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# Considerations in Medicare Reform: The Impact of Medicare Preemption on State Laws

*Michael J. Jacksonis, Jr.\**

## I. INTRODUCTION

The promise of health care coverage under Medicare<sup>1</sup> is by no means comprehensive or secure.<sup>2</sup> Its very structure has been questioned and the

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1. See 42 U.S.C. § 1395c (2000); 42 U.S.C. § 1395d (2000); 42 U.S.C. § 1395k (2000). See also 42 U.S.C.A. § 1395k (West 2003). See generally CCH INC., 2002 MEDICARE AND MEDICAID BENEFITS; CTRS. FOR MEDICARE & MEDICAID SERVS. (CMS), U.S. DEP'T OF HEALTH & HUMAN SERVS. (DHHS), PUB. NO. CMS-10050, MEDICARE & YOU 2003 (Apr. 2003), available at <http://www.medicare.gov/publications/pubs/pdf/10050.pdf> [hereinafter MEDICARE & YOU 2003].

2. HENRY J. KAISER FAMILY FOUND., *New Bush Medicare Plan Reportedly Would Offer Drug Benefit to Seniors in Fee-for-Service Medicare*, KAISER DAILY HEALTH POL'Y REP. 1 (Feb. 28, 2003) (quoting Alan Greenspan, Chairman of the Federal Reserve Board, "The Medicare program is 'unsustainable in the long run . . . Rapidly advancing medical technologies, essentially inelastic demand for medical services for the elderly, and a subsidized third-party payment system have created virtually unconstrained demand.'"), available at [http://www.kaisernetwork.org/daily\\_reports](http://www.kaisernetwork.org/daily_reports) [hereinafter *New Bush Medicare Plan*]; Amy Goldstein & Dana Milbank, *Hill GOP, Bush Split on Tax Cuts, Medicare*, WASH. POST, Feb. 14, 2003, at A1. See also Press Release, American Association of Health Plans (AAHP), *Policymakers Missing Full Extent of Medicare+Choice Crisis* (Jan. 9, 2003) (noting that, in absence of Congressional action, an estimated 670,000 more seniors and disabled could be forced out of their Me+C plan by January 2004), available at <http://www.aahp.org> [hereinafter AAHP Press Release]; Carlos Zarabozo, *Milestones in Medicare Managed Care*, 22 HEALTH CARE FIN. REV. 61, 67 (2000).

program faces significant efforts at reform.<sup>3</sup> The relationship between federal and state law affecting Medicare has a significant role to play in the design of any reformed federal health insurance program. Preemption provisions<sup>4</sup> contained in federal legislation affecting health care have a profound impact on the ability of state legislatures to reform and control the quality and design of managed care plans, including Medicare products, available to their citizens. The scope of preemption coupled with the absence of federal regulation can create a legislative void,<sup>5</sup> leaving managed care beneficiaries with restricted benefits and limited recourse when faced with denial of benefits or care. In the context of ERISA<sup>6</sup>-governed, employer-sponsored health plans, the broad scope of federal preemption plus the lack of sufficient federal regulation of managed care products sold to employee benefit plans creates an uncertain environment, as the courts are left to address challenges to the quality and quantity of care provided under such plans.<sup>7</sup> Medicare preemption of state law affecting Managed Care Organizations (MCOs), by contrast, is characterized by an extensive regulatory scheme that governs plan design and challenges to denials of coverage.<sup>8</sup> The Republican-dominated 108th Congress took a major step toward fulfilling expectations of reforming Medicare by passing the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. As Congress continues to revise Medicare in the future it must consider the proper function of federal preemption when crafting new programs such as the premium support model added to Medicare managed care<sup>9</sup> that was initially proposed by some members of the National

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3. See RAND E. ROSENBLATT ET AL., LAW AND THE AMERICAN HEALTH CARE SYSTEM 407 (1997); Amy Goldstein & Helen Dewar, *Senate Passes Medicare Bill*, WASH. POST., Nov. 25, 2003, available at <http://www.washingtonpost.com/wp-dyn/articles/A12583-2003Nov25.html>. See also Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173 (2003), available at <http://thomas.loc.gov/>.

