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Mr. Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-3337-IFC: Medicare Program; Conditions for Coverage for End-Stage Renal Disease Facilities--Third Party Payment

Dear Secretary Burwell and Acting Administrator Slavitt:

The American Kidney Fund (AKF) herein submits comments on the U.S. Department of Health and Human Services (HHS) Centers for Medicare and Medicaid Services (CMS) *Interim Final Rule: Conditions for Coverage for End-Stage Renal Disease Facilities-Third Party Payment* (rule).

Among its provisions, the rule requires thorough patient education, transparency and compliance in dialysis center processes of helping patients navigate their health coverage options. Although we have concerns, described in our comments, about the practical ability of clinics to implement these requirements as currently proposed, we do very strongly support increased transparency and insurance education as absolutely necessary to the empowerment and protection of end-stage renal disease (ESRD) patients. We also want to do everything we can to ensure AKF's premium assistance program is transparent, compliant, and part of a healthy system in which ESRD patients are independently selecting insurance coverage without undue influence from their dialysis clinic or the insurance plan. We've explained to HHS in previous discussions the steps we have recently taken to that end, and we look forward to working with the Department as we continue to move forward.

We are very deeply concerned, however, that another provision in the rule goes too far and will have a devastating impact upon low-income ESRD patients in this country. Our concern is with the rule's requirement that, effective immediately, these individuals must seek permission from insurance companies to be granted individual market coverage if they cannot afford that coverage on their own.

Nearly half a million Americans are living with ESRD in the U.S. today. ESRD is a devastating and life-changing disease that leaves patients unable to cleanse their blood of life-threatening toxins and forces them into a treatment regimen that requires them to undergo dialysis treatment three times a week. It robs people of their ability to work and to lead the kind of productive lives they and their loved ones want.

The patients who will be harmed by this provision are, predominantly, low-income, unemployed, and overwhelmingly are members of racial and ethnic minority groups. These people have historically been underserved by our healthcare system and rejected by health insurance companies due to the high-cost of their treatment. This rule will erect a powerful new barrier that will prevent far too many patients from obtaining health coverage. This runs counter to everything the Affordable Care Act and the Department of Health and Human Services stand for. As we describe below, this rule is already having adverse effects on some patients. We urge you, in no uncertain terms, to withdraw it before it does more harm to ESRD patients.

We are also deeply concerned about how this rule was developed and released in fewer than 90 days. This haste resulted in a rule that will cause harm to patients. The rule contains grievous factual errors; the rule is not based in fact, but on anecdote; and the rule gives vastly unequal weight to input the Department has received from the insurance industry. For more than 20 years, the nation's low-income ESRD patients have turned to AKF to help them obtain insurance when they had no other choice. Since our inception, AKF has been the safety net for U.S. dialysis patients. But the rule would cripple our ability to continue supporting thousands of patients who need and deserve our help. As written, the rule stands to cause irrevocable harm to low-income dialysis patients who need charitable assistance to afford their health coverage.

Because the rule will become effective immediately, we have no comment period in which to provide HHS information about the rule's very serious consequences to patients. Under a normal comment period, the Department could review this information and adjust the rule to avoid harming patients. The Department claims there is an urgent need to implement the rule immediately, but has not provided valid reasons for bypassing the normal rulemaking process. By fast-tracking the process in the waning days of the Obama administration, the Department has left it up to the incoming administration to attempt to clean up the damage to a vulnerable, disabled population that will occur if this rule stands.

The consequences of this rule have already begun to set in, even before it becomes final: this week, we have been contacted by patients who are attempting to enroll in the individual market, but cannot access the same individual market coverage they had in 2016. As one wrote to us: "Due to [these] guidelines, a letter of confirmation is needed for you to pay my premiums, but [the insurance carrier] won't give a letter... I can't get treatments for my neuropathy by a specialist. I'm in desperate need of [this coverage]. I've got so many different conditions and can't see a specialist without it."

This cannot be the result that the Department intended to achieve when it set out to protect ESRD patients from improper steering.

We are, therefore, calling upon HHS to rescind the rule and allow time for the new Administration to thoughtfully consider this issue under a standard notice-and-comment period. We are convinced such careful consideration will result in a policy that puts patients, not insurers, first.

