No. 20-1641

IN THE

Supreme Court of the United States

MARIETTA MEMORIAL HOSPITAL EMPLOYEE HEALTH BENEFIT PLAN., *et al.*,

Petitioners,

v.

DAVITA INC., *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

BRIEF OF MR. THOMAS A. SCULLY AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

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STATEMENT OF INTEREST OF *AMICUS CURIAE*[1]

Mr. Thomas A. Scully has over 30 years of experience with health care public policy in both public and private positions. He served as the Administrator of the Centers for Medicare and Medicaid Services (CMS) from 2001 through 2004, and as Deputy Assistant to the President for Domestic Policy and Associate Director of the White House Office of Management and Budget for Health (OMB) from 1989 through 1993 under President George H.W. Bush. In his role as CMS Administrator, Mr. Scully was responsible for, among other duties, directing the planning, coordination, and implementation of programs under Title XVIII of the Social Security Act—which includes the Medicare program for end-stage renal disease (ESRD)—and directing the development of effective relationships between those programs and private and federally supported health-related initiatives. Mr. Scully's responsibilities at OMB included the oversight of agency performance and financial management, as well as the coordination and review of federal regulations from executive agencies. Thus, Mr. Scully's work in the public sector was deeply intertwined with the very programs and issues at the heart of this lawsuit.

Mr. Scully also has served as the President and CEO of the Federation of American Hospitals, which represents

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1. Pursuant to Supreme Court Rule 37.3, counsel of record for all parties have consented to this filing. Pursuant to Supreme Court Rule 37.6, *amicus curiae* states that no counsel for a party has authored this brief in whole or in part. *Amicus curiae* further states that no such counsel or party has made a monetary contribution to fund the preparation or submission of this brief, but non-party Fresenius Medical Care Holdings Inc. has made such a monetary contribution.

approximately 1700 privately-owned hospitals, and he currently advises clients on health care matters in the private sector with the law firm of Scully, Roskey and Missmar. From 1997 to 2001, Mr. Scully served on the board of directors of DaVita, Inc., before becoming CMS Administrator. Accordingly, Mr. Scully has extensive experience with Medicare policies and operations regarding ESRD and dialysis, which gives him a unique understanding of the role of the Medicare Secondary Payer Act (MSPA) in the system of coverage for ESRD patients and the policy choices Congress has made to protect public funds and patient access to care.

SUMMARY OF ARGUMENT

Petitioners' argument for reversal rests on their assertion that a group health plan may adopt dialysis-only benefit restrictions as long as the plan treats ESRD and non-ESRD outpatient dialysis services in the same manner. As a practical matter, such a dichotomy between ESRD and dialysis is meaningless. Outpatient dialysis is an almost exclusively ESRD treatment, with over 99% of dialysis treatments provided to ESRD patients. Non-ESRD uses for dialysis are infrequent, limited, and temporary, particularly in the outpatient setting. They simply do not comprise a meaningful portion of a facility's dialysis services. Petitioners' attempt to justify the discriminatory dialysis benefit based on a supposed ESRD – non-ESRD parity cannot be squared with the realities of the dialysis industry. It is nothing more than a backdoor strategy to evade the plan's obligation to pay for dialysis for plan members with ESRD.

The MSPA prevents exactly that. Medicare's ESRD program and the MSPA contribute to a long-standing

framework that Congress designed to balance the interests of patients, providers, insurers, and public funds. Medicare covers the cost of treating over 80% of ESRD patients, and thus, the federal government relieves commercial insurers of much of the responsibility for that care and allows access to individuals who otherwise lack insurance. To sustain the ESRD system, Medicare limits reimbursement for dialysis services to near cost—at times less than cost—and requires commercial insurers to cover their members during a limited period after an ESRD diagnosis.

For decades, legislators, regulators, and industry participants have understood the critical role of the MSPA's coordination period in Medicare's ESRD program. During that period, commercial insurers are to pay primary for their members with ESRD, and the plans cannot manipulate their benefits to discriminate in coverage against such members. Thus, the coordination period provides necessary financial protection for Medicare, while commercial insurers pay for plan members' ESRD care, most notably dialysis. The period also gives providers a limited time of market reimbursement and revenue which is needed to sustain the large-scale system of accessible, quality dialysis services for a medically compromised, complex, and expensive patient population.

Discriminatory limitations on outpatient dialysis benefits, like those adopted by Marietta's plan, disrupt the cost-sharing balance implemented by the MSPA and maintained for years. Targeting the treatment synonymous with ESRD to avoid the central expense of the ESRD system creates an imbalance that legislative and regulatory measures have sought to avoid for decades.

Such restrictions will likely push ESRD patients onto Medicare prematurely—as happened in this case. By doing so, the dialysis-benefit restrictions will not only increase Medicare's costs but also threaten patient access by decreasing providers' period of market revenue and risk harming patients through increased out-of-pocket and prescription costs, potential gaps in coverage, and the loss of coverage for dependents who are ineligible for Medicare.

