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 FOR AMICI CURIAE KIDNEY CARE COUNCIL AND RENAL HEALTHCARE ASSOCIATION IN SUPPORT OF RESPONDENTS

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INTEREST OF AMICI CURIAE¹

The Kidney Care Council (KCC) is a nonprofit national health care association comprising eleven of the leading kidney dialysis provider companies in the United States. Collectively, KCC's members provide dialysis services to more than 85% of the end-stage renal disease (ESRD) patients in the United States.

KCC's mission includes legal and regulatory advocacy that supports and advances the highest standards of dialysis care delivery. KCC's advocacy seeks to advance patient care through improvements in outcomes, safety, and quality of life for patients receiving dialysis in the United States. KCC provides research-based, results-driven policy solutions to Members of Congress, Executive Branch agencies, and state governments.

The Renal Healthcare Association (RHA) is a voluntary organization representing dialysis providers throughout the United States that provide life-sustaining dialysis services to nearly 135,000 Medicare beneficiaries. RHA's membership primarily includes small and independent providers serving patients in free-standing and hospital-based facilities.

RHA supports its members in building a stronger community to achieve the best possible patient outcomes through education, advocacy, and services.

The parties have consented to the filing of this amici brief. No counsel for any party authored this brief in whole or in part; no such counsel or any party made a monetary contribution intended to fund the preparation or submission of this brief. No person or entity, other than amici and their counsel, made a monetary contribution intended to fund the preparation or submission of this brief.

RHA advocates to improve Medicare fee-for-service providers, streamline payments to measurement programs, and expand early intervention efforts. RHA's efforts aim to protect patient access to dialysis providers and improve care including pediatric delivery, in the population.

This case presents issues of exceptional importance to amici and their members, as well as to the nearly 800,000 Americans with ESRD today and the many millions more who depend on the financial health of the Medicare Trust Fund. In seeking to overturn the Sixth Circuit's decision, petitioners advocate for a result that would nullify the protections and objectives of the Medicare Secondary Payer Act (MSPA), by interpreting that statute to permit group health plans to discriminate against individuals who have chronic renal disease and require dialysis. Such a result would mark a sharp departure from the status quo, encouraging private insurers to shift the financial burden of treating ESRD patients to Medicare—an outcome manifestly contrary to the MSPA's text and purpose. That would not only impose a burden on the Medicare Trust Fund at odds with the MSPA, but seriously erode the stability and viability of the model for providing dialysis care to ESRD patients in the United States. Such consequences, which threaten to harm ESRD patients and reduce access to life-saving dialysis care, are antithetical to amici's missions.

INTRODUCTION AND SUMMARY OF ARGUMENT

In extending both Medicare coverage and the MSPA to ESRD patients, Congress provided ESRD

patients with access to life-sustaining dialysis, while ensuring that both private and public insurance would share in undertaking financial responsibility for that indispensable, but costly, care.

That compromise has been the foundation of the dialysis care treatment and reimbursement model in the United States for four decades. Under that settled paradigm. Medicare provides health insurance coverage for a large majority of ESRD patients in the United States. Pursuant to the MSPA, however, private insurers remain the primary payer during the first 30 months of an ESRD patient's eligibility for During that 30-month period, private insurers are prohibited from discriminating in their provision of benefits to ESRD patients, and cannot "take into account" the Medicare eligibility of such patients in designing their plan. 42 U.S.C. $\S 1395y(b)(1)(C)$. After the 30-month period ends, Medicare assumes primary responsibility for covering insurance needs for those patients.

In practice, therefore, Medicare and other government programs are responsible for providing health insurance to the lion's share of ESRD patients, the majority of the time, and take responsibility for the majority of the cost. But although private insurers provide health insurance to only a small share of ESRD patients, for a limited time, they play a critical role in ensuring the financial viability of the dialysis care model.

Petitioners ask this Court to blow up that successful paradigm for dialysis care, inviting this Court to hold that group health plans are free to discriminate against ESRD patients by providing reduced benefits for outpatient dialysis that are out of step with the benefits they provide for other medical

services—and even diminished relative to the benefits that they provide to non-ESRD enrollees who need dialysis in inpatient settings. In so doing, they ask this Court to endorse a model of discrimination against outpatient dialysis benefits that third-party consultants like petitioner MedBen continue to market but which the overwhelming majority of private insurers have never embraced.

As respondents show, petitioners' reading of the MSPA is at odds with the MSPA's text and history, as well as common sense. But as this brief shows, the result for which petitioners advocate would radically upend the status quo, undermining the financial viability of many dialysis facilities, harming patients who are disproportionately low income, and shifting substantial costs to Medicare—all results that contravene Congress's purposes in extending the MSPA to ESRD. This Court should firmly reject petitioners' attempt to undo Congress's carefully designed statutory compromise and destabilize a treatment paradigm responsible for providing lifesaving care to nearly a million Americans annually.

ARGUMENT

I. THE MEDICARE SECONDARY PAYER ACT ENVISIONS THAT PRIVATE INSURANCE AND MEDICARE WILL SHARE FINANCIAL RESPONSIBILITY FOR ESRD CARE

A. The ESRD Provisions Of The Medicare Secondary Payer Act

Medicare was originally enacted in 1965 to provide health insurance to individuals aged 65 and over. See 42 U.S.C. § 1395 et seq. Since then, it has repeatedly been expanded to include various categories of qualified individuals under 65, including persons

with ESRD. Social Security Amendments of 1972, Pub. L. No. 92-603, § 299I, 86 Stat. 1329, 1463-64. When Medicare was extended to ESRD patients in 1972, it was expected that, once the ESRD program was in a "steady-state," approximately 20,000-30,000 patients would be receiving maintenance dialysis, with annual costs of approximately \$1 billion (\$6.1) billion in 2019 dollars). United States Renal Data System, National Institutes of Health, 2021 Annual Data Report: End Stage Renal Disease, ch. 9 (2021), https://adr.usrds.org/2021/end-stage-renal-disease/9healthcare-expenditures-for-persons-with-esrd visited Jan. 23, 2022) ("End Stage Renal Disease"). By 1981, however, annual Medicare expenditures for ESRD patients were approximately \$1.4 billion, and over 64,000 individuals with ESRD were enrolled in Medicare. See Paul W. Eggers, Trends in Medicare Reimbursement for End-Stage Renal Disease: 1974-1979, 6 Health Care Financing Rev. 31, 33 (1984).

Congress responded to these unexpected and growing costs by amending the MSPA to include ESRD patients. See Omnibus Budget Reconciliation Act of 1981, Pub. L. No. 97-35, § 2146, 95 Stat. 357, 800-01; 42 U.S.C. § 1395y(b)(1)(A)(iv). The MSPA, enacted in 1980, reverses the usual order of insurance payment by identifying specific conditions under which private insurers are required to pay for healthcare expenses before Medicare. Prior to the MSPA, Medicare served as the primary payer for except those covered beneficiaries federal workers' compensation programs. Cong. Rsch. Serv.. RL33587. Medicare Secondary Payer: Coordination of Benefits 1 (May 8, 2014), https://crsreports.congress.gov/product/pdf/RL/RL335 As the primary payer, Medicare assumed

responsibility for a beneficiary's medical bills up to designated program limits. *Id.* Only after Medicare paid would any other health insurance, such as a group health plan, kick in to fill any gaps in coverage. *Id.*

In extending the MSPA's provisions to ESRD, Congress recognized that "private health insurance plans," despite providing "very comprehensive health benefit protection," were "pay[ing] little, if anything toward the costs of kidney dialysis treatments or organ transplantation." S. Rep. No. 97-139, at 469 (1981). Indeed, most private group health plans had adopted provisions "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." *Id.*

The MSPA ESRD provisions addressed that imbalance by making private insurance the primary payer during a short upfront period and leaving Medicare responsible only for any remaining qualified payments. *See id.* For the first twelve months after "a regular course of dialysis is initiated," Congress provided that private insurance would assume primary responsibility for covered costs. Pub. L. No. 97-35, § 2146(a), 95 Stat. at 800-01. After that, Medicare would revert back to being the primary payer for ESRD patients. *Id.* at 801.

Since the original enactment of the MSPA ESRD provisions in 1981, Congress has twice extended the statutory period during which private insurance is the primary payer for ESRD patients. Today, if an ESRD patient has private health insurance, that plan is the primary payer for the first 30 months of ESRD Medicare eligibility. 42 U.S.C. § 1395y(b)(1)(C)(ii).

B. Congress Intended The MSPA's ESRD Provisions To Protect Medicare's Finances And Promote Patient Care

Congress crafted the MSPA ESRD provisions as a compromise between private insurance and Medicare in order to achieve three interlocking goals.

First, and most obviously, Congress designed the MSPA ESRD provisions to cut costs to the public fisc. ESRD patients typically require dialysis for several hours three times a week, every week. See JA11. Owing to the frequency of treatment, and because patients with ESRD often have comorbidities requiring costly management, coverage of ESRD patients is expensive, both for group health plans and for the federal government. Total Medicare-related expenditures for beneficiaries with ESRD rose to \$51 billion in 2019. End Stage Renal Disease, ch. 9. number of Americans living with ESRD continues to rise. In 2019, 130,400 individuals were newly diagnosed with ESRD, representing an increase of 2.5% from 2018 and 15.1% from a decade ago. End Stage Renal Disease, ch. 1, https://adr.usrds.org/2021/end-stage-renal-disease/ 1-incidence-prevalence-patient-characteristics-andtreatment-modalities (last visited Jan. 23, 2022).

Congress had not anticipated the full financial cost of making ESRD patients eligible for Medicare in 1972, see supra at 5, nor had it anticipated that private plans would stop paying for health care coverage for most ESRD patients, see S. Rep. No. 97-139, at 469. Congress therefore enacted the MSPA ESRD provisions in important part to curb future depletion of the Medicare Trust Fund. The coordination of benefits provision was expected to

shift "about 90 percent of current annual Medicare costs per affected enrollee (about \$21,000 for 9,400 enrollees) . . . to private insurers for the last three quarters of the first year of dialysis." *Id.* at 569. Congress predicted savings to Medicare of \$440 million in the first four years. *Id.* Those cost savings only became more substantial when Congress increased the statutory coordination period to 30 months. *See, e.g.*, H.R. Rep. No. 105-149, at 1404 (1997) (anticipating that increasing period to 30 months would save Medicare an additional \$19.2 billion between 1998 and 2007).²

The MSPA ESRD provisions are more than a simple cost-saving mechanism, however. They also reflect Congress's well-reasoned determination that private health plans have a responsibility to provide coverage to ESRD patients—a responsibility they had evaded in the past. See S. Rep. No. 97-139, at 469. Congress specifically recognized that group health plans had enacted provisions that were "intended to prevent payment of benefits" for ESRD patients. *Id.* Congress now sought to require otherwise. Accordingly, Congress's cost-saving predictions reflected that "private insurers would not be able to exclude coverage of end-stage renal disease from their policies." Id. at 569. And Congress enacted penalties to prevent private insurers from shirking financial responsibility for ESRD—including by prohibiting tax

The 30-month coordination period was enacted as part of the Balanced Budget Act of 1997, Pub. L. No. 105-133, 111 Stat. 251, a major bipartisan deficit reduction bill brokered by a Republican Congress and Democratic President. The extension of the coordination of benefits period was included precisely because it would lower Medicare costs, thereby serving the overall deficit reduction objective of the Act.

deductions for a group plan "if such plan contains a discriminatory provision that reduces or denies payment of benefits for renal patients." *Id.* at 470.

Finally, the extension of the MSPA to ESRD reflected Congress's solicitude for ESRD patients. Congress emphasized that, despite the change in the coordination of benefits relationships Medicare and private insurance, "no end-stage renal patients will be denied needed care or services." Id. It was critically important to Congress that "[r]eimbursement for covered expenses for care of [ESRD] patients [would] still [be] assured" despite the sharing of costs between public and private insurance. Id. Congress also sought to "minimize [ESRD] patient anxiety" about payment for coverage. Id. Although ESRD patients place financial strain on both public and private insurance, Congress's solution was not to eschew responsibility for ESRD patients, but rather to spread the cost of their care across all payers, while ensuring that ESRD patients were not harmed by a private insurer's attempt to "reduce[] or den[y] payment of benefits for renal patients." H.R. Rep. No. 97-208, at 956 (1981) (Conf. Rep.).

Since 1981, Congress has amended the Act to further safeguard ESRD patients' access to care and to re-emphasize group health plans' responsibilities to the ESRD patient population. See Resp'ts Br. 9-10. First, Congress created a private cause of action for damages for when an insurance plan fails to provide primary payment. Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 9319(b), 100 Stat. 1874, 2010 (1986). And in 1989, Congress added additional protections to ensure that group health plans did not treat ESRD patients worse than other

See Omnibus patient populations. Budget Reconciliation Act of 1989. Pub. L. No. 101-239. § 6202(b)(1)(B), 103 Stat. 2106, 2230. Congress mandated that a group health plan not "take into account" that an individual is eligible for Medicare benefits due to ESRD during the 30-month coordination period, 42 U.S.C. § 1395y(b)(1)(C)(i), and re-codified the tax penalty for discrimination as a prohibition on "differentiat[ing] in the benefits [a group health plan provides between individuals with ESRD and other individuals "on the basis of the existence of end stage renal disease, the need for renal other manner," dialysis, in any § 1395y(b)(1)(C)(ii). As the Ninth Circuit has explained, these provisions "go well beyond protecting the Medicare Trust Fund." DaVita Inc. v. Virginia Mason Mem'l Hosp., 981 F.3d 679, 693 (9th Cir. 2020).

Critically, the MSPA ESRD provisions only serve the goals that Congress intended when group health plans and Medicare adhere to the compromise that Congress struck. Group health plans have a responsibility to pay for dialysis costs for the first 30 months of an ESRD patient's Medicare eligibility, to protect both the Medicare Trust Fund and ESRD patients' access to care. During those 30 months, Medicare is intended to play a limited role to fill in any coverage gaps when necessary. And after the coordination period elapses, Medicare steps back into its historical role as primary payer and group health plans are relieved of primary financial liability. Without both payers working in tandem to share the burden, the MSPA's compromise, and its promise to ESRD patients, is empty.

II. NONDISCRIMINATORY TREATMENT BY PRIVATE INSURERS IS CRUCIAL TO THE VIABILITY OF THE MSPA'S COMPROMISE

A. Private Insurance Plays A Vital Role In Limiting Medicare's Costs And Ensuring Access To Care For All Patients

Although private insurers are responsible for providing health insurance to only a small share of ESRD patients, they play a critical role in ensuring the overall viability of the dialysis care model in the United States.

Most Americans relv private health on insurance—primarily employer-based insurance to cover their healthcare needs. In 2020, private health insurance was nearly twice as prevalent as public coverage (66.5% versus 34.8%). Katherine Keisler-Starkey & Lisa N. Bunch, U.S. Census Bureau, Health Insurance Coverage in the United States: 2020 at 3 (Sept. 14, 2021), https://www.census.gov/library/publications/2021/ demo/p60-274.html. By contrast, only a small of percentage ESRD patients have private insurance. See. Inc., e.g., DaVita Annual (Feb. 2021) Report (Form 10-K) at 4 12. https://app.quotemedia.com/data/downloadFiling?w ebmasterId=101533&ref=115629422&type=PDF&sy mbol=DVA&companyName=DaVita+Inc.&formType =10-K&dateFiled=2021-02-12&CK=927066 ("DaVita Annual Report") ("For the year ended December 31, 2020, approximately 90% of our total dialysis patients were covered under some form of government-based program, with approximately 74% of our dialysis patients covered under Medicare and Medicare Advantage plans."). For the subset of those patients

who are eligible for Medicare, private insurance remains their primary form of coverage for just 30 months, after which Medicare takes over pursuant to the MSPA. 42 U.S.C. § 1395y(b)(1)(C)(ii).³

Even though the number of privately insured ESRD patients is relatively small and their coverage often is temporary, they play an outsized role in making outpatient dialysis care viable. *See, e.g.*, DaVita Annual Report 8 (stating that the 10% of patients with private insurance accounted for 25% of revenue).

One reason for this is that reimbursement rates for patients with private insurance generally are higher than Medicare rates. Private insurance rates are negotiated between dialysis providers and insurers, whereas Medicare rates are unilaterally set by the government. While group health plans obtain discounted rates through such negotiations, they nonetheless can substantially exceed Medicare rates. See, e.g., id. ("[A]verage commercial payment rates established under commercial contracts are generally significantly higher than Medicare rates."); Fresenius Medical Care AG & Co. KGaA, Annual Report (Form 20-F) at 6 (Feb. 23,2021), https://www.freseniusmedicalcare.com/fileadmin/dat a/com/pdf/investors/Hauptversammlung/2021/20F_2 020.pdf ("Fresenius Annual Report") (similar).

³ Although Medicare can serve as a secondary payer when an ESRD patient opts to enroll in Medicare during the 30-month coordination period, Medicare expenditures as a secondary payer are "low in absolute terms," totaling less than a billion dollars out of the \$51 billion Medicare expends on ESRD beneficiaries. *End Stage Renal Disease*, ch. 9 (Fig. 9.1).

The higher rates paid by private insurers play a critical role in limiting Medicare's own rates and ensuring the viability of dialysis care facilities. Currently, Medicare sets its reimbursement rate for dialysis services at an artificially low amount that barely covers—or in many cases does not cover—the cost of dialysis services. In 2020, Medicare's base reimbursement rate was \$239.33 per treatment. 84 Fed. Reg. 60,648, 60,650 (Nov. 8, 2019). By contrast, Fresenius's cost per treatment in 2019 was \$297. See Fresenius Form 6-K Ex. 99.1 at 4 (July 30, 2019), https://www.freseniusmedicalcare.com/en/investors/p ublications-archive. DaVita's cost per treatment was likewise roughly \$290. See Resp'ts Br. 12. Similarly, Medicare Payment Advisory Commission, government agency that provides Congress with analysis and policy advice on the Medicare program, has determined that Medicare rates do not cover treatment costs at many clinics, especially rural and low-volume facilities. See Nancy Ray & Andy Johnson, Medicare Payment Advisory Commission, Assessing payment adequacy and updating payments: Outpatient dialysis services (Dec. 9, 2021), https://www.medpac.gov/ wp-content/uploads/2021/09/Dialysis-update-MedPAC-Dec-2021.pdf ("2021 MedPac Report"). This means that, in many cases, dialysis facilities actually lose money by treating Medicare patients.

Another issue is that dialysis providers do not actually receive the full Medicare rate for each treatment they provide to a patient without private insurance. There are three main reasons why.

First, patients who qualify for Medicare based solely on their ESRD usually cannot obtain coverage until three months after becoming eligible. See 42

U.S.C. § 426-1(b)(1). If they lack other coverage, then dialysis providers may receive little or nothing for treating them during this waiting period.

Second, some patients owe more in cost-sharing with Medicare than private insurance. Both private insurance and Medicare require patients to pay for a portion of their own healthcare costs in the form of deductibles and co-insurance. Private insurance plans often include a cap on patients' out-of-pocket expenses, after which the insurer covers all costs. For example, once a patient enrolled in private insurance offered through the exchanges established by the Affordable Care Act incurs \$8,700 in cost-sharing, the insurer pays all covered expenses for the rest of the year. See 86 Fed. Reg. 24,140, 24,325 (May 5, 2021). By contrast, the traditional Medicare program has no out-of-pocket limit, and co-insurance under Medicare Part B is typically 20%, Ctrs. for Medicare & Medicaid Servs., Medicare costs at a glance, https://www.medicare.gov/your-medicarecosts/medicare-costs-at-a-glance (last visited Jan. 25, 2022). This can result in ESRD patients incurring cost-sharing obligations in the tens of thousands of dollars per year for dialysis and treatments for other medical conditions. ESRD patients frequently have difficulty remaining employed and are unable to pay these costs, in which case dialysis providers may not receive the entire amount due. See, e.g., DaVita Annual Report 8 ("If a patient does not have secondary insurance coverage, we are generally unsuccessful in our efforts to collect from the patient the remaining 20% portion of the ESRD composite

rate that Medicare does not pay."); Fresenius Annual Report 52 (similar).⁴

Third, some patients are not eligible for Medicare at all, either because they lack lawful immigration status or because they have not worked and paid Social Security taxes long enough to qualify. 42 U.S.C. § 426-1(a)(1). Medicaid is often not available to these patients either because of their status or because their immigration disqualifies them. Even when Medicaid is available, it typically reimburses providers for medical care at a lower rate than Medicare. See Kaiser Family Found... Medicaid-to-Medicare Fee https://www.kff.org/medicaid/state-indicator/Medicaidto-medicare-fee-index (last visited Jan. 24, 2022) (finding that Medicaid pays doctors less across all services than Medicare in 48 of the 50 states).

This problem can be avoided when patients enroll in Medicare Advantage (an arrangement whereby patients receive Medicare benefits through a private company) because those plans have out-of-pocket limits. But Medicare Advantage only just became available to ESRD patients under the age of 65 in 2021, and some patients choose to enroll in the traditional Medicare program instead of Medicare Advantage. See Cong. Rsch. Serv., R46655, Medicare Advantage (MA) Coverage of End Stage Renal Disease (ESRD) and Network Requirement Changes 1 (Jan. 11, 2021) https://crsreports.congress.gov/product/pdf/R/R46655. Another option is for patients to enroll in the traditional Medicare program and a supplemental insurance program called Medigap, but Medigap is not available to ESRD patients under the age of 65 in many states. See Ctrs. for Medicare Medicaid Servs.. Whencan IbuvMedigap?, https://www.medicare.gov/supplements-other-insurance/whencan-i-buy-medigap (last visited Jan. 24, 2022).

Absent the contribution of private insurance at present levels, the low reimbursement that dialysis providers receive from public healthcare would be unsustainable. As such, private insurance is indispensable to the viability of dialysis care, particularly in rural, underserved, or lower volume areas, where the government has found that cost of treatment exceeds the Medicare reimbursement rate—sometimes significantly. See, e.g., 2021 MedPac Report 11 (noting that the 20% of dialysis facilities with the lowest patient volume absorb a negative 20% margin—or a 20% loss—on each Medicare patient).

B. Revenue from Privately Insured Patients Helps to Fund Dialysis for Other Patients And Protect The Public Fisc

Because Medicare's reimbursement rate often is inadequate to cover the cost of treatment, private insurance under the MSPA plays an essential role in making dialysis care viable, limiting the financial burden on Medicare, and protecting patients.

First, the greater reimbursement offered by private insurance makes it possible for dialysis providers to treat patients with both private and public insurance. Because private insurers generally provide reimbursement at negotiated rates that exceed Medicare's, they effectively subsidize care to the majority of patients treated by dialysis providers, who rely on public insurance.⁵ For decades, that

⁵ It is hardly uncommon for private insurance to subsidize the cost of public insurance in the United States. From 2010-2017, private insurance paid roughly double the Medicare reimbursement rate for hospital services, and nearly 265% the rate for outpatient hospital services. Eric Lopez et al., Kaiser

dynamic has kept dialysis care viable, allowing providers to offer high-quality treatment to patients with both public and private insurance.

Second, the higher reimbursement rate paid by private insurance has expanded access to care by making it possible for dialysis providers to provide outpatient dialysis care to a broader geographic range of patients. For instance, the Medicare Payment Advisory Commission has concluded that the 16% of freestanding dialysis facilities that service rural areas on average *lose* money on patients with Medicare. 2021 MedPac Report 11. Absent reimbursement by private insurers for some share of the patients who receive care from those facilities, those facilities would be financially unsustainable.

The same is true for dialysis centers that serve a lower volume of patients. In dividing freestanding dialysis facilities into five quintiles, ranked by the volume of patients those facilities serve, the Medicare Payment Advisory Commission has determined that, in the 60% of facilities serving the lowest volume of patients, the financial return for treating Medicare patients ranges from break-even to a negative 20% margin.

Family Found., How Much More Than Medicare Do Private Insurers Pay? A Review of the Literature (Apr. 15, 2020), https://www.kff.org/medicare/issue-brief/how-much-more-than-medicare-do-private-insurers-pay-a-review-of-the-literature/.

Patient Volume	Medicare Margin
(Quintiles)	
Lowest	-20.2%
Second	-8.2%
Third	0.3%

See id. Absent the MSPA's requirement that private insurance provide coverage for certain ESRD patients in a nondiscriminatory manner, it is doubtful that many (if any) of those facilities would be financially sustainable.

Third, by effectively subsidizing patients on public insurance, private insurance makes it possible for Medicare to maintain lower reimbursement rates and preserve the Medicare Trust Fund. For all the reasons explained above, many dialysis facilities are financially viable only because the MSPA requires private insurers to provide coverage for at least some ESRD patients. and prohibits insurers disfavoring such patients or their medical providers with respect to benefits or reimbursement. If the MSPA did not compel such results, and private insurers were permitted to disfavor reimbursement ESRD care, itwould compromise sustainability of many dialysis care facilities. As a result, Medicare would likely be compelled to substantially increase its reimbursement rate for dialysis in order to ensure the continued viability of many, if not most, dialysis care facilities.

Finally, by barring group plans from providing differential benefits to ESRD patients 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), or from "taking into account" the

Medicare eligibility of ESRD patients during the coordination period, the MSPA protects patients who choose to maintain their private insurance even after becoming eligible for Medicare. "[T]he precise problem that Congress sought to ameliorate [with the MSPA was that private plans would provide inferior benefits or coverage for medical treatment that was also covered by Medicare." Bio-Medical Applications of Tenn., Inc. v. Cent. States Se. & Sw. Areas Health & Welfare Fund, 656 F.3d 277, 281 (6th Cir. 2011). By prohibiting that result, the MSPA ensures that ESRD patients who choose to remain on private insurance receive comprehensive coverage for life-saving dialysis care, and often at a lower total cost to the patient than he or she would experience upon switching to Medicare.⁶

For all those reasons, private insurance is essential to the sustainability and viability of dialysis providers, and the MSPA's objectives of reducing Medicare costs while protecting ESRD patients.

III. PETITIONERS' PLAN FAILS THE MSPA'S NONDISCRIMINATION REQUIREMENT

At bottom, petitioners claim that a plan that discriminates in its provision of benefits for dialysis does not discriminate 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). Given the legal and factual overlap between ESRD and the need for dialysis, that claim is untenable.

⁶ Group health plans often place caps on the total out-of-pocket expenses that enrollees must pay in a given plan year, while Medicare has no such cap.

Congress has consistently defined ESRD reference to ESRD patients' need for dialysis. 1972, when making ESRD patients eligible for Medicare, Congress defined an ESRD patient as one who "is medically determined to have chronic renal disease and who requires hemodialysis or renal transplantation for such disease." Social Security Amendments of 1972, Pub. L. No. 92-603, § 299I, 86 Stat. 1329, 1463 (emphasis added). Congress also mandated that Medicare eligibility "begin with the third month after the month in which a course of renal dialysis is initiated" and "end with the twelfth month after the month in which the person has a renal transplant or such course of dialysis is terminated." Id. at 1464. As that illustrates, Congress recognized that a patient's need for dialysis was part and parcel of a patient's ESRD status.

Congress again recognized the relationship between dialysis and ESRD in 1981, extending the MSPA's provisions to ESRD while noting that "in the case of end-stage renal patients, [private health insurance plans now pay little, if anything, toward the costs of kidney dialysis treatments or organ transplantation." S. Rep. No. 97-139, at 469. Congress used renal dialysis and end stage renal disease interchangeably in the bill. Thus, in the section of the bill estimating costs titled "Medicare Secondary for End-Stage Renal Disease," Congress described its legislation as making "Medicare the secondary payer during the first year of renal dialysis," id. at 569 (emphasis added). Congress could have just as easily said "the secondary payer during the first year of ESRD" without changing the substantive meaning of the provision.

Most importantly, the enforcement tools enacted by Congress prohibit an employer from deducting the costs of its group health plan if the plan "differentiates 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." Pub. L. No. 97-35, § 2146(b), 95 Stat. at 801. Consistent with its strong command that "no end-stage renal patients ... be denied needed care or services," S. Rep. No. 97-139, at 470, Congress enacted an airtight provision that precluded any discriminatory treatment on the basis of a patient's end stage renal disease or their need for renal dialysis—thereby preventing the kind of endaround that petitioners attempt to make in this case.

Congress was right to recognize that a plan's discriminatory treatment of ESRD patients and of dialysis are effectively two sides of the same coin. Absent a transplant, ESRD patients require dialysis to survive. In 2019, 97% of ESRD patients underwent dialysis; the other 3% received a transplant before dialysis needed to be initiated. See End Stage Renal *Disease*, ch. 1 (Fig. 1.2). As such, a plan that differentiates in the benefits that it provides for dialysis services versus other medical services is, by definition, differentiating in the benefits that it provides to ESRD patients. And for all the reasons that respondents point out, petitioners' attempt to show otherwise cannot be squared with the MSPA's text or purpose, let alone common sense.

Congress is not alone in this understanding—in fact, so-called cost consultants like petitioner MedBen expressly market their services not simply as a means of targeting the cost of dialysis, but rather as a means

of limiting benefits for and costs related to ESRD patients. See infra at 27-29 (petitioner MedBen marketed its "proprietary health plan language for dialysis services" as designed to realize savings in the face of a potential extension of "the Medicare endstage renal disease (ESRD) waiting period an additional 3 months (to 33) before Medicare becomes primary payor"; Stealth Partner Group marketed its "proprietary plan language" as including "cost saving mechanisms to help protect plan assets when members do progress to End Stage Renal Disease and require dialysis services" (citations omitted)).

Even petitioners, however, appear to concede that the plan at issue in this case would run afoul of the MSPA if it provided less benefits when *ESRD patients* need dialysis than when *individuals without ESRD* need dialysis. *See* Pet. Br. 45-46. But that admission is alone fatal to petitioners because petitioners' plan does just that.

Dialysis is almost exclusively performed on patients with ESRD. Virtually the only other patient population that may require dialysis are patients with acute kidney injury (AKI). But such patients require dialysis only rarely. See United States Renal Data System, 2020 Annual Data Report: Chronic Kidney Disease, ch. 5 (Fig. 5.2) (2020), https://adr.usrds.org/2020/chronic-kidney-disease/5acute-kidney-injury (only 3.1% of patients with AKI required dialysis during first hospitalization in 2018). And the experience is fundamentally different. ESRD patients typically need dialysis treatments three times per week, indefinitely, see Nat'l Kidney Found., Dialysis, https://www.kidnev.org/atoz/content/dialysisinfo (last visited Jan. 24, 2022), and overwhelmingly receive dialysis in an outpatient setting. Most AKI

patients, by contrast, recover within one week. See John A. Kellum et al., Recovery after Acute Kidney Injury, 195 Am. J. Respiratory & Critical Care Med. 784, 786 (Fig. 2) (2017). And given the short period of time AKI patients need dialysis, it is typically provided in an inpatient setting, especially since mostpeople with AKI already hospitalized for another reason. See Nat'l Kidney Found., Acute KidneyInjury https://www.kidney.org/atoz/content/AcuteKidneyInjury (last visited Jan. 25, 2022).

The plan at issue in this case expressly differentiates in the benefits it provides to members of the plan who receive outpatient (overwhelmingly enrollees with ESRD), and those who receive inpatient dialysis (largely enrollees with AKI). The plan treats inpatient dialysis as a potential Tier I service for which no deductible must be met and the patient's coinsurance is only 10% of the provider's negotiated charge. JA88. In contrast, the plan treats outpatient dialysis as a disfavored service, for which reimbursement is capped at 125% of the Medicare rate, JA91-92. Moreover, patient cost obligations are substantially higher. Patients receiving outpatient dialysis are subject to a deductible, \$1000 for an individual, JA83, and their coinsurance is 30% of the reimbursement rate set by the plan, JA88. The plan also states that "[t]here is no network for [outpatient dialysis] services." JA91. By offering lower benefits for dialysis services needed by ESRD patients than it does for dialysis services needed by AKI patients, the Plan violates the MSPA even under petitioners' parsimonious reading of the anti-differentiation clause.

IV. PERMITTING GROUP HEALTH PLANS TO DISCRIMINATE AGAINST DIALYSIS RECIPIENTS WOULD UPEND THE STATUS QUO AND IMPOSE SUBSTANTIAL BURDENS ON THE MEDICARE TRUST FUND

A. Petitioners Seek To Upend The Status Quo

Although petitioners insist that the MSPA permits them to disfavor reimbursement for outpatient dialysis, they do not seriously grapple with the disruptive consequences that would follow for ESRD patients or the Medicare Trust Fund if this Court endorsed that result. Permitting group health plans to discriminate in their provision of benefits to ESRD patients on the basis of their need for dialysis services not only would contravene the MSPA's text and undercut its purpose, it would work a profound change to the status quo that would undermine health outcomes for dialysis patients and shift billions of dollars in costs to the Medicare Trust Fund.

Prior to the extension of the MSPA to ESRD, Congress observed that "private plans pa[id] little of the expenses incurred by most end-stage renal patients." S. Rep. No. 97-139, at 469. In extending the MSPA to ESRD, Congress sought to shift some of that financial responsibility back to private health plans. Because Medicare continues to retain primary financial responsibility for $_{
m the}$ overwhelming majority of ESRD patients, for the majority of time, the MSPA's compromise still represents a major financial benefit to private insurers. continues to cover the overwhelming majority of those patients and spent \$51 billion on beneficiaries with

ESRD in 2019. *End Stage Renal Disease*, ch. 9. Private insurers, by contrast, retain primary responsibility for a substantially smaller share of patients and expenditures. *Id*.

In exchange for that benefit, private group health plans prohibited from implementing "discriminatory provision that reduces or denies payment of benefits for renal patients," S. Rep. No. 97-139, at 470, as by differentiating in the benefits it provides to individuals with ESRD on the basis of: (1) "the existence of end stage renal disease"; (2) "the need for renal dialysis"; "or" (3) "in any other manner," Pub. L. No. 97-35, § 2146(b)(1), 95 Stat. at 801. Moreover, group health plans "may not take into account that an individual is entitled to [Medicare benefits due to ESRD during the [coordination period]." Pub. L. No. 101-239, § 6202(b)(1)(B), 103 Stat. at 2231.

Unlike petitioners in this case, the overwhelming majority of group health plans in the United States are faithful to that compromise. For instance, KCC's members provide ESRD services to more than 85% of the dialysis patients in the United States and negotiate with innumerable private group health plans with respect to the provision of coverage for dialysis care. In the collective experience of KCC's members, the overwhelming majority of plans including America's largest private health insurers, like Aetna, Cigna, and UnitedHealth—deliver the same insurance coverage for dialysis that they do for other types of medical care. As such, the lion's share of private group health plans provide innetwork access to outpatient dialysis care at negotiated rates that ensure comprehensive coverage for ESRD services, fair reimbursement to dialysis

providers, and lower out of pocket costs for patients. See, e.g., Fresenius Kidney Care, In-Network for dialysis services with major insurance providers, https://www.freseniuskidneycare.com/tools-and-resources/insurance-patient-ed-handout.pdf (last visited Jan. 24, 2022) ("If you have insurance coverage with a major health insurance provider, your dialysis services are most likely in-network with Fresenius Kidney Care.").

The overwhelming majority of group health plans likewise provide reimbursement for dialysis care that accords with reimbursement for other services and which generally exceeds the Medicare rate. See Lopez et al., supra n.5 (noting that private insurers pay over twice the rate of Medicare for hospital services generally and even more for outpatient hospital services). In so doing, the lion's share of group health plans thus comply with the MSPA's text and promote its objectives by reducing Medicare's financial responsibility for ESRD, providing comprehensive and nondiscriminatory coverage of ESRD healthcare needs, and protecting ESRD patients. Respondents' interpretation of the MSPA would maintain that status quo.

Petitioners, by contrast, seek to profoundly disrupt that status quo. Petitioner MedBen is one of a number of third party "cost containment" consultants that invite group health plans like the one funded and administered by Petitioner Marietta Memorial Hospital to adopt certain proprietary and atypical language promising to sharply reduce the plans' financial responsibility for ESRD patients and dialysis in particular.

Third parties like petitioner MedBen leave little doubt that they advise plans to single out dialysis

distinct and disfavored treatment. Thus. MedBen long described a core pricing strategy as an effort to "[t]arget high-cost medical treatments, such as kidnev dialysis." MedBen, Network Directories (Apr. 11, 2021), https://web.archive.org/web/20210411215153/http:/ www.medben.com/resources/networks/ (last visited Jan. 24, 2022) (emphasis added). And in August 2018, MedBen told potential customers:

If you've been on the fence about having MedBen help you implement proprietary health plan language for dialysis services, now is the time to act.

The American Journal of Managed Care House reports that recent of Representatives legislation includes a provision that would extend Medicare end-stage renaldisease(ESRD) waiting period an additional 3 months (to 33) before Medicare becomes primary payor. For employer health plans, this represents hundreds of millions of dollars more in added costs.

However, by implementing *proprietary* dialysis health plan language, employers can realize a substantial savings on the procedure.

MedBen Blog, Costly Dialysis Legislation Should Spark Plan Language Change (Aug. 24, 2018) https://web.archive.org/web/20200926213855/http://blog.medben.com/index.php/house-bill-provision-could-be?blog=2 (last visited Jan. 24, 2022) (emphasis added).

Similarly, another cost-containment consultant— Renalogic—markets its services by claiming that "[t]he costs of ... dialysis are catastrophic for ... health plans" and trumpets its "commitment" to "[f]ighting high dialysis costs" through its "true dialysis costs containment" strategy. Contain Dialysis Costs and Prevent Chronic Kidney Disease Risks, https://renalogic.com (last visited Jan. 21, 2022). Renalogic's CEO has also suggested that health plans should differentiate the reimbursement they provide for dialysis from that which they provide for other medical services. See, e.g., Smart Brief, HealthCanAvoidHow *Plans* andContain Spiking Dialysis Costs(Aug. 23, 2018), https://www.smartbrief.com/original/2018/08/howhealth-plans-can-avoid-and-contain-spiking-dialysiscosts (advising that, with respect to plans who generally engage in reference-based pricing, in which reimbursement is tied to a multiple or fraction of the Medicare price, "it is imperative that dialysis be excluded and managed differently" because "it is a complex procedure that is handled differently by Medicare than any other treatment").

Other third-party cost-containment consultants follow a similar approach, criticizing the majority of plans for health "almost universally overlook[ing]" so-called "creative reimbursement strategies and techniques" that can be used to save hundreds of millions of dollars on dialysis costs. Dialysis PPO Cost Containment, Proven Performance, https://dialysisppo.com/proven-performance.html (last visited Jan. 24, 2022); see also Stealth Partner Group, Dialysis Carve Out Program, https://www.stealthpartnergroup.com/productsservices/costcontainment/dialysiscarveoutprogram

(last visited Jan. 24, 2022) (marketing "Dialysis Carve Out program" including "proprietary plan language" with "cost-saving mechanisms to help protect plan assets when members do progress to End Stage Renal Disease and require dialysis services" (emphasis added)); J&K Consultants, Putting Employers First in Health Benefits Management, http://www.jandkcons.com/ (last visited Jan. 24, 2022) ("This [Dialysis Medical Reimbursement Plan] is designed to prevent providers of dialysis services from overcharging for their services. By amending the employer's plan, dialysis patients become eligible Medicare Beneficiaries on a secondary basis within 4 months.").

As many of these third-party cost-containment experts candidly admit, the lynchpin of these strategies—like the one adopted by petitioners here—is to carve out dialysis services for disfavored treatment. As one such consultant explains:

[M]any health plans have elected to use "carve-outs," which are provisions in a plan document or an amendment which specify that a given service—for this example, dialysis—will be paid at a rate different from the rest of the plan's benefits. In the case of the now-popular dialysis carve-out, dialysis claims are paid at what is generally a percentage of Medicare rates Patients who are Medicare-eligible by virtue of end-stage renal disease (ESRD) have certain protections from balance-billing by providers who accept Medicare payments, so plans sometimes view dialysis carve-outs as a no-brainer.

