

**INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
THE ASSISTANCE FUND, INC.**

**I. PREAMBLE**

The Assistance Fund, Inc. (TAF) hereby enters into this Integrity Agreement (IA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this IA, TAF is entering into a Settlement Agreement with the United States.

In 2006, pursuant to 42 C.F.R. Part 1008, OIG issued Advisory Opinion 10-07 to TAF. That Advisory Opinion was modified in 2015. In consideration of the obligations of TAF set forth in this IA and the Settlement Agreement referenced above, OIG agrees it will not rescind or terminate Advisory Opinion 10-07, as modified, based on the Covered Conduct resolved through the Settlement Agreement.

**II. TERM AND SCOPE OF THE IA**

A. Unless otherwise specified, the period of the compliance obligations assumed by TAF under this IA shall be three reporting periods as defined below. The Effective Date shall be the date on which the final signatory signs this IA. The first Reporting Period shall be from the Effective Date through December 31, 2020. The second and third Reporting Periods shall be from January 1 through December 31 of 2021 and 2022, respectively. The Effective Date shall be the date on which the final signatory signs this IA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) TAF's final Annual Report; or (2) any additional materials submitted by TAF pursuant to OIG's request, whichever is later.

- C. The scope of this IA shall be governed by the following definitions:
1. “Covered Persons” includes:
    - a. all owners, officers, directors, employees of TAF; and
    - b. 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.
  2. 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.

### **III. INTEGRITY OBLIGATIONS**

TAF shall establish and maintain a Compliance Program that includes the following elements:

#### **A. Compliance Officer**

Within 90 days after the Effective Date, TAF shall appoint a Compliance Officer and shall maintain a Compliance Officer for the term of the IA. The Compliance Officer shall be an employee and a member of senior management of TAF, shall report directly to the Chief Executive Officer of TAF, and shall not be or be subordinate to the General Counsel or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for TAF. The Compliance Officer shall be responsible for, without limitation:

- a. developing and implementing policies, procedures, and practices designed to ensure compliance with the

requirements set forth in this IA and with Federal health care program requirements;

- b. making periodic (at least quarterly) reports regarding compliance matters to the Board of Directors of TAF (Board) and shall be authorized to report on such matters to the Board at any time. Written documentation of the Compliance Officer's reports to the Board shall be made available to OIG upon request; and
- c. monitoring the day-to-day compliance activities engaged in by TAF as well as any reporting obligations created under this IA.

Any noncompliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this IA.

TAF shall report to OIG, in writing, any changes in the identity of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this IA, within five days after such a change.

B. Board Compliance Obligations The Board shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements and the obligations of this IA. The Board must include independent (i.e., non-executive) members.

The Board shall, at a minimum, be responsible for the following:

- a. meeting at least quarterly to review and oversee TAF's Compliance Program, including but not limited to the performance of the Compliance Officer;
- b. submitting to OIG a description of the documents and other materials it reviewed, as well as any additional steps taken, such as the engagement of an independent advisor or other third party resources, in its oversight of the compliance program and in support of making the resolution below during each Reporting Period; and

- c. for each Reporting Period of the IA, adopting a resolution, signed by each member of the Board, summarizing its review and oversight of TAF's compliance with Federal health care program requirements and the obligations of this IA.

At minimum, the resolution shall include the following language:

“The Board has made a reasonable inquiry into the operations of TAF's Compliance Program including the performance of the Compliance Officer. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, TAF has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the Integrity Agreement.”

If the Board is unable to provide such a conclusion in the resolution, the Board shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Compliance Program at TAF.

TAF shall report to OIG, in writing, any changes in the composition of the Board, or any actions or changes that would affect the Board's ability to perform the duties necessary to meet the obligations in this IA, within 15 days after such a change.

C. Policies and Procedures

Within 90 days after the Effective Date, TAF shall develop and implement written policies and procedures regarding the operation of its compliance program, including the compliance program requirements outlined in this IA and TAF's compliance with applicable Federal health care program requirements (Policies and Procedures). The Policies and Procedures also shall address:

- a. compliance with applicable Federal health care program requirements, including but not limited to, the False Claims Act (codified at 31 U.S.C. §§ 3729-3733) and the Federal Anti-Kickback Statute (codified at 42 U.S.C. § 1320a-7b(b)), the regulations and other guidance documents related to these statutes, and business or financial arrangements or contracts that generate unlawful Federal health care program business in violation of the Anti-Kickback Statute:

- b. arrangements and interactions with any and all donors and potential Donors. “Donor” shall mean any pharmaceutical manufacturer or any affiliate, subsidiary, or other entity acting on its behalf which donates money to TAF for its patient assistance programs. These Policies and Procedures shall be designed to ensure that TAF’s arrangements and interactions with Donors and potential Donors comply with all applicable Federal health care program requirements. The Policies and Procedures shall also be designed to ensure that TAF’s arrangements and interactions (including donations and sponsorship) comply with all guidance issued by OIG relating to the support and funding of patient assistance programs, including but not limited to, the OIG’s Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623 (Nov. 22, 2005) and OIG’s Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31120 (May 30, 2014); and
- c. arrangements and interactions with any and all third parties (including vendors, hubs, pharmacies, and other entities) with which TAF interacts in connection with Patient Assistance Related Functions. These Policies and Procedures shall be designed to ensure that TAF’s arrangements and interactions with these third parties comply with all applicable Federal health care program requirements. The Policies and Procedures shall also be designed to ensure that TAF’s arrangements and interactions with such third parties comply with all guidance issued by OIG relating to the support and funding of patient assistance programs, including but not limited to, the OIG’s Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623 (Nov. 22, 2005) and OIG’s Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31120 (May 30, 2014).

The Policies and Procedures shall be made available to all Covered Persons. Throughout the term of this IA, TAF shall enforce its Policies and Procedures and shall

make compliance with its Policies and Procedures an element of evaluating the performance of all employees.

At least annually (and more frequently, if appropriate), TAF shall assess and update, as necessary, the Policies and Procedures. Any revised or new Policies and Procedures shall be made available to all Covered Persons. All Policies and Procedures shall be made available to OIG upon request.

D. Posting of Notice

Within 60 days after the Effective Date, TAF shall post in a prominent place accessible to all Covered Persons a notice that provides the name and phone number of the Compliance Officer and the HHS OIG Fraud Hotline telephone number (1-800-HHS-TIPS) as a confidential means by which suspected fraud or abuse in the Federal health care programs may be reported.

E. Training and Education

1. *Covered Persons Training.* All Covered Persons except members of the Board of Directors shall receive at least three hours of training during the first Reporting Period. Any individuals who become Covered Persons after the Effective Date and during the term of this IA shall receive at least three hours of training within 90 days of becoming a Covered Person.

Training may be completed in-person or online. At a minimum, the required training sessions must include the following topics: TAF's IA requirements and Compliance Program and Federal health care program requirements applicable to Patient Assistance Related Functions, including the requirements of the Anti-Kickback Statute.

The OIG may, in its discretion, require that Covered Persons complete additional hours of training regarding the topics identified above, or additional topics, in the second and third years of the IA. The OIG shall provide notice to TAF of such additional required training at least 180 days prior to the required completion date for such training.

2. *Board Training.* Within 90 days after the Effective Date, each member of the Board of Directors shall receive at least two hours of training. This training shall address the corporate governance responsibilities of board members, and the responsibilities of board members with respect to review and oversight of the Compliance Program. Specifically, the training shall address the unique responsibilities of health care board members, including the risks, oversight areas, and strategic

approaches to conducting oversight of a health care entity. The training shall also address TAF's IA requirements and Compliance Program and those Federal health care program requirements applicable to Patient Assistance Related Functions, including the requirements of the Anti-Kickback Statute. This training may be conducted by an outside compliance expert hired by the Board and should include a discussion of OIG's guidance on Board member responsibilities.

New members of the Board shall receive the Board Training described above within 30 days after becoming a Board member or within 90 days after the Effective Date, whichever is later.

3. *Training Records.* TAF shall maintain written documentation (e.g., written or electronic certificates of completion from the training provider) that all Covered Persons required to receive training have in fact completed such training. The documentation shall specify the type of training received, the individual who completed the training, and the date received.

#### F. Patient Assistance Program Activities

TAF shall implement the policies, procedures, and practices set forth in this Section III.F (hereafter "PAP Measures") within 90 days after the Effective Date. TAF shall continue the PAP Measures described below (or equivalent processes) throughout the term of the IA, and shall notify OIG in writing at least 60 days prior to the implementation of any modifications to such PAP Measures.

1. *Independent Operations.* TAF shall operate independently from all Donors<sup>1</sup>. Among other things, TAF shall operate with absolute, independent, and autonomous discretion as to the establishment of disease funds and the use of Donor contributions. At a minimum, TAF shall operate in accordance with the following policies and practices:

- a. All individual officers, directors, employees, and agents of TAF shall be independent from all Donors. No such individual receives, or shall receive, directly or indirectly, any form of compensation from any Donor. No Donor, or immediate family member, director, officer, employee, or person otherwise affiliated with a Donor is or shall be eligible

---

<sup>1</sup> For purposes of this Section III.F, the term "Donor" shall mean both existing and prospective Donors of TAF and shall include all affiliates and agents of existing and prospective Donors.

to serve as an officer, director, employee or agent of TAF. No former director, officer, or employee of a Donor who maintains an ongoing relationship with the Donor (via consulting or otherwise), or immediate family members of such individuals shall serve as an officer, director, employee, or agent of TAF.

- b. The compensation paid by TAF to its officers, directors, employees, and agents shall be consistent with fair market value. The compensation shall not be determined in a manner that takes into account the volume or value of any referrals or other business generated for any Donor.
- c. TAF in its sole discretion, shall determine the diseases it supports through its funds. TAF shall establish a standardized, independent internal process for the establishment, delineation, and modification of any disease funds (hereafter, "Disease Fund Process"). TAF shall base its decisions about the establishment, delineation, or modification of funds on TAF's independent assessment of whether the new or modified fund will best serve patient needs.
- d. TAF shall establish and maintain disease funds in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of products. It shall not define any disease fund by reference to specific symptoms, severity of symptoms, the method of administration of drugs, or in a manner that narrows a widely recognized disease state by including a genetic test result as a patient eligibility criterion.
- e. For each fund, TAF shall document and maintain records reflecting all donations to the fund and all financial assistance requested and provided from the fund. This shall include records reflecting financial assistance provided to each and every individual patient who applied for and/or received co-payment or other assistance from the fund.
- f. If TAF is unable to provide financial assistance to patients because monies are not available in a disease fund to which



the patients have applied or a fund has been closed, TAF shall offer such patients the option of being placed on a list in order to be notified in the event the fund resumes providing grants (Notification List). TAF shall maintain the names on each fund Notification List in the order in which the individuals requested to be placed on the Notification List. When and if monies become available in the disease fund or the fund re-opens, TAF shall not provide financial assistance to any new patients until after it has provided financial assistance to all eligible patients on the Notification List in the order in which the patients appeared on the Notification List. That is, TAF shall provide financial assistance to all eligible patients, including patients on the Notification List, on a first-come, first-served basis.

- g. TAF shall not limit its assistance to high-cost or specialty drugs. Instead, TAF shall make assistance available for, at a minimum, all prescription medications, including generic or bioequivalent drugs, approved by the FDA for treatment of the disease state(s) covered by the fund. TAF may choose to provide assistance for a broader scope of drugs (e.g., all prescription medications covered by the patient's insurance plan when prescribed for the disease state(s) covered by the fund). However, TAF shall apply the same drug coverage methodology across all its funds. For example, if one fund provides assistance for all prescription medications covered by the patient's insurance, another fund cannot be limited to prescription medications that are approved by the FDA for the treatment of the disease state(s) covered by the fund.
- h. TAF shall establish written policies and procedures describing the Disease Fund Process outlined above.
- i. 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.

2. *Interactions with Donors.* TAF shall interact with all Donors in a manner designed to maintain TAF's true independence from Donors. At a minimum, TAF shall operate in accordance with the following policies and practices:

- a. TAF shall not establish, delineate, or modify a disease fund at the request or suggestion of Donors or prospective Donors (or their affiliates).
- b. TAF shall not provide any Donor (directly or indirectly) with any data that would enable the Donor to correlate the amount or frequency of its donations with the amount or frequency of the use of its products or services. TAF shall not convey to any Donor (directly or indirectly) any individual patient information or any data related to the identity, amount, or nature of products or services for which assistance was provided through the fund. TAF shall not share the Notification Lists referenced in Section III.F.1.f or information contained on, or derived from, the Notification Lists with any outside individual or entity except that TAF may provide information directly to individual patients concerning their status on the Notification List.
- c. 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.
- d. TAF shall establish written policies and procedures regarding any sharing of any data with Donors (Data Sharing Policies).
- e. TAF shall document and maintain written records reflecting all communications (oral and written) with Donors regarding:
  - i) donation offers or requests;
  - ii) requests for data and all data shared with Donors; and
  - iii) requests or suggestions (oral and written) from Donors relating to the identification, establishment, or delineation of a fund and TAF's response to such requests and suggestions.

3. *Assistance to Patients.* TAF shall interact with patients in a manner designed to ensure that the provision of any financial assistance does not improperly influence any patient's selection of a particular provider, practitioner, supplier, product, or test. At a minimum, TAF shall implement the following policies and practices:

- a. TAF shall assist all eligible, financially needy patients on a first-come, first-served basis to the extent funding is available. Patients shall not be eligible for assistance unless they meet TAF's financial need eligibility criteria and the patient has been diagnosed with a disease covered by the fund. TAF shall provide assistance on a fund-by-fund basis that is based on a reasonable, verifiable, and uniform measure of financial need that is applied to all patients within the fund in a consistent manner.
- b. TAF shall establish a uniform process for screening all applicants for compliance with a fund's designated financial eligibility and medical criteria (Screening Process) prior to enrolling applicants in a fund or within a reasonable amount of time thereafter. TAF shall not require that an applicant demonstrate an inability to receive financial assistance from other sources before applying for assistance from TAF's fund.
- c. TAF's determination of a patient's qualification for assistance shall be based on his or her financial need and a determination that the patient has a disease that is covered by the fund. In assessing a patient's financial need, TAF shall not consider the identify of any of his or her health care providers, practitioners, suppliers, products or tests; the identity of any referring party; or the identity of any Donor that may have contributed for the support of the patient's specified disease or the amount of the donation.
- d. TAF shall award assistance in a manner that severs any link between Donors and patients. TAF shall not provide patients with any information regarding Donors or the identity of Donors to the fund from which patient receives assistance. TAF shall communicate a decision to provide a grant or other financial assistance to a patient only to the patient or a personal representative (who is acting on behalf of the patient

in seeking financial assistance from TAF) and who is not acting on behalf of any Donor to the fund. TAF shall not communicate such decision to a third party such as a hub.

- e. TAF shall make no referrals or recommendations regarding specific providers, practitioners, suppliers, tests, or products. TAF's assistance shall not limit patients' freedom of choice in any regard. Patients shall remain free to select any provider, practitioner, supplier, product, or test, regardless of whether that provider, practitioner, supplier, or the manufacturer<sup>2</sup> of a product or test has donated to TAF. Patients shall be free at any time to switch providers, practitioners, suppliers, or products without affecting their continued eligibility for assistance from TAF.
- f. TAF shall establish written policies reflecting the factors it considers as part of the Screening Process. TAF shall maintain copies of these policies over time including any changes to the policies.
- g. TAF shall maintain written records documenting its evaluation and eligibility determination for each patient who seeks financial assistance from TAF.

G. Review Procedures

1. *General Description.*

- a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, TAF shall engage an entity (or entities) such as a consulting firm (hereinafter "Independent Review Organization" or "IRO"). The IRO shall perform the reviews referenced in this Section III.G and explained more fully in Appendix B. The applicable requirements relating to the IRO are outlined in Appendix A to this IA, which is incorporated by reference.

---

<sup>2</sup> For purposes of this Section III.F, the term "manufacturer" shall include the company that makes or markets a drug product, all affiliates of the company, and any entity that has a joint venture or co-promotion arrangement with the company relating to the drug product.

- b. *Retention of Records.* The IRO and TAF shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and TAF) related to the reviews.
- c. *Responsibilities and Liabilities.* Nothing in this Section III.G affects TAF's responsibilities or liabilities under any criminal, civil, or administrative laws or regulations applicable to any Federal health care program including, but not limited to, the Anti-Kickback Statute.
- d. *Access to Records and Personnel.* TAF shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in this Section III.G and that all records furnished to the IRO are accurate and complete.

2. *IRO Review.* For each of the three Reporting Periods, the IRO shall perform a review of TAF's Patient Assistance Related Functions and prepare an IRO Review Report as outlined in Appendix B to this IA, which is incorporated by reference. Each annual IRO Review shall cover the applicable calendar year (e.g., the IRO Review for the first Reporting Period shall cover calendar year 2020.)

3. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to TAF a certification that the IRO has: (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.G including any individual(s) who has been retained by the IRO to perform the legal analysis required by Section D.2.b.iv of Appendix B (such individual(s) shall be referred to hereinafter as the "Legal Reviewer(s)"); and (b) concluded that the IRO and the Legal Reviewer are, in fact, independent and objective in accordance with the requirements specified in Appendix A to this IA. The IRO's certification shall include a summary of current and prior engagements between TAF and the IRO and between TAF and the Legal Reviewer.

