No. 20-1641

In The Supreme Court of the United States

MARIETTA MEMORIAL HOSPITAL EMPLOYEE HEALTH BENEFIT PLAN, ET AL.,

Petitioners,

v.

DAVITA INC., ET AL.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Sixth Circuit

BRIEF OF THE PACIFIC HEALTH COALITION, ET AL. AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICUS CURIAE*[1]

Amicus Health Care Cost Management Corporation of Alaska d/b/a Pacific Health Coalition represents 45 members including Taft-Hartley funds, governmental health plans, public sector health benefits trust funds and single employer plans. Groups range from 100 to more than 8,000 employees, providing coverage to approximately 250,000 members combined.

The National Labor Alliance of Health Care Cost Coalitions, Inc. is a national alliance of over 20 coalitions of Taft-Hartley funds and labor management coalitions, serving plans including over 6 million covered lives combined.

ASEA/AFSCME Local 52 Health Benefits Trust is a self-funded, non-federal governmental plan which covers approximately 18,000 State of Alaska governmental employees and dependents.

Public Employees Local 71 Trust Fund is a self-funded, non-federal governmental plan which covers approximately 3,000 State of Alaska and Alaska municipality employees and dependents.

APEA-AFT Health and Welfare Trust is a self-funded, non-federal governmental plan which covers

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

approximately 500 school district employees and dependents.

Alaska Pipe Trades U.A. Local 367 Health and Security Trust is a Taft-Hartley, multi-employer Trust Fund which covers approximately 1,200 local union members and dependents.

SUMMARY OF THE ARGUMENT

The Sixth Circuit's holding is a drastic departure from long-settled principles of deference to benefits design in self-insured employment-based group health plans ("Self-Insured EGHPs") which creates an unprecedented dialysis benefits mandate by a novel reinterpretation of the Medicare Secondary Payer Act ("MSPA").

Medicare's extension of coverage to individuals with end-stage renal disease ("ESRD") in 1972 required a Medicare dialysis procurement system which in turn created a noncompetitive private dialysis market. This market is controlled by two very large dialysis organizations ("LDOs") which use Self-Insured EGHPs as a major profit center. The profits taken by the LDOs already impose unaffordable charges on Self-Insured EGHPs unless they can use one of a very few cost containment strategies.

One of these strategies is plan benefits design, but the Sixth Circuit has prohibited Self-Insured EGHPs from using it to limit dialysis payments. This unique

prohibition means that plans facing unaffordable dialysis costs are left with the alternatives of excluding dialysis from coverage or terminating the plan altogether. The perhaps ironic result would be to shift many more individuals needing dialysis from EGHP to Medicare coverage.

ARGUMENT

I. The Structure of the U.S. Dialysis Financing System.

Understanding these issues requires some understanding of U.S. healthcare financing, which uses a mix of private and governmental payers:[2]

- Employment-based plans ("EGHPs")[3] cover 54.4 percent of the population, covering employees and their dependents. EGHPs include Self-Insured EGHPs covering 34.8% of the population, and fully-insured EGHPs which make up the rest of the EGHP sector.[4]

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[2] Except where otherwise specified data is from Keisler-Starker and Bunch, *Health Insurance Coverage in the United States: 2020* (U.S. Bureau of the Census September 2021).

[3] Plans are "group health plans," which are fully- or self-insured plans established by a plan sponsor to provide health care to the employees, former employees and others associated with the employer in a business relationship, or their family members. *See* 26 U.S.C. §§ 5000(b)(1) and 9832(a).

[4] Kaiser Family Foundation, *Employer Health Benefits 2021 Annual Survey* at 151–52.

- Medicare covering 18.4 percent, aged and disabled individuals.
- Medicaid covering 17.8 percent, low-income individuals state-by-state. Most are also covered by Medicare.[5]
- Direct-purchase individual coverage for 10.5 percent.
- TRICARE, Department of Veterans Affairs or Civilian Health and Medical Program of the Department of Veterans Affairs covering 3.7 percent.

The dominant payer is Medicare, followed by the major commercial issuers[6] covering both the fully-insured EGHP and individual markets,[7] followed by Self-Insured EGHPs.

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[5] *See* Erickson et al., *Safety-Net Care for Maintenance Dialysis in the United States*, 31 J. Am. Soc. Nephrol. 424 (2020) and CMS Medicare-Medicaid Coordination Office, *Data Analysis Brief: Medicare-Medicaid Dual Enrollment 2006 through 2018* (September 2019).

[6] "The term 'health insurance issuer' means an insurance company, insurance service, or insurance organization (including a health maintenance organization . . . which is licensed to engage in the business of insurance in a State and which is subject to State law which regulates insurance. . . . Such term does not include a group health plan." 26 U.S.C. § 9832(b)(2).

[7] *See* U.S. Government Accountability Office, *Private Health Insurance: Enrollment Remains Concentrated among Few Issuers, Including in Exchanges* (March 2019).

Medicare and EGHPs act as a "system" to cover dialysis across the population.[8] Within this system the Medicare dialysis procurement process created a non-competitive provider side while enabling inflated private sector charges, especially to Self-Insured EGHPs, at prices far beyond cost. Excessive dialysis provider profit-taking imbalances this system by imposing unaffordable dialysis costs on the plans.

Benefits design is one of the few dialysis cost containment options for Self-Insured EGHPs. The Sixth Circuit prohibition means that Self-Insured EGHPs which cannot obtain affordable dialysis prices have to exclude dialysis or terminate the plan altogether. At the same time this prohibition is contrary to established deference to benefit design decisions for Self-Insured EGHPs.

II. Mandatory Dialysis Benefit Terms Are Contrary to Established Principles of Benefit Design Deference.

The Self-Insured EGHP is the most flexible and individual-oriented of the payers in U.S. healthcare financing. Medicare and other governmental programs are bureaucratic, while commercial issuers provide highly standardized benefits across large populations.