I. Introduction

AKF is the nation's leading nonprofit organization working on behalf of the 31 million Americans with kidney disease. For the past half-century, AKF has existed to help people fight kidney disease and live healthier lives. We provide a complete spectrum of programs and services: top-rated health education materials; free kidney disease screenings in more than 20 cities nationwide; clinical research funding; and need-based financial assistance enabling 1 in 5 U.S. dialysis patients to access lifesaving medical care, including dialysis and transplantation. AKF is an independent 501(c)(3) nonprofit. We are governed by an independent Board of Trustees from all walks of life. None of our Board members are employed by dialysis providers, and none of our 75-person staff has ever worked for a dialysis provider.

Fully 63,000 donors—individuals, corporations and foundations—support our mission. The nation's charity watchdog organizations have consistently recognized AKF as one of the nation's most trusted and reputable nonprofits. Charity Navigator, Consumer Reports, Charity Watch have evaluated AKF and have awarded us the highest possible ratings for many years running. Out of 8,000 charities evaluated by Charity Navigator, AKF is on the top 10 list of organizations with the most 4-star ratings. Consumer Reports recently named AKF one of the two best health nonprofits in the country. We spend 97 cents of every donated dollar on programs that directly serve and educate patients and the public.

One out of every 5 U.S. dialysis patients turns to AKF for assistance with treatment-related costs—not only health insurance premiums, but also expenses not covered by insurance; emergency aid during times of natural disaster; and free medications to treat common complications of kidney failure.

For 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 HHS Office of Inspector General (OIG). We helped nearly 80,000 people in 2016 through this program. About two-thirds of those 80,000 grant recipients received our support for Medicare Part B and Medigap premiums. The remaining one-third received AKF assistance for COBRA, employer group health plan (EGHP), and commercial premiums, including less than 7,000 who received our assistance to access the individual market.

We have explained to the Department on many occasions and in numerous comment letters that, consistent with AO 97-1, AKF maintains a firewall between contributions dialysis companies make to AKF, and decisions AKF makes about how to distribute HIPP grants. Our donors do not, and cannot, influence individual patient grant decisions, and our program makes it possible for low-income dialysis patients to have a real choice in insurance coverage. We provide grant assistance for the full plan year, and our decision to award grants is based solely on strict criteria patients must meet to demonstrate their financial need. The purpose of our HIPP program is not to enrich dialysis companies with commercial insurance reimbursement; the purpose is to give low-income dialysis patients access to the coverage that makes the most sense for their personal situation, in keeping with our half-century-long mission of service to dialysis patients. There is no "earmarking" of donations to individual patients. In fact, 40 percent of dialysis clinics with patients in the HIPP program do not make any contributions to AKF, and AKF has never turned away a dialysis patient who applies to us for assistance, provides full and accurate personal information, and qualifies financially.

Controversy over charitable premium assistance first arose in 2014, when HHS hastily issued an IFR protecting premium assistance for individuals living with HIV/AIDS, as well as those individuals assisted by federal, state and Indian/tribal programs. The Department left to insurers the decision of whether to accept premium payments on behalf of other individuals. This created a situation in which insurance companies

began steering dialysis patients away by rejecting charitable premium assistance. At first, a few insurance companies rejected premium assistance on behalf of our grant recipients; the practice spread over the following years, and reached its nadir in 2016, when major insurers wrote into their plan materials that they would terminate the coverage of any individual who accepted help from a nonprofit to pay their premiums. Some insurers even applied the CMS guidance to plans outside the exchange, and AKF grant recipients lost their Medigap coverage.

We have worked since 2014 to educate the Department about the problem of insurance companies improperly steering dialysis patients onto Medicare and Medicaid as they attempt to avoid their ACA-mandated responsibility to provide coverage to this population. They have achieved this goal not only by refusing charitable premium assistance, but also through other methods: falsely telling patients that federal law requires them to enroll in Medicare four months after ESRD diagnosis; financially incentivizing patients to shift to Medicare; and increasing patients' coinsurance obligations by only reimbursing providers at Medicare rates, leaving patients to shoulder the significant difference. All of these practices have been harming patients for some time and require federal intervention, as we and others have been requesting for years. We have urged the Department in letters and multiple meetings to take thoughtful action, but the agency has consistently chosen not to act.

This rule followed a Request for Information (RFI) that HHS issued in August 2016, shortly after United Healthcare sued a dialysis company over allegations that this provider had inappropriately steered about two dozen patients away from public coverage and into United plans. AKF wants to be very clear that we absolutely oppose any steering of patients in their selection of health plans or health care providers. Those decisions should be made by patients. AKF has worked for nearly a half century to protect such patient rights and will always do so.

