¶¶2, 50. These restrictions on coverage for dialysis leave patients in a precarious position. They can choose to pay huge out-of-pocket expenses because the treatment is now out-of-network, subjecting them to far higher deductibles and co-insurance requirements *or* drop the benefits of their private insurance and enroll in Medicare. For most patients, these costs will force them onto Medicare, and in doing so, patients risk losing coverage for their spouse and children, their choice of doctors, and coverage of health needs excluded from Medicare (e.g., eyeglasses). *See* Dialysis Patient Citizens, *supra*, at 2–3. Eliminating in-network coverage leaves healthcare providers in a challenging position that puts access to dialysis at risk for patients. Providers must deal with reduced reimbursements such that the cost of providing care now exceeds the reimbursement they receive, which can put some clinics at risk, or pass on the difference in cost to the patient though balance billing, which is also substantially harmful to patients. Compl. at ¶¶4–5. These are the very choices and harms Congress designed the MSPA to avoid.

I. Congress sought to protect patients with ESRD while preserving the financial strength of Medicare.

Until the 20th Century, a diagnosis of kidney failure meant that death was imminent. That all changed when the first rudimentary artificial kidney was developed in the 1940s. *See* Rettig, *supra*, at 177. The 1960s saw both refinements in dialysis techniques and dramatic developments in the success of kidney transplants. *See id.* at

178. These two advancements in concert meant that kidney failure was no longer a death sentence.

Hemodialysis, the dominant form of dialysis, essentially withdraws blood from a patient, uses artificial filters to remove wastes and excess fluids, and returns the filtered blood back to the patient. *See* Suzanne M. Kirchoff, Cong. Research Serv., *Medicare Coverage of End-Stage Renal Disease* 5 (Aug. 16, 2018). Typically, this requires three treatments per week, with each treatment lasting about four hours. *Id.* For the vast majority of patients in the 1960s, dialysis was too rare and too expensive. *See id.* at 6. A growing movement for Congressional intervention in this problem culminated in 1971 when an ESRD patient underwent dialysis in front of the House Ways and Means Committee. *See* Rettig, *supra*, at 187–88. The next year, President Richard Nixon signed the Social Security Amendments on 1972 into law, guaranteeing Medicare coverage, including dialysis, for almost every American diagnosed with ESRD. *See* Pub. L. No. 92–603, § 299I, 86 Stat. 1329, 1463–64.

A. Congress passed the Medicare Secondary Payer Act to preserve Medicare and shift ESRD treatment costs back to private insurers.

Initial estimates in 1971 suggested an annual cost to Medicare of $100 million to treat 25,000 ESRD patients. *See* Rettig, *supra*, at 197. By 1980, however, the annual costs had grown to over $1.2 billion, with 55,000 ESRD patients enrolled. *See* Nissenson & Rettig, *supra*, at 165. These costs were mostly due to an underestimate of the prevalence of ESRD, a rise in dialysis costs, and hasty actuarial estimates prepared for legislative

review. *See* Rettig, *supra*, at 197–201. To protect Medicare, Congress enacted the Medicare Secondary Payer Act as part of the Omnibus Budget Reconciliation Act of 1980. Pub. L. No. 96–499, 94 Stat. 2599, 2647–48; 42 U.S.C. § 1395y (2012). Essentially, the MSPA makes Medicare the secondary payer for a patient's medical services and makes any private insurance—held by or owed to the patient—the primary payer. *See* 42 U.S.C. § 1395y(b).

In 1981, Congress amended the MSPA to add 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). This initially created a 12-month "coordination period" wherein the ESRD patient may remain on their private insurance if they so choose. 42 U.S.C. § 1395y(b)(4). After the coordination period, Medicare serves as the primary payer. *Id.* Subsequent amendments extended the coordination period to its present length, 30 months. 42 U.S.C. § 1395y(b)(1)(C)(ii).

Initial estimates of the MSPA as applied to ESRD predicted savings of $440 million in the first four years. S. Rep. 97–139, at 446 (1981). In 2012 alone, the MSPA resulted in over $300 million in savings for Medicare ESRD expenditures. Cong. Research Serv., *supra*, at 25.

