In the Supreme Court of the United States

 $\begin{array}{c} \text{MARIETTA MEMORIAL HOSPITAL} \\ \text{EMPLOYEE HEALTH BENEFIT PLAN, ET AL.,} \\ Petitioners, \end{array}$

v.

DAVITA INC., ET AL.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Sixth Circuit

BRIEF OF KIDNEY CARE PARTNERS AS AMICUS CURIAE IN SUPPORT OF RESPONDENTS

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INTERESTS OF AMICUS CURIAE¹

Kidney Care Partners is a non-profit coalition of more than 30 organizations, comprising patients, dialysis professionals, physicians, nurses, researchers, therapeutic innovators, transplant coordinators, and manufacturers. They are dedicated to working together to improve the quality of care for individuals living with kidney disease.

This case presents an issue of great importance for Kidney Care Partners and its members, as well as the patients who depend on them for dialysis treatments each year. Health insurance plans like the Marietta Memorial Hospital Employee Health Benefit Plan at issue here force patients off of private insurance and onto Medicare. This results in reduced quality of patient care, increased patient expenses, and reduced access to lifesaving treatment. Such a scheme runs directly contrary to Kidney Care Partners' goals of improving the coordination of care, further understanding chronic kidney disease, and lowering the barriers that block patients from accessing and choosing treatments.

SUMMARY OF ARGUMENT

Hundreds of thousands of Americans with End Stage Renal Disease are alive right now due to the widespread availability of dialysis—a change that occurred only within the last fifty years. The dialysis payment system is structured around a careful

¹ Pursuant to Supreme Court Rule 37.6, *amicus curiae* states that no counsel for any party authored this brief in whole or in part and that no entity or person, aside from *amicus curiae*, its members, or its counsel, made any monetary contribution intended to fund the preparation or submission of this brief. Pursuant to Supreme Court Rule 37.3, counsel of record for all parties have consented to this filing.

balance struck by Congress between public and private insurers. Plans like Petitioners' threaten to upset this balance, running directly contrary to Congress's clear intent and statutory design.

A. When dialysis first emerged as a treatment for End Stage Renal Disease, its lifesaving promise was limited due to the complexity and expense of the procedure. Recognizing the transformative potential of dialysis, Congress chose to expand Medicare to cover nearly all End Stage Renal Disease patients. This expansion quickly proved extremely expensive, in part because private insurers began to design plans to force patients onto Medicare instead of covering dialysis like they would pay for treatment for nearly any other chronic disease. In addition to shifting costs to the government, these practices deprived patients of the many benefits that accrued from the choice to retain private coverage. To preclude this behavior, Congress enacted the Medicare Secondary Payer Act, which struck a careful balance. Private insurance covers treatment costs for a fixed period, after which Medicare becomes the primary payer. To prevent private insurers from gaming the system, Congress enacted broad antidiscrimination provisions barring discrimination on the basis of End Stage Renal Disease.

B. 1. Plans like Petitioners' accomplish—and, in fact, are designed to accomplish—exactly what Congress sought to prohibit. They limit coverage for necessary treatment, thereby foreclosing patient choice and exposing patients to significant financial risk. These measures are especially effective in forcing patients off of private plans and onto Medicare because End Stage Renal Disease disproportionally affects already-vulnerable populations. In this way, such outlier plans exacerbate existing healthcare inequities.

2. In addition to flouting the will of Congress, plans like Petitioners' create enormous systemic risk. To begin, they risk destabilizing the Medicare system by significantly increasing Medicare costs, despite Congress's attempt to control costs through the Medicare Secondary Payer Act. But without Medicare, few Americans would be able to access dialysis, which would be catastrophic. Additionally, outlier plans like the one at issue here threaten the viability of private, standalone dialysis facilities. These facilities provide the vast majority of dialysis to End Stage Renal Disease patients. But they receive less from Medicare than it costs to provide dialysis treatments; independent analysis by the Medicare Payment Advisory Commission has shown Medicare rates to be near or below breakeven in most years. Dialysis facilities rely on private insurance reimbursement to remain in operation. If patients are all forced onto Medicare, many facilities—especially in rural areas—may close, limiting the availability of lifesaving treatments.

