No. 20-1641

IN THE Supreme Court of the United States

MARIETTA MEMORIAL HOSPITAL EMPLOYEE HEALTH BENEFIT PLAN, MARIETTA MEMORIAL HOSPITAL, AND MEDICAL BENEFITS MUTUAL LIFE INSURANCE CO., Petitioners,

v. DAVITA INC. AND DVA RENAL HEALTHCARE, INC., Respondents.

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

BRIEF FOR RESPONDENTS

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QUESTIONS PRESENTED

1. Whether the Medicare Secondary Payer Act's ("MSPA") prohibition on group health plans differentiating between individuals with end-stage renal disease ("ESRD") and those without "on the basis of … the need for renal dialysis" or "in any other manner," 42 U.S.C. §1395y(b)(1)(C)(ii), forbids a plan from targeting ESRD patients for disfavored treatment by providing inferior benefits for outpatient dialysis services on which ESRD patients uniquely depend to live.

2. Whether the MSPA's prohibition of plans "tak[ing] into account" an ESRD patient's eligibility for Medicare, 42 U.S.C. \$1395y(b)(1)(C)(i), forbids a group health plan that has been designed with participants' ESRD-related Medicare eligibility in mind.

3. Whether the MSPA prohibits group health plans with terms that have a disparate impact on plan enrollees with ESRD.

CORPORATE DISCLOSURE STATEMENT

DVA Renal Healthcare, Inc. is a wholly owned subsidiary of DaVita Inc., which has no parent corporation. Berkshire Hathaway, Inc., a publicly held company, owns more than 10% of DaVita's stock.

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BRIEF FOR RESPONDENTS

INTRODUCTION

For five decades, federal law has recognized the inseparable link between end-stage renal disease ("ESRD") and dialysis as a life-saving medical treatment for that disease. In 1972, in light of the medical promise of dialysis but in recognition of the high costs of the treatment, Congress took the extraordinary step of extending Medicare eligibility to persons with ESRD regardless of age. That decision, though, gave rise to unintended consequences by creating the opportunity for private health plans to drive ESRD patients onto Medicare to avoid having to pay for dialysis. By 1981, Medicare was paying for nearly all dialysis treatments, even for ESRD patients with private insurance.

Congress responded by enacting two statutory protections in the Medicare Secondary Payer Act ("MSPA"). Those protections bar group health plans from providing differential benefits to ESRD patients, including based on their "need for renal dialysis," 42 U.S.C. §1395y(b)(1)(C)(ii), and from "tak[ing] into account" the Medicare eligibility of ESRD patients in plan design, during a congressionally mandated coordination period during which private plans must be the ESRD primary insurer for patients. id. 1395y(b)(1)(C)(i). Congress thus advanced the goals of protecting the Medicare fisc while safeguarding ESRD patients from adverse treatment.

Consistent with those congressional judgments, for decades, the vast majority of group health plans across the country have fully covered ESRD patients during the coordination period, including by offering innetwork dialysis benefits, thus ensuring that during this critical period these chronically ill patients have access to the private insurance they have paid for and relieving stress on the Medicare fisc. The group health plan at issue here is an outlier that flouts those statutory commands—and thus imperils Congress's dual statutory objectives—by singling out outpatient dialysis, on which ESRD patients uniquely depend, for unfavorable treatment, with the purpose and effect of causing ESRD enrollees to abandon their private coverage in favor of Medicare.

Straightforward principles of statutory interpretation, including the statute's text, history, context, structure, and purpose, compel affirmance of the Sixth Circuit's core holdings that differential treatment of outpatient dialysis *is* differential treatment of individuals with ESRD based on their "need for renal dialysis," and that DaVita has sufficiently alleged that the plan at issue has impermissibly "take[n] into account" the Medicare eligibility of ESRD patients.

STATEMENT

A. End-Stage Renal Disease

ESRD is a devastating condition that occurs when the kidneys lose the ability to filter waste and excess fluids from the blood. JA4. In 2019, more than 782,000 people in the United States lived with ESRD. See United States Renal Data System, 2021 Annual Data Report: End Stage Renal Disease ch. 1 (2021) (Figure 1.5). ESRD affects already vulnerable populations. In the United States, ESRD disproportionately afflicts African-Americans, Hispanics, and Native Americans. See National Institute of Diabetes and Digestive and Kidney Diseases, Race, Ethnicity, & Kidney Disease. The disparities for African-Americans are particularly stark: In 2018, African-Americans developed ESRD at more than three times the rate of whites. See United States Renal Data System, 2021 Annual Data Report: End Stage Renal Disease ch. 1 (2021) (Figure 1.8). Socioeconomic factors play a significant role as well, as ESRD disproportionately affects lower-income individuals. See Ward, Socioeconomic Status and the Incidence of ESRD, 51 Am. J. Kidney Dis. 563, 565-566 (2008).

Individuals with ESRD will die within weeks without either routine dialysis or a kidney transplant. JA4, 11. In fact, ESRD is defined by the need for dialysis on a permanent basis or a kidney transplant to survive. *See* 42 C.F.R. §406.13(b) (ESRD "requires a regular course of dialysis" or transplant); The Council of Economic Advisers, *Increasing the Number of Kidney Transplants to Treat End Stage Renal Disease* 3 n.5 (Jan. 2021) ("ESRD is defined by the need for renal replacement therapy (dialysis or transplant)."); Centers for Medicare & Medicaid Services ("CMS"), *Medicare Coordination of Benefits & Recovery Overview: ESRD* (ESRD patients "need ... a regular course of long-term dialysis or a kidney transplant to maintain life").

Kidney transplants are difficult to obtain. In any given year, only about 20,000 kidneys are available for transplantation but more than 100,000 patients are on waiting lists. See The Kidney Project, Annual Report 2014, at 4 (2014). The median wait time for a transplant is more than four years, see United States Renal Data System, 2021 Annual Data Report: End Stage Renal Disease ch. 7 (2021), and many individuals are ineligible due to other health conditions, see Kirchhoff, Congressional Research Service, Medicare Coverage of End-Stage Renal Disease (ESRD) 4 (2018).

Consequently, ESRD patients depend on dialysis to survive. The most common type of dialysis, hemodialysis, is typically performed at least three times per week and each session ordinarily lasts three to four hours. JA11. Hemodialysis is a complex medical procedure through which a machine removes a patient's blood from the body, filters and cleans it, and replaces the blood—all while keeping a patient stable. A typical ESRD patient requires approximately 150 hemodialysis treatments a year. *Id*.

Given the frequency and stresses of these treatments, virtually all ESRD patients receive routine maintenance dialysis "in outpatient facilities," U.S. Br. 4—most at a clinic, others in a home-based setting. Virtually all ESRD patients—approximately 97% undergo dialysis (the other 3% receive a transplant before dialysis), and the great majority of ESRD patients need dialysis for the rest of their lives. *See* United States Renal Data System, 2021 Annual Data Report: End Stage Renal Disease ch. 1 (2021) (Figure 1.2).

Other than ESRD patients, virtually the only individuals who might ever require dialysis are certain patients with an "acute kidney injury."¹ By definition, acute kidney injury is temporary: although kidney function is impaired, the kidney returns to adequate function, even in the minority of cases that require dialysis. JA11. If the kidney does not return to adequate function, a patient's diagnosis changes to ESRD. Unlike ESRD patients, most individuals with acute kidney injury do not need dialysis. See United States Renal Data System, 2020 Annual Data Report: Chronic Kidney Disease ch. 5 (2020) (Figure 5.2) (only 3.1% of patients with acute kidney injury required dialysis during first hospitalization). And the few acute kidney injury patients that do need dialysis require it for only days or weeks, typically in an (inpatient) hospital setting associated with the condition that caused the injury. See Hickson et al., Predictors of Outpatient Kidney Function Recovery Among Patients Who Initiate Hemodialysis in the Hospital, 65 Am. J. Kidney Dis. 592, 594 (2015) ("Most recovery (73%) occurred within the first 3 months of [renal replacement therapy] initiation."); CMS, Medicare Benefit Policy Manual ch. 11, §100.5 ("individuals with [acute kidney injury] will need renal dialysis services for a finite number of days").

¹ Other, rarer, illnesses, such as poisonings and tumor lysis syndrome, may occasionally require temporary dialysis on an inpatient basis.

In medical and practical terms, then, people with ESRD and those who need outpatient dialysis are essentially the same population. In fact, ESRD patients—including a small number of patients initially diagnosed with acute kidney injury whose diagnosis subsequently changes to ESRD—account for 99.5% of all outpatient dialysis treatments that DaVita provides.

B. Congress Creates An ESRD Medicare Entitlement To Ensure Access To Dialysis

Sixty years ago, a diagnosis of ESRD meant almost immediate death. Dialysis changed that. First administered to ESRD patients in the United States in 1960, dialysis progressed over the following decade from experimental to a viable medical treatment. See Rettig. Origins of the Medicare Kidney Disease Entitlement: The Social Security Amendments of 1972, in Biomedical Politics 176, 177-178 (1991). But dialysis was-and is—"beyond the means of most individuals" because so many treatments are required (150 per year). Rettig, Special Treatment—The Story of Medicare's ESRD Entitlement, 364 New Eng. J. Med. 596, 596 (2011). Thus, prior to 1972, "only a very small percentage" of ESRD patients "actually receive[d] the therapy." National Health Insurance Proposals: Hearings Before the H. Comm. on Ways and Means, 92nd Cong., pt. 10, at 2226 (1971) (statement of Dr. William J. Flanigan, National Kidney Foundation). The rest died, lacking "adequate funds and/or insurance coverage." Id.

