Case No. 19-15963

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

DAVITA, INC.; STAR DIALYSIS, LLC,
Plaintiffs-Appellants,

v.

AMY'S KITCHEN, INC.; AMY'S KITCHEN, INC.
EMPLOYEE BENEFIT HEALTH PLAN,
Defendants-Appellees.

On Appeal from the United States District Court
for the Northern District of California, San Francisco
Case No. 3:18-cv-06975-JST
The Honorable Jon S. Tigar

BRIEF OF AMICI CURIAE SELF-INSURANCE INSTITUTE OF AMERICA, INC. AND PACIFIC HEALTH COALITION IN SUPPORT OF DEFENDANTS/APPELLEES AMY'S KITCHEN, INC., AND AMY'S KITCHEN, INC. EMPLOYEE BENEFIT HEALTH PLAN

Mary L. Stoll
Stoll Law Group, PLLC
2033 6th Avenue, Suite 993
Seattle, WA 98121
Email marys@mlstoll-law.com
Telephone (206) 623-2855

Attorney for Amici Curiae Self-Insurance Institute of America, Inc. and Health Care Cost Management Corporation of Alaska d/b/a Pacific Health Coalition

CERTIFICATE OF INTEREST

Counsel for Amici Curiae certifies the following:

1. The full name of every party represented by me is:

Self-Insurance Institute of America, Inc. ("SIIA")

Health Care Cost Management Coalition of Alaska d/b/a Pacific Health Coalition ("PHA")

2. The name of the real party in interest (please only include any real party in interest NOT identified in Question 3) represented by me is:

Not Applicable

3. Parent corporations and publicly held companies that own 10% or more of the stock in the party:

Not Applicable. SIIA and PHC are nonprofit member-owned corporations with no parent corporations and no stock.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court (and who have not or will not enter an appearance in this case) are:

Mary L. Stoll
Stoll Law Group, PLLC
2033 6th Avenue, Suite 993, Seattle, WA 98121
Email marys@mlstoll-law.com
Telephone (206) 623-2855

No person or entity, other than amicus or its counsel, made a monetary contribution to the preparation or submission of this brief or authored this brief in whole or in part.

Dated: December 23, 2019

s/ Mary L. Stoll
Mary L. Stoll

TABLE OF CONTENTS

CERTIFICATE OF INTEREST i

TABLE OF CONTENTS ii

TABLE OF AUTHORITIES iv

STATEMENT OF INTEREST OF AMICI CURIAE 1

INTRODUCTION 2

ARGUMENT 6

A. The Court Should Reject the DaVita Interpretation Due to the High Risk of Unanticipated, Far-Reaching Consequences. 6

B. EGHP Subsidies Are Not Needed to Subsidize Dialysis for Medicare Beneficiaries with ERSD. 8

1. Medicare Payments Are Intended to Cover the Cost of Dialysis Services to Medicare Beneficiaries. 9

2. The MSP Was Intended to Balance Medicare and Other Coverage Cost Exposures, Not Subsidize Services to Medicare Beneficiaries. 10

3. CMS Has Determined that Medicare Dialysis Payments Are Currently Adequate to Cover Reasonable Dialysis Costs, Including Provider Profits. 13

C. LDOs Use Private Insurance as Their Profit Center, Not to Subsidize Services for Medicare Beneficiaries. 18

1. LDOs Strongly Dominate the Dialysis Supply Side 18

2. The Self-Insured Plan Demand Side is Small and Extremely Fragmented. 21

3. Self-Insured Plans Have Suffered Severe Dialysis Charge Inflation Due to LDO Profit-Taking. 22

D. LDO Profit-Taking Shifts Plan Assets Away from Coverage of Other Services and Erodes Incentives to Maintain Health Benefit Plans....................26

CONCLUSION....................30

TABLE OF AUTHORITIES

CASES

Lubbock County Hospital District v. Specialty Care Management,
No. 5:16-CV-037-C (U.S. N.D. Tex.) 25

Pegram v. Herdich, 530 U.S. 211, 221, 120 S. Ct. 2143,
147 L. Ed. 2d 164 (2000)..7, 28

Stalley v. Methodist Healthcare, 517 F.3d 911 (6th Cir. 2008) 11

UnitedHealthCare of Florida v. American Renal Associates,
No.9:16-cv-81180-KAM (U.S. S. D. Fla.) 25

STATUTES AND REGULATIONS

29 U.S.C. § 1104(a)(1)..28

42 C.F.R. § 413.171 14

42 C.F.R. §§ 413.231, 332, 233, 235 15

42 U.S.C. § 1395y(b)(1)(C) 2

56 Fed.Reg. 1200 (January 11, 1991) 12, 14

57 Fed.Reg. 36006 (August 12, 1992)..12

60 Fed.Reg. 45344 (August 31, 1995)..12

71 Fed.Reg. 9466 (February 24, 2006) 12

77 Fed.Reg. 13324 (March 12, 2012)..20

84 Fed.Reg. 60648 (November 8, 2019) 14, 16, 17

Pub.L. 92–603, 92nd Congress (1972) 10

OTHER AUTHORITIES

American Renal Associates Annual Report (2018) 20

Austin and Hungerford, *The Market Structure of the Health Insurance Industry* (Congressional Research Service April 8, 2018) 3, 8, 22

Ball, *Social Security Amendments of 1972: Summary and Legislative History*, Social Security Bulletin (March 1973) 10, 11

CMS, 2018-2019 Medicaid Managed Care Rate Development Guide For Rating Periods Starting between July 1, 2018 and June 30, 2019 (May 2018) 21

Crosson, Chairman, MedPac, *letter to Seema Verma, Administrator, Centers for Medicare and Medicaid Services, re file code CMS-1713-P* (September 20, 2019) 15

Cubanski, Swoope, Boccuti, Jacobson, Casillas, Griffin, and Neuman, *A Primer on Medicare* (Kaiser Family Foundation, March 2015) 10

DaVita, Inc. Annual Report (2018) 20, 24

DCIInc.org website, About Us, https://www.dciinc.org/about-dci/ 20

Deloitte, *Self-Insured Health Benefits Plans 2019 Based on Filings through Statistical Year 2016*, Appendix B to U.S. Department of Health and Human Services and U.S. Department of Labor, Report to Congress on a Study of the Large Group Market (2019) 22

