because of the nature of the investigation or certain legal requirements. Anyone concerned about confidentiality may consider making an anonymous report through the TAF compliance hotline over the telephone or electronically. The compliance hotline is available 7 days a week/24 hours a day. Detailed hotline information how to access the hotline is contained in **Attachment 1**.

Employees are required to sign annual certifications, attached hereto at Attachment 2, stating that they are not aware of any compliance issues, or that they have reported any such issues to the Compliance Officer or Compliance Committee Chair. As part of this certification, employees are required to state that they are not aware of any compliance issues, including but not limited to information security breaches or kickbacks. Employees that fail to sign or provide false information on the annual certification form will be subject to discipline in accordance with TAF's Enforcement and Discipline Policy set forth below.

Upon termination of employment, employees are required to sign an exit interview certification, attached hereto as **Attachment 2a**, stating that they are not aware of any compliance issues that have not been reported. If an employee is aware of such an issue, he or she must provide a detailed

description of the issue so that the Compliance Officer may investigate the report.

Questions with regard to the procedures outlined above, or particular issues as they relate to TAF's Compliance Plan, may be directed (orally or in writing) to the Compliance Officer or any Compliance Committee member, who will promptly provide an appropriate response.

(c) Non-retaliation

Retaliation against any employee, consultant, major vendor, or other Covered Person, 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 his or her position at TAF, retaliates against an individual who has truthfully and in good faith reported a potential violation, TAF will take appropriate action. If you believe that you or another individual has been retaliated against for in good faith seeking advice, raising a concern, reporting misconduct or providing information in an investigation, you should contact the Compliance Officer, Compliance Committee Chair or Human Resources immediately. You may also use the compliance hotline.

However, an employee, consultant or major vendor will be subject to disciplinary action in accordance with this Compliance Plan if TAF determines that the employee, consultant or major vendor has knowingly fabricated a report of wrongdoing to either protect or benefit him or herself or others, or to injure another.

**C. Conclusion**

We hope that this Compliance Plan provides useful and effective guidance to you. We are committed, at all levels, to ensuring that TAF complies with existing laws and ethical provisions, and we thank you for your cooperation and ongoing vigilance in this important effort.

## **II. ADMINISTRATION OF THE COMPLIANCE PLAN**

### **A. Oversight Responsibilities**

The Compliance Officer is responsible for the day-to-day management and administration of this Plan. In addition, TAF will designate members of leadership to serve on the Executive Compliance Committee (“Compliance Committee”). The Compliance Committee’s charge is to assist the Compliance Officer in the administration of the Plan, including without limitation, the investigation of complaints, as requested by the Compliance Officer or the CEO.

It is essential that each TAF Covered Persons fully adhere to this Plan. If any Covered Person has any question regarding the applicability or meaning of any section of this Plan, he or she should address such question to the Compliance Officer or the Compliance Committee Chair, in writing, orally, or through the compliance hotline.

### **B. Employee Training**

TAF recognizes the importance of communicating this Compliance Plan to all Covered Persons. It is the intent of TAF to require its employees to participate in training programs annually. Training may include lectures, workshops, case studies, videos, classes and other modalities. The Compliance Officer, in conjunction with other TAF employees and consultants, will be responsible for training. All Covered Persons must attend and successfully complete compliance training. All new hires must also be appropriately trained as part of the orientation program provided to new employees of TAF.

Training programs will be targeted to specific departments. Employees will receive training that is specific to their job responsibilities and to their obligations under this Plan. Examples of some of the topics to be addressed by TAF’s training programs are as follows:

- TAF’s Compliance Plan (including the OIG Advisory Opinions and Integrity Agreement discussed above);
- Privacy and Security Compliance;
- Proper communications with patients, prescribers and donors; and
- Response to government investigations.

The Compliance Officer, in conjunction with other TAF employees and consultants, will periodically update TAF’s training procedures to ensure that all sessions and materials are reflective of the most recent developments, including new and modified OIG Advisory Opinions and decisions in the law. All employees 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.

