TRENDS IN MANAGED CARE PREEMPTION

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I. INTRODUCTION

Federal law plays an important role in the regulation of the managed care industry. However, the federal regulation of ma

naged care companies and the health benefit plans they administer is highly fragmented. This paper will address three of the principle sources of regulation: the Employee Retirement Income Security Act (ERISA), which governs the administration of a broad range of employer-sponsored health benefit plans, the Federal Employee Health Benefits Act (FEHBA), which governs the administration of health benefit plans for federal employees, and the Medicare Act, which governs the administration of Medicare benefits. Each body of law includes a disparate preemption provision that can have a substantial impact on the course of manage care litigation.

However, determining whether specific claims fall within the scope of a federal preemption clause can be extremely complicated because preemption law is always in flux. For instance, while Supreme Court opinions in the mid-to-late 1990's seemed to sound the death knell of ERISA preemption, the Supreme Court reversed course in 2004 and, many have argued, dramatically expanded its scope. Conversely, the scope of FEHBA preemption, which had generally been characterized by its close resemblance to ERISA preemption, was decisively narrowed by the Supreme Court earlier this year. Nevertheless, the Supreme Court left holes in its opinion, leaving critical questions about the interpretation of FEHBA's preemption clause to be decided at a later date.

The scope of Medicare preemption has perhaps undergone the most dramatic change in recent years, following the enactment of the Medicare Prescription Drug Improvement and Modernization Act of 2003. However, the newly enacted statutory provisions are relatively untested in the courts. As a result, the extent to which Medicare preemption has truly been strengthened remains to be seen.

This paper will address each body of preemption law in turn. Each subsection will provide a general overview of the preemption principles associated with each statute, followed by an update of recent preemption decisions and an analysis of the issues that may be at the center of preemption cases in the coming years. Undoubtedly, preemption analysis differs markedly under ERISA, FEHBA and Medicare, and it

is therefore critical to become familiar with the salient aspects of each.

II. ERISA PREEMPTION

A. Background

The Employee Retirement Income Security Act was passed in 1974 to protect the interests of participants in employee benefit plans by establishing standards of conduct for administrators of those plans and providing "appropriate remedies, sanctions, and ready access to the federal courts." Importantly, this regulatory structure was developed "to provide a uniform regulatory regime over employee benefit plans." As a result, ERISA includes expansive preemption provisions, intended to ensure that employee benefit plan regulation remains "exclusively a federal concern."

It is important to emphasize that there are two different paths to preemption under ERISA.⁴ First, the statute contains a general preemption clause, which provides that ERISA "shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan...." The Supreme Court has recognized that this preemption clause (established under §1144(a) of the statute) is "deliberately expansive" and "conspicuous for its breadth." However, it has also attempted to place some limits on its scope, emphasizing that "if 'relate to' were taken to extend to the furthest stretch of its indeterminacy, then for all practical purposes pre-emption would never run its course." This area of ERISA preemption has come to be known as "conflict" preemption.

The comprehensive civil enforcement system imbedded in §1132(a) of ERISA provides a separate path to preemption. In *Pilot Life Ins. Co. v. Dedeaux*, the Supreme Court described the basic principles of 1132(a) preemption. The Court emphasized that the

¹ 29 U.S.C. § 1001(b).

² Aetna Health Inc. v. Davila, 542 U.S. 200, 208 (2004).

³ *Id.* (quoting *Alessi v. Raybestos-Manhattan, Inc.*, 451 U.S. 504, 523 (1981) (internal quotations omitted).

⁴ *Cleghorn v. Blue Shield of California*, 408 F.3d 1222, 1225 (9th Cir. 2005).

⁵ 29 U.S.C. §1144(a).

⁶ Pilot Life Ins. Co. v. Dedeaux, 481 U.S. 41, 46 (1987); see also FMC Corp. v. Holliday, 498 U.S. 52, 58 (1990).

⁷ New York State Conference of Blue Cross and Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 655 (1995).

⁸ *Davila*, 542 U.S. at 208.

⁹ See 29 U.S.C. §1132(a).