#### H. Ineligible Persons

- 1. *Definitions.* For purposes of this IA:

- a. an “Ineligible Person” shall include an individual or entity who:
  - i. is currently excluded from participation in any Federal health care program; or
  - ii. has been convicted of (a) a criminal offense that is related to the delivery of an item or service under Medicare or any state health care program; (b) a criminal offense relating to neglect or abuse of patients; (c) a felony criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of a health care item or service or with respect to a government funded health care program (other than Medicare or a state health care program); or (d) a felony criminal offense relating to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance, but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.
- b. “Exclusion List” means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at <http://www.oig.hhs.gov>).

2. *Screening Requirements.* TAF shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

- a. TAF shall screen all prospective Covered Persons against the Exclusion List prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.
- b. TAF shall screen all current Covered Persons against the Exclusion List within 30 days after the Effective Date and on a monthly basis thereafter.

- c. TAF shall require all Covered Persons to immediately disclose immediately if they become an Ineligible Person.

TAF shall maintain documentation demonstrating that TAF: (1) has checked the Exclusion List (e.g., print screens from search results) and determined that its Covered Persons are not Ineligible Persons; and (2) has required its Covered Persons to disclose if they are an Ineligible Person.

Nothing in this Section III.H affects TAF's responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by an excluded person. TAF understands that items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and that TAF may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether TAF meets the requirements of Section III.H.

3. *Removal Requirement.* If TAF has actual notice that a Covered Person has become an Ineligible Person, TAF shall remove such Covered Person from responsibility for, or involvement with, TAF's business operations related to the Federal health care program(s) from which such Covered Person has been excluded and shall remove such Covered Person from any position for which the Covered Person's compensation or the items or services furnished, ordered, or prescribed by the Covered Person are paid in whole or part, directly or indirectly, by any Federal health care program(s) from which the Covered Person has been excluded at least until such time as the Covered Person is reinstated into participation in such Federal health care program(s).

4. *Pending Charges and Proposed Exclusions.* If TAF has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term, TAF shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary or the accuracy of any claims submitted to any Federal health care program.

#### I. Notification of Government Investigation or Legal Proceeding

Within 30 days after discovery, TAF shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to TAF conducted or brought by a governmental entity or its agents involving an allegation that TAF has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the

allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. TAF shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceeding, if any.

J. Reportable Events

1. *Definition of Reportable Event.* For purposes of this IA, a “Reportable Event” means anything that involves:

- a. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;
- b. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.H.1.a; or
- c. the filing of a bankruptcy petition by TAF.

A Reportable Event may be the result of an isolated event or a series of occurrences.

2. *Reporting of Reportable Events.* If TAF determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, TAF shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Section III.J.1.a.* For Reportable Events under Section III.J.1.a, the report to OIG shall include:

- a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of entities and individuals believed to be implicated, including an explanation of their roles in the Reportable Event;



- b. a statement of the Federal criminal, civil or administrative laws that are probably violated by the Reportable Event, if any;
- c. the Federal health care programs affected by the Reportable Event; and
- d. a description of TAF's actions taken to correct the Reportable Event and prevent it from recurring.

4. *Reportable Events under Section III.J.1.b.* For Reportable Events under Section III.J.1.b, the report to OIG shall include:

- a. the identity of the Ineligible Person and the job duties performed by that individual;
- b. the dates of the Ineligible Person's employment or contractual relationship;
- c. a description of the Exclusion List screening that TAF completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the screening process that led to the hiring or contracting with the Ineligible Person;
- d. a description of how the Ineligible Person was identified; and
- e. a description of any corrective action implemented to prevent future employment or contracting with an Ineligible Person.

5. *Reportable Events under Section III.J.1.c.* If the Reportable Event involves the filing of a bankruptcy petition, the report to the OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program requirements implicated.

#### **IV. SUCCESSOR LIABILITY; CHANGES TO LOCATIONS OR BUSINESS**

In the event that, after the Effective Date, TAF proposes to (a) sell any or all of its locations or businesses that are subject to this IA (whether through a sale of assets, sale of stock, or other type of transaction), or (b) purchase or establish a new location or business

engaged in Patient Assistance Related Functions, the IA shall be binding on the purchaser of any such location or business and any new location or business (and all Covered Persons at each new location or business) shall be subject to the requirements of this IA, unless otherwise determined and agreed to in writing by OIG. TAF shall give notice of such sale or purchase to OIG within 30 days following the closing of the transaction.

If, in advance of a proposed sale or proposed purchase, TAF wishes to obtain a determination by OIG that the proposed purchaser or the proposed acquisition will not be subject to the requirements of the IA, TAF must notify OIG in writing of the proposed sale or purchase at least 30 days in advance. This notification shall include a description of the location or business to be sold or purchased, a brief description of the terms of the transaction and, in the case of a proposed sale, the name and contact information of the prospective purchaser.

## **V. IMPLEMENTATION AND ANNUAL REPORTS**

### **A. Implementation Report**

Within 90 days after the Effective Date, TAF shall submit a written report to OIG summarizing the status of its implementation of the requirements of this IA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
2. the names of the Board members who are responsible for satisfying the compliance obligations described in Section III.B;
3. a list of the Policies and Procedures required by Section III.C.;
4. a copy of the notice required by Section III.D, a description of where the notice is posted, and the date the notice was posted;
5. a description of the PAP Measures required by Section III.F;
6. the following information regarding the IRO: (a) identity, address, and phone number of the IRO; (b) a copy of the engagement letter between TAF and the IRO; (c) identity, address, and phone number of the Legal Reviewer; (d) information to demonstrate that the IRO and the Legal Reviewer have the qualifications outlined in

Appendix A to this IA; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to TAF (including any Legal Reviewer) as specified in Section E of Appendix A that includes a summary of all current and prior engagements between TAF and the IRO and between TAF and the Legal Reviewer;

7. a copy of the documentation demonstrating that TAF has screened all Covered Persons against the Exclusion List as required by Section III.H within 30 days of the Effective Date;

8. a list of all of TAF's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, and each location's Medicare and state Medicaid program provider number(s) and/or supplier number(s) (if applicable); and

9. a certification by the Compliance Officer and the Chief Executive Officer that: (a) he or she has reviewed the IA in its entirety, understands the requirements described within, and maintains a copy for reference; (b) to the best of his or her knowledge, except as otherwise described in the Implementation Report, TAF is in compliance with all of the requirements of this IA; (c) he or she has reviewed the Implementation Report and has made a reasonable inquiry regarding its content and believes that the information is accurate and truthful; and (d) he or she understands that this certification is being provided to and relied upon by the United States.

#### B. Annual Reports

TAF shall submit to OIG a written report on its compliance with the IA requirements for each of the three Reporting Periods (Annual Report). Each Annual Report shall include, at a minimum, the following information:

1. (a) any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer described in Section III.A; (b) a current list of the Board members who are responsible for satisfying the Board of Directors compliance obligations described in Section III.B; and (c) a description of any changes made during the Reporting Period to the Board:

2. the dates of each report made by the Compliance Officer to the Board (written documentation of such reports shall be made available to OIG upon request);

3. the Board resolution required by Section III.B and a description of the documents and other materials reviewed by the Board, as well as any additional steps taken, in its oversight of the compliance program and in support of making the resolution;
4. a list of any new or revised Policies and Procedures developed during the Reporting Period;
5. the following information regarding any training required by Section III.E: a description of the Covered Persons and Board training required by Section III.E (including a summary of the topics covered, the length of the training and when the training was provided). A copy of all training materials shall be made available to OIG upon request;
6. a description of any changes to the PAP Measures required by Section III.F;
7. a complete copy of all IRO reports prepared pursuant to Section III.G and TAF's response to the reports, along with corrective action plan(s) related to any issues raised by the reports;
8. a certification from the IRO regarding its professional independence and objectivity with respect to TAF (including the Legal Reviewer) that includes a summary of all current and prior engagements between TAF and the IRO and between TAF and the Legal Reviewer;
9. a copy of the documentation demonstrating that TAF screened all prospective and current Covered Persons against the Exclusion List, as required by Section III.H;
10. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.I. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;
11. a summary of Reportable Events (as defined in Section III.J) identified during the Reporting Period;
12. a description of all changes to the most recently provided list of TAF's locations (including addresses) as required by Section V.A.8; and

13. a certification signed by TAF's Compliance Officer and Chief Executive Officer that: (a) he or she has reviewed the IA in its entirety, understands the requirements described within, and maintains a copy for reference; (b) to the best of his or her knowledge, except as otherwise described in the Annual Report, TAF is in compliance with all of the requirements of this IA; (c) he or she has reviewed the Annual Report and has made a reasonable inquiry regarding its content and believes that the information is accurate and truthful; (d) he or she understands that this certification is being provided to and relied upon by the United States; and (e) the Disease Fund Process policies and the Data Sharing Policies referenced in Section III.F have been reviewed by independent and qualified legal counsel and have been found to be compliant with all applicable laws, regulations, and OIG guidance.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Designation of Information

TAF shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. TAF shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

**VI. NOTIFICATIONS AND SUBMISSION OF REPORTS**

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this IA shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch  
Office of Counsel to the Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services  
Cohen Building, Room 5527  
330 Independence Avenue, SW  
Washington, DC 20201  
Telephone: (202) 619-2078  
Facsimile: (202) 205-0604

The Assistance Fund:

Steve Alsene  
Chief Financial Officer/Treasurer  
The Assistance Fund  
4700 Millenia Blvd.  
Suite 400  
Orlando, FL 32839  
Telephone: (407) 377-1303  
Facsimile: (855) 430-0590

Unless otherwise specified, all notifications and reports required by this IA shall be made by electronic mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. Upon request by OIG, TAF may be required to provide OIG with an additional copy of each notification or report required by this IA, in OIG's requested format (electronic or paper).

**VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS**

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may conduct interviews, examine and/or request copies of TAF's books, records, and other documents and supporting materials and conduct on-site reviews of any of TAF's locations, for the purpose of verifying and evaluating: (a) TAF's compliance with the terms of this IA and (b) TAF's compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by TAF to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of

TAF's owners, employees, and contractors who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. TAF shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. TAF's owners, employees, and contractors may elect to be interviewed with or without a representative of TAF present.

#### **VIII. DOCUMENT AND RECORD RETENTION**

TAF shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this IA for six years (or longer if otherwise required by law) from the Effective Date.

#### **IX. DISCLOSURES**

Consistent with IHHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify TAF prior to any release by OIG of information submitted by TAF pursuant to its obligations under this IA and identified upon submission by TAF as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, TAF shall have the rights set forth at 45 C.F.R. § 5.42(a).

#### **X. BREACH AND DEFAULT PROVISIONS**

TAF is expected to fully and timely comply with all of its IA obligations.

##### **A. Stipulated Penalties for Failure to Comply with Certain Obligations**

As a contractual remedy, TAF and OIG hereby agree that failure to comply with certain obligations set forth in this IA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of \$1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day TAF fails to establish, implement or comply with any of the following obligations as described in Section III:

- a. appoint a Compliance Officer as required by Section III.A;
- b. Board compliance obligations as required by Section III.B;

- c. written Policies and Procedures required by Section III.C;
- d. post a notice in accordance with the requirements of Section III.D;
- e. complete the training and education required for Covered Persons and Board members and maintain training records, in accordance with the requirements of Section III.E;
- f. the PAP Measures required by Section III.F;
- g. screen Covered Persons in accordance with the requirements of Section III.H or require Covered Persons to disclose if they are excluded in accordance with the requirements of Section III.H; and maintain documentation of screening and disclosure requirements in accordance with the requirements of Section III.H;
- f. notify OIG of a government investigation or legal proceeding, in accordance with the requirements of Section III.I; or
- g. report a Reportable Event in accordance with Section III.J.

2. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the day after the date the obligation became due) for each day TAF fails to engage and use an IRO, as required by Section III.G, Appendix A, or Appendix B.

3. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the day after the date the obligation became due) for each day TAF fails to submit a complete Implementation Report, Annual Report, or any certification to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the day after the date the obligation became due) for each day TAF fails to submit any IRO Review Report in accordance with the requirements of Section III.G and Appendix B.

5. A Stipulated Penalty of \$1,000 for each day TAF fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date TAF fails to grant access.)



6. A Stipulated Penalty of \$50,000 for each false certification submitted by or on behalf of TAF as part of its Implementation Report, any Annual Report, additional documentation to a report (as requested by OIG), or as otherwise required by this IA.

7. A Stipulated Penalty of \$2,500 for each day TAF fails to grant the IRO access to all records and personnel necessary to complete the reviews listed in Section III.G, and for each day TAF fails to furnish to the IRO accurate and complete records, as required by Section III.G and Appendix A.

8. A Stipulated Penalty of \$1,000 for each day TAF fails to comply fully and adequately with any obligation of this IA. OIG shall provide notice to TAF stating the specific grounds for its determination that TAF has failed to comply fully and adequately with the IA obligation(s) at issue and steps TAF shall take to comply with the IA. (This Stipulated Penalty shall begin to accrue 10 business days after the date TAF receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-7 of this Section.

B. Timely Written Requests for Extensions

TAF may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this IA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after TAF fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after TAF receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties

1. *Demand Letter.* Upon a finding that TAF has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify TAF of: (a) TAF's failure to comply; and (b)

OIG's exercise of its contractual right to demand payment of the Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, TAF shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event TAF elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until TAF cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this IA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that TAF has materially breached this IA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this IA

1. *Definition of Material Breach.* A material breach of this IA means:
  - a. a failure by TAF to report a Reportable Event, take corrective action as required in Section III.J;
  - b. repeated violations or a flagrant violation of any of the obligations under this IA, including, but not limited to, the obligations addressed in Section X.A;
  - c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
  - d. a failure to engage and use an IRO in accordance with Section III.G, Appendix A, or Appendix B.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this IA by TAF constitutes an independent basis for TAF's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in the OIG's discretion, but not more than five years per material breach. Upon a determination by OIG that TAF has materially breached this IA and that exclusion is the appropriate remedy, OIG shall notify TAF of: (a) TAF's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")

3. *Opportunity to Cure.* TAF shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate that:

- a. the alleged material breach has been cured; or
- b. the alleged material breach cannot be cured within the 30 day period, but that: (i) TAF has begun to take action to cure the material breach; (ii) TAF is pursuing such action with due diligence; and (iii) TAF has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, TAF fails to satisfy the requirements of Section X.D.3, OIG may exclude TAF from participation in the Federal health care programs. OIG shall notify TAF in writing of its determination to exclude TAF. (This letter shall be referred to as the "Exclusion Letter.") Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of TAF's receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, TAF may apply for reinstatement, by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to TAF of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this IA, TAF shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this IA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS

Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter. The procedures relating to the filing of a request for a hearing can be found at <http://www.hhs.gov/dab/divisions/civil/procedures/divisionprocedures.html>.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this IA shall be: (a) whether TAF was in full and timely compliance with the obligations of this IA for which OIG demands payment; and (b) the period of noncompliance. TAF shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this IA and orders TAF to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless TAF requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this IA shall be whether TAF was in material breach of this IA and, if so, whether:

- a. TAF cured such breach within 30 days of its receipt of the Notice of Material Breach; or
- b. the alleged material breach could not have been cured within the 30 day period, but that, during the 30 day period following TAF's receipt of the Notice of Material Breach: (i) TAF had begun to take action to cure the material breach; (ii) TAF pursued such action with due diligence; and (iii) TAF provided to OIG a reasonable timetable for curing the material breach.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for TAF, only after a DAB decision in

favor of OIG. TAF's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude TAF upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that TAF may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. TAF shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of TAF, TAF shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this IA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this IA.

## **XI. EFFECTIVE AND BINDING AGREEMENT**

TAF and OIG agree as follows:

A. This IA shall become final and binding on the date the final signature is obtained on the IA.

B. This IA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this IA.

C. OIG may agree to a suspension of TAF's obligations under this IA based on a certification by TAF that it is no longer engaging in Patient Assistance Related Functions. If TAF is relieved of its IA obligations, TAF shall be required to notify OIG in writing at least 30 days in advance if TAF plans to resume Patient Assistance Related Functions or to obtain an ownership or control interest in any entity that engages in Patient Assistance Related Functions. At such time, OIG shall evaluate whether the IA will be reactivated or modified.

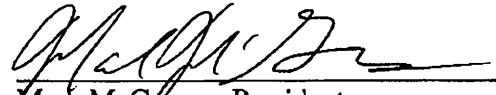
D. All requirements and remedies set forth in this IA are in addition to and do not affect (1) TAF's responsibility to follow all applicable Federal health care program requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable Federal health care program requirements. This IA does not supersede OIG's rights as set forth in 42 C.F.R. 1008.45 in connection with conduct other than the

Covered Conduct or conduct that occurs on or after the Effective Date of the Settlement Agreement described in the Preamble.

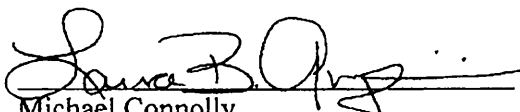
E. The undersigned TAF signatories represent and warrant that they are authorized to execute this IA. The undersigned OIG signatories represent that they are signing this IA in their official capacity and that they are authorized to execute this IA.

F. This IA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same IA. Electronically-transmitted copies of signatures shall constitute acceptable, binding signatures for purposes of this IA.

ON BEHALF OF THE ASSISTANCE FUND, INC.

  
Mark McGreevy, President  
The Assistance Fund, Inc.

11/19/2019  
Date

  
Michael Connolly  
Laura Angelini  
Hinckley Allen  
Counsel for The Assistance Fund, Inc.