4. See 42 U.S.C. § 405(h) (2000); 42 U.S.C. § 1395w-26(b)(3) (2000); 29 U.S.C. § 1132(e)(1) (2000); 42 U.S.C. § 1144(a) (2000). See also 42 U.S.C.A. § 405(h) (West 2003); 42 U.S.C.A. § 1395w-26(b)(3) (West 2003); 42 U.S.C.A. § 1132(e)(1) (West 2003).

5. Margaret G. Farrell, *ERISA Preemption and Regulation of Managed Care: The Case for Managed Federalism*, 23 AM. J.L. & MED. 251, 265 (1997).

6. Employee Retirement Income Security Act (ERISA) of 1974, P.L. 93-406, 88 Stat. 829 (1974) (ERISA regulates most private employer-sponsored health plans. It appears generally beginning at 29 U.S.C. § 1001).

7. RAND E. ROSENBLATT ET AL., LAW AND THE AMERICAN HEALTH CARE SYSTEM 98 (Supp. 2001-02). See SARA ROSENBAUM, AM. ASS'N OF RETIRED PERSONS, AN OVERVIEW OF MANAGED CARE LIABILITY: IMPLICATIONS FOR PATIENT RIGHTS AND FEDERAL AND STATE REFORM (Mar. 2001), at [http://research.aarp.org/health/2001\\_06\\_liability\\_1.html](http://research.aarp.org/health/2001_06_liability_1.html).

8. See generally 42 C.F.R. pt. 422 (2003).

9. Bill Brubaker, *Health Care Bill Would Revive Public-Private Alliance*, WASH. POST, Nov. 23, 2003, at A7; Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173.

Bipartisan Commission on the Future of Medicare,<sup>10</sup> and that was included in both the President's Enhanced Medicare proposal<sup>11</sup> and the House and Senate Medicare reform bills passed in 2003.<sup>12</sup> At the heart of this program design challenge is the issue of increasing reliance on market-based methods to deliver coverage, while at the same time maintaining a heavily regulated federal structure in order to overcome prior market failures in providing comprehensive coverage for the elderly.

Medicare reformers are faced with a Hobson's choice: rely on a highly regulated express and conflict preemption program that could diminish the market of available participating plans, or deregulate Medicare managed care to broaden the market of providers while facing the problems created by field preemption in a regulatory void. Failure to address preemption issues or to include comprehensive preemption language in new program designs may drive MCOs away from the Medicare managed care market based on increased cost and complexity of compliance with varying state requirements.<sup>13</sup> On the other hand, failure to provide regulation of the structure and operation of a Medicare managed care plan invites the difficulties inherent in the current ERISA-governed plans,<sup>14</sup> compounded by the current lack of a comparable insurance savings clause in Medicare.<sup>15</sup> Any further reform of Medicare must address the impact of federal preemption on the quality and quantity of care purchased to ensure the

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10. NAT'L BIPARTISAN COMM'N ON THE FUTURE OF MEDICARE, BUILDING A BETTER MEDICARE FOR TODAY AND TOMORROW (Mar. 1999), available at <http://medicare.commission.gov/medicare/bbmtt31599.html>.

11. President's Remarks to the American Medical Association's National Advocacy Conference, 39 WKLY. COMP. PRES. DOC. 289 (Mar. 4, 2003), available at <http://www.gpoaccess.gov/wcomp>. See also Press Release, The White House, President's Framework to Modernize and Improve Medicare Fact Sheet (Mar. 4, 2003), at <http://www.whitehouse.gov/news/releases/2003/03/print/20030304-1.html>.

12. Medicare Prescription Drug and Modernization Act, H.R. 1, 108th Cong. (2003); Prescription Drug and Medicare Improvement Act, S. 1, 108th Cong. (2003). See also Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173 (2003), which was signed into law by President George W. Bush on December 8, 2003.