B. ESRD patients face large out-of-pocket expenses on Medicare

Even when their dialysis is covered by Medicare, ESRD patients still face significant out-of-pocket costs for dialysis treatment—costs otherwise not incurred while on private insurance using in-network providers. For example, an ESRD patient

enrolled in Medicare Part B—the program that covers outpatient services like dialysis—would need to pay a minimum monthly premium of $135.50 per month that scales up with income. *2018 Medicare Part A & B Premiums and Deductibles*, Ctrs. for Medicare and Medicaid Servs. (Nov. 17, 2017), https://www.cms.gov/newsroom/fact-sheets/2018-medicare-parts-b-premiums-and-deductibles. This equates to a minimum annual cost of over $1,600 in premiums alone. While some low-income Medicare patients may qualify for reduced cost sharing responsibilities, *see generally Get Help Paying Costs*, Medicare, https://www.medicare.gov/your-medicare-costs/get-help-paying-costs (last visited Oct. 28, 2019), many still face significant out-of-pocket costs.

In addition, patients on Part B pay a 20% co-insurance on all outpatient procedures, including dialysis, with no out-of-pocket maximum. *See id.* For dialysis, the base Medicare allowable cost in 2018 was $232.37 per treatment. *See CMS Updates to Policies and Payment Rates for End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury*, Ctrs. for Medicare and Medicaid Servs. (Oct 27, 2017) https://www.cms.gov/newsroom/fact-sheets/cms-updates-policies-and-payment-rates-end-stage-renal-disease-prospective-payment-system-quality. For ESRD patients who require three treatments per week, co-insurance results in an additional $7,250 in medical costs per year. Between annual premiums of $1,600 and dialysis co-insurance of $7,250, an ESRD patient on Medicare faces a minimum of almost $9,000 in out-of-pocket costs each year just to obtain dialysis, without even considering other medical

issues the patients may also need to pay for. These mounting costs pose a real and substantial threat to ESRD patients who may ultimately have to ration their own care because they simply cannot afford it.

Medigap coverage can offset these expenses; however, federal law does not mandate the availability of Medigap for patients under the age of 65, who make up over half of all ESRD patients on Medicare. *See Ensure ALL Medicare ESRD Patients Have Access to Medigap Plans*, Dialysis Patient Citizens (Sept. 2019) https://www.dialysispatients.org/sites/default/files/medigap_201909.pdf. Moreover, states like California, Washington, and Arizona allow Medigap providers to reject ESRD patients in the first instance, rendering Medigap useless as a potential way to address their medical expenses. *Id.* For those few that may obtain Medigap coverage, premiums are often so high that coverage is functionally unattainable. *See id.*

Patients forced off their private insurance also need to pay the premiums, deductibles, and co-insurance associated with Medicare Part D, the prescription drug benefit. *See, e.g.*, Nat'l Council on Aging, *How Much Does Medicare Part D Cost?*, My Medicare Matters, https://www.mymedicarematters.org/costs/part-d/ (last visited Oct. 23, 2019). In contrast, patients covered by private insurance, and especially employer-sponsored insurance like Amy's Plan, need not pay Medicare premiums and co-insurance for dialysis and drug costs. Indeed, Medicare's costs are "far less generous than employer . . . health coverage." Dialysis Patient Citizens, *supra*, at 3. Congress designed the MSPA to give ESRD patients the option of remaining on their private

insurance if they wanted, and patients generally prefer their private insurance to Medicare. *See id.* at 2.

C. Congress enacted strong anti-discrimination provisions to protect patients with ESRD

Knowing that Medicare serves as a (costly) backstop for ESRD patients, private insurers, focused on cost-savings, are tempted to structure plans to force patients onto Medicare. To combat this temptation, Congress enacted anti-discrimination provisions into the MSPA. *See* 42 U.S.C. § 1395y(b)(1)(C). The MSPA forbids private insurers from taking three broad categories of action against their patients.

First, a group health plan "may not take into account that an individual" is entitled to Medicare based on ESRD when making benefits decisions. 42 U.S.C. § 1395y(b)(1)(C)(i); 42 C.F.R. § 411.161(a) (1995). Examples of "taking into account" include "[f]ailure to pay primary benefits as required" for patients with ESRD, providing "less comprehensive health care coverage" for patients with ESRD than others in the plan, and "[p]roviding misleading or incomplete information" that would induce a patient onto Medicare, among others. 42 C.F.R. § 411.108(a) (1995); 42 C.F.R. § 411.161(a)(1). According to the Centers for Medicare and Medicaid Services ("CMS"), the administrative agency that implements Medicare, a group health plan may "make[] benefit distinctions among various categories of individuals" so long as those distinctions "are unrelated to the fact that the individual" is eligible for Medicare. 42 C.F.R. § 411.108(b)(1).

Second, a group health plan "may not differentiate in the benefits it provides between individuals having [ESRD] and other individuals . . . on the basis of the existence of [ESRD], the need for renal dialysis, or in any other manner." 42 U.S.C. § 1395y(b)(1)(C)(ii); 42 C.F.R. § 411.161(b). Examples of impermissible differentiation include "[t]erminating coverage of individuals with ESRD, when there is no basis . . . unrelated to ESRD," "[i]mposing [benefit limitations] on persons who have ESRD, but not others enrolled in the plan," and "failure to cover routine maintenance dialysis or kidney transplants, when a plan covers other dialysis services or other organ transplants," among others. 42 C.F.R. § 411.161(b).

Finally, the MSPA prohibits insurers from offering "any financial or other incentive" to an ESRD patient to not enroll or terminate enrollment in a group health plan that would otherwise be the primary payer. 42 U.S.C. § 1395y(b)(3)(C).

1. Amy's Plan violates the MSPA by taking into account ESRD patients' Medicare eligibility

Amy's Plan plainly "provides less comprehensive health coverage" and "reduc[es] benefits" for patients with ESRD compared to others in the plan. 42 C.F.R. § 411.108(a). By converting dialysis, and *only* dialysis, to out-of-network coverage, Amy's Plan subjects ESRD patients, who are almost universally eligible for Medicare, to substantially reduced benefits while similarly situated individuals—i.e. those without ESRD—may still obtain costly procedures and medications with the benefits of in-network coverage. Thus far, DaVita has not subjected their patients to balance billing

in order to provide affordable care for all ESRD patients. *See* Tr. of Mot. to Dismiss Hr'g 7. However, if every private insurer were to follow the subterfuge of Amy's Kitchen, dialysis providers may have no choice but to balance bill their patients to avoid operating at a loss. It is no accident that Amy's Kitchen removed in-network coverage and dramatically lowered reimbursement rates for dialysis—and only dialysis—once a Medicare-eligible ESRD patient began actually utilizing these benefits. Amy's Kitchen's means and motive are clear: move ESRD patients off the plan to save money knowing that Medicare will foot the bill. The MSPA forbids this.

2. Amy's Plan violates the MSPA by differentiating between ESRD and all other health conditions

Plans that restrict access to dialysis, but not other costly treatments, specifically discriminate against ESRD patients. The district court below incorrectly interpreted the non-differentiation provision of Section 1395y to allow the restricted dialysis coverage of Amy's Plan, under the guise of facially neutral limitations. *See DaVita, Inc. v. Amy's Kitchen, Inc.*, 379 F. Supp. 3d 960, 972–73 (N.D. Cal. 2019). This interpretation is inconsistent not only with the core purpose of the MSPA's non-discrimination provisions, but also the plain text of the statute.

Namely, the MSPA forbids discrimination against patients with ESRD based, in part, on "the need for renal dialysis, or in any other manner." 42 U.S.C. § 1395y(b)(1)(C)(ii). The district court below cited the CMS regulations that permit, for example, limits in "coverage of renal dialysis to 30 per year for all plan enrollees . . . ."

42 C.F.R. § 411.161(c); *Amy's Kitchen*, 379 F. Supp. 3d at 973 (citing the Federal Register publication for the regulation). This interpretation suggests that restrictions on access to dialysis do not violate the law, so long as these restrictions apply equally to those diagnosed with ESRD and those not so diagnosed. However, restricting or eliminating coverage for dialysis inherently discriminates against those with ESRD and, effectively, *only* those with ESRD. Indeed, the interpretative guidance released contemporaneously to the non-differentiation provision explicitly states that a group health plan "that does not cover routine maintenance dialysis would be in violation of" the MSPA. 56 Fed. Reg. 1081, 1202 (1991). This is precisely what Amy's Plan does, and is precisely what Congress forbade.

