

# CORPORATE COMPLIANCE PLAN: PROGRAM SUMMARY

M A Y 2 0 2 2



The  
Assistance  
Fund

# Letter From the CEO and Chairman of the Board

## FELLOW TAF ASSOCIATES,

TAF's updated Corporate Compliance Plan: Program Summary demonstrates how we have upheld our commitment to a culture of compliance throughout our operations. With the launch of our nine-member Compliance Champion Team and new Board of Directors Compliance Committee, our Compliance Program is moving forward while successfully applying best practices every step of the way.

TAF's Compliance Plan: Program Summary is intended to be a guide for the conduct of TAF, its employees, and Covered Persons. More specifically, it provides an overview of the TAF Compliance Program Policies & Procedures; summarizes the significant federal laws governing our operations; and defines the conduct expected of TAF

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

employees and Covered Persons in connection with regulatory requirements and guidance issued to TAF by the OIG. Moreover, it contains guidance on how employees and Covered Persons may inquire and resolve questions regarding potential legal or ethical issues, including the various mechanisms for internally reporting possible violations under TAF's non-retaliation policy.

The Compliance Program applies to all work situations, from conflicts of interest to development and implementation of disease programs, from interactions with patients to handling confidential information.

It is our responsibility to know and understand the Compliance Program and related policies that govern our work. We are all accountable.

Thank you for your continued cooperation and commitment to TAF!