In short, discriminatory plans that force End Stage Renal Disease patients onto Medicare as soon as they are eligible to enroll threaten to undermine Congress's goal of ensuring that dialysis is available and affordable for all Americans. Such violations of Congress's clear intent and statutory design must not be permitted to stand.

ARGUMENT

Kidney failure is a widespread and fatal ailment. Each year, over 100,000 Americans are diagnosed with irreversible kidney failure, known as End Stage Renal Disease (ESRD). See U.S. Renal Data System, *ESRD in the United States* 291 (2018). Less than a century ago, a diagnosis of ESRD would have been a death sentence for nearly all of these patients. By the middle of the last century, advances in medical

technology (including the development of the artificial kidney and refinements in dialysis techniques and kidney transplants) began to offer hope to ESRD patients. Richard A. Rettig, *Origins of the Medicare Kidney Disease Entitlement: The Social Security Amendments of 1982, in Biomedical Politics* 177-78 (Kathi E. Hannah ed., 1991).

Unfortunately, the overall impact of these advances was limited. In the 1960s, dialysis was too rare and expensive for nearly all ESRD patients. Rettig, *supra*, at 6. After a growing movement for federal intervention (*id.* at 187-88), Congress enacted the Social Security Amendments of 1972, guaranteeing Medicare coverage, including dialysis, for almost every American diagnosed with ESRD. Pub. L. No. 92-603, § 299I (1972).

Ensuring the availability of dialysis for ESRD patients was enormously expensive, however, and the ballooning need for and cost of dialysis threatened the viability of the Medicare program as a whole. Allen R. Nissenson & Richard A. Rettig, Medicare's End-Stage Renal Disease Program: Current Status and Future Prospects, 18 Health Affairs 161, 165 (1999). To combat these costs and safeguard the Medicare fisc—in addition to protecting the benefits to patients from the choice of retaining private coverage—Congress enacted a careful public-private balancing scheme in the Medicare Secondary Payer Act (MSPA) in 1980. Pub. L. No. 96-499 (1980) (codified at 42 U.S.C. § 1395y). Essentially, Congress decided that during a "coordination period," private insurance should be the primary payer for ESRD treatments, but that after the coordination period Medicare would become the primary payer for the duration of the patient's need. 42 U.S.C. $\S 1395y(b)(4), (b)(1)(C)(ii).$

Recently, some outlier private health plans have sought to upend Congress's carefully calibrated distribution of dialysis costs. By adopting terms that are specifically and intentionally unfavorable to insureds with ESRD, plans like the Marietta Memorial Hospital Employee Health Benefit Plan are designed to force patients to abandon their private health insurance in favor of Medicare during the coordination period. These plans threaten both the viability of the Medicare fisc and the availability of affordable dialysis for ESRD patients. Such plans violate Congress's clear intent, and cannot be sustained.

A. Congress struck a delicate public-private cost-distribution scheme in the MSPA.

On March 9, 1960, Clyde Shields started hemodialysis at University Hospital in Seattle. Christopher R. Blagg, *The Early History of Dialysis for Chronic Renal Failure in the United States: A View from Seattle*, 49 Am. J. Kidney Diseases 482, 483 (2007). Thus began "one of the most important medical advances of the 20th century," ushering in a new era of hope for ESRD patients around the world. *Ibid*.

Dialysis, however, remained largely inaccessible to most Americans for years. "[I]n the early 1970s, a dialysis treatment lasted around twelve hours and was very expensive, due to the high outlay for materials and the treatment itself." The History of Dialysis, Fresenius Medical Care (accessed Jan. 20, 2022), perma.cc/7VTZ-AXU5. In particular, dialysis treatment for ESRD patients is expensive because most patients receive dialysis regularly and frequently—typically three times a week, or more than 150 times per year. Ctr. for Medicare & Medicaid Servs., Medicare Benefit Policy Manual, Ch. 11 at 10(A)(1) (Mar. 1, 2019), perma.cc/JN5R-LR3N. As a result, this

lifesaving treatment was rationed—"committees decided on how the small number of treatment slots should be allocated." *Id.*; see Shana Alexander, *They Decide Who Lives, Who Dies*, 53 Life 102 (1962); H.G. Lawson, *Kidney Machines Save "Doomed" Patients Lives but Raise Ethical Issue*, Wall St. J. (Aug. 22, 1963).