Outside of ESRD, the only other patient diagnosis that *may* require dialysis is acute kidney injury ("AKI"). *See Acute Kidney Injury*, Nat'l Kidney Found. (2015) https://www.kidney.org/atoz/content/AcuteKidneyInjury. In 2014, only about 30,000 patients with AKI required dialysis, while almost 500,000 ESRD patients required dialysis. *Compare* Meda E. Pavkov et al., *Trends in Hospitalizations for Acute Kidney Injury—United States, 2000–2014*, Cents. for Disease Control & Prevention, 67 Morbidity and Mortality Weekly Rep. 289, 291 (2018) (28,075 patients combined, with and without diabetes) *with* Chronic Kidney Disease Surveillance System, *Treated ESRD in the United States*, Cents. for Disease Control & Prevention, https://nccd.cdc.gov/CKD/detail.aspx?Qnum=Q67 (last visited Oct. 24, 2019) (463,639 patients, prevalence rate multiplied by U.S. total population in 2014). This

means that, of those receiving dialysis in 2014, 94% had ESRD and only 6% had AKI. *See id.* Patients with AKI only require dialysis if their kidney function drops below the critical level (90%), and only until the kidney recovers. *See* Nat'l Kidney Found., *supra.* Indeed, one study showed the majority of patients with AKI recover within one week and no longer need dialysis, in stark contrast to ESRD patients who require dialysis on an ongoing basis. *See* John A. Kellum et al., *Recovery after Acute Kidney Injury*, 195 Am. J. Respiratory & Critical Care Med. 784, 786 (2017). Moreover, of those with AKI, only 2% to 10% will ultimately require dialysis, in contrast to ESRD patients, who *all* require dialysis to survive. *See* Eric A.J. Host & Marie Schurgers, *Epidemiology of Acute Kidney Injury: How Big is the Problem?*, 36 Critical Care Med. S146, S146 (2008); Anatole Harrois et al., *Prevalence and Risk Factors for Acute Kidney Injury among Trauma Patients: A Multicenter Cohort Study*, 22 Critical Care 1, 4 (2018).

Because only a few patients with AKI will ultimately require limited dialysis treatments, and all ESRD patients require ongoing dialysis, any plan that limits dialysis coverage (as Amy's Plan does) effectively discriminates against patients with ESRD and only ESRD. Restrictions on dialysis access are restrictions on ESRD patients. This is what Congress prohibited in the MSPA. *See* 42 U.S.C. 1395y(b)(1)(C)(ii) (prohibiting differentiation between ESRD patients and others based on "the need for renal dialysis"); *Chevron U.S.A. v. Natural Res. Def. Council*, 467 U.S. 837, 842–43 (1984) ("If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.").

D. Amy's Plan violates the MSPA by providing financial incentives for patients to enroll in Medicare.

Limiting coverage for dialysis forces the patient to decide between two options; either enroll in Medicare and face thousands of dollars in annual costs, or stay on their employer-sponsored insurance and face even higher costs each year in out-of-pocket medical expenses for out-of-network dialysis treatments. *Compare* Section I.B., *supra* (detailing almost $9,000 in annual costs to an ESRD patient for dialysis under Medicare Part B alone) *with* Steven Johnson, *Home Dialysis Grows Despite Cost and Logistical Hurdles*, Modern Healthcare (Oct. 11, 2014), https://www.modernhealthcare.com/article/20141011/MAGAZINE/310119932/home-dialysis-grows-despite-cost-and-logistical-hurdles (citing annual costs of $72,000 for hemodialysis). This is precisely the choice Congress sought to avoid with the MSPA, and it is the very choice Amy's Kitchen forces upon its ESRD employees by removing in-network coverage for all dialysis treatments. *See* 42 U.S.C. § 1395y(b)(3)(C) (forbidding private insurers from providing financial incentive to enroll in Medicare). Amy's Kitchen knew that Medicare served as a backstop for ESRD patients, and by eliminating in-network coverage for dialysis and no other costly treatment, Amy's Kitchen unlawfully took into account ESRD patients' Medicare eligibility, unlawfully differentiated between benefits provided to patients with ESRD and those without, and unlawfully incentivized ESRD patients to drop out of Amy's Plan and enroll in Medicare.