The life-saving promise of dialysis catalyzed federal legislation to ensure access and provide hope to ESRD patients. To prevent "needless deaths" of Americans "who could have been saved if they had been able to afford an artificial kidney machine or transplantation," Congress established "a national program of kidney disease treatment assistance." S. Rep. No. 92-1230, at 1243-1244 (1972) (statement of Sen. Hartke); see Anumudu & Eknoyan, A Historical Perspective on How Public Policy Shaped Dialysis Care Delivery in the United States, in 33 Seminars in Dialysis 5, 7 (2018) ("medical progress" in "dialysis" drove "policy change" resulting in 1972 Medicare entitlement). Legislation gained momentum in 1971 when Congress heard testimony from ESRD patients, one of whom was dialyzed in person before a congressional committee. See Rettig, Origins of the Medicare Kidney Disease Entitlement: The Social Security Amendments of 1972, in Biomedical Politics 176, 187-190 (1991).

The following year, Congress extended Medicare to ESRD patients regardless of age. Congress amended the Social Security Act to "deem[] ... disabled" nearly all individuals with "chronic renal disease [who] require[] hemodialysis or renal transplantation," entitling them to Medicare beginning three months after the start of treatment. Social Security Amendments of 1972, Pub. L. No. 92-603, §299I, 86 Stat. 1329, 1463-1464. But Congress did not require ESRD patients under age 65 to enroll in Medicare. It preserved a patient's choice to retain private insurance, which was then a principal source of payment. See Rettig & Marks. The Federal Government and Social Planning for End-Stage Renal Disease: Past, Present, and Future 26 (Feb. 1983).

C. Congress Enacts ESRD Protections To Combat Plans' Efforts To Avoid Paying Dialysis Costs

By the early 1980s, it was clear that Congress's extension of Medicare to ESRD patients to help pay for dialysis had led to an unintended consequence: it enabled group health plans to limit coverage for ESRD patients and shift dialysis costs onto Medicare. Congress addressed the problem head-on in 1981 by enacting ESRD-specific provisions of the MSPA.

Congress enacted the original MSPA in 1980 to "protect[] Medicare Trust Funds by ensuring that Medicare does not pay for items and services that certain health insurance or coverage is primarily responsible for paying." CMS, *Medicare Secondary Payer*.

"[I]n the case of [ESRD] patients," Congress recognized that private plans were "pay[ing] little, if anything, toward the costs of kidney dialysis," because "most health plans ... contain[ed] provisions that [were] intended to prevent payment of benefits where the insured [was] also entitled to benefits as a result of coverage under a program such as [M]edicare." S. Rep. No. 97-139, at 469 (1981). In 1981, Congress enacted integrated statutory protections to remedy this concern. To begin with, Congress created an ESRD "coordination of benefits" period. S. Rep. No. 97-139, at 469-70. During that period (set initially at 12 months after "a regular course of dialysis is initiated"), a group health plan must be the primary payer-meaning it has primary responsibility for paying claims. Omnibus Budget Reconciliation Act of 1981, Pub. L. No. 97-35, §2146(a), 95 Stat. 357, 800-801. After that, Medicare would become the primary paver for those ESRD patients. Id. at 801. Congress designed this provision to advance the mutually reinforcing goals of protecting the public fisc and safeguarding coverage for ESRD patients, saving the government \$440 million (more than \$1 billion in today's dollars) over its first three years while ensuring that "no end-stage renal patients [would] be denied needed care or services." S. Rep. No. 97-139, at 735-736.

To ensure that group plans did not evade compliance through disadvantageous treatment of ESRD patients in plan design, Congress paired the coordination period with an anti-differentiation protection that denied tax deductions for any "plan contain[ing] a discriminatory provision that reduces or denies payment of benefits for renal patients." S. Rep. No. 97-139, at 470; see also H. Rep. No. 97-208, at 956 (1981) (Conf. Rep.) (same). Congress directed the Internal Revenue Service to deny a plan's tax deduction "if the plan differentiate[d] in the benefits it provide[d] between individuals having end stage renal disease and other individuals covered by such plan." Pub. L. No. 97-35, §2146(b). Prohibited differentiation could occur in three ways: "on the basis of the existence of end stage renal disease"; "on the basis of ... the need for renal dialysis"; "or" "in any other manner." Id. The effect of this mandate, as a later committee report emphasized, was to target "plan[s] that differentiate[d] directly or indirectly on the basis of the existence of [ESRD] or the need for renal dialysis." S. Rep. No. 99-146, at 363 (1985).

Since 1981, Congress has augmented these protections to ensure that group health plans do not force ESRD patients onto Medicare prematurely—thus helping spread the costs of dialysis and protecting patients against differential treatment:

First, Congress has twice extended the coordination period during which private plans must be the primary payer for ESRD patients, to 18 months in 1990 and to 30 months in 1997. *See* Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, tit. IV, §4203, 104 Stat. 1388, 1388-107; Balanced Budget Act of 1997, Pub. L. No. 105-133, tit. IV, §4631, 111 Stat. 251, 486. Consistent with Congress's original cost-sharing objectives under the MSPA, Congress estimated that the 1997 amendments would save an additional \$19.2 billion over ten years (more than \$33 billion in today's dollars). *See* H.R. Rep. No.105-149, at 1404 (1997).

Second, in 1984 and 1986, Congress strengthened the MSPA's enforcement mechanisms by creating a cause of action for the federal government, Medicare and Medicaid Budget Reconciliation Amendments of 1984, Pub. L. No. 98-369, tit. III, §2344(a), 98 Stat. 494, 1095, and a private right of action, Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, §9319(b), 100 Stat. 1874, 2010 (1986).

Third, Congress enhanced the MSPA in 1989 by directing that group health plans "may not take into account that an individual is entitled to [Medicare benefits due to ESRD] during the [coordination period]." Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, §6202(b)(1)(B), 103 Stat. 2106, 2230.²

The statutory framework remains materially the same today. Under the anti-differentiation provision, a plan "may not differentiate 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." 42 U.S.C. \$1395y(b)(1)(C)(ii). Under the take-into-account provision, a plan "may not take into account that an individual is entitled to or eligible for [Medicare benefits due to ESRD] during the [30]-month period which begins

² Congress also imposed a substantial excise tax on employers who contribute to plans that violate the MSPA. *See* Pub. L. No. 101-239, §6202(b)(2), 103 Stat. 2106, 2233 (1989) (amending 26 U.S.C. §5000).

with the first month in which the individual becomes entitled to benefits under [Medicare]." *Id.* $$1395y(b)(1)(C)(i).^{3}$

D. The Unique Cost-Sharing Model For ESRD Care Resulting From Congressional Action

These congressional enactments result in a unique public-private coverage system for ESRD and dialysis. For decades, this model has reflected Congress's objective of prohibiting group health plans from shirking their responsibility for covering dialysis for ESRD patients during the coordination period while allowing plans to avoid the costs of primary coverage of ESRD patients after that period.

Viability of the dialysis care system in the United States depends in critical ways on this public-private cost sharing. Because of the Medicare entitlement, "[t]he vast majority of patients with ESRD approximately 90%—receive primary coverage through Medicare" or other government programs. JA23. The public-private ratio is important in all areas of health care, but it is significantly more skewed toward public coverage for ESRD patients than in other contexts. *Compare* Keisler-Starkey & Bunch, U.S. Census Bureau, *Health Insurance Coverage in the United States:* 2020 3 (noting that 66.5% of U.S. population has private health coverage and 34.8% has public coverage). That ratio has significant implications for dialysis care because the Medicare reimbursement rate does not cover

³ In 1995, CMS issued regulations identifying non-exhaustive examples of conduct that violates these provisions. 42 C.F.R. §411.108. CMS did not provide for notice and comment before promulgating the regulations, opining that the statute was "self-implementing." 60 Fed. Reg. 45,344, 45,359-45,360 (Aug. 31, 1995).

the full costs of dialysis (DaVita's cost per treatment is approximately \$290), and is "generally significantly lower than rates paid by commercial plans." *id.* In 2020 the base rate was \$239.33 per treatment, 84 Fed. Reg. 60,648, 60,650 (Nov. 8, 2019)—an increase of only 12 cents since 2011, *see* 75 Fed. Reg. 49,030, 49,147 (Aug. 12, 2010). (With additional payments, DaVita received approximately \$256 per treatment from Medicare.) To an even greater degree than other providers in the U.S. healthcare system, dialysis providers accordingly depend on revenue from private insurance to sustain and expand access to dialysis. JA23.

Congress's determination that private plans should share in paying dialysis costs thus serves as a critical pillar of the dialysis care system. And as a result of the MSPA's protections, most plans do just that: in DaVita's experience, the overwhelming majority of plans treat dialysis like other covered medical services during the coordination period, including by providing in-network options with preferred co-pays and deductibles and rates negotiated between a plan and provider. Private insurance thus remains an important option for the majority of ESRD patients on group plans who have paid insurance premiums for years expecting to be able to rely on private coverage if a life-threatening health condition, such as ESRD, were to develop.

E. The Marietta Plan's Differential Treatment Of ESRD Enrollees

The conduct at issue in this case, if sanctioned by this Court, would upend Congress's public-private costsharing regime for dialysis care by providing a blueprint for plans to drive ESRD patients prematurely onto Medicare. Petitioner Marietta Memorial Hospital Employee Health Benefit Plan ("the Plan") is a selffunded plan under the Employee Retirement Income Security Act ("ERISA"). JA8. Petitioner Marietta Memorial Hospital funds and administers the Plan, JA9, while Petitioner MedBen is the Plan's Benefit Manager, JA9. MedBen markets its services based on its ability to reduce "dialysis procedures provided to ESRD patients," including "by implementing [its] proprietary dialysis health plan language." JA7.