ARGUMENT

I. Dialysis Is Synonymous With ESRD.

A. Only ESRD Patients Require Maintenance Dialysis to Survive.

Kidney failure is a prevalent and deadly condition affecting millions of Americans nationwide. *See* Nat'l Kidney Found., *Kidney Disease: The Basics*. Kidney failure typically results from chronic kidney disease, which impacts an estimated 37 million Americans—nearly 15% of the population. *Id*. ESRD, the final stage of chronic kidney disease, is defined by the cessation of kidney function "on a permanent basis leading to the need for a regular course of long-term dialysis or a kidney transplant to maintain life." CMS, *Coordination of Benefits & Recovery Overview, ESRD*; 42 C.F.R. § 406.13(b) (ESRD "requires a regular course of dialysis" or transplant). ESRD is fatal without treatment. Kirchhoff, Congressional Research Service, *Medicare Coverage of End-Stage Renal Disease (ESRD)* 2 (2018) ("Kirchhoff"). Nearly 800,000 Americans live with ESRD. *See* Nat'l Inst. of Diabetes and Digestive and Kidney Diseases ("NIDDK"), *Kidney Disease Statistics for the United States*.

Because kidney transplants, though often a preferred treatment, are difficult to obtain, the majority of ESRD patients undergo dialysis as their primary form of renal replacement therapy—most often at an outpatient clinic, such as those operated by DaVita. *E.g.*, United States Renal Data System, *2021 Annual Data Report, End Stage Renal Disease* ch. 1 (2021) (Figure 1.6) (68.8% of ESRD patients were treated with dialysis in 2019); *id.* at Summary (in-center hemodialysis "remains the most common form of kidney replacement therapy by a wide margin"); *id.* at ch. 7 (Figure 7.2) (in 2019, 78,690 patients with ESRD were on the waitlist for kidney transplant); *id.* (Figure 7.10) (median wait-time of 51.6 months for kidney transplant patients who were initially waitlisted in 2014); NIDDK, *Kidney Disease Statistics for the United States* (only 29% of ESRD patients receive a kidney transplant). In dialysis, an external machine removes blood from the patient's body and filters it with a dialysate solution to eliminate waste, salt, and water. NIDDK, *Hemodialysis*. ESRD patients typically receive dialysis three times per week. *Id.*

B. Nearly All Patients Served by Outpatient Dialysis Clinics Have ESRD.

The need for ongoing dialysis is unique to ESRD patients; they account for at least 98% of the patients receiving dialysis treatments from outpatient dialysis facilities. While dialysis occasionally is used on a temporary basis to treat other kidney impairments, such as acute kidney injury ("AKI") or kidney injury caused by a heart attack, this use of dialysis materially differs from the regular course of dialysis ESRD patients receive. Kirchhoff, at 2. Instead of regular thrice-weekly sessions,

non-ESRD patients need dialysis only on a limited basis, and, for some, the dialysis occurs in the hospital while the patient is treated for the underlying cause.

Examination of the largest group of non-ESRD dialysis patients—those with AKI—is particularly telling. AKI is a "sudden episode of kidney failure" or damage that generally lasts only a few days and is primarily caused by a result of decreased blood flow, direct damage to the kidneys, or blockages in the urinary tract. *See* Nat'l Kidney Found., *Acute Kidney Injury (AKI)*; Forni, *Renal recovery after acute kidney injury*, 43 Intensive Care Med. 855-66 (2017); Am. Kidney Fund, *Acute Kidney Injury & Failure (AKI) Symptoms, Causes, & Treatments*. In contrast with the maintenance dialysis needed by ESRD patients, treatment for AKI usually consists of *temporary* dialysis treatments or medications. *Id.* Unsurprisingly, then, the number of AKI patients treated by outpatient dialysis facilities is very small. For example, DaVita reports that 99.5% of the treatments at its facilities are for ESRD patients. Resp. Br. 6; App.42 (acknowledging DaVita's assertion that "in a pie chart of dialysis-users, ESRD-diagnosed individuals would take up almost the full pie.").

Medicare numbers are comparable. Due to the gross disparity between ESRD patients and those seeking dialysis at an outpatient clinic for another reason, Medicare historically did not provide coverage for patients with AKI who sought dialysis at those facilities. Kirchhoff, at 19. In January 2017, however, the Trade Preferences Extension Act of 2015 took effect and extended Medicare coverage for dialysis services to Medicare beneficiaries with AKI. *See* Trade Preferences Extension Act of 2015, Pub. L. No. 114-

27 § 808, 129 Stat. 362, 418-19 (2015). Even so, the number of AKI patients who seek treatment at outpatient dialysis clinics remains remarkably low compared to those with ESRD. United States Renal Data System, *2021 Annual Data Report, Chronic Kidney Disease* ch. 4 (Figure 4.13) (in 2019, approximately 11,380 Medicare patients sought dialysis from an outpatient center for AKI). Considering the 550,000 Medicare ESRD patients who rely on thrice weekly maintenance dialysis, AKI patients account for just 2% of Medicare beneficiaries who seek dialysis—98% are ESRD patients. *See* United States Renal Data System, *2021 Annual Data Report, End Stage Renal Disease* ch. 9.

In short, dialysis is not merely a rough proxy or "associated" treatment for ESRD patients, and the suggestion that there are distinct groups of ESRD and non-ESRD dialysis services covered by commercial plans is far removed from the reality of outpatient dialysis treatments. Dialysis was created for ESRD, and outpatient dialysis remains an almost exclusively ESRD treatment today.

II. Congress Understood the Unavoidable Link Between ESRD and Dialysis and Crafted a Cost-Sharing System to Provide a Sustainable ESRD Program and Protect Patient Access to Dialysis.

A. The Need for Ongoing Dialysis and Its Availability and Expense Motivated Congress's Policy Choices Regarding Medicare Coverage and Payment for the Treatment of ESRD.

Congress was well-aware of the inescapable connection between dialysis and ESRD and did not intend the

proposed dichotomy Petitioners suggest. Indeed, dialysis—particularly outpatient maintenance dialysis—was the impetus for both the adoption of Medicare coverage for ESRD patients and Congress's subsequent measures to control costs and sustain the program, including the MSPA.

1. Congress established the Medicare entitlement for ESRD patients in 1972 to enable widespread access to life-saving dialysis treatments. *See generally* 47 Fed. Reg. 6556-01, 6556 (Feb. 12, 1982) (history of ESRD program); 42 U.S.C. §§ 426-1, 1395rr. Before the Medicare program, maintenance dialysis was accessible only for a fraction of the ESRD population due to cost and limited availability. Kirchhoff, at 6. Congress responded with an unprecedented expansion of Medicare. ESRD patients are entitled to Medicare coverage based solely on their medical condition, without regard to age or disability. Thus, almost all ESRD patients are eligible for benefits within a few months of diagnosis. 42 U.S.C. §§ 426-1, 1395rr.

Dialysis has been the primary driving force behind Congress's delineation of the entitlement program's benefits and requirements. References to "dialysis" or "renal dialysis facilities" pervade the statutory scheme. Specifically, the ESRD provisions link the beginning of Medicare coverage to the initiation of a "regular course of renal dialysis" (or the receipt of a kidney transplant), 42 U.S.C. § 426-1; establish detailed provisions regarding the reimbursement of dialysis facilities, *id.* § 1395rr(b), (e), (g); create networks of dialysis and transplant facilities, *id.* § 1395rr(c); provide for experiments, studies, and pilot programs related to dialysis, *id.* § 1395rr(f); and

adopt quality incentives and performance standards for dialysis services and facilities, *id.* § 1395rr(h). In short, the ambit of Medicare ESRD coverage, to a great extent, rests on the role of maintenance dialysis in treating ESRD patients.

2. Not surprisingly, then, maintenance dialysis—and, more specifically, its expense—also underlies Congress's cost-containment measures. Medicare's ESRD program quickly surpassed the anticipated costs, driven predominantly by the expense of covering ongoing dialysis treatments and the growing number of individuals with ESRD. *See* Part III.A, *infra.* The program began with 11,000 beneficiaries in 1973, and Medicare spent $229 million on services for ESRD beneficiaries in 1974. *See generally* 47 Fed. Reg. at 6556. Within five years, there were over 42,000 beneficiaries, and Medicare's expenses were around $985 million, including for over six million dialysis treatments. *Id.* By 1980-81, ESRD patients comprised less than 1% of the individuals enrolled in Medicare yet accounted for over 4% of the total expenditures and 9% of the Part B expenditures (which includes payments for outpatient services, including dialysis). *Id.*; CMS, *CMS Statistics Reference Booklet, 2008 Edition* (Tables I.1 & I.5).

Congress adopted cost-containment and cost-sharing measures in the following decades to fund the rapidly expanding program while sustaining widespread access to treatments. *See* Inst. of Med. Comm. for the Study of the Medicare End Stage Renal Disease Program, *Kidney Failure and the Federal Government* ("IOM Rep."). In the 1980s, Congress switched to a mandated prospective composite rate payment to cover most outpatient dialysis

services and reduced the reimbursement rate, which had remained fixed from 1973 to 1983. Pub. L. No. 97-35, 95 Stat. 357 (1981), § 2145; IOM Rep. (reimbursement rate fixed between 1973 and 1983 with no adjustment for inflation and reduced in 1983 and 1986). Since then, Congress has authorized only limited rate increases, and, today, Medicare pays a prospective bundled payment covering an even greater number of dialysis services at a rate that is significantly lower than the market rate and subject to only marginal adjustments. *See* Pub. L. No. 110-275, 122 Stat. 2494 (2008), § 153 (effective Jan. 1, 2011); 42 C.F.R. § 413 *et seq.* (Medicare dialysis prospective payment system); DaVita, Inc., *Annual Report (Form 10-K)*, at 8 (2020) ("all of our non-hospital dialysis profits came from commercial payors").

Congress also expanded the MSPA provisions to help finance the ESRD program. In proposing such an expansion, the Senate Report accompanying the Omnibus Budget Reconciliation Act of 1981, S. Rep. 97-139 (1981), stressed that private health insurers were not shouldering much, if any, of the burden of paying for dialysis or kidney transplants, despite offering otherwise comprehensive benefits. The Report explained the disparity:

> Today many private health insurance plans provide very comprehensive health benefit protection, including protection against catastrophic health expenses. However, in the case of end-stage renal patients, such plans now pay little, if anything, toward the costs of kidney dialysis treatments or organ transplantation. This is because most health plans (and particularly group plans that

> cover workers and their dependents) contain provisions that are intended to prevent payment of benefits where the insured is also entitled to benefits as a result of coverage under a program such as Medicare.

S. Rep. 97-139 (1981), *reprinted in* 1981 U.S.C.C.A.N. 396, 735. Thus, Congress recognized the ability of group health plans to share in the costs for ESRD patients and the implications to Medicare for their failure to do so.

Congress chose to spread the expense of ESRD treatments by expanding the MSPA provisions that previously had applied only to workers' compensation programs and automobile and liability insurance plans. Limiting the provisions to the ESRD program, Congress required group health plans to pay primary to Medicare, but only for the first 12 months after an individual was eligible for Medicare ESRD benefits ("coordination period"). Pub. L. No. 97-35, 95 Stat. 357, § 2146(a) (1981). After that period, Medicare would be the primary payer for the duration of the patient's care. *Id.* Congress also imposed tax consequences on employers if the plan attempted to evade its primary-payment obligation by "differentiat[ing] in the benefits it provides 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." *Id.* (amending 26 U.S.C. § 162).

Over the next two decades, Congress amended the MSPA to adjust Medicare ESRD coverage and MSP policy. Congress twice expanded the coordination period

to impose greater financial responsibility on commercial insurance and provide additional relief to Medicare, first to 18 months, Pub. L. No. 101-508, 104 Stat. 1388 (1990), § 4203, and then to 30 months, Pub. L. No. 105-33, 111 Stat. 251 (1997), § 4631(b). Congress also stressed the role of anti-discrimination provisions within the MSPA's ESRD framework. It moved the anti-differentiation provision from the Tax Code to the MSPA and added a provision prohibiting group health plans from "taking into account" a member's Medicare eligibility under the ESRD program, Pub. L. No. 101-239, 103 Stat. 2106 (1989), § 6202(b).[2]

2. Congress also expanded the MSPA to include provisions applicable to Medicare benefits based on age or disability. 42 U.S.C. § 1395y(b)(1)(A) & (B). The MSPA's ESRD provisions remain unique. The age and disability provisions have no time limitation comparable to the ESRD's coordination period, and they apply only (1) to plans of employers above a certain size, (2) for services provided to members entitled to Medicare benefits and qualified for coverage under the plan based on current employment status. *Id.* In contrast, as explained, the MSPA's ESRD provisions apply only during the coordination period. *Id.* § 1395y(b)(1)(C). During that period, however, the ESRD provisions apply to *any* group health plan with respect to services provided to a member eligible for Medicare ESRD benefits, regardless of employment status. *Id.* Thus, Congress limited the exposure of group health plans to the coordination period but established the broadest reach possible during that period. Congress also highlighted the importance of the balance struck with the MSPA's ESRD program by providing that the ESRD provisions have priority whenever a beneficiary is entitled to Medicare benefits based on both ESRD and age or disability. *Id.* § 1395y(b)(1)(A) & (B).

B. Congress Has Long Debated the ESRD System, and the Period of Private Insurance Coverage and Commercial Rates Is Critical to Sustaining It.

1. In establishing and modifying Medicare's ESRD program and the MSPA, Congress considered the varied interests of patients, providers, insurers, and Medicare's financial integrity. Congress was acutely aware that any coverage for ESRD patients necessarily centered on the payment for maintenance dialysis, and Congress evaluated the competing concerns and trade-offs considering that expense. Thus, Congress requested reports on the impact of extending the MSPA's coordination period, private insurers' costs per dialysis treatment, Medicare's expenditures and savings under the MSPA program, patients' out-of-pocket costs for dialysis and access to employment-based health insurance, the availability and quality of dialysis services, and the effect of dialysis reimbursement on that care. *See, e.g.*, Pub. L. No. 101-508, 104 Stat. 1388 (1990), § 4203 (requesting report regarding extension of MSPA's coordination period); Pub. L. No. 100-203, 101 Stat. 1330 (1987), § 4036(d) (requesting study by the Institute of Medicine of Medicare's ESRD program); Pub. L. No. 106-554, 114 Stat. 2763 (2000), § 422(d) (requesting GAO report on whether dialysis facilities satisfy need for patient access and the sufficiency of Medicare reimbursement).

2. Congress took all of this into consideration and carefully constructed an ESRD program to balance the relevant interests and provide a sustainable system of accessible, quality dialysis services. That system has relied on for-profit facilities to develop the requisite

large-scale access for outpatient dialysis treatments and to expand and adjust as necessary to meet patients' needs. U.S. Gov't Accountability Office, GAO-04-450, *Medicare Dialysis Facilities: Beneficiary Access Stable and Problems in Payment System Being Addressed* (June 2004) (report to Congress). Congress understood early on, however, that Medicare's reimbursement for dialysis services, by itself, could not sustain such a program. Not only would the expense of universal ESRD coverage strain the Medicare program, but the Medicare reimbursement alone would not be adequate to support patient access to quality care and needed innovation. IOM Rep. (report to Congress on sufficiency of Medicare reimbursement and patient access).