II. Patients with ESRD rely on dialysis facilities and private insurance to access life-saving care

The majority of ESRD patients will receive dialysis treatment from private, freestanding facilities, like DaVita. MedPAC, *supra*, at 162. Of those ESRD patients covered under Medicare, freestanding facilities provide over 90% of dialysis treatments. *Id.* Due to the low reimbursement rates from Medicare, these facilities—especially those in rural and other low-volume areas—require private insurance to operate. *See* Section II.B, *infra*. In effect, privately insured patients provide the revenue to keep open the very dialysis facilities that Medicare ESRD patients require.

A. Dialysis facilities require private insurance reimbursement to operate

Dialysis facilities, such as DaVita, provide life-saving dialysis treatments, but they cannot operate at a loss and therefore risk closing, putting patient access at risk. That, however, would be the precise outcome if Medicare served as primary payer for every ESRD patient. A third-party review of public information estimates DaVita's average cost per dialysis treatment was $269 in 2017. Adam A. Shpigel et al., *A Comparison of Payments to a For-Profit Dialysis Firm from Government and Commercial Insurers*, 179 JAMA Internal Med. 1136, 1137 (2019). However, DaVita only received $248 per treatment from government sources (Medicare and Medicaid combined). *Id.* This amounts to a net *loss* to DaVita of $21 (~10%) per treatment to those patients covered by public insurance. *Id.* From commercial insurers—who cover only 10% of ESRD patients—DaVita received $1,041 per treatment on average, over four times the reimbursement

from public insurance. *Id.* Over all facilities, Medicare reimbursed for 1.1% *less* than the allowable cost of providing dialysis. *See* MedPAC, *supra*, at 173. DaVita and other dialysis facilities face the prospect of failing to meet operating costs if they receive reimbursement solely through Medicare. As such, the minority of privately insured patients remain critical to subsidizing the cost of care for all patients covered by Medicare.

B. Rural and low-volume dialysis providers will close without private insurance reimbursement

Rural facilities make up 12% of dialysis treatments paid by Medicare. *See* MedPAC, *supra*, at 173. Yet rural facilities face disproportionately negative margins from Medicare due to higher costs. *See id.* Accordingly, rural and low volume facilities rely heavily on privately insured patients. To offset the low margins on low-volume facilities, Medicare instituted a program to increase reimbursement to these facilities. *See id.* at 173; *see also* 42 C.F.R. § 413.232 (2018). However, the program only applies when the facility provides fewer than 4,000 dialysis treatments per year, averaged over three years. MedPAC, *supra*, at 173; 42 C.F.R. § 413.232(b)(1). As a result, if a facility provides 4,000 treatments or more per year, it no longer qualifies for the increased reimbursement and would be back in the same position of potentially operating at a loss. This threshold applies to dialysis treatments reimbursed by both Medicare and private insurers combined. *See* 42 C.F.R. § 413.232(b). Difficulty in administering the adjustment program has resulted in non-payment of $6.7 million to eligible facilities in 2011 alone.

Gov't Accountability Office, *End Stage Renal Disease: CMS Should Improve Design and Strengthen Monitoring of Low-Volume Adjustment*, Report 13-287, at 11 (2013). Given the underpayment of the low-volume adjustment and low treatment volume, rural facilities rely even more heavily on revenues generated from private health insurance. If Amy's Kitchen is allowed to make all dialysis treatment out-of-network and reimburse dialysis providers at only Medicare reimbursement rates, other private insurers will follow suit. Rural and low-volume facilities will be unable to operate, and the ESRD patients who rely on these facilities will be unable to receive life-saving treatment.

C. Allowing ESRD patients to remain on their private insurance protects patient health

If private insurers are allowed to limit their payments for dialysis as Amy's Kitchen has done here, they will be less incentivized to provide coverage for other essential treatments—like medications and kidney transplants—that patients may require before they get to the point of needing dialysis. Once a patient reaches the dialysis stage, an insurer like Amy's Kitchen is effectively off the hook because the reimbursements are low and many patients are forced to Medicare. So the insurer has no incentive to cover drugs and other treatments that may prevent or delay the patient from reaching the dialysis stage.

One such preemptive drug is Procysbi®, used to treat a rare genetic kidney disease called cystinosis that targets children. *See* Emily Kopp & Jay Hancock, *The High Cost of Hope: When the Parallel Interests of Pharma and Families Collide*, The Daily Beast (Oct.