Eibner, Girosi, Miller, Cordova, McGlynn, Pace, Price, Vardavas and Gresenz, *Employer Self-Insurance Decisions and the Implications of the Patient Protection and Affordable Care Act as Modified by the Health Care and Education Reconciliation Act of 2010 (ACA)*, (RAND Corporation March 2011) 27

Enthoven and Fuchs, *Employment-Based Health Insurance: Past, Present, And Future*, 25 Health Affairs 1538 (November/December 2006)........................9

Erickson, Zheng, Winkelmayer, Ho, Bhattacharya and Chertow, *Consolidation in the Dialysis Industry, Patient Choice, and Local Market Competition*, 12 Clinical J. of Am. Soc. of Nephrology 536 (March 2017).............................20

Fresenius Medical Care Annual Report (2018) 20, 24

Fronstin, *Self-Insured Health Plans: Recent Trends by Firm Size, 1996–2018*, EBRI Issue Brief, No. 488 (Employee Benefits Research Institute, August 1, 2019)...22

Fronstin, *The Future of Employment-Based Health Benefits: Have Employers Reached a Tipping Point?* EBRI Issue Brief, No. 312 (Employee Benefits Research Institute, December 2007)...28

Hana, ed., Biomedical Politics (Institute of Medicine 1991) 10

Havighurst, *American Health Care and The Law - We Need to Talk!* 19 Health Affairs 84 (July/August 2000) 7

Jamgochian, Chief Executive Officer, Dialysis Patient Citizens, *letter to Seema Verma, Administrator, Centers for Medicare and Medicaid Services, re CMS-1713-P - 2020 Medicare End Stage Renal Disease Payment Rule,* (September 17, 2019)... 15, 16

KFF Issue Brief, *An Overview of Medicare* (Henry J. Kaiser Family Foundation, February 2019) 9

Kirchhoff and Chaikind, *Medicare Secondary Payer: Coordination of Benefits* (Congressional Research Service, March 22, 2013)..12

Kirchhoff, *Medicare Coverage of End-Stage Renal Disease (ESRD)* (Congressional Research Service August 16, 2018) 14

MedPac, *Report to the Congress: Medicare Payment Policy* (March 2019) (“MedPac 2019”) 15, 16

MedPac/Medicaid and CHIP Payment and Access Commission, *Data Book: Beneficiaries dually eligible for Medicare and Medicaid* (January 2015)..........17

National Association of Insurance Commissioners, *White Paper: Stop Loss Insurance, Self-Funding and the ACA* (2015) 27

Outpatient Dialysis Services Payment System (October 2017) ("*MedPac Payment Basics*") 14, 15

Rettig, *Origins of the Kidney Disease Entitlement: The Social Security Amendments of 1972* 10, 11

Shpigel, Saeed, Novak, Alhamad, Rich, and Brown, *A Comparison of Payments to a For-profit Dialysis Firm from Government and Commercial Insurers*, 179 J. Am. Med. Assoc. 1136 (August 2019)......................................25

Study Panel on Medicare Management and Governance, Reflections on Implementing Medicare (National Academy of Social Insurance, January 2001)...9

Szymendera, *Social Security Disability Insurance (SSDI) and Medicare: The 24-Month Waiting Period for SSDI Beneficiaries Under Age 65* (Congressional Research Service, January 7, 2009)..11

The Kaiser Family Foundation, Employer Health Benefits 2019 Annual Survey (Henry J. Kaiser Family Foundation, 2019) 9

U.S. Government Accountability Office, *Private Health Insurance: Enrollment Remains Concentrated among Few Issuers, Including in Exchanges* (March 2019) ("GAO Report") 21, 22

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 20

U.S. Renal Data System, 1994 Annual Data Report 18

U.S. Renal Data System, 2003 Annual Data Report 23

U.S. Renal Data System, 2006 Annual Data Report 23

U.S. Renal Data System, 2007 Annual Data Report 11, 23

U.S. Renal Data System, 2008 Annual Data Report 18, 24

U.S. Renal Data System, 2009 Annual Data Report 8

U.S. Renal Data System, 2010 Annual Data Report 18

U.S. Renal Data System, 2017 Annual Data Report 19

Zumwalt, Group Vice President, Government Affairs and Purchasing, DaVita, Inc., *letter to Seema Verma, Administrator, Centers for Medicare and Medicaid Services, Attention: CMS-1713-P* (September 18, 2019)....... 15, 17

STATEMENT OF INTEREST OF AMICI CURIAE[1]

Amicus Self-Insurance Institute of America, Inc. ("SIIA") is a member-based association dedicated to protecting and promoting the business interests of companies involved in the self-insurance industry. Members include self-insurance sponsors, third party administrators, excess/stop loss insurance carriers, and other industry service providers. Self-insurance is a risk transfer strategy used by tens of thousands of employers across the country to finance their group health plans (self-insured employment-based group health plans, "Self-Insured EGHPs" for purposes of this brief).

Amicus Health Care Cost Management Corporation of Alaska d/b/a Pacific Health Coalition ("PHC") was established in 1994 to negotiate discounts on behalf of Self-Insured EGHPS with hospitals, physicians, provider groups, as well as vision, disease management and prescription drug services providers. PHC also offers member access to PHC-sponsored programs, including near-site health clinics, health fairs, physical therapy services, chronic kidney disease management and dialysis cost containment. PHC is a voluntary, member-funded organization representing 45 members ranging in size from just 100 to more than 8,000 employees, providing coverage to approximately 250,000 individuals. Members

---

[1] Pursuant to Federal Rule of Appellant Procedure Rule 29(a)(2), amici state that all parties have consented to the filing of this brief.

include self-funded Taft-Hartley trust funds, self-funded governmental health plans including the State of Alaska, public sector health benefits trust funds and single employer plans.

INTRODUCTION

Appellant DaVita, Inc. ("DaVita") and amicus Dialysis Patient Citizens ("DPC") have raised an issue with important implications for the financial future of Self-Insured EGHPs and the balance between Medicare and private health coverage in the U.S. health system.

DaVita and DPC assert a questionable and unsubstantiated theory (the "DaVita Interpretation") that Congress specifically intended 42 U.S.C. § 1395y(b)(1)(C) (the "ESRD Subsection"), a short subsection in the collection of statutes and regulations which make up the Medicare Secondary Payor act ("MSP")[2] to (1) prohibit discrimination against individuals eligible for Medicare due to end-stage renal disease ("ESRD")[3] and their need for dialysis (collectively, "Individuals

[2] Discussions of 42 U.S.C. § 1395y(b)(1)(C) habitually refer to this statutory subsection as "the Medicare Secondary Payor act" or "MSP" as if it were the entire MSP. This is misleading; the MSP proper is a complex of statutes and regulations intended to coordinate benefits for all individuals for whom another benefits plan or program shares dual coverage with Medicare. This brief will use "MSP" to refer to this full complex of statutes and regulations, and "ESRD Subsection" to refer to 42 U.S.C. § 1395y(b)(1)(C).

