KATIE PORTER
Putting Orange County families first

Dying on Dialysis: Inside an Industry Putting Profits Over Patients

Report by the Office of Congresswoman Katie Porter (CA-45)

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Executive Summary

On July 23, 2019, **Representative Katie Porter sent a letter to the Department of Health and Human Services (HHS) Office of the Inspector General requesting that the agency open an investigation into the relationship of the American Kidney Fund (AKF) with leading dialysis providers**, specifically, DaVita and Fresenius Medical Care. This letter was based on troubling evidence suggesting that **these providers and AKF have collaborated to implement practices that benefit their bottom line at the expense of patients with kidney disease**.

This staff report—based on additional investigation and documents obtained by Rep. Porter's office, academic studies, and unsealed whistle-blower lawsuits—provides **significant new support for opening such an OIG investigation**. The evidence outlined below reveals practices that may interfere with patients' ability to receive kidney transplants, raise premiums, lead patients to enroll in plans that include less comprehensive coverage or higher out-of-pocket costs, and destabilize the private insurance market.

> **"Recent reports and this investigation suggest that AKF's for-profit benefactors are inappropriately steering patients to private insurance plans rather than Medicare or Medicaid, as the dialysis companies can receive up to four times more from the private plans for the very same dialysis treatment."**

Specifically, credible concerns exist about **possible conflicts of interest involving the structure and practices of AKF's patient assistance program**, in which dialysis clinics donate to AKF and provide dialysis treatment for patients whose insurance premiums were paid by AKF and in return receive payments many times the size of their donations from the patients' insurance. Recent reports and this investigation suggest that **AKF's for-profit benefactors are inappropriately steering patients to private insurance plans rather than Medicare or Medicaid, as the dialysis companies can receive up to four times more from the private plans for the very same dialysis treatment**. This not only distorts the health insurance market,[1] but more importantly it can make it more difficult for patients to get the kidney transplants they need and result in higher patient costs.

This report concludes that these developments – combined with Centers for Medicare and Medicaid Services (CMS) research and the major changes to the private health insurance market for those with kidney disease as a result of the Affordable Care Act's prohibition on insurers discriminating against patients with pre-existing conditions – warrant the Office of the Inspector General revisiting the conclusions of the 1997 Advisory Opinion that permitted the operation of the AKF's Health Insurance Premium Program (HIPP).[2] **It is also time for CMS to take action to bring transparency and accountability to third party premium payments through the rulemaking process**.[3]

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[1] Stephanie Hedt, "Dialysis Costs the Healthcare System Three Times More in the Individual Market." USC Leonard Schaeffer Center For Health Policy & Economics. https://healthpolicy.usc.edu/article/dialysis-costs-the-healthcare-system-3x-more-in-the-individual-market/.

[2] HHS OIG. Advisory Opinion No. 97-01. (1997). https://oig.hhs.gov/fraud/docs/advisoryopinions/1997/kdp.pdf

[3] CMS FACT SHEET: PROMOTING TRANSPARENCY AND APPROPRIATE COVERAGE FOR DIALYSIS PATIENTS, Centers for Medicare and Medicaid Services, Department of Health and Human Services. https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/downloads/esrd-ifc-factsheet-final-2-12-12-16.pdf.

End Stage Renal Disease and Dialysis Treatment

People whose kidneys are failing, otherwise known as a condition called end stage renal disease (ESRD), require dialysis treatment, which performs the functions otherwise performed by the kidneys.[4] A dialysis machine removes blood from the patient, cleans the blood as a healthy kidney would, and then gives the blood back to the patient. Dialysis usually involves treatments several times a week for several hours at a time.[5] **For patients with ESRD, there are few other options for care other than dialysis or kidney transplants**.[6]

In 1973, **President Richard Nixon signed legislation to ensure that patients with ESRD could afford dialysis care by making patients, regardless of their age, eligible for Medicare coverage**.[7] Starting in 1983, Medicare paid dialysis facilities a set rate for dialysis treatment. In 2011, Medicare began paying for dialysis care using a bundled, prospective payment system that "is intended to cover all operating and capital costs that efficient providers would incur in furnishing dialysis treatment episodes in dialysis facilities or in patients' homes."[8] Medicare spends more than $12.9 billion per year on dialysis treatments alone.[9]

Most patients with ESRD are low-income. According to a Loyola University Chicago Stritch School of Medicine study, the percentage of adults beginning dialysis treatment who live in zip codes with high poverty rates rose from 27.4% to 34% from 1995 to 2010.[10] At the same time, the general population beginning dialysis treatment saw a much smaller increase, from 11% to 12.5%.[11] Many ESRD patients have multiple health conditions, as ESRD is related to various other health concerns that cause the kidneys to deteriorate.

"Compared with white Americans, Black Americans are about 3.7 times more likely to have ESRD."

As a result of the Affordable Care Act (ACA), Medicaid expansion has improved dialysis patients' access to affordable care, particularly for patients with lower incomes. Many ESRD patients are "dual eligibles," and can enroll in both Medicaid and Medicare. **In the first three years of the ACA's implementation, the number of patients with ESRD who died within their first year of treatment decreased in expansion states, while it remained stagnant or worsened in non-expansion states**.[12]

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[4] "Dialysis | Hemodialysis | Peritoneal Dialysis." *MedlinePlus*, U.S. National Library of Medicine, 27 Dec. 2018, medlineplus.gov/dialysis.html.
[5] "What Is Dialysis?" National Kidney Foundation, 2 July 2018, www.kidney.org/atoz/content/dialysisinfo.
[6] "End Stage Renal Disease (ESRD)." *Johns Hopkins Medicine*, The Johns Hopkins University, www.hopkinsmedicine.org/health/conditions-and-diseases/end-stage-renal-failure.
[7] Eggers, Paul W. "Medicare's End Stage Renal Disease Program." *National Center for Biotechnology Information*, National Institutes of Health, United States Department of Health and Human Services, 2000, www.ncbi.nlm.nih.gov/pmc/articles/PMC4194691/.
[8] Medicare Payment Advisory Commission. *Outpatient Dialysis Services Payment System*. Washington, DC: Medicare Payment Advisory Commission; 2019. medpac.gov/docs/default-source/reports/mar21_medpac_report_to_the_congress_sec.pdf#page=197.
[9] Ibid.
[10] Loyola University Health System. "More dialysis patients living in poor neighborhoods." ScienceDaily. ScienceDaily, 15 June 2015. <www.sciencedaily.com/releases/2015/06/150615162902.htm>.
[11] Preidt, Robert. "U.S. Dialysis Patients Increasingly Live in Poor Areas." *Consumer HealthDay*, HealthDay, 24 June 2015, consumer.healthday.com/diseases-and-conditions-information-37/misc-kidney-problem-news-432/u-s-dialysis-patients-increasingly-live-in-poor-areas-700497.html.
[12] Swaminathan, Shailender, et al. "Association of Medicaid Expansion With 1-Year Mortality Among Patients With End-Stage Renal Disease." Journal of the American Medical Association, vol. 320, no. 21, 2018, p. 2242., doi:10.1001/jama.2018.16504.

> **"Early reports found that up to 30% of patients hospitalized with COVID-19 in China and New York developed kidney problems, often severe enough to require dialysis."**

Throughout the world, but especially in the United States, **ESRD disproportionately harms people of color**. Compared with white Americans, Black Americans are about 3.7 times more likely to have ESRD.[13] This disparity showcases one of the major inequities in our health care system: **Black Americans are 3.5 times more likely to progress from early stage kidney disease to kidney failure (ESRD).**[14] **In the Latinx community, ESRD is about twice as common as it is for white communities.**[15] And research shows that people who suffered from severe cases of COVID-19— which also disproportionately harmed people of color[16]—are showing serious signs of kidney damage. **Early reports found that up to 30% of patients hospitalized with COVID-19 in China and New York developed kidney problems, often severe enough to require dialysis.**[17]

The Dialysis Industry's "Duopoly" and Disregard for Patients

Since 1973, the nation's largest dialysis providers have seen record profits while rapidly consolidating. The number of patients receiving insurer-covered dialysis treatment has risen from 65,700 in 1982 to more than 500,000 in 2019. Despite this growth in treatment, nonprofit, independently owned, and hospital-based dialysis facilities have disappeared over time, as for-profit dialysis facilities affiliated with large dialysis organizations (LDOs) have consolidated power and money in the industry.[18]

> **"Since 1973, the nation's largest dialysis providers have seen record profits while rapidly consolidating."**

Recent research published in the Journal of the American Medical Association (JAMA) found that "in 1995, 41% of all dialysis facilities were affiliated with 7 LDOs, which increased to 63% in 2005 when consolidation reduced the number of LDOs to 5. **This consolidation trend has continued to the point where the dialysis industry today can be characterized as a duopoly—with 2 corporations that together own nearly 70% of dialysis facilities in the United States.**"[19] Those two corporations are DaVita and Fresenius.

The Herfindahl-Hirschman index (HHI) is a commonly used measure of market concentration by the Department of Justice

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[13] Jenna M. Norton, et al.,"Social Determinants of Racial Disparities in CKD." Journal of the American Society of Nephrology Sept. 2016, https://jasn.asnjournals.org/content/27/9/2576.
[14] Jenna M. Norton, et al.,"Social Determinants of Racial Disparities in CKD." Journal of the American Society of Nephrology Sept. 2016, https://jasn.asnjournals.org/content/27/9/2576.
[15] Michael J. Fischer, et al., "CKD Progression and Mortality among Hispanics and Non-Hispanics." Journal of the American Society of Nephrology, Nov. 2016, https://jasn.asnjournals.org/content/27/11/3488.
[16] Health Equity Considerations and Racial and Ethnic Minority Groups. Centers for Disease Control and Prevention, Updated Apr. 19, 2021, https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html.
[17] C. John Sperati, "Coronavirus: Kidney Damage Caused by COVID-19." Johns Hopkins Medicine, May 14, 2020, https://www.hopkinsmedicine.org/health/conditions-and-diseases/coronavirus/coronavirus-kidney-damage-caused-by-covid19.
[18] Wang, Virginia, and Matthew L. Maciejewski. "Patient Outcomes and Dialysis Consolidation—Two Big to Fail?" *JAMA*, vol. 2, no. 5, 2019, doi:10.1001/jamanetworkopen.2019.3962.
[19] Ibid.

(DOJ).[20] The index ranges from less than 1 to 10,000. Increases in the index generally indicate a decrease in competition and increase in market power. **The Department of Justice defines a highly concentrated market at 2,500. A 2016 study published in the International Journal of Health Economics and Management estimated that the average HHI for outpatient dialysis services at the county level was 4,778.[21] In the state of California, the average HHI is over 6,000.[22]**

	DaVita	Fresenius	All Other
Number of Dialysis Clinics	279	127	191
Percent of Total Dialysis Clinics	46.7%	21.3%	32.0%
Total Stations	6,055	2,689	3,765
Percent of Total Stations	48.4%	21.5%	30.1%

Source: Dialysis Facility Compare Sets from CMS (2017)

This lack of competition combined with a focus on profits to the detriment of patients can have sharply negative results. A recently published academic study found that **Medicare per-treatment reimbursement increased by 6.9% at facilities acquired by large dialysis chains while patients experienced worse outcomes at these facilities.**[23] Additionally, for nearly every dimension of patient care measured, patient outcomes were worse at the facility after the acquisition, "most prominently in terms of fewer kidney transplants, more hospitalizations, and lower survival rates." The study found that independent facilities acquired by large chains end up replicating the business practices of the acquiring organization, including replacing high-skill nurses with lower-skill dialysis technicians, increasing the patient-load of each employee, and increasing the number of patients treated at each dialysis station, all of which potentially reduce the quality of care delivered to patients.[24] Moreover, "overall Medicare spending increases at acquired facilities, mostly as a result of higher drug reimbursements," meaning **taxpayer dollars are not being put to their best use.** Additional JAMA research found that independently owned dialysis facilities acquired by LDOs often had slower decreases in mortality and hospitalization rates than

"Additionally, for nearly every dimension of patient care measured, patient outcomes were worse at the facility after the acquisition, 'most prominently in terms of fewer kidney transplants, more hospitalizations, and lower survival rates.'"

[20] "Herfindahl-Hirschman Index." *Justice.Gov*, The United States Department of Justice, 31 July 2018, www.justice.gov/atr/herfindahl-hirschman-index.
[21] Wilson, Nathan E. "For-profit status and industry evolution in health care markets: evidence from the dialysis industry." International journal of health economics and management 16, no. 4 (2016): 297-319.
[22] "Datasets: Data.Medicare.gov." *Data.Medicare.Gov*, Centers for Medicare and Medicaid Services, 2018, data.medicare.gov/data/dialysis-facility-compare.
[23] P.J. Eliason, B. Heebsh, R.C. McDevitt, J.W. Roberts. (2019). *How Acquisitions Affect Firm Behavior and Performance: Evidence from the Dialysis Industry. https://economics.harvard.edu/files/economics/files/ms29704.pdf*
[24] Ibid.

would have otherwise occurred for the independently owned facilities.[25]

Anecdotal evidence tells a similar story. Megallan Handford, a nurse in a clinic in Fontana, California, told Medscape, that "it doesn't take much to kill a patient on hemodialysis. Just overlook a dislodged needle, and a patient can bleed out in a matter of minutes." He explained, "When you look on the floor and you see a pile of gelled blood, you know you've got a problem."[26] Reports of understaffing in LDOs are common, and place patients in Orange County and across the country at risk. During one ProPublica investigation, researchers "found blood encrusted in the folds of patients' treatment chairs or spattered on walls, floors or ceiling tiles."[27]

One explanation for these adverse patient outcomes may be the profit motives of the large LDOs. **In 2019, DaVita engaged in company stock buybacks in the amount of up to $1.2 billion, which intentionally increase companies' share prices and line the pockets of executives rather than investing in patient care.**[28] During the pandemic, in 2020, DaVita completed another stock buyback of more than $1 billion.[29] **The former CEO of DaVita, Kent Thiry, gave a speech at the University of California, Los Angeles to students where he described DaVita clinics as being similar to the fast food industry – and made clear "to me, it's not about the patients."**[30] In short, DaVita treats the provision of life-saving dialysis care as just another way to make the most money for their product, disregarding the sensitive nature of medical care for those with kidney disease and the substantial taxpayer funding dedicated to it. **According to Thiry, "If I had 1,400 Taco Bells and 32,000 people who worked in them, I would be doing all the same stuff."**[31]

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Though Thiry ended his nearly twenty-year tenure as the CEO of DaVita in May 2019, he remained the Executive Chairman of the company's Board of Investors, leaving in May 2020 to join KKR, a private equity firm.[32] **Current DaVita Board Chair Pamela**

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[25] Erickson, Kevin F., et al. "Association of Hospitalization and Mortality Among Patients Initiating Dialysis With Hemodialysis Facility Ownership and Acquisitions." *JAMA Network Open*, vol. 2, no. 5, 2019, doi:10.1001/jamanetworkopen.2019.3987.
[26] Harrison, Laird. "California First to Address Dialysis Staffing Problems." *Medscape*, 21 Apr. 2017, www.medscape.com/viewarticle/878870#vp_3.
[27] Fields, Robin. "In Dialysis, Life-Saving Care at Great Risk and Cost." *ProPublica*, 9 Mar. 2019, www.propublica.org/article/in-dialysis-life-saving-care-at-great-risk-and-cost
[28] "Improving Health, Health Care and Quality of Life." *DaVita News*, 22 July 2019, pressreleases.davita.com/2019-07-22-DaVita-Commences-Self-Tender-Offer-To-Purchase-For-Cash-Shares-Of-Its-Common-Stock-For-An-Aggregate-Purchase-Price-Of-No-More-Than-1-2-Billion-At-A-Purchase-Price-Of-Not-Less-Than-53-50-Per-Share-And-Not-More-Than-61-50-Per-Share.
[29] DaVita Stock Buybacks (Quarterly), Y Charts, https://ycharts.com/companies/DVA/stock_buyback.
[30] Foley, Katherine Ellen. "John Oliver Ripped into a CEO Who Proudly Compared His Healthcare Business to Taco Bell." *Quartz*, Quartz, 15 May 2017, qz.com/983716/john-oliver-rips-into-fresenius-fms-and-davita-dva-whose-ceo-proudly-compared-kidney-dialysis-to-taco-bell-yum/.
[31] Ibid.
[32] "DaVita CEO Kent Thiry Steps down and Is Named Executive Chair of Board of Directors." *Healio - Nephrology News and Issues*, 30 Apr. 2019, www.healio.com/nephrology/kidney-care-community/news/online/%7Bad74d628-76ef-

Arway has no health care background, joining the company from financial giant American Express.[33] Unfortunately, consolidation in the industry and attitudes like Thiry's have harmed patient outcomes. While in some industries consolidation can increase the provision of a service, LDOs have focused on volume over quality of care in the dialysis space.

Potential Conflicts of Interest That Harm ESRD Patients

The American Kidney Fund's work centers around a patient assistance program, the Health Insurance Premium Program (HIPP), which helps pay insurance premiums for individuals who need dialysis. Specifically, **HIPP covers premiums for Medicare, Medicaid, and private insurance plans.**[34] While this program has benefitted thousands of individuals over the years, **Rep. Porter wrote a letter in July raising concerns about possible conflicts of interest that could result in negative patient outcomes**. In short, dialysis clinics donate to AKF and provide dialysis treatment for patients whose insurance premiums were paid by AKF and in return receive payments many times the size of their donations from the patients' insurance.

> **"In short, dialysis clinics donate to AKF and provide dialysis treatment for patients whose insurance premiums were paid by AKF and in return receive payments many times the size of their donations from the patients' insurance."**

Complaints from patients and providers have yielded reports that the country's largest dialysis providers are "intentionally and illegally" steering Medicare- and Medicaid-eligible patients "into commercial plans by paying their premiums for them through AKF."[35] Doing so increases dialysis center profits. Before the ACA, private insurance coverage was rarely an option because ESRD was an expensive pre-existing condition. Since the ACA prohibits insurance companies from discrimination based on pre-existing conditions, those with kidney disease now have access to private insurance through the ACA exchanges in addition to access to Medicare coverage. As discussed, many ESRD patients are also covered by Medicaid due to the ACA's expansion of eligibility.

It appears that **the large dialysis providers may have abused this reform and HIPP by pushing patients to private plans that generate more profit 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."[36] Since 2010, DaVita and Fresenius have experienced significant growth in annual profits, bringing in billions of dollars annually.[37] In January 2018, at

48fb-9cf1-b6343c64dc0d%7D/davita-ceo-kent-thiry-steps-down-and-is-named-executive-chair-of-board-of-directors.

[33] "Board and Management." *DaVita Inc.* https://investors.davita.com/corporate-governance/board-of-directors

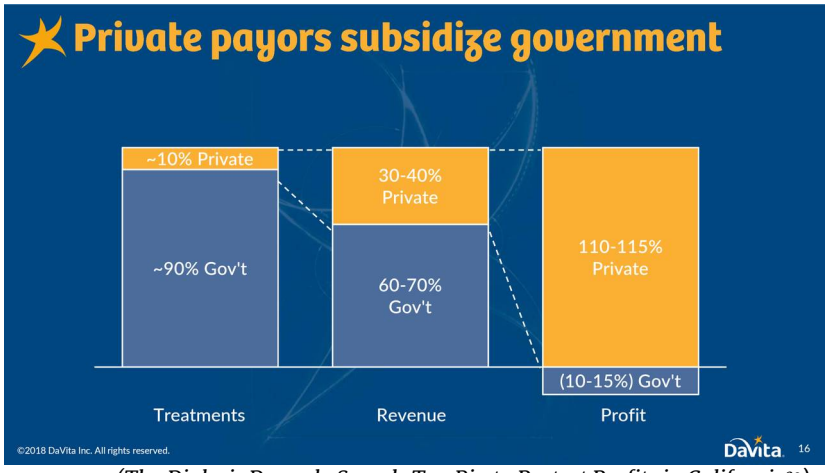
[34] "Health Insurance Premium Program (HIPP)." American Kidney Fund (AKF), www.kidneyfund.org/financial-assistance/information-for-patients/health-insurance-premium-program/.

[35] United States District Court of Colorado, Case 1:17-cv-00304-WJM-NRN.

[36] 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.

[37] "Fresenius Medical Care Gross Profit 2006-2019: FMS." *Macrotrends*,

the annual JP Morgan Healthcare Conference, DaVita displayed the chart below, which shows how the company relies on private plans to make its large profits despite far more patients being enrolled in Medicare.[38]



(The Dialysis Duopoly Spends Too Big to Protect Profits in California[39])

To bring in millions in annual profits, DaVita seeks to have a substantial number of patients in their treatment pool who are not on Medicare or Medicaid. 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 significantly higher than if they received insurance from Medicaid or Medicare**.

Moreover, this steering toward private plans also has potentially life-threatening consequences for patients. **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**.[40] Patient mortality rates increase after the first year of dialysis treatment. While in the first year, the chance of death is only 25%, it rapidly increases to 65% after five years.[41]

Additionally, **the cost per patient drops significantly after patients receive transplants**. Annual dialysis treatments are 3.5 times more expensive than annual post-transplant care. Dialysis treatment costs an average of $89,000 per patient annually in the United States. While the average cost of a kidney transplant is $32,000, post-surgery care and covering other

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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.

[38] Sammon, Alexander. "The Dialysis Duopoly Spends Big to Protect Profits in California." *The American Prospect*, 23 Aug. 2019, prospect.org/article/dialysis-duopoly-spends-big-protect-profits-california.

[39] Ibid.

[40] Wang, Jeffrey H., et al. "Current Status of Kidney Transplant Outcomes: Dying to Survive." *Advances in Chronic Kidney Disease*, vol. 23, no. 5, 2016, pp. 281–286., doi:https://www.srtr.org/media/1102/wang-jh_current-status-of-kidney-transplant-outcomes-dying-to-survive_2016-ackd.pdf.

[41] Foley, Katherine Ellen. "John Oliver Ripped into a CEO Who Proudly Compared His Healthcare Business to Taco Bell." *Quartz*, Quartz, 15 May 2017, qz.com/983716/john-oliver-rips-into-fresenius-fms-and-davita-dva-whose-ceo-proudly-compared-kidney-dialysis-to-taco-bell-yum/.

transplant-related concerns costs an average of $25,000.[42] However, this outcome is not in the financial interests of dialysis providers, who permanently lose patients once they receive transplants, especially if the providers are receiving higher payments from commercial insurers.

To be eligible for transplants, patients need to be able to show continuous access to medical care. Eligible patients on Medicare or Medicaid typically can meet this requirement, but many patients on private plans where premiums are supported by AKF cannot. This is because of an AKF policy that ends premium assistance for patients who receive transplants after a certain amount of time, despite patients needing proof of ongoing insurance in order to be eligible for a transplant. The HIPP guidelines on AKF's website as of September 2019 read that they would continue support "through the end of the insurance coverage plan year for the same insurance policy(ies) in which the patient was enrolled prior to the transplant."[43] Patients do not get to choose when they receive a transplant during their insurance coverage plan year.

"Consider a patient who receives financial assistance from AKF and becomes eligible for a transplant after a year on dialysis. If the patient received a transplant, the patient could cease undergoing dialysis and live a healthy life. But if the patient is denied support from AKF for the transplant, the patient could be forced to remain on dialysis for years. This result is in the interest of the dialysis providers, but it is not in the interest of the patient."

AKF informed Rep. Porter's office that if a patient receives a transplant in the last quarter of the plan year, AKF will continue support into the following plan year. Since that time, there have been no updates that this policy has changed. Still, those who receive a kidney transplant in the third quarter of the insurance plan year have little certainty or security. In contrast, Medicare covers patients for up to three years after transplants.[44]

In discussions with Rep. Porter's office, **AKF also claimed that they cannot continue assistance for longer periods after a patient receives a transplant because of funding concerns.** The effect of the policy, however, is to advance the financial interests of the dialysis providers at the expense of the health interests of the patients. Consider a patient who receives financial assistance from AKF and becomes eligible for a transplant after a year on dialysis. If the patient received a transplant, the patient could cease undergoing dialysis and live a healthy life. But if the patient is denied support from AKF for the transplant, the patient could be forced to remain on dialysis for years. This result is in the interest of the dialysis providers, but it is not in the interest of the patient.

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[42] Schools of Pharmacy and Medicine, Department of Bioengineering and Therapeutic Sciences University of California, San Francisco, The Kidney Project. https://pharm.ucsf.edu/kidney/need/statistics.
[43] "Health Insurance Premium Program (HIPP)." American Kidney Fund (AKF), www.kidneyfund.org/financial-assistance/information-for-patients/health-insurance-premium-program/.
[44] United States Department of Health and Human Services., Centers for Medicare and Medicaid Services. "Medicare Coverage of Kidney Dialysis & Kidney Transplant Services." https://www.medicare.gov/Pubs/pdf/10128-Medicare-Coverage-ESRD.pdf

Rep. Porter's office asked AKF for financial data to support its claim that it could not afford to support patients receiving transplants, but AKF refused to provide this information. According to publicly available information from its 2019 tax filings, the American Kidney Fund received a total of $298,438,440 in contributions.[45] The majority of this funding goes to their patient assistance program. Yet **AKF paid a total of $974,338 in executive compensation, including the salary of $590,795 for CEO LaVarne Burton**.[46] In its federal lobbying filings, the AKF spent nearly $800,000 in 2018 and more than $500,000 in 2019 on lobbying fees, which does not include spending on state and local lobbying.[47] Additionally, it bears noting that Federal Street Strategies, which advocates on behalf of AKF, also lobbies for DaVita.[48]

Revelations Regarding Dialysis Industry Practices

In a whistleblower case unsealed in 2019, former AKF employee David Gonzalez accused the charity of creating a "so-called blocked list" of dialysis clinics whose patients did not receive financial assistance.[49] The 2016 lawsuit was unsealed in August 2019. **The lawsuit alleges that DaVita and Fresenius increased their profits by donating money to the AKF, "so that the patient can obtain government funding for dialysis treatment to be spent on providers."**[50] The case outlines complaints regarding alleged blocking of financial assistance when not requested from a provider that donates to AKF. One such allegation asserts that AKF disposed of applications for financial assistance from patients receiving dialysis at Methodist Hospital in Texas when the hospital would not donate to the program.[51]

"One such allegation asserts that AKF disposed of applications for financial assistance from patients receiving dialysis at Methodist Hospital in Texas when the hospital would not donate to the program"

The whistleblower was asked to ensure that patients at clinics operated by DaVita and Fresenius were approved.[52] The *New York Times* reported that:

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[45] "American Kidney Fund Inc - Nonprofit Explorer." *ProPublica*, projects.propublica.org/nonprofits/organizations/237124261.
[46] Ibid.
[47] "Lobbying Spending Database - American Kidney Fund, 2018." *OpenSecrets.org*, www.opensecrets.org/lobby/clientsum.php?id=D000046966&year=2018.
[48] "Lobbying Spending Database – Federal Street Strategies, 2018." *OpenSecrets.org*, https://www.opensecrets.org/lobby/firmsum.php?id=F222086&year=2018.
[49] Abelson, Reed, and Katie Thomas. "Top Kidney Charity Directed Aid to Patients at DaVita and Fresenius Clinics, Lawsuit Claims." *The New York Times*, The New York Times, 2 Aug. 2019, www.nytimes.com/2019/08/02/health/kidney-dialysis-kickbacks.html.
[50] Tozzi, John. *DaVita, Fresenius Broke Kickback Rules, Whistleblower Says*. Bloomberg, 2 Aug. 2019, www.bloomberg.com/news/articles/2019-08-02/davita-fresenius-violated-kickback-rules-whistleblower-says.
[51]Livingston, Shelby. *Whistleblower Alleges DaVita, Fresenius Involved in Kickback Scheme*. Modern Healthcare, 2 Aug. 2019, www.modernhealthcare.com/legal/whistleblower-alleges-davita-fresenius-involved-kickback-scheme.
[52] Abelson, Reed, and Katie Thomas. "Top Kidney Charity Directed Aid to Patients at DaVita and Fresenius Clinics, Lawsuit Claims." *The New York Times*, The New York Times, 2 Aug. 2019, www.nytimes.com/2019/08/02/health/kidney-dialysis-kickbacks.html.

> The lawsuit . . . says **the charity went to great lengths to ensure no aid was given to patients at clinics that were not donors**. Mr. Gonzalez said in his lawsuit that the charity began formally tracking donors in 2009, labeling those clinics that did not contribute as "free riders."
>
> When the charity was criticized for its use of a "blocked list" of clinics, it changed the name to "training list," according to the lawsuit. The charity would contact these clinics to request donations in specific amounts, calculated by looking at the payments made to patients at these clinics.[53]

In statements to the press and Hill offices, **DaVita has implied that DOJ's decision not to intervene proves it did nothing wrong. Not so. As the OIG told Rep. Porter's staff, a decision not to intervene is not a ruling on the merits of a case**. Indeed, even after DOJ has declined to intervene, whistleblowers have gone on to win large recoveries for the government.[54] In conversations with Rep. Porter's office and AKF, DaVita made similar claims, further asserting that "the DOJ and OIG (the Office of the Inspector General) fully investigated all of these related allegations and announced that no action would be taken by the government. . . Nothing in this unsealed document is new." This is a misleading characterization of the DOJ's decision not to intervene. The decision not to take action is a commonplace practice and does not imply that the defendant is fully absolved of anything alleged in the suit. Rep. Porter's office reached out to the Office of the Inspector General to further discuss the agency's involvement with the "full" investigation. OIG noted that DOJ's choice to decline to intervene in the case is, by definition, not a ruling on the merits of the case.

"AKF asks participating providers to sign a 'Code of Conduct.' But signing is voluntary, and AKF has informed Rep. Porter's office that it has no enforcement mechanism in place to ensure the Code is followed."

Similarly, the American Kidney Fund's President and Chief Executive Officer, LaVarne Burton, stated, "We now know that this suit was brought by a former employee who, prior to making this complaint, was terminated for cause. AKF strictly adheres to the federal advisory opinion that governs our charitable premium assistance program, and we have in place strict safeguards and conflict of interest policies to ensure that."[55] Rep. Porter's office asked AKF for copies of the "strict safeguards and conflict of interest policies" that they employ. At the request AKF provided the OIG compliance guidelines, a Code of Conduct for dialysis providers, and AKF's internal guardrails. These resources are intended to help providers participating in HIPP follow Advisory Opinion 9701. AKF's internal guardrails are not included out of respect for AKF's request that they remain confidential; however, Rep. Porter's office concluded that the guardrails are inadequate for ensuring compliance with Advisory Opinion 97-01.

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[53] Abelson, Reed, and Katie Thomas. "Top Kidney Charity Directed Aid to Patients at DaVita and Fresenius Clinics, Lawsuit Claims." *The New York Times*, The New York Times, 2 Aug. 2019, www.nytimes.com/2019/08/02/health/kidney-dialysis-kickbacks.html.
[54] Tozzi, John. *DaVita, Fresenius Broke Kickback Rules, Whistleblower Says*. Bloomberg, 2 Aug. 2019, www.bloomberg.com/news/articles/2019-08-02/davita-fresenius-violated-kickback-rules-whistleblower-says.
[55] Ibid.

AKF asks participating providers to sign a "Code of Conduct." But signing is voluntary, and AKF has informed Rep. Porter's office that it has no enforcement mechanism in place to ensure the Code is followed. The Code of Conduct is intended to be a set of guidelines for providers ("Companies") participating in HIPP. The "Company" reading and signing the Code of Conduct is, in the case of large dialysis providers like DaVita, the company itself and not each of its individual clinics. As of September 2018, DaVita "operated or provided administrative services at 2,625 outpatient dialysis centers located in the United States serving approximately 201,000 patients."[56] **AKF was unable to tell Rep. Porter's office if the Code of Conduct is shared with all staff at each of DaVita's clinics**.

Point 10 of the Code of Conduct states that the Company understand[s] that if AKF has reason to suspect any of our employees of violating this Code of Conduct, AKF will immediately notify the Company's compliance officer." **Rep. Porter's office inquired if AKF had ever investigated any of the reports that "Company" employees were violating the Code of Conduct in relation to the reporting published in the *Los Angeles Times, Washington Post,* and *New York Times*. AKF responded in an email, "We generally cannot discuss personnel matters. Having said that, many of the referenced articles have been either simply not true or are opinion pieces masquerading as news."**

The whistleblower case is not the only litigation alleging that **the major LDOs are responsible for a clearly articulated and well documented plan to push patients toward commercial plans and away from Medicare and Medicaid**. Allegations in another lawsuit brought against American Renal Associates (ARA) by UnitedHealth Group explain the ways in which AKF enables this process:

> 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.'**[57]

[56] "About DaVita® Kidney Care 2018." *DaVita News*, 2018, pressreleases.davita.com. pressreleases.davita.com › download › About+DaVita+Kidney+Care+2018

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

ARA settled this lawsuit and a similar lawsuit for $32 million.[58] Sometime after public reports emerged about this "fair share" requirement, AKF removed this language from its guidelines. Rep. Porter's office obtained the previous guidelines, which clearly include the fair share policy. While this "fair share" practice is no longer formally included in the HIPP program guidelines, **the *New York Times*, the *Los Angeles Times*, and social workers across the country assert that AKF continues to discriminate against patients at non-donor clinics.**[59] Insurers have also brought civil suits, which have since been settled, against DaVita in Pennsylvania.[60]

"The *New York Times*, the *Los Angeles Times*, and social workers across the country assert that AKF continues to discriminate against patients at non-donor clinics."

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."[61] The court denied DaVita's motion to dismiss the case on March 28.[62] The securities class action suit revealed documents showing how **"DaVita tracked the acquisition of 'private pay' patients at its facilities, incentivized patient steering by offering bonuses to employees, prepared training and instructional materials for employees that disparaged Medicare and Medicaid, and designed materials to convince patients that Medicare and Medicaid were worse options than private insurance."**[63] Further, the plaintiffs cited comments from DaVita insurance counselors who would "assure ESRD patients that they would 'preapprove them for AKF' charitable premium assistance."[64]

"Receiving a transplant is nearly always the best option for a patient with ESRD, but if they do so while receiving premium assistance, they could be left on a healthcare plan they are unable to afford."

Perhaps most notably, DaVita confirmed in this lawsuit that it would lose $450 million in operating income if AKF stopped providing patients with assistance for commercial non-ACA plans.[65] Bringing in ACA plan

[58] Sweeney, Evan. "American Renal Associates Pays $32M to Settle Fraud Accusations from UnitedHealth." FierceHealthcare, 12 July 2018, www.fiercehealthcare.com/payer/american-renal-associates-unitedhealthcare-32m-settlement-premium-assistance.
[59] "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.
[60] Court of Common Pleas of Montgomery County, PA, Case 17-07795-0.
[61] "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.
[62] Shareholders Foundation, Inc. "Update: Lawsuit for Investors in Davita Inc (NYSE: DVA) Shares Announced by Shareholders Foundation." GlobeNewswire Newsroom, 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.
[63] United States District Court of Colorado, Case 1:17-cv-00304-WJM-NRN.
[64] Ibid.
[65] Ibid.

assistance as well, third-party reports found that as much as "60-80% of DaVita's earning derived from its AKF relationship."[66] In September 2020, DaVita and the parties entered into a settlement agreement for $135 million.[67] The Court granted final approval of the Settlement on April 13, 2021.[68]

These lawsuits make plain the tension between the best interests of patients and the financial interests of the dialysis providers. Dialysis providers appear to have, as described in one of the cases, "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**."[69] This can make it difficult for patients who were steered into high premium private plans to pursue transplants, particularly since—as noted above and as CMS has stated—patients often must demonstrate proof of ongoing insurance to receive transplants. **Receiving a transplant is nearly always the best option for a patient with ESRD, but if they do so while receiving premium assistance, they could be left on a healthcare plan they are unable to afford**.

An administrator at an independent clinic told the *New York Times* that AKF "demanded that [his] 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 revelations in these lawsuits also reinforce the findings from media reports, state legislative hearings, and information gathered by CMS about AKF's practices, including the personal experiences of a number of social workers who had requested financial assistance from AKF.[70] **An administrator at an independent clinic told the *New York Times* that AKF "demanded that [his] 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."**[71]

Laura Fiallos worked in a DaVita clinic in Pasadena Foothills, California as an administrative assistant and insurance specialist for nearly twelve years until 2016. She testified about her experience before the California State Senate on July 3, 2019[72]:

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[66] Ibid.
[67] DaVita, Inc. Settles Shareholder Class Action for $135 Million, ISS Insights, October 2020, https://insights.issgovernance.com/posts/davita-inc-settles-shareholder-class-action-for-135-million/.
[68] Case Summary: DaVita Inc. Securities Litigation, Securities Class Action Clearinghouse, Stanford Law School, April 13, 2021, https://securities.stanford.edu/filings-case.html?id=106035.
[69] United States District Court of Florida, Case 9:16-cv-81180-KAM.
[70] 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.
[71] Ibid.
[72] "Senate Health Committee, Wednesday, July 3rd, 2019." 2019. https://www.senate.ca.gov/media/senate-health-committee-20190703/video

> [B]efore the annual open enrollment period a few years ago, I was assigned to a new team that was instructed to persuade dialysis patients to apply for individual market health insurance plans, for which the American Kidney Fund would pay the premiums. **I was given a list of patients and told to approach them at the dialysis clinic and persuade them.**[73]

AKF denies these reports as hearsay and "inaccuracies," yet information from CMS buttresses these allegations.[74] In 2016, CMS issued a request for information regarding third party premium payments in the dialysis industry. One social worker employed by two California-based DaVita clinics wrote to CMS:

> They asked us to "educate" the patients with marketing material DaVita designed specifically to entice the patient into enrolling in a secondary private payer plan with the promise of being able to travel outside of the state and improved chances of passing financial clearance for kidney transplant. DaVita also assured our most vulnerable population of patients that they would not have to worry about paying their health insurance premium because our Insurance Counselors would preapprove them for the AKF HIPP Grant.[75]

Another social worker, who was unaffiliated with a clinic donating to AKF, also told CMS about AKF's misconduct. When a patient requested support from AKF, AKF sent the social worker a set of guidelines. "If your company cannot make fair and equitable contributions," the guidelines read, "we respectfully request that your organization not refer patients."[76]

Flaws in the 1997 Advisory Opinion Allowing AKF's Patient Assistance Program

On July 23, 2019, **Rep. Porter requested that the Office of the Inspector General revisit Advisory Opinion 97-01, which AKF requested and received in 1997.** AKF requested this opinion out of concern that receiving funds from dialysis providers could be considered an impermissible violation of federal anti-kickback laws designed to prevent financial conflicts from interfering in the referrals and advice provided by medical providers.

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[73] Ibid.
[74] 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.
[75] Request for Information: Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans (CMS-6074-NC). https://www.regulations.gov/docket?D=CMS-2016-0145.
[76] Ibid.

The advisory opinion outlined conditions under which HHS would choose to exercise its enforcement discretion and not find this arrangement between AKF and the for-profit dialysis providers unlawful.[77] These conditions include treating all patient applications for assistance equally – regardless of the type of insurance patients have or whether the clinics from which they receive treatment donate to AKF. **In the advisory opinion, the HHS Office of the Inspector General 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."**[78] Essentially, AKF is not allowed to take into consideration whether or not a patient was receiving care at a provider that supported AKF financially.

In the advisory opinion, the HHS Office of the Inspector General 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."

A lot has changed since the advisory opinion was issued over 20 years ago. 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 10 percent" was provided by the major dialysis providers.[79] **Based on AKF's 2018 990 tax form, AKF's current donations are 60 times larger than they were in 1997. Moreover, the vast majority of them – nearly 80% – come from DaVita and Fresenius.**[80] 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.[81] **Because of their larger market share, the likelihood of any given AKF dollar returning to these two providers is fairly high, even were AKF technically in compliance with the advisory opinion**.

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[77] HHS OIG. Advisory Opinion No. 97-01. (1997). https://oig.hhs.gov/fraud/docs/advisoryopinions/1997/kdp.pdf
[78] Ibid.
[79] Ibid.
[80] 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/.
[81] 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.

"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."

Most concerning is the potential adverse impact on patients that result from steering patients from Medicare and Medicaid to private plans. This was essentially impossible in 1997 because private plans would reject dialysis patients through the underwriting process.

CMS recognized the changed circumstances in 2016 and 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). This rule would have established new "Conditions for Coverage" standards for dialysis facilities. The standard would have applied to any third-party premium payments, including "dialysis facility making premium payments for individual market health plans, whether directly, through a parent organization (such as a dialysis corporation), or through another entity (including by providing contributions to entities that make such payments)."[82] Dialysis facilities subject to the new standard would be required to educate patients about all of their coverage options. CMS 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**.[83]

The IFC was published in December 2016 and would have taken effect on January 14, 2017, but **Judge Amos Mazzant of the U.S. District Court for the Eastern District of Texas postponed the implementation of the rule pending consideration of a request for a temporary restraining order from dialysis providers**.[84] Mazzant ultimately enjoined CMS from enforcing the rule, concluding that CMS failed to provide adequate public notice for comment on the proposed rule and lacked good cause to issue an IFC without notice and comment.[85]

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[82] 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.
[83] Ibid.
[84] United States District Court for the Eastern District of Texas, Case 4:17-cv-00016-ALM.
[85] Ibid.

Rep. Porter asked that the Inspector General revisit and update Advisory Opinion 97-01 as necessary rather than rescind it, since she understands the consequences that rescinding would have on patients currently receiving premium assistance. If OIG chooses to rescind the opinion in its entirety, HHS would bear the responsibility of implementing a program to help patients receiving premium assistance afford their care or transition to another plan.

In 2019, legislation (AB 290) passed in California that would place new disclosure and reimbursement requirements on dialysis third-party premium payment programs. The legislation includes a clause that prevents any piece of the legislation from going into effect until AKF has the opportunity to request confirmation from the Office of the Inspector General that the provisions in the bill do not put their program in conflict with their advisory opinion. This gives AKF the opportunity to request and receive a new advisory opinion that ensures their compliance with existing anti-kickback laws. At this time, AKF has refused to request a new opinion from the Office of the Inspector General.

"In 2019, legislation (AB 290) passed in California that would place new disclosure and reimbursement requirements on dialysis third-party premium payment programs… AKF threatened to leave California on January 1, 2020, regardless of the effect it may have on patients they support."

AKF threatened to leave California on January 1, 2020, regardless of the effect it may have on patients they support. The only part of the bill that immediately takes effect is a requirement that dialysis clinics will not "steer, direct, or advise" a patient towards any specific insurance options. This requirement is consistent with both the 1997 Office of the Inspector General advisory opinion and current AKF Patient Handbook guidelines, which state that "You have the right to independently choose the health care coverage that is best for you."[86] **The remainder of the bill would not take effect until months later, and may not be implemented in any form if AKF requests a new advisory opinion and OIG finds that the legislation would force them out of compliance.**

AKF submitted a request for an injunction to prevent the law from taking effect in California. **On December 9, 2019, Rep. Porter led a letter with 14 of her California colleagues, including Senator Dianne Feinstein and then-Senator Kamala Harris, requesting that AKF provide sufficient time or a clear pathway to alternative coverage for constituents currently receiving support from the organization, regardless of the court's decision.**[87] AKF refused to comment on its decision making while the case is ongoing. On December 30, the court granted AKF's motion for an injunction.[88] The case is still ongoing. AKF chose after this decision to remain in California for the remainder of 2020.

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[86] "Patient Handbook." American Kidney Fund (AKF), https://www.kidneyfund.org/assets/pdf/financial-assistance/akf-hipp-patient-handbook.pdf

[87] "Rep. Porter Slams American Kidney Fund for Abandoning California Dialysis Patients." *U.S. Representative Katie Porter*, 10 Dec. 2019, porter.house.gov/news/documentsingle.aspx?DocumentID=80.

[88] "Judge Blocks California Law on Dialysis Clinics." *AP NEWS*, Associated Press, 31 Dec. 2019, apnews.com/4abfe32e51972f95bb4b39be6e4ae853.

Conclusion: It's Time for an OIG Investigation and for CMS to Take Action

The Office of the Inspector General has previously reviewed and later rescinded other advisory opinions in order to address concerns raised by Members of Congress, lawyers, and patient groups.

For example, in April 2006, the OIG published Advisory Opinion 06-04 for the Caring Voice Coalition (CVC).[89] CVC was similarly providing financial assistance for premium and cost-sharing obligations, though 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 Office of the Inspector General rescinded Advisory Opinion 06-04, based on the charity's "failure to fully, completely, and accurately disclose all relevant and material facts to OIG."[90] 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."[91]

"This evidence establishes credible concerns about possible conflicts of interest involving the structure and practices of AKF's patient assistance program that could have negative consequences for patient care, premiums, and the private insurance market. ESRD patients and taxpayers deserve action."

While the office will continue following this issue closely, as well as other cases in which large corporations in the healthcare industry may be placing patients at risk in order to increase profits, it is clear the time for an investigation is now.

In short, the findings of HHS' own agencies and OIG's past precedent, when combined with this new staff report based on additional investigation and documents obtained by Rep. Katie Porter's office, recent academic studies, and newly unsealed whistle-blower lawsuits, provides significant new support for opening an OIG investigation as soon as possible.

This evidence establishes credible concerns about possible conflicts of interest involving the structure and practices of AKF's patient assistance program that could have negative consequences for patient care, premiums, and the private insurance market. ESRD patients and taxpayers deserve action.

Further, CMS should reissue the 2016 rule to make long overdue changes to Medicare's dialysis policies to increase transparency regarding third-party premium payments. The procedural

[89] HHS OIG. Advisory Opinion No. 06-04. (2006). https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpnRescission06-04.pdf
[90] "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/.
[91] HHS OIG. Advisory Opinion No. 06-04. (2006). https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpnRescission06-04.pdf.

suspension of the 2016 CMS rule marked a missed opportunity to hold AKF and dialysis providers to an appropriate standard and to protect vulnerable patients in the process. **CMS can and should reissue the rule through the appropriate rulemaking process required under the Administrative Procedure Act to reduce the cost of treatment for patients and taxpayers, improve quality of care, and increase access to transplants.**