¹⁰ See Pilot Life Ins. Co. v. Dedeaux, 481 U.S. 41, 52 (1987).

Congressional intent behind ERISA is clear: §1132(a) must be "the exclusive vehicle for actions by ERISAplan participants and beneficiaries asserting improper processing of a claim for benefits...." As a result, the Court held that ERISA preempts any state law cause of action that would expand upon the remedies available under §1132(a). Further, it has long been recognized that the ERISA civil enforcement mechanism "converts an ordinary state common law complaint into one stating a federal claim for purposes of the wellpleaded complaint rule." That is, causes of action that fall within the scope of §1132(a) preemption are removable to federal court.¹⁴ In contrast, conflict preemption under §1144(a) does not establish jurisdiction in federal courts; it merely provides a federal defense that can be raised in state courts.¹⁵ Because of its broad scope, §1132(a) preemption is often referred to as "complete preemption." ¹⁶

While a detailed discussion of the evolution of conflict preemption and complete preemption is beyond the scope of this paper, it is critical to emphasize that the strength of each doctrine is constantly changing. After the Supreme Court's 1995 decision in New York State Conference of Blue Cross and Blue Shield Plans v. Travelers Ins. Co., the scope of conflict preemption, which had until that time seemed almost limitless, was significantly reduced.¹⁷ Likewise, the Supreme Court's 2000 decision in Pegram v. Herderich was widely interpreted as a fundamental reinterpretation of ERISA preemption until the Supreme Court issued its seminal decision in Aetna Health Inc. v. Davila, which decisively reinforced the strength of the complete preemption doctrine.¹⁸

Davila

Davila is a critical decision not only for the questions that it addressed, but also for the questions that it left unanswered. The case arose when Juan Davila brought suit against his health plan for refusing to pay for a certain prescription drug and forcing him to take a substitute which allegedly caused him injuries. 19 Instead of pursuing his remedies under ERISA, Davila brought suit under the Texas Health Care Liability Act, alleging that the health plan breached its duty of ordinary care.²⁰ The health plan, in turn, argued that Davila's state law claims were preempted by ERISA.

The Supreme Court began its preemption analysis by emphasizing that "the purpose of ERISA is to provide a uniform regulatory regime over employee benefit plans."21 The Court also stressed that the remedies established in ERISA are exclusive.²² Congress, the Court noted, "did not intend to authorize other remedies that it simply forgot to incorporate expressly."²³ As a result, the Court restated the scope of ERISA preemption:

Any state-law cause of action that duplicates, supplements, or supplants the ERISA civil enforcement remedy conflicts with the clear congressional intent to make the ERISA remedy exclusive and is therefore pre-empted.²⁴

The Court proceeded to determine whether Davila's claim for benefits could have been brought under ERISA. Section 1132(a) of ERISA provides, in relevant part:

A civil action may be brought...(1) by a participant or beneficiary...(B) to recover benefits due to him under the terms of his plan, to enforce his rights under the terms of the plan, or to clarify his rights to future benefits under the terms of the plan.25

Applying this enforcement provision to the claims at issue, the Court recognized that Davila "complained only about denials of coverage promised under the terms of [an] ERISA-regulated employee benefit plan."

¹² Pilot Life, 481 U.S. at 54-56; see also Ingersoll-Rand Co. v. McClendon, 498 U.S. 133, 143-45 (1990).

¹³ Davila, 542 U.S. at 209 (citing Metropolitan Life Ins. Co. v. Taylor, 481 U.S. 58, 65-66 (1987)).

¹⁴ *Id*.

¹⁵ *Id*.

¹⁷ See New York State Conference of Blue Cross and Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 655 (1995) (limiting the scope of "relate to" preemption, reasoning that if the phrase "relate to" was "taken to extend to the furthest stretch of its indeterminacy, then for all practical purposes pre-emption would never run its course, for '[r]eally, universally, relations stop nowhere."")

¹⁸ See Pegram v. Herdrich, 530 U.S. 211, 229 (2000) (holding that the requirements of ERISA do not apply when an eligibility decision and the disputed treatment decision were "inextricably mixed.")