[3] ESRD, sometimes called kidney failure, is a condition in which kidney function is so impaired that dialysis is required. ESRD is the "end stage" of chronic kidney disease ("CKD"), which is categorized in progressive stages of kidney impairment.

with ESRD"), and (2) ensure that "private insurance" pays inflated charges for dialysis services in order to subsidize dialysis facilities for the benefit of Medicare beneficiaries.

The DaVita Interpretation could be disastrous for private health coverage in general, and for Self-Insured EGHPs in particular. The DaVita Interpretation ignores the fact that dialysis providers already use their domination of the market to inflate charges to commercial insurers and Self-Insured EGHPs which are used for provider profits, not Medicare subsidies. It also ignores the fact that Self-Insured EGHPs cover a wide range of benefits from wellness visits and vaccinations, to daily treatment for chronic conditions such as diabetes, to prenatal and natal care from the most routine to the most complex, to surgery and other care for catastrophic conditions such as heart attack and cancer. Every dollar which goes to dialysis provider profits is a dollar which cannot be used to pay for health care.

The term "private insurance" is misleading and may create an impression that it is only provided by big, profit-minded commercial insurers. This is false. EGHPs include both fully-insured EGHPs which purchase policies from commercial insurers, and Self-Insured EGHPs which bear risk and reserve assets in trust to cover benefits. *See* Austin and Hungerford, *The Market Structure of the Health Insurance Industry* (Congressional Research Service April 8, 2018) at 22 – 23. EGHPs may be sponsored by private employers, multi-employer Taft-Hartley trusts, governmental

units, Indian tribes and churches. Self-Insured EGHPs are governed by fiduciaries required by law to ensure that plan assets are used only to provide health benefits to covered members.

Commercial insurers fund and provide benefits policies to individuals and to fully-insured EGHPs and administer Medicare Advantage and some other types of health benefits. There are relatively few commercial insurers, which are indeed mostly very large companies such as UnitedHealthCare, Cigna and the various Blue Cross/Blue Shield organizations.[4]

A clearer picture of the health care payment side is only part of the broader context needed to analyze the DaVita Interpretation; the broader legal and public policy context of the ESRD Subsection is also needed. The ESRD Subsection is only a part of the MSP, which has a much broader set of functions and in turn is only one element of Medicare. As such the MSP is the principal mechanism for coordination of benefits for individuals entitled to Medicare coverage who also have other coverage, regardless of the basis for Medicare entitlement – including age and disability as well as ESRD. The ESRD Subsection cannot be interpreted except as part of this mechanism, in which it clearly is not intended to serve as an individual anti-discrimination or Medicare subsidy obligation.

---

[4] While adoption of the DaVita Interpretation would have serious consequences for commercial insurers and fully-insured EGHPs, no commercial insurer or fully-insured EGHP is represented in this case and amici cannot speak for their interests.

The assertion that the ESRD Subsection is intended to subsidize dialysis for Medicare beneficiaries is further belied by the fact that Medicare is designed to cover all costs of dialysis for Medicare beneficiaries, including reasonable profits. The Centers for Medicare and Medicaid Services ("CMS") annually redetermines Medicare dialysis payment rates using a rule-making process that includes detailed reports on the adequacy of funding and participation by the provider community. This process addresses the adequacy of Medicare payments and any necessary corrections. CMS' most recent (2018) determination was that a payment of $239 per treatment ($35,348 annually, subject to certain adjustments) is sufficient to cover provider costs plus reasonable profits, and this is what Medicare pays.

The rates dialysis providers seek from commercial insurers and Self-Insured EGHPs are far higher. This is because the dialysis market is dominated by two large public companies, DaVita and Fresenius Medical Care ("Fresenius") ("large dialysis organizations" or "LDOs"), which can inflate their charges to Self-Insured EGHPs to the range of $5,000 per treatment ($780,000 annually). Payments exceeding the Medicare rate go straight to LDOs' bottom lines and make them highly profitable, but their uncontrolled charges are so high many Self-Insured EGHPs cannot afford them.

Adoption of the DaVita Interpretation would prohibit Self-Insured EGHPs from controlling LDO charges, giving LDOs windfall profits while driving Self-

Insured EGHPs out of the market, with the result that Individuals with ESRD who once had or could have had Self-Insured EGHP coverage could simply enroll in Medicare as their only coverage, and everyone else who lost coverage would have to find another employer offering health benefits or individual coverage, if they could.

It must further be noted that adoption of the DaVita Interpretation would be precedent for the same interpretation of the MSP for individuals entitled to Medicare due to age or disability, which could have wide-ranging consequences across the U.S. health funding system far beyond the ability of amici to anticipate in this brief.

Amici therefore respectfully request that the Court reject the DaVita Interpretation, and affirm the trial court's dismissal.

ARGUMENT

A. The Court Should Reject the DaVita Interpretation Due to the High Risk of Unanticipated, Far-Reaching Consequences.

The DaVita Interpretation is wrong on the law and would have very serious consequences for Self-Insured EGHPs, and indeed all private health insurance, if it were accepted.

Legal decisions affecting health policy pose particular risks of unintended consequences.

> The U.S. legal system has been a major factor, for better or for worse, in creating the conditions that determined how American health care would

> evolve in the past half-century. In several watershed events, important implications of the legal changes were not recognized by the observant public, industry insiders, or even decisionmakers themselves. Yet each of these events set in motion powerful economic and political forces that dramatically altered the face of the industry. Although it is too much to expect that law will always evolve according to pure logic, lawmaking for the health care industry has been driven by chance to a particularly surprising degree.

Havighurst, *American Health Care and The Law - We Need to Talk!* 19 Health Affairs 84 (July/August 2000) at 86.