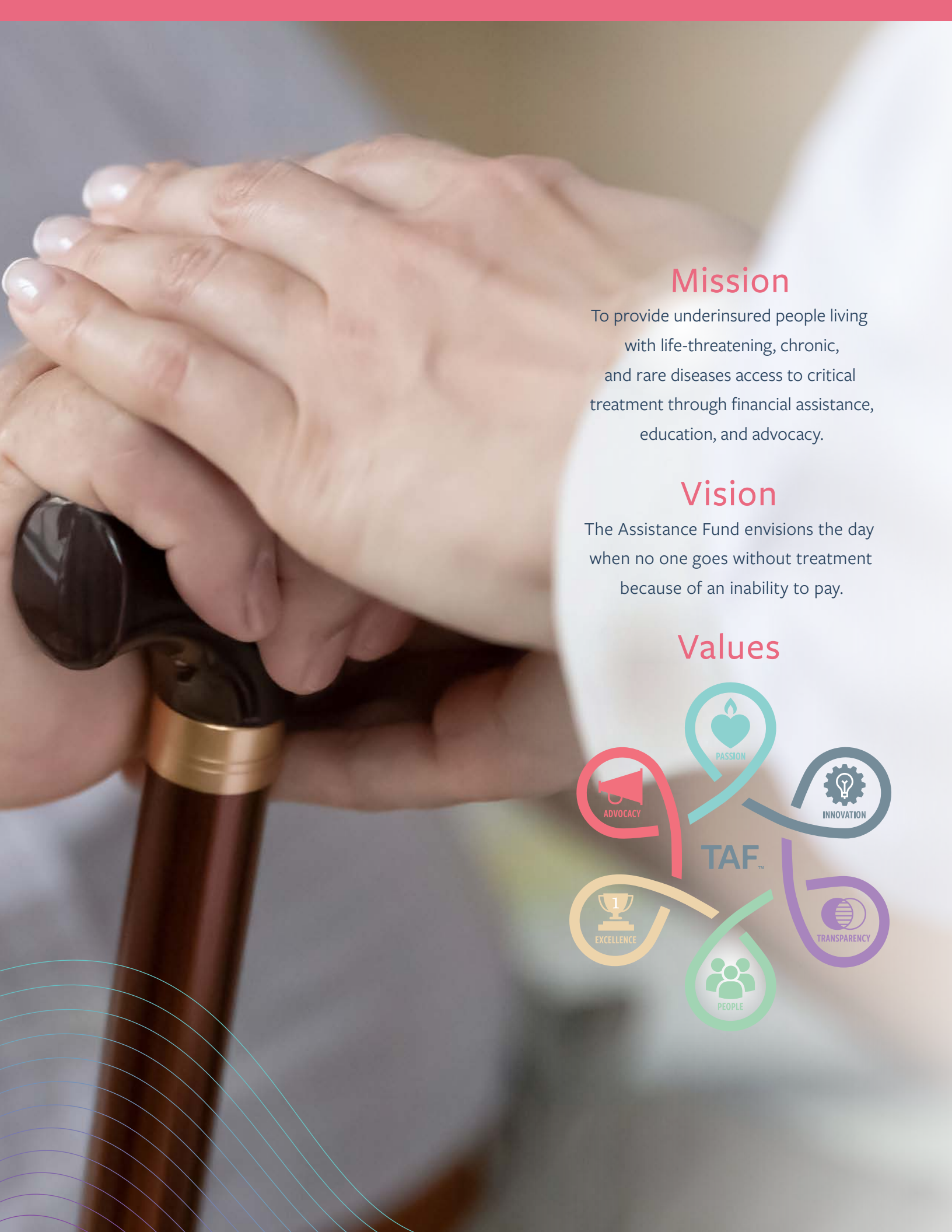
  
**MARK P. MCGREEVY**  
President & CEO



  
**LAWRENCE HATCH**  
Chair, Board of Directors



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## 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 80 funds referred to as disease programs (“Programs”), each of which covers the FDA-approved treatments 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 more than 160,000 children and adults in all 50 states and U.S. territories access critical treatment to manage their illness.

As an independent charitable patient assistance organization, TAF operates pursuant to 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, and the Internal Revenue Service Code (“IRS”).

## TAF’S CORPORATE COMPLIANCE PROGRAM

The legal and regulatory requirements under which independent charitable patient assistance organizations operate are often complex. TAF is fully committed to conducting all activities in full compliance with the highest level of ethics and integrity. Prioritizing transparency and being accountable and open in all our business practices is a core value at TAF. Accordingly, the TAF Board of Directors (“Board”) has implemented a Corporate Compliance Program (“TAF Compliance Program”). This program evolves every year to ensure TAF’s culture of compliance is implemented at every level of the organization.

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



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The TAF Board provides oversight to TAF's Compliance Program to ensure our commitment to our patients and our work, and to 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.

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



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

## COMPLIANCE PROGRAM ELEMENTS

The TAF Compliance Program embodies many interwoven activities that together form our compliance best practices.



## 1.1 GOVERNANCE AND OVERSIGHT

### *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 Compliance Program functions, regulatory risks, and methods for achieving organization-wide accountability to achieve compliance goals and effectiveness.

### *Chief Compliance Officer*

The Vice President of Regulatory Compliance (“Compliance Officer”), is TAF’s chief Compliance Officer and 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 CEO and Board.

### *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 Compliance Program’s effectiveness; and (2) assist the Compliance Officer in the administration of the Plan.

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.

## 1.2 WRITTEN COMPLIANCE GUIDANCE

### *Policies and Procedures*



Detailed compliance policies and procedures supporting the operations of TAF’s Compliance Program are readily accessible to all employees and

“Detailed compliance policies and procedures supporting the operations of TAF’s Compliance Program are readily accessible to all employees and Covered Persons through a shared file system.”

### **Compliance Program Code of Business Conduct and Ethics (“Code of Conduct”)**

TAF is committed to complying with all applicable federal healthcare laws, regulations, Advisory Opinions, and guidelines. Toward that goal, TAF has developed and implemented a comprehensive Corporate Compliance Program that provides an internal mechanism intended to guide TAF’s business practices and principles. The Compliance Program shall govern the performance, behavior, and actions of TAF and its Covered Persons when engaged in patient assistance operations. The Code of Conduct is an overarching standard for conducting all business activities with the highest degree of ethics and integrity. It is supported by the standards and guidelines set forth throughout this Program Summary.



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Covered Persons through a shared file system. They address program requirements including, but not limited to, applicable federal healthcare program requirements; interactions with Donors and other third parties; patient assistance program activities; conflicts of interest; and other program elements. These policies and procedures also require employees to report concerns and establish internal controls to contain identified compliance risk areas.