Unlike almost all other plans, by implementing MedBen's scheme, the Plan singles out ESRD patients (including Patient A) for adverse treatment. JA6. In several ways, the Plan disfavors outpatient dialysis (whether at a clinic or at home)—and thus uniquely burdens ESRD enrollees—with the intent to cause them to "prematurely abandon their coverage under the Plan to go onto Medicare." $Id.^4$

The Plan's terms convey the disfavored status of outpatient dialysis by making clear that "[t]here is no network for [outpatient dialysis] services." JA13. Reading that provision, an enrollee diagnosed with ESRD and learning that there are no in-network options for the medical treatment she will need to survive would think twice about retaining the private coverage, despite the fact that she may have been paying premiums for years for protection against chronic illnesses. Indeed, the Plan explicitly *encourages* enrollees with

⁴ Patient A passed away after the complaint was filed. Patient A received dialysis from DaVita on an outpatient basis, JA15, with the Plan's reimbursement of Patient A's dialysis beginning in April 2017, JA10; JA15. Had Patient A remained on the Plan throughout the 30-month ESRD coordination period, the Plan would have continued to be the primary payer through December 2019. Instead, Patient A dropped coverage under the Plan 16 months early, changing to Medicare as the primary payer. JA15.

ESRD to enroll in Medicare. *See* JA195 (reminding beneficiaries that "[c]overed Persons that are diagnosed with a condition re-quiring dialysis may be able to enroll in Medicare.").

Further, the Plan adversely affects ESRD patients in at least two additional ways:

First, it exposes ESRD enrollees to the risk of "balance billing." As is typical of health care providers, DaVita's patients assume the financial obligation for the difference between the amount charged for each dialysis treatment and the amount a patient's insurer pays for each treatment. The Plan provides no innetwork options for outpatient dialysis and significantly under-reimburses out-of-network dialysis providers, thus exposing ESRD patients to significant personal financial liability.

Specifically, the Plan reimburses other out-ofnetwork providers at the "reasonable and customary" rate, which "is understood in the healthcare industry" to refer to the "amount ... providers in the area usually charge for the same or similar medical service." JA13 & n.2. Outpatient dialysis (both home and in center), however, is subject to "an alternative basis for payment"—which the plan also misleadingly characterizes as "reasonable and customary" even though the Plan redefines that term solely for outpatient dialysis. JA13-14. This rate-setting scheme pays DaVita only 87.5% of the Medicare rate. JA13-14. The Plan also subjects dialysis-related testing and medications to the same unfavorable terms. JA194-195.

This differential under-reimbursement of outpatient dialysis treatments that ESRD patients need creates more than a "billing dispute," Pet. Br. 13; it directly exposes ESRD patients (and ESRD patients alone) to the risk of balance billing, JA17; JA82. Because the delta between the charged rate and the reimbursed rate for dialysis can be hundreds of dollars or more per treatment and because the typical patient needs three dialysis treatments per week, a patient's financial obligation escalates quickly. Incurring such significant obligations is a significant injury (even if a provider never demands payment) and the anxiety of these debts on top of the stresses of a life-threatening disease incentivizes ESRD enrollees—who are disproportionately of limited means, *see supra* p.3—to abandon private coverage in favor of Medicare.

Second, the unfavorable design exposes ESRD patients to higher deductibles and coinsurance payments than experienced by those who need other comparable medical services covered by the Plan. See JA24-25; JA29. For example, the Plan classifies *inpatient* dialysis (the typical setting for treating acute kidney injury) as a potential Tier I service, for which there is no deductible and a patient's coinsurance is 10% of the provider's negotiated charge. JA88. By contrast, outpa*tient* dialysis (home or clinic) is subject to a deductible and a patient's coinsurance is 30% of the rate set by the Plan. Id. This facial differential treatment of inpatient and outpatient dialysis uniquely disadvantages ESRD patients. As explained above, ESRD patients require thrice-weekly dialysis to stay alive and such treatments are almost always provided in an outpatient setting, while inpatient dialysis is ordinarily used by those suffering from acute kidney injury who require shortterm, inpatient dialysis, if at all. See supra p.5.⁵

⁵ Impermissibly resisting the complaint's allegations, Petitioners argue that ESRD enrollees do not face out-of-pocket risks because the Plan treats outpatient dialysis as Tier II for deducti-

Faced with this inferior benefits design, ESRD enrollees confront a forced choice: incur escalating out-ofpocket financial obligations or abandon private coverage and switch to Medicare as a primary payer. The latter outcome, DaVita has alleged, is precisely what Petitioners intend. JA6. Although an ESRD patient could theoretically *both* enroll in Medicare (thus burdening the Medicare fisc) *and* maintain private coverage (with Medicare secondary during the coordination period), most patients do not choose to simultaneously pay for both private insurance and Medicare—which can require hundreds of dollars per month in premiums.

F. This Litigation

In 2018, DaVita filed a complaint in its own right and as an assignee of Patient A against the Plan, Marietta Memorial Hospital, and MedBen. JA3; JA16. Count I alleged that Petitioners violated the MSPA by treating outpatient dialysis differently from other services covered under the Plan, thus differentiating

ble and coinsurance purposes. Pet. Br. 15-16. The specific out-ofpocket risks ESRD enrollees face were not briefed below; no court has addressed them; and Petitioners did not seek certiorari on this basis. Because this is "a court of review, not of first view," Brownback v. King, 141 S. Ct. 740, 747 n.4 (2021) (citation omitted), any conflict between the complaint's allegations and plan documents should be resolved on remand. In any event, even crediting Petitioners' interpretation, the Plan treats ESRD enrollees disadvantageously, including by subjecting them to the risk of balance billing and requiring them to pay for outpatient dialysis at Tier II deductible and coinsurance levels, rather than Tier I. The Plan also "subject[s]" dialysis, and dialysis alone, to "cost containment review" and "claim audit and/or review." JA26. These "unusual plan terms" single out dialysis for special scrutiny and "heighten[] the incentives of the dialysis patient to abandon their employer plan and move onto Medicare." Id.

ESRD enrollees in violation of the anti-differentiation and take-into-account provisions. JA28-30. Counts II through VII alleged ERISA violations. JA30-40.

The district court granted Petitioners' motions to dismiss, holding that the Plan had not violated the antidifferentiation and take-into-account provisions because "all Plan enrollees receiving dialysis (including those without ESRD) [were] subject to the same" terms. Pet.App.104.

The Sixth Circuit reversed in relevant part. Pet.App.1-54. It held that DaVita had plausibly alleged the Plan had violated the "plain text" of the antidifferentiation provision by differentiating "ESRD patients based on their need for dialysis by targeting the primary treatment that individuals with ESRD (1) need exclusively, with the exception of rare, non-ESRD patients, and (2) need with far greater frequency than those few non-ESRD dialysis-users." Pet.App.41, 43. The court also held that DaVita had plausibly alleged that the Plan had violated the take-into-account provision by "singl[ing] out" ESRD patients in an attempt to shift dialysis costs to Medicare. Pet.App.53. In the "[a]lternative[]," the court held that DaVita had alleged "disparate-impact" violation of the MSPA. a Pet.App.45.

Judge Murphy concurred in part and dissented in part. In his view, DaVita did not state an MSPA claim because the plan documents did not explicitly differentiate ESRD patients. Pet.App.70-87.

Following remand, DaVita filed an amended complaint, JA292-326, and, before the grant of certiorari, discovery was ongoing, JA286-287.

SUMMARY OF ARGUMENT

I.A. DaVita has plausibly alleged a violation of the MSPA's anti-differentiation provision. Differential treatment of outpatient dialysis *is* differential treatment of individuals with ESRD.

Textually, the provision defines impermissible differentiation of ESRD enrollees to mean differentiation "on the basis of ... the need for renal dialysis" or "in any other manner." 42 U.S.C. §1395y(b)(1)(C)(ii). The text thus establishes that targeting ESRD patients' unique "need for renal dialysis" is the same as targeting persons with ESRD themselves. The phrase "any other manner" confirms that Congress intended to cast a broad net, capturing all manners of differentiation.

Congress's linkage of adverse treatment of ESRD enrollees with unfavorable treatment of dialysis makes sense in light of the history of federal ESRD law. Congress's decision to extend Medicare to ESRD patients regardless of age was based on Congress's desire to ensure these patients received dialysis. And Congress's enactment of the MSPA provisions at issue was a direct response to efforts by private plans to evade their obligations to pay the costs of dialysis for ESRD patients. The disease and the treatment are thus inextricably intertwined in law, as they are in medical reality.

Considerations of statutory structure and purpose confirm this understanding. Reading the provision to treat adverse classification of dialysis as impermissible differentiation of ESRD directly advances Congress's objectives of protecting the Medicare fisc and safeguarding ESRD patients' right to benefit from their existing private insurance. A contrary reading permitting plans to provide inferior benefits to ESRD enrollees through the simple ploy of singling out outpatient dialysis for "all"—would seriously disrupt the status quo, imperil the Medicare fisc, and risk significant harm to vulnerable ESRD patients. Congress does not enact statutes to be so easily circumvented.

Background legal principles support this reading. Courts in a variety of contexts have held that discrimination against a proxy for a protected class amounts to facial discrimination against the class itself. Because the MSPA recognizes that the need for outpatient dialysis is a near-perfect proxy for ESRD, those principles apply here.

B. DaVita has stated a claim that Petitioners have violated the anti-differentiation provision. By subjecting outpatient dialysis—a medical treatment that ESRD enrollees uniquely need to survive—to disfavored treatment, the Plan has the purpose and effect of burdening ESRD enrollees, incentivizing them to drop coverage under the Plan. Furthermore, the plan facially singles out ESRD patients for inferior benefits through differential treatment of inpatient dialysis (typically used by individuals suffering acute kidney injury) and outpatient dialysis (used almost exclusively by those with ESRD).