The Department stated that the RFI was for “information and planning purposes” only; it did not propose new rules. The RFI indicated that the Department was concerned about insurers' position that alleged steering of patients into individual market coverage, and away from public programs, was having a negative effect on the individual market risk pool. The RFI sought input from interested parties as to whether improper steering was occurring—but it was solely focused on the question of whether healthcare providers were steering patients. It sought no comment on the clear evidence we have presented over the years that insurers are steering ESRD patients onto public programs.

As soon as the Department released the RFI, it became apparent in tweets and retweets by the CMS Acting Administrator that the Department had already taken a position. Mr. Slavitt tweeted, “Insurance companies are not the issue in this situation.” Mr. Slavitt also announced on Twitter that the Department would “welcome public statements from some kidney & dialysis orgs who do not improperly steer Medicare/caid patients into exchange plans,” implying that in his view, some kidney organizations do engage in steering.

Thus, it is not surprising to see that the Department apparently did not closely review nor consider the majority of the substantive comments submitted that demonstrated how most ESRD patients are making informed choices about their coverage and are not being steered. Indeed, the rule devotes only one paragraph to summarize the great number of detailed comments the agency received in support of charitable premium assistance: “Comments show that some ESRD patients are satisfied with their current premium arrangements. In particular, more than 600 individuals currently receiving assistance for

premiums participated in a letter writing campaign in response to the RFI and stated that charitable premium assistance supports patient choice and is valuable to avoid relying on ‘taxpayer dollars.’”

This lone paragraph summarizing the “other side” of the issue is factually inaccurate. It states that these 600 letters came from dialysis patients, when in fact, the form letters were submitted by individuals not with ESRD, but with a variety of chronic conditions who have received copay and premium assistance through an unrelated nonprofit that serves a completely different population than the ESRD population. It should also be noted that the Department has chosen not to address the challenges these other patient populations are facing because of issuer rejection of charitable premium assistance; the rule focuses exclusively on ESRD patients and provides no guidance regarding premium payments that are made by a wide variety of nonprofits, hospitals and other healthcare providers.

The Department’s failure to accurately characterize the positive comments it received is an indicator that the agency did not carefully review and consider those comments. What HHS left out of the rule’s RFI summary is the following: More than 800 individuals and organizations responded. Everyone who commented on the steering topic, including AKF, was in strong agreement: steering of patients into individual market plans must not be permitted. Dozens of ESRD patients wrote personal letters, explaining in detail the value of charitable premium assistance, discussing how they had chosen their coverage independently and of their own free will, and urging the Department to continue the 20-year-long, well-established federal track record of permitting nonprofits to provide charitable premium assistance. Sixteen patient advocacy organizations and charities explained the importance of their programs to patients. Organizations holding OIG advisory opinions, including AKF, discussed the rigorous controls they have in place. Eighteen providers explained the benefits of such payments to patients, while also recognizing that any improper steering should be eliminated.

Yet the rule seems to almost completely ignore the evidence HHS received from those commenters. The rule focuses solely on anecdotal comments that support the Department’s conclusions that charitable premium assistance exposes dialysis patients to harm. The vast majority of those comments came from 15 insurance companies who commented. These commenters urged the Department to end premium assistance—a self-serving recommendation, indeed.

On the basis of these anecdotal comments, the Department has taken an extreme action—not only imposing immediate new standards that will effectively make it impossible for dialysis patients to access charitable assistance for individual market plans, but also questioning whether charitable assistance for such plans should even be permitted. The agency is irresponsibly upending the entire safety net that exists for dialysis patients who can’t afford their health coverage.

Plainly stated, we must conclude that the Department has not listened to the multitude of credible organizations and individuals who have presented information that contradicts the insurance industry’s position on this issue. In this matter, the Department has failed in its responsibility to ensure the marketplace works not just for the insurance industry, but also for the individual consumer. We urge the agency to withdraw this rule so that a more objective review of evidence can occur.