15, 2018), https://www.thedailybeast.com/the-high-cost-of-hope-when-the-parallel-interests-of-pharma-and-families-collide. Cystinosis, if left untreated, can result in ESRD. *See id.* Previously, a child had to take a medication called cysteamine every six hours, wherein a single missed dose could result in permanent kidney damage. *Id.* In 2013, Procysbi®, a dramatically improved version of cysteamine, was released that only needed to be taken twice a day and had far fewer side effects. *Id.* This new drug, however, costs $300,000 annually. *Id.* If insurers are allowed to force patients onto Medicare as soon as they develop ESRD, the insurer no longer has an incentive to cover medications, like Procysbi® that can delay progression to ESRD.

Similarly, a private insurer with no stake in a patient's health after they become Medicare eligible has no incentive to facilitate transition of care from chronic kidney disease to ESRD. For example, insurers have no incentive to cover preemptive kidney transplants—transplants before the onset of ESRD—that improve both patient and transplanted kidney survival. *See* Bertram L. Kasiske et al., *Preemptive Kidney Transplantation: The Advantage and the Advantaged*, 13 J. Am. Soc'y Nephrology 1358, 1358 (2002). The insurer is not motivated to pay for a preemptive kidney transplant if they can postpone treatment long enough for the patient to develop ESRD and be forced onto Medicare, who would then cover—at taxpayer expense—a transplant with worse health outcomes.

Nor would insurers have incentive to cover the creation of a fistula—a surgical connection of a vein and artery—that is often required to produce enough blood flow

for efficient dialysis. Importantly, a fistula takes up to 8 to 12 weeks post-surgery to mature before it can be accessed for dialysis. *See Frequently Asked Questions about Dialysis Access Surgery*, Beth Israel Deaconess Med. Ctr, https://www.bidmc.org/centers-and-departments/transplant-institute/dialysis-access-center/frequently-asked-questions-about-dialysis-access-surgery (last visited Oct. 28, 2019). If a patient does not have a matured fistula by the time they require dialysis, the patient will have to undergo dialysis using alternative forms of access that are more prone to infection and blood clots. *See* Nat'l Kidney Found., *Hemodialysis Access: What You Need to Know* 7–9 (2006). Once again, the private insurer has no incentive to provide for this preemptive treatment if, in failing to prevent the patient from developing ESRD, the patient is forced onto Medicare.

If private insurers do not cover and promote these preemptive steps to transition care, ESRD patients may suddenly require dialysis without proper preparation—otherwise known as "crashing" into dialysis. Crashing can result in complications like infections and extended hospital stays that then result in increased medical costs. *See* Amber O. Molnar et al., *Risk Factors for Unplanned and Crash Dialysis Starts: A Protocol for a Systematic Review and Meta-Analysis*, 5 Systematic Revs. 1, 1–2 (2016). When "crashed" ESRD patients are then forced onto Medicare, these increased costs due to complications are passed along to the taxpayer. If Amy's Kitchen and others are allowed to limit ESRD patients' access to life-saving dialysis, then life-saving drugs and preemptive procedures could very well be next on the chopping block.

D. Congress gave dialysis providers a powerful private enforcement mechanism to deter private insurers from forcing patients onto Medicare

In light of potentially tremendous out-of-pocket costs, Congress ensured that ESRD patients could still obtain treatment if a private insurer wrongfully denied them coverage. *See* H.R. Rep. 97–208, at 956 (1981). Accordingly, Congress designed the conditional payment system in the MSPA. *See* 42 U.S.C. § 1395y(b)(2)(B). Under this system, if a private insurer fails to pay the dialysis facility, the facility may ask Medicare to make a conditional payment so the patient continues receiving treatment. *Id.* This payment is "conditioned" on reimbursement to Medicare. 42 U.S.C. § 1395y(b)(2)(B)(i). Medicare may only make conditional payments under limited circumstances. *See, e.g.*, 42 U.S.C. § 1395y(b)(2)(A)(forbidding payment when it "can be reasonably be expected to be made" under private insurance); 42 C.F.R. § 411.165(b)(1)(ii) (forbidding payment when a group health plan "limits its payments when the individual is eligible for Medicare"). Private insurers, as the primary payer under the MSPA, must then reimburse Medicare. *See* 42 U.S.C. § 1395y(b)(2)(B)(ii). The federal government may sue the private insurer for reimbursement. 42 U.S.C. § 1395y(b)(2)(B)(iii).

