

CORPORATE COMPLIANCE PLAN: PROGRAM SUMMARY

F E B R U A R Y 2 0 2 1



The
Assistance
Fund

Letter From the CEO and Chairman of the Board

FELLOW TAF ASSOCIATES,

The Assistance Fund (“TAF”) is committed to the highest standards of ethics, integrity, and accountability as we carry out our mission to provide underinsured people living with life-threatening, chronic, and rare diseases access to critical treatment through financial assistance, education, and advocacy.

We are each responsible for adhering to the laws, regulations, and policies that govern charitable patient assistance organizations. It is both our organizational and individual responsibility. TAF’s Compliance Program helps us to ensure we are operating in full compliance with these legal and regulatory requirements.

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

It serves as a foundation to promote proper conduct and emphasize our commitment to ethical behavior. It reminds us that operational excellence must be accompanied by personal and organizational integrity.

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. This Program Summary is your guide. For more detailed information, please refer to the TAF Compliance Program Policies & Procedures.

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 cooperation and commitment to TAF!




MARK P. MCGREEVY
President & CEO




LAWRENCE HATCH
Chair, Board of Directors



TAF

THE ASSISTANCE FUND
CORPORATE COMPLIANCE PLAN:
PROGRAM SUMMARY



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





C O N T E N T S

1

Introduction

3

Compliance Program Elements

9

Federal Laws, Regulations, Guidance, and Prohibited Activities

18

Conclusion

19

Glossary

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 over 70 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 nearly 135,000 adults and children 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 Health Care Program Beneficiary Inducement Prohibition, 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”).

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



TAF

THE ASSISTANCE FUND
CORPORATE COMPLIANCE PLAN:
PROGRAM SUMMARY

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 our conduct in all TAF activities. A failure by an individual or the organization to comply with our legal or ethical obligations, even if inadvertent, can lead to civil or criminal liability.

“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 our conduct in all TAF activities.”



This TAF Compliance Program summary is intended as 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 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.



TAF

THE ASSISTANCE FUND
CORPORATE COMPLIANCE PLAN:
PROGRAM SUMMARY

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

COMPLIANCE PROGRAM ELEMENTS

The TAF Compliance Program embodies many interwoven activities—also referred to as elements—including the following:



1.1 Governance and Oversight



1.2 Written Compliance Guidance



1.3 Education and Training



1.4 Open Lines of Communication, including a Hotline



1.5 Auditing & Monitoring



1.6 Investigation of Complaints/Responses to Detected Offenses/Corrective Action



1.7 Enforcement and Disciplinary Action/Exclusions Screening



TAF

THE ASSISTANCE FUND
CORPORATE COMPLIANCE PLAN:
PROGRAM SUMMARY

1.1 OVERSIGHT

Board of Directors (“Board”)



As the organization’s governing body, the Board has oversight responsibility for TAF 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 Senior Director, Compliance and Medical Affairs (“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 health-care 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 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.



TAF

THE ASSISTANCE FUND
CORPORATE COMPLIANCE PLAN:
PROGRAM SUMMARY

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 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.



TAF

THE ASSISTANCE FUND
CORPORATE COMPLIANCE PLAN:
PROGRAM SUMMARY

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 non-delegable duties.

If you become aware of an issue or have a concern:

- speak to your supervisor or a member of the senior leadership team;
- report your concern to Judith Fox, Compliance Officer, at Judith.Fox@tafcares.org or 407-801-7051; or
- report your concern to the TAF Compliance Hotline (ReportIt) by calling 877-778-5463 or going to www.reportit.net (user name: 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 you 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.
- 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.



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 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 seeking advice, raising a concern, reporting misconduct, or providing information in an investigation, you should contact the Compliance Officer immediately. You 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.



TAF

THE ASSISTANCE FUND
CORPORATE COMPLIANCE PLAN:
PROGRAM SUMMARY

1.5 AUDITING AND MONITORING



TAF conducts periodic audits designed to assess current systems, processes, policies, and procedures. Audits include periodic internal and annual external audits of appropriate departments to assess levels of compliance with this Compliance Plan.

