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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-kga/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/ebe2ce6a64714fc884ad655241d3bfbb.

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>.