C. Petitioners and the United States insist that the provision prohibits only plan terms that target ESRD patients expressly. That interpretation is deeply flawed. Among other things, it would reduce the provision to an empty formalism, focusing myopically on specific words used in plan documents while allowing plans to exploit ESRD patients' unique reliance on outpatient dialysis. Their reading also improperly renders a nullity the second half of the anti-differentiation provision, giving no effect whatever to Congress's definition of impermissible differentiation as including differentiation "on the basis of ... the need for renal dialysis" or differentiation "in any other manner."

Petitioners and the United States attack a strawman by insisting that DaVita is seeking "priority" status for dialysis or a substantive entitlement to fixed levels of dialysis benefits. The statute requires equal treatment of ESRD enrollees, which demands equal treatment of outpatient dialysis. That does not guarantee any fixed level of benefits, much less priority status.

Nor can CMS's regulations salvage Petitioners' and the United States' interpretation. The statute's text is clear; CMS issued the regulations without advance notice and comment; and the regulations are internally inconsistent. Even the government declines to invoke deference. And in any event, the most intelligible reading of the regulations prohibits the Plan's facially differential treatment of outpatient and inpatient dialysis.

II.A. DaVita has also stated a claim for violation of the MSPA's prohibition on plans "tak[ing] into account" an ESRD enrollee's Medicare eligibility. 42 U.S.C. §1395y(b)(1)(C)(i). "Take into account" means to consider. The statute thus requires an inquiry into whether Medicare eligibility was a consideration influencing plan design.

B. DaVita has plausibly alleged that Petitioners designed the Plan in consideration of the eligibility of ESRD patients to enroll in Medicare, eligibility not shared by most others under the age of 65. Indeed, Petitioners' brief here strongly suggests that the Plan was designed with that eligibility in mind.

C. Petitioners' and the United States' position that plans "take into account" Medicare eligibility only when eligibility is expressly addressed on the face of a plan would render that provision a dead letter because, as Petitioners' scheme makes clear, the statute would be easily evaded. The statute's reference to "group health plan" does not foreclose an inquiry into intent, because a "plan" is an entity by law and, in any event, common usage readily confirms that a document "takes" a factor into account when the drafters of a document do so.

III. Alternatively, DaVita has stated an MSPA violation based on the significant disparate impact of plan provisions on ESRD enrollees. The anti-differentiation provision's "in any other manner" clause is plainly effects-oriented language. Neither Petitioners nor the United States persuasively explain why the framework set forth in *Texas Department of Housing & Community Affairs* v. *Inclusive Communities Project, Inc.*, 576 U.S. 519 (2015), is not controlling here.

IV. The Court should decline to address Petitioners' request for review of DaVita's ERISA claims because Petitioners did not seek, and the Court did not grant, certiorari on that basis.

ARGUMENT

I. DAVITA HAS STATED A CLAIM FOR VIOLATION OF THE MSPA'S ANTI-DIFFERENTIATION PROVISION

A. The Anti-Differentiation Provision Prohibits Differentiation Of ESRD Enrollees Accomplished By Disfavoring Outpatient Dialysis

Settled principles of statutory interpretation establish that the anti-differentiation provision prohibits the differential treatment of ESRD patients by disfavoring outpatient dialysis—a medical treatment that ESRD enrollees uniquely need to stay alive.
1. Text

Analysis of the anti-differentiation provision, of course, "begins with the text." *Merit Mgmt. Grp., LP* v. *FTI Consulting, Inc.*, 138 S. Ct. 883, 893 (2018). And the text demonstrates that Congress cast a wide net in prohibiting differential treatment of ESRD enrollees by group health plans. The provision prohibits a plan from "differentiat[ing] in the benefits it provides between individuals having [ESRD] and other individuals covered by such plan" in three ways: (i) "on the basis of the existence of end stage renal disease"; (ii) "on the basis of ... the need for renal dialysis"; or (iii) "in any other manner." 42 U.S.C. §1395y(b)(1)(C)(ii).⁶

As a matter of plain meaning, to "differentiate" means (and meant at the time of enactment) to "make different," "discriminate," or "distinguish." *Webster's Third New International Dictionary* 630 (1976). By its terms, the first half of the anti-differentiation provision thus embodies a protection for ESRD patients against adverse treatment: a plan may not differentiate "in the benefits it provides between individuals having [ESRD] and other individuals covered by such plan."

But Congress did not stop there. In the second half of the provision, Congress defined the types—or "manner[s]"—of differentiation it was prohibiting. To begin with, a plan may not explicitly single out ESRD enrollees for disfavored treatment. That outright

⁶ The text contains an obvious drafting error because it would make no sense to bar differentiation "on the basis of … in any other manner." Pet.App.73 (Murphy, J., dissenting in part); see also Scalia & Garner, *Reading Law: The Interpretation of Legal Texts* 234 (2012) (courts may "correct[]" a 'scrivener's error.").

disadvantaging of ESRD enrollees would be differentiation "on the basis of the existence of [ESRD]."

The second and third clauses must also be given effect, and in them Congress defined and expanded prohibited differentiation beyond facial singling out of ESRD. In the second clause, Congress prohibited differentiation "on the basis of ... the need for renal dialysis." In doing so, Congress textually defined differential treatment of dialysis to be the same as differentiation of ESRD enrollees. Congress used similar language in the Pregnancy Discrimination Act, enacted just a few years before the anti-differentiation provision, to establish that pregnancy is a proxy for sex under Title VII. See Act of Oct. 31, 1978, Pub. L. No. 95-555, 92 Stat. 2076, 2076 (codified at 42 U.S.C. §2000e(k)) (defining "because of sex" or "on the basis of sex" to mean "because of or on the basis of pregnancy, childbirth, or related medical conditions"). Similar to the Pregnancy Discrimination Act, the MSPA embodies a congressional judgment that differential treatment of dialysis *is* differentiation of ESRD.

An example illustrates the textual point. Imagine a statute said a "plan may not differentiate in the benefits it provides to Black enrollees on the basis of race, on the basis of the need for treatment of sickle cell anemia, or in any other manner." That prohibition would bar a plan from providing one set of benefits for Black enrollees as compared to others. But it would also prohibit a plan that covers medical services broadly from providing unequal, unfavorable coverage for treatment of sickle cell anemia. It would be no answer to say that adverse classification of sickle cell anemia affects all plan enrollees uniformly. That is because the text itself links differential treatment of sickle cell anemia to prohibited race-based differentiation. The same is true here.

In addition, to ensure that Congress captured all manners of differentiation beyond the first two listed, the third clause of the provision includes a catch-all, prohibiting a plan from differentiating ESRD patients "in any other manner." This phrase is noteworthy in several respects. First, "any other manner" demonstrates Congress's intent that differentiation be defined broadly: "any naturally carries 'an expansive meaning," "without distinction or limitation."" SAS Inst., Inc. v. Iancu, 138 S. Ct. 1348, 1354 (2018). The text thus confirms that Congress was concerned with plans that "differentiat[e] directly or indirectly," S. Rep. No. 99-146, at 363 (1985), with respect to ESRD enrollees, cf. Abramski v. United States, 573 U.S. 169, 184 (2014) (statutory references to "sale or other disposition' of a firearm" evinced a "substance-over-form approach" that required "maximum coverage").

Moreover, because the word "manner" means "the way in which a thing is done," *American Heritage Dictionary* 795 (1979), Congress's use of "other manner" underscores that the first two clauses ("on the basis of the existence of [ESRD]" and "on the basis of ... the need for renal dialysis") define *how*—the "way in which"—impermissible differentiation may occur.

In sum, the text of the anti-differentiation provision reaches both explicit differentiation of ESRD enrollees as well as differentiation of ESRD enrollees accomplished through the artifice of targeting their "need for renal dialysis" or "in any other manner."

2. Statutory history and context

The history and "legal backdrop against which Congress enacted" the MSPA overwhelmingly "confirms" that Congress prohibited adverse treatment of dialysis as a "manner" of differentiating ESRD patients. *Tanzin* v. *Tanvir*, 141 S. Ct. 486, 490 (2020).

For decades, federal ESRD law and policy including at the time Congress enacted the antidifferentiation provision—has recognized the inseparable link between ESRD as a disease and dialysis as a treatment. Congress's decision to create the ESRD Medicare entitlement was driven by the aim of ensuring access to dialysis as a life-saving treatment. See supra p.7. In fact, Congress expressly defined ESRD by reference to dialysis: the 1972 statute "deemed" an individual eligible for Medicare if she was "medically determined to have chronic renal disease and require[d] hemodialysis." 86 Stat. at 1463-1464. In addition, Congress enacted the ESRD coordination period and MSPA protections at issue because commercial plans were "pay[ing] little, if anything, toward the costs of kidney dialysis." S. Rep. No. 97-139, at 469.

ESRD and dialysis remain inextricably linked today. The current Medicare program for ESRD patients, 42 U.S.C. §1395rr—amended as recently as 2020—references "dialysis" more than 130 times. And policymakers as well as regulations define ESRD by reference to the need for dialysis. *See supra* pp.3-4 (collecting examples). As one compelling example, CMS defines an "ESRD facility" under Medicare not by reference to ESRD patients but by reference to dialysis: "an entity that provides outpatient dialysis services, or home dialysis training and support services, or both." CMS, Medicare Benefit Policy Manual, Ch. 11, §10(B).

Real-world experience confirms that the need for outpatient dialysis is almost a perfect proxy for ESRD. As explained above, outpatient dialysis is almost exclusively required by, and provided to, ESRD patients. See supra pp.5-6. The only individuals who require long-term dialysis are ESRD patients, whose kidneys no longer function and will never regain function. In contrast, most individuals with acute kidney injury never need dialysis and those who need it do so for only a short time. These patients, moreover, typically receive dialysis in an inpatient setting while being treated for the condition that gave rise to the temporary decline in kidney function. That is presumably why the United States all but concedes outpatient dialysis is a proxy for ESRD. See U.S. Br. 13, 29 (acknowledging without disputing this fact).

3. Statutory structure and purpose

The plain meaning of the anti-differentiation provision is supported by "the design of the statute as a whole." *K Mart Corp.* v. *Cartier, Inc.*, 486 U.S. 281, 291 (1988). Significantly, Congress paired the provision with the ESRD coordination period—Congress's considered response to the fact that, as a consequence of the 1972 Medicare entitlement, plans were "pay[ing] little, if anything, toward the costs of kidney dialysis." S. Rep. No. 97-139, at 469. Both the coordination period and the anti-differentiation provision accordingly advance Congress's mutually reinforcing goals to protect ESRD patients from differential treatment and prohibit plans from shifting dialysis costs to Medicare during the coordination period.

The anti-differentiation provision's plain meaning adverse classification of dialysis is impermissible differentiation of ESRD-directly advances those objectives, while a contrary reading would manifestly defeat them. Imagine a group health plan that wanted to reduce costs by driving ESRD enrollees prematurely onto Medicare. One option would be to expressly single out ESRD enrollees for facially disfavored treatment. A plan thus could adopt a provision making ESRD enrollees responsible for payment of 40% of all covered medical services, while all other plan enrollees were responsible for payment of only 10% of covered services. That would uniquely disfavor ESRD enrollees and predictably cause them to abandon private coverage and switch to Medicare, burdening the federal fiscdefeating each of Congress's objectives under the MSPA. All agree that the provision prohibits this design. *E.g.*, U.S. Br. 21.

But imagine that the plan adopts an alternative scheme, imposing unfavorable cost-sharing obligations on ESRD enrollees through the ploy of targeting the outpatient dialysis benefits for which they have a virtually unique need. A plan could make all enrollees responsible for 40% of outpatient dialysis costs while other covered services (including inpatient dialysis) required only 10% cost-sharing. That design would not single out ESRD enrollees by name, but would have precisely the same effect as if it did: by imposing potentially crushing out-of-pocket financial obligations on ESRD patients alone, it would cause them to abandon private coverage in favor of Medicare.

It is exceptionally implausible that Congress intended the MSPA to be so easily evaded. Indeed, if plans were free to impose differential burdens on ESRD enrollees simply by adversely classifying outpatient dialysis, the adverse consequences for Congress's goals of protecting the Medicare fisc and patients could be severe. As to the fisc, patients who switch from employer group plans to Medicare before the end of the coordination period cost Medicare \$81,000 more on average than patients who switch between the end of the coordination period and 90 days thereafter. See Lin, The Cost of Transferring Dialysis Care From the Employer-Based Market to Medicare, JAMA Network Open 2 (Mar. 18, 2021). The vast majority of plans today provide equal treatment to ESRD patients, including with respect to dialysis benefits, meaning that many patients retain their private coverage as primary insurance throughout the ESRD coordination period. If the differential scheme employed by Petitioners here were lawful, other plans would predictably follow suit and Congress's cost-sharing regime would be upended, with added costs to the Medicare fisc annually in the billions, given that DaVita estimates there are as many as 25,000 new ESRD patients per year on group plans.

The harm to ESRD patients would also be severe just as severe as if plans had singled out ESRD patients by name rather than by the treatment they alone depend upon to stay alive. ESRD enrollees unwilling or unable to pay double premiums to maintain private insurance and Medicare would lose access to all of the benefits of private insurance they had been paying for to protect them and their families from chronic illness. *See* JA19-20. Unlike Medicare, for example, private insurance often covers a spouse or children, *see* CMS, Consumer Information and Insurance Oversight, *Young Adults and the Affordable Care Act*, and unlike most private plans Medicare does not cover dental treatment (which may be a pre-condition for a kidney transplant) or hearing aids and eyeglasses (which are often needed by the many ESRD patients who suffer from diabetes), see generally Ghaderian et al., Diabetes and End-Stage Renal Disease; A Review Article on New Concepts, 4 J. Renal Injury Prevention 28 (2015).

4. Background antidiscrimination law

Finally—although unnecessary to the outcome here—background legal principles reinforce the conclusion that by prohibiting differentiation "on the basis of ... the need for renal dialysis" or "in any other manner," Congress deemed differential treatment of dialysis to be differential treatment of ESRD enrollees.

"Differentiate" means to discriminate: The terms are (and were) interchangeable. E.g., "differentiate," American Heritage Dictionary 368 (1979) ("discriminate; distinguish"); Bostock v. Clayton Cnty., 140 S. Ct. 1731, 1740 (2020) (discriminate means "[t]o make a difference in treatment or favor (of one as compared with others)"); Babb v. Wilkie, 140 S. Ct. 1168, 1173 (2020) ("normal definition" of discrimination is "differential treatment"). And the provision operates like an antidiscrimination protection; prohibiting the provision of differential benefits to persons with ESRD is conceptually the same, for instance, as prohibiting discrimination in the terms and conditions of employment based on race. E.g., 42 U.S.C. §2000e-2(a)(1). This understanding is also consistent with Congress's objective of targeting "discriminatory [plan] provision[s]," S. Rep. No. 99-146, at 470, and CMS's established view that the MSPA prohibits "discrimination against ... individuals under age 65 who have ESRD," 56 Fed. Reg. 1,200, 1,201 (Jan. 11, 1991) (capitalization altered).

Congress's broad framing of the anti-differentiation provision—including "on the basis of … the need for renal dialysis" and "any other manner"—is thus consistent with background legal principles, including "[p]roxy discrimination" principles: a "policy that treats individuals differently on the basis of seemingly neutral criteria that are so closely associated with the disfavored group that discrimination on the basis of such criteria is, constructively, facial discrimination against the disfavored group." Schmitt v. Kaiser Found. Health Plan of Wash., 965 F.3d 945, 958 (9th Cir. 2020).

For decades, this Court has recognized that it is as unlawful to single out the unique characteristics of a protected class for unfavorable treatment as it is to target the class itself. In *Newport News Shipbuilding* & Dry Dock Co. v. EEOC, 462 U.S. 669, 684 (1983), the Court held that "discrimination based on a woman's pregnancy is, on its face, discrimination because of her sex." In Bray v. Alexandria Women's Health Clinic, 506 U.S. 263 (1993), this Court explained that "[a] tax on wearing yarmulkes is a tax on Jews." Id. at 270. And in Rice v. Cayetano, 528 U.S. 495 (2000), this Court held that a provision limiting the right to vote on the basis of "ancestry" was unconstitutional because ancestry, in that context, was "a proxy for race." Id. at 514.⁷

⁷ Courts have long applied this proxy principle to policies that target treatments or symptoms that are characteristic of protected health conditions. See School Bd. of Nassau Cnty. v. Arline, 480 U.S. 273, 282 (1987) ("discrimination based on the contagious effects of a physical impairment" was discrimination on the basis of that impairment); Erie County Retirees Ass'n v. County of Erie, 220 F.3d 193, 211 (3d Cir. 2000) (employer policy that differentiated in health benefits based on eligibility for Medicare was unlawful age discrimination because "Medicare status is a direct proxy for

B. DaVita Has Plausibly Alleged A Violation Of The Anti-Differentiation Provision

Under the interpretation above, DaVita has plausibly alleged a violation of the anti-differentiation provision. In multiple ways, the Plan disfavors outpatient dialysis with the purpose and effect of incentivizing ESRD enrollees to "prematurely abandon their coverage under the Plan to go onto Medicare." JA6; *see also supra* pp.13-16.

Critically, the Plan exposes ESRD enrollees to balance billing by artificially capping the allowed amount it will pay at 125% of the Medicare rate and requiring enrollees to pay 30% of that amount. Pet.App.5. This purposeful under-reimbursement of outpatient dialysis forces ESRD enrollees to assume the financial obligation for the difference between the charged dialysis price and the allowed amount, as well as the 30% coinsurance—a substantial financial burden. *See supra* p.15.

In addition, by relegating outpatient dialysis to outof-network status, the Plan ensures that ESRD enrollees never receive the more favorable deductible and coinsurance obligations associated with many Tier I services (including inpatient dialysis). This differential treatment uniquely disadvantages ESRD patients who rely on outpatient routine maintenance dialysis vis-à-vis those suffering from acute kidney injury—who

age"); Sullivan v. Vallejo City Unified Sch. Dist., 731 F. Supp. 947, 958 (E.D. Cal. 1990) (discriminating against use of service dog is discrimination because of physical disability); Bowers v. NCAA, 563 F. Supp. 2d 508, 519 (D.N.J. 2008) (discriminating based on enrollment in special education is discriminating based on disability because former "is inextricably linked" with latter).

require short-term dialysis, if at all, and typically receive that dialysis in a hospital. *See supra* pp.5-6.

C. Petitioners' And The United States' Contrary Interpretation Is Unpersuasive

Petitioners and the United States read the antidifferentiation provision so narrowly that it would accomplish almost nothing. In their view, the provision prohibits only plan "terms [that] *expressly target*[]" ESRD enrollees. Pet. Br. 28. So long as "outpatient dialysis benefits are the same for all individuals," the theory goes, the provision is not implicated. U.S. Br. 20. This interpretation is deeply flawed.

1. The anti-differentiation provision is not an empty formalism

The key assumption underlying Petitioners' and the United States' statutory interpretation rests on the formalism that "[l]imiting dialysis benefits for all individuals equally does not constitute 'differentiat[ing] in the benefits' the plan provides." U.S. Br. 29.

Importantly, the Plan here violates that reading of the provision because it plainly does *not* "provide[] the same [dialysis] benefits" to individuals with ESRD and those without. U.S. Br. 13. Only ESRD patients require routine outpatient dialysis. The only other persons who might ever need dialysis typically receive it in an inpatient setting, covered under favorable Tier I terms. *See supra* p.5. This under-reimbursement of outpatient dialysis vis-à-vis inpatient dialysis thus breaches the provision even under the government's reading by "singl[ing] out" ESRD patients "for different treatment with respect to benefits as compared to other individuals covered by the plan." U.S. Br. 21. Indeed, the notion that special limitations on outpatient dialysis "treat" ESRD and non-ESRD patients "the same"—"is reminiscent of Anatole France's sardonic remark that '[t]he law, in its majestic equality, forbids the rich as well as the poor to sleep under bridges, to beg in the streets, and to steal bread."" *Espinoza* v. *Montana Dep't of Revenue*, 140 S. Ct. 2246, 2274 (2020) (Alito, J., concurring) (citing Cournos, *A Modern Plutarch* 35 (1928)). A school forbidding students from wearing rosaries or crucifixes does not treat the religious and non-religious "uniformly" because such items might be worn for secular purposes. Likewise, a city's ban on the sale of kosher food would not treat Jewish and non-Jewish individuals "the same" because some might eat kosher food for secular reasons.

The same is true with respect to ESRD and dialysis. ESRD patients depend on outpatient dialysis typically three times a week to stay alive. No one else does. Given that, it is frankly inconceivable that Congress elevated form over substance by requiring courts to turn a blind eye to adverse classification of a treatment that ESRD enrollees uniquely need to live so long as plan documents are not so ham-handed or careless as to identify ESRD by name. Cf. Aetna Health Inc. v. Davila, 542 U.S. 200, 214 (2004) (rejecting reading that would "elevate form over substance and allow parties to evade" preemption "simply 'by relabeling ... claims"); Abramski, 573 U.S. at 180 (rejecting interpretation that would focus statute on "empty formalities," not "substance"). Congress does not enact statutes to be so easily circumvented.

2. Petitioners and the United States render half of the provision surplusage

Petitioners' and the United States' reading of the anti-differentiation provision treats nearly half of its text as a nullity. If Congress wanted to prohibit only express differentiation of ESRD patients, it "could simply have said that." *Great-West Life & Annuity Ins. Co. v. Knudson*, 534 U.S. 204, 218 (2002). Congress could have ended the anti-differentiation provision after the first 22 words.

But that is not the statute Congress wrote. Congress provided not only that a plan "may not differentiate in the benefits it provides between individuals having end stage renal disease and other individuals covered by such plan." Congress also specified the "manner[s]" by which a plan impermissibly differentiates between ESRD and non-ESRD individuals-"on the basis of the existence of [ESRD]," "on the basis of ... the need for renal dialysis," or "in any other manner." See Arkansas Game & Fish Comm'n v. United States, 568 U.S. 23, 36, (2012) ("the first rule of ... statutory interpretation is: Read on"). In disregarding the second half of the provision, Petitioners and the United States countermand the "cardinal principle ... that courts must give effect, if possible, to every clause and word of a statute." Loughrin v. United States, 573 U.S. 351, 358 (2014). That interpretive canon has particular force here because Petitioners' and the United States' reading assigns no "work" to "a large amount of text." *City* of Chicago v. Fulton, 141 S. Ct. 585, 591 (2021).

The United States argues that the second half of the provision limits the breadth of the first clause by "specif[ying] ... the impermissible *bases* for differentiation in benefits." U.S. Br. 22. That makes no sense in this context because the second half of the provision performs no limiting function under the government's reading—after all, "any ... manner" of differentiation is prohibited. The government suggests that the second half of the provision would do work in a scenario in which a plan differentiates "by providing more generous benefits to employees with longer tenures." U.S. Br. 22. But under the government's reading, that plan would not violate the first half of the provision because a distinction based on work tenure is not based on ESRD. The government's inability to identify a scenario in which the second half of the provision does any work confirms why its interpretation is unsound.⁸

By contrast, the reading advanced here gives effect to the second half of the provision: "on the basis of existence of ESRD," "on the basis of … the need for renal dialysis," and "any other manner" define *what it means* to provide differential benefits.

⁸ Petitioners twist themselves in knots attempting without avail to give effect to "on the basis of ... the need for renal dialysis." Pet. Br. 52-53. Petitioners acknowledge that a plan adopting different "dialysis reimbursement" for those who need 30 or more dialysis treatments annually than for enrollees who need "far fewer dialysis treatments" would violate the statute, Pet. Br. 53, but they assert that the statute permits a plan designed to produce the same result by providing one reimbursement rate for the first 30 treatments and a significantly reduced rate for additional treatments. Statutory construction does not turn on this sort of empty formalism. In any event, the Plan violates the statute under Petitioners' reading because it subjects outpatient dialysis (overwhelmingly used by ESRD patients) to disfavored reimbursement, while affording preferential reimbursement to inpatient dialysis (overwhelmingly used by individuals suffering temporary acute kidney injury). See supra pp.5-6.

3. The phrase "group health plan" does not support Petitioners' interpretation

In support of their cramped reading, Petitioners insist "the subject" of the anti-differentiation provision is the "group health plan," which, they claim, refers to plan documents only, not to the "entity that picks its terms." Pet. Br. 47 (emphasis omitted). This is both wrong and irrelevant.

It is wrong because a group health plan is more than a legal document: under 29 U.S.C. §1132(d), it is an "entity" that may "sue or be sued." Indeed, the Plan is a Petitioner here. JA9-10. Just as a corporation can discriminate, *e.g.*, *Heart of Atlanta Motel*, *Inc.* v. *United States*, 379 U.S. 241, 243 (1964), so too can a group health plan as an entity.

It is irrelevant because even if a group health plan were nothing more than a legal document, the plan could readily differentiate in the benefits it provides, just as a redistricting plan, voting restriction, or employment practice can be discriminatory if it is designed to disfavor a protected group. And in this case, as in other ERISA contexts, it is easy to look behind the Plan and plan documents to the actors (MedBen and Marietta) capable of making design decisions with the purpose and effect of disfavoring ESRD enrollees. E.g., Slaughter v. AT&T Info. Sys., Inc., 905 F.2d 92, 94 (5th Cir. 1990) (unfunded plan administered by employer was "merely a nominal defendant" in suit against employer); Acosta v. Pacific Enters., 950 F.2d 611, 617-619 (9th Cir. 1991) (focusing on conduct of plan trustee in suit naming plan as defendant).

4. Dismissal of proxy discrimination principles is unpersuasive

The United States acknowledges that proxy discrimination is an established disparate treatment theory, U.S. Br. 28, but contends that it has no purchase here because the MSPA "reaches only the provision of different benefits." U.S. Br. 29. That ignores the statute's text. Congress expressly *instructed* that dialysis should be treated as a proxy for ESRD by stating that differentiation "on the basis of ... the need for renal dialysis" is a "manner" of differentiating benefits between ESRD patients and others. Differentiation targeted at dialysis is differentiation regarding ESRD patients. This is how proxy discrimination works. Courts (or, here, Congress) use proxies to identify when impermissible differentiation is occurring. If a statute said that a federal agency may not differentiate in providing benefits between individuals with cancer and those without, a regulation subjecting oncology treatment to extra penalties would contravene the statute.

Applying this established principle would not "alter the operation of the statutory scheme" by making "subjective intent" dispositive. U.S. Br. 29. Practices that "involve[] disparate treatment through explicit facial discrimination do[] not depend on why" an entity "discriminates but rather on the explicit terms of the discrimination." International Union, United Auto., Aerospace & Agric. Implement Workers of Am., UAW v. Johnson Controls, Inc., 499 U.S. 187, 199 (1991). Again, proxy discrimination principles simply help identify when "facial discrimination" has occurred. No inquiry into subjective intent is necessary.

In any event, an intent inquiry would hardly be unworkable. "Differentiate" can include an intent to cause differential treatment. See "differentiate," Webster's Third New International Dictionary 630 (1976) ("to effect a difference in as regards classification"). The question, then, would be whether Petitioners intentionally selected facially neutral provisions in order to target ESRD patients. E.g., Personnel Adm'r of Mass. v. Feeney, 442 U.S. 256, 279 (1979). There is every reason to believe that discovery in this and related cases would confirm just that. Petitioner MedBen promotes itself based on its ability to reduce "dialysis procedures provided to ESRD patients," including "by implementing [its] proprietary dialysis health plan language." JA7. And in Amy's Kitchen, the plan singled out dialysis for disfavor only after one of its enrollees needed dialysis-at which point the plan enlisted a consultant specializing in "dialysis cost containment." Compl. ¶¶ 34, 39, 55-56, *DaVita*, *Inc.* v. *Amy's Kitchen*, Inc., No. 18-6975, ECF No. 1 (N.D. Cal. Nov. 16, 2018). Evaluating whether these efforts were indeed intended to differentiate between ESRD patients and other enrollees would be straightforward. What is extraordinary is the United States' apparent position (Br. 14-15, 29) that the purposeful creation of a plan to disadvantage ESRD patients is entirely lawful so long as the drafters avoid proclaiming that purpose directly.