As the U.S. Supreme Court noted when the Court was asked to define standards for health plan expenditures:

> [Determining such standards] would embody, in effect a judgment about socially acceptable medical risk. A valid conclusion of this sort would, however, necessarily turn on facts to which courts would probably not have ready access[.] . . . And, of course, assuming such material could be obtained by courts in litigation like this, any standard defining the unacceptably risky [services reimbursement] structure . . . would depend on a judgment about the appropriate level of expenditure for health care in light of the associated [medical] risk. But such complicated factfinding and such a debatable social judgment are not wisely required of courts unless for some reason resort cannot be had to the legislative process, with its preferable forum for comprehensive investigations and judgments of social value, such as optimum treatment levels and health care expenditure.

Pegram v. Herdich, 530 U.S. 211, 221, 120 S. Ct. 2143, 147 L. Ed. 2d 164 (2000). The Court therefore declined to reach the issue presenting this highly consequential determination. *Id*. at 222.

As in *Pegram*, the DaVita Interpretation represents a serious change to a core part of a dense fabric of laws, facts, policy determinations and financial practices

with important implications, well beyond the scope of the issue DaVita and DPC purport to raise. This Court should reject the DaVita Interpretation.

B. EGHP Subsidies Are Not Needed to Subsidize Dialysis for Medicare Beneficiaries with ERSD.

The DaVita Interpretation asserts that Medicare does not pay dialysis providers enough to support dialysis services Medicare beneficiaries need, and that Congress intended the ESRD Subsection to remedy this by requiring "private insurance" to pay for dialysis at inflated charges to subsidize dialysis services for Medicare beneficiaries. This assertion lacks support in the MSP statutes, their history, their regulations and caselaw, and is contrary to Congress' intent to have Medicare cover all dialysis costs for Medicare beneficiaries.

For health policy purposes Medicare and EGHP coverage are a "system" for covering dialysis services across the population. *See e.g.* U.S. Renal Data System, 2009 Annual Data Report at 336.[5] EGHPs developed after World War II as part of worker compensation by large corporations, with strong union support. *See* Austin and Hungerford, *supra*, at 4 – 5 and Enthoven and Fuchs, *Employment-Based Health Insurance: Past, Present, And Future*, 25 Health Affairs 1538 (November/December

[5] Much of the history discussed in this brief is derived from U.S. Renal Data System ("USRDS") Annual Data Reports ("ADRs"). The USRDS is funded by the National Institute of Diabetes and Digestive and Kidney Diseases as a national resource for chronic kidney and end-stage renal disease incidence, treatment, payment and related data, including lengthy and authoritative ADRs.

2006) at 1539 – 40. While EGHP health coverage "was the nation's principal source of health care coverage . . . it was clear . . . that it could never come close to covering the entire population[,]" in particular the elderly. Enthoven and Fuchs, *supra*, at 1540. Medicare was therefore enacted in 1965 to "provide health care coverage to 19 million elderly Americans." Study Panel on Medicare Management and Governance, Reflections on Implementing Medicare (National Academy of Social Insurance, January 2001) at 7.

The EGHP/Medicare system continues to be the linchpin of U.S. healthcare funding. As of 2018 EGHPs covered approximately 153 million individuals. The Kaiser Family Foundation, Employer Health Benefits 2019 Annual Survey (Henry J. Kaiser Family Foundation, 2019) at 7. Medicare covered some 60 million individuals. KFF Issue Brief, *An Overview of Medicare* (Henry J. Kaiser Family Foundation, February 2019).

1. Medicare Payments Are Intended to Cover the Cost of Dialysis Services to Medicare Beneficiaries.

Congress specifically intended to ensure Medicare covers dialysis costs for Medicare beneficiaries based on tax-based federal funding without private subsidies.

> Funding for Medicare comes primarily from general revenue [to the federal government, i.e., principally taxes], payroll tax revenues, and premiums paid by beneficiaries. Other sources include taxes on Social Security benefits, payments from states, and interest.

Cubanski, Swoope, Boccuti, Jacobson, Casillas, Griffin, and Neuman, *A Primer on Medicare* (Kaiser Family Foundation, March 2015) at 32.

Medicare coverage was expanded to cover individuals with disabilities as well as the elderly in the Social Security Amendments of 1972 ("SSA 1972"). *See* Ball, *Social Security Amendments of 1972: Summary and Legislative History*, Social Security Bulletin (March 1973) at 3, 18 – 19. SSA 1972 added dialysis coverage by defining individuals diagnosed with CKD who need dialysis (*i.e.*, have ESRD) as "disabled for purposes of" Medicare coverage. Social Security Amendments of 1972, Pub.L. 92–603, 92nd Congress (1972) at §§ 201 and 299I.

Nothing in the text or history of the SSA provides for cost-shifting to EGHPs. *See* Ball, *supra*; see also Rettig, *Origins of the Kidney Disease Entitlement: The Social Security Amendments of 1972*, in Hana, ed., *Biomedical Politics* (Institute of Medicine 1991) at 181 – 82. Congress clearly intended Medicare to fully pay dialysis costs for Medicare beneficiaries. *See* Rettig, *supra*, at 187 – 200. These costs were to be covered by an increase in the FICA health insurance contribution. *Id.* at 198.

2. <u>The MSP Was Intended to Balance Medicare and Other Coverage Cost Exposures, Not Subsidize Services to Medicare Beneficiaries.</u>

Congress limited Medicare's exposure to dialysis costs for the expanded coverage under SSA 1972, by providing (1) for "coordination" of benefits for individuals covered by both Medicare and federal employee health benefits ("FEHB") under which FEHB would pay primary to Medicare, a model for EGHP

coordination of benefits under the ESRD Subsection, (2) a "waiting period" of twenty-four months for Medicare eligibility based on a general disability,[6] and (3) a "waiting period" for Medicare eligibility of three months from the start of dialysis for individuals covered on that basis. [7] *See* Ball, *supra*, at 18 – 19, 21.

By 1980 Congress had determined additional cost controls were needed and enacted the first of the statutes around which the MSP developed. *See Stalley v. Methodist Healthcare*, 517 F.3d 911 (6th Cir. 2008) at 915. The MSP is a complex mechanism for coordination of benefits, not just isolated bits of legislation, and as such is by no means limited to the ESRD Subsection:

> Beginning with the Omnibus Budget Reconciliation Act of 1980 ["1980 OBRA"] . . . Congress created the Medicare Secondary Payer ("MSP") program, which spells out specific conditions under which other insurers are required to pay first and Medicare is responsible for qualified, secondary payments. MSP is designed to ensure that certain insurers make contractually required payments, reduce Medicare expenditures, and extend the life of the Medicare Trust Fund.
>
> The 1980 OBRA made Medicare a secondary payer for medical claims involving non-group health insurance such as liability and no-fault insurance.