II. The Department has not met the standard necessary to waive the Administrative Procedures Act (APA)

Under the APA, HHS is required to publish a substantive rule no less than 30 days before its effective date and to go through notice-and-comment rulemaking, unless one of three exceptions waiving these

requirements applies. The Department claims it has “good cause” to waive the rulemaking process because in its view patients receiving charitable premium assistance are at risk of three harms: Negatively impacting their determination of readiness for a kidney transplant; potentially exposing patients to additional costs for health care services; and putting them at significant risk of a mid-year disruption in health care coverage.

As noted above, the agency has reached these sweeping and broad conclusions about “risk of harm” on the basis of comments from 15 insurance companies and a handful of social workers. Below, we provide accurate facts that demonstrate the Department has leapt to misplaced conclusions on all three points, and the agency should, at minimum, gather more data before acting.

Factual correction 1: Charitable assistance helps patients obtain transplants

The Department’s first justification for eliminating the notice-and-comment period is the agency’s speculation that charitable assistance could interfere with a patient’s ability to obtain transplant. The agency presents no data to support this speculation, and ignores several key facts. First, we need to correct the record: assistance from AKF is what makes it possible for many ESRD patients to go through the transplant workup process and have a transplant. We continue charitable premium assistance to these individuals post-transplant, for up to one quarter. We make clear to grant applicants, through our program materials, program application and patient newsletter, that premium assistance from AKF is for dialysis patients; after someone has had a successful transplant, we will discontinue the assistance. We provide this information so that patients can incorporate it into their planning process to ensure a continuum of coverage post-transplant. We provided detailed information to HHS about how this process works in our previous comments and meetings with the agency; we must conclude that the Department failed to carefully consider this information.

The Department justifies its concern by speculating that dialysis patients “may have difficulty demonstrating continued access to care due to loss of premium support after transplant.” ESRD patients who can’t demonstrate they will have access to care post-transplant are not eligible for transplant. The rule glosses over the fact that ESRD patients are permitted to enroll in Medicare at the time of transplant, and to remain on Medicare for 36 months post-transplant. The Department bases its claim of harm on the speculation that some ESRD patients “many not understand their coverage options.” This speculation ignores the fact that existing HHS guidance requires dialysis providers to explain post-transplant coverage options. It is irresponsible of the Department to claim an immediate risk of harm around access to transplant, based not in factual data but in speculation. In reality, any patient who wishes to have a kidney transplant undergoes a rigorous medical evaluation and financial preparation process, working not only with the dialysis provider but also with the transplant center to ensure that if a patient receives a donated kidney, the transplant will have the best possible chance of long-term success because the patient will have in place the needed access to medical care and medications.

Additionally, commenters on the RFI provided the Department with detailed, factual, research-backed information about why having private insurance coverage makes it more likely for an individual to have a transplant. The fact of the matter is that without help from AKF, many people today would not be living with successful transplants. Our grant assistance provides the primary and secondary coverage that is an absolute requirement to undergo the transplant workup process and the transplant surgery. When we consider all of the programs and services that AKF offers, and all of the impact data showing the results we have achieved on behalf of patients, one of our proudest accomplishments is that we have made it possible for people to have transplants. If AKF is unable to assist ESRD patients with individual market

plans, it will become more difficult for some low-income dialysis patients to have access to a transplanted kidney. It is an outrageously false argument to claim that charitable assistance is making it more difficult for these individuals to be transplanted.

Factual correction 2: For some patients, individual market plans offer lower costs and better access to care

The Department's second justification for eliminating the notice-and-comment period is that Qualified Health Plans may result in higher costs for ESRD patients than Medicare or Medicaid. Yet HHS does not quantify this claim; there is no data presented to indicate that there is a cost emergency facing patients to justify immediate implementation of this rule.

The Department does acknowledge that “for some” patients, there are “financial benefits from [QHPs] if total premiums and cost sharing are lower.” This statement is absolutely true—and it is the reason charitable premium assistance for ESRD patients must be protected. The rule does not discuss the ample, detailed data that dozens of commenters provided on this point. About half of the states don't mandate Medigap coverage to ESRD patients under 65, exposing those patients not eligible for Medicaid to an uncapped, 20 percent out-of-pocket share of costs under Medicare Part B. For patients in this situation, a QHP can be the best financial option. Similarly, some patients are not eligible for Medicare and/or Medicaid. There is no one-size-fits-all coverage solution for ESRD patients; AKF's program works the way it is designed to function, making it possible for patients to have the choice they need.