In 1986, Congress added an additional enforcement mechanism for MSPA violations, a private cause of action. *See* Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99–509, 100 Stat. 1874, 2011; 42 U.S.C. § 1395y(b)(3). The MSPA provides a private cause of action "for [double] damages . . . in the case of a primary plan which fails to provide for primary payment (or appropriate reimbursement) in accordance with

[42 U.S.C. § 1395y(b)(1) & (2)(A)]. 42 U.S.C. § 1395y(b)(3). This provision has caused confusion among the courts as to what precise requirements the MSPA lays out before a private party may sue a private insurer. *See, e.g.*, *Bio-Medical Applications of Tenn., Inc. v. Cent. States Health and Welfare Fund*, 656 F.3d 277, 279 (6th Cir. 2011) (calling the relevant portion of the Medicare Act a "convoluted statute" and "tortuous text"). However, the most straightforward reading of the provision—in light of Congress's purpose to protect ESRD patients under the MSPA—is simply to provide one additional avenue to hold private insurers accountable for violations of the anti-discrimination provisions in the MSPA.

Broadly, "[t]he Private Cause of Action was intended to allow private parties to vindicate wrongs occasioned by the failure of primary plans to make payments." *Parra v. PacifiCare of Ariz., Inc.*, 715 F.3d 1146, 1154–55 (9th Cir. 2013). Notably, "there is no legislative history of the private right of action provision . . . ." *Nat'l Renal Alliance v. Blue Cross Blue Shield*, 598 F. Supp. 2d 1344, 1353 (N.D. Ga. 2009). Most courts have found that Medicare must first make a conditional payment before a private party may sue. *See id.* at 1355 (citing cases). These courts often justify such requirement by asserting the private party must ultimately reimburse Medicare from a portion of the double damages it receives under the statute. *See Star Dialysis, LLC v. WinCo Foods Emp. Benefit Plan*, Case No. 1:18-cv-00482-CWS, 2019 WL 3069849, at *23 (D. Idaho, Jul. 12, 2019). That is, the double damages provision purportedly exists to ensure there are sufficient proceeds from the private litigation to reimburse CMS for whatever conditional

payment it made. This interpretation, however, cannot be the sole purpose for double damages.

Other courts have emphasized that reimbursement is not automatic. For example, the Second Circuit in *Woods v. Empire Health Choice*, 574 F.3d 92 (2d Cir. 2009), stated that "the victorious private party will keep the entirety of any recovery," and that CMS has the discretion of filing a separate action to recover from the successful litigant. *Id.* at 99. Moreover, Medicare *itself* can collect double damages under the MSPA, 42 U.S.C. § 1395y(b)(2)(B)(iii), and Medicare was entitled to sue before the private cause of action was even added to the MSPA. *See* Deficit Reduction Act of 1984, Pub. L. No. 98–369, § 2344(a), 98 Stat. 494, 1095–96.

The double damages provision clearly serves additional important purposes, namely deterrence and incentive to sue. As the Sixth Circuit explained in *Bio-Medical Applications v. Cent. States Health and Welfare Fund*, 656 F.3d 277 (6th Cir. 2011), "First, much like treble damages in the antitrust laws, they punish and deter disfavored conduct—here, the shifting of costs from private insurers to Medicare. Second, double damages provide a needed incentive for healthcare providers to bring lawsuits to vindicate Medicare's interests." *Id.* at 290. Moreover, "providers usually suffer their own injury when private insurers refuse to pay, because providers generally are paid less by Medicare than they would be paid by private insurers." *Id.* at 295–96. This is especially true with ESRD, where private insurance reimbursement rates are five to ten times that of Medicare. *See* Section II.A, *supra*.