By the 1970s, however, support was growing for a federal solution to the dialysis shortage. Congressman John Fogarty "visited Seattle in November 1965 to see a patient dialyzing at home" and "returned to Washington expressing support for a home dialysis policy." Blagg, supra, at 490. A year later, the Committee on Chronic Kidney Disease "recommended establishment of a national treatment program" funded by Medicare. Id. (citing Report of the Committee on Chronic Kidney Disease, Bureau of the Budget (1967)). In 1971, Shep Glazer underwent dialysis treatment on the floor before the House Committee on Ways and Means. Id. at 491. These efforts culminated in the passage of the Social Security Amendments of 1972, which expanded Medicare coverage to nearly all Americans diagnosed with ESRD. Pub. L. No. 92-603 (1972).

Initial estimates predicted that the Medicare expansion would cost around \$100 million to treat 25,000 ESRD patients. Rettig, supra, at 197; see also Blagg, supra, at 492 (noting that the National Kidney Foundation estimated a first-year cost of \$35 to \$75 million). These figures almost immediately proved to be dramatic underestimates. By the beginning of 1973, federal experts calculated first-year costs at \$135 million and predicted that costs would rise to \$1 billion annually within ten years. Richard D. Lyons, Program to Aid Kidney Victims Faces Millions in Excess Costs, N.Y. Times (Jan. 11.

perma.cc/D59H-XGPJ. By 1980, increases in ESRD frequency and dialysis cost had driven Medicare ESRD costs above \$1.2 billion. Nissenson & Rettig, *supra*, at 165.

To combat ballooning Medicare costs, Congress passed the MSPA in 1980. Pub. L. No. 96-499 (1980); see United Seniors Ass'n v. Philip Morris USA, 500 F.3d 19, 21 (1st Cir. 2007) ("The MSP statute . . . was enacted in 1980 to reduce federal health care costs."). The MSPA functions by making Medicare the secondary payer for "medical services provided to Medicare beneficiaries" in certain circumstances where "payment is available from another primary payer." *Ibid*. In 1981, Congress extended the MSPA to cover ESRD patients. Pub. L. No. 97-35, § 2146 (1981). Congress created a coordination period (now 30 months) in which ESRD patients' private insurance plans (if any) serve as the primary payer for ESRD treatments, including dialysis. See 42 U.S.C. § 1395y(b)(4). After this coordination period ends. Medicare assumes responsibility as the primary payer.

In passing the MSPA, Congress intended to address the situation in which Medicare was paying for "services [that] could have been paid for by a private insurance carrier." H.R. Rep. 96-1167 at 389 (1980). In particular, Congress was concerned that Medicare was being used to "relieve private insurers of obligations to pay the costs of medical care in cases where there would otherwise be liability under the private insurance contract." *Ibid*.

Similar concerns animated Congress's decision to extend the MSPA to cover ESRD patients. At the time, "many private health insurance plans provide[d] very comprehensive health benefit protection, including protection against catastrophic health expenses." S. Rep. 97-139 at 735 (1981). But those plans paid "little,

if anything, toward the costs of kidney dialysis treatments or organ transplantation." Ibid. Congress had no trouble identifying the cause of this discrepancy: "most health plans * * * contain provisions that are intended to prevent payments of benefits where the insured is also entitled to benefits as a result of coverage under a program such as Medicare." *Ibid.* In essence, "since Medicare pays first and provides very comprehensive benefits for those with end-stage renal disease, private plans pay little of the expenses incurred by most end-stage renal patients." *Ibid.*; accord Bio-Medical Applications of Tenn., Inc. v. Cent. States Health and Welfare Fund, 656 F.3d 277, 281 (6th Cir. 2011) ("[T]he precise problem that Congress sought to ameliorate was that private plans would provide inferior benefits or coverage for medical treatment that was also covered by Medicare.").

In addition to concerns of national finance, protecting patients' ability to remain on private health plans benefits the patients directly. As Congress has recognized in the Affordable Care Act, patient choice of health plans and freedom from discriminatory practices are both important values in the federal regulation of health insurance. Under the current MSPA structure, dialysis patients can and do choose to retain commercial coverage during the coordination period. And they do so for a variety of reasons. For some patients, family members who are also covered by a plan would have different deductibles and cost-sharing requirements if the patient enrolls in Medicare. Some plans may provide coverage that Medicare does not offer or have lower coinsurance obligations. Some patients rely on private insurance as long as they can because they live in one of the many states that does not allow dialysis patients to purchase Medigap policies. Congress sought to protect these patients'

interests, as well, by extending and then repeatedly reauthorizing the MSPA.

Congress recognized that this new cost allocation created warped incentives for private insurance plans. Without additional guardrails, private insurers could continue to foist nearly all of the costs of ESRD onto the federal government simply by limiting or eliminating coverage for ESRD patients or ESRD treatments. It should come as no surprise, therefore, that Congress sought to address such "discriminatory provision[s]." S. Rep. 97-139 at 736.

The antidiscrimination provisions of the MSPA broadly prohibit several categories of actions by private insurance plans. See 42 U.S.C. § 1395y(b)(1)(C). In general, a plan "may not take into account that an individual is eligible for or entitled to Medicare benefits on the basis of ESRD during the coordination period." 42 C.F.R. § 411.161(a)(1). The "take into account" regulations echo Congress's concern that plans will attempt to structure themselves in such a way as to force ESRD patients to rely on Medicare. See, e.g., 42 C.F.R. § 411.108(a)(9) (prohibiting plans from "[p]roviding misleading or incomplete information that would have the effect of inducing a Medicare entitled individual to reject the employer plan, thereby making Medicare the primary payer"). Nor can plans "differentiate in the benefits [they] provide[] between individuals having end stage renal disease and other individuals covered by such plan on the basis of the existence of end stage renal disease, the need for renal dialysis, or in any other manner." 42 U.S.C. § 1395y(b)(1)(C)(ii) (emphasis added). This provision extends to blatantly discriminatory practices such as differential pricing based on an ESRD diagnosis as well as "[f]ailure to cover routine maintenance dialysis or kidney transplants, when a plan covers other dialysis services or other organ transplants." 42 C.F.R. § 411.161(b). Congress crafted these broad provisions with the clear intent to prevent plans from forcing dialysis patients off of private coverage and onto Medicare.

B. Petitioners' health plan was designed specifically to defeat Congress's preferred allocation of costs.

Congress crafted an intricate, well-balanced scheme to ensure that dialysis would remain available to ESRD patients. But unlike the vast majority of insurers, plans like Petitioners' threaten to upset that delicate balance by attempting to game the system. By crafting plan terms that are designed to force ESRD patients off of private insurance and onto Medicare, Petitioners and similar plans flaunt Congress's intent and threaten the stability of the entire dialysis system.

1. The unambiguous intent and clear consequence of Petitioners' plan design is to force insureds to rely on Medicare during the coordination period.

Health plans like Petitioners' will have the predictable result of driving insureds with ESRD off of the private insurance and onto Medicare during the coordination period—as Respondents have ably explained. Respondents' Br. 12-16. Unlike nearly all other large private insurance plans, Petitioners' plan has "no network for [outpatient dialysis] services." JA 13. This lack of a network exposes ESRD patients to significant financial risk, putting them on the hook for the delta between what the plan pays out-of-network providers and the cost of the treatment. Respondents' Br. at 15-16. And the plan exposes ESRD patients to higher deductible and coinsurance payments. *Ibid.*

Unsurprisingly, these factors combine to nudge patients with ESRD to turn to Medicare instead.

Nor can there be any real doubt that this is precisely the result that these nonstandard plan-designers intend. MedBen, for example, is a benefit manager who advertised that its "proprietary dialysis health plan language" can save employers "substantial savings on" outpatient dialysis. Costly Dialysis Legislation Should Spark Plan Language Change, WayBack Machine — MedBen Blog (Aug. 24, 2018), perma.cc/69ZW-78XW?type=image. Until recently, MedBen also described the company's Layered Reference-Based Pricing as specifically "[t]arget[ting] high-cost medical treatments, such as kidney dialysis." Networks, MedBen (Apr. 11, 2021), perma.cc/NZA7-3PPU.