13. See Jennifer E. Gladieux, *Medicare+Choice Appeal Procedures: Reconciling Due Process Rights and Cost Containment*, 25 AM. J.L. & MED. 61, 102 (1999); BETH C. FUCHS, CONG. RESEARCH SERV., NO. 97-938 EPW, MANAGED HEALTH CARE: FEDERAL AND STATE REGULATION 9 (Oct. 1997), at <http://countingcalifornia.cdlib.org/crs/pdf/97-938.pdf>.

14. See generally PATRICIA A. BUTLER, NAT'L ACAD. FOR STATE HEALTH POLICY, ERISA PREEMPTION MANUAL FOR STATE HEALTH POLICY MAKERS (Jan. 2000) (discussing the complexities of ERISA), available at <http://statecoverage.net/pdf/erisa2000.pdf>.

15. The Medicare Act contains no provision comparable to ERISA's insurance savings clause, 29 U.S.C. § 1144(b)(2)(A), which allows state insurance regulation to escape preemption. However, 29 U.S.C. § 1144(b)(2)(B), known as the ERISA "deemer clause," prevents the application of state insurance regulations to self-insured employee benefit plans.

existence of a market of product providers<sup>16</sup> as well as essential protection of patient rights and benefits.<sup>17</sup>

Should Congress eventually replace the current Medicare managed care structure with a less regulated program, the incidence of preemption challenges by MCOs and states concerning mandates affecting Medicare benefits and patient rights will increase. Thus, federal preemption must be a critical consideration in the design of future Medicare reform proposals to avoid the inherent difficulties in managed care created by a regulatory void.

This article explores key issues involved in understanding the impact of Medicare preemption on state laws affecting the federal purchase of managed care products as a consideration in Medicare reform. Specifically, Part II discusses the rise of federal purchasing of health insurance and the development of managed care options in Medicare. Part III analyzes the issues raised by the current federal preemption scheme that could be faced in an unregulated Medicare program. Finally, Part IV explains the significance of current preemption problems on future Medicare reforms.

## II. THE FEDERAL PURCHASE OF HEALTH INSURANCE AND THE DEVELOPMENT OF MANAGED CARE OPTIONS IN MEDICARE

Medicare was created in 1965 as part of President Lyndon Johnson's Great Society programs to serve as the federal health insurance plan for the aged and disabled.<sup>18</sup> Now administered by the Centers for Medicare and Medicare Services (CMS) of the U.S. Department of Health and Human Services (DHHS), it is the largest health insurance organization in the world.<sup>19</sup> CMS, formerly the Health Care Financing Administration (HCFA), insures approximately forty million Americans who are primarily

16. See Gladieux, *supra* note 13, at 101.

17. See generally OFFICE OF THE INSPECTOR GEN. (OIG), DHHS, PUB. NO. OEI-02-99-00030, MEDICARE+CHOICE HMO EXTRA BENEFITS: BENEFICIARY PERSPECTIVES (Feb. 2000) (suggesting ways to improve the Medicare managed care environment), available at <http://oig.hhs.gov/oei/reports/oei-02-99-00030.pdf> [hereinafter OIG, MEDICARE+CHOICE HMO EXTRA BENEFITS].

18. Theodore R. Marmor & Gary J. McKissick, *Medicare's Future: Fact, Fiction and Folly*, 26 AM. J.L. & MED. 225, 227 (2000); PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE: THE RISE OF A SOVEREIGN PROFESSION AND THE MAKING OF A VAST INDUSTRY 369 (1982); RASHI FEIN, MEDICAL CARE, MEDICAL COSTS: THE SEARCH FOR A HEALTH INSURANCE POLICY 62-63 (1986); ROSENBLATT ET AL., *supra* note 3, at 368. See generally PETER A. CORNING, THE EVOLUTION OF MEDICARE . