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IN THE UNITED STATES DISTRICT COURT
 FOR THE CENTRAL DISTRICT OF CALIFORNIA
 SOUTHERN DIVISION

**JANE DOE; STEPHEN ALBRIGHT;
 AMERICAN KIDNEY FUND, INC.;
 and DIALYSIS PATIENT
 CITIZENS, INC.,**

Plaintiffs,

v.

**XAVIER BECERRA, in his Official
 Capacity as Attorney General of
 California; RICARDO LARA in his
 Official Capacity as California
 Insurance Commissioner; SHELLY
 ROUILLARD in her official Capacity
 as Director of the California
 Department of Managed Health
 Care; and SUSAN FANELLI, in her
 Official Capacity as Acting Director
 of the California Department of
 Public Health,**

Defendants.

8:19-cv-2105-DOC-(ADSx)

**DECLARATION OF AMIE L.
 MEDLEY IN OPPOSITION TO
 MOTION FOR PRELIMINARY
 INJUNCTION**

Date: December 16, 2019
 Time: 8:30 a.m.
 Courtroom: 9D
 Judge: The Honorable David O.
 Carter
 Trial Date: n/a
 Action Filed: 11/5/2019

1 I, Amie L. Medley declare as follows:

2 1. I am an attorney licensed to practice law in California. I am a deputy
3 attorney general in the Office of the California Attorney General in Los Angeles,
4 California and one of the attorney of record for Defendants Xavier Becerra, in his
5 Official Capacity as Attorney General of California; Ricardo Lara in his Official
6 Capacity as California Insurance Commissioner; Shelly Rouillard in her Official
7 Capacity as Director of the California Department of Managed Health Care; and
8 Susan Fanelli, in her Official Capacity as Acting Director of the California
9 Department of Public Health (“Defendants”) in this matter.

10 2. I have personal knowledge of the following facts and, if called as a
11 witness in a relevant proceeding, I could and would testify competently to them.

12 3. Attached hereto as Exhibit 1 is a true and correct copy of an article by
13 Katie Thomas and Reed Abelson and published in *The New York Times* on
14 December 25, 2016, entitled “Kidney Fund Seen Insisting on Donations, Contrary
15 to Government Deal.” This article is also , available at
16 [https://www.nytimes.com/2016/12/25/business/kidney-fund-seen-insisting-on-](https://www.nytimes.com/2016/12/25/business/kidney-fund-seen-insisting-on-donations-contrary-to-government-deal.html)
17 [donations-contrary-to-government-deal.html](https://www.nytimes.com/2016/12/25/business/kidney-fund-seen-insisting-on-donations-contrary-to-government-deal.html) (last accessed November 23, 2019).

18 4. Attached hereto as Exhibit 2 is a true and correct copy of a news release
19 dated July 3, 2019, and posted on the website of the American Kidney Fund at
20 [https://www.kidneyfund.org/news/news-releases/akf-president-testimony-to-senate-](https://www.kidneyfund.org/news/news-releases/akf-president-testimony-to-senate-health-committee-on-california-ab-290.html)
21 [health-committee-on-california-ab-290.html](https://www.kidneyfund.org/news/news-releases/akf-president-testimony-to-senate-health-committee-on-california-ab-290.html) (last accessed November 23, 2019).

22 5. Attached hereto as Exhibit 3 is a true and correct copy of an excerpt from
23 the American Kidney Fund’s website, available at
24 [https://www.kidneyfund.org/financial-assistance/information-for-patients/health-](https://www.kidneyfund.org/financial-assistance/information-for-patients/health-insurance-premium-program/)
25 [insurance-premium-program/](https://www.kidneyfund.org/financial-assistance/information-for-patients/health-insurance-premium-program/) (last accessed November 23, 2019).

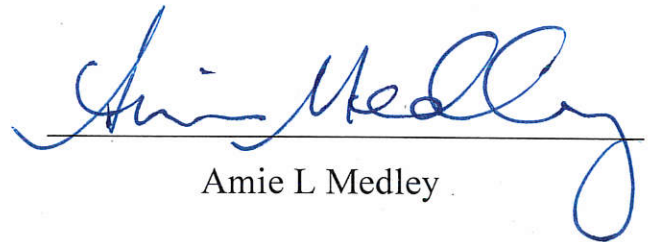
26 6. Attached hereto as Exhibit 4 is a true and correct copy of the American
27 Kidney Fund’s Patient Handbook for its Health Insurance Premium Program, also
28

1 available at <https://www.kidneyfund.org/assets/pdf/financial-assistance/akf-hipp->
2 [patient-handbook.pdf](https://www.kidneyfund.org/assets/pdf/financial-assistance/akf-hipp-patient-handbook.pdf) (last accessed November 24, 2019).

3 7. Attached hereto as Exhibit 5 is a true and correct copy of a letter from
4 Representative Katie Porter to Joanne Chiedi, Acting Inspector General at the
5 Department of Health and Human Services, dated July 23, 2019. This letter is also
6 available at
7 [https://porter.house.gov/sites/porter.house.gov/files/Porter%20Letter%20to%20HHS](https://porter.house.gov/sites/porter.house.gov/files/Porter%20Letter%20to%20HHS%20OIG%20re%20Dialysis.pdf)
8 [S%20OIG%20re%20Dialysis.pdf](https://porter.house.gov/sites/porter.house.gov/files/Porter%20Letter%20to%20HHS%20OIG%20re%20Dialysis.pdf) (last accessed November 25, 2019.)

9 I declare under penalty of perjury that the foregoing is true and correct, and
10 that I signed this declaration on November 25, 2019, at Los Angeles, California.

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Amie L Medley

EXHIBIT 1

The New York Times

Kidney Fund Seen Insisting on Donations, Contrary to Government Deal

By Katie Thomas and Reed Abelson

Dec. 25, 2016

The American Kidney Fund is one of the largest charities in the country, with an annual budget of over \$250 million. Its marquee program helps pay insurance premiums for thousands of people who need dialysis, a lifesaving and expensive treatment for kidney failure.

The organization has earned accolades for its efficient use of the money.

Under an agreement with the federal government, the Kidney Fund must distribute the aid based on a patient's financial need. But the charity has resisted giving aid to patients at clinics that do not donate money to the fund, an investigation by The New York Times has found. The actions have limited crucial help for needy patients at these clinics. The agreement governing the relationship between the group and the companies forbids choosing patients based on their clinic.

In multiple cases, the charity pushed back on workers at clinics that had not donated money, discouraging them from signing up their patients for assistance. Until recently, the Kidney Fund's guidelines even said clinics should not apply for patient aid if the company had not donated to the charity.

"I watched many patients who were not able to get that assistance," said Elaine Brecher, a former social worker at a small clinic in rural Arkansas. After an application for one patient was declined, she said, she did not apply for others, because a colleague believed that only clinics that donated could refer patients.

Ms. Brecher now works at a clinic owned by Fresenius, one of the two largest dialysis companies along with DaVita. Together, the two companies provide nearly 80 percent of the charity's funding. She said her current patients benefited from the Kidney Fund, whose assistance can amount to thousands of dollars in financial aid a year.

"If our patients didn't get that assistance, they would be owing great big huge bills to hospitals and doctors," she said.

The financial help is available to patients with kidney failure, known as end-stage renal disease, many of whom are unable to work. The money covers the insurance premiums for many types of coverage, including Medicare and employer and individual private plans.

The Kidney Fund's payments are part of an unusual deal it made with the government and the dialysis industry 20 years ago. The arrangement allows the dialysis companies to avoid violating anti-kickback laws. It allows dialysis clinics to donate to the Kidney Fund, treat patients whose insurance premiums are paid by the charity and then collect money from the insurers for those patients' treatments — essentially guaranteeing a steady stream of paying customers for the companies.

But the agreement also has a caveat: It requires that all patient applications be treated equally, regardless of whether their clinic donates.

In an interview this month, LaVarne A. Burton, the Kidney Fund's chief executive, said that the charity treated all patients equally, and that the fund had never denied anyone assistance if they qualified financially.

"It is simply not true that we require any provider to contribute to the program," she said. "Never have, and never will."

She acknowledged, though, that the charity pushed clinics hard to donate, particularly if they applied on behalf of patients.

"We believe there is a moral obligation for providers to contribute to the organization," she said.

Ms. Burton said the concerns raised by social workers like Ms. Brecher and others arose because many in the industry misunderstood how the charity worked. The charity recently updated its guidelines, she said, to provide more clarity.

An examination of public documents, as well as interviews with more than a dozen social workers, employees of dialysis clinics, insurance officials and regulators, and a former executive at the charity, put the actions in a different light. Many of the clinic workers, from about a half-dozen states around the country, were called randomly, to limit any chance of coordinated talking points.

For years, The Times found, the Kidney Fund's preference for patients at the biggest clinics has been an open secret among many social workers, who said that as a result they had stopped applying for assistance entirely.

The findings also add to a list of concerns about the group's relationship with the dialysis industry.

This year, for example, the fund faced questions about whether it was helping dialysis companies game the Affordable Care Act. In some cases, insurers and government officials have argued, the dialysis clinics used the charity's assistance program to push people who were eligible for Medicaid, government health insurance for the poor, into private health coverage available under the new law.

The private plans pay the clinics much more than Medicaid — up to four times as much, adding up to an additional \$200,000 per patient per year — for the same dialysis treatment.

In recent months, the federal government has raised concerns about how patients are steered into private plans. UnitedHealthcare sued one company, American Renal Associates, over the practice, claiming it was harming patients by converting them to less generous coverage. American Renal, which declined to comment for this article, has denied the claims and is fighting the suit.

The suit against American Renal also says the Kidney Fund directed some donations directly back to patients at American Renal. As part of an investigation by Medicare, social workers and insurers have made similar accusations against the Kidney Fund.

Ms. Burton denied those accusations and attributed the recent scrutiny of the insurance assistance program to insurers that want to avoid covering the often costly medical bills of people who need dialysis.

"The insurance industry has let us have it full force," she said.

A Costly Treatment

Dialysis filters toxins from the blood when a patient's kidneys no longer work. The process is lifesaving, but also onerous, often requiring that patients be tethered to a machine for hours at a time, three times a week. Patients on dialysis often cannot hold full-time jobs, studies have shown, and those receiving the treatment are disproportionately poor.

The poorest people with kidney disease qualify for Medicaid, which covers all of their costs. But Medicare covers most of the 500,000 or so Americans who need the treatment, regardless of their age, under a government program that has existed since the 1970s and that costs the federal government more than \$30 billion a year.

Even with help, people covered by Medicare are left with significant out-of-pocket costs. Most must pay a monthly premium of about \$120, as well as a portion of their medical expenses, which can add up to several thousand dollars a year.

Until the late 1990s, the dialysis companies routinely paid these expenses. But a federal law outlawed that practice, out of concern that covering a patient's bills might dissuade that patient from switching to another clinic that might provide better care.

That was when the American Kidney Fund stepped in. In 1995, the charity was relatively small, with a \$5 million annual budget and contributions from the dialysis industry that accounted for less than 10 percent of its donations.

The Kidney Fund and the biggest dialysis clinics presented the government with a proposal that would allow the companies to indirectly pay insurance premiums for patients.

The deal, reached with the Office of Inspector General at the Department of Health and Human Services in 1997, has had a profound effect on the charity. In 2015, the Kidney Fund reported revenue of \$264 million, making it one of the country's 100 largest nonprofits.

The dialysis industry has also flourished. DaVita and Fresenius in particular have grown quickly, buying smaller chains, consolidating their market share and locking in profits. The Kidney Fund says it got 78 percent of its revenue in 2015 from two companies, which insurers, state regulators and others identified as DaVita and Fresenius.

“There’s a long history of recognition of the unique needs of that patient population,” said Philipp Stephanus, a senior vice president at DaVita who handles patient support and insurance issues.

The Kidney Fund, DaVita and Fresenius said the federal agreement prohibited them from disclosing what percentage of applications the fund approved from those companies’ clinics, or how much the charity paid in insurance aid for patients at those clinics.

But the 1997 deal tried to prevent any preferential treatment, no matter how big the companies became.

Kevin McAnaney, a former government lawyer who helped draft the original agreement, said fairness to patients was at the heart of the deal.

Everyone understood that “they were covering free riders who weren’t contributing anything,” said Mr. McAnaney, a lawyer in private practice who previously worked at the Office of Inspector General.

But if the rules are not followed, the Office of Inspector General has the right to end the agreement, which would profoundly change the relationship of the industry and the charity.

“If all the conditions are not met, the opinion is without force and effect,” said Donald White, a spokesman for the agency. In keeping with the agency’s policy, he would not confirm or deny whether the agency was investigating the group.

Patients Turned Away

Tracey Dickey works as a social worker for a nonprofit dialysis clinic in rural Missouri with no connection to a big dialysis company, and many of her patients struggle to pay their medical bills, she said. They are exactly the kind of people the Kidney Fund says it is there to help.

In November 2014, Ms. Dickey emailed an executive at the fund. She said she had heard that only clinics that donated to it could apply for financial aid for patients. Her clinic had not donated, she said — but she still had a patient in need.

“I need to know the facts before I tell her there isn’t premium assistance,” Ms. Dickey wrote in an email to the fund. She provided a copy of the email to The Times.

An executive at the fund wrote back the same day. He was noncommittal, but attached a set of guidelines that he asked her to review. “If your company cannot make fair and equitable contributions,” the guidelines read, “we respectfully request that your organization not refer patients.”

And so she didn’t. The patient, Ms. Dickey said, continues to struggle financially.

This summer, after Ms. Dickey and other social workers shared their experiences in an industry discussion group, the Kidney Fund invited them to contact the charity about their concerns. When she followed up, the charity told Ms. Dickey that she would need some computer training to enroll in the program. She has not pursued it, she said.

Ms. Burton said that Ms. Dickey had apparently misunderstood the exchange with the Kidney Fund employee and that had she applied, her patient would have been approved, assuming the person qualified financially.

But Ms. Brecher and several workers at other nonprofit or independent clinics told similar stories.

An administrator at an independent clinic in a Midwestern city said he had helped a handful of patients maintain their coverage through the fund after they transferred to his clinic from a large chain. He declined to be identified because, he said, he did not want to anger DaVita and Fresenius, who sometimes send him patients.

Each time, he said, the charity’s workers later demanded that the clinic make a donation that at a minimum covered the amount it had paid for the patient’s premium. If he did not pay, he said he had been told, the patient risked losing the financial help from the charity for his insurance.

The administrator said he had refused to donate to the charity. The Kidney Fund continued to help pay for the patients’ insurance, he said, but the aggressive approach angered him.

Ms. Burton said the charity never declined a patient because a clinic did not donate. But she said the Kidney Fund did not hesitate to ask clinics for donations.

“We are a charitable organization,” she said. “We fund-raise for everything that we do.”

She said nearly 40 percent of the 213 dialysis companies whose clinics had successfully helped patients apply to the fund had never donated. She would not say, though, what percentage of the 80,000 patients the fund helps annually comes from clinics that do not donate, or how many of those patients come from the biggest companies, which donate most of their revenue.

Still, some social workers say the assumption at many clinics where they work is that the aid decisions are not always based on financial need.

Jennifer Bruns, now a social worker at the St. John Transplant Specialty Center in Detroit, worked for years in dialysis clinics and said she had many clients who received assistance from the American Kidney Fund. She said sometimes patients would tell her that their insurance premiums — which the Kidney Fund had agreed to pay — had not been paid that month.

Ms. Bruns called the fund to find out why, she said in an interview, “and they would say, ‘Well you haven’t made your contribution this month.’”

EXHIBIT 2

Donate Now

News Releases

American Kidney Fund President Testimony to Senate Health Committee on California AB 290

FOR IMMEDIATE RELEASE

SACRAMENTO, Calif. (July 3, 2019)—The American Kidney Fund (AKF) president and CEO LaVarne A. Burton delivered the following testimony today at hearing held by the California State Senate Health Committee on AB 290 (Wood), a bill that will harm thousands of low-income dialysis and transplant patients throughout California. The bill was opposed by 70 organizations and numerous individuals representing a diverse cross section of consumer interests.

In reaction to the bill passing committee, Burton added: “I am extremely concerned that thousands of dialysis and transplant patients who depend on AKF in California are closer to losing an essential financial lifeline that gives them access to lifesaving medical care. All of our State Senators have to understand the gravity of the consequences if AB 290 becomes law and AKF is forced to discontinue its charitable premium assistance program in California.”

Testimony:

My name is LaVarne Burton. I’m President and CEO of the American Kidney Fund. I want to talk about who we are and why we oppose AB 290.

AKF is a servant organization helping people fight kidney disease at every stage—from prevention to dialysis and transplant.

We've done this work for almost 50 years. Last year, almost 4,000 Californians depended on us to help pay their health insurance premiums. We paid Medicare and Medigap premiums for just over half of them.

We have always operated with the highest ethical standards and efficiency. Charity Navigator

has given us a 4-Star rating for 17 years running and we are on their Top 10 charities list. We do this with fewer than 80 staff people.

Despite our great work and commitment to patients, our lawyers have determined that we will be forced to shut down in California if AB 290 is enacted. My general counsel is here today.

First, I know that legal opinions differ about whether we can safely continue operations under AB 290. But, the advisory opinion for our premium assistance program from the Inspector General at the U.S. Department of Health and Human Services is legally binding, and it requires that we act in good faith to comply. Should we not do so, we become liable to IG sanctions.

Your own Legal Counsel, on page 6 of its letter, confirms AKF's conclusion that AB 290 would take us outside of the protections of our Advisory Opinion.

Why would we, an organization that has always played by the rules, step out on a limb when our best judgment and that of your own Legal Counsel says that AB 290 takes us outside our protections?

When the HIPAA law that enables the IG opinion was written, I was a Presidential Appointee in the Clinton Administration working at HHS. I co-chaired efforts in the department to develop this legislation. Our chief concern was protecting against disclosure so that patients could have true freedom of choice in selecting health care professionals. AB 290 undermines that.

Now, if AKF is forced to shut down in California, here's what happens to thousands of Californians if they cannot find another way to pay their premiums:

- Many will lose Medicare altogether or face unlimited out-of-pocket expenses without their Medigap.
- Those who depend on COBRA will lose coverage for themselves and their families
- Those turning to Medi-Cal may face unaffordable spenddown requirements
- Many will lose insurance altogether and have to seek emergency dialysis at hospitals.

Finally, there is something very disturbing about the fact that folks in kidney failure are overwhelmingly black and brown. This is not true at the beginning of the disease when it affects all groups proportionately. Why is this the case? It is because we have a broken health care system that does not provide adequate access to care for low-income minority people. I urge you not to break the system even further by taking away the AKF safety net for people who are literally fighting for their lives.

And now, I want to introduce AKF grant recipient Russell Desmond.

About the American Kidney Fund

As the nation's leading independent nonprofit working on behalf of the 30 million Americans with kidney disease, the American Kidney Fund is dedicated to ensuring that every kidney patient has access to health care, and that every person at risk for kidney disease is empowered to prevent it. AKF provides a complete spectrum of programs and services: prevention outreach, top-rated health educational resources, and direct financial assistance

enabling low-income U.S. dialysis and transplant patients to access lifesaving medical care. AKF holds the highest ratings from the nation's charity watchdog groups, including Charity Navigator, which includes AKF on its "top 10" list of nonprofits with the longest track records of outstanding stewardship of the donated dollar, and GuideStar, which has awarded AKF its Platinum Seal of Transparency.