[6] This waiting period was specifically established to "help keep the costs within reasonable bounds, avoid overlapping private health insurance protection, particularly where a disabled worker may continue his membership in a group insurance plan for a period of time following the onset of his disability[.]" Szymendera, *Social Security Disability Insurance (SSDI) and Medicare: The 24-Month Waiting Period for SSDI Beneficiaries Under Age 65* (Congressional Research Service, January 7, 2009).

[7] The first few months after the onset of kidney failure include the highest ESRD-related costs. *See* USRDS, 2007 ADR at 227. Congress considered the cost implications of waiting periods of zero, three or six months before settling on three. Rettig, *supra* at 199 – 200.

> In 1981, Congress expanded MSP to cover certain Medicare beneficiaries in employer-sponsored group health plans. MSP was further refined in the Tax Equity and Fiscal Responsibility Act ["TEFRA"] of 1982 and other statutes. . . . In general, Medicare is now the secondary payer for an item or service when payment has been made, or can reasonably be expected to be made, by responsible third-party payers. . . . Medicare also does not cover services paid for by another government entity such as the Department of Veterans Affairs.

Kirchhoff and Chaikind, *Medicare Secondary Payer: Coordination of Benefits* (Congressional Research Service, March 22, 2013) at 1. The MSP evolved through a series of enactments, regulations, regulatory interpretations and a few court actions, into the form it takes today. *See e.g.* U.S. Department of Health and Human Services, *Medicare Program; Medicare Secondary Payer Amendments*, 71 Fed.Reg. 9466 (February 24, 2006); *Medicare Program; Medicare Secondary Payer for Individuals Entitled to Medicare and Also Covered Under Group Health Plans*, 60 Fed.Reg. 45344 (August 31, 1995); *Medicare Program; Self-Implementing Coverage and Payments Provisions: 1990 Legislation*, 57 Fed.Reg. 36006 (August 12, 1992); *Changes to Medicare Secondary Payer (MSP) Provisions*, 56 Fed.Reg. 1200 (January 11, 1991); *et al*.

The goal of the MSP is to ensure a balance between Medicare and private sector cost exposures, not just for Individuals with ESRD but for all individuals entitled to Medicare due to age, disability or ESRD. The MSP prohibitions—not just those in the ESRD Subsection—against "taking into account" and "differentiating benefits" were designed to ensure EGHPs could not circumvent the obligation to pay

primary during the coordination period, but the coordination period itself was the mechanism Congress established to strike that balance.

None of this was intended to require payment of increased provider charges by EGHPs and commercial insurers to subsidize care for Medicare beneficiaries—or LDO profits, the actual use of these payments. And because the ESRD Subsection is only one small part of this larger mechanism, a new interpretation which applied to ESRD would necessarily also apply to age and disability.

3. <u>CMS Has Determined that Medicare Dialysis Payments Are Currently Adequate to Cover Reasonable Dialysis Costs, Including Provider Profits.</u>

Congress' intent to ensure Medicare payments cover Medicare beneficiary dialysis costs is accomplished through an annual regulatory process in which DaVita and DPC are active participants. This is intended to include sufficient funding for rural and other units with greater than average costs.

Since 2011 Medicare dialysis payment rates for Individuals with ESRD have been set by CMS under a Prospective Payment System ("PPS").

> . . . This program 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.

Id. at 6, see *id*. at 17 – 18. Under the PPS CMS sets a base rate ("Medicare Base Rate" or "MBR") and revises adjustments to dialysis coverage in an annual process including a report to Congress, a proposed rule, public comment and a final rule. *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, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, DMEPOS Competitive Bidding (CBP) Proposed Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements*, 84 Fed.Reg. 60648 (November 8, 2019) ("2019 ESRD Rule") at 60652 – 53. In determining ESRD reimbursement CMS is advised by the Medicare Payment Advisory Commission ("MedPac").

"The base payment under the [MBR] is intended to cover all operating and capital costs that efficient providers would incur in furnishing dialysis treatment episodes[.]" MedPac payment basics, *Outpatient Dialysis Services Payment System* (October 2017) ("MedPac Payment Basics") at 2, 4. *See* 42 C.F.R. § 413.171 *accord* Kirchhoff, *Medicare Coverage of End-Stage Renal Disease (ESRD)* (Congressional Research Service August 16, 2018), at 18 – 19. The MBR may be adjusted by

patient- and facility-level factors affecting treatment costs ("Adjustments") and additional payments for particularly high-cost patients ("Outliers"). MedPac Payment Basics at 3 – 4. *See* 42 C.F.R. §§ 413.231, 332, 233, 235. CMS annually determines whether the MBR, Adjustment and Outlier rates are adequate to cover all reasonable costs (including profits) of dialysis for Medicare beneficiaries. MedPac and other interested parties, including DaVita and DPC, participate in the rule-making. *See e.g.* Crosson, Chairman, MedPac, *letter to Seema Verma, Administrator, Centers for Medicare and Medicaid Services, re file code CMS-1713-P* (September 20, 2019); Jamgochian, Chief Executive Officer, Dialysis Patient Citizens, *letter to Seema Verma, Administrator, Centers for Medicare and Medicaid Services, re CMS-1713-P - 2020 Medicare End Stage Renal Disease Payment Rule,* (September 17, 2019); and Zumwalt, Group Vice President, Government Affairs and Purchasing, DaVita, Inc., *letter to Seema Verma, Administrator, Centers for Medicare and Medicaid Services, Attention: CMS-1713-P* (September 18, 2019).

In advising Congress and CMS MedPac reports on factors material to the adequacy of payments. *See e.g.* MedPac, *Report to the Congress: Medicare Payment Policy* (March 2019) ("MedPac 2019") at 155 – 56. In its most recent annual report and comments MedPac determined that Medicare dialysis payments were adequate subject to minor adjustment:

- "[Medicare] beneficiaries' ability to obtain care, and changes in the volume of services suggest payments are adequate."
- "The **17 percent marginal profit** [for providers] in 2017 suggests that dialysis providers have a financial incentive to continue to serve Medicare beneficiaries." (Emphasis added.)
- "[M]ortality, hospitalization, and 30-day readmission rates declined," indicating payments support good quality of care.
- "Access to capital for dialysis providers continues to be strong. The number of facilities, particularly for-profit facilities, continues to increase. Under the [Medicare payment system] the two largest dialysis organizations have grown through acquisitions and mergers with midsized dialysis organizations." MedPac considered this an indication that payments are adequate.
- "Between 2016 and 2017 cost per dialysis treatment increased by 2 percent, while Medicare payment per treatment increased by 0.6 percent."

MedPac 2019 at xvii. MedPac did recommend minor increases in the MBR and Adjustments for low-volume and rural facilities. *Id.* at 174 – 75.

In 2019 CMS initially proposed an MBR just over $240 per treatment. *See* 2019 ESRD Rule at 60712. DPC argued that "viability of dialysis clinics outside regions of high population density rests entirely on reimbursements from commercial insurers [sic]," Jamgochian, *supra*, at 1, without supporting

documentation. DaVita asserted that average payments fell short of its costs by $11.11 per treatment, without supporting documentation. *See* Zumwalt, *supra*, at 2, 10 – 12. In the final 2019 ESRD Rule CMS adopted an MBR of just over $239 per treatment. 2019 ESRD Rule at 60713.

CMS responded as follows to a comment that the MBR was not adequate for rural and smaller units:

> Response: We appreciate the commenter's concern that the proposed annual update factor may not be sufficient to cover the cost of care for small independent providers or those in rural areas. The annual update factor is intended to account for the overall increase in cost of care at the national level. The patient case-mix payment adjustments and the facility level adjustments, such as the rural adjustment and low-volume payment adjustment account for differences in both patient and facility characteristics. These payment adjustments are provided to address the variation of costs of a particular facility relative to the national standard.

2019 ESRD Rule at 60701. That is, the MBR with Adjustment for rural facilities covers their costs, without subsidies. Otherwise, in general CMS found that $239 per treatment covered providers' costs of dialysis for Medicare beneficiaries, including a reasonable profit.[8]

---

[8] Medicare beneficiaries also pay cost-shares, and Medicare beneficiaries who cannot afford Medicare cost-shares will be eligible for Medicaid as well. As of 2010 some 41% of Medicare enrollees with ESRD were also eligible for Medicaid. MedPac/Medicaid and CHIP Payment and Access Commission, *Data Book: Beneficiaries dually eligible for Medicare and Medicaid* (January 2015) at 16 – 17.

C. LDOs Use Private Insurance as Their Profit Center, Not to Subsidize Services for Medicare Beneficiaries.

Medicare gives LDOs a very large, robust revenue stream which covers the costs of dialysis for their Medicare beneficiary patients plus reasonable profits. But the Medicare revenue stream does not provide the level of profits LDOs want to support their desired share prices as public companies, and for that LDOs turn to the private sector.

1. LDOs Strongly Dominate the Dialysis Supply Side.

The private dialysis market has been highly concentrated and anticompetitive since at least 2005, and this has been especially true for Self-Insured EGHPs.[9]

The establishment of Medicare coverage for Individuals with ESRD created a platform for the evolution of a few small dialysis units into LDOs as giant, profitable public companies. This evolution was fueled by the consolidation of Medicare-supported units into today's LDOs, coupled with profit-taking from the private sector.

[9] The history in this section is principally derived from USRDS, 1994 ADR at 164, USRDS 2008 ADR at chapter 10 Table 10.1, and USRDS, 2010 ADR at 354.

When Medicare coverage for dialysis began in 1972 there were very few independent and hospital-based dialysis facilities ("units").[10] By 1982 there were over a thousand units, and by 1996 there were over three thousand and dialysis "chains" had begun to form. During this period DaVita (then Total Renal Care) became a public company and Fresenius was formed as the public U.S. subsidiary of a German company. Investors clearly saw dialysis as a growth opportunity.

Through a series of acquisitions by 2005 Fresenius and DaVita established themselves as clearly dominant in the dialysis market, with Fresenius at 1,510 units and DaVita at 1,209 units. This trend continued:

> At the end of 2014, there were 6,757 dialysis units . . . in the U.S. Together the two LDOs . . . [controlled] 4,362 dialysis units (65%). DCI [controlled] . . . 230 (3%) units, Independent and Hospital-based providers [controlled] . . . respectively . . . 814 (12%) and 611 (9%) units, and all Other provider organizations collectively [controlled] 740 units (11%).[11]

USRDS, 2017 ADR at 433.

By 2018 the five largest dialysis providers collectively operated some 7,288 units, with the two LDOs controlling more than nine times more units than the other three combined.[12]

---

[10] All analyses in this brief concern dialysis provided in outpatient clinics, centers and facilities rather than in the course of hospital or other inpatient care. For simplicity such clinics, centers and facilities will be referred to as "units."
[11] USRDS, 2017 ADR at 433
[12] Dialysis market share is often discussed in terms of percentages of patients under care, under which metric in 2018 Fresenius had 38% of the market and DaVita 37%. Patient share metrics are valuable for discussing provider financial

- Fresenius had 3,928 units (53.3%, an increase of 176 over the previous year). Fresenius Medical Care Annual Report (2018) at 21, 38 – 39.
- DaVita had 2,664 units (36.2%, an increase of 154 over the previous year), DaVita, Inc. Annual Report (2018) at 8.
- American Renal Associates ("ARA") had 241 units (3.3%), American Renal Associates Annual Report (2018).
- Dialysis Clinic, Inc. ("DCI") had 230 units, (3.1%), see DCIInc.org website, About Us, https://www.dciinc.org/about-dci/ (last visited December 7, 2019).
- U.S. Renal Care had 225 units (3.1%), see 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

In other words, LDOs control 89.5% of units nationwide, and all units in many markets. With this dominance comes the leverage to demand whatever rates they can make the private market bear.

---

performance, since they are paid per-patient, but unit share metrics are better for considering the harmful effects of dialysis market concentration. *See* Erickson, Zheng, Winkelmayer, Ho, Bhattacharya and Chertow, *Consolidation in the Dialysis Industry, Patient Choice, and Local Market Competition*, 12 Clinical J. of Am. Soc. of Nephrology 536 (March 2017). *See also* U.S. Federal Trade Commission, *Fresenius Medical Care AG & Co. KGaA; Analysis of Agreement Containing Consent Orders to Aid Public Comment*, 77 Fed.Reg. 13324 (March 12, 2012).

