

## AMERICAN KIDNEY FUND

### POLICY ON OIG COMPLIANCE (COMPLIANCE WITH 97-1)

#### I. Commitment to Compliance

The American Kidney Fund (AKF) is an independent 501(c)(3) charitable organization dedicated to fighting kidney disease and helping people live healthier lives. AKF achieves its mission, in part, by providing eligible patients with financial assistance to help treatment-related expenses.

AKF operates in compliance with all applicable laws, including specifically the requirements and guidance of the U.S. Department of Health and Human Services, Office of the Inspector General (OIG), which provides oversight for charitable programs such as AKF's Health Insurance Premium Program (HIPP). In 1997, the OIG issued a favorable advisory opinion (OIG Advisory Opinion 97-1), which concluded that AKF's HIPP program complied with applicable legal and OIG requirements and guidance.

Specifically, in OIG Advisory Opinion 97-1, the OIG concluded that AKF's HIPP program would not violate 42 U.S.C. § 1320a-7a(a)(5) (the "Beneficiary Inducements CMP") because: (1) contributions to AKF by the Donor-Providers would not be made "to or on behalf of" the HIPP recipients, and therefore would not constitute remuneration under the Beneficiary Inducements CMP; and (2) while the premium grants made by AKF to HIPP recipients could constitute remuneration to beneficiaries, such grants would not be likely to influence patients to order or receive services from particular providers.

In arriving at these conclusions, the OIG considered several key safeguards of HIPP. AKF's policies and procedures were created to bolster compliance education efforts for staff as outlined below.

#### II. OIG Advisory Opinion 97-1 Safeguards and AKF Compliance

- a. **Safeguard:** *AKF is a bona fide, independent charity, and will have absolute discretion regarding the use of contributions from donor-providers*

**Compliance:** AKF's structure and policies and procedures provide it with absolute discretion regarding the use of contributions to HIPP. AKF's

management, specifically the President/CEO, General Counsel and EVP/COO) and the employee-led Compliance Working Group have day-to-day oversight of AKF's Compliance Program. Management reports to the AKF Audit and Compliance Committee on the status of the compliance program and results of external and internal audits. The AKF Board of Trustees and HIPP subcommittee have primary oversight authority for HIPP. Membership on the AKF Board of Trustees HIPP subcommittee is restricted to exclude any employees, officers, shareholders or owners of any dialysis provider. Decisions affecting the operation of HIPP are made by AKF without influence of donor-providers.

- b. ***Safeguard:*** *AKF staff will not consider the identity of the referring provider or the amount of any donation to AKF when making patient grant eligibility determinations.*

***Compliance:*** HIPP assistance is available to all financially needy ESRD and transplant patients regardless of the identity of the referring provider or the amount of donations made to AKF. Patients, their caregivers and renal professionals are provided access to the AKF Grants Management System (GMS) for purposes of applying for and receiving HIPP assistance. If a patient or caregiver applies directly to AKF, GMS will secure confirmation from a renal professional that the patient is in fact on dialysis or recently transplanted and attends their facility. When completing their profile an ESRD patient on dialysis or one who has been recently transplanted, provides their assets, income and expense information and eligibility to apply for AKF financial assistance. AKF determines eligibility for such assistance based solely on the patient's financial status. Only after financial eligibility has been confirmed in the automated system can a patient apply for a HIPP grant. When applying for a HIPP grant, GMS does not consider the name or location of the patient's dialysis or transplant facility and only requires the patient to have a health insurance plan in place and copy of a current bill that matches the grant request.

As a safeguard, AKF separates its development and fundraising efforts from the

HIPP grant application process. HIPP staff who process grant applications and approvals do not have access to contributor records and do not know which providers make voluntary contributions and which providers choose not to make contributions. Similarly, AKF development and fundraising staff do not have access to GMS or the ability to know which patients are tied to specific dialysis and transplant facilities.

- c. ***Safeguard:*** *Donor-providers will not base the amount of their contributions to AKF on the amount of HIPP funding their patients receive, and contributions will not be earmarked for the use of particular beneficiaries or groups of beneficiaries.*

***Compliance:*** If AKF receives a restricted or conditioned voluntary HIPP contribution, it does not recognize such restrictions and places the contribution in the HIPP pool for all patients. It then educates the donor on the requirements of 97-1. AKF's fundraising employees view incoming checks and are responsible for acknowledging provider voluntary contributions. These fundraising employees are distinct and independent from employees from patient services staff who work with GMS and review eligibility determinations for HIPP assistance.

When educating donors on making voluntary contributions, AKF's sole suggestion is that they may use guidance included in 97-1 that says they can account for "the amounts that the [donor-provider] would have otherwise expended on financially needy patients" but they are otherwise instructed that 97-1 will not permit restricted or conditioned contributions. With respect to issuing HIPP grants, they are made on a first-come, first-served basis to U.S. dialysis patients or recent transplant recipients who meet HIPP financial eligibility requirements and the availability of funding in the HIPP pool.

- d. ***Safeguard:*** *HIPP recipients have already selected a dialysis provider.*

***Compliance:*** HIPP recipients are not able to request a grant from AKF prior to selecting a dialysis provider or being enrolled in a transplant facility. After agreeing to the GMS User Agreement, a patient is prompted to create a GMS

profile. Once a GMS profile is completed a patient is able to see whether HIPP or other AKF financial assistance is available to them based on their financial information provided. However, a profile cannot be completed and a HIPP grant cannot be requested before a facility is entered in the profile and confirmed by AKF.

*e. **Safeguard:** HIPP will not be advertised to the public by donor-providers.*

**Compliance:** This provision covers prohibited activities by donor-providers and is intended to reduce the probability that a HIPP recipient would select a dialysis provider based on its participation in HIPP, potentially implicating Section 231(h) beneficiary inducement issues. While AKF cannot directly control the actions of dialysis providers and is not under any obligation to do so, it is aware that non-compliance in this area could threaten the integrity of HIPP. Thus, AKF will notify a provider, including the provider compliance officer if one exists, of any significant noncompliance with this safeguard of which it becomes aware.

In addition to the AKF HIPP Guidelines, dialysis providers are reminded of their obligations vis-à-vis advertising HIPP during their orientation to the program .

f. **Safeguard.** *HIPP recipients will be able to select the provider of their choosing.*

**Compliance:** A hallmark of 97-1 is patient's freedom to select the dialysis provider of his or her choice. AKF's payment of health insurance premiums for that patient through HIPP will expand, rather than limit, the patient's freedom of choice. Patients may change dialysis providers without affecting their eligibility for HIPP assistance. In addition, HIPP assistance is provided for the full plan year, even for those HIPP patients who receive a kidney transplant and no longer require dialysis treatment.

While caregivers, medical social workers and other renal professionals continue to assist patients in identifying available sources of assistance (including grants from AKF), it should be noted that patients, or their designated caregiver can apply directly to AKF for assistance through GMS. Even if a patient applies directly and without assistance, he or she must have already selected their preferred dialysis provider or transplant facility and have a health insurance in place before requesting HIPP assistance through GMS. AKF does not consider a request for financial assistance or respond to specific requests prior to it completing a patient profile within GMS.

AKF's *Provider Code of Conduct*, in the section on patient education, requires that patients are always allowed the freedom to choose not only the health insurance coverage that best meets their needs but also the provider of dialysis treatment. HIPP grants will follow a patient if they choose to transfer facilities and the process and their assistance will be uninterrupted in such instances.

g. **Safeguard.** *Grant requests are reviewed on a first-come, first served basis to the extent funding is available.*

**Compliance.** As indicated above, HIPP assistance is available to any financially needy ESRD patient regardless of their choice of provider or insurance plan and is not limited to patients of facilities that make voluntary

contributions to the HIPP pool. To the contrary, eligible patients from non-donor facilities may create a GMS profile and request HIPP assistance. Any such assistance, whether the patient is from a donor or non-donor facility, is provided on a first-come, first-served basis to the extent funding is available for HIPP. Once a patient completes a profile and is determined to be eligible for HIPP, the grant approval process within GMS is based on two safeguards: (1) the grant being placed into an automated queue; and (2) the grant status being tagged as urgent or non-urgent. An urgent grant is one where the insurance coverage date of the grant request is within 10 days of its termination date or where the coverage has already lapsed and in a grace period. In these situations, the patient faces an emergency and may lose access to critical healthcare if the coverage is not kept active. In the best interest of the patient, urgent grants, like non-urgent grants, are also processed on a first-come, first served basis. AKF fulfills urgent and non-urgent grants concurrently on a daily basis.

### III. Additional Commitment to Best Practices

AKF operates in full compliance with requirements of the law and OIG guidance and has also adopted and enforces best compliance practices. Donors, patients and local communities place their trust in AKF because it continuously meets the highest ethical and compliance standards. AKF's service to kidney patients is further supported by:

- An independent and diverse Board of Trustees:
  - Financial and governance transparency through IRS Form 990, annual audits, annual reports and a listing of AKF's independent Board of Trustees are posted to AKF's website;
  - A commitment to efficiency and spending most of its resources on its programs. For over 18 years, AKF has spent at least 97 cents of every dollar to the exclusive use by its programs of patient services and education.
- Continuous monitoring of HIPP and other programs and issuing periodic enhancements when in the best interest of the patient.

- Annual or more frequent updates to GMS, the AKF HIPP Guidelines and AKF HIPP Patient Handbook as needed.
- Annual or more frequent Compliance trainings for all staff including training on the AKF Policy on OIG Compliance.
- Maintaining an internal legal office, headed by a General Counsel, that reviews our compliance program regularly, gets updates from outside counsel, and attends key educational webinars or conferences on recent trends in maintaining an effective compliance program.