Renalogic, a consulting company based in Arizona, similarly touts a "dialysis cost containment" program that it claims can save insurers huge sums in dialysis payments each year. Br. for Appellants, Davita, Inc. v. Amy's Kitchen, Inc., No. 19-15963 (9th Cir. 2019). The structure of Renalogic's cost containment program is similar to the plan at issue here—it eliminates in-network coverage for outpatient dialysis treatments while leaving all other coverage the same. *Ibid.* But separately, Renalogic's chief legal officer has explained that the "well established strategies * * * to pay dialysis claims at less than provider-billed charges-for example, using specifically designed plan language and consistent methodologies, such as defined 'usual and customary' or 'usual and reasonable rate' provisions * * * vary in legal defensibility." John Christiansen, The Hidden Perils of Dialysis Claims, Leader's Edge (Oct. 29, 2019), perma.cc/JGE4-8ZUJ.

Plans such as Petitioners'—along with those who develop and sell these strategies—unabashedly seek to reduce dialysis costs by shifting costs and risk to ESRD patients. But ESRD patients are already disproportionately members of vulnerable communities. According to the United States Renal Data System. the adjusted prevalence of ESRD was 3.4 times higher in Black Americans than White Americans. United States Renal Data System, 2020 USRDS Annual Data Report: Epidemiology of Kidney Disease in the United States, Vol. 2, Ch. 1, at 1 (2020). This reflects only incremental progress over the last ten years—the ratio was 3.7 in 2008. *Ibid.* Similarly, the ESRD prevalence in Hispanic populations was found to be more than 1.5 times higher than in non-Hispanics in 2018. Ibid. Patients in these populations are also less likely to receive transplants, meaning that they will need dialysis for longer. *Ibid.* at Figure 6.9.

There can be no question that these outlier insurers' goal is to force patients off of their plans and onto Medicare, seeking to do precisely what Congress prohibited: "gaming' Medicare when it comes to ESRD." Christiansen, *supra*. On top of the blatant inconsistency with Congressional purpose and statutory design, Petitioners' approach will expand existing inequities in the delivery of healthcare to individuals with kidney disease.

2. Petitioners' defiance of Congress's costallocation scheme carries grave risks.

In addition to directly contradicting Congress's designs, outlier plans like Petitioners' create significant risk to the availability of dialysis as a whole. Forcing patients to rely on Medicare during the coordination period undermines the stability of both the

public and private components of the system, to the ultimate detriment of ESRD patients.

1. First, plans that disregard Congress's allocation of costs during the coordination period threaten the viability of the Medicare fisc. As described above, Congress passed the MSPA in part to curb ballooning Medicare dialysis payments. Increased prevalence of ESRD and cost of dialysis caused Medicare expenditures to quickly outstrip early estimates. See, *e.g.*, Lyons, *supra*. The Senate estimated in 1981 that extending the MSPA to cover ESRD patients would save \$440 million within the first four years alone. S. Rep. 97-139 at 736.

The MSPA has been enormously effective in reducing Medicare dialysis costs. When Congress extended the coordination period to its current 30-month length in 1997, the Congressional Budget Office estimated that the extension alone "would save \$7.5 billion between 1998 and 2002." H.R. Rep. No. 105-149, at 1400 (1997). The Congressional Research Service has estimated that the MSPA reduced Medicare expenditure by about \$50 billion between 2006 and 2012, billions of dollars of which are attributable to the inclusion of ESRD. Suzanne M. Kirchhoff, Cong. Rsch. Serv., RL33587, Medicare Secondary Payer: Coordination of Benefits 2 (May 8, 2014).