Plan sponsors offer health benefits to attract and retain employees, and try to design benefits that suit

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[8] *See, e.g.*, U.S. Renal Data System, *2009 Annual Data Report* at 336.

their employees' needs and preferences.[9] Plans cover all occupations from pipeline workers, to hospital staff, to food processing workers, to Indian tribal casino staff, to school employees, to retail workers, to law firm and bank personnel, in rural and metropolitan areas and all points in between. Some covered populations skew younger and need more prenatal and pediatric care; some skew older and need more cardiac and chronic condition care; in some regions different health conditions are more prevalent than others. Self-Insured EGHPs need flexibility to design plans to meet all these variables and more, so U.S. health policy gives great deference to benefits design.

A. ERISA and the Invention of the EGHP.

Employers have long been the major payer in U.S. healthcare.[10] After the Second World War employment-based health coverage became a central feature of most employees' compensation.

The most-cited reason for this was to increase compensation for union members, and as an alternative to national health insurance.[11] Other key factors

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[9] *See e.g.*, Fronstin and Werntz, *The "Business Case" For Investing in Employee Health: A Review of the Literature and Employer Self-Assessments*, EBRI Issue Brief, No. 267 (Employee Benefits Research Institute, March 2004).

[10] *See* Starr, *The Social Transformation of American Medicine* (1982) at 311–12, 321–22.

[11] *See* Fronstin, *What Does the Future Hold for the Employment-Based Health Benefits System?* EBRI Issue Brief, No. 476

were new rules allowing collective bargaining for health benefits and excluding health benefits from taxation.[12] Unlike some national health systems, in the U.S. "the federal government, having decided not to provide health insurance to most of its citizens, privatized the job by default, delegating it to private employers and insurance companies."[13]

At first all EGHPs were fully-insured. "Private health insurance plans [were] traditionally . . . fully insured indemnity or service plans and . . . commonly referred to as 'purchased' insurance. Either Blue Cross/Blue Shield or commercial insurance companies assume the immediate financial risk, and the employer is only responsible for paying premiums."[14]

This changed with ERISA in 1974.[15] ERISA exempts self-insured but not fully-insured EGHPs from state insurance laws,[16] which encouraged many more employers to establish self-insured plans.[17]

(Employee Benefits Research Institute, March 14, 2019) at 5 and Starr, *supra* at 311–12.

[12] *See* Fronstin, *supra* note 11, at 5 and Blumenthal, *Employer-Sponsored Health Insurance in the United States—Origins and Implications*, 355 N. Engl. J. Med. 82, 83 (2006).

[13] Blumenthal, *supra* at 83.

[14] McDonnell et al., *Self-Insured Health Plans*, 8 Health Care Financ. Rev. 1 (Winter 1986).

[15] Employee Retirement Income Security Act of 1974, Pub.L. 93–406, 88 Stat. 829 (September 2, 1974).

[16] *See Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 747, 105 S. Ct. 2380, 2393 (1985).

[17] McDonnell et al., *Self-Insured Health Plans supra*.

The distinction between fully-insured and self-insured EGHPs[18] may be summarized as follows:[19]

> Sponsors of self-insured plans pay covered health expenses directly (either from their general assets or from a trust), as the plans incur claims. In contrast, sponsors of fully insured plans generally pay premiums to insurers [issuers], which, in turn, assume the responsibility of paying claims. . . .
>
> Self-insured and fully insured group health plans are governed by somewhat different rules. For example, state insurance laws generally do not apply to self-insured, ERISA-covered plans. Likewise, some Affordable Care Act provisions apply to group health insurance but not to self-insured plans.

Thus, in fully-insured EGHPs benefits are determined by a few dominant issuers under federal and state benefits requirements.[20] This model is unavoidably standardized and not responsive to individual needs and preferences.

Since ERISA enabled the growth of Self-Insured EGHPs by allowing them the flexibility to design

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[18] Some EGHPs are "mixed insured," meaning they contract for insurance for some benefits, and self-insure others. For purposes of this analysis mixed-insured EGHPs will be included with Self-Insured.

[19] U.S. Department of Labor Report to Congress, *Annual Report on Self-Insured Group Health Plans* (March 2021) at 4.

[20] In 2016 the three largest healthcare insurers held 80 percent or more of their market in at least 37 states. *See* U.S. Government Accountability Office, *supra* at 7.

benefits which meet their employees' needs and preferences, this brief now turns to the ways in which ERISA (and subsequent laws) defer to their discretion.

B. Legislative Deference to Plan Benefit Design.

ERISA regulates all types of employment-based benefit plans, including EGHPs as "welfare plans."[21] ERISA struck a difficult balance between "Congress' desire to offer employees enhanced protection for their benefits, on the one hand, and, on the other, its desire not to create a system that is so complex that administrative costs, or litigation expenses, unduly discourage employers from offering . . . benefit plans in the first place."[22] Accordingly, welfare plans are not subject to the substantive standards applicable to pension plans.[23]

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[21] "Welfare plans" include "any plan, fund, or program which was heretofore or is hereafter established or maintained by an employer or by an employee organization, or by both . . . for the purpose of providing for its participants or their beneficiaries, through the purchase of insurance or otherwise . . . medical, surgical, or hospital care or benefits, or benefits in the event of sickness, accident, disability, death or unemployment, or vacation benefits, apprenticeship or other training programs, or day care centers, scholarship funds, or prepaid legal services. . . ." 29 U.S.C. § 1002(1).

[22] *Varity Corp. v. Howe*, 516 U.S. 489, 497 (1996).

[23] *See* Muir and Stein, *Two Hats, One Head, No Heart: The Anatomy of the ERISA Settlor/Fiduciary Distinction*, 93 N.C. L. Rev. 459 (2015) at 472.

> [ERISA] does not go about protecting plan participants and their beneficiaries by requiring employers to provide any given set of minimum benefits, but instead controls the administration of [EGHPs] . . . as by imposing reporting and disclosure mandates . . . participation and vesting requirements, . . . funding standards . . . and fiduciary responsibilities for plan administrators[.][24]

Instead of benefits required by law, the "set of benefits" provided by a Self-Insured EGHP is determined as a "settlor" function of the plan sponsor.[25] "Settlor" are distinguished from "fiduciary" functions. "Fiduciaries" are identified by their performance of actions included with the ERISA definition.[26] Since this definition does not include the actions of creating, amending or terminating a plan, these are "settlor" acts.

> ERISA's fiduciary duty requirement simply is not implicated where [a plan sponsor], acting as the Plan's settlor, makes a decision regarding the form or structure of the Plan such as who is entitled to receive Plan benefits and in

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[24] *N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 650–51, 115 S. Ct. 1671, 1674–75 (1995) (citations omitted, emphasis added).

[25] A "plan sponsor" is (i) an employer, an (ii) employee organization (labor union), (iii) two or more employers or jointly one or more employers and one or more employee organizations through a group of representatives, or (iv) a pooled plan provider. 29 U.S.C. § 1002(16)(B).

[26] *See* 29 U.S.C. § 1002(21)(A) and *Lockheed Corp. v. Spink*, 517 U.S. 882, 890 (1996). Accord *Hughes Aircraft Co. v. Jacobson*, 525 U.S. 432 (1999).

> what amounts, or how such benefits are calculated.[27]

Consistently ERISA itself did not require any specific benefits, though it has a limited anti-discrimination provision which does not apply to benefits.[28] Subsequent amendments cautiously added a few requirements not relevant here.[29]

Deference continued with the next major enactment affecting EGHPs, HIPAA.[30] As material, HIPAA prohibits EGHP discrimination in plan eligibility determinations, which expressly did not create substantive benefits obligations:

> [This provision] . . . shall not be construed (A) to require [an EGHP], or [EGHP] coverage, to provide particular benefits other than those provided under the terms of such plan or coverage, or (B) to prevent such a plan or coverage from establishing limitations or restrictions on the amount, level, extent, or

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[27] *Lockheed Corp. v. Spink*, *supra*, 517 U.S. at 890.

[28] "[ERISA] Section 510 prohibits discrimination driven by a desire to retaliate against an employee or to deprive an employee of a right to which he or she may become entitled. It does not prohibit an employer from crafting its medical plan to meet economic imperatives." *Owens v. Storehouse, Inc.*, 984 F.2d 394, 400 (11th Cir. 1993).

[29] The Consolidated Omnibus Budget Reconciliation Act, 29 U.S.C. § 1161–1168 ("COBRA") added requirements for continuation of EGHP coverage with no benefits requirements, and the Omnibus Budget Reconciliation Act, 29 U.S.C. § 1169, added a few specific requirements for children's coverage.

[30] The Health Insurance Portability and Accountability Act of 1996, Pub.L. 104-191 (August 21, 1996).

> nature of the benefits or coverage for similarly situated individuals enrolled in the plan or coverage.[31]

In general, "HIPAA does not prohibit a plan design or terms which are generally applicable to all plan participants, but which may have a disparate impact on individual enrollees due to the individual's need for more or specific benefits under the plan."[32]

Deference continued again with the Affordable Care Act ("ACA").[33] The ACA requires issuers to provide specified "essential health benefits" but does not extend this requirement to "large" Self-Insured EG-HPs (more than 100 employees).

> The Act [ACA] makes few changes to the large-group market, consistent with the belief that the market has been functioning acceptably well in providing health care access to most people working for large organizations. . . .
>
> . . .
>
> For large employers that already provide health care benefits . . . the new mandate will not impose much in the way of new obligations because . . . the [ACA] exempts the

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[31] 29 U.S.C. § 1182(a)(1).

[32] Medill, *HIPAA and Its Related Legislation: A New Role for ERISA in the Regulation of Private Health Care Plans?* 65 Tenn. L. Rev. 485, 502 (Winter 1998) (footnotes omitted).

[33] Affordable Care Act of 2010, Pub.L. 111-148, 124 Stat. 199 (2010).

> large-group market from the "essential health benefits" requirements. . . .[34]

The ACA did establish a few limited benefit requirements for large EGHPs (e.g., preventive services) but otherwise deferred benefits design to sponsors.

Finally, while not in the direct line of EGHP statutory authorities the Americans with Disabilities Act ("ADA")[35] also defers to Self-Insured EGHPs in benefits design. The ADA prohibits employers from discriminating against individuals with disabilities in health coverage[36] but specifically allows risk-based benefits design, permitting benefits which might otherwise be discriminatory as long as the design is not a "subterfuge."[37] " 'Subterfuge' refers to disability-based disparate treatment that is not justified by the risks or costs associated with the disability."[38] A sponsor may therefore design benefits which have a disparate impact on

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[34] Baker, *Health Insurance, Risk, and Responsibility after the Patient Protection and Affordable Care Act*, 159 U. Penn. L. Rev. 1577, 1592 (June 2011) (footnotes omitted). Due to the inability of most smaller organizations to procure or reserve sufficient funds to self-insure there are very few groups below the ACA threshold.

[35] 42 U.S.C. § 12101

[36] 29 C.F.R. § 1630.4(a)(vi). *See* Equal Employment Opportunity Commission (EEOC), *Interim Enforcement Guidance on the Application of the ADA to Disability-Based Distinctions in Employer-Provided Health Insurance* (June 8, 1993). ESRD and the need for dialysis are "disabilities" under the ADA. *See Fiscus v. Wal-Mart Stores, Inc.*, 385 F.3d 378, 384 (3d Cir. 2004).

[37] 29 C.F.R. § 1630.16(f)(3), (4).

[38] EEOC, *supra* at 10–11.

members with particular disabilities, if justified by costs of the benefit without differentiation.

Federal law therefore provides only a few marginal requirements for Self-Insured EGHP benefit design, and exempts them from state requirements. Substantive decisions about benefit design are deferred to the sponsor to meet employee needs and preferences.

C. Benefits Design and the Financial Realities of Self-Insured EGHPs.

While they do have legal discretion over benefit design, Self-Insured EGHPs must fund the wide range of services their Members expect. This includes everything from catastrophic cases such as traumatic injury and cancer; to costly chronic conditions such as diabetes and hemophilia; to prenatal, wellness and preventive care; and more. Expensive ancillary services such as air ambulances may be needed. Even if not legally required dialysis is part of the preferred benefits set.

Once established a Self-Insured EGHP is required to fund all benefits. In doing so it must be administered "for the exclusive purpose of (i) providing benefits to participants and their beneficiaries; and (ii) defraying reasonable expenses of administering the plan[,]" using the "care, skill, prudence, and diligence under the circumstances then prevailing that a prudent man acting in a like capacity and familiar with such matters

would use in the conduct of an enterprise of a like character and with like aim[.]"[39]

This obligation extends to selection of healthcare providers:[40]

> In selecting a health care provider in this context, as with the selection of any service provider under ERISA, the responsible plan fiduciary must engage in an objective process designed to elicit information necessary to assess the qualifications of the provider, the quality of services covered, and the reasonableness of the fees charged in light of the services provided. . . .
>
> . . . it should be noted that, because numerous factors necessarily will be considered by a fiduciary when selecting health care service providers, the fiduciary need not select the lowest bidder when soliciting bids, although the fiduciary must ensure that the compensation paid to a service provider is reasonable in light of the services provided to the plan.

Prudent plan administration therefore requires cost containment if charges may be unaffordable.

Provider networks, usually associated with an issuer, are common but prices for Self-Insured EGHPs are not as favorable as those issuers negotiate for

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[39] *Pegram v. Herdrich*, 530 U.S. 211 (2000) at 227; *see* 29 U.S.C. § 1104(a)(1).

[40] U.S. Department of Labor Employee Benefits Services Administration, *Information Letter 02-19-1998*.

their fully-insured plans[41] and may not provide a reasonable reduction from otherwise uncontrolled charges.

A second common strategy is stop-loss insurance, but expensive cases are usually "lasered":

> Within self-funded medical programs, individuals having serious ongoing medical conditions that are likely to incur large expenses related to those conditions, are "known" risks that are frequently isolated by a stop loss carrier to receive a higher specific deductible in relation to the rest of the insured population. Isolating specific individuals for a higher stop loss deductible is known as "lasering" and has always been a common practice in the medical stop loss industry.
>
> Here's an over-simplified illustration: Assume that a 500-life employer group has a $100,000 specific stop loss deductible. An individual in the group is currently being treated for cancer with an expected treatment cost of $500,000 during the plan year. Medical stop loss coverage with a $100,000 specific deductible is issued to the employer for each covered individual except for the cancer patient who will be "lasered" with a $500,000 specific deductible. . . .[42]

Dialysis cases are usually lasered.

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[41] Craig et al., *How Important is Price Variation Between Health Insurers?* National Bureau of Economic Research Working Paper 25190, October 2018).

[42] Giles, *Demystifying Stop Loss Lasers* (QBE 2017) at 1.

If network prices are not affordable and stop-loss has an unaffordable laser a sponsor has only four options to control dialysis costs:

- Terminate the plan.
- Exclude dialysis from benefits.
- Increase employee cost shares (premiums, deductibles and copayments).
- Establish targeted treatment or dollar amount limitations.

Cost-share increases may be unaffordable for Members. A 500-Member plan may need to increase each Member's premium by $1,800 annually to cover a single dialysis case at $900,000 per year. Members may drop the plan for the individual market or go uninsured, further increasing costs for those who remain, who in turn may drop the plan, and so on. This phenomenon is called a 'death spiral' and can cause a plan's financial collapse.

If a sponsor terminates the plan or excludes dialysis, members needing dialysis will have no coverage choice but Medicare or the individual market. Since individuals needing dialysis due to ESRD are automatically eligible for Medicare, if benefits limitations are prohibited dialysis coverage may ultimately collapse into Medicare alone.

Benefits design using targeted treatment or dollar amount limitations are the option which preserves the Medicare/EGHP dialysis coverage system. It is also the

strategy adopted by the Self-Insured EGHP sponsored by Amy's Kitchen:[43]

> In 2017, Amy's Plan modified its terms of coverage by implementing a "Dialysis Benefit Preservation Program." The Plan explained that it had found evidence of "significant inflation" of prices charged by dialysis providers; the use of inflated revenues "to subsidize reduced prices to other types of payers as incentives"; and "the specific targeting of the Plan and other non-governmental and non-commercial plans by the dialysis providers as profit centers." The Plan implemented the program because of its fiduciary obligation to preserve Plan assets against charges which (i) exceed reasonable value due to factors not beneficial to covered persons . . . and (ii) are used by the dialysis providers for purposes contrary to the covered persons' interests, such as subsidies for other plans and discriminatory profit-taking.

The reason for the Amy's Kitchen strategy was precisely the need to control unaffordably high dialysis costs, to preserve funding for all types of benefits for all Members. While the record in this case does not include this kind of specific documentation, it must be inferred that the same issues motivated the cost containment strategy used by petitioners.

Benefits-design based cost containment strategies to limit dialysis costs and protect the interests of all Members in all types of care is well within the

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[43] *DaVita Inc. v. Amy's Kitchen, Inc.*, 981 F.3d 664, 668 (9th Cir. 2020).

deference accorded Self-Insured EGHPs, and helps preserve the Medicare/EGHP dialysis coverage system.

II. Medicare Dialysis Procurement Created Dialysis Monopoly Pricing.

Medicare was created because EGHPs, while "the nation's principal source of health care coverage . . . could never come close to covering the entire population[,]" in particular the elderly.[44] Medicare was therefore enacted in 1965 to "provide health care coverage to 19 million elderly Americans."[45] Medicare's extension to dialysis had unanticipated consequences for the Medicare fisc, and created the noncompetitive dialysis marketplace.

A. The Creation of the Medicare Dialysis Benefit: Emerging Technology Meets Social Welfare Ambition.

The Medicare Dialysis Benefit was enacted almost accidentally at the high-water mark of Medicare expansion.

> . . . the enactment of ESRD coverage was not anticipated at all during the Medicare debate. Instead, its addition to Medicare in 1972 was a product of 'serendipity. . . . [rather] than

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[44] Enthoven and Fuchs, *Employment-Based Health Insurance: Past, Present, And Future*, 25 Health Affairs 1538 (November/December 2006) at 1540.

[45] Study Panel on Medicare Management and Governance, *Reflections on Implementing Medicare* (National Academy of Social Insurance, January 2001) at 7.

> the result of a grand design.' And the passage of ESRD coverage was more than a little peculiar, since it represented the first and only extension of Medicare to a specific disease category.[46]

The serendipity was that dialysis emerged as a charismatic technology as Medicare hit its furthest expansion, just before cost considerations curtailed further growth.

The technology for effective dialysis were principally developed through the early 1960s.[47] A few pioneering centers demonstrated that the technology could save lives but only had funding for a few patients, stirring vigorous public debate about the ethics of deciding who should get the treatment and live, and who should not.[48] Media coverage led to recommendations for Medicare coverage.[49]

Despite a dramatic "live" dialysis demonstration at a Congressional hearing actual debate on the

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[46] Oberlander, *The Political Life of Medicare* (2003) at 41.

[47] *See* Sanford, *What Scribner Hath Wrought: How the Invention of Modern Dialysis Shaped Health Law and Policy*, XIII Richmond J. Law & Pub. Interest 337 (2010) at 338–39; Blagg, *The Early History of Dialysis for Chronic Renal Failure in the United States: A View from Seattle*, 49 Am. J. Kidney Diseases 482 (March 2007).

[48] *See* Sanford, *supra*.

[49] *See* Sanford, *supra*, at 341; Blagg, *supra*, at 490; and Rettig, *Origins of the Medicare Kidney Disease Entitlement: The Social Security Amendments of 1972*, Biomedical Politics (National Academies Press 1991) 176, at 177–82.

Medicare Dialysis Benefit was very brief.[50] The Medicare Dialysis Benefit was enacted as part of the Social Security Amendments of 1972 ("SSA Amendments"); since their principal purpose was expansion of Medicare coverage to disabled individuals, the Medicare Dialysis Benefit was enacted by defining ESRD as a "disability."[51]

Subsequent decades were marked by Medicare retrenchment amid concerns about containing costs.[52] This was especially true for the Medicare Dialysis Benefit, since "estimates of the of cost of the [benefit] were wildly off."[53] "The [pre-enactment] 'estimates' . . . seriously underestimated the costs of the program. Neither the actuaries nor the congressional staff took them seriously; yet no one challenged them[.]"[54] One estimate was that "once the program was in 'steady-state,' approximately 20,000-30,000 patients would be receiving maintenance dialysis and that average annual costs of the ESRD program would equilibrate at approximately $1B ($6B in 2018 dollars)."[55]

It didn't work out that way. When the Medicare Dialysis Benefit became effective on July 1, 1973 it

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[50] Social Security Amendments of 1972, Pub.L. 92–603 (October 30, 1972). *See* Blagg, *supra*, at 492 and Rettig, *supra*, at 187, 194.

[51] *See* Ball, *Social Security Amendments and Legislative History*, Social Security Bulletin (March 1973).

[52] *See* Oberlander, *supra*, at 43–53; Sanford, *supra*, at 354; and U.S. Renal Data System, *2003 Annual Data Report* at 162–63.

[53] Blagg, *supra*, at 493.

[54] *See* Rettig, *supra*, at 195–201.

[55] U.S. Renal Data System, *2020 Annual Data Report* at v. 2 ch. 9.

covered about 11,000 beneficiaries, increasing to 42,500 by 1979.[56] This number grew to 135,000 in 1988, 437,000 as of 2007 and over 500,000 in 2018.[57]

The Medicare Dialysis Benefit was not the only benefit whose costs had been underestimated and from 1972 onward Medicare policy focused on containing costs.[58] The Medicare Dialysis Benefit represents the high-water mark of Medicare expansion.

B. Medicare Dialysis Benefit Cost Containment: Legislative Strategies

The only cost containment strategy initially applied to the Medicare Dialysis Benefit was a three month "waiting period" from start of dialysis to eligibility for Medicare.[59] A second cost containment strategy, mandatory coordination of benefits by EGHPs, was enacted in the MSPA.

> As originally enacted in 1965, the MSP [sic] designated Medicare as the secondary

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[56] U.S. Department of Health and Human Services, Health Care Financing Administration *Proposed Rule, Medicare Programs; End-Stage Renal Disease Program; Prospective Reimbursement for Dialysis Services*, 47 Fed. Reg. 6556 (February 12, 1982).

[57] *See* Sanford, *supra*, at 352–53 and U.S. Renal Data System, *2020 Annual Data Report* at v. 2 ch. 9.

[58] *See, e.g.*, Oberlander, *supra* at 47–49.

[59] The reason for the waiting period is that medical costs associated with ESRD are highest in the first few months of onset of kidney failure. *See* U.S. Renal Data System, *2007 Annual Data Report* at 227. Congress considered waiting periods of zero, three or six months before settling on three. Rettig, *supra* at 199–200; *see* Ball, *supra*, at 18–19.

> payer solely with respect to state and federal worker's compensation laws and plans. All other insurers, mainly tort-liability insurers and [EGHPs], remained off the hook. If Medicare and a private policy both covered a healthcare expense, the private insurer simply could decline to pay the expense until Medicare had paid first. The private insurers would pick up the tab for any remaining costs (provided, of course, that those additional costs were covered by the private insurance).
>
> In 1980, Congress responded to that costly arrangement. Congress expanded the reach of the MSP by designating Medicare as the secondary payer with respect to tort-liability insurance of all stripes[.] . . . In 1981, Congress next designated Medicare as the secondary payer with respect to [EGHPs], but only for persons eligible to enroll in Medicare solely because of ESRD. . . . The next year, Congress extended Medicare's secondary-payer status with respect to [EGHPs] to encompass some persons enrolled in Medicare due to age. . . . And in 1986, Congress added the third category of Medicare eligibility: disability. . . .[60]

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[60] *DaVita Inc. v. Va. Mason Mem'l Hosp.*, 981 F.3d 679, 684 (9th Cir. 2020) (citations omitted). *See also Bio-Medical Applications of Tennessee, Inc. v. Central States Southeast and Southwest Areas Health and Welfare Fund*, 656 F.3d 277, 278 (6th Cir. 2011) and U.S. Department of Health and Human Services, Medicare Program; *Medicare Secondary Payer for Individuals Entitled to Medicare and Also Covered Under Group Health Plans*, 60 Fed. Reg. 45,344 (August 31, 1995) at 45,345.

The MSPA first established a twelve month "coordination period" for individuals covered by EGHPs, from the date of Medicare eligibility (i.e., the end of the "waiting period") during which EGHP coverage was required to be primary to Medicare. The coordination period was lengthened to 18 months in 1990 and its current period of 30 months in 1997.[61]

C. Medicare Dialysis Procurement and the Noncompetitive Private Market.

The Medicare Dialysis Benefit created a noncompetitive private dialysis market because its implementation required a complex Medicare dialysis procurement system.

Initially dialysis services were paid based on facility charges, but 1980 legislation directed the implementation of a cost-based "prospective reimbursement method" including incentives for more efficient and cost-effective services to be implemented by regulation.[62] As of 2011 this Prospective Payment System ("PPS"):[63]

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[61] *See, e.g.*, Eggers, *Medicare's End Stage Renal Disease Program*, 22 Health Care Financing Review 55 (Fall 2000) at 56.

[62] *See* U.S. Department of Health and Human Services, *Medicare Programs; End-Stage Renal Disease Program; Prospective Reimbursement for Dialysis Services*, 47 Fed. Reg. 6556 (February 12, 1982)

[63] *See* Kirchhoff, *Medicare Coverage of End-Stage Renal Disease (ESRD)* (Congressional Research Service August 16, 2018), at 6; *see also* 17–18.

> . . . bundled Medicare's payment for renal dialysis services together with separately billable ESRD-related supplies . . . into a single, per treatment payment amount. The bundle payment supports up to three dialysis treatments per individual per week, with additional treatments covered on the basis of medical necessity. The reimbursement to facilities is the same regardless of dialysis modality, but is adjusted for case-mix, geographic area health care wages, and facility size.

Dialysis payments are determined under a "Medicare Base Rate" ("MBR") set annually through a report to Congress and a public rule-making process.[64] "The [MBR] is intended to cover all operating and capital costs that efficient providers would incur in furnishing dialysis treatment episodes[.]"[65] The MBR may be adjusted by patient- and facility-level factors affecting treatment costs and "outlier" payments for particularly high-cost patients.[66] MBR rates are principally based on recommendations by the Medicare Payment Advisory Commission ("MedPac") on the adequacy of

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[64] *See, e.g.*, U.S. Department of Health and Human Services, Medicare Program; *End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program*, 82 Fed. Reg. 50,738 (November 1, 2017).

[65] MedPac Payment Basics, *Outpatient Dialysis Services Payment System* (October 2017) ("MedPac Payment Basics") at 2, 4. *See also* Kirchhoff, *supra* note 69, at 18–19.

[66] MedPac Payment Basics at 3–4. *See* 42 C.F.R. §§ 413.231, 232, 233, 235.

Medicare payments to sustain beneficiaries' access to high-quality care and provider incentives to treat Medicare beneficiaries (i.e., marginal profits).[67]

The ability to provide and challenge data and to lobby regulators is therefore key to capturing the Medicare revenue stream. Medicare participation also requires compliance with extensive regulatory requirements and reporting obligations.[68] Such activities most efficiently carried out by larger, standardized organizations. This procurement process thus caused a standardization of dialysis care and provider consolidation.

For providers, while not as lucrative as it might be the Medicare revenue stream is adequate and very reliable. "Although Medicare reimbursement limits the allowable charge per treatment, it provides industry participants with a relatively predictable and recurring revenue stream for dialysis services provided to patients without commercial insurance."[69]

Standardization and consolidation are also supported by the lack of major dialysis innovation.

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[67] *See, e.g.*, *MedPac Report to the Congress: Medicare Payment Policy* (March 2021) at ch. 6: Outpatient Dialysis Services. MedPac and CMS analyses also rely on detailed information reported by the U.S. Renal Data System in its Annual Data Reports.

[68] *See, e.g.*, U.S. Department of Health and Human Services, Medicare and Medicaid Programs; *Conditions for Coverage for End-Stage Renal Disease Facilities; Final Rule*, 73 Fed. Reg. 20,370 (February 15, 2008).

[69] DaVita, Inc. *Annual Report* (2020) at 4.

> Despite some refinements in dialytic devices, innovation has been modest, especially when compared with the technological advancements in many other areas of medicine and society in general. Although transformative communication technologies such as cell phones and the internet have revolutionized daily lives, dialysis for KRT [kidney replacement therapy, i.e., hemodialysis] has changed little since it was introduced approximately 70 years ago. This stagnation has occurred despite unacceptably high morbidity and mortality rates, very high cardiovascular risk, infectious and hematologic complications, hospitalizations, and poor quality of life.[70]

Standardized treatment does not, however, preclude business innovations to capture greater revenues.

> We find that acquired facilities alter their treatments in ways that increase reimbursements and decrease costs. For instance, facilities capture higher payments from Medicare by increasing the amount of drugs they administer to patients, for which Medicare paid providers a fixed per-unit rate during our study period. The most noteworthy of these is

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[70] Bonventre et al., *A Technology Roadmap for Innovative Approaches to Kidney Replacement Therapies: A Catalyst for Change*, 14 Clin. J. Am. Soc. Nephrol. 1539 (October 2019). *See also Kidney Health Initiative, Technology Roadmap for Innovative Approaches to Kidney Health* (2018) at 5: The "high cost of care and limited technology innovation in the renal replacement therapy (RRT) [dialysis] landscape since the introduction of dialysis more than 60 years ago has left all Americans—especially ESRD patients—paying a heavy price."

> Epogen (EPO), a drug used to treat anemia, which represented the single largest prescription drug expenditure for Medicare in 2010, totaling $2 billion. Perhaps reflecting the profits at stake, patients' EPO doses increase 129% at independent facilities acquired by large chains. Similarly, acquired facilities increase their use of the iron-deficiency drug Venofer relative to Ferrlecit, a perfect substitute that offers lower reimbursements. On the cost side, large chains replace high-skill nurses with lower-skill technicians at the facilities they acquire, reducing labor expenses. Facilities also increase the patient-load of each employee by 11.7% and increase the number of patients treated at each dialysis station by 4.5%, stretching resources and potentially reducing the quality of care received by patients.[71]

While it may be hard to specify exact causation[72] there is a clear correlation between the Medicare dialysis

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[71] Eliason et al., *How Acquisitions Affect Firm Behavior and Performance: Evidence from the Dialysis Industry* (June 18, 2018) at 1–2 (citation omitted). For additional insight into providers' ability to alter and manage treatment protocols to maximize reimbursement *see* Thamer et al., *Major Declines in Epoetin Dosing After Prospective Payment System Based on Dialysis Facility Organizational Status*, 40 Am. J. Nephrol. 554 (2014).