5. Petitioners and the United States disregard the MSPA's structure and purposes

Petitioners' effort to align their reading with the structure and purposes of the MSPA shows just how disconnected their interpretation is from Congress's design. According to Petitioners, if plans must "prioritize[]" outpatient dialysis, that will increase plan expenses and "necessarily" lead them to raise premiums or cut benefits—which will cause enrollees "to drop plan coverage and enroll solely in Medicare, ... increas[ing] ... Medicare['s] expenditures." Pet. Br. 42.

That cascade of speculation bears no relationship to the real world—and Petitioners do not even attempt to substantiate it. The anti-differentiation provision requires only that dialysis be treated the same as, not "prioritized" above, other services. Pet. Br. 42. And conjecture that enforcing Congress's prohibition on ESRD differentiation will cause non-ESRD enrollees to drop coverage in favor of Medicare makes little sense. Non-ESRD enrollees under age 65 are not even eligible to shift to Medicare, and the vast majority of those on an employer group plan are working and under age 65. Fears that equal treatment of ESRD patients would cause enrollees to abandon private coverage are contradicted by the reality that almost all group health plans do treat dialysis on equal terms with other medical services; yet the disastrous scenario Petitioners hypothesize has not remotely materialized.

Although the United States does not embrace Petitioners' speculation, it contends (Br. 23-24) that its interpretation finds support in the "broader context and purpose of the [MSPA]," based on the premise that Congress did not intend to establish a substantive entitlement to dialysis coverage. That is a strawman. The provision requires equal treatment of persons with ESRD-including equal treatment of outpatient dialysis; it does not guarantee a substantive entitlement to any fixed level of dialysis benefits, nor does it require dialysis alone to be reimbursed at "undiscounted" rates. Pet. Br. 2. If a plan provided barebones coverage for treatment of all chronic conditions, including dialysis, or reimbursed outpatient dialysis under the same formula as other comparable services, that plan would not violate the anti-differentiation provision.

A similar error infects the United States' argument that "[t]he statutory scheme ... contemplates that some plans may lawfully provide benefits at levels that leave the Medicare program to cover gaps." U.S. Br. 24. Again, the anti-differentiation provision demands equal treatment of outpatient dialysis; it does not guarantee a fixed level of coverage. If a plan provided 70% coverage (with a 30% coinsurance obligation) for all medical services, including dialysis, that would not violate the provision, yet a patient might well choose to enroll in Medicare secondary "to cover gaps."

6. Reliance on CMS regulations is misplaced

The reliance Petitioners and the United States place on CMS regulations, *see* Pet. Br. 50-51, U.S. Br. 24-27, is completely unwarranted.

To begin with, where, as here, this Court can "discern Congress's meaning" by "employing traditional tools of statutory construction," it "owe[s the] agency's interpretation of the law no deference." SAS Inst., Inc. v. Iancu, 138 S. Ct. 1348, 1358 (2018) (quoting Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 843 n.9 (1984)). The government's failure to invoke deference is unsurprising—not only because the regulations were promulgated without notice and comment but also because CMS asserted that notice and comment was unnecessary because the statutory text is clear. See 60 Fed. Reg. at 45,359-45,360; e.g., United States v. Mead Corp., 533 U.S. 218, 230 (2001).

The regulations are also internally inconsistent, as the United States concedes both expressly, U.S. Br. 27 n.4, and implicitly in a labored effort to reinterpret them, *id.* at 24-27. Both the Sixth and Ninth Circuits found that the regulations "appear to conflict with one another" and "do more to confuse than to clarify." Pet App.49; see also DaVita Inc. v. Amy's Kitchen, 981 F.3d 664, 677 (9th Cir. 2020) (similar). Agency actions reflecting "unexplained inconsistency" "receive[] no *Chevron* deference," *Encino Motorcars, LLC* v. Navarro, 579 U.S. 211, 222 (2016) (alteration omitted), and have no claim to a "power to persuade," Mead Corp., 533 U.S. at 228 (quoting Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944)).

If anything, the most intelligible reading of the regulations supports DaVita's position, for they provide that a plan's "[f]ailure to cover routine maintenance dialysis ... when a plan covers other dialysis services" constitutes prohibited differentiation. 42 C.F.R. §411.161(b)(2)(v). That example rests on the premise that differential treatment of outpatient dialysis (the method by which ESRD patients receive "routine maintenance dialysis") as compared to inpatient dialysis (the method by which patients with acute kidney injury might receive "other dialysis") is prohibited. See U.S. Br. 26 (acknowledging this point). The Plan does just that. See supra pp.13-16.

By contrast, the provision on which Petitioners and the United States rely, 42 C.F.R. §411.161(c), facially conflicts with other regulations and the statute. It conflicts with §411.161(b) because if it is unlawful not to cover "routine maintenance dialysis"—as §411.161(b)(2)(v) provides—it cannot be lawful for a plan to "limit[] its coverage of renal dialysis ... to 30 [sessions] per year"—as §411.161(c) suggests—because "routine maintenance dialysis" by definition requires 150 sessions per year. As noted above, routine maintenance dialysis must typically be performed three times a week, 52 weeks a year. The regulation also

countermands the statutory scheme, which establishes a 30-month coordination period during which plans must remain primary payers. A plan that covers only 30 dialysis treatments would barely cover *two months* of dialysis, but most with ESRD are not even able to enroll in Medicare until three months after dialysis begins. Section 411.161(c) is thus "manifestly contrary to the [MSPA]," and unworthy of "controlling weight." *Chevron*, 467 U.S. at 844.

II. DAVITA HAS STATED A CLAIM FOR VIOLATION OF THE MSPA'S TAKE-INTO-ACCOUNT PROVISION

Independently, DaVita has plausibly alleged that the Plan has impermissibly "take[n] into account that an individual is entitled to or eligible for benefits [based on ESRD] ... during the [30]-month period ... in which the individual becomes entitled to benefits under [Medicare]." 42 U.S.C. \$1395y(b)(1)(C)(i).

A. The Take-Into-Account Provision Prohibits Plans That Take Medicare Eligibility Into Consideration In Plan Design

Ordinary tools of statutory interpretation establish that the take-into-account provision reaches plans that are designed with the Medicare eligibility of ESRD enrollees as a consideration, whether or not the plan documents expressly reference Medicare eligibility.

Because the MSPA does not define "take into account," the statutory inquiry begins with "the phrase's plain meaning at the time of enactment." *Tanzin*, 141 S. Ct. at 490. And here the statutory inquiry ends with the text because it is "unambiguous," meaning the "judicial inquiry is complete." *Connecticut Nat'l Bank* v. *Germain*, 503 U.S. 249, 254 (1992) (internal quotation omitted). As a matter of plain meaning, at the time the "take into account" provision was enacted, to "take [something] into account" meant to "take into consideration," as it does today. Webster's Third New International Dictionary 2331. "Consider," in turn, meant (and means) "to think of." Webster's Third New International Dictionary 483; see id. (listing "contemplate," "study," and "weigh" as synonyms for "consider").

B. DaVita Has Alleged A Violation Of The Take-Into-Account Provision

DaVita has plausibly alleged that Petitioners impermissibly considered the Medicare eligibility of ESRD patients in designing the Plan. The complaint alleges (1) that "Plan provisions expressly target dialysis treatment and, in doing so, the Plan ... takes into account an ESRD patient's Medicare eligible status," JA26, and (2) that Petitioners designed the documents "motivated by their desire to induce members of the Plan with ESRD to drop out of the Plan and instead enroll in Medicare," JA29. This entire scheme attempting to move ESRD enrollees prematurely onto Medicare—is made possible only because of the Medicare eligibility of ESRD enrollees. See JA31-32; see also JA195 (telling enrollees needing dialysis they "may be able to enroll Medicare").

These well-pled allegations "state a claim to relief that is plausible on its face." *Ashcroft* v. *Iqbal*, 556 U.S. 662, 678 (2009). Indeed, Petitioners' brief confirms the allegations' plausibility. Acknowledging that the Plan's unfavorable coverage of dialysis exposes ESRD patients to out-of-pocket obligations, Petitioners suggest that no harm will come to ESRD patients because they can simply enroll in Medicare secondary to cover those obligations. Pet. Br. 17-18. If, as Petitioners' brief strongly suggests, Petitioners designed the plan in consideration of the fact that ESRD enrollees can enroll in Medicare to obtain secondary coverage (thus paying a double set of premiums), that is obviously a way in which the Plan "takes into account" the Medicare eligibility of ESRD enrollees.

C. Petitioners' And The United States' Contrary Interpretation Is Unpersuasive

1. Although acknowledging that "tak[ing] into account" means "giving consideration to," Pet. Br. 33; U.S. Br. 17, Petitioners and the United States insist that the provision reaches "only group health plans that contain terms *expressly targeting* Medicareeligible individuals who are eligible because of [ESRD]," Pet. Br. 34; U.S. Br. 17. In support, they lean heavily on the claim that the subject of the provision is "group health plan," an "inanimate" entity supposedly incapable of motive. Pet. Br. 33; U.S. Br. 17.

This misses the mark. First, as explained, a plan is by law a juridical entity, *see supra* p.36, and it is perfectly common to say that an entity may take something into account. In any event, courts routinely look past the veneer of a plan document to the actors that design and administer a plan. *See id*.

Second, even if a "group health plan" were nothing more than the legal documents setting forth plan terms, the plain meaning of the provision would still require an inquiry into the intent of those drafting plan documents. In common parlance, to say that a document takes something into account means that the drafter took it into account. For instance, §5 of the Voting Rights Act spoke of a "qualification, prerequisite, standard, practice, or procedure" having the "purpose ... of denying or abridging the right to vote on account of race or color." 52 U.S.C. §10304(a). This Court had no trouble understanding the relevant "purpose" was that of the policy drafter. *See Reno* v. *Bossier Parish Sch. Bd.*, 528 U.S. 320, 330 (2000) (§5 violated where "jurisdiction" "act[ed]" with impermissible "purpose").