11/19/19  
Date

**ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL  
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**



Lisa M. Re  
Assistant Inspector General for Legal Affairs  
Office of Inspector General  
U.S. Department of Health and Human Services



DATE



Mary E. Rordan  
Senior Counsel  
Office of Inspector General



DATE



## APPENDIX A

### INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.G of the IA.

#### A. IRO Engagement

1. TAF shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph E. Within 30 days after OIG receives the information identified in Section V.A.6 of the IA or any additional information submitted by TAF in response to a request by OIG, whichever is later, OIG will notify TAF if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, TAF may continue to engage the IRO.

2. If TAF engages a new IRO during the term of the IA, that IRO must also meet the requirements of this Appendix. If a new IRO is engaged, TAF shall submit the information identified in Section V.A.6 of the IA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by TAF at the request of OIG, whichever is later, OIG will notify TAF if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, TAF may continue to engage the IRO.

#### B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the IRO Reviews who have expertise in all applicable Federal health care program requirements relating to Patient Assistance Related Functions, including but not limited to the Federal Anti-Kickback Statute and False Claims Act.

2. assign or retain individuals to conduct the IRO Reviews who are knowledgeable in the requirements of the Federal Anti-Kickback Statute and the regulations and other guidance documents relating to the statute. Advisory Opinion 10-07, and guidance documents from the OIG relating to patient assistance programs (including those referenced in Section III.C of the IA), including individuals with the expertise and qualifications necessary to perform the legal analysis required by Section D.2.b.iv of Appendix B and to serve as Legal Reviewer(s) (as defined in Section III.G.3 of the IA); and

3. have sufficient staff and resources to conduct the reviews required by the IA on a timely basis.

C. IRO Responsibilities

The IRO shall:

1. perform each component of the IRO Reviews in accordance with the specific requirements of the IA;

2. follow all applicable Federal health care program requirements in making assessments in the IRO Reviews;

3. respond to all OIG inquiries in a prompt, objective, and factual manner; and

4. prepare timely, clear, well-written reports that include all the information required by Appendix B to the IA.

D. TAF Responsibilities

TAF shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in III.G of the IA and that all records furnished to the IRO are accurate and complete.

E. IRO Independence and Objectivity

The IRO must perform each component of the IRO Reviews in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the U.S. Government Accountability Office. The Legal Reviewer retained by the IRO shall not: (1) currently be employed or engaged by TAF; (2) currently represent TAF or a current, past, or potential Donor to TAF; or (3) have a current or prior relationship with TAF, or a current, past, or potential Donor to TAF that would cause a reasonable person to question such individual's objectivity in performing such reviews.

F. Assertions of Privilege

TAF shall not assert claims of attorney-client privilege in order to avoid disclosing to OIG information related to or resulting from the IRO's engagement. TAF's engagement letter with the IRO shall include a provision stating that the IRO agrees not to assert claims of work product privilege in order to avoid disclosing to OIG information related to or resulting from its engagement.

G. IRO Removal/Termination

1. *TAF and IRO.* If TAF terminates its IRO or if the IRO withdraws from the engagement during the term of the IA, TAF must submit a notice explaining (a) its reasons for termination of the IRO or (b) the IRO's reasons for its withdrawal to OIG, no later than 30 days after termination or withdrawal. TAF must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. *OIG Removal of IRO.* In the event OIG has reason to believe the IRO (including the Legal Reviewer(s)) does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph E or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify TAF in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. TAF shall have 30 days from the date of OIG's written notice to provide information regarding the IRO's qualifications, relationship or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by TAF regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify TAF in writing that TAF shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. TAF must engage a new IRO within 60 days of its receipt of OIG's written notice. The final determination as to whether or not to require TAF to engage a new IRO shall be made at the sole discretion of OIG.

## **Appendix B**

### **Independent Review Organization Reviews**

#### **A. IRO Engagement, General Description**

As specified more fully below, TAF shall retain an Independent Review Organization (IRO) to perform engagements to assist TAF in assessing and evaluating its systems, processes, policies, and procedures related to Patient Assistance Related Functions as defined in the IA (IRO Reviews). Each review shall be performed with respect to the applicable Reporting Period. More specifically, for the first Reporting Period, the IRO Review shall cover calendar year 2020. For the second and third Reporting Periods, the IRO Reviews shall cover calendar years 2021 and 2022, respectively. The IRO Reviews shall consist of two components - a systems review (Systems Review) and a transactions review (Transactions Review) as described more fully below. TAF may engage, at its discretion, a single entity to perform both components of the IRO Reviews provided that the entity has the necessary expertise and capabilities to perform both.

If there are no material changes in TAF's systems, processes, policies, and procedures relating to Patient Assistance Related Functions, the IRO shall perform the Systems Review outlined below for the first and third Reporting Periods.

If TAF materially changes its systems, processes, policies, and procedures relating to Patient Assistance Related Functions, the IRO shall perform a Systems Review for the Reporting Period(s) in which such material changes were made in addition to conducting the Review below for the first and third Reporting Periods. The additional Systems Review(s) shall consist of: 1) an identification of the material changes; 2) an assessment of whether other systems, processes, policies, and procedures previously reported did not materially change; and 3) a review of the systems, processes, policies, and procedures that materially changed.

The IRO shall conduct the Transactions Review for each of the three Reporting Periods of the IA.

#### **B. IRO Systems Review**

The Systems Review shall be a review of TAF's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to Patient Assistance Related Functions. Where practical, TAF personnel may compile documentation, schedule and organize interviews, and undertake other efforts to assist the IRO in performing the Systems Review. The IRO is not required to undertake a de novo review of the information gathered or activities undertaken by TAF pursuant to

the preceding sentence.

More specifically, the IRO shall review TAF's systems, processes, policies, and procedures associated with the following (hereafter "Reviewed Policies and Procedures"):

1. Patient Assistance Related Functions.

a. TAF's systems, policies, processes, and procedures relating to Patient Assistance Related Functions. This review shall include an assessment of the following:

- i. TAF's systems, policies, and practices for ensuring that TAF and the officers, directors, employees and agents of TAF are independent from and do not have any conflicts of interest with Donors or potential Donors.
- ii. TAF's systems, policies, and practices relating to disease funds, including:
  - (a) the systems, policies, and practices that TAF uses to establish, delineate, and modify any disease fund. This includes the bases upon which TAF makes decisions about funds (as referenced in Section III.F.1.c of the IA), the definition and type of disease funds, the scope of coverage for disease funds (as referenced in Section III.F.1.d), the Notification List practices (as referenced in Section III.F.1.f) and the drug coverage methodology used by TAF in connection with its funds (as outlined in Section III.F.1.g); and
  - (b) TAF's documentation and recordkeeping practices relating to disease funds as outlined in Section III.F.1.
- iii. TAF's systems, policies, and practices as they relate to interactions with Donors and potential Donors, including:
  - (a) interactions relating to seeking or receiving donations for any fund (as referenced in Section III.F.2.c);

- (b) interactions relating to requests for or the provision of data to any Donor (as referenced in Section III.F.2.b); and
  - (c) TAF's documentation and recordkeeping practices relating to interactions with Donors (as outlined in Section III.F.2).
- iv. TAF's systems, policies, and practices as they relate to providing financial assistance to patients, including:
  - (a) the systems, policies, and practices that TAF utilizes in connection with its Screening Process for determining patient eligibility for assistance (as referenced in Sections III.F.3.a-c);
  - (b) the systems, policies, and practices relating to TAF's award of assistance to patients and the communication about decisions to award financial assistance (as referenced in Sections III.F.3.d and e); and
  - (c) TAF's documentation and recordkeeping practices relating to providing assistance to patients (as reference in Section III.F.3).

### C. IRO Systems Review Report

The IRO shall prepare a report based upon each Systems Review, which shall contain the following information.

1. Patient Assistance Related Functions. For each of the Reviewed Policies and Procedures identified in Section II.A.1 above, the report shall include the following items:
  - a. a description of the documentation (including policies) reviewed and any personnel interviewed;
  - b. a detailed description of TAF's systems, policies, processes, and procedures relating to the items identified in Section II.A.1 above, including a general description of TAF's control and accountability systems (e.g., documentation and approval requirements, and tracking mechanisms) and written policies regarding the

## Reviewed Policies and Procedures:

- c. a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Section II.A.1 above are made known or disseminated within TAF;
- d. findings and supporting rationale regarding any weaknesses in TAF's systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and
- e. recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

2. Credentials. The names and credentials of the individuals who performed the Systems Review.

## D. IRO Transactions Review

The Transactions Review shall consist of a review and assessment of whether TAF has complied with the PAP Measures outlined in Section III.F of the IA. For the first Reporting Period, the IRO shall review six of the active disease funds operated by TAF during calendar year 2020. (Active disease funds are those which provided financial assistance to patients during the applicable Reporting Period.) Four of the six funds reviewed shall be funds with a single donor. Those single-donor funds shall be randomly selected by the IRO from among the ten TAF single-donor funds that provided assistance to the largest number of patients in 2020. The remaining two funds reviewed for calendar year 2020 shall be randomly selected by the IRO from the active disease funds with multiple donors.

For the second and third Reporting Periods, the IRO shall review six, or ten percent, of the active disease funds operated by TAF, whichever is a larger number. OIG shall have the discretion to select the types of funds to be reviewed by the IRO, and the number of each fund type reviewed (up to a total of six or 10% of the active disease funds), and shall do so based on information provided by TAF and other information known to OIG. No later than November 1 of each calendar year beginning in 2020, TAF shall submit to OIG information about the number of active disease funds operated by TAF, which of those funds are single-donor funds, and other information requested by OIG.

For purposes of the Transactions Review, the term "Reviewed Materials" shall include, for each disease fund reviewed, the records specifically referenced in Section III.F of the IA and other documents sufficient to allow the IRO to review and assess whether TAF complied with each element of the PAP Measures outlined in Section III.F. In addition,

the IRO may interview TAF personnel regarding TAF's policies and practices relating to Patient Assistance Related Functions.

1. Review of Compliance with PAP Measures. Based upon the Reviewed Materials and any interviews of TAF personnel, the IRO shall assess for each disease fund reviewed:

- a. whether TAF complied with each element of the PAP Measures relating to independent operations and disease funds as required under Section III.F.1 of the IA;
- b. whether TAF complied with each element of the PAP Measures relating to interactions with Donors as outlined in Section III.F.2 of the IA; and
- c. whether TAF complied with each element of the PAP Measures relating to assistance to patients as outlined in Section III.F.3 of the IA.

2. Transactions Review Report. For each Reporting Period, the IRO shall prepare a report based on its Transactions Reviews. The report shall include the following:

- a. *General Elements to Be Included in Report.*
  - (i) Review Objectives: A clear statement of the objectives intended to be achieved by each part of the review;
  - (ii) Review Protocol: A detailed narrative description of the procedures performed; and
  - (iii) Sources of Data: A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Transactions Review.
- b. *Results to be Included in Report.* The following results shall be included in each Transactions Review Report:
  - (i) a list of the disease funds reviewed by the IRO for the applicable Reporting Period;
  - (ii) for each disease fund reviewed by the IRO, a description of the review conducted by IRO;



- (iii) for each disease fund reviewed by the IRO, findings regarding whether TAF complied with each element of the PAP Measures outlined in Section III.F of the IA;
- (iv) for each disease fund reviewed, the IRO's (i.e., the Legal Reviewer's) determination as to whether or not TAF complied with the Federal Anti-Kickback Statute and applicable OIG guidance relating to Patient Assistance Related Functions and an explanation of the legal analysis that forms the basis for such determination; and
- (v) recommendations, if any, for changes in TAF's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to its Patient Assistance Related Functions.

c. *Credentials.* The names and credentials of the individuals who performed the Transactions Review.