

American Kidney Fund Policy Agenda 2020

The American Kidney Fund (AKF) fights kidney disease on all fronts as the nation's leading kidney nonprofit. AKF works on behalf of the 37 million Americans living with kidney disease, and the millions more at risk, with an unmatched scope of programs that support people wherever they are in their fight against kidney disease—from prevention through post-transplant living. With programs of prevention, early detection, financial support, disease management, clinical research, innovation and advocacy, no kidney organization impacts more lives than AKF. AKF is one of the nation's top-rated nonprofits, investing 97 cents of every donated dollar in programs, and holds the highest 4-Star rating from Charity Navigator and the Platinum Seal of Transparency from GuideStar.

We are a strong and independent voice advocating for policies that improve access to health care and that strengthen quality of care for Americans living with kidney disease. We work with Congress, the Administration, federal agencies and state governments to make kidney disease a national priority. Following are AKF's policy priorities for 2020.

Fighting insurance discrimination against patients on dialysis

The issue: Health insurers systematically discriminate against low-income end-stage renal disease (ESRD, or kidney failure) patients who depend on charitable assistance to afford their health insurance premiums. These patients, who are disproportionately members of racial and ethnic minorities, depend on the American Kidney Fund's charitable premium assistance to afford the premiums for their Medicare Part B, Medigap, Medicare Advantage, employer group health, COBRA and other commercial plans, including Qualified Health Plans (QHPs).

For over 20 years, our federally approved Health Insurance Premium Program (HIPP) has supported dialysis patients in all 50 states, consistent with the guidance provided in Advisory Opinion 97-1 (AO 97-1) from the U.S. Department of Health and Human Service (HHS) Office of Inspector General (OIG). In 2018, AKF's HIPP program assisted more than 75,000 patients in maintaining their health insurance so they could access the health care they need to stay alive. Our program is 100% needs-based; to receive help from AKF, patients must demonstrate that without our assistance, they would be unable to afford their coverage.

At least 70 percent of AKF's HIPP grant recipients are enrolled in Medicare Part B. Most of them also have a second insurance policy—Medigap, Medicare Advantage, an employer-provided plan or a commercial plan—to provide comprehensive coverage and lower their out-of-pocket costs. About 8 percent of grant recipients received our assistance to access the Affordable Care Act's (ACA) QHPs in the individual insurance market for the 2018 plan year (both on and off-exchange).

- **Working to ensure that insurance carriers accept charitable payments on behalf of ESRD patients**

In March 2014, the Centers for Medicare and Medicaid Services (CMS) released an Interim Final Rule (IFR), the *Patient Protection and Affordable Care Act: Third Party Payments of Qualified Health Plans Premiums*, requiring insurance carriers to accept charitable premium payments from state and federal organizations, tribal organizations, and the Ryan White HIV/AIDS

organizations for the payment of premiums for QHPs. Since the IFR does not explicitly require insurance companies to accept charitable premium payments from not-for-profit organizations, many insurance carriers are refusing third-party payments from AKF on behalf of ESRD patients.

Unfortunately, many insurers across the country have extended this practice to other types of insurance coverage beyond QHPs, including to Medigap. Several of the plans stipulate that coverage will be terminated if the individual accepts any direct or indirect contribution or reimbursement by or on behalf of any charitable organization, except for the entities mandated by CMS as third-party payers in the 2014 IFR.

AKF is fighting these discriminatory practices and we are advocating for HHS to clarify their position on third-party payments to require insurance companies to accept premium payments made on behalf of individuals with kidney disease. We are also actively communicating with state legislators and insurance commissioners and their staff members about AKF and our HIPP program with the goal of encouraging state insurance departments to direct insurance companies to accept AKF's charitable assistance payments via formal bulletins or directives.

Legislatively, AKF supports passage of the federal Access to Marketplace Insurance Act, which was introduced in the previous Congress and is expected to be reintroduced this year. The legislation would protect patient access to coverage by requiring insurance companies to accept payments from nonprofit charitable organizations like AKF. On the state level, AKF will advocate against state legislation that seeks to limit our ability to provide financial assistance to HIPP grant recipients.

- **Protecting ESRD patients from insurance carriers pushing them off private insurance**
Individuals on dialysis are legally entitled to stay on their group health plan private insurance for 30 months as primary payer before being required to move to Medicare as primary payer. Many dialysis patients prefer to be on private insurance for as long as legally allowed, and it is their choice. More importantly, staying on employer-based and other commercial insurance is often the only way that ESRD patients can access the specific benefits that they need, including family coverage. Insurance carriers have employed tactics to encourage patients on dialysis to move to Medicare early by offering to pay for the patient's Medicare Part B premium. Some insurance carriers have told beneficiaries that they must move to Medicare prior to the legal date. AKF is working with state regulators to address these practices.

Ensuring adequate funding for kidney research and promoting innovation

***The issue:** Kidney disease affects 37 million Americans—far more than many other diseases. Yet federally funded research for kidney disease has lagged compared with many other diseases. This has slowed innovation in the diagnosis and treatment of a disease that is the fastest-growing noncommunicable disease in the United States.*

Appropriations funding is a critical resource in supporting agencies focused on kidney research and public health. These funds allow agencies to support research, award grants to community-based organizations, and make advancements in the development of new life-saving medical treatment and drugs. The National Institutes of Health (NIH) and Center for Disease Control and Prevention (CDC) rely

on Congress for the funding needed to deliver services and programs to improve the lives of patients with ESRD.

AKF supports increased appropriations funding to ensure adequate funding levels for programs focused on patients with kidney disease.

- **Kidney research funding**

Basic and clinical research is critical to understanding kidney disease—its causes, its progression, and the treatments that can either prevent it from developing or halt its progression. Kidney disease research is funded through the National Institute of Diabetes, Digestive and Kidney Disease (NIDDK), which is part of the NIH. Federal funding for kidney disease research must be increased, especially given the prevalence of kidney disease and its disproportionately low level of funding compared to other diseases. AKF works to increase funding of kidney disease research.

- **Chronic Kidney Disease (CKD) Initiative**

CDC classifies CKD as a serious public health issue—it is the ninth-leading cause of death in the United States. The CDC’s CKD Initiative was mandated by Congress in 2006 to help solve the growing problem of kidney disease. The CKD Initiative currently funds projects such as surveillance, epidemiology, state-demonstration projects and economic studies. Early detection and treatment of patients with CKD can help prevent or delay cardiovascular death and progression to kidney failure. Since the program’s inception, Congress has provided direct funding for the CKD Initiative at approximately \$2.2 million per year. AKF supports increased funding for the CKD Initiative.

- **Kidney Innovation Accelerator Program (KidneyX)**

In 2018, the U.S. Department of Health and Human Services launched a public-private partnership, KidneyX, to accelerate innovation in preventing, diagnosing and treating kidney diseases. AKF supports this innovation initiative and is an active participant to help provide the patient perspective as the program progresses.

Encouraging organ donation

The issue: *More than 80% of those on the transplant waiting list are waiting for a kidney. Most will die before they receive one because of the dire shortage of kidneys for transplant.*

Kidney transplant is considered the best treatment option for many people facing kidney failure because it can increase your chances of living a longer, healthier life. However, the number of people on the organ transplant waiting list is great—about 113,000 Americans are on the list, with 85 percent of those in need of a kidney. Research has shown that patients who get a kidney from a living donor live longer than patients who get a kidney from a deceased donor. On average, living kidney donor transplants last 15-20 years, and deceased kidney donor transplants last 10-15 years.

AKF supports federal legislation that would encourage organ donation and protect living organ donors, such as the Living Donor Protection Act of 2019. The legislation would ensure living organ donors are not denied or given limited coverage or higher premiums for life, disability and long-term care insurance. It would also clarify that living organ donors may use Family and Medical Leave time to recover from donation surgery and maintain job security. On the state level, AKF supports legislation that provides tax

breaks to living donors and employers who provide paid leave, as well as state legislation that mirrors the federal Living Donor Protection Act.

Supporting comprehensive immunosuppressive drug coverage for kidney transplant patients

The issue: For ESRD patients under 65, Medicare only covers immunosuppressive drug therapy for 36 months. Without these expensive drugs, kidney transplant recipients face the prospect of organ rejection and returning to dialysis to stay alive.

Immunosuppressive drugs prevent transplanted organs from being rejected. Medicare currently provides 36 months of coverage for immunosuppressive drugs for non-disabled kidney transplant patients under the age of 65, but transplant recipients must take immunosuppressive medications for the life of their transplanted organ to prevent organ rejection. Kidney transplant recipients who stop taking immunosuppressive drugs because they can't afford them face the loss of their transplanted kidney, necessitating a return to dialysis. Providing extended coverage for these medications would result in better health outcomes for patients, as well as substantial cost savings to Medicare because fewer transplant patients would need to resume dialysis. Recent analyses from HHS found potential cost savings of up to \$300 million over 10 years if Medicare coverage for immunosuppressive drugs was extended beyond 36 months.

AKF supports the Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act of 2019, which would extend Medicare immunosuppressive drug coverage for kidney transplant patients beyond 36 months. Kidney transplant patients under age 65 would be eligible to remain in the Medicare program solely for the purpose of receiving these critical medications, and only if the transplant recipient lacks private or other public coverage for these drugs.

Supporting Medigap reform

The issue: Most ESRD patients are eligible for Medicare even if they are under 65. But 20 states do not require health insurers to offer Medigap plans to these younger Medicare beneficiaries. Without Medigap, patients face daunting out-of-pocket expenses for the 20% of medical care not covered by Medicare Part B.

Most ESRD patients become eligible for Medicare three months after diagnosis, and most patients with ESRD are enrolled in Medicare as their primary health insurance coverage. For many of these patients, private supplemental Medigap insurance is needed to afford their cost-sharing, as Medicare Part B covers only 80 percent of medical care with no cap on out-of-pocket (OOP) expenses. ESRD patients have complex health care needs and face high out-of-pocket costs—the average OOP costs for ESRD patients on Medicare are \$7,000 and the average annual income of AKF's HIPP grant recipients is just under \$25,000. However, in 20 states Medigap is not required to be made available to ESRD patients under the age of 65, and these patients represent a sizable portion of dialysis patients in those states—about 92,000.

On the federal level, we support legislation that would ensure guaranteed availability of Medigap supplemental insurance to all Medicare ESRD beneficiaries, regardless of age. This provision is included in the Chronic Kidney Disease Improvement in Research and Treatment Act, which was reintroduced in this Congress. In addition, the Medigap Consumer Protection Act of 2019, which has been introduced in

the House and Senate, would provide guarantee issue for Medigap insurance for all Medicare beneficiaries, regardless of age; we support this legislation as well. We also support the passage of state legislation that would require insurance companies that offer Medigap coverage to make it available to ESRD patients under 65 and that would place limits on the premiums charged to ESRD patients so that Medigap is affordable.

Supporting the Advancing American Kidney Health Initiative

The issue: *Kidney disease is the fastest-growing noncommunicable disease in the United States. An estimated 37 million Americans have kidney disease, and as many as 1 in 3 are at risk. Changing the trajectory of kidney disease in this country must become a national priority.*

AKF supports HHS' *Advancing American Kidney Health* initiative and its main objectives: to increase efforts to prevent, detect, and slow the progression of kidney disease; provide patients with kidney disease with more options for treatment; and deliver more organs for transplant. As HHS implements provisions of the initiative, AKF will provide input and feedback to ensure the patient voice is heard and that rulemaking and programs are designed to achieve the intended goals of *Advancing American Kidney Health*.

Fighting insurance discrimination against patients with chronic diseases

The issue: *Americans living with chronic diseases by necessity consume health care at far higher rates than average. Our health care system often erects obstacles that make it difficult for these patients to receive the health care they need.*

Despite protections provided to patients through existing statutes, insurer policies and protocols can still create barriers to needed care for patients with chronic diseases and can be discriminatory in practice. They include: burdensome prior authorization requirements that can restrict or delay needed treatments; drug formulary exclusions and adverse tiering that make treatments for certain diseases unaffordable; and benefit designs and narrow provider networks that may deter those with chronic diseases from enrolling. AKF will continue to monitor these practices and advocate for public policies that mitigate the ability of insurers to discriminate against patients with chronic diseases.

Protecting access to coverage under the Affordable Care Act

The issue: *The elimination of preexisting condition exclusions for health insurance under the Affordable Care Act (ACA) has enabled patients with chronic diseases, including kidney disease, to enroll in private commercial health plans that provide comprehensive coverage.*

Congress has allowed ESRD patients to stay on private health plans, which provides an option for patients who can afford to stay on their private insurance. This option is particularly important given the lack of access to Medigap supplemental plans for ESRD patients under the age of 65 in 20 states. Many low-income individuals need assistance to exercise the option of staying on their private insurance.

Any proposed legislative or regulatory changes to the ACA should maintain patient protections that help people with chronic conditions such as kidney disease access the services they need to manage their conditions. AKF is fighting to protect the access of patients with chronic kidney disease and ESRD to affordable and high-quality health care. AKF has the following principles to guide our support:

- **Access to comprehensive, affordable coverage** – It is imperative that Congress and the administration ensure protections for people with preexisting conditions and maintain the integrity of the essential health benefit (EHB) standards established under the ACA. Doing so ensures that people in need of comprehensive and affordable coverage have access to it. We oppose the expansion of less comprehensive insurance options, such as association health plans and short-term limited duration plans, which are exempt from covering the essential health benefits or are able to deny or limit coverage for people with preexisting conditions. The expansion of such plan options will siphon healthier individuals from the risk pool, leading to higher premiums for individuals who purchase comprehensive ACA coverage. We also oppose proposed changes to states’ selection of EHB benchmark plans that could lead to less comprehensive categories of coverage and jeopardize access to lifesaving services and treatments such as chronic kidney disease management, dialysis treatment, and kidney transplant.
- **Strengthening the ACA Marketplace** – AKF supports proposals that would help strengthen the ACA Marketplace, such as funding reinsurance programs, cost-sharing reduction payments, and ACA enrollment outreach and education activities. We also support proposals that would expand eligibility for cost-sharing reduction subsidies and advanced premium tax credits beyond the current income thresholds of 250 percent and 400 percent of the federal poverty level, respectively. By compensating insurers for high-cost patients, providing subsidies for a greater number of people to help them purchase coverage, and increasing enrollment through outreach efforts, these measures will further strengthen the ACA Marketplace and ensure access to comprehensive, affordable coverage options.

Protecting Medicaid

The issue: *For the poorest Americans, Medicaid is an essential program that provides access to comprehensive health care and it is a vital program for many patients living with kidney disease. As the federal government and states seek to reduce the cost of Medicaid, their efforts may jeopardize patient access to the program.*

Medicaid is a critical source of health coverage and an important safety net for the one in five low-income individuals the program covers. By providing access to care for so many Americans, Medicaid plays a vital role in helping enrollees prevent and manage chronic conditions such as chronic kidney disease and its leading causes, diabetes and hypertension.

AKF strongly supports the core statutory objective of the Medicaid program, which is “to furnish medical assistance [to individuals] whose income and resources are insufficient to meet the cost of necessary medical services.” Therefore, AKF opposes policy proposals that would undermine Medicaid’s core objective, such as those included in recent Section 1115 demonstration waivers that have been approved or are pending. Changes to Medicaid eligibility and benefits, such as imposing work or service requirements, lifetime coverage limits, lock-out penalties, elimination of retroactive eligibility, and elimination of non-emergency medical transportation, do not further the statutory purpose of the Medicaid program. Rather, these policy changes will increase administrative burden, complexity and costs, which create barriers to coverage for eligible individuals and lead to fewer people, especially vulnerable populations, with access to health care.

AKF also opposes proposals that would change the Medicaid program's open-ended federal matching fund structure to a block grant or per capita cap system. Capped spending proposals would lead to decreased eligibility and enrollment, harmful cuts to benefits and care, and lessen the ability of state Medicaid programs to respond to an increased need for coverage, such as during a recession—all of which would be in direct conflict with the statutory purpose of the Medicaid program.

Protecting funding for Medicare and Medicaid

Given recent projections for increased budget deficits in future years, policymakers may look to cut spending for the Medicare and Medicaid programs. AKF will work to ensure that funding for these critical health programs, which collectively cover more than 129 million Americans, is not jeopardized.

Protecting patient access to needed medications; supporting lower prescription drug costs

The issue: *Access to medically appropriate prescription drugs for kidney patients must be preserved amid federal efforts to address the rising cost of prescription drugs.*

Patients with chronic kidney disease, kidney failure and kidney transplants rely on prescription drugs to manage their kidney disease and comorbidities. Patients need access to medically-appropriate prescription drugs that are effective and right for their individual situation, and they must be able to afford them. As Congress and the administration explore policies to address the rising cost of prescription drugs, AKF has the following principles to guide our support:

- **Protect patient access to medically-appropriate treatments** – AKF supports efforts that encourage the introduction and availability of generic prescription drugs and biosimilars, and many of the drugs prescribed to kidney patients are generics. However, effective safeguards must be in place to ensure that patients for whom generic substitution is not medically appropriate still have access to branded drugs that are part of their stable drug regimen. AKF also supports maintaining patient access to prescription drugs in the Medicare Part D program as it relates to the six categories and classes of drugs of clinical concern (the six protected classes), which includes immunosuppressive drugs for treatment of transplant rejection. We oppose policy proposals that create additional barriers to access for immunosuppressive and other drugs in the protected classes, which could disrupt a transplant patient's stable drug regimen and jeopardize their health.
- **Lower prescription drug costs and patient out-of-pocket costs** – Patients with chronic conditions who rely on prescription drugs are particularly affected by high drug list prices because their cost-sharing obligations are tied to the list price, instead of the lower net price negotiated between drug companies and pharmacy benefit managers. AKF supports policy proposals that would result in lower drug costs and lower out-of-pocket costs for patients. We also support policies that protect a patient's ability to use drug copay coupons, discount cards, charitable assistance and other assistance to afford needed medications, and to have that assistance count towards their annual deductible and out-of-pocket spending cap.

Supporting new Medicare Advantage coverage options for ESRD patients

As part of the 21st Century Cures Act, Medicare beneficiaries with ESRD will be able to enroll in Medicare Advantage (MA) plans starting in 2021. AKF supports increased coverage options for ESRD patients and

we will work with CMS and other stakeholders to ensure that implementation of this new coverage option works in the best interest of patients. Specifically, we will work to ensure that any proposed MA payment system and risk adjustment changes are appropriate, that any proposed ESRD quality measures in MA are meaningful to patients, and that the guidelines for MA plan marketing materials are fair and transparent for ESRD beneficiaries.

Supporting patient-centered quality measurement

Meaningful, patient-centered quality measurement is critical to ensuring quality health care for patients with kidney disease. AKF will continue to provide input and recommendations on potential changes to quality measurement in the Medicare ESRD program with the patient perspective in mind, and that further the goal of improving patient care, experience and outcomes.

Protecting patients from surprise medical bills

Surprise medical bills can result from a person receiving emergency care at an out-of-network facility or receiving care from an out-of-network physician/specialist at an in-network facility. Patients then receive an unexpected and costly bill after their care that can cause a significant financial burden. Because kidney disease patients have a chronic condition and possibly other comorbidities that may necessitate emergency care, the issue of surprise medical bills is a concern for AKF. As legislators consider ways to address surprise medical bills, AKF believes proposals should ensure that patients are held financially harmless from additional costs associated with out-of-network care that the patient cannot control.

Working to support policies that lead to delaying or preventing ESRD by partnering with diabetes and heart groups

Because diabetes and heart disease account for 75% of all cases of new kidney failure, AKF works to educate members of Congress, the administration, and the public on the link between diabetes, heart disease, and kidney disease. Government proposals that focus on addressing these two chronic diseases must include information on ESRD. Additionally, AKF aims to partner with these patient groups on issues such as access to affordable insulin and heart medications to prevent or delay ESRD. AKF also intends to work with these patient groups on social determinants of health, nutrition and exercise to address these chronic illnesses in the United States.