That reflects the point that when "take into account" is used in connection with a document, nothing in plain meaning requires that a consideration be discussed expressly on the face of a document. If one asked: "Does the Constitution take into account that States were pre-existing sovereigns prior to ratification?," the answer would be yes, even though no express provision of the Constitution says as much. *E.g.*, *Seminole Tribe of Fla.* v. *Florida*, 517 U.S. 44, 54 (1996). Similarly, if a seller of commercial goods drafted a contract that, the seller explained, takes into account the purchaser's ability to pay, one would expect the contract to be designed with that in mind—not that there would be a specific reference to the purchaser's ability to pay in the contract.

Moreover, reading the take-into-account provision to prohibit only those plans careless enough to expressly reference Medicare eligibility would allow plans effortlessly to evade this prohibition. Sensibly, courts "cannot interpret federal statutes to negate their own stated purposes." New York State Dep't of Social Servs. v. Dublino, 413 U.S. 405, 419-420 (1973).

2. Petitioners contend (Br. 37-39) that it would be "inconsistent with ERISA to apply an implicit requirement of priority dialysis benefits over all other potential benefits." But enforcing Congress's requirement that a plan may not take into account Medicare eligibility does not mandate a "fixed level of [dialysis] benefits," much less require "priority" treatment. *Id.* at 37. It simply forbids plan designs based in part on ESRD enrollees' entitlement to Medicare.

In any event, in seeking to generate a conflict between a plain-meaning reading of the MSPA and ERISA, Petitioners "face[] a stout uphill climb." *Epic Sys. Corp.* v. *Lewis*, 138 S. Ct. 1612, 1624 (2018). This Court's obligation is to "to give effect to both" statutes, *id.*, which is easy to do: although plan sponsors are "generally free" under ERISA to adopt or modify plans, Pet. Br. 37, they may not contravene the MSPA's more specific statutory protection for ESRD patients.

The same point responds to Petitioners' contention that a plain-text reading is unworkable because the same meaning will apply to other MSPA provisions that use the phrase "take into account." Pet. Br. 39-41. Again, the take-into-account prohibition does not require plans to "reimburse on a priority basis" services used more frequently by seniors, the disabled, or ESRD patients. Pet. Br. 40. It forbids plans only from taking Medicare eligibility into account in plan design.

3. Nor can CMS regulations save Petitioners' and the United States' atextual interpretation. See Pet. Br. 43-45; U.S. Br. 18-19. As explained, see supra pp.40-42, those regulations deserve no deference. Even setting that aside, the regulations—which identify nonexclusive "[e]xamples" of prohibited conduct, 42 C.F.R. §411.108(a)—clearly proscribe acts that go beyond singling out Medicare eligibility on the face of plan documents. For example, the regulations prohibit "[p]roviding misleading ... information that would have the effect of inducing a Medicare entitled individual to reject the employer plan," *id.* §411.108(a)(9), which has nothing to do with plan terms. And several of the examples prohibit conduct without specifying whether Medicare eligibility is singled out on the face of the plan documents. *See id.* §411.108(a)(4), (a)(5), (a)(11). The regulations thus support the text's plain meaning, as the Sixth Circuit held. Pet.App.52-53.

III. DAVITA HAS PLAUSIBLY ALLEGED THAT THE PLAN HAS A PROHIBITED DISPARATE IMPACT

Finally, this Court may affirm on the "[a]lternative[]" ground, Pet.App.45, that the statutory prohibition against "differentiat[ion]" "in any other manner" bars facially neutral policies that, like the Plan, have a disparate impact on ESRD patients.

A. The MSPA Includes Disparate-Impact Liability

"[A]ntidiscrimination laws must be construed to encompass disparate-impact claims when their text refers to the consequences of actions and not just to the mindset of actors, and where that interpretation is consistent with statutory purpose." *Texas Dep't of Housing & Cmty. Affairs* v. *Inclusive Cmtys. Project, Inc.*, 576 U.S. 519, 533 (2015). The anti-differentiation provision satisfies both conditions.

To "differentiate" can mean "to make different" or "to effect a difference in as regards classification." *Webster's Third New International Dictionary* 630. Thus, "differentiate" is a verb that encompasses consequences, as the Court recognized in construing the Age Discrimination in Employment Act (ADEA). That statute includes an exemption from liability where otherwise prohibited "differentiation is based on reasonable factors other than age," 29 U.S.C. §623(f)(1) (emphasis added)—a provision that "plays its principal role" "in cases involving disparate-impact claims," *Smith* v. *City of Jackson*, 544 U.S. 228, 239 (2005) (plurality op.); *accord id.* at 246 & n.3 (Scalia, J., concurring in the judgment).

The phrase "in any other manner" particularly embraces differential effects. As explained, "any" makes this phrase exceedingly broad. *See supra* p.24. Where, as here, "Congress did not add any language limiting the breadth of that word," it must be read "as referring to all" manners of differentiation, *United States* v. *Gonzales*, 520 U.S. 1, 5 (1997)—including in a plan's impact on ESRD patients.

Moreover, "in any other manner" plays an identical role in the MSPA's structure as the key language in other disparate impact provisions: It is a "catchall phrase looking to consequences, not intent" that is "[l]ocated at the end of" a "lengthy sentence[] that begin[s] with prohibitions on disparate treatment." *Inclusive Cmtys.*, 576 U.S. at 534-35 (comparing the Fair Housing Act to the ADEA and Title VII). Those other statutes "use the word 'otherwise"—meaning "in a different way or manner"—to "signal[] a shift in emphasis from an actor's intent to the consequences of his actions." *Id.* The MSPA uses nearly identical language— "in any other manner"—to do the same.

Construing the MSPA to encompass disparateimpact claims is also "consistent with statutory purpose." *Inclusive Cmtys.*, 576 U.S. at 533. Just as under the Fair Housing Act, "disparate-impact liability" under the MSPA ensures that Congress's objectives are not frustrated through "covert" strategies that could otherwise "escape easy classification as disparate treatment." *Id.* at 540; *see supra* pp.32-33.

B. Petitioners' And The United States' Contrary Arguments Fail

Petitioners and the United States contend that Congress would not have used "differentiate," rather than "discriminate," if it had intended to create disparate-impact liability. Pet. Br. 57; U.S. Br. 30. That ignores the breadth of the word "differentiate," which, as explained, encompasses conduct generating differential results—as Congress recognized in the ADEA by using "differentiation" to refer to employment practices that produce a disparate impact. See supra p.47. One could say, for example, that the employer in *Smith* differentiated between older and younger workers in compensation by giving proportionately higher raises to employees with fewer than five years of experience. See 544 U.S. at 235 (plurality). By the same token, the Plan here differentiates between ESRD patients and others by uniquely limiting coverage for a treatment (outpatient dialysis) that is paradigmatically and almost exclusively needed by ESRD patients.

Petitioners likewise err in comparing the MSPA to various statutes that bar only intentional discrimination or retaliation. See Pet. Br. 55-56. Titles VI and IX of the Civil Rights Act prohibit intentional discrimination alone because they refer to discrimination "on the ground of," 42 U.S.C. §2000d (Title VI), or "on the basis of," 20 U.S.C. §1681(a) (Title IX), protected characteristics, see Gross v. FBL Fin. Servs., Inc., 557 U.S. 167, 176 (2009). By contrast, the corresponding phrase in the MSPA ("on the basis of") does not extend to the catch-all phrase ("in any other manner") that creates disparate-impact liability. See supra p.22 n.6. And the provision Petitioners cite (Br. 56) from the Family and Medical Leave Act is limited to retaliatory conduct. See 29 U.S.C. §2615(a)(2). The anti-differentiation provision contains no comparably limiting text.

The United States' contention that disparateimpact liability is unworkable, see U.S. Br. 30-32, ignores that "policies are not contrary to the disparateimpact requirement unless they are 'artificial, arbitrary, and unnecessary barriers," *Inclusive Cmtys.*, 576 U.S. at 543. Unlike the Plan's scheme to target outpatient dialysis here, not every provision that disproportionately disfavors ESRD patients will impose an "artificial, arbitrary, and unnecessary barrier[]."" *Id.* For example, a plan's coverage levels for cardiovascular diseases, *cf.* U.S. Br. 31-32, without more would not be an artificial or arbitrary barrier. Courts have experience applying this contextual inquiry.

Finally, the United States' extended discussion (Br. 24-27) of CMS's regulations is unpersuasive—not only for the reasons previously given, but also because 42 C.F.R. §411.161(b)(2)(v) certainly contemplates disparate-impact liability. As the United States concedes, that provision focuses not on whether plan limits are "imposed uniformly" (U.S. Br. 27 n.4), but instead states that a plan impermissibly "differentiat[es]" if it covers medical procedures needed by other enrollees ("other organ transplants"), while excluding a medical procedure that is disproportionately but not exclusively needed by ESRD enrollees (a "kidney transplant[]").

IV. ERISA CLAIMS ARE NOT BEFORE THIS COURT

Petitioners spend less than a page inviting reversal of the Sixth Circuit's holding that two of DaVita's ERISA claims (Counts II and VII) can proceed. Pet. Br. 58-59. But "those claims ... are not before this Court." U.S. Br. 10 n.2. Each Question Presented is limited to the MSPA; not one mentions ERISA. See Pet. i; Pet. Br. i. Because this Court considers "[o]nly the questions set out in the petition, or fairly included therein," S. Ct. R. 14.1(a), this Court should decline Petitioners' request for review of these ERISA claims.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted.

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