The small number of patients AKF is helping with QHPs should definitively demonstrate to the Department that there is not a widespread, mass enrollment into QHPs by dialysis patients, and that those who do enroll are by and large doing so for appropriate reasons. There are nearly 500,000 dialysis patients in this country, and AKF is helping a tiny fraction of them—fewer than 7,000—with QHPs. The Department states in the rule: “Information available from the risk adjustment program in the individual market show that between 2014 and 2015, the number of individual market enrollees with an ESRD diagnosis more than doubled. In some states increases were more rapid, with some states seeing more than five times as many patients with ESRD in the individual market in 2015 as in 2014.” But ESRD patients did not have access to the individual insurance market prior to the ACA—they were excluded because of pre-existing conditions. Of course enrollment has increased over the past several years; enrollment started out at zero in 2013 when the ACA came online. Total enrollment supported by AKF premium assistance, in actual numbers, was fewer than 7,000 patients nationwide in 2015—certainly not the mass enrollment implied by HHS in stating enrollment increased between two and five times. The vast majority of our grant recipients are coming to us for assistance with other insurances—most often, Medicare Part B and Medigap premiums.

We absolutely agree that dialysis patients need more information and education about insurance options, but the Department draws a false conclusion in stating that, as a group, the patients we help are facing a cost emergency because of the insurance they have selected; similarly, HHS uses alarming-sounding semantics to describe enrollment increases that are insignificant both in absolute numbers and relative to overall individual market enrollment. That some ESRD patients have enrolled in the individual market should not be surprising, given that the purpose of the ACA was to ensure all Americans would have equal access to coverage, regardless of pre-existing condition. In this section of the rule, HHS has failed to provide a valid reason for implementation of a regulation that would make it harder for these patients to receive AKF assistance.

Factual correction 3: Mid-year disruptions are caused by insurance carriers, not by charitable premium assistance

The Department's third and final justification for implementing this rule immediately is that ESRD patients receiving charitable premium assistance are at risk for mid-year disruption in coverage. We are incredulous that HHS would put forward this argument, as it is circular reasoning, a backward interpretation of what has been happening in the marketplace. Some insurance carriers have terminated ESRD patients' insurance coverage upon learning that patients have received charitable premium assistance. Some issuers have sent letters to policyholders, requiring them to attest to the fact that they are not receiving assistance, or be terminated. In some cases, issuers have attempted to implement these policies mid-year, and state insurance regulators have rightly intervened to stop these practices.

These are outrageous practices on the part of the insurance industry—and the insurance industry is where HHS should direct its concern. AKF, in contrast, provides premium assistance to patients for the full policy year. Assistance from AKF is not causing mid-year disruptions in coverage; actions by insurance companies are causing the disruptions. We have been very strongly advocating for patients' rights in this matter, meeting frequently with state insurance commissioners to request interventions. Yet the federal government has consistently failed to take any action against these issuers.

III. The rule does not protect patients from steering—it protects insurance companies from having to cover dialysis patients

A. Proposed Requirements

Disclosures to Consumers (42 C.F.R. § 494.70(c)) We very much believe that all dialysis patients need comprehensive, transparent, objective information about their insurance choices so that they may make such choices without undue influence from either dialysis providers or insurers.

HHS has recognized the importance of this, establishing in the rule a new standard for patient education that requires dialysis facilities to provide detailed insurance education to patients. We believe that most dialysis facilities are already providing proper education to patients, but the rule's requirement will, in theory, ensure that patients have more robust, comprehensive and standardized education—something that is essential to patient empowerment. Patients would certainly benefit from a standard process that transparently explains each insurance option and its implications.

We are concerned that making the requirement effective immediately will impose a very challenging burden at the clinic level, where clinics may have to divert social workers away from the vitally important psychosocial patient care that is so critical to the well-being of this patient population. Additionally, in its comment letter, which we support, Kidney Care Partners has highlighted some concerns about clinics' practical ability to provide insurance information at the level of detail that the Department is requiring, and has provided thoughtful recommendations that would ensure patients receive thorough and accurate education. We urge HHS to adopt those recommendations. Further, as we explained to the Department in the fall, AKF is in the process of developing an insurance education tool to provide comprehensive and objective information to patients and we look forward to rolling out this education tool in 2017.