Elimination of these savings would constitute a significant diminution of the benefits from the MSP program that could threaten the Medicare fisc. Congress has made that clear with the passage, continuous reenactment, and expansion of the MSPA. The nation's experience with the early days of dialysis rationing illustrates that a purely private solution cannot ensure the widespread availability of lifesaving ESRD treatments including dialysis. See Alexander, *supra*; Lawson, *supra*. As Congress recognized when

extending the MSPA to cover ESRD patients, the existence and solvency of Medicare is a precondition to the availability of dialysis relied on by hundreds of thousands of Americans each year. Plans such as Petitioners' threaten the entire system and must therefore not be permitted to dodge Congress's allocation of costs.

2. Just as a purely private payment system was inadequate to ensure widespread availability of dialysis for ESRD patients, so too would a purely public reimbursement scheme fail. Dialysis providers rely on private insurance payments to remain in business. Forcing ESRD patients to rely on Medicare during the coordination period threatens the availability of dialysis from these providers, creating a risk of dialysis scarcity and imposing additional burdens on patients who may have to travel further or wait longer for necessary treatments.

Freestanding dialysis facilities provide the vast majority of dialysis treatments. In 2019, for example, freestanding outpatient facilities furnished 96% of treatments, and for-profit facilities furnished 89%. MedPAC, Report to the Congress: Medicare Payment Policy 174 (Mar., 2021), perma.cc/ESM9-EYYK.

But for years, the cost of providing dialysis has exceeded the amount Medicare reimburses for the treatment. In 2017, for example, an independent review of public information estimated that Respondent lost \$21 for each dialysis treatment provided to a Medicare patient—almost 10% of the total cost of the treatment. Adam A. Shpigel et al., A Comparison of Payments to a For-Profit Dialysis Firm from Government and Commercial Insurers, 179 JAMA Internal Med. 1136, 1137 (2019). Naturally, dialysis providers must recoup this deficit in order to stay afloat—the only alternative to

ceasing operation and thus depriving ESRD patients of necessary dialysis treatments.

But experts estimate that Medicare is the secondary payer for nearly 10% of all ESRD patients, as compared to the nearly 60% for which it is the primary payer. Suzanne M. Kirchhoff, Cong. Rsch. Serv., R45290, *Medicare Coverage of End-Stage Renal Disease (ESRD)* 7-8 (Aug. 16, 2018). The MSP population represents a significant portion of the patient population from which dialysis providers can recoup enough of their costs to continue operations—especially since nearly 15% of the patients for whom Medicare was not counted as the primary payer were in Part C Medicare Advantage plans. *Id.* at 7.

These risks are especially acute for rural dialysis facilities, which make up 17% of all freestanding dialvsis facilities and account for 12% of all dialysis treatments at such facilities. MedPAC, supra, at 188. Rural facilities have lower margins than urban facilities, due to the lower treatment volume. Id. at 186. And government incentives designed to keep low-volume facilities in business have historically resulted in dramatic underpayment. See U.S. Gov't Accountability Off., GAO-13-287, End Stage Renal Disease: CMS Should Improve Design and Strengthen Monitoring of Low-Volume Adjustment 11 (2013). These rural facilities—which many Americans rely on for life-sustaining treatments multiple times per week—are uniquely vulnerable to the decreased margins from plans forcing patients off of private insurance and onto Medicare.²

² The same is true for low-volume urban dialysis facilities, which often provide treatments in underserved areas. While urban facilities typically have higher operating margins than rural facilities, facilities across locations in the lower two quintiles of

Congress sought to ensure that Americans with ESRD have access to lifesaving dialysis treatments by extending access to Medicare. It then sought to ensure the continued viability of Medicare by carefully balancing the allocation of costs between the government and private insurance plans, to which many patients had been making payments for decades with the expectation that the plans would pay for treatment in the event of chronic illness. Plans like Petitioners' flaunt Congress's well-considered and delicate choices about these programs. In doing so, they jeopardize both the solvency of Medicare and of private, freestanding dialysis facilities that provide the vast majority of treatments. Such an outcome is plainly inconsistent with Congress's intent, and with the intricate statutory and regulatory scheme that it crafted to help create a world in which a diagnosis of ESRD no longer spelled imminent, needless death for Americans.

treatment volume typically have negative margins when compared to the Medicare reimbursement rate. MedPAC, *supra*, at 189 Fig. 6-6.

CONCLUSION

The Court should affirm. Respectfully submitted.

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