¹⁹ Aetna Health Inc. v. Davila, 542 U.S. 200, 205 (2004).

²⁰ *Id*.

²¹ *Id.* at 208.

²² *Id*.

²³ *Id.* at 209.

²⁵ 29 U.S.C. §1132(a)(1)(B).

The Court noted that, after being denied benefits, Davila could have paid for the treatment himself and then sought reimbursement under ERISA.²⁶ Thus, the Court concluded that Davila's state law claims were pre-empted because they would supplement the remedies available to Davila under ERISA.²⁷

The lower court had reached a different conclusion in part because Davila had asserted a tort claim for damages and was not seeking reimbursement for benefits he was denied.²⁸ But the Supreme Court rejected this argument:

...distinguishing between pre-empted and nonpreempted claims based on the particular label affixed to them would elevate form over substance and allow parties to evade the pre-emptive scope of ERISA simply be relabeling their contract claims as claims for tortious breach of contract.²⁹

The Supreme Court also rejected Davila's argument that its decision in Pegram v. Herdrich precluded preemption. In Pegram, the plaintiff sued her HMO and her treating physician, who was employed by the HMO, for malpractice and breach of fiduciary duty under ERISA.³⁰ The plaintiff contended that the cost-cutting mechanisms developed by the HMO to limit treatment utilization breached the HMO's obligation to administer the plan "solely in the interest of the participants and beneficiaries."31 However, the Supreme Court concluded that the fiduciary standards established by ERISA did not apply to the HMO's actions, reasoning that "Congress did not intend an HMO to be treated as a fiduciary to the extent that it makes mixed eligibility decisions acting through its physicians."32

In the wake of Pegram, many courts began to trim back the scope of ERISA preemption, reasoning that under the Supreme Court's murky "mixed eligibility" standard, the standards established in ERISA (and therefore the ERISA preemption provisions) no longer applied to a broad range of administrative activities.

However, in Davila, the Supreme Court decisively curtailed its ruling in *Pegram*, concluding that "a

benefit determination under ERISA...is generally a fiduciary act," and is therefore subject to complete and conflict preemption under ERISA.³³ The Court held that *Pegram* is only applicable where the treating physician making the benefit determination owns, or is employed by, the HMO.³⁴ As the Court emphasized, "the reasoning of *Pegram* only make[s] sense where the underlying negligence also plausibly constitutes medical maltreatment by a party who can be deemed to be a treating physician or such a physician's employer."³⁵

As a result, the Supreme Court's decision in *Davila* had two primary effects on preemption law. First, it strengthened the scope of complete preemption by affirmatively stating that all causes of action that "duplicate, supplement, or supplant" the remedies established by ERISA are preempted. And, more importantly, it dramatically limited the applicability of its decision in *Pegram*, which had cast much more fundamental doubts over the scope of ERISA preemption in general.

While *Davila* offered much needed clarification in some critical areas of ERISA, it also left an important question unanswered. As discussed below, Justice Ginsburg's concurrence in *Davila* briefly highlights the possibility of expanding the remedies available under ERISA. As a result, Ginsburg's comments have steered the plaintiff's bar into a new avenue of ERISA litigation.

C. "Make Whole" Relief and the Ginsburg Concurrence

Despite being urged to amend their complaint to include claims under ERISA's civil enforcement mechanism, \$502(a)(3), the plaintiffs in *Davila* decided to pursue only their state law claims. Thus, the Supreme Court held that the plaintiffs' state law claims were preempted but did not reach another fundamental issue in ERISA jurisprudence: whether \$502(a)(3) provides monetary remedies for breach of fiduciary duty.

The issue stems from the statute's vague description of the remedies available under §502(a)(3). This section provides, in relevant part, that a participant may bring a civil action "to obtain **other appropriate equitable relief**" to redress violations of

²⁶ *Id*.

²⁷ *Id.* at 214.

 $^{^{28}}$ *Id*

²⁹ Id. (citing Allis-Chalmers Corp. v. Lueck, 471 U.S. 202,

^{217 (1985))(}internal quotations omitted).

³⁰ Pegram, 530 U.S. at 216-217.

³¹ *Id.*; see 29 U.S.C. 1104(a)(1).

³² *Id.* at 231.

³³ *Davila*, 542 U.S. at 218.

³⁴ *Id*. at 221.

³⁵ *Id*.

the statutory provisions.³⁶ (Emphasis added). While a detailed analysis of the Supreme Court cases interpreting that critical phrase is beyond the scope of this paper, it is important to point out that the Court's interpretation of "equitable relief" has not been expansive.

For instance, in *Mertens v. Hewitt Associates*³⁷ and *Great-West Life & Annuity Ins. Co. v. Knudson*, ³⁸ the Supreme Court reasoned that because ERISA includes a carefully crafted enforcement scheme that limits available legal remedies, 502(a)(3) does not authorize all "relief a court of equity is empowered to provide...(which could include legal remedies...)." As a result, the Supreme Court held that the term "equitable relief" in §502(a)(3) refers to "those categories of relief that were *typically* available in equity." Monetary relief, the Court emphasized, was not typically available in equity.

In her concurrence in *Davila*, Justice Ginsburg lamented that the Court's expansive interpretation of ERISA's preemption clause, when coupled with the Court's narrow interpretation of the remedies available under ERISA, has created a "regulatory vacuum," and emphasized that "fresh consideration of the availability of consequential damages under §502(a)(3) is plainly in order." Given the Court's decisions in *Mertens* and *Great-West*, though, many have argued that reconsideration of the availability of consequential damages under ERISA would be impossible without overturning a substantial amount of precedent.

However, in their amicus brief, the Labor Department attempted to distinguish the Court's earlier rulings. The Government noted that the Supreme Court "has construed Section 502(a)(3) not to authorize an award of money damages against a *non-fiduciary*," and suggested that the Act, as currently written and interpreted, "may allo[w] at least some forms of 'make-whole' relief against a breaching *fiduciary* in light of the general availability of such relief in equity at the time of the divided bench." Ginsburg seized on this distinction, concluding that although the plaintiffs in *Davila* chose not pursue remedies under 502(a)(3),

"the Government's suggestion may indicate an effective remedy others similarly circumstanced might fruitfully pursue."

The question remains, however, if Justice Ginsburg's distinction is truly viable. For instance, the Ninth Circuit has already taken a position on this matter. In McLeod v. Oregon Lithoprint Inc. - which was decided in between the Supreme Court's decisions in Mertens and Great-West - the plaintiff brought suit against her employer and her ERISA plan administrator for failing to give her timely notice that she had become eligible for benefits under an insurance policy. 45 She sought the amount of benefits she would have received under her policy and compensatory damages for emotional distress.⁴⁶ The plaintiff characterized these remedies as "appropriate equitable relief" available under 502(a)(3) and insisted that Mertens only established that monetary relief is not available under ERISA for claims against nonfiduciaries.⁴⁷ The Court rejected this distinction:

[T]he status of the defendant, whether fiduciary or nonfiduciary, does not affect the question of whether damages constitute 'appropriate equitable relief' under §502(a)(3)....Given the statutory structure and policy compromises of ERISA, we cannot construe 'appropriate equitable relief' under §502(a)(3) in an expanded manner on the basis that a plan participant is bringing an individual action against a fiduciary, rather than against a nonfiduciary.⁴⁸

Thus, *McLeod* is, in all likelihood, an insurmountable obstacle for plaintiff's attorneys seeking to utilize Ginsburg's concurrence in the Ninth Circuit. It is also important to point out that the Ninth Circuit's opinion in *McLeod* has been cited across the country with approval.

In 2004, six months after the decision in *Davila* came down, the Tenth Circuit addressed this exact issue. In *Callery v. United States Life Insurance*, the plaintiff brought suit against her ERISA plan administrator for wrongful denial of life insurance benefits, alleging, inter alia, breach of fiduciary duty.⁴⁹

³⁶ 29 U.S.C. 1132(a)(3)(B).

³⁷ *Mertens v. Hewitt Associates*, 508 U.S. 248 (1993).

³⁸ Great-West Life & Annuity Ins. Co. v. Knudson, 534 U.S. 204 (2002).

³⁹ Great-West, 534 U.S. at 210.

⁴⁰ Mertens, 508 U.S. at 256.

⁴¹ Great-West, 534 U.S. at 210.

⁴² Aetna v. Davila, 542 U.S. 200, 223 (2004).

⁴³ *Id*.

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⁴⁵ *McLeod v. Oregon Lithoprint Inc.*, 102 F.3d 376, 377 (9th Cir. 1996).

⁴⁶ *Id*.

⁴⁷ *Id.* at 378.

⁴⁸ Id

⁴⁹ Callery v. United States Life Insurance, 392 F.3d 401 (10th Cir. 2004).

The plaintiff sought \$100,000 (the face-value of the life insurance policy) in "equitable" relief under 502(a)(3), and advanced Ginsburg's argument, emphasizing that *Mertens* and *Great-West* addressed the availability of 'make-whole' relief against a non-fiduciary, but did not address whether monetary relief was "typically available at equity" against a breaching fiduciary. The Tenth Circuit, however, was unpersuaded by this distinction. The Court adopted the Ninth Circuit's position in *McLeod*, concluding that the monetary damages the plaintiff sought were legal relief that is unavailable under 502(a)(3). 52

Finally, in June 2005, the Second Circuit addressed this issue. The plaintiff in *Pereira v. Farace*, like the plaintiffs in *Callery* and *McLeod*, sought compensatory damages under 502(a)(3) and argued that although monetary relief was not available under ERISA for claims against a non-fiduciary, the Supreme Court had not addressed whether such relief is available under ERISA for claims against a fiduciary.⁵³ However, the Second Circuit followed *Callery* and *McLeod*, and rejected the distinction, holding that monetary relief was not "appropriate equitable relief" against a breaching fiduciary.⁵⁴

Thus, the Ninth, Tenth and Second Circuits have all rejected the distinction advanced by Justice Ginsburg in her Davila concurrence. However, the remaining Circuit Courts of Appeal have yet to address the issue. And, given the forceful manner in which Ginsburg advanced the argument, plaintiffs will likely continue to target her concurrence.

III. FEHBA PREEMPTION

A. Background

The Federal Employees Health Benefits Act of 1959 (FEHBA) established a comprehensive system of health insurance for federal employees. FEHBA authorizes the Office of Personnel Management (OPM) to contract with private insurers to provide health benefits to federal employees under the Act. To ensure that private insurers contracting with the OPM are only subject to federal regulation, Congress included the following preemption clause in FEHBA:

The terms of any contract under this chapter which relate to the nature, provision, or extent of coverage or benefits (including payments with respect to benefits) shall supersede and preempt any State or local law, or any regulation issued thereunder, which relates to health insurance or plans.⁵⁷

Given the similarity between the preemption clauses in FEHBA and ERISA, and the dearth of case law addressing FEHBA, federal courts often utilized ERISA case law while interpreting the scope of FEHBA preemption.⁵⁸ As a result, strength of FEHBA preemption generally waxes and wanes with the strength of ERISA preemption. Prior to 2004, for instance, courts were beginning to utilize the Supreme Court's decision in *Pegram* to limit the applicability of the FEHBA preemption clause to "pure eligibility" decisions.⁵⁹ And, since the Supreme Court issued its decision in Davila, the scope of FEHBA preemption has expanded. However, in June of 2006, the Supreme Court limited the scope of federal jurisdiction under FEHBA, which may lead to a significant break between the interpretation of ERISA preemption and the interpretation of FEHBA preemption.

B. Empire Healthchoice Assurance, Inc. v. McVeigh

Empire Healthchoice Assurance, Inc. v. McVeigh was a subrogation case in which Empire, a Blue Cross Blue Shield entity that had contracted with OPM to provide health benefits under FEHBA, brought suit against McVeigh, a FEHBA plan beneficiary, seeking reimbursement for medical benefits expended on his behalf after McVeigh received a damage award for those medical expenses from a third party in a settlement. Empire filed suit in federal court, arguing that federal common law governed its reimbursement claim and that the health plan itself constituted federal law. The District Court disagreed and granted McVeigh's motion to dismiss for lack of subject matter jurisdiction. On appeal, the Second Circuit upheld the District Court's decision, holding, inter alia, that

⁵⁰ *Id.* at 408.