### 1.3 EDUCATION AND TRAINING



The purpose of compliance training is to communicate standards and procedures in a meaningful and effective manner that explains the requirements of the compliance program, applicable laws, and how they impact our daily operations.

#### *Orientation*

All newly hired employees and Covered Persons must complete an intensive, three-hour compliance training as part of TAF's new hire orientation program. Topics focus on the details of TAF's Compliance Program and independent charitable patient assistance organization-specific requirements under TAF's Advisory Opinion and Integrity Agreement.

All new Board members receive at least two hours of training relevant to their corporate governance responsibilities and Compliance Program oversight.

#### *Annual Training*

All employees and Covered Persons are required to participate in annual compliance training. Topics include, but are not limited to, TAF's Compliance Program elements (e.g., policies and procedures); TAF's OIG Advisory Opinions and Integrity Agreement; applicable laws and regulations; and privacy and security compliance.

#### *Specialty Training*

Additional operational compliance training sessions are targeted to specific departments. Employees receive training that is specific to their job responsibilities and to their obligations under the Compliance Program.

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 and Covered Persons 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.

### 1.4 OPEN LINES OF COMMUNICATION



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



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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. Compliance and reporting non-compliance are not duties that can be delegated.

### *TAF Compliance Champion Team*

To encourage open communication, TAF established the 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 Department;
- 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.

### *Channels to Voice Concerns*

If an employee becomes aware of an issue or concern:

- speak to a Compliance Champion, their supervisor, or a member of the senior leadership team;
- report their concern to Judith Fox, Compliance Officer, at **Judith.Fox@tafcares.org** or (407) 801-7051; 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).

*“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 hotline resources are available 365 days a year, seven days a week, and 24 hours a day, and employees can choose to be anonymous.

Below are important things to consider when reporting a concern:

- An employee need not be certain that a violation has occurred before making a report; reasonable belief that a violation may have occurred is sufficient.



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- Reporting enables TAF to investigate potential problems quickly and to take prompt action to address them.
- TAF will not retaliate against any employee who reports a compliance concern in good faith.

## 1.5 AUDITING AND MONITORING



TAF conducts internal monitoring and external independent audits to assess levels of compliance and opportunities to improve current systems, processes, policies, and procedures. If an audit identifies compliance risks, TAF proactively mitigates those risks and implements corrective action if necessary and as appropriate.

## 1.6 INVESTIGATIONS/RESPONSES

### 1.6.1 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 in a professional and expeditious manner, maintaining confidentiality to the extent practicable under the circumstances. All TAF employees and Covered Persons 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.

“TAF is committed to conducting thorough, fair, and impartial internal investigations of reported and perceived errors, abuses, and violations.”



**Retaliation against** any employee, consultant, 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 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 Hotline.

AND

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



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### 1.6.2 *Response and Prevention*

TAF ensures that 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.

### 1.6.3 *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 reviewed by legal counsel prior to any voluntary disclosure.

## 1.7 ENFORCEMENT AND DISCIPLINARY ACTIONS



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. Based on the facts and circumstances of the offense, the Compliance Officer will recommend to the CEO disciplinary action for those who fail to adhere to the standards of this Plan. Such a recommendation shall be consistent with HR progressive disciplinary action policies and procedures. The recommendation for disciplinary action may include termination or—for consultants or major vendors—contract termination. The decision to execute such action(s) shall be implemented consistently across the organization.



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## Federal Laws, Regulations, Guidance, and Prohibited Activities

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 employment-related sanctions, such as suspension or termination, they may also be responsible for civil money damages and potential criminal sanctions, including imprisonment.

**Sections 2.1-3** provide the main points of three primary federal laws—categorized as fraud and abuse statutes—that apply to TAF: the Anti-Kickback Statute; the Beneficiary Inducement Law; and the Civil False Claims Act.

**Section 2.4** outlines key regulatory documents under which TAF operates.

**Section 2.5** describes how applicable laws and guidance govern TAF's operations.

**Section 2.6** outlines other applicable laws.



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## 2.1 FEDERAL ANTI-KICKBACK STATUTE (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 (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.