### **C. Monitoring and Auditing**



TAF's written procedures and policies delineate a system to routinely identify compliance risk areas specific to TAF. TAF conducts periodic risk assessments designed to identify principal risks areas.

The Compliance Committee will develop monitoring and audit procedures, which will include, at a minimum, periodic internal audits of appropriate departments to assess levels of compliance with this Compliance Plan.

If any audit reveals that there have been violations of this Compliance Plan, the Compliance Officer may consult with counsel regarding the various questions raised by the report. Among the issues that may be addressed when a violation is reported are the following:

- Should an internal investigation be conducted?
- Should counsel conduct the investigation?
- Should a disclosure be made to an appropriate government agency?
- Do employees need separate counsel?

#### **D. Reporting System**

It is the obligation of each TAF Covered Person to report to the Compliance Officer or Compliance Committee Chair any conduct he or she knows or reasonably believes to be criminal in nature or a violation of this Plan.

1. **Compliance Hotline.** TAF will provide a compliance hotline as a means for Covered Persons to provide information to the Compliance Officer. Reports of suspected wrongdoing may be made by contacting the Compliance Officer or a member of the Compliance Committee or via the compliance hotline. The Compliance Officer, Compliance Committee or other individuals designated by the CEO will investigate any and all information received.

2. **Complaint Review Process.** Information and records relating to reports made to the Compliance Officer will be handled, as follows:

- Allegations of violations of the Plan will be recorded by the Compliance Officer on a form that will be maintained in the Compliance Officer's office. Names, dates and the identity of witnesses with information will be included on these forms. All such information will, to the extent possible, be kept confidential and will be accessible only to the Compliance Officer and the members of the Compliance Committee. All Compliance Committee papers other than the form discussed above will refer to the reporter by an identifying code only.
- The Compliance Officer in conjunction with the Compliance Committee and legal counsel where appropriate, will determine the steps for handling the information, including making a determination whether the alleged wrongdoing violates state or federal law, violates the Compliance Plan, poses a risk to the general public or otherwise jeopardizes TAF in any way. The Compliance Officer in conjunction with legal counsel also will recommend to the CEO

what remedial action and/or disciplinary action should be taken.

- The Compliance Officer will be responsible for all internal investigations. TAF will make a thorough, fair, and impartial internal investigation of reported and perceived errors, abuses and violations. Internal investigations will be conducted in such a way as to maintain confidentiality to the extent practicable under the circumstances. All TAF Covered Persons and agents must fully cooperate with internal investigations. TAF is committed to fairness with respect to all persons involved. Internal investigations will be conducted in a professional and expeditious manner. When TAF or its agents complete an internal investigation, TAF will, to the extent appropriate, inform the person reporting the alleged violation of the results of the investigation and, if appropriate, of the determination by TAF.
- The Compliance Officer will report directly to TAF's CEO, and make reports, on a regular basis, of all allegations of wrongdoing to the CEO, the Compliance Committee and the Board of Directors, including the results of investigations and remedial action taken.
- The Compliance Officer will ensure that all records relating to reports of wrongdoing are secured and preserved, and also will ensure, to the extent applicable, that the attorney-client privilege and attorney-work product doctrine are preserved.
- The Compliance Officer's office will ensure that the reporting system offers Covered Persons opportunities to report wrongdoing after work hours, so that Covered Persons can contact the Compliance Officer's office from home. This will include providing employees the opportunity to meet with the Compliance Officer.
- The Compliance Officer cannot promise confidentiality to a Covered Person providing information because it is always a possibility that TAF may be compelled to report the Covered Person's information to the authorities, thus disclosing the Covered Person's name. However, to the extent possible, the Covered Person's identity will be kept confidential.

## **E. Self-Reporting to Government Agencies**

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

## **G. Enforcement and Discipline**

TAF recognizes the necessity to enforce the standards and procedures of its Compliance Plan and to discipline those who violate the Plan or negligently fail to detect an offense. The Compliance Officer will recommend to the CEO disciplinary action for those who fail to adhere to the standards of this Plan. The recommendation for disciplinary action may include a

recommendation for termination, or, for consultants or major vendors, contract termination. The decision to execute such action(s) will rest with the CEO.