The requested report to Congress from the Institute of Medicine in 1991 addressed this very issue. The report examined the impacts of prior rate reductions on the ESRD program and advised against proposed further decreases to the Medicare reimbursement rate for dialysis. The report warned of potential impacts on quality-of-care or staffing and suggested that decreased reimbursement could impact the ability of providers to advance care or meet patient needs. *See* IOM Rep.; *see also* U.S. Gov't Accountability Office, GAO-04-450, *Medicare Dialysis Facilities: Beneficiary Access Stable and Problems in Payment System Being Addressed* (June 2004) (discussing inadequacy of composite rate payment and small overall profit driven by separately billed items and recommending a change to Medicare reimbursement methodology); DaVita, Inc., *Annual Report (Form 10-K)*, at 8 (2020) (all profit from non-hospital-based dialysis came from commercial payors).

Congress created the MSPA's cost-sharing program to address limitations in public funding while still supporting a large-scale, accessible dialysis system. Under that program, Medicare covers the vast majority of ESRD expenses, but commercial plans must bear the costs of treating their members who have ESRD by paying primary during the coordination period. Providers share in the compromise by receiving market compensation during the coordination period but accepting the limited Medicare dialysis reimbursement thereafter. In striking this balance, Congress protected access to care, insurers' financial health, and Medicare's financial integrity.

3. Within this constructed framework, the role of commercial insurers and the MSPA's coordination period is critical to the maintenance of the ESRD system and well-understood by Congress, regulators, insurers, and providers. Indeed, the interested entities have recognized two basic features of this system: (1) the coordination period is designed to help finance the ESRD care system by requiring commercial insurers to bear the costs of treating their plan members with ESRD; and (2) commercial plans' payments will provide higher reimbursement for providers than Medicare's regulated rate when dialysis is treated comparably to similar services under the plans' comprehensive benefits.[3]

Comments regarding proposals to expand the MSPA coordination period in 2007 and 2008 reflect this shared

3. The importance of the MSPA policy for financing Medicare's ESRD program is also apparent in the fact that CMS's Office of Financial Management oversees the MSPA program as opposed to one of the policy offices. CMS, *Office of Financial Management*.

understanding of the MSPA's purpose and commercial insurers' attendant responsibilities. Proponents and opponents of those proposals highlighted the "financing" role of such an extension and/or the burden on private insurers. Supporters and neutral evaluators of the proposals stressed that the expansion would strengthen "program integrity" and "ensure appropriate payment," Office of Mgmt. & Budget, Executive Office of the President, *Major Savings and Reforms in the President's 2007 Budget*, at 177 (Feb. 2006); Office of Mgmt. & Budget, Executive Office of the President, *Major Savings and Reforms in the President's 2008 Budget*, at 154 (Feb. 2007); help finance reforms to the ESRD program, H.R. Rep. 110-284, 246 (2007); or create savings for Medicare and bring Medicare ESRD coverage in line with coverage of other chronic diseases, Cong. Budget Office, Pub. No. 2921, *Budget Options*, at 194 (Feb. 2007).

Tellingly, the proposal's opponents also acknowledged that the extension of the coordination period would provide financing for the ESRD system and that private insurers pay more than Medicare for dialysis services. The Corporate Health Care Coalition lobbied the House Ways and Means Committee to consider alternative ways to assist with Medicare's financing of the ESRD program while also decreasing the costs to commercial insurers at the providers' expense. The Coalition's suggestions included: allowing employer-based plans to buy Medicare coverage for their members with ESRD so employees could receive coverage at Medicare rates; requiring providers to accept Medicare rates for services when employer plans are the primary payors; or reducing the length of the coordination period. Implicit in these suggestions was the recognition that such measures were

not permissible under the current system and required congressional authorization.

Congress did not adopt either the proposed extensions of the MSPA period or the suggested alternatives to limit provider reimbursement to Medicare rates during the coordination period. Rather, Congress maintained the ESRD and MSPA framework previously chosen to balance the competing interests.

The widely accepted understanding of the cost-sharing balance under the MSPA's ESRD provisions was also referenced during the regulatory process for policies that may impact dialysis facilities. CMS's proposed rulemaking to implement the prospective bundled payment elicited comments reflecting the economics of outpatient dialysis, the balance between public and private sources, and the importance of the MSPA's coordination period. In response, CMS stressed that a change to Medicare reimbursement policy would not impact commercial insurance or change coverage under private plans. *See, e.g.*, 75 Fed. Reg. 49030-01, 49126 (Aug. 12, 2010) (comments explaining that rural ESRD facilities are reimbursed less than costs in part because they have a smaller population of patients with higher paying private insurance); *id.* at 49167 (responding to commenters' concerns that bundled payment would impact private health insurance costs and coverage of co-insurance and co-pay obligations); *id.* at 49171 (explaining that bundling reimbursement for drugs into the dialysis services payment will not impact private insurance). Similarly, HHS received numerous concerns regarding the application of the MSPA's ESRD provisions to qualified health plans offered in the small group market of the insurance exchanges. 77 Fed. Reg. 18310-01, 18315

(Mar. 27, 2012). The agency affirmed the importance of the MSPA's ESRD framework by clarifying that such plans are also subject to the MSPA's requirements. *Id.*

4. Finally, Congress chose to protect this considered framework through broad anti-discrimination provisions. In enacting the MSPA's ESRD provisions, Congress noted that employment-based plans often provided comprehensive benefits, including for catastrophic health expenses, but used plan provisions to shift responsibility for coverage of their members with ESRD onto Medicare. S. Rep. 97-139 (1981), *reprinted in* 1981 U.S.C.C.A.N. 396, 735. Congress targeted that practice through the MSPA.