## 2.2 FEDERAL BENEFICIARY INDUCEMENT LAW (42 USC 1320a-7a(a)(5))

Many of the products that are covered by our Programs are ultimately reimbursed under Medicare, Medicaid, or other federal or state healthcare programs. Besides the AKS, the Beneficiary Inducement Law also 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. OIG may initiate administrative proceedings to seek such CMPs and exclude such person from federal healthcare programs. A subsidy for cost-sharing obligations provided by a patient assistance program may implicate this law if the subsidy is likely to influence a Medicare or Medicaid beneficiary’s selection of a particular provider, practitioner, or supplier. One example of prohibited behavior is making eligibility requirements to enroll in our disease programs dependent on the patient’s use of certain prescribing physicians or certain pharmacies to dispense the medication.

## 2.3 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 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. One example of prohibited behavior is steering patients to particular drugs in violation of the Anti-Kickback Statute.



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## 2.4 FEDERAL GUIDANCE AND REQUIREMENTS

TAF's Compliance Program requirements are also based on OIG guidance issued to TAF and the independent charitable patient assistance program industry, and the TAF Integrity Agreement.

All employees and Covered Persons are required to understand and be familiar with the contents of both the OIG Advisory Opinions and Integrity Agreement. These are summarized below and reflected throughout this Compliance Program Plan Summary and TAF policies and procedures.

***The full text of the OIG Advisory Opinions, Special Advisory Bulletins, and Integrity Agreement documents are located on the TAF website at: [www.tafcares.org/compliance/](http://www.tafcares.org/compliance/).***

### 2.4.1 *TAF Advisory Opinion No. 10-07, as modified*

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.

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.

### 2.4.2 *TAF Integrity Agreement*

An Integrity Agreement ("IA") is a document outlining the contractual obligations that an organization involved in healthcare makes with a federal government agency as part of a civil settlement.

In 2019, TAF entered into an Integrity Agreement with the OIG that contractually defines TAF's compliance and reporting obligations through calendar year 2022. The IA reaffirms the existing OIG Advisory Opinion with some additional structural and operational compliance obligations.



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## 2.5 TAF SYSTEMS, PRACTICES, POLICIES, AND PROCEDURES: PROHIBITED ACTIVITIES

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



### 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;
- 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.

Any employee who receives, accepts, or condones a bribe, kickback, or other unlawful payment, or attempts to initiate such activities, will be terminated and subject to possible criminal proceedings. Employees who attempt or engage 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.

### 2.5.1 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, and its Integrity Agreement. 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. To this end, TAF employees must adhere to the following safeguards when developing disease programs:

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

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



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- Donors to TAF's disease programs cannot influence the identification of any disease program, and TAF cannot solicit suggestions from any Donor regarding the identification, delineation, or modification of any disease programs.
- Disease programs cannot be defined by reference to specific symptoms, severity of symptoms, or the method of treatment administration. TAF conducts an independent assessment and uses a pharmacist and Medical Advisory Board to determine disease state definitions and covered treatment.
- TAF's Board will define additional disease programs after an independent assessment of patient needs.
- Disease programs cannot be defined by reference to the stages of a particular disease, the type of treatment, and any other ways of narrowing the definition of widely recognized disease states. Excepted from this prohibition are disease programs for metastatic stages of cancer, as approved by the 2016 OIG Notice of Modification of Advisory Option No. 10-07.
- Disease programs cannot limit assistance to high-cost or specialty drugs. Disease programs must provide assistance for all FDA-approved treatment intended to treat the disease states covered by the disease program, including generic or bioequivalent medications.
- If a disease program is defined by reference to multiple disease states, Donors may earmark their donations to any disease program, but TAF will not allow Donors to earmark donations for any specific treatment or disease state within a given disease program.
- Disease programs cannot be defined in a manner that intentionally results in the coverage of medications exclusively or primarily manufactured or distributed by Donors.
- Disease programs cannot limit assistance to a subset of available products, rather than all products approved by the FDA for treatment of the disease state(s) covered by the disease program or reimbursed by relevant federal healthcare programs when prescribed for the treatment of the disease state(s).