 $^{^{51}}$ Id

⁵² Id.

⁵³ *Pereira v. Farace*, 413 F.3d 330, 339 (2nd Cir. 2005).

⁵⁴ Id

⁵⁵ See 5 U.S.C. §8901 et seq.

⁵⁶ Id.

⁵⁷ 5 U.S.C. §8902(m)(1)

⁵⁸ See e.g., Hayes v. Prudential Ins. Co. of America, 819 F.2d 921 (9th Cir. 1987).

⁵⁹ See Roach v. Mail Handlers Benefit Plan, 298 F. 3d 847 (9th Cir. 2002); see also Kincade v. Group Health Services of Oklahoma, 945 P.2d 485 (Okla. 1997).

⁶⁰ See, e.g., McCoy v. Unicare Life and Health Ins. Co., 2004 WL 2358277 (N.D.III. October 14, 2004).

⁶¹ Empire Healthchoice Assurance, Inc. v. McVeigh, 547 U.S.____ (2006).

⁶² *Id.* at 7

⁶³ *Id*.

FEHBA's preemption clause "makes no reference to a federal right of action [in] or to federal jurisdiction [over] the contract-derived reimbursement claim here at issue."

The Supreme Court affirmed, holding that FEHBA ensures "that suits brought by beneficiaries for denial of benefits will land in federal court," but it contains no similar provision providing for federal jurisdiction over contract-derived reimbursement disputes between private carriers and beneficiaries. 65 As the Court emphasized,

[E]ven if FEHBA's preemption provision reaches contract-based reimbursement claims, that provision is not sufficiently broad to confer federal jurisdiction. If Congress intends a preemption instruction completely to displace ordinarily applicable state law, and to confer federal jurisdiction thereby, it may be expected to make that atypical intention clear.⁶⁶

The Supreme Court then highlighted a critical distinction between FEHBA and ERISA:

Section 8902(m)(1)'s text does not purport to render inoperative any and all State laws that in some way bear on federal employee-benefit plans. Cf. 29 U.S.C. §1144(a) (portions of ERISA "supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan.")⁶⁷

Importantly, the Supreme Court stressed that it was not deciding whether contract-based reimbursement claims are covered by FEHBA's preemption provision. ⁶⁸ Rather, the Court emphasized that its decision was limited to whether FEHBA's preemption provision conferred federal jurisdiction over the claims at issue. ⁶⁹

As a result, the Court's decision could steer FEHBA preemption law in a drastically different direction. First, *Empire* curtails removal jurisdiction, which may lead to the diffusion of FEHBA preemption jurisprudence, as the various state appellate and Supreme Courts attempt to interpret the FEHBA preemption clause, which is, in the words of Justice

⁶⁶ *Id.* at 17

Ginsburg, "a puzzling measure, open to more than one construction." And second, the distinctions drawn by the Supreme Court between FEHBA's preemption provision and ERISA's preemption provision may inspire some courts to begin disentangling FEHBA preemption from ERISA preemption. If the Supreme Court's decision in *Empire* has either effect, the law on FEHBA preemption is likely to grow much cloudier.

IV. MEDICARE PREEMPTION

A. Background

The Medicare program, which is administered by the Centers for Medicare and Medicaid Services ("CMS"), originally consisted of two parts: Part A, which covers the cost of hospitalization and related expenses, and Part B, the voluntary supplemental medical insurance program which covers physicians' services and outpatient care.⁷¹ The Medicare Act authorizes the federal government to delegate the administration of Medicare benefits under Parts A and B to health maintenance organizations.⁷² HMOs contracting with CMS under Parts A and B perform claims processing functions, but the federal government remains responsible for the payment of benefits.⁷³