### Guidelines Regarding Disciplinary Action for Violating the Plan

Where an employee or other Covered Person does not comply with the Plan, TAF may take disciplinary action against such employee or other Covered Person. Depending on the facts and circumstances of each case, and in compliance with any applicable collective bargaining agreements, TAF may take one or more of the following actions:

- reprimand;
- place the employee on probation;
- suspend the employee;
- terminate employment;
- refer the employee for criminal prosecution; and/or
- demand that the employee reimburses TAF for any losses or damages resulting from the violation.

Where a consultant, major vendor under contract with TAF or other Covered Person violates the Plan, TAF may:

- terminate the applicable agreement with the consultant or major vendor;
- refer the consultant or major vendor for criminal prosecution;
- demand that the consultant or major vendor reimburse TAF for any losses or damages resulting from the violation; and/or,
- take any other actions that may be permitted by law or by TAF's agreement with the consultant or major vendor.

If a Director, officer or supervisor or higher violates the Plan, such individual will be subject to disciplinary action if such individual:

- knows that any Covered Person is considering or plans to engage in conduct that is prohibited by the Plan and such individual does not report it in accordance with the Plan; or
- knows that any Covered Person has engaged in conduct that is prohibited by the Plan and such individual does not report it in accordance with the Plan; or
- fails to be aware that anyone who reports to such individual has engaged in conduct that is prohibited by the Plan, when proper management and supervision would have brought the prohibited conduct to such individual's attention.

As with all matters involving investigations and discipline, TAF intends to be fair and treat people with dignity. If a Covered Person is charged with violating the Plan, such Covered Person will be given an opportunity to explain his or her actions to the Compliance Officer, in accordance with applicable policies, before disciplinary action is taken.

TAF will also take disciplinary action against:

- anyone who deliberately fails to report a violation or suspected violation, including failing to sign or providing false information on the annual compliance certification, or who deliberately withholds relevant and material information about a violation of the Plan;
- anyone who participates in non-compliant behavior or acts in violation of existing external or internal legal or ethical standards
- anyone who encourages, directs, facilitates, permits, or knowingly or negligently condones non-compliant behavior by others.
- a violator's supervisor, to the extent that the circumstances of the violation reflect inadequate supervision or lack of diligence;
- any supervisor who directly or indirectly retaliates against someone who reports a violation of the Plan;
- any supervisor who encourages anyone else to retaliate against someone who reports a violation of the Plan;
- any employee who retaliates against another employee who makes a report under the Plan; and
- anyone who knowingly falsely accuses someone of violating the Plan.

Violations of the Plan are not the only basis for taking disciplinary action with respect to employees. TAF has certain policies, procedures and performance criteria that govern employees' actions. Questions about these policies, procedures and/or performance criteria, can be discussed with an applicable supervisor, the Compliance Officer or the Compliance Committee Chair.

## **H. Availability and Waivers of Compliance Plan**

This Compliance Plan is internally available in the TAF SharePoint document management system and TAF website. All Covered Persons of TAF are expected to follow this Compliance Plan. Generally, there should be no waivers of this Compliance Plan. However, in rare circumstances conflicts may arise that necessitate waivers. A waiver of this Compliance Plan may be made by TAF's Board of Directors.

## **I. Non-Retaliation Policy**

TAF shall not take any retaliatory action against any Covered Person due to the Covered Person's good faith reporting of potential compliance issues, or good faith participation in investigations, self-evaluations, audits, and remedial actions. Examples of prohibited retaliation

include: denial of benefits, termination, demotion, suspension, threats, harassment or discrimination. If any individual, regardless of his or her position at TAF, retaliates against an individual who has truthfully and in good faith reported a potential violation, TAF shall take appropriate action. However, Covered Person's will be subject to disciplinary action in accordance with this Compliance Plan if TAF determines that the Covered Person has knowingly fabricated a report of wrongdoing to either protect or benefit him or herself or others, or to injure another.