[72] *But see, e.g.*, Erickson et al., *Market Competition and Health Outcomes in Hemodialysis*, 53 Health Services Research 3680 (October 2018); Eliason et al., *Consolidation in the Dialysis Industry, Patient Choice, and Local Market Competition*, 12 Clin J. Am. Soc. Nephrol. 1536 (March, 2017); and Wilson, *For-Profit Status & Industry Evolution in Health Care Market: Evidence*

procurement system and the consolidation of the dialysis supply side.

D. The Creation and Results of a Noncompetitive Dialysis Market.

Medicare participation guarantees that a dialysis provider will cover its costs, capital needs and if it is efficient a reasonable profit, but making extraordinary profits requires lots of facilities and buyers which pay inflated prices.

When the Medicare Dialysis Benefit was enacted there were only a few dialysis facilities, all either independent or hospital-based.[73] The years since have seen a steady increase in facilities in consolidated chains:

- By 1982 there were over a thousand facilities, and by 1996 there were over three thousand and dialysis chains had begun to form.
- Principally through a series of acquisitions, by 2005 Fresenius and DaVita (the "large dialysis organizations," or "LDOs") established themselves as the dominant providers, with Fresenius at 1,510 facilities and DaVita at 1,209.

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from the Dialysis Industry, Federal Trade Commission Working Paper No. 314 (February 2013).

[73] The history in this section is principally derived from the U.S. Renal Data System *Annual Data Reports* for 1994, 2008, 2010 and 2017.

- By 2014, there were 6,757 dialysis units, 65% of them controlled by the LDOs.
- By 2018 the five largest dialysis providers collectively operated some 7,288 units, with the two LDOs controlling more than nine times the number controlled by the other three combined:
    - Fresenius had 3,928 units (53.3%, an increase of 176 over the previous year).[74]
    - DaVita had 2,664 units (36.2%, an increase of 154 over the previous year).[75]
    - American Renal Associates ("ARA") had 241 units (3.3%).[76]
    - Dialysis Clinic, Inc. ("DCI") had 230 units, (3.1%).[77]
    - U.S. Renal Care had 225 units (3.1%).[78]

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[74] Fresenius Medical Care *Annual Report* (2018) at 21, 38–39.

[75] DaVita, Inc. *Annual Report* (2018) at 8.

[76] American Renal Associates *Annual Report* (2018).

[77] DCIInc.org website, *About Us*, https://www.dciinc.org/about-dci/ (last visited December 7, 2019).

[78] U.S. Renal Care, *U.S. Renal Care to Be Acquired by Investor Group* (March 13, 2019), https://www.usrenalcare.com/media/press-release/investor-group.html (last visited December 7, 2019).

As of 2018 the LDOs thus controlled 89.5% of chain units nationwide, and all units in many markets. For example:[79]

1. Marietta, Ohio. Six dialysis facilities within 25 miles. Four DaVita, two Fresenius.

2. Medford, Oregon. Three dialysis facilities within 25 miles. All DaVita.

3. Yakima, Washington. Four dialysis facilities within 25 miles. All DaVita.

4. Fresno, California. Twenty dialysis facilities within 25 miles. Ten DaVita, six Fresenius, two independents, one American Renal Associates, one pediatric hospital.

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[79] From an individual patient's point of view the relevant geographic dialysis market is the area no more than 30 minutes or 30 miles from their residence. U.S. Federal Trade Commission/ U.S. Department of Justice, *Commentary on the Horizontal Merger Guidelines* (2006) at 6.

In this list, one through seven are the geographic locations of the facilities identified in the complaints in the five recent cases filed by DaVita seeking prohibition of dialysis benefits limitations under the MSPA, including *DaVita v. WinCo*, U.S.D.Ct. No. 1:18-cv-00482 (D. Idaho) (Fresno, Reno, Menifee); *DaVita v. Virginia Mason Memorial Hospital*, U.S.D.Ct. No. 2:19-cv-302 (W.D. Wa.) (Yakima); *DaVita v. Marietta Memorial Hospital*, U.S.D.Ct. No. 2:18-cv-1739 (S.D. Ohio) (Marietta); *DaVita v. Smithfield Foods*, U.S.D.Ct. No. 2:18-cv-653 (E.D. Va.); and *DaVita v. Amy's Kitchen*, U.S.D.Ct. No. 4:18-cv-6975 (N.D. Cal.) (Medford). Eight through twelve are provided to flesh out geographic scope.

Facility availability data is from Medicare.gov, https://www.medicare.gov/care-compare/ (visited December 11, 2021).

5. Reno, Nevada. Ten dialysis facilities within 25 miles. Five DaVita, four Fresenius, one DCI.

6. Menifee, California. Twenty dialysis facilities within 25 miles. Fourteen DaVita, three Fresenius, one independent, one hospital.

7. Des Moines, IA. Nine dialysis facilities within 25 miles. Seven DaVita, two Fresenius.

8. Midland, Texas. Seven dialysis facilities within 25 miles. Four DaVita, two Fresenius, one ARA.

9. Wilmington, NC. Eight dialysis facilities within 25 miles. Six DaVita, two Fresenius.

10. Battle Creek, MI. 12 dialysis facilities within 25 miles. Seven Fresenius, two DaVita.

11. Winchester, VA. Seven dialysis facilities within 25 miles. Four DaVita, three Fresenius.

12. Dover, NH. Four dialysis facilities within 25 miles, all Fresenius.

The dialysis supply side has therefore for many years been a "highly concentrated market" under Federal antitrust guidelines, which creates a presumption

the providers have substantial market power.[80] Consistently, dialysis charges have inflated dramatically over the years, especially since LDO consolidation in 2005, especially for EGHPs.