For example, disease programs will not be limited to covering patients' cost-sharing obligations related to only expensive or specialty drugs. 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.

- TAF cannot 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.
- With respect to disease programs 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



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the patient in addition to cost-sharing support for the FDA-approved treatment of the disease. These include 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 treatment.

- 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. Examples include cost-sharing assistance for related physician office visits, home visits, medical devices, and other tests, as well as incidental expenses related to receiving treatment such as childcare, 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.

### 2.5.2 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. Some criteria for determining financial need described in the federal guidance for independent charitable patient assistance programs are as follows:

- TAF will screen all applicants to determine financial eligibility prior to enrolling the applicants in a disease program. This process will be applied across all disease programs and must include verifying each participant's financial resources through information provided by a third-party service and collecting documentation of financial need from the applicant.

“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.”

- Applications for assistance will be considered on a first-come, first-served basis, to the extent of available funding. If funding is not available, TAF shall offer the applicant the option of being placed on a waitlist to receive notification if and when funds become available.
- Applicants will be required to have already selected their healthcare providers, practitioners, suppliers, and products, and will already have a treatment regimen in place. However, all patients may change their healthcare providers, practitioners, suppliers, and products while receiving assistance from TAF.

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



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- TAF cannot make eligibility determinations based in whole or in part on (i) 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.
- Eligibility can be determined based on poverty guidelines, which take into account household size and household income.
- 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.
- Eligibility cannot be based solely on the cost of the particular treatment for which the patient is applying for assistance.
- 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.

### 2.5.3 *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. The following safeguards apply:

- TAF will not refer applicants to, recommend, or arrange for the use of any particular medication, test, practitioner, provider, or supplier.
- TAF will not inform patients or Donors of the donations made to TAF by Donors or others.

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

- TAF cannot 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 to avoid the administrative burden and cost of reimbursing multiple small claims.
- For patients who are receiving assistance with health insurance premiums through a TAF disease program, TAF will provide the premium system grants directly to the insurance company or will make grants payable to the patient upon proof that the recipient incurred such cost.



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#### 2.5.4 *Interaction with Donors*

- 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.”

- 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.

## 2.6 OTHER APPLICABLE LAWS

### 2.6.1 *Privacy and Confidentiality*

TAF expects all employees to follow established policies and procedures when using or disclosing information that may be considered Protected Health Information (“PHI”) as that term is defined under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”). While TAF is not formally subject to HIPAA, it recognizes the importance of confidentiality in the provision of its services and has implemented systems and practices to ensure strict confidentiality of patient information.

TAF does not share confidential patient or Donor information with other Donors or patients, or unauthorized parties, unless obligated to do so under law. All Covered Persons with access to confidential information must adhere to TAF's policies, and contracts if applicable, in this regard.

“TAF does not share confidential patient or Donor information with other Donors or patients, or unauthorized parties, unless obligated to do so under law.”



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Workplace privacy and confidentiality are especially important in a hybrid work environment. Employees must refrain from sharing, discussing, texting, or otherwise revealing any patient or patient information to anyone other than to a fellow employee who needs to know this information to perform their job responsibilities.

If an employee becomes aware of unauthorized or inappropriate disclosure of confidential information, they should immediately contact a Compliance Champion, their supervisor, or the Compliance Officer.

To ensure confidential information is secure, documents containing sensitive data, including information concerning prescribers, recipients, or donors, must not be left in public view or in an unsecured location. Particular attention must be paid to how computer data is entered, secured, and stored. Given the nature of TAF's business, the potential for a breach of security exists and must be considered at all times. Unauthorized usage of TAF technology must be immediately reported to a Compliance Champion, their supervisor, the Vice President of Business Intelligence, or the Compliance Officer.

#### **2.6.2 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.

TAF has a strict policy that prohibits employing individuals or engaging with any Covered Persons who have been subject to exclusion.