For more information, please visit [KidneyFund.org <http://www.kidneyfund.org/>](http://www.kidneyfund.org/) , or connect with us on [Facebook <http://www.facebook.com/americankidneyfund>](http://www.facebook.com/americankidneyfund) , [Twitter <http://www.twitter.com/kidneyfund>](http://www.twitter.com/kidneyfund) and [Instagram. <https://instagram.com/americankidneyfund/>](https://instagram.com/americankidneyfund/)

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EXHIBIT 3

Donate Now

Health Insurance Premium Program (HIPP)

If you have kidney failure and have health insurance coverage but are unable to afford the cost of your premiums, the American Kidney Fund's Health Insurance Premium Program (HIPP) may be able to help. Patients may qualify for this program if they have demonstrated insufficient income and savings to pay their premium bills. HIPP covers premiums for Part B Medicare, Medigap, Medicare Advantage, Medicaid (in states that charge premiums), commercial plans (including Marketplace plans), employer group health plans and COBRA plans.

AKF is an independent nonprofit organization. Our HIPP program depends on the generosity of donors, and we accept new applications for HIPP assistance as funding becomes available.

- ▶ **What is HIPP?**
- ▶ **HIPP eligibility criteria**
- ▶ **Things you should know about HIPP**
- ▶ **Download the HIPP guidelines and patient handbook**
- ▶ **How do I get a copy of all HIPP programmatic forms?**
- ▶ **Dialysis providers who have signed AKF's Code of Conduct**
- ▶ **How AKF complies with Advisory Opinion 97-1**

What is HIPP?

If you have kidney failure and have health insurance coverage but are unable to afford the cost of your premiums, AKF's HIPP program may be able to help if you meet program eligibility qualifications.

HIPP covers premiums for:

- Medicare Part B
- Medicare Advantage Plans
- Medicaid (if your state requires a premium payment)
- Medigap
- Commercial plans (including Marketplace plans)
- Employer group health plans
- COBRA plans

[Return to top](#)

HIPP eligibility criteria

- You must live and receive dialysis treatment for end-stage renal disease (ESRD) in the U.S. or its territories.
- When an existing HIPP patient receives a transplant, we provide health insurance premium assistance to the patient through the end of the insurance coverage plan year. Persons eligible to receive post-transplant assistance must already have been receiving HIPP assistance for at least three consecutive months prior to the time of their transplant.
- You must meet the eligibility requirements of the insurance coverage for which premium assistance is being requested.
- You must show that you cannot afford your health coverage. AKF will review your household income, reasonable expenses and liquid assets before granting assistance.
- You must carefully review all forms of health insurance coverage (Medicare, Medicaid, Medigap, COBRA, EGHP, and commercial insurance) and available assistance for paying health insurance premiums (Medicaid, state and local assistance, charitable organizations) and select the combination that best serves your specific financial needs and medical condition.
- For more detailed HIPP information and rules please review the HIPP guidelines available on AKF's Grants Management System (GMS).

[Return to top](#)

Things you should know about HIPP

1. HIPP is for people who can't afford their monthly insurance premiums. We determine your eligibility based on our financial need criteria.
2. We help you to pay for health coverage you've already chosen that best meets your needs. We don't help you choose or enroll in an insurance plan.

3. When you receive grant assistance from AKF, it doesn't matter where you are treated. We will assist you whether or not your dialysis provider or transplant center makes charitable contributions to AKF, and you're free to change providers at any time. We do not help you choose a dialysis clinic or other health care providers.
4. Assistance with primary and secondary insurances is available (AKF will not assist with more than two types of insurance).
5. Once you have assistance from HIPP, you'll be able to access all of the health care services offered covered by your insurance, including transplant workups and transplants allowed under your plan.
6. When an existing HIPP patient receives a transplant, we provide health insurance premium assistance to the patient through the end of the insurance coverage plan year. For example, a patient whose health plan year is on a calendar basis and who receives a transplant in May would be eligible to receive HIPP assistance through the end of December. If the transplant occurs in the final quarter of a plan/policy year and AKF has already begun paying premiums for the next plan/policy year, then AKF will continue grant assistance for the full new plan/policy year.
7. We help you regardless of whether your health care provider makes charitable contributions to AKF.
8. Although you receive HIPP assistance from AKF, you are the policy holder for your health insurance. The contract is between you and the insurance company. You are responsible for understanding all of the terms of your contract and for making sure that your health insurance premium is paid on time.
9. AKF reviews grant requests on a "first-come, first-served" basis. We are an independent nonprofit organization. Our HIPP program depends on the generosity of donors, and we accept new applications for HIPP assistance as funding becomes available.
10. AKF processes applications within 10–14 business days on average.
11. You should work with your dialysis social worker or HIPP coordinator to complete your HIPP application so that they have all the information to submit a complete and accurate application.
12. It is important that you bring your most current insurance bill (no older than 90 days) to your dialysis social worker before applying to AKF for assistance. You must also sign and date a HIPP patient consent form. Not providing all required documentation can slow down the grant approval process and delay getting the grant to you.
13. All applications must be submitted via AKF's online Grants Management System (GMS).

[Return to top](#)

Download the HIPP guidelines and patient handbook

Download PDF versions of our HIPP guidelines and patient handbook:

- [HIPP guidelines <http://www.kidneyfund.org/assets/pdf/financial-assistance/akf-hipp-guidelines.pdf>](http://www.kidneyfund.org/assets/pdf/financial-assistance/akf-hipp-guidelines.pdf)
- [HIPP patient handbook <http://www.kidneyfund.org/assets/pdf/financial-assistance/akf-hipp-patient-handbook.pdf>](http://www.kidneyfund.org/assets/pdf/financial-assistance/akf-hipp-patient-handbook.pdf)

[Return to top](#)

How do I get a copy of all HIPP programmatic forms?

All forms available within AKF's Grants Management System (GMS) please log into the [GMS site](#). <<https://gms.kidneyfund.org/login>>

[Return to top](#)

Dialysis providers who have signed AKF's Code of Conduct

The American Kidney Fund's (AKF) voluntary Code of Conduct reflects our firm expectation that all renal providers and renal professionals who refer patients to AKF for HIPP program assistance will do so in an ethical manner and in compliance with Advisory Opinion 97-1, with the underlying goal of putting patients' interests first. By signing the Code of Conduct, companies have affirmatively agreed to educate patients about the HIPP program and to ensure that patients have access to accurate and impartial information about health insurance coverage options. This enables patients to make informed decisions about selecting the best coverage and their ability to receive assistance from AKF to pay for such coverage if they qualify for the HIPP program.

The following dialysis providers have signed the AKF Code of Conduct. AKF will update this information on a routine basis.

American Home Dialysis, LLC
American Renal Associates
Antelope Valley Kidney Institute
Boson Health
CentraCare Health
DaVita Kidney Care
Dialysis Center of Lincoln, Inc.
Dialysis Clinic, Inc.
Dreiling Medical Management
Fresenius Medical Care
Harrison Dialysis Center
Home Dialysis of North Alabama
Infiniti Dialysis Center of Cincinnati, LLC
Jefferson Health Dialysis
Kidney Care Center
Kidney Spa, LLC
NEA Baptist Clinic Dialysis Center
North Central PA Dialysis Clinic
Physicians Dialysis Trinity
Physicians Choice
Santa Barbara & Lompoc Artificial Kidney Centers

Satellite Healthcare
SNG Dialysis
Tift Regional Dialysis
U.S. Renal Care
Union County Dialysis Center
Waycross Dialysis Facility

[Return to top](#)

How AKF complies with Advisory Opinion 97-1

AKF's HIPP program operates under federal guidance in Advisory Opinion 97-1, with a strong compliance program that prevents conflicts of interest and ensures that the program operates in accordance with all applicable laws. **For further details, see our [OIG Compliance Policy](#).**
<<http://www.kidneyfund.org/assets/pdf/financial-assistance/akf-oig-compliance-policy.pdf>>

[Return to top](#)

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EXHIBIT 4



PATIENT HANDBOOK



HEALTH INSURANCE PREMIUM PROGRAM

TABLE OF CONTENTS

ABOUT THE AMERICAN KIDNEY FUND	4
INTRODUCTION.....	4
GRANTS MANAGEMENT SYSTEM(GMS).....	5
MY RIGHTS AND RESPONSIBILITIES	6
WHAT IS HIPPA?.....	9
HIPPA ELIGIBILITY.....	10
HOW DO I APPLY?.....	11
REQUIRED DOCUMENTATION	13
GRANT PAYMENTS	14
GRANT PAYMENT: CHECKS	14
GRANT PAYMENT: DEBIT CARDS	15
GRANT PAYMENT: DIRECT DEPOSIT	16
FREQUENTLY ASKED QUESTIONS ABOUT HIPPA	17
APPENDIX 1: GMS PATIENT PROFILE REGISTRATION GUIDE	21

ABOUT THE AMERICAN KIDNEY FUND

The American Kidney Fund, a national nonprofit organization founded in 1971, is working to fight kidney disease and help people live healthier lives. Through our many programs, we support people no matter where they are in the fight against kidney disease—from prevention through treatment and transplant.

For the 1 in 5 U.S. dialysis patients who can't afford the cost of care, AKF provides lifesaving financial assistance, and in 2018 we expanded the scope of that program to continue helping patients with insurance premium support for up to a year post-transplant.

To reach people who are at risk of developing kidney disease, we run the nation's largest free kidney disease screening program, providing prevention services to individuals in more than 20 cities annually. Our programs and services to help people manage and live better with kidney disease include a robust website full of up-to-date health information; free monthly webinars; and professional education programs for those who care for kidney patients. We reach into communities with the Kidney Health Coach program and we advocate for issues that matter to patients through our nationwide AKF Advocacy Network of more than 10,000 patients and loved ones.

Our work is possible thanks to more than 62,000 individuals, corporations and foundations who support our mission through charitable contributions to AKF. We spend those contributions where they will do the most good—on programs, not overhead. Our consistent track record of spending 97 cents of every donated dollar on programs has earned AKF the top "Four Star" rating from Charity Navigator for 17 years in a row, placing AKF on the top 10 list of nonprofits nationwide for fiscal accountability.

For more information about AKF and to learn how you can become involved, visit our website at [KidneyFund.org](https://www.kidneyfund.org), or find us on Facebook, Twitter and Instagram.

INTRODUCTION

This handbook is intended to help you fully understand your role and responsibilities as a patient applying for financial help through AKF's **Health Insurance Premium Program (HIPP)**. It will help you in navigating the eligibility, grant entry and grant approval process. It will also help you understand the benefits, responsibilities, and limits of HIPP.

This handbook is not meant to take the place of the HIPP guidelines. Those guidelines are located on our website at <http://www.kidneyfund.org/assets/pdf/financial-assistance/hipp-guidelines.pdf>.

If you would like to apply for HIPP, please speak with your dialysis team. You have the option to apply through your dialysis team, through a caregiver, or by yourself.

GRANTS MANAGEMENT SYSTEM(GMS)

GMS is AKF's online system for managing your financial grant requests. We suggest that you register to use GMS. By registering, you may:

- Submit/monitor grant requests
- Monitor payments
- Update your profile
- Send messages to AKF
- Download important documents
- Review educational information
- Receive important program updates
- Add a caregiver to assist you

To register in GMS, you must have an email account. Please visit gms.kidneyfund.org to register. For information on how to register, please refer to the **Patient Registration Guide** in Appendix 1 of this handbook.

MY RIGHTS AND RESPONSIBILITIES

Since 1971, AKF has helped more than 1.5 million kidney patients like you to afford healthcare expenses.

If you are currently being assisted by AKF's HIPP, or if you are thinking about applying, you should know that you have rights and responsibilities as an AKF grant recipient. The rights and responsibilities below apply to any patient who, following submission of a HIPP application, is approved and remains eligible for HIPP assistance.

Your Rights

1. You have the right to **independently choose** the health care coverage that is best for you.
2. You have the right to **change** your health care coverage to any plan that is available to you and that best suits your health and financial needs.
3. You have the right to **cancel** your HIPP assistance from AKF at any time.
4. You have the right to **reapply** for HIPP assistance from AKF at any time.
5. You have the right to **change dialysis providers** and maintain your HIPP eligibility. When you move to another provider, you are still approved for grant assistance for your current full policy year. Please make sure to update your information in your GMS profile. You may do this yourself or get assistance from your caregiver that has registered to assist you on your behalf. You may also inform your new dialysis center so they can update the profile for you or contact AKF directly if employees at your new dialysis clinic cannot assist you.
6. You have the right to **access AKF's GMS** to track the status of your grant request. (gms.kidneyfund.org) If you have questions about registering please contact patientservice@kidneyfund.org.
7. You have the right to **receive a copy of your records** in GMS (grant request, supporting documents and grant history).
8. You have the right to **report to AKF any concerns about the application or grant process** without fear of retribution.
9. As a HIPP grant recipient or applicant, you have the right to **get answers to your questions directly from an AKF staff member**. You may contact us at patientservice@kidneyfund.org or call 800.795.3226.

Your Responsibilities

1. You have the responsibility to provide complete, accurate, and timely information on your HIPP personal profile and grant request, and inform AKF immediately about any changes to your contact information, financial status, dialysis provider or facility, or any other information that may impact your eligibility for HIPP.
2. If you change dialysis providers, it is your responsibility to inform your new provider or AKF directly that you receive grant assistance from AKF so that we may work with you in submitting future grant requests.
3. You have the responsibility to review your GMS patient profile information and grant request for accuracy and completeness. You should do so on a regular basis to be sure that all changes are captured and up to date.
4. You have the responsibility to share information relevant to an AKF grant (i.e. change in address, financial situation, insurance changes, etc.) in a timely fashion on your own through GMS or with your renal professional¹ or caregiver, who will assist you in completing the application and submitting it to AKF. You may currently go to your account in GMS and download the patient profile worksheet and complete that for your renal professional or you may complete your information online through GMS.
5. You have the responsibility to make sure that your current health insurance bills are uploaded into GMS in a timely manner. This will allow AKF to process your grants so that premiums are paid on time.
6. You have the responsibility to read the HIPP Guidelines, Patient Handbook and patient information materials provided to you by AKF through GMS and your renal professional and ask questions about anything that you do not understand. These documents are also available online: [kidneyfund.org/information](https://www.kidneyfund.org/information).
7. You are ultimately responsible for your own health insurance coverage, including timely payment of premiums. AKF offers no guarantee of an initial grant or renewal of grants. If you qualify for assistance from HIPP, AKF will provide a grant to help cover premiums so long as HIPP funds are available. AKF reserves the right to modify or discontinue HIPP assistance if funding becomes limited or for any other reason.

If you are planning to have a kidney transplant, it is extremely important that you understand that AKF will provide health insurance premium help through the end of the insurance coverage plan year. To be eligible for this post-transplant assistance you must already have been receiving HIPP assistance for at least three consecutive months immediately preceding the transplant. You must work with your dialysis social worker

¹ Renal professional means your dialysis facility's social worker, financial coordinator, insurance counselor or other staff member responsible for assisting patients with the insurance coverage and other financial aspects of their care.

and transplant center to make sure that they understand your post-transplant coverage and related health insurance premium grants or you may update your patient profile in AKF's GMS to reflect that you have received a transplant.

8. You are responsible for all aspects of your health insurance plan. The receipt of financial assistance from HIPP does not alter the fact that health insurance coverage represents a contractual relationship solely between you and your health insurance plan, not between AKF and the health insurance plan.
9. If there is an overpayment for your insurance and that amount is refunded to you, you must send the refunded amount to AKF so that we may place these funds in the HIPP pool for use for other eligible patients.
10. You have responsibility to promptly inform your provider staff and/or AKF if you believe that any of these rights have been violated. You may reach AKF by contacting 800.795.3226 or patientservice@kidneyfund.org.

WHAT IS HIP?

HIP is a charitable program run by AKF that provides grants to financially eligible patients with kidney failure. The grants help pay for medical insurance premiums.

HIP grants help with premium payments for:

- Medicare Part B
- Medicare Advantage (Part C)
- Medicaid (if your state requires a premium payment)
- Medigap/Medicare Supplemental
- Commercial plans (including Marketplace plans)
- Employer Group Health Plans (EGHP)
- COBRA plans

HIP grants do not:

- Help with copays, spend-downs or medical device purchases.
- Locate or recommend insurance policies or dialysis facilities or other health care providers.
- Assist with dental and vision insurance.
- Cover union dues.



HIPP ELIGIBILITY

In order to qualify for HIPP, you must:

- Receive dialysis treatment for end-stage renal disease (ESRD).
- Be currently enrolled in or applying for health insurance coverage.
- Live in the U.S. or its territories.
- Show that you cannot afford your health coverage.
 - AKF will review your household income, reasonable expenses and liquid assets (such as savings accounts and investment accounts) before granting help.
 - Monthly household income may not be \$600 more than reasonable monthly expenses. If you have no income at the time of application, you will need to provide an explanation.
 - Total liquid assets may not be more than \$7,000. (IRAs and other retirement accounts are excluded and are not counted towards this amount.)
- For transplant patients seeking HIPP assistance, you must have been on HIPP for at least three months prior to receiving your kidney transplant.
- Carefully review all forms of health insurance coverage (Medicare, Medicaid, Medigap, COBRA, EGHP, and commercial insurance) and available assistance for paying health insurance premiums (Medicaid, state and local assistance, other charitable organizations), and select the combination that best serves your specific medical and financial needs. The selection of health insurance is your choice. AKF will ask you to acknowledge that you have selected the health insurance for which you are requesting help.

NOTE: If you get a kidney transplant you may be eligible for continued assistance for the remainder of your current health insurance policy year based on the following:

- You must update your GMS profile to show you are a transplant patient.
- You must update your clinic information to your current transplant center.
- You must request a grant for the same insurance AKF assisted with prior to your transplant.
- You must request assistance within three months of your transplant date.

Although you may receive HIPP assistance from AKF, remember that it is your health insurance policy. The contract is between you and the insurance company. You are responsible for understanding all of the terms of your contract and for making sure that your health insurance premium is paid on time.

For more HIPP information and rules, please review the **HIPP Guidelines** available through your dialysis team or on GMS.



HOW DO I APPLY?

You have the ability to create your own eligibility profile on gms.kidneyfund.org, or you can allow your renal professional or a caregiver create an eligibility profile on your behalf.

1. HIPP Eligibility Application

AKF uses the **HIPP patient profile** to help determine if you are eligible for financial help from AKF.

If you wish to apply for assistance by yourself, please complete the following steps:

- Read the **HIPP Guidelines**. Make sure you ask AKF or your dialysis team about anything that you do not understand.
- Go to gms.kidneyfund.org and click on the **Register** button. Follow the steps on the webpage. A detailed **registration walkthrough** can be found at the end of this Handbook.
- Read, sign, date and date the **HIPP consent form** (and upload it to your profile within the **Agreements** tile).

If you allow your renal professional to create your eligibility profile, please complete the following steps:

- Read the **HIPP Guidelines**. Make sure you ask AKF or your dialysis team about anything that you do not understand.
- Fill out the **HIPP worksheet** with your dialysis team. The application requires financial, medical and other information about you.
- Read, sign, date and date the **HIPP consent form**.
- Give the worksheet and consent form to your renal professional to start the application process.

If you allow your caregiver to create your eligibility profile, please complete the following steps:

- Read the **HIPP Guidelines**. Make sure you ask AKF or your dialysis team about anything that you do not understand.
- Fill out the **HIPP worksheet** with your caregiver. You will need to provide financial, medical and other information about you.
- Read, sign, date and date the **HIPP consent form**.
- Provide your caregiver's name and signature on the consent form.
- Give the worksheet and consent form to your caregiver to start the application process.
- Your caregiver can start the registration and profile creation process at gms.kidneyfund.org.

2. HIPP Grant Requests

HIPP grant requests are submitted for assistance in paying insurance premiums.

If you wish to enter your own grant request, please complete the following steps:

- After you have created your profile in GMS, click on **Grant Program Eligibility** from your dashboard.
- Click on **Apply Now** for the grant program that you are requesting assistance from.
- Follow the steps within the grant request process. Please note that you will need to upload your insurance bill, know your requested amount and coverage dates.

If you allow your renal professional to enter your grant request, please complete the following steps:

- Provide your dialysis renal professional with a health insurance bill or statement dated within the last three months.
- Your dialysis team will enter the grant request into GMS.

If you allow your caregiver to enter your grant request, please complete the following steps:

- Provide your caregiver with a health insurance bill or statement dated within the last three months.
- Your caregiver will enter the grant request into GMS.

AKF reviews grant requests within 10-14 business days. If your grant is approved, a payment will usually be issued in two business days.



REQUIRED DOCUMENTATION

As previously noted, AKF requires that you provide an insurance bill in order to process your grant request. If your health insurance does not send a bill or payment coupon, AKF will usually accept the following documents in place of a current bill:

Employer Group Health Plan (EGHP)

A letter from the employer that includes:

- Monthly amount for medical portion
- Name of employee
- Name of patient (if not employee and indicate the relationship to employee)
- Any surcharges (smokers, union, weight, or other fees)

Annuity Plans

- Document that shows an amount taken out of the patient's retirement/annuity fund for health insurance
- Must be current and be from the annuity supplier or employer if the patient is still employed.

COBRA

- If your COBRA administrator does not send bills/coupons, AKF can accept a letter from the COBRA administrator from the current year noting the amount of the monthly or quarterly premium.

Medicare

- CMS-500 (dated within 90 days of the grant request)
- Awards/Entitlement Letter (within 60 days of the letter's issue date)
- Termination Letter (within 30 days of the letter's issue date)



Things to remember:

- All bills/invoices/other accepted documents must reference the insured's name, policy number and coverage period. This information must match the grant payment request.
- If you change insurances, update your profile in GMS or tell your dialysis team or caregiver. Please also enter a new grant request after you update your profile if you have applied by yourself, or provide your dialysis team or caregiver with a new insurance application or bill.
- If your premium increases or decreases, please submit a new grant payment request if you have applied by yourself, or bring a current bill to your renal professional or your caregiver to submit a new grant payment request.

If you have any questions regarding your application or grant request, please contact AKF at 1-800-795-3226, message AKF through **GMS messages**, or email patientservice@kidneyfund.org.



GRANT PAYMENTS

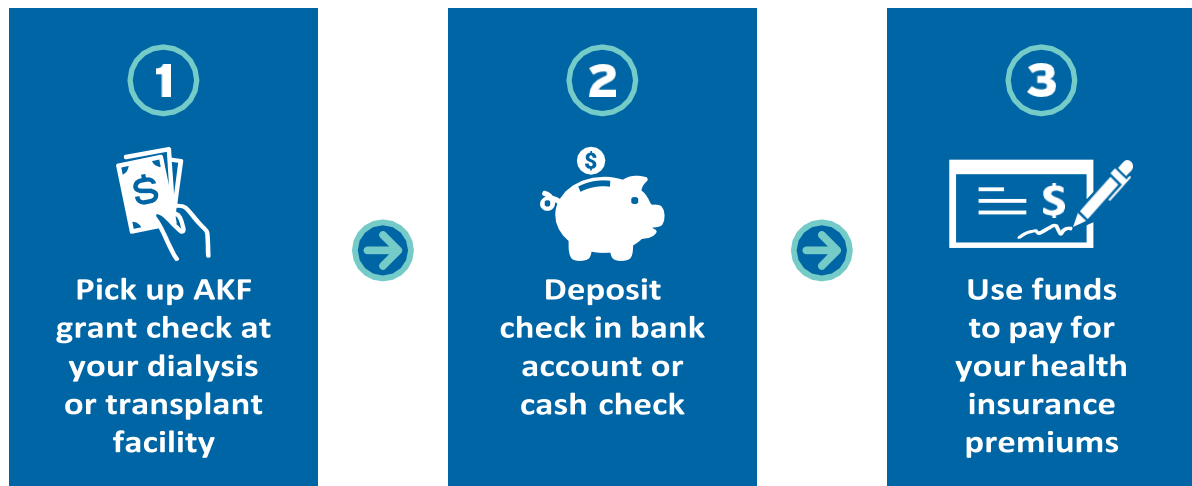
Once approved, all grant payments are issued by check, debit card, or direct deposit.

When possible, AKF will send grant payments directly to the insurance company. However, some insurance companies do not accept payments directly from AKF. In such cases, AKF will mail checks or debit cards to either your dialysis/transplant center or to your home address. Please review your GMS profile and make any updates if necessary. If your insurance company accepts AKF grant payments, the only option will be to send it directly to the insurance company.



GRANT PAYMENT: CHECKS

If you receive a check at your dialysis/transplant center or your home address, do not endorse and/or send it to the insurance company as it will not be accepted. Instead, please follow the steps below:





GRANT PAYMENT: DEBIT CARDS

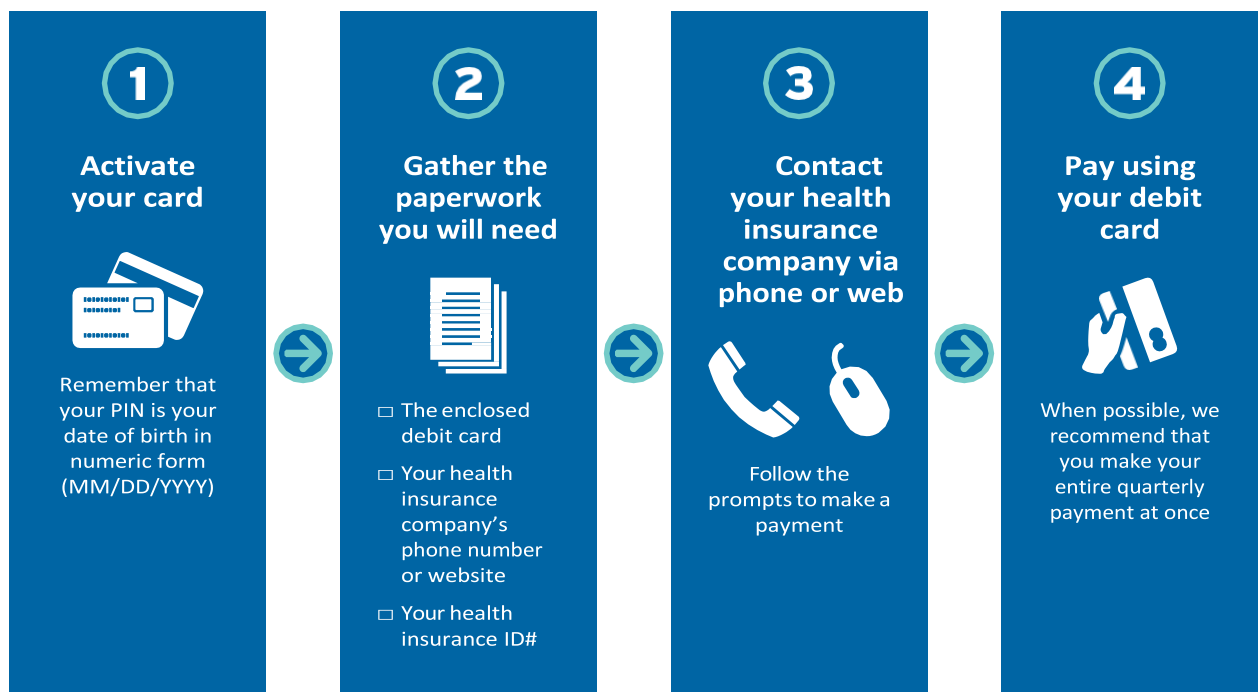
Debit cards are a payment method instituted by AKF for some, but not all, insurance plans. **AKF-issued debit cards will ONLY allow you to pay your insurance premiums. They may not be used for any other purpose.**

How do I use my HIPP debit card?

- You must activate the debit card before using it.
- The PIN number is your date of birth in this form (MM/DD/YYYY). Please press pound (#) after you enter your PIN. If your birthdate has been entered in GMS incorrectly, a new grant request will need to be entered and a new card will need to be issued.

If your insurance company requires a zip code to verify the payment, please use **your home zip code** (as it appears in your GMS patient profile).

4 Easy Steps to Using Your HIPP Debit Card



What will I receive?

- An actual plastic debit card (mailed to your home or dialysis facility) with each new grant payment.
- A letter of explanation and step-by-step instructions in English (as pictured above) and in Spanish.

What else do I need to know?

- Cards are valid for 90 days. Once your card expires, it will not be reissued.
- If you lose your debit card, you, your dialysis/transplant team or caregiver must contact AKF so we can void the card and a new one-time grant request will need to be entered if the payment is still needed. You **cannot** request a new card directly from the debit card provider.
- For security reasons AKF does not have access to the debit card information (card number, etc.) and cannot give it to you if the card is lost or stolen.
- Each debit card is for a specific coverage period and will not be reloaded or reused.
- For any debit card related questions, please message AKF within GMS Messages.

Who do I contact if I have questions?

- Questions sent about a debit card related grant (including lost or cards not received) should be directed to AKF at patientservice@kidneyfund.org or by messaging AKF through **GMS Messages** or by calling **1-855-541-0950**.



GRANT PAYMENT: DIRECT DEPOSIT

In those cases where an insurance company does not accept third-party payments or AKF is reimbursing the patient, AKF offers the ability to receive your HIPP grant by ACH/direct deposit to your bank account.

If you have chosen this method of receiving your grant payment, you will be prompted to enter your banking information, including routing and account number. For security reasons, AKF does not store this information within GMS.

ACH/direct deposit will go directly into your bank checking or savings account. A list of insurance companies that do not accept third-party payments directly from AKF is available within GMS.



FREQUENTLY ASKED QUESTIONS ABOUT HIPPA

Is my grant considered income?

No. In accordance with Internal Revenue Code Section 102, all AKF grants are charitable gifts, which are not considered gross income. Additionally, you will not receive tax forms from AKF, because AKF's grant to you is a charitable gift, not taxable income.

Can AKF pay for more than two health insurance premiums?

No. AKF only provides premium assistance for maximum of two health insurance policies.

I'm receiving HIPPA grants and I just received a transplant; can I still receive HIPPA assistance?

Yes—after a transplant, AKF will continue to provide financial assistance to you for your current insurance plan year. For example, if you have a calendar year policy and you get a transplant on April 2 and AKF has paid your insurance premium for the quarter January 1-March 31, your grant assistance will end on December 31. If you are already receiving or are applying for assistance from HIPPA, talk to your transplant center to make sure that receiving assistance from AKF will not affect your kidney transplant eligibility. In order to receive HIPPA grant assistance after your transplant, you must have been a HIPPA recipient for at least three months prior to receiving the transplant.

What if I received a termination/delinquent (past due) payment notice?

If you receive a past due notice, if you are in a grace period, either you, your dialysis/transplant center, or caregiver will need to enter a **one-time** grant request for the past due amount.

With most insurance companies there is a grace period in which a payment can be made before the account is terminated. If you are in the grace period, contact your dialysis team immediately for help submitting a grant request to AKF. If you have applied directly through AKF, please contact your AKF contact or call 1.800.795.3226/ email patientservice@kidneyfund.org.

If your insurance is terminated, please contact your insurance company to determine if you can get your insurance reinstated. A reinstatement letter or a new policy will be required to get future help from AKF.

Will AKF pay my family or spouse/domestic partner's portion of the insurance plan?

AKF only pays for the patient's portion of a family plan. Please contact your plan administrator for a breakdown of the insurance coverage. If the premium is being

deducted from your spouse/domestic partner's paycheck, please provide the necessary documentation that details your portion of the insurance premium.

My insurance company hasn't received my payment, what should I do?

You should check your grant payment status in GMS. If you do not have access to the internet, please contact your caregiver or your dialysis/transplant center to check your grant payment status in GMS.

You may then need to contact your insurance company directly to find out why the payment has not yet been credited.

For more information on how to register to GMS, please refer to the **Patient Registration Guide** attached to this Handbook.

What if I receive a refund check from my insurance company?

Any premium refund in connection with any health insurance plan paid by AKF is the property of AKF and must be promptly returned. These refunds are deposited into the HIPP funding pool to support others in the program. If you do not return the refund to AKF, you may be ineligible for future HIPP assistance.

What if I require a loved one or caregiver to speak to AKF on my behalf?

AKF requires that your caregiver information be provided through your consent/acknowledgement form and stored within your GMS account profile.

I've switched dialysis centers. Can I still get help from AKF?

Yes, regardless of where you dialyze, AKF will provide assistance to you. Please update your facility information on your GMS profile. You may also ask your new dialysis/transplant center to put in your grant requests. If your new center is not registered in AKF's GMS, please have them contact AKF at 1-800-795-3226 or at patientservice@kidneyfund.org. The registration process for a new center is quick and simple. If your new center declines to help you with the HIPP application process, please contact AKF at **1-800-795-3226**, through **GMS messages**, or by emailing patientservice@kidneyfund.org.

How do I edit my profile or grant request?

Please refer to the **Resources** tab in GMS for detailed instructions on how to edit any information within your GMS profile.

What if I am experiencing technical issues?

Please contact AKF via GMS chat or please call 800-795-3226.

What if I cannot cash a check?

If you are unable to cash your check, log on to GMS and send a **GMS chat message** explaining the situation. An AKF representative will assist you.

What is a plan year?

Your policy plan year is determined based upon your policy effective date and the amount of time your premium is effective. Please contact your insurance company if you need to know what your plan year is.

Can you accept screenshots?

Yes. Please be sure the screenshot is legible and clear. All necessary information needs to be visible within the screenshot.

What information needs to be on a bill?

The patient name, requested amount and coverage dates, date the bill was created, policy ID number and the remittance address for the insurance company need to be printed on the bill. If the amount requested is not clearly shown on the bill, a breakdown of the requested amount will be needed as well.

What to do if my insurance has termed?

- In the case that your insurance has termed, contact your insurance company for information on whether or not the policy can be reinstated and cancel any future payments for the terminated insurance within GMS.
- If the policy can be reinstated enter a grant request with a document from the insurance company showing the owed amount for reinstatement.
- If the policy cannot be reinstated, you will need to enroll in a new insurance plan in order to continue receiving Health Insurance Premium Assistance from AKF.

My bill is due today. What do I do?

It's important to submit grant requests to AKF in a timely manner, because it takes 10-14 business days for AKF to process a grant request. In the case that you have a payment due, it is your responsibility to maintain your health insurance coverage. AKF will not process grant requests out of order.

Where is my check?

We send our checks via USPS. You may log onto GMS to check the status and the address of the check.

What type of insurance do I have?

Please contact your insurance company to inquire about your insurance type or please look for the insurance type on your premium bill.

How do I upload documents from my computer?

Please refer to the document titled **How to Upload Documents** in the **Resources** tab on GMS.

How long will it take my grant to be processed?

Please allow 10-14 business days for pending grant requests to be processed.

What other expenses does AKF assist with?

AKF assists with health insurance premiums, reimbursement costs for transportation to and from dialysis, over-the-counter medicines, co-payments; and other needs, for example, dentures.

Do you help international patients?

AKF assists all people who reside within the United States and its territories.

Do you help undocumented patients?

AKF assists all people who reside within the United States and its territories.

How do I remove a caregiver or renal professional from my account?

Please update your profile in GMS in the **Contacts** section. You may add or remove renal professionals and caregivers in this section.

How often do I need to apply?

You will need to update your profile once a year. You will also need to request a new grant request if you are in a new policy year or if your policy has changed. Please remember that you can create “one-time” grant requests that can be used to pay for balance due requests.

How do I upload documents from my phone?

You can upload documents by emailing them as images on your cellphone:

1. Take the photo using the photo app and save it on your phone.
2. Tap the **Share** icon and choose your desired email.
3. **Select** the photo(s) you want to email.
4. Tap the **Next** button to attach the photos to the email.
5. Compose your email and send.



APPENDIX 1: GMS PATIENT PROFILE REGISTRATION GUIDE

The following Patient profile registration guide provides step-by-step instructions for the profile registration process. If you have questions, please contact AKF at patientservice@kidneyfund.org or call 1-800-795-3226.

Step One: To start the registration process, please click the **Register** button:

The screenshot shows the American Kidney Fund Grants Management System login and registration interface. It features a logo at the top, followed by fields for Username and Password. A 'Forgot Password' link is located below the password field. A blue 'Log In' button is positioned below the password field. Below the login section, there is a message: 'Don't have an account? Click on Register to sign up for Grants Management System'. At the bottom of this section is a blue 'Register' button.

Step Two: Click **I am a Patient** to start the registration process:

The screenshot shows a selection screen for the registration process. It begins with the text: 'First, please tell us which of the following best describes you.' Below this, there is a section titled 'I am a...' with three options: 'Renal Professional', 'Patient', and 'Caregiver'. Each option has a brief description and a corresponding button. A large red arrow points to the 'I am a Patient' button.

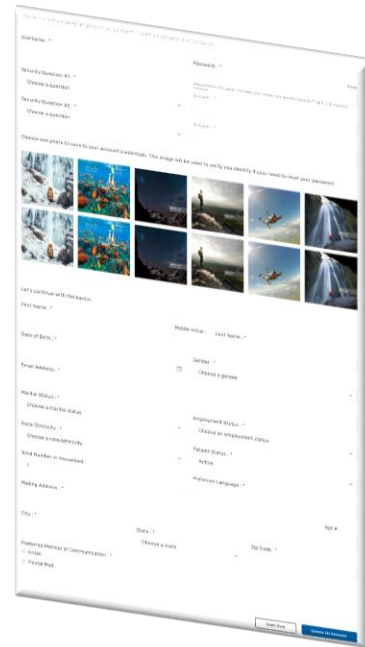
Renal Professional
Renal Professionals are individuals who work at facilities; providing treatment to Dialysis and /or Transplant Patients.
I am a Renal Professional

Patient
Patients are individuals undergoing dialysis treatment and/or post transplant.
I am a Patient

Caregiver
Caregivers are family members over the age of 18 or legal representatives assisting Patients in requesting financial assistance.
I am a Caregiver

Step Three:

- Please fill out every information box on this page. Please also select an image by clicking on it. This image will be used to verify your identity if you need to reset your password. When finished, click **Create My Account**.
- You will receive a verification email at the address you provided. Remember to verify your profile by following the instructions within the verification email.



Step Four: Please follow the step-by-step instructions for each of the sections shown in the screenshot below. Each section asks specific questions on your health history, insurance information, personal finances, dialysis facility information, contact information, and important/relevant documents.

<h3>Health Information</h3> <p>It is important for us to have your current health information so we can determine your eligibility for grants.</p> <p>Review</p>	<h3>Health Insurance</h3> <p>Please let us know which health insurance plan(s) your patient currently has. Supplying this information does not mean you are requesting assistance with that insurance.</p> <p>Review</p>	<h3>Finances</h3> <p>Understanding your patient's financial situation will help us understand their eligibility.</p> <p>Review</p>
<h3>Facility</h3> <p>Let's work on your patient's clinic information.</p> <p>Review</p>	<h3>Contacts</h3> <p>Let us know who else we can contact about your patient's grant application.</p> <p>Review</p>	<h3>Agreements</h3> <p>Review some important documents here.</p> <p>Review</p>

Have questions? Need assistance?

Call 1-800-795-3226

or email:

patientservice@kidneyfund.org



11921 Rockville Pike, Suite 300 | Rockville, MD 20852
Phone: 800-638-8299

KidneyFund.org

EXHIBIT 5

KATIE PORTER
45TH DISTRICT, CALIFORNIA

FINANCIAL SERVICES COMMITTEE
SUBCOMMITTEE ON
INVESTOR PROTECTION, ENTREPRENEURSHIP, AND
CAPITAL MARKETS
SUBCOMMITTEE ON
CONSUMER PROTECTION AND FINANCIAL SERVICES

Congress of the United States
House of Representatives
Washington, DC 20515-0545

WASHINGTON OFFICE:
1117 LONGWORTH HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-5611

DISTRICT OFFICE:
2151 MICHELSON DRIVE
SUITE #195
IRVINE, CA 92612
(949) 668-6600

porter.house.gov

July 23, 2019

Joanne Chiedi
Acting Inspector General
Department of Health and Human Services
330 Independence Ave SW
Washington, DC 20201

Dear Inspector General Chiedi,

I am writing to request that the Office of the Inspector General (OIG) open an investigation into the American Kidney Fund's (AKF) relationship with leading dialysis providers, including DaVita, Fresenius Medical Care, and American Renal Associates (ARA), in the wake of recent revelations that suggest these organizations have collaborated to implement practices that benefit their bottom line at the expense of patients with kidney disease.

The last twenty years have seen a revolution in how the American Kidney Fund is funded, and this warrants OIG revisiting the conclusions of the 1997 Advisory Opinion that permitted the operation of the AKF's Health Insurance Premium Program (HIPP).

Background

People whose kidneys are failing, otherwise known as end stage renal disease (ESRD), require dialysis treatment, which performs the functions that kidneys typically do.¹ Dialysis usually involves treatments several times a week for several hours at a time.² There are few other options for patients other than kidney transplants.

The American Kidney Fund primarily operates a program, the Health Insurance Premium Program, which helps pay the insurance premiums for individuals who need dialysis. Specifically, HIPP covers premiums for Medicare, Medicaid, and private insurance plans.³ Large dialysis clinics are major benefactors of the AKF. In short, dialysis clinics donate to AKF, provide treatment for patients whose insurance premiums were paid by AKF, and then receive payments from the patients' insurance companies for the treatment.

¹ "Dialysis | Hemodialysis | Peritoneal Dialysis." *MedlinePlus*, U.S. National Library of Medicine, 27 Dec. 2018, medlineplus.gov/dialysis.html.

² "What Is Dialysis?" National Kidney Foundation, 2 July 2018, www.kidney.org/atoz/content/dialysisinfo.

³ "Health Insurance Premium Program (HIPP)." American Kidney Fund (AKF), www.kidneyfund.org/financial-assistance/information-for-patients/health-insurance-premium-program/.

Complaints from patients and providers have yielded reports that the country's largest dialysis providers are using their financial influence over the American Kidney Fund to push patients toward more expensive insurance options. Doing so increases dialysis center profits while making it more difficult for patients to access kidney transplants due to policies that end premium assistance for patients who receive transplants despite patients needing proof of ongoing insurance in order to be eligible for a transplant. In some cases, the AKF has also reportedly denied patients financial assistance if they are not receiving care at a major AKF donor.

On July 10, 2019 the President issued an Executive Order announcing a new initiative for ESRD care. Secretary of Health and Human Services Alex Azar announced that the Administration hopes that, as a result of this initiative, 80 percent of end-stage renal disease patients will be receiving home dialysis or a kidney transplant by 2025 and double the number of kidneys available for transplant by 2030. Yet the practices described by patients and providers working with the AKF, DaVita, Fresenius, and American Renal Associates threaten to undercut the Department's ability to achieve these objectives.

Potential Conflicts of Interest and Kickbacks That Harm ESRD Patients

As you know, ESRD can be covered by Medicare, even for patients who are not 65 or older, and Medicaid. Yet recent reports from patients and health care providers suggest that the two largest providers of dialysis, DaVita and Fresenius Medical Care, are using their financial influence over AKF to steer patients toward more expensive private insurance options or to clinics who provide large donations.

HIPP has long raised concerns about potential violations of federal anti-kickback and anti-competition laws because of the potential tension between the financial interests of AKF and dialysis providers and the health and finances of patients. To address these concerns, AKF requested and received an OIG advisory opinion (No. 97-1) in 1997 that outlines conditions under which HHS would choose to exercise its enforcement discretion and not find this arrangement unlawful.⁴ These conditions include treating all patient applications for assistance equally – regardless of the type of insurance they have or whether the clinics from which they receive treatment donate to AKF.

For example, HIPP provides financial assistance for “transportation, medication, and health insurance premiums,” for low-income individuals with ESRD. In the advisory opinion, HHS OIG made clear that “AKF staff involved in awarding patient grants will not take the identity of the referring facility or the amount of any provider's donation in consideration when assessing patient applications or making grant determinations.”⁵ Essentially, AKF was not allowed to take into consideration whether or not a patient was receiving care at a provider that supported AKF financially.

When the advisory opinion was issued in 1997, AKF assisted “over 12,000 patients with ESRD and received over \$5 million in donations. Of that amount, less than ten percent” was provided by

⁴ HHS OIG. Advisory Opinion No. 97-01. (1997). <https://oig.hhs.gov/fraud/docs/advisoryopinions/1997/kdp.pdf>

⁵ Ibid.

the major dialysis providers.⁶ In 2018, AKF received nearly 80 percent of all donations from DaVita and Fresenius.⁷ Over the same time period, DaVita and Fresenius have brought in record profits and acquired many smaller dialysis providers, while patients and clinicians at dialysis clinics owned by providers other than DaVita and Fresenius have reported discriminatory practices by AKF.

This advisory opinion also predated the passage and implementation of the Affordable Care Act (ACA), which made major changes to the healthcare system affecting patients with kidney disease. Before the ACA, private insurance coverage was rarely an option for people with ESRD because ESRD was an expensive pre-existing condition. Since the ACA prohibits insurance companies from discriminating against patients with pre-existing conditions, those with kidney disease now have access to private insurance through the ACA exchanges.

It appears that the AKF and the large dialysis providers may have abused this reform by pushing patients to private plans that generate significantly higher reimbursements for the providers than Medicare or Medicaid, even though private plans may have higher premiums and may not be in the best interest of the patients. The commercial plans reimburse the clinics at significantly higher rates, up to four times more than Medicaid, “adding up to an additional \$200,000 per patient per year.”⁸ Since 2010, DaVita and Fresenius have experienced significant growth in annual profits, bringing in billions of dollars annually.⁹ While private coverage brings higher reimbursement rates and is consistently better for providers, it is not always in the best interest of patients. AKF may provide premium support, but often fails to pay for additional healthcare expenses, such as prescriptions or medical devices. For a patient on a private plan, especially a high deductible plan, these costs could be astronomically higher than if they received insurance from Medicaid or Medicare.

Disturbing Revelations Regarding the American Kidney Fund’s Practices

Based on recent investigative reporting and legal challenges, AKF and its donors’ practices appear to be clear violations of OIG’s 1997 Advisory Opinion and may be putting patients’ lives at risk. In short, the dialysis providers providing the biggest donations seem to exert significant influence on how AKF distributes its financial assistance to patients and clinics.

In 2016, the New York Times published a detailed report about AKF’s practices, including personal anecdotes from various social workers who had reached out to AKF to request financial assistance. One patient advocate informed the New York Times that “Each time ... the charity’s workers later demanded that the clinic make a donation that at a minimum covered the amount it

⁶ Ibid.

⁷ Karch, Lauren. “Dialysis Patients’ Use of Charitable Funds Questioned in Kickback Investigation.” *Nonprofit News | Nonprofit Quarterly*, 19 Jan. 2017, nonprofitquarterly.org/dialysis-patients-use-of-funds-questioned/.

⁸ Reed Abelson and Katie Thomas. “Dialysis Chains Receive Subpoenas Related to Premium Assistance.” *The New York Times*, 7 Jan. 2017, www.nytimes.com/2017/01/06/business/american-kidney-fund-fresenius-davita-subpoena.html.

⁹ “Fresenius Medical Care Gross Profit 2006-2019: FMS.” *Macrotrends*, www.macrotrends.net/stocks/charts/FMS/fresenius-medical-care-ag-kgaa/gross-profit; DaVita Medical Care Gross Profit 2006-2019: FMS.” *Macrotrends*, <https://www.macrotrends.net/stocks/charts/DVA/davita/gross-profit>; American Renal Association AG KGaA Gross Profit 2006-2019: FMS.” *Macrotrends*, <https://www.macrotrends.net/stocks/charts/ARA/american-renal-associates-holdings/gross-profit>.

had paid for the patient's premium. If he did not pay, he said he had been told, the patient risked losing the financial help from the charity for his insurance."¹⁰

One social worker, unaffiliated with a clinic donating to AKF, received an email responding to a request for support in which an AKF staff person attached a set of guidelines he asked her to review. "If your company cannot make fair and equitable contributions," the guidelines read, "we respectfully request that your organization not refer patients."¹¹

According to a lawsuit in Massachusetts brought against American Renal Associates,

"As recently as 2016, AKF had posted its HIPP Guidelines, which included a section describing the "HIPP Honor System" on its website. In that section, AKF set forth its requirement that "each referring dialysis provider should make equitable contributions to the HIPP pool" and that each provider should 'reasonably determine its 'fair share' contribution to the pool [i.e., the funds available for premium assistance] by considering the number of patients it refers to HIPP.' AKF emphasized that all providers had an 'ethical obligation to contribute their respective 'fair share' to ensure that the HIPP pool is adequately funded.' And AKF instructed providers that '[i]f your company cannot make fair and equitable contributions, we respectfully request that your organization not refer patients to the HIPP program.'"¹²

Sometime after the publication of the New York Times article, AKF removed language about this "fair share" requirement from its guidelines. While this "fair share" practice is no longer formally included in the HIPP program guidelines, reports from the New York Times, the Los Angeles Times, and social workers across the country assert that AKF is continuing to discriminate against patients at non-donor clinics.¹³

Insurers have also brought civil suits, which have since been settled, against DaVita in Pennsylvania and against American Renal Associates in Massachusetts and Florida.¹⁴ Additionally, on February 1, 2017, a securities class action lawsuit was filed against DaVita alleging that it "made false and/or misleading statements and/or failed to disclose its scheme to steer patients into unneeded insurance plans in order to maximize profits, using the AKF to facilitate the improper practices."¹⁵ The court denied DaVita's motion to dismiss the case on March 28, 2019 and the case is still ongoing.¹⁶

¹⁰ Reed Abelson and Katie Thomas. "Dialysis Chains Receive Subpoenas Related to Premium Assistance." *The New York Times*, The New York Times, 7 Jan. 2017, www.nytimes.com/2017/01/06/business/american-kidney-fund-fresenius-davita-subpoena.html.

¹¹ Thomas, Katie, and Reed Abelson. "Kidney Fund Seen Insisting on Donations, Contrary to Government Deal." *The New York Times*, 25 Dec. 2016, www.nytimes.com/2016/12/25/business/kidney-fund-seen-insisting-on-donations-contrary-to-government-deal.html.

¹² United States District Court of Massachusetts, Case 1:18-cv-10622-ADB.

¹³ "The Profiteering Dialysis Industry Made Big Bucks from Killing Proposition 8. Here's How." *Los Angeles Times*, 9 Nov. 2018, www.latimes.com/business/hiltzik/la-fi-hiltzik-dialysis-20181109-story.html.

¹⁴ Court of Common Pleas of Montgomery County, PA, Case 17-07795-0.

¹⁵ "DAVITA INVESTIGATION INITIATED by Former Louisiana Attorney General: Kahn Swick & Foti, LLC Investigates the Officers and Directors of DaVita Inc. - DVA." AP NEWS, Associated Press, 6 Apr. 2019, www.apnews.com/eb2ce6a64714fc884ad655241d3bfbb.

¹⁶ Shareholders Foundation, Inc. "Update: Lawsuit for Investors in Davita Inc (NYSE: DVA) Shares Announced by Shareholders Foundation." GlobeNewswire News Room, 1 Apr. 2019, www.globenewswire.com/news-release/2019/04/01/1790632/0/en/Update-Lawsuit-for-Investors-in-Davita-Inc-NYSE-DVA-shares-announced-by-Shareholders-Foundation.html.

Discouraging Patient Access to Transplants

Not only do these alleged practices result in unnecessary spending, they may also interfere with the best interest of patients with ESRD. Experts agree that a kidney transplant offers the best outcome for an individual with kidney disease, as a transplant allows the patient to stop dialysis treatments. This outcome hurts the financial interests of dialysis providers, especially if they are receiving high payments from commercial insurers. The lawsuits in Massachusetts and Florida examined this tension between the best interests of patients and the financial interests of the dialysis providers, noting that the dialysis providers “intentionally failed to inform patients that AKF’s premium assistance program (as it existed prior to the filing of this lawsuit) was only available for patients receiving dialysis treatments. Consequently, the patients did not know that they would be ineligible for premium assistance if they sought to cure their condition through a kidney transplant.”¹⁷ This can make it difficult for patients who were steered into high premium private plans to pursue transplants, particularly since patients often must demonstrate proof of ongoing insurance to receive transplants.

On August 18, 2016, the Center for Medicare and Medicaid Services (CMS) issued a request for information (RFI) on “Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans.” In response to comments, CMS issued an interim final rule with comment (IFC) in which the regulator wrote:

“The comments in response to the RFI support the conclusion that, today, enrollment in individual market coverage for which there are third party premium payments is hampering patients’ ability to be determined ready for a kidney transplant. Comments make clear that, consistent with clinical guidelines, in order for a transplant center to determine that a patient is ready for a transplant, they must conclude that the individual will have access to continuous health care coverage. (This is necessary to ensure that the patient will have ongoing access to necessary monitoring and follow-up care, and to immunosuppressant medications, which must typically be taken for the lifetime of a transplanted organ to prevent rejection.) However, when individuals with ESRD are enrolled in individual market coverage supported by third parties, they may have difficulty demonstrating continued access to care due to loss of premium support after transplantation.”¹⁸

The IFC was published in December 2016 and was scheduled to take effect on January 14, 2017, but Judge Amos Mazzant of the U.S. District Court for the Eastern District of Texas granted a request for a temporary restraining order from DaVita, Fresenius, and U.S. Renal Care on January 12, 2017 and permanently suspended the rule on January 25, 2017.¹⁹ Mazzant found that CMS had not appropriately provided public notice for comment on the proposed rule prior to implementation and concluded that CMS did not have good cause to bypass notice and comment in moving from the RFI to the IFC.

¹⁷ United States District Court of Florida, Case 9:16-cv-81180-KAM.

¹⁸ 42 CFR Part 494, Medicare Program; Conditions for Coverage for End-Stage Renal Disease Facilities – Third Party Payment. December 14, 2016. <https://www.govinfo.gov/content/pkg/FR-2016-12-14/pdf/2016-30016.pdf>.

¹⁹ United States District Court for the Eastern District of Texas, Case 4:17-cv-00016-ALM.

Requesting HHS OIG Investigation

The Department of Justice is currently investigating pharmaceutical companies' financial support of charities that provide assistance to patients seeking support to cover out-of-pocket costs.²⁰ I request that the OIG (possibly in conjunction with the Department of Justice) undertake a similar investigation into the practices of the American Kidney Fund and its effects on the patients whose lives they may be putting at risk. In this investigation I request that you consider:

1. Whether or not AKF favors providers that donate funds to AKF;
2. Whether or not AKF terminates support for patients after they seek transplants; and
3. Whether or not AKF has violated anti-kickback laws in their practices.

During this time, I request that OIG suspend its agreement with the AKF and all relevant companies in order to reevaluate the legality of this agreement and the effects that it has on patients' ability to access affordable, quality ESRD care.

This would not be the first time that the OIG has rescinded an advisory opinion addressing concerns regarding a previously issued advisory opinion. In April 2006, the OIG published Advisory Opinion 06-04 for the Caring Voice Coalition (CVC).²¹ CVC was similarly providing financial assistance for premium and cost-sharing obligations, though in this case they were funded by pharmaceutical companies and were providing assistance to patients who were unable to afford prescriptions manufactured by the companies donating to CVC.

In November 2017, the OIG rescinded Advisory Opinion 06-04, based on the charity's "failure to fully, completely, and accurately disclose all relevant and material facts to OIG."²² The letter states that CVC "provided patient-specific data to one or more donors that would enable the donor(s) to correlate the amount and frequency of their donations with the number of subsidized prescriptions or orders for their products, and (ii) allowed donors to directly or indirectly influence the identification or delineation of Requestor's disease categories."²³ I ask that you consider ways to ensure patients' continued access to care with your partners throughout HHS during this time. I hope that this can complement the Administration's efforts to drive down the cost of care for patients with ESRD, improve the quality of treatment, and increase the number of transplants.

Sincerely,



Representative Katie Porter

²⁰ Raymond, Nate. "Drug Charity Halts Patient Aid after U.S. Health Agency Pulls Approval." Reuters, 5 Jan. 2018, www.reuters.com/article/us-usa-healthcare-charity-idUSKBN1EU1V6.

²¹ HHS OIG, Advisory Opinion No. 06-04. (2006). <https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpnRescission06-04.pdf>

²² "Increased Scrutiny of Patient Assistance Programs: Enforcement Overview and Considerations." K&L Gates, 20 Mar. 2018, m.klgates.com/increased-scrutiny-of-patient-assistance-programs-enforcement-overview-and-considerations-03-20-2018/.

²³ HHS OIG, Advisory Opinion No. 06-04. (2006). <https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpnRescission06-04.pdf>.

CERTIFICATE OF SERVICE

Case Name: **Jane Doe, et al v. Xavier
Becerra, et al.**

Case No.: **8:19-cv-2105-DOC-(ADSx)**

I hereby certify that on November 25, 2019, I electronically filed the following documents with the Clerk of the Court by using the CM/ECF system:

DECLARATION OF AMIE L. MEDLEY IN OPPOSITION TO MOTION FOR PRELIMINARY INJUNCTION

I certify that **all** participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

I declare under penalty of perjury under the laws of the State of California the foregoing is true and correct and that this declaration was executed on November 25, 2019, at Los Angeles, California.

Colby Luong
Declarant

/s/ Colby Luong
Signature