By 2002:

> . . . [N]on-Medicare expenditures [for dialysis had] grown from $2.2 billion in 1991 to $7.4 billion in 2001—a 237 percent increase. . . . The increased proportion of non-Medicare patients has been accompanied in the last three years by an equally steep increase in expenditures [for such patients]. For the Medicare program there was actually a steady slowing in the total and per patient per year expenditures from 1991 to 1998. . . .[81]

As of 2004 EGHPs paid on average, over 260 percent of Medicare rates for dialysis, and their per-patient costs increased 56 percent.[82]

> Data contrasting per person per year (PPPY) costs in the Medicare and employed populations show considerably higher expenditures in the latter group, suggesting that employed patients, though on average 20 years younger, are paying more for their ESRD care, and may [sic] be supplementing provider income streams and potential

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[80] *See* U.S. Federal Trade Commission/U.S. Department of Justice, *Horizontal Merger Guidelines* (August 19, 2010) at 18.

[81] U.S. Renal Data System, *2003 Annual Data Report* at 162–63.

[82] U.S. Renal Data System, *2006 Annual Data Report* at 206.

> margins. From this standpoint, [EGHPs] may want to assess the source of this difference to determine the quality and value for these expenditures. . . .

Inflation-adjusted Medicare spending per patient year actually fell over the next two years,[83] while EGHPs continued to experience substantial increases:

> Comparisons between Medicare per person per month (PPPM) expenditures and those for EGHP patients show that hospital and outpatient costs for dialysis services have grown 24 and 39 percent [for EGHPs], respectively, between 2000 and 2006. Although EGHP patients are younger, their costs for inpatient and outpatient services are higher. . . .[84]

Medicare thus gave the LDOs a platform to create a highly concentrated, noncompetitive private market in which they could charge highly inflated prices.

E. Specific Impacts on Provider Prices to Self-Insured EGHPs.

Data about dialysis provider prices to EGHPs is hard to come by but the LDOs are clear that private payers are their principal profit center. "The payments we receive from commercial payers generate nearly all of our profit and all of our nonacute dialysis profits

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[83] U.S. Renal Data System, *2007 Annual Data Report* at 217

[84] U.S. Renal Data System, *2008 Annual Data Report* at 176.

come from commercial [sic] payers."[85] The current scale of these profits per-patient is shown by the following information gleaned from available public records:

- DaVita's 2018 costs per treatment were $247.[86]
- DaVita's 2018 average revenue per treatment from all payers was $350[87] ($54,600 annualized,[88] $150,150 through end of coordination period[89]).
    - Net profit,[90] $103 per treatment; $3,750 per year; $44,187 coordination period.
- DaVita's 2017 average revenue per treatment from "commercial payers" was $1,041 per treatment;[91] $162,396 per year; $446,589 coordination period.

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[85] DaVita, Inc. *Annual Report* (2018) at 14. *See also* Fresenius Medical Care *Annual Report* (2018) at 40. The LDO reports distinguish only between "governmental" or "public" and "private" or "commercial" payers. The latter combines issuers and EGHPs, and so reports a combined average for the category which is lower than for Self-Insured EGHPs alone.

[86] DaVita, Inc. *Annual Report* (2018) at 12.

[87] *Id.* at 14.

[88] 156 treatments per year, i.e., three treatments per week as covered by Medicare.

[89] The end of the coordination period is 33 months from the start of dialysis. At three treatments per week this means 429 treatments payable through the end of the coordination period.

[90] Revenue minus 2018 costs.

[91] Shpigel et al., *A Comparison of Payments to a For-profit Dialysis Firm from Government and Commercial Insurers*, 179 J.

- Net profit, $794 per treatment; $123,864 per year; $340,626 coordination period.

- In 2016 the commercial (not EGHP) rate payable by the largest issuer, UnitedHealthcare, to the third-largest provider, ARA, was $4,000 per treatment;[92] $624,000 per year; $1,716,000 coordination period.

    - Net profit, $3,753 per treatment; $585,468 per year; $1,610,037 coordination period.

- From 2013 to 2014 the network rate payable to Fresenius under a network agreement was $5,200 per treatment;[93] $811,200 per year; $2,230,800 through coordination period.

    - Net profit, $4,953 per treatment; $772,668 per year; $2,124,837 coordination period.

- In 2015 the out-of-network rate charged by a small chain provider was approximately $6,000 per treatment;[94] $936,000 per year; $2,574,000 coordination period.

Am. Med. Assoc. 1136 (August 2019). *See* comment on "commercial" payers in note 90, *supra*.

[92] *See UnitedHealthcare of Florida v. American Renal Associates*, U.S.D.Ct. No. 9:16-cv-81180-KAM (S.D. Fla.), Complaint filed July 1, 2016 at 2.

[93] *See Lubbock County Hospital District v. Specialty Care Management*, No. 5:16-CV-037-C (U.S. N.D. Tex.), Appendix in Support of Plaintiff's Motion for Summary Judgment Exhibit A-4, 6/18/14 Fresenius Letter to UMC (Document 15–7) at 2.

[94] This rate is derived from *Dialysis Newco, Inc. v. Cmty. Health Sys. Grp. Health Plan*, 938 F.3d 246, 249 (5th Cir. 2019),

- Net profit, $5,753 per treatment; $897,468 per year; $2,468,037 coordination period.

Prices have only increased since then.

The Medicare Dialysis Benefit and dialysis procurement process have created a reliable platform for a noncompetitive dialysis market which enables extraordinarily inflated provider profits which impose unaffordable costs on Self-Insured EGHPs. And every dollar paid to dialysis profits is a dollar not available for any other benefits, for any Member, and any other benefit.

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in which the payer limited dialysis benefits to 200% of Medicare during the period December 2012 through November 2013, which was "roughly 8%" of what the provider billed.

The MBR for 2013 was $240. U.S. Department of Health and Human Services, Medicare Program; *End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Bad Debt Reductions for All Medicare Providers*, 77 Fed. Reg. 67,450 (November 9, 2012). 200% of $240 is $480, which is eight percent of $6,000.

CONCLUSION

For the foregoing reasons, this Court should reverse the decision of the Court of Appeals.

Respectfully submitted,

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