A critical part of those efforts was Congress's adoption of the anti-differentiation provision, which prohibits group health plans from differentiating in the benefits provided between individuals with ESRD and other plan members "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). It is evident from the statutory language that Congress again recognized the undeniable overlap between those who receive maintenance dialysis services and ESRD patients. Dialysis is the very treatment—required thrice-weekly for an indefinite period—that contributes to the expense of ESRD coverage. Commercial plans' policies that avoid payment for dialysis and force Medicare to pay in full upfront disrupt the framework Congress has long supported.

Petitioners and the United States argue otherwise and suggest the anti-differentiation provision effectively establishes a "same benefits" requirement—that is, it

simply requires that a group health plan offer the same benefits under the same conditions to ESRD and non-ESRD plan members. Ptrs. Br. 45-51; U.S. Br. 19-30. That is not what Congress said. Congress easily could have stated that a group health plan must provide the "same benefits" under the same conditions. Indeed, Congress did *exactly* that a few lines earlier in the MSPA's age provisions, stating that a group health plan "shall provide that any individual age 65 or older . . . shall be entitled to the *same benefits under the plan under the same conditions* as any such individual (or spouse) under age 65." 42 U.S.C. § 1395y(b)(1)(A)(i)(ll) (emphasis added). There is no comparable language in the ESRD anti-differentiation provision, and Congress's choice of distinct language to define the ESRD prohibition strongly suggests Congress intended something other than the "same benefits" requirement adopted in the age provisions.

This is particularly true given the parallel structure and overall similarities between the MSPA's age and ESRD subsections. *Compare* 42 U.S.C. § 1395y(b)(1)(A)(i) (prohibiting a plan from taking into account a member's entitlement to Medicare based on age and requiring the plan to provide the same benefits to members over 65) *with id.* § 1395y(b)(1)(C) (prohibiting a plan from taking into account a member's entitlement or eligibility for Medicare based on ESRD and prohibiting differentiation in the benefits provided to members with ESRD based on ESRD, the need for dialysis, or in any other manner). Neither Petitioners nor the United States explains why Congress would use different and materially broader language to mean the same thing in the same statutory section. It does not. Rather, for all the reasons Respondents aptly explain,

the ESRD provision prohibits forms of "differentiation" beyond express discrimination against ESRD patients, including discriminatory limitations applied to a plan's outpatient dialysis benefit.

III. Allowing Private Insurers to Subvert Congress's Cost-Sharing Balance Established under the MSPA Will Have Wide-Ranging Implications for Public Financing, for Dialysis Providers that Provide Life-Saving Care, and for ESRD Patients.

Discriminatory limitations on dialysis benefits, such as Marietta's, also violate the policy of the MSPA and disrupt the balanced framework Congress sought to protect. As described, Congress continually considered the MSPA's coordination period for ESRD patients over the years, and it achieves critical objectives in spreading the costs of ESRD treatment between private and public payors, ensuring that group health plans do not force patients onto Medicare prematurely, and protecting ESRD patients from disadvantageous treatment by group health plans. Enabling private insurers to subvert these goals by curtailing coverage for dialysis will have negative consequences for public funds, for dialysis providers who treat ESRD patients, and for ESRD patients who will face rising costs and diminished access to care.

A. Marietta's Scheme Will Shift Costs to Medicare during the Coordination Period.

Preservation of the cost-sharing balance established by Congress in the MSPA is especially important given the primary role of the federal government in providing coverage for ESRD treatment, which generally requires

maintenance dialysis. As stated, individuals diagnosed with ESRD who have worked in Social Security-covered employment for a minimum number of quarters, who are entitled to an annuity under the Railroad Retirement Act, or who are dependents of individuals who satisfy those criteria, are eligible to enroll in Medicare, regardless of age. 42 U.S.C. § 426-1(a). Beneficiaries who qualify for Medicare based on ESRD are entitled to benefits under Medicare Part A (hospital insurance) and are eligible to enroll in Medicare Part B (medical insurance) three months after initiation of dialysis. 42 U.S.C. § 426-1(b)(1).[4]

The federal government, therefore, has undertaken to cover the expense of maintenance dialysis treatments for the vast majority of ESRD patients, including a substantial number who would otherwise be entitled to coverage under their group health plan. *See, e.g.*, JA23 (90% of ESRD patients receive primary coverage through Medicare); Mendu, *Health Policy and Kidney Care in the United States: Core Curriculum 2020*, 76 Am. J. Kidney Dis. 721 (2020) ("Currently, Medicare and Medicare Advantage cover >80% of US residents with ESRD, accounting for ~1% of Medicare beneficiaries, whose care contributes to nearly 7% of the Medicare budget."); United States Renal Data System, *2021 Annual Data Report, End Stage Renal Disease* ch. 9 (2021) (Figure 9.4(b)) (in 2019, Medicare provided coverage for 79% of patients with prevalent ESRD). In 2019, total Medicare-related expenditures for ESRD beneficiaries were $51 billion—approximately

4. As of 2021, ESRD patients are eligible to enroll in Medicare Advantage, a bundled plan offered by Medicare-approved private insurers that includes Parts A and B and may offer supplemental benefits to enrollees. Kirchhoff, at 21.

7.2% of total Medicare expenditures. United States Renal Data System, *2021 Annual Data Report, End Stage Renal Disease* ch. 9 (2021) (Figures 9.1 & 9.3). These figures far exceed the original estimates anticipated for Medicare's expenditure on the ESRD program. United States Renal Data System, *2021 Annual Data Report, End Stage Renal Disease* ch. 9 (2021) (in 1972, the ESRD program was estimated to have 20,000-30,000 patients once in "steady state" with estimated cost to Medicare of $6.1 billion in 2019 dollars; but in 2019, over 550,000 patients received maintenance dialysis).

Given the significant role of Medicare in providing coverage for ESRD patients, and the necessity of dialysis in treating ESRD, allowing group health plans to enact cost-saving measures to skirt the limited window in which they provide primary coverage for ESRD will upend the balance that Congress continually considered and will impose even greater costs on the Medicare program. It is undeniable that if ESRD patients are effectively forced off their group health plan during the coordination period due to escalating costs imposed by private insurers, the costs to Medicare stand to increase considerably.

B. Dialysis Providers Will Lose Necessary Revenue, Compromising Quality and Access to Care.

A scheme by private insurers that threatens to disturb the MSPA's cost-sharing balance also will have serious implications for the dialysis industry participants that are responsible for providing life-saving treatment to hundreds of thousands of ESRD patients across the United States. As discussed, Congress chose to rely on

private dialysis providers to build up the ESRD program. Since January 2011, Medicare has reimbursed dialysis providers for dialysis services using a bundled system that is well-below commercial rates. *See* Part II.A, *supra*. As Congress understood, the Medicare rate generally does not compensate dialysis providers for the full cost of dialysis treatment and services. *See* Shpigel, *A Comparison of Payments to a For-profit Dialysis Firm from Government and Commercial Insurers*, 179 J. Am. Med. Assoc. Internal Med. 1137 (2019) (noting average government-based revenue of $248 per dialysis treatment in 2017, compared to provider's reported mean expenses of $269 per treatment, and observing that "[c]ommercial payers represented 10.5% of volume but generated 33% of revenue").

Congress is well-aware of the delta between Medicare and commercial reimbursement rates, as discussed. The MSPA's coordination period reflects Congress's considered judgment to spread the costs of ESRD treatment among public and private payors and ensure that the system is sustainable for dialysis providers who provide essential care to ESRD patients. This time-limited window in which private insurers pay primary to Medicare for the treatment of individuals with ESRD on their plan ensures necessary revenue for dialysis providers that is unavailable under Medicare. If private insurers skirt this responsibility, however, providers will lose revenue needed to operate—an outcome that, in turn, may negatively affect the quality and availability of treatment for ESRD patients, some of whom, for example, live in rural areas with compromised access to care. Maripuri, *Rural and Micropolitan Residence and Mortality in Patients on Dialysis*, 7 Clinical J. Am. Soc'y Nephrology 1126, 1126-27 (2012) (noting the "limited availability of in-center

[hemodialysis] units in remote areas and difficulty with transportation").

C. ESRD Patients May be Forced Off their Group Health Plans Prematurely.

Enabling insurers to circumvent the cost-sharing balance that Congress established also will force an untenable choice on ESRD patients: whether to retain private coverage during the coordination period, despite escalating costs uniquely imposed on dialysis patients, or to switch to Medicare as primary payer (if eligible), which, in many cases, will require enrollees to pay 20% coinsurance for Part B benefits without any annual limit.

ESRD disproportionately affects vulnerable populations: it is approximately 3 times more prevalent in African Americans than Caucasians and 1.3 times more prevalent in Hispanics than Caucasians. NIDDK, *Kidney Disease Statistics for the United States*; United States Renal Data System, *2021 Annual Data Report, End Stage Renal Disease* ch. 1 (2021) (Figure 1.8) (adjusted prevalence of ESRD among Black individuals was "more than four-fold higher than in White individuals"). There is, moreover, a well-documented correlation between ESRD risk and low socio-economic status. Ward, *Socioeconomic Status and the Incidence of ESRD*, 51 Am. J. Kidney Dis. 563, 565-66 (2008).

Unlike individuals over age 65 who are subject to penalties for late enrollment in Medicare, ESRD patients under age 65 are *eligible* for Medicare—but not required to enroll during the coordination period. Kirchhoff, at 11. While Medicare is a critical pillar of the healthcare safety net for ESRD patients, there are important reasons why

such individuals might prefer to retain coverage through their group health plan during the coordination period. Indeed, not all ESRD patients under age 65 qualify for Medicare due to duration-of-work requirements. 42 U.S.C. § 426-1(a). Even for those who do qualify, ESRD patients are eligible for Medicare coverage starting on the first day of the fourth month of dialysis treatment, leaving an initial, three-month window of ineligibility. Kirchhoff, at 10. Group health plans that are allowed to single out dialysis for disadvantageous treatment leave ESRD patients vulnerable to escalating costs during the critical initial months of treatment.