The rule also establishes a process for greater transparency and disclosure around how dialysis providers interact with AKF, specifically in terms of whether the providers donate to AKF. We understand the intent

with which HHS is recommending this requirement, but we question whether it is possible for providers to disclose such information to patients without violating existing HHS guidance. We are especially concerned about the implications for AKF if we assist patients who have been provided such information in clear violation of the Advisory Opinion. In requiring dialysis providers to disclose to patients that they donate to AKF, the rule would force providers to violate the strict prohibition in 97-1 against this exact practice. By prohibiting such disclosure, 97-1 ensures that dialysis companies cannot unduly influence a patient's choice of provider; if dialysis providers notify patients that they support AKF's HIPP program, patients may be inappropriately swayed to choose a contributing provider over another clinic, in the mistaken belief that they will be more likely to receive assistance from AKF. We have always held fast to this requirement and have not disclosed information about providers' donations to AKF. As a nonprofit, it is our standard process to disclose all of our major contributors on our website, but we are unable to include HIPP donors in this listing. We believe the public has a right to review all of a charity's funding sources and thus we would support a more transparent process, in compliance with federal law and regulation, that would make this possible.

We are also concerned that the rule appears to consider a dialysis facility's charitable contribution to AKF as the "payment of premiums" by that facility, in direct opposition to AO 97-1, which states that such contributions "should not be attributed" to dialysis facilities that donate to AKF in accordance with the guidelines set forth in 97-1. As explained in 97-1, dialysis companies that donate to AKF have no control over what AKF does with the contributions. There is no "earmarking" of funds for individual patients. Instead, all contributions go into one funding pool, from which we award grants to applicants regardless of where those applicants have dialysis treatment. It doesn't matter to us whether a grant applicant is treated at a facility that contributes to AKF, or at one that does not contribute. We treat all patients the same, as HHS has previously recognized and should continue to recognize.

Disclosures to Issuers (42 C.F.R. § 494.180(k)) We strongly oppose this requirement. By requiring dialysis facilities to notify issuers that individual patients will be supported through charitable premium assistance, and by further requiring the dialysis facilities to obtain confirmation from the issuer that it will, in fact, cover such an individual, HHS has reintroduced the pre-existing condition issue under a new guise. It will now be completely up to issuers to decide whether they will offer coverage to low-income ESRD patients.

In creating this requirement, the rule establishes a very troubling, striking dichotomy within the ESRD patient population. The population that will be harmed by this requirement is one that is low-income, unemployed, and overwhelmingly comprised of racial and ethnic minorities. Fully 70 percent of the patients we assist are unemployed, while another 20 percent work only part-time, reflective of the fact that the dialysis treatment regime makes it difficult to stay employed. To qualify for HIPP assistance, a patient's monthly household income may not exceed reasonable monthly expenses by more than \$600, and 60 percent of the patients we assist have annual household incomes under \$20,000. More than 60 percent of our grant recipients are people of color: 37 percent are African American; 18 percent are Hispanic, 4 percent are Asian or Pacific Islander and 1 percent are Native American. These minority groups, which have been underserved historically, will be disproportionately affected by this new federal requirement that erects a barrier to obtaining health coverage. This is the population that will be hurt by the rule. Meanwhile, higher-income ESRD patients who are able to afford insurance coverage will continue to be able to purchase individual market coverage on their own, and insurers will not be able to deny them coverage because these individuals will not require charitable assistance.

We fundamentally oppose this requirement because it is our position that issuers should be required to accept premium payments from nonprofits that adhere to a set of guardrails which prevent steering and protect patients. We have previously provided to HHS our proposed guardrails that would achieve this goal, but HHS has never responded to our recommendations. If the guardrails that we have proposed are not, in the agency's view, sufficient, we would welcome the opportunity to discuss them further to arrive at a set of measures that would meet the Department's evolving standard.

If the Department has introduced the disclosure requirement out of concern that issuers are unaware when a policyholder is receiving charitable premium support, we offer to work with the agency to find a way to make such disclosures to the issuers in a uniform and compliant manner. What must not be allowed to happen is for HHS to implement this requirement as written. It virtually guarantees that no low-income ESRD patient will be "approved" for insurance coverage by issuers. It also sets a dangerous precedent for issuers to impose similar requirements on people who have other chronic conditions and are supported by other nonprofits.

B. AKF's responses to the rule's specific questions

Finally, the rule asks for comment on the following questions:

- Whether patients would be better off if premium payments in this context were more strictly limited;
- Alternative options where payments would be prohibited absent a showing that a third party payment was in the individual's best interest; and
- What such a showing would require and how it could prevent mid-year disruptions in coverage.