In 1997, Congress passed the Balanced Budget Act, which established Medicare Part C (now referred to as "Medicare Advantage"), 74 a program designed to "utilize innovations that have helped the private market contain costs and expand health care delivery options." Under the Medicare Advantage program, qualified HMOs receive a fixed monthly payment for each Medicare Advantage beneficiary enrolled in their health plan, in exchange for assuming the responsibility to supply the enrollees with all of the medical benefits they may require. 76

As a result of this risk-based reimbursement system, the Medicare Act contains strict mandates which govern the array of benefits that must be provided under Medicare Advantage plans. Moreover, the Act authorizes the Secretary of the Department of

⁶⁴ *Id.* at 8 (internal quotations omitted)

⁶⁵ *Id*. at 16

⁶⁷ *Id.* at 18

⁶⁸ *Id.* at 17

⁶⁹ *Id*.

⁷⁰ *Id.* at 16

⁷¹ See 42 U.S.C. 1395c et seq.

⁷² See Wartenburg v. Aetna Ü.S. Healthcare, Inc., 2 F.Supp.2d 273, 276 (E.D.N.Y. 1998).

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⁷⁴ Until the enactment of the Medicare Modernization and Prescription Drug Act, Medicare Part C was referred to as "Medicare + Choice."

⁷⁵ House Conf. Rep. No. 105-217, at 585 (1997).

⁷⁶ See 42 U.S.C. 1395w-23.

Health and Human Services ("HHS") to promulgate regulations to implement the Medicare Advantage program. See 42 U.S.C. 1395w-22; see also 42 U.S.C. 1395w-26(b)(1) (authorizing the Secretary of HHS to "establish by regulation other standards...for Medicare + Choice organizations and plans consistent with, and to carry out, this part").

In an effort to design a comprehensive system of beneficiary protections, the Secretary of HHS, through CMS, has developed regulations requiring all Medicare Advantage organizations to "provide coverage of, by furnishing arranging for, or making payment for, all services that are covered by Part A and Part B of Medicare..." Moreover, the regulations require Medicare Advantage organizations to comply with:

- (1) CMS's national coverage determinations;
- (2) General coverage guidelines included in original Medicare manuals and instructions unless superseded by regulations in [42 C.F.R 422 et seq.] or related instructions; and
- (3) Written coverage decisions of local Medicare contractors with jurisdiction for claims in the geographic area in which services are covered under the MA plan....42 C.F.R. 422.101.

Thus, the benefits that must be provided under the terms of a Medicare Advantage plan are strictly regulated by the federal government. And, CMS has accordingly established channels through which Medicare Advantage beneficiaries must bring benefit disputes and grievances.

B. Expansion of the Medicare Advantage Preemption Clause

Prior to 2003, the Medicare Act contained a limited preemption clause that was applicable to the Medicare Advantage (then Medicare + Choice) program. The narrow preemption clause applied to state laws that were inconsistent with the rules established in the Medicare Act. The preemption clause also applied to state laws relating to benefits, the inclusion or exclusion of treatment providers, coverage determinations, and marketing materials. The preemption of treatment providers are coverage determinations, and marketing materials.

However, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) replaced the Medicare+Choice program with the Medicare Advantage program, and reinforced Medicare Advantage with a dramatically strengthened preemption clause. The preemption clause now reads:

The standards established under this part shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to MA [Medicare Advantage] plans which are offered by MA organizations under this part.⁸⁰

Thus, the preemption clause has been greatly simplified and expanded. As CMS observed,

[T]he presumption was that a State law was *not* preempted if it did not conflict with an M+C requirement, and did not fall into one of the four specified categories. MMA reversed this presumption, providing that State laws are presumed to be preempted unless they fall into two specified categories....The reason for such broad preemption authority is that the Congress intended that the MA program, as a Federal program, operate under Federal rules.⁸¹

Not surprisingly, the language employed by CMS closely tracks the legislative comments in the House Conference Report that accompanied the MMA:

The conference agreement clarifies that the MA program is a federal program operated under Federal rules. State laws, do not, and should not apply, with the exception of state licensing laws or state laws related to plan solvency. There has been some confusion in recent court cases. This provision would apply prospectively; thus it would not affect previous and ongoing litigation.⁸²

⁷⁷ 42 C.F.R. 422.101(a).