Medicare exposes enrollees to substantial cost-sharing obligations that can be financially onerous given the frequency with which ESRD patients need dialysis treatments. Part A (hospital insurance) generally does not require a monthly premium but imposes significant deductible and coinsurance costs. Medicare.gov, *Medicare Costs at a Glance* ($1,556 deductible in 2022 for each benefit period). In 2022, Part B, which provides coverage for outpatient services, including dialysis, has a standard monthly premium of "$170.10 (or higher depending on your income)" and a $233 deductible. *Id.* Part B beneficiaries typically pay 20% coinsurance for dialysis-related services, with no annual out-of-pocket maximum. *Id.* Medicare supplemental coverage, or "Medigap" insurance, that typically picks up these expenses is not available to beneficiaries with ESRD in all states, and in many cases, it is otherwise prohibitively expensive.

It is unsurprising, therefore, that individuals with ESRD "incur[] significantly higher out-of-pocket spending" than most other beneficiaries. Cubanski, *How Much Is Enough? Out-of-Pocket Spending Among*

Medicare Beneficiaries: A Chartbook (2014) (ESRD patients spent, on average, $6,918 out-of-pocket in 2010). ESRD patients who meet strict income and eligibility criteria may qualify for Medicaid to help defray these out-of-pocket costs, or otherwise, where available, may purchase Medigap insurance to cover expenses such as coinsurance and deductibles. CMS, *Medicare Coverage of Kidney Dialysis & Kidney Transplant Services*, at 40. Federal law, however, does not require carriers to offer Medigap policies to ESRD patients under age 65, and 20 states do not provide access to these policies. Hartwell, *It's time for Congress to guarantee Medigap Health Insurance for vulnerable Americans with Kidney Disease* (61% of ESRD patients are under age 65 but only 11% have Medigap coverage).

Beyond cost-sharing, there are other substantial reasons why ESRD patients might choose to retain group health coverage during the coordination period. ESRD patients with private insurance are significantly more likely to obtain kidney transplants than those insured by Medicare. Gill, *Access to Kidney Transplantation among Patients Insured by the United States Department of Veterans Affairs*, 18 J. Am. Soc'y Nephrology 2592 (2007) (patients insured by Medicare/Medicaid 35% less likely to receive kidney transplant than those privately insured). "Medicare-insured patients are less likely to be placed on the waiting list for transplantation before initiation of dialysis and less likely to have transplantation as their first form of ESRD treatment than patients with private insurance." *Id.* at 2592-93. Access to kidney transplantation is important for ESRD patients' health: "recipients live longer, have improved quality of life, and consume fewer health care resources than patients who are treated with dialysis." *Id.* at 2592; *cf.* Schold, *Barriers to Evaluation*

and Wait Listing for Kidney Transplantation, 6 Clinical J. Am. Soc'y of Nephrology 1760 (2011) ("Older age, lower median income, *and noncommercial insurance* were associated with decreased likelihood to ascend steps to receive a transplant.") (emphasis added).

Medicare does not cover dependents unless they are independently eligible. CMS, *Young Adults and the Affordable Care Act: Protecting Young Adults and Eliminating Burdens on Businesses and Families* ("Dependents must be individually eligible in order to have Medicare coverage."). ESRD patients with Medicare-ineligible dependents who are effectively forced off their group health plan during the coordination period due to the disfavored treatment of dialysis may incur additional expenses in securing coverage for dependents or experience disruption in care. Mendu, *Health Policy and Kidney Care in the United States: Core Curriculum 2020*, 76 Am. J. Kidney Dis. 723 (2020) (noting that "[m] any patients may have key reasons for pursuing private insurance, including coverage of dependents . . . ."). These concerns are significant since ESRD patients often have comorbidities and require access to a range of primary-care providers and specialists. Hing, *Generalist and Specialty Physicians: Supply and Access, 2009-2010*, Nat'l Ctr. for Health Statistics Data Br. No. 105, 3 (2012) (in 2009-10, 89% of generalist physicians accepted new commercial patients, but only 73% accepted new Medicare patients).

Thus, in addition to balancing the competing interests of payors and providers, the MSPA's ESRD provisions also account for the varying needs of ESRD patients. The coordination period preserves the right of ESRD patients to retain primary coverage through their group health

plan for 30 months after diagnosis, protecting patient choice and continuity of care.

CONCLUSION

This Court should preserve the cost-sharing balance that Congress carefully established. The system may not be pretty or perfect but it is quite intentional. It was well understood by Congress and the Executive Branch during the service of *amicus curiae* as a senior health advisor to President George H.W. Bush and later to President George W. Bush. *Amicus curiae* is also certain that it was well understood before 1989, when his service started, and continues to this day.

The judgment of the Court of Appeals should be affirmed.

Respectfully submitted,

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