2. The Self-Insured Plan Demand Side is Small and Extremely Fragmented.

The demand side of the dialysis market equation is characterized by three sectors: A few government programs (the vast majority Medicare, secondarily Medicaid) cover most of the population of Individuals with ESRD, paying rates set by rule-making rather than market-based negotiations.[13] The balance of the demand side is far from monolithic:

> Private health insurance is the leading source of health coverage in the United States. Small and large employers may offer fully insured group plans (by purchasing coverage from an issuer) or self-funded group plans (by setting aside funds to pay for employee health care). Most small employers purchase fully insured plans, while most large employers self-fund at least some of their employee health benefits. While the majority of health insurance coverage is provided through the small or large group market, Americans without access to group health coverage, such as those with employers that do not offer health coverage, may choose to purchase it directly from an issuer through the individual market.

U.S. Government Accountability Office, *Private Health Insurance: Enrollment Remains Concentrated among Few Issuers, Including in Exchanges* (March 2019) ("GAO Report") at 7.

> Employment-based health plans generally fall into one of two categories — fully insured plans or self-insured plans. The key distinction is whether the employer has decided to purchase an insurance contract to cover the costs and financial risks associated with its employee health plan [i.e., is fully insured] or to use its own funds, including funds that might be set aside in a separate

[13] Medicaid rates are also set by a regulatory process. *See e.g*. CMS, 2018-2019 Medicaid Managed Care Rate Development Guide For Rating Periods Starting between July 1, 2018 and June 30, 2019 (May 2018).

> trust maintained by the employer (e.g., a voluntary employee beneficiary association), to cover such costs [i.e., is self-funded]. . . .

Fronstin, *Self-Insured Health Plans: Recent Trends by Firm Size, 1996–2018*, EBRI Issue Brief, No. 488 (Employee Benefits Research Institute, August 1, 2019) at 3.

Commercial insurers provide coverage in the fully-insured employer and individual markets. In 2016 the three largest healthcare insurers held 80 percent or more of their market in at least 37 states. *See* GAO Report at 10. This leverage helps them negotiate lower charges from providers. *See* Austin and Hungerford, *supra*, at 27 – 30.

The balance of the private demand side is Self-Insured EGHPs. As of 2018 38.7% of private-sector establishments offered self-insured plans, covering about 59% of private-sector employees. Fronstin, *supra*, at 3, 5. There were an estimated 24,000 Self-Insured EGHPs nationally as of 2016. See Deloitte, *Self-Insured Health Benefits Plans 2019 Based on Filings through Statistical Year 2016*, Appendix B to U.S. Department of Health and Human Services and U.S. Department of Labor, Report to Congress on a Study of the Large Group Market (2019). This is a highly fragmented sector, with limited resources and leverage for dialysis rate negotiation.

3. <u>Self-Insured Plans Have Suffered Severe Dialysis Charge Inflation Due to LDO Profit-Taking.</u>

Dialysis charges to the private sector have inflated dramatically over the years, especially since LDO consolidation in 2005. Even before then, by 2002:

> The economics of ESRD [came to] constitute a major public policy issue for Medicare, state Medicaid programs, and other [sic] private insurers. . . . [Because of the MSP] non-Medicare expenditures have 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. . . . From the perspective, then, of projected trends in both the general and ESRD populations over the next 30 years, the economics of the ESRD program [i.e., Medicare and all other payors] are going to be a critical challenge for all payors

USRDS, 2003 ADR at 162 – 63. As of 2004 EGHPs paid on average, over 260% of Medicare payments for dialysis, and per-patient costs increased an incredible 56 percent.

> 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 be supplementing provider income streams and potential margins**. From this standpoint, employer group health plans (EGHPs) may want to assess the source of this difference to determine the quality and value for these expenditures. . . . Medicare PPPY expenditures for dialysis, for example, approach $67,000, while dialysis costs for EGHPs—which cover younger patients—are now close to $180,000.

USRDS, 2006 ADR at 206 (emphasis added).

Inflation-adjusted Medicare spending per patient year actually fell over the next two years, USRDS, 2007 ADR at 217, 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 such plans], respectively, between 2000 and 2006. Although EGHP patients are younger, their costs for inpatient and outpatient services are higher . . . These differences may represent cost shifting between Medicare and EGHP payors, but could also illustrate differences in the ability of smaller payors to negotiate pricing compared to Medicare.

USRDS, 2008 ADR at 176.

While data about dialysis provider charges from publicly available records is hard to come by, LDOs are clear that they use private payors as their principal profit center. See DaVita, Inc. Annual Report (2018) at 14 and Fresenius Medical Care Annual Report (2018) at 68. The scale of these profits currently is shown by the following data:

- The 2018 Medicare Base Rate was just over $239 per treatment, for a typical 156 treatments per year[14] ($35,348 annually).
- DaVita's costs per treatment were $247 ($38,352 annually).
- DaVita's average revenue per treatment was $350 ($54,600 annually).
- Independent analysis indicates DaVita's average revenue per treatment in 2017 from "commercial payors"[15] was $1,041 per treatment ($162,396 annually). Shpigel, Saeed, Novak, Alhamad, Rich, and Brown, *A Comparison*

[14] Three dialysis treatments per week is standard, and covered by Medicare, so annualized amounts are calculated at 156 treatments per year.
[15] This reference is evidently to commercial insurers, not Self-Insured EGHPs.

of Payments to a For-profit Dialysis Firm from Government and Commercial Insurers, 179 J. Am. Med. Assoc. 1136 (August 2019).

- As of 2016 the third-largest provider, ARA, was being paid $4,000 per treatment by the largest commercial insurer, UnitedHealthCare ("United"). *See UnitedHealthCare of Florida v. American Renal Associates*, No.9:16-cv-81180-KAM (U.S. S. D. Fla.), First Amended Complaint filed September 2, 2016 (Document 13) at 3.[16]

- While it is difficult to locate public records of dialysis charges to Self-Insured EGHPs, according to documents filed in litigation about Fresenius claims to a Self-Insured Health Plan, in 2013 Fresenius charges to a Self-Insured EGHP were around $5,000 per treatment ($780,000 annually). *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, 4/8/14 Fresenius Letter to UMC (Document 15 – 5) at 2.[17] Given

[16] While ARA is not an LDO it had the same public company profit-seeking motivation since its parent company, American Renal Associates Holdings, was going public. According to United, to support its initial stock price ARA implemented a scheme to switch patients covered by Medicaid and steer patients away from Medicare, to United's commercial coverage under which ARA could be paid more than twenty times its governmental reimbursement. *Id*. at 2 – 3.
[17] This document is an invoice which indicates charges per treatment ("tx"). It is not clear what the basis for variation is but the minimum charge for one treatment was $4,778 and all others were higher.

LDOs' dominance DaVita's charges were surely in the same range, and charges have surely only increased since 2013.

Taking DaVita's stated costs in 2018 of $247 per treatment ($38,532 annually) at face value, any revenues above that amount are pure profit. ***In the range charged by Fresenius in 2013, taking DaVita's claimed costs, this profit would be around $4,753 per treatment ($5,000 - $247), i.e., $741,468 per year, per patient.***

This profit-taking does not create a subsidy for dialysis for Medicare beneficiaries, it creates strong profits for large public companies. And while there is nothing wrong with profits, Self-Insured EGHPs have no legal obligation to fund them at the cost of their own assets and coverage for other health services.

D. LDO Profit-Taking Shifts Plan Assets Away from Coverage of Other Services and Erodes Incentives to Maintain Health Benefit Plans.

Self-Insured EGHPs are heavily regulated under a complex set of laws, and compliance requires careful, prudent balancing between two fundamental, often conflicting goals: Ensuring adequate coverage for health care services, many of which are legally mandated; and ensuring adequate funding which both the plan and the beneficiaries can afford.

Unlike fully-insured EGPHs, Self-Insured EGHPs depend on their own assets to pay for covered health services.[18] Eibner, Girosi, Miller, Cordova, McGlynn, Pace, Price, Vardavas and Gresenz, *Employer Self-Insurance Decisions and the Implications of the Patient Protection and Affordable Care Act as Modified by the Health Care and Education Reconciliation Act of 2010 (ACA)*, (RAND Corporation March 2011) at 13 - 14:

> A key distinction between self-insured and fully insured health plans is the amount of risk an employer bears for the health claims of its employees. Employers with fully insured health plans bear no risk for claims and have complete certainty about the cost of the plan for their employees. . . . By comparison, self-insuring employers bear some or all of the risk of their covered employees' health care claims and face uncertainty about their plans' ultimate cost. The smaller the firm, the greater the uncertainty. In addition, claims are likely to occur unevenly throughout the year, so self-insuring firms must be able to manage cash flow in order to pay claims in a timely manner.

A Self-Insured EGHP which experiences "catastrophically high" expenditures, defined as 125% of expected health expenditures, is at substantial risk of bankruptcy. *Id*. at 3 – 4.[19]

A sponsor may terminate a Self-Insured EGHP if it cannot or no longer wants to try to afford payments for covered services for its members. There is no legal

---

[18] If a fully-insured EGHP experiences unexpectedly high costs, the commercial insurer providing the coverage can pass them along in premium increases.

[19] Self-Insured EGHPs use stop-loss insurance to help cover high claims, *id*. at 14, but such policies usually include "laser-specific" coverage attachment points for individuals with high-cost conditions, such as ESRD, so the plan often must bear the costs of such claims. See National Association of Insurance Commissioners, *White Paper: Stop Loss Insurance, Self-Funding and the ACA* (2015) at 4 – 5.

obligation for any employer to offer health benefits. *Pegram v. Herdich, supra*, 530 U.S. at 226 – 27. Termination of a plan is a reasonable response to unaffordable costs. *See e.g.* Fronstin, *The Future of Employment-Based Health Benefits: Have Employers Reached a Tipping Point?* EBRI Issue Brief, No. 312 (Employee Benefits Research Institute, December 2007).

While a plan operates its fiduciaries must administer it "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[.]" 29 U.S.C. § 1104(a)(1). *Pegram v. Herdrich, supra*, 530 U.S. at 227. The plan must also comply with (*inter alia*): The Employee Retirement Income Security Act of 1974 ("ERISA"); the Consolidated Omnibus Budget Reconciliation Act of 1985; the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"); the Newborns' and Mothers' Health Protection Act of 1996, ("Newborns' Act"); the Women's Health and Cancer Rights Act of 1998 ("WHCRA"); the Genetic Information Nondiscrimination Act of 2008 ("GINA"); the Mental Health Parity and Addiction Equity Act of 2008 ("MHPAEA"); the Affordable Care Act of 2010 ("ACA"); the Americans with

Disabilities Act ("ADA"); and the Internal Revenue Code—and of course the MSP. This can be an expensive set of obligations to meet.

Any dollar used to fund LDO profits is taken away from plan assets used to pay claims for all other covered services, from wellness visits to treatment of chronic conditions such as diabetes, prenatal and natal care from the routine to the most complex, to surgery and other treatment for catastrophic health events such as cancer, heart attack and stroke.

Self-Insured EGHPs vary considerably in size, but most are small enough that payments of several hundred thousands of dollars annually are a severe hardship. Some plans would become insolvent; others would have to increase their premiums to potentially unaffordable levels, or limit payments for serious health conditions other than ESRD. Some sponsors would stop offering plans, and potential new sponsors would be discouraged from starting plans.

Adoption of the DaVita Interpretation therefore risks eroding Self-Insured EGHPs' finances and driving such plans out of the health care funding system. This is the kind of potentially disastrous policy change which should be rejected by the Court, and not decided as an ancillary issue with a scant factual and limited public policy record.

CONCLUSION

For the forgoing reasons, this Court should affirm the district court's dismissal of DaVita's complaint with prejudice in its entirety.

Dated: December 23, 2019

Respectfully submitted,

s/ Mary L. Stoll
Mary L. Stoll
Stoll Law Group, PLLC
2033 6th Avenue, Suite 993
Seattle, WA 98121
Email marys@mlstoll-law.com
Telephone (206) 623-2855

Attorney for Amici Curiae Self-Insurance Institute of America, Inc. and Health Care Cost Management Corporation of Alaska d/b/a Pacific Health Coalition

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 6,991 words as determined by Microsoft Word.

Dated: December 23, 2019

s/ Mary L. Stoll
Mary L. Stoll
Stoll Law Group, PLLC
2033 6th Avenue, Suite 993
Seattle, WA 98121
Email marys@mlstoll-law.com
Telephone (206) 623-2855

Attorney for Amici Curiae Self-Insurance Institute of America, Inc. and Health Care Cost Management Corporation of Alaska d/b/a Pacific Health Coalition

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on December 23, 2109. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

Dated: December 23, 2109

s/ Mary L. Stoll

Mary L. Stoll