Phia Group, TheCarve-Out Cost-Containment Compliance Conundrum (Mar. 8. 2017). https://www.phiagroup.com/Media/Posts/the-costcontainment-carve-out-compliance-conundrum; id. ("In theory a dialysis carve-out is a virtually flawless solution to large dialysis claims exposure. The plan can reprice claims based on its clear plan language [and] pay only a fraction of billed charges"). Such strategies, of course, are exactly what the MSPA prohibits. Compare id. (marketing "carveout" strategy where dialysis "will be paid at a rate different from the rest of the plan's benefits"), with S. Rep. No. 99-146, at 363, (1986), reprinted in 1986 U.S.C.C.A.N. 42, 322 (explaining that the MSPA's penalties are designed to target "plan[s] that differentiate[d] directly or indirectly on the basis of the existence of [ESRD] or the need for renal dialysis").

Through strategies that target and disfavor dialysis treatment, this burgeoning industry of ESRD cost-containment consultants promises to reduce dialysis costs for group health plans by 75-80%. See, e.g., DialysisPPO Cost Containment, Unique Patented Solution, http://dialysisppo.com/patentedprotection.html (last visited Jan. 25, 2022) (asserting its "unique program" enables plans "to reduce their dialysis costs by up to 80%"); MedBen Blog, supra at 27 ("One MedBen client who amended their plan reported that their dialysis costs fell by 80%."); Amwins, Dialysis Management Solutions, https://www.amwins.com/products/dialysis-managementsolutions (last visited Jan. 24, 2022) ("On average, our clients save over 75% off billed charges through the Reasonable Value re-pricing.").

The vast majority of group health plans have not adopted the approaches advocated for by third-party consultants like MedBen—under which dialysis treatment is singled out and disfavored. But that outlier approach could soon become a model if this Court were to adopt petitioners' interpretation of the MSPA.

B. If Petitioners Succeed In Upending The Status Quo, The Consequences For Patients, Providers, And The Medicare Fisc Will Be Dire

If this Court were to adopt petitioners' reading of the MSPA, and private insurers were to cut their reimbursement for dialysis by up to 80%, it would precipitate a sea change—emboldening group health plans to differentiate and reduce the benefits that they provide in relation to outpatient dialysis. That would impose catastrophic consequences on ESRD patients and dialysis providers, and inevitably result in a shift of substantial financial responsibility from private insurance to Medicare.

First, if private insurers can unilaterally reduce benefits and reimbursement for dialysis, it would render many dialysis facilities financially unviable. As explained above, reimbursement from Medicare is often insufficient to cover the cost of treatment. Dialysis providers thus depend on the higher, negotiated reimbursement rates that they receive from private insurers to keep dialysis facilities financially viable. If private insurers are permitted to single out and disfavor reimbursement for dialysis—reducing reimbursement by up to 80% and placing dialysis services out of network—facilities will be unable to count on private insurance to make

it financially sustainable to treat all patients, both those publicly and privately insured. Petitioners' rule would therefore likely lead to the closure of many dialysis clinics—particularly in rural or lowerpatient-volume areas. Patients in these areas would likely be forced to seek out dialysis services in hospital emergency rooms, straining local hospital resources at a time when hospitals are already overburdened and underfunded. See Harold D. Miller. Ctr. for Healthcare Quality and Payment Reform, Saving Rural Hospitals andSustaining Rural Healthcare I, (Sept. https://chqpr.org/downloads/Saving_Rural_Hospitals. pdf (last visited Jan. 25, 2022).

Second, petitioners' rule would impose significant financial pressure on patients to drop private insurance in favor of Medicare even before the end of the coordination period. This case is illustrative. Petitioner Marietta capped the amount it agreed to pay for dialysis services at 125% of the Medicare rate, required enrollees with ESRD to pay 30% of that amount, and exposed those enrollees to the risk of balance billing. This placed plan members with ESRD in an untenable financial situation. Owing to the substantial cost of dialysis, enrollees who remained solely on petitioner Marietta's health plan were—at minimum—obligated to annually pay a deductible and an out-of-pocket maximum that could have (at minimum) exceeded \$15,000 for a family plan. In addition, enrollees were placed at risk of balance billing for any amounts unpaid by Marietta which itself pays only 87.5% of the Medicare rate and leaves the patient on the hook for the rest. That financial risk is particularly troubling because ESRD disproportionately impacts low-income individuals.

In fact, many ESRD patients cannot work due to their disease and the time-intensive needs of dialysis treatment.

On the other hand, if the enrollee enrolls in Medicare as a secondary payer, the enrollee must pay premiums both to private insurance and to Medicare. along with co-insurance fees to both. That too would impose an outsized financial burden. As such, many enrollees—like Patient A in this case—may feel it necessary to give up their private insurance in favor of enrolling only in Medicare. That would not only contravene the MSPA's purpose, it would compromise the sustainability of many dialysis facilities and harm patients. A number of dialysis clinics likely would close, forcing ESRD patients to travel longer distances and to receive treatment at inconvenient times as dialysis treatments become concentrated in a smaller number of higher volume clinics. because family members often cannot follow an enrollee with ESRD onto Medicare, forcing an ESRD patient to abandon private insurance significantly harm family members reliant on that insurance.

Third, by reducing private insurers' financial responsibility for dialysis, petitioners' rule would inevitably shift that responsibility to the public fisc. If private insurance no longer subsidized the cost of care. Medicare would be forced dialysis substantially increase its reimbursement rates to dialysis facilities remained that most financially viable. The result would impose a greater burden on taxpayers, who would again have to bear the vast majority of dialysis costs as they did before the MSPA was enacted.

In short, petitioners' interpretation of the MSPA would upend the status quo, jeopardize the financial viability of dialysis facilities and thereby harm patients, all while shifting financial responsibility for ESRD back in the direction of Medicare—results fundamentally at odds with the text and purpose of the MSPA's extension to ESRD.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

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