Requiring a dialysis provider like DaVita to seek reimbursement first from Medicare before the provider may sue a private insurer makes little sense economically. Some courts have suggested that Medicare "will be protected more directly by [being reimbursed] for the payments it was forced to make due to private insurers' illegal conduct." *Bio-Medical*, 656 F.3d at 295. That is not true. Medicare is most directly protected when it need not pay out in the first place and hope that it will eventually be reimbursed from the responsible primary payer. In fact, the MSPA allows the Secretary of Health and Human Services—the department where CMS is located—to waive its right to reimbursement if, for example, the amount in question does not justify a government lawsuit. *See* 42 U.S.C. § 1395y(b)(2)(B)(v); *see also* H.R. Conf. Rep. 96–1479, at 133 (1980) (acknowledging the Senate amendment allowing waiver if "the probability of recovery or the amount involved under such a policy or plan does not warrant pursuing of the claim."). The MSPA, therefore, contemplates scenarios where Medicare would pay out conditional payments and not seek reimbursement. *See id.* If a private party can sue a private insurer before seeking a conditional payment from Medicare, then CMS would not have to undergo constant cost-benefit analyses to justify the expense of seeking reimbursement through suit. Moreover, allowing dialysis providers to challenge unlawful private insurance plans can preemptively keep ESRD patients from being forced onto Medicare, saving the government even more money.

Indeed, the plain text of the MSPA envisions a private cause of action outside a Medicare conditional payment. The MSPA permits a private cause of action when a

primary plain "fails to provide primary payment (*or* appropriate reimbursement) . . . ." 42 U.S.C. § 1395y(b)(3)(A) (emphasis added). This envisions two alternate scenarios; one where Medicare has made a conditional payment and the dialysis provider sues the private insurer for "appropriate reimbursement" to Medicare and another where the private insurer "fails to provide primary payment" to the dialysis provider. In the end, private providers, like DaVita, are in the best position to enforce the requirements of the MSPA against private insurers, like Amy's Kitchen, on behalf of vulnerable ESRD patients. Medicare is also in the best financial position when it need not hunt for reimbursement at all and when ESRD patients remain on their private insurance.

CONCLUSION

It the midst of interpreting a complicated and dense statute like Medicare, one can lose sight of the real human costs involved. Over 500,000 Americans rely on constant dialysis to survive. In a remarkable and unprecedented moment, Congress made a promise; no one diagnosed with ESRD would go untreated. Congress then created the MSPA and amended it over time to maintain that promise.

In the end, history reveals the outcome if private insurers can flout the MSPA and limit benefits specifically to patients with ESRD. Dialysis facilities that rely on the small number of ESRD patients who retain the benefits of private insurance will no longer be able to cover their costs and operate. Patients who rely on these facilities will no longer be able to access life-saving care. ESRD patients will face the impossible

choice of extraordinary out-of-pocket costs for Medicare premiums and co-insurance or extraordinary costs for out-of-network care under their private insurance.

Congress created the strong protections embedded in the MSPA to ensure that all ESRD patients had access to affordable care and to force otherwise unwilling private insurers to take responsibility for the well-being of their patients. Allowing Amy's Kitchen to undermine the MSPA's protections will no doubt incentivize other private insurers to follow suit, forcing more ESRD patients onto Medicare all in the name of cost saving. That is the very scenario Congress sought to avoid. These restrictions are unlawful, immoral, and dangerous.

For these reasons, *amicus* respectfully requests that this Court reverse the judgment of the district court.

Dated: October 30, 2019

Respectfully submitted,

s/ Deanna J. Reichel

Deanna J. Reichel
FISH & RICHARDSON P.C.
60 South Sixth Street, Suite 3200
Minneapolis, MN 55402
Telephone: (612) 335-5070
Facsimile: (612) 288-9696

Attorney for Amicus Curiae,
Dialysis Patient Citizens

CERTIFICATE OF SERVICE AND FILING

I hereby certify that I electronically filed the foregoing document with the Clerk of the Court of the United States Court of Appeal for the Ninth Circuit by using the Court's CM/ECF filing system.

I certify that all participants in the case are registered CM/ECF users and that all counsel were served via CM/ECF on October 30, 2019.

/s/ Deanna J. Reichel
Deanna J. Reichel

CERTIFICATE OF COMPLIANCE

The undersigned attorney certifies that this brief complies with the type-volume limitation set forth in Fed. R. App. P. 32(a)(7)(B)(ii). The relevant portions of the brief, including all footnotes, contain 6,164 words as determined by Microsoft Word.

Dated: October 30, 2019

/s/ Deanna J. Reichel
Deanna J. Reichel
FISH & RICHARDSON P.C.
60 South Sixth Street, Suite 3200
Minneapolis, MN 55402
Telephone: (612) 335-5070
Facsimile: (612) 288-9696

Attorneys for Amicus Curiae,
Dialysis Patient Citizens