⁷⁸ 42 U.S.C. §1395w-26(b)(3) (2002).

⁷⁹ 42 C.F.R. 422.402 (1999).

^{80 42} U.S.C. §1395w-26(b)(3).

⁸¹ 69 Fed.Reg. 148, 46904 (August 3, 2004) (emphasis in original).

⁸² H.R. Report 108-391, at 557.

While the overall impact of this expansion on Medicare Advantage litigation remains unclear, the federal government's interpretation of the expansion is fairly explicit: Medicare Advantage is a federal program that operates exclusively under federal law, and "State laws are presumed to be preempted" unless they regulate plan licensure or plan solvency. 83

C. Medicare Advantage Preemption in the Courts

To date, only one court has interpreted the scope of the recently expanded Medicare Advantage preemption clause. In *Do Sung Uhm v. Humana, Inc.*, the plaintiffs brought various state law claims against Humana for allegedly making misrepresentations while marketing their Medicare Part D prescription drug plan. Humana argued that the plaintiff's claims were preempted under the new Medicare Advantage preemption clause (which applies equally to Medicare Part D administrators). The plaintiffs, on the other hand, insisted that "Congress did not intend for MMA's express preemption language to preempt state tort and contract claims."

The Court concluded that "the language of the MMA preemption clause is clear: if Part D establishes standards that cover plaintiffs' claims, then those standards supersede state law, and plaintiffs' state law claims are preempted."⁸⁷ The Court reasoned that because Medicare regulates the marketing materials published by Part D contractors, and prohibits materials that could mislead Medicare beneficiaries or misrepresent the Part D plan, "those standards supersede state law pursuant to the express preemption language of Part D."⁸⁸

Moreover, the Court held that because the plaintiffs alleged that Humana "failed to provide prescription drug benefits as promised," they were challenging a coverage determination. ⁸⁹ And, the Court held that the coverage determination regulations promulgated by CMS supersede plaintiffs' state contract, unjust enrichment, and fraud claims "to the

extent that those stem from a failure to provide benefits as promised."⁹⁰

Finally, the Court concluded that even if the were not challenging a coverage determination, their claims would still be preempted by the Part D grievance procedures, which "apply to any non-coverage-determination dispute between a PDP sponsor and its enrollees about any operations, activities, or behavior of the PDP sponsor."91 The Court supported this remarkably broad interpretation of the scope of Medicare preemption by highlighting CMS's conclusion that "state laws are presumed to be preempted unless they relate to licensure or solvency."92 The Court noted that "however harsh preemption may seem to particular claimants, it is consistent with the structure and purpose of the MMA."93

Thus, while it is difficult to anticipate how the federal circuit courts will interpret the recent expansion of the Medicare Part C preemption clause, *Do Sung* gives at least a preliminary indication that the new preemption clause will play a critical role in managed care litigation.

V. CONCLUSION

The preemption provisions of ERISA, FEHBA, and the MMA can have a tremendous impact on the course of managed care litigation. When applicable, they radically alter – and in many cases eliminate - the claims that a plaintiff can pursue against a managed care entity. As a result, in order to determine whether these preemption clauses establish removal jurisdiction in federal court or merely a federal defense in state court, it is necessary for managed care companies, as well as providers contracting with managed care companies, to have a complete understanding of their scope and the circumstances in which they are triggered.

^{83 69} Fed.Reg. 148, 46904 (August 3, 2004).

⁸⁴ *Do Sung Uhm v. Humana, Inc.*, 2:06-cv-00185-RSM, 3 (West. Dist. Wash. 2006)

⁸⁵ *Id*.

⁸⁶ *Id*. at 2

⁸⁷ *Id*. at 4

⁸⁸ *Id*.

⁸⁹ *Id.* at 5

⁹⁰ *Id*.

⁹¹ *Id*.

 $^{^{92}}$ *Id.* at 7

⁹³ *Id*.