## **J. Conclusion**

The Compliance Officer and the Compliance Committee will review the Compliance Plan annually to assess whether revisions may be appropriate.

## **Attachments**

Attachment 1- Compliance Contacts/Hotline Information

Attachment 2- Annual Employee Compliance Certification

Attachment 2a- Employee Exit Interview Compliance Certification

**Attachment 1**  
**Compliance Contacts and Hotline Information**

**COMPLIANCE OFFICER:**

Judith M. Fox  
[Judith.Fox@TAFcares.org](mailto:Judith.Fox@TAFcares.org)  
4700 Millenia Blvd., Ste. 410  
Orlando, FL 32839  
(407) 801.7051

**COMPLIANCE COMMITTEE MEMBERS:**

Judith M. Fox, Chairperson, Senior Director, Compliance and Medical Affairs  
Steve Alsene, Chief Financial Officer  
Gerald Lauria, Vice President, Business Development and Strategic Initiatives  
Mark McGreevy, CEO/President  
Danielle Vizcaino, Vice President, Operations

You may report your knowledge or suspicion of fraud and abuse to any person listed in this Attachment, as well as the compliance hotline:

**877.778.5463 OR @ [www.reportit.net](http://www.reportit.net)** (User name: TAFcares | Password: Assistance)  
Information reported to the Compliance Officer, Compliance Committee or via the compliance hotline will be treated confidentially, to the extent possible

**Attachment 2**  
**The Assistance Fund, Inc.**  
**Annual Employee Compliance Certification**

I, \_\_\_\_\_, am not aware of any compliance issues, including billing compliance issues that have not been reported to the Compliance Officer or the Compliance Committee. I understand that failing to sign or providing false information on this form will result in disciplinary action, up to and including termination.

\_\_\_\_\_  
Employee Signature

\_\_\_\_\_  
Date

Examples of compliance issues include, but are not limited to:

- Offering, paying, soliciting or receiving any kickback, bribe or rebate;
- 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 financial eligibility determinations for grant assistance based upon any donor's interests;
- Making financial eligibility determinations for grant assistance based upon the applicant's choice in provider, practitioner, supplier, test or product;
- 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;
- Permitting donors to control or influence the identification of disease funds;
- Intentionally submitting incorrect, misleading or fraudulent information to any payor;
- Failing to maintain recipient, donor and prescriber confidentiality in accordance with applicable federal and state laws as part of the billing and claims submission; and
- Offering or paying bribes or other financial incentives, including future employment or contracts for non-audit services, or otherwise improperly exerting influence over the conduct of audits.

**Attachment 2a**  
**The Assistance Fund, Inc.**  
**Employee Exit Interview Compliance Certification**

**PLEASE CHECK ONE OF THE FOLLOWING:**

- I am not aware of any compliance issues, including billing compliance issues that have not been reported to the Compliance Officer or Compliance Committee.
- I am aware of a compliance issue that has not been reported.  
(Please provide description below).

Examples of compliance issues include, but are not limited to:

- Offering, paying, soliciting or receiving any kickback, bribe or rebate;
- 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 financial eligibility determinations for grant assistance based upon any donor's interests;
- Making financial eligibility determinations for grant assistance based upon the applicant's choice in provider, practitioner, supplier, test or product;
- 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;
- Permitting donors to control or influence the identification of disease funds;
- Intentionally submitting incorrect, misleading or fraudulent information to any payor;
- Failing to maintain recipient, donor and prescriber confidentiality in accordance with applicable federal and state laws as part of the billing and claims submission; and
- Offering or paying bribes or other financial incentives, including future employment or contracts for non-audit services, or otherwise improperly exerting influence over the conduct of audits.

Please provide a detailed description of any compliance issues that you are aware of, including names of employees involved, dates, and a description of the activity. Please attach additional sheets, if necessary.

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\_\_\_\_\_  
Employee Signature

\_\_\_\_\_  
Date