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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 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 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.

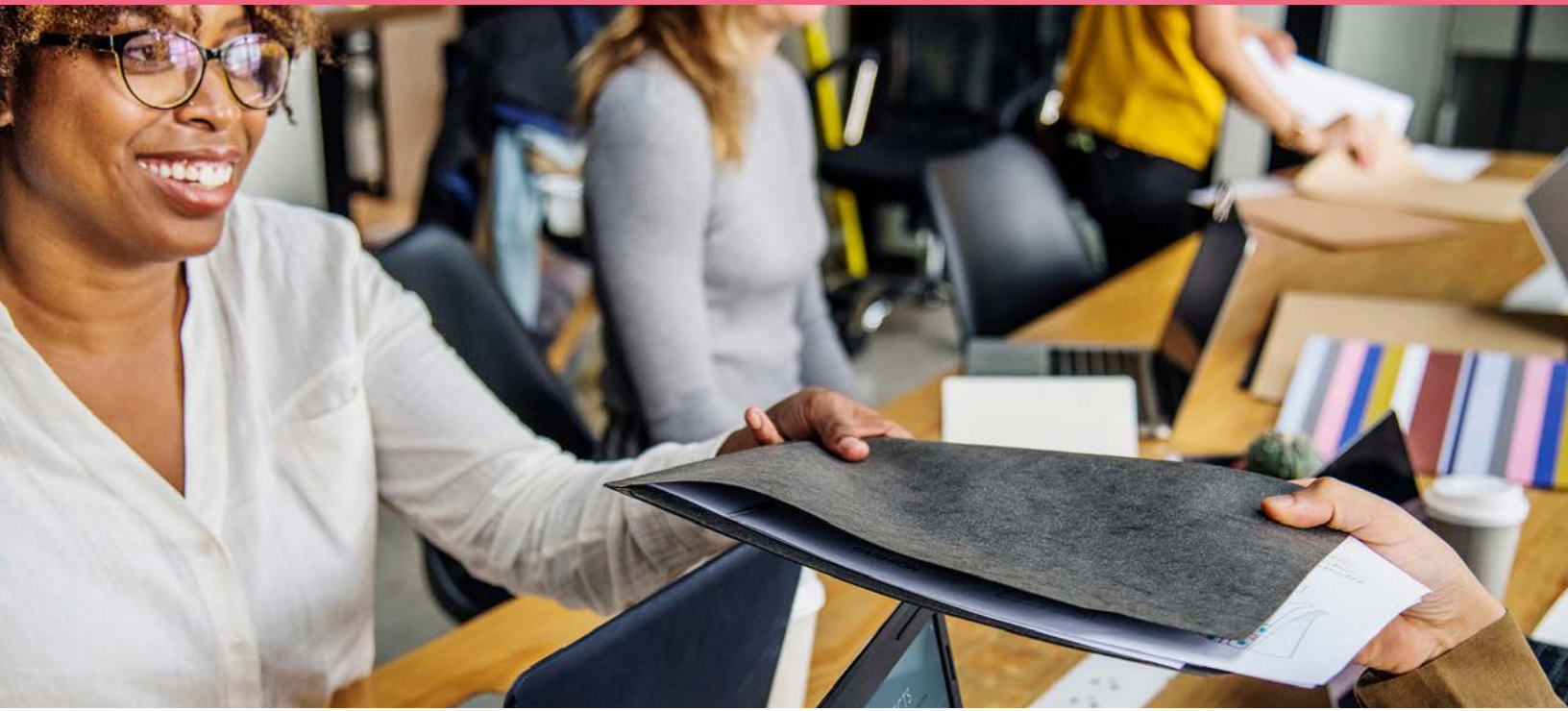


**JUDITH FOX**  
*VP of Regulatory  
Compliance*



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## Glossary



**Covered Persons** include 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.



**Donor** shall mean any pharmaceutical manufacturer of any affiliate, subsidiary, or other entity acting on its behalf which donates money to TAF for its patient assistance 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 Program Summary is not meant to include non-industry 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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