If an audit identifies potential compliance risks, TAF is proactive to mitigate such risks. In the event potential violations of this Compliance Plan are revealed, corrective action is developed and implemented. The Compliance Officer may consult with counsel regarding questions raised by the audit 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?
- What is the appropriate corrective action?
- Should a disclosure be made to an appropriate government agency?

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.”

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 and training, and policy and/or operational changes.



TAF

THE ASSISTANCE FUND
CORPORATE COMPLIANCE PLAN:
PROGRAM SUMMARY

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.



TAF

THE ASSISTANCE FUND
CORPORATE COMPLIANCE PLAN:
PROGRAM SUMMARY



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 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 federal Anti-kickback Statute; the federal Beneficiary Inducement Statute; and the federal 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.



TAF

THE ASSISTANCE FUND
CORPORATE COMPLIANCE PLAN:
PROGRAM SUMMARY

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 Medicaid, Medicare, or other federal or state healthcare programs. Besides the AKS, the Beneficiary Inducement Statute 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 the 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 dependent on the patient’s use of certain prescribing physicians or certain pharmacies to dispense the drugs.

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.



TAF

THE ASSISTANCE FUND
CORPORATE COMPLIANCE PLAN:
PROGRAM SUMMARY

2.4 FEDERAL GUIDANCE AND REQUIREMENTS

TAF's Compliance Program requirements are also based on OIG guidance issued to TAF and the independent charity 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/.

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 program features that it had previously approved and required TAF to modify its 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.



TAF

THE ASSISTANCE FUND
CORPORATE COMPLIANCE PLAN:
PROGRAM SUMMARY

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

The following provides specific activities that TAF has identified to ensure compliance with the aforementioned 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 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.

2.5.1 Disease Program Funds

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. 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 healthcare provider choices. To this end, TAF employees shall adhere to the following safeguards in developing disease programs:

- Donors to TAF's disease programs shall not be permitted to exert any direct or indirect influence or control over TAF.



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TAF

THE ASSISTANCE FUND
CORPORATE COMPLIANCE PLAN:
PROGRAM SUMMARY

- Donors to TAF's disease programs shall not be permitted to influence the identification of any disease program, and TAF shall not solicit suggestions from any Donor regarding the identification, delineation, or modification of any disease programs.
- Disease programs 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 uses a pharmacist and Medical Advisory Board to determine disease state definitions and covered drugs.
- Any additional disease programs will be defined by TAF's Board based on such independent assessment of whether a new disease program arrangement would serve patient needs.
- Disease programs 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 programs for metastatic stages of cancer, as approved by the 2016 OIG Notice of Modification of Advisory Option No. 10-07.
- Disease programs shall not be defined such to limit assistance to high-cost or specialty drugs. Disease programs 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 disease program.
- In the event that a disease program is defined by reference to multiple disease states, Donors may earmark their donations to any disease program, but TAF will not permit Donors to earmark donations for any specific drug or disease state within a given disease program.
- Disease programs shall not be defined in a manner that intentionally results in the coverage of medications exclusively or primarily manufactured or distributed by Donors.
- Disease programs 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 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 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 disease program.
- TAF shall not 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.



TAF

THE ASSISTANCE FUND
CORPORATE COMPLIANCE PLAN:
PROGRAM SUMMARY

- 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 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 treatments.
- 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 such 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 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:

- TAF will employ a process for screening all applicants for compliance with the disease program's designated financial eligibility criteria prior to enrolling the applicants in a disease program. Such process shall be uniformly applied across all disease programs 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.

“TAF must determine eligibility according to a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner.”

- Applications for assistance will be considered on a first-come, first-served basis, to the extent of available funding. If funding is not available in disease program to which the applicant applied, TAF shall offer the applicant the option of being placed on a waitlist and 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 will remain free to 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.”



TAF

THE ASSISTANCE FUND
CORPORATE COMPLIANCE PLAN:
PROGRAM SUMMARY

- 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.
- 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 solely be based on the cost of the particular drug for which the patient is applying for assistance.
- TAF may establish disease programs that serve only Federal healthcare program beneficiaries, provided that such 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 drug 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 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.
- 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 shall make grants payable to the patient upon proof that the recipient incurred such cost.



TAF

THE ASSISTANCE FUND
CORPORATE COMPLIANCE PLAN:
PROGRAM SUMMARY

2.5.4 *Interaction with Donors*

- TAF shall operate independently from all Donors.
- Donors shall not be eligible 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 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 disease program during that reporting period.
- TAF shall not request specific donation amounts from any Donor for a disease program. TAF shall provide Donors only with information about the total estimated amount needed for each disease program. TAF shall not permit Donors to earmark for any drug or disease state within a given disease program.

“TAF shall operate independently from all Donors.”

- TAF shall not convey any individual patient information to any Donor.
- TAF shall document and maintain written records reflecting all communications (oral or written) with Donors about donation offers or requests; request for data and all data shared with Donors; and requests or suggestion 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 has established policies and procedures to which all of its workforce are expected to adhere 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.

More specifically, 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

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TAF

THE ASSISTANCE FUND
CORPORATE COMPLIANCE PLAN:
PROGRAM SUMMARY

must adhere to TAF's policies, and contracts if applicable, in this regard. If you become aware of unauthorized or inappropriate disclosure by TAF personnel of confidential information, you should immediately contact your 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. You also must pay particular attention to the manner in which you enter, secure, and store computer data. Given the nature of TAF's business, the potential for a breach of security exists and must be considered at all times. If you observe individuals you do not recognize using computers or other TAF technology, immediately report this to your 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 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 has been subject to exclusion.



TAF

THE ASSISTANCE FUND
CORPORATE COMPLIANCE PLAN:
PROGRAM SUMMARY



Conclusion

TAF's commitment to corporate compliance begins and ends with each individual. Understanding our legal and ethical obligations is essential for us all to support a culture of compliance throughout our organization. The information contained in this Compliance Plan serves as a foundation to promote proper conduct and emphasize our duty to ethical behavior.

All of us have an important role to play to ensure that public confidence remains strong, so that 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.



TAF

THE ASSISTANCE FUND
CORPORATE COMPLIANCE PLAN:
PROGRAM SUMMARY



Glossary



Business Associate A person or entity who, on behalf of a covered entity, performs or assists in performance of a function or activity involving the use or disclosure of individually identifiable health information, such as data analysis, claims processing or administration, utilization review, and quality assurance reviews, or any other function or activity regulated by the HIPAA Administrative Simplification Rules, including the Privacy Rule. Business associates are also persons or entities performing legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, or financial services to or for a covered entity where performing those services involves disclosure of individually identifiable health information by the covered entity or another business associate of the covered entity to that person or entity. A member of a covered entity's workforce is not one of its business associates. A covered entity may be a business associate of another covered entity.



Covered Entities are defined in the HIPAA rules as (1) health plans, (2) healthcare clearinghouses, and (3) healthcare providers who electronically transmit any health information in connection with transactions for which HHS has adopted standards. Generally, these transactions concern billing and payment for services or insurance coverage. For example, hospitals, academic medical centers, physicians, and other healthcare providers who electronically transmit claims transaction information directly or through an intermediary to a health plan are covered entities. Covered entities can be institutions, organizations, or persons.



TAF

THE ASSISTANCE FUND
CORPORATE COMPLIANCE PLAN:
PROGRAM SUMMARY



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 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, co-payment assistance, premium assistance, or any other financial assistance that TAF may provide to patients.



TAF

THE ASSISTANCE FUND
CORPORATE COMPLIANCE PLAN:
PROGRAM SUMMARY