Our responses are below.

Patients would not be better off if premium payments in this context were more strictly limited—to the contrary, they would suffer great harm. ESRD patients should have the same right that HHS has provided to HIV/AIDS patients—the guaranteed right to receive financial assistance to pay their premiums in the individual market. Congress has always given ESRD patients the option to stay out of the Medicare program, if they prefer. But when issuers are not required to accept premium payments from AKF, the only ESRD patients who have the practical ability to choose the coverage that is best for them are those individuals who have the personal financial means to do so. Certainly, insurance carriers would answer this question in the strong affirmative, and we expect the Department will receive many comments from them to that effect. We urge the Department to consider the self-interest that issuers have in this matter, and to much more carefully consider the patient perspective. If the Department more strictly limits premium payments, it will cause irrevocable harm to low-income ESRD patients and it will establish a dangerous precedent for all Americans who depend on some form of assistance to afford premiums.

Probably the person who answers this question best is one of the RFI commenters—28-year-old Jason Early of Texas. Mr. Early developed ESRD as a result of juvenile diabetes, and AKF has been helping him to maintain coverage under an individual market plan that he selected because it made sense for him financially. As Mr. Early commented on the RFI:

I understand that private insurance companies aren't in the business to save lives. They are businesses, and businesses are "in the business" of making money. I am not some naïve soul who thinks that the world is full of nothing but good people and good intentions. But as these private insurances are in the business of making money, I am in the business of staying alive and doing it while not completely destitute. If I can maintain a private insurance through the Marketplace for \$343 a month while meeting that \$6,500 out-of-pocket max for the year, I will certainly do that instead of thousands [of dollars] in medications alone, not to mention the barebones coverage of a supplemental Medicare plan that isn't covered by the original Medicare 80%.

We urge the Department not to take a precipitous action that will result in people like Mr. Early becoming impoverished and lacking access to the health care they need to survive.

It is inappropriate for the Federal government to determine whether one insurance option over another is in a patient's best interest. We are surprised that the Department would suggest imposing such a requirement. ESRD patients already face a significant uphill battle if they wish to enroll in coverage other than Medicare. The insurance industry has clearly shown in its actions over recent years that it would much prefer that all ESRD patients be enrolled in Medicare. Issuers reject AKF's premium payments on patients' behalf, and they find other ways, described earlier in this letter, to steer patients into Medicare. These activities can make it impossible for an ESRD patient to have any real choice in coverage other than Medicare. A person should not be forced into Medicare just because their kidneys fail, and the federal government must not encourage such an environment by attempting to dictate or rule on which insurance options are in every individual's "best interest."

There is an obvious solution to the problem of mid-year disruptions in coverage: require insurers to accept third party payments directly from legitimate nonprofit organizations, and disallow insurer actions to terminate policyholders midyear on the basis of how they've paid their premium. AKF has provided premium assistance for the full policy year since the inception of our program in 1997. Midyear terminations are not occurring because of AKF. We have provided ample evidence to the Department that insurance companies are engaging in numerous tactics to dis-enroll people who need charitable help paying for their coverage. The solution to this problem is to require the issuers to accept the payments directly on behalf of ESRD patients in the same manner that HHS has protected those living with HIV/AIDS. Anything less is discriminatory toward the patient population we serve.

IV. Conclusion

ESRD patients are facing a life-threatening condition. For 20 years, they have relied upon AKF to help them when they cannot afford their public or private insurance coverage. The Department's interim final rule has already had a chilling effect on our ability to help these individuals; in addition to individual market plans, we are hearing from COBRA administrators, Medigap plans and others that they will no longer accept AKF's payments. The people we serve will have nowhere to go without our assistance, except for Medicare and Medicaid if they are eligible, and many will be saddled with crippling medical debt as a result. We strongly believe the Department has issued this rule in haste and is unaware of the severe implications it will have. We reiterate the request we have made over the past several years: we want to work with the Department to find a solution to this issue, and we urge you to put patients first. Please do not implement the rule as written, but instead, work with the patient and provider communities to find

practical ways of ensuring that every ESRD patient is fully informed and fully independent when selecting insurance coverage.

We look forward to your response and look forward to further discussions with the Department.

Sincerely,



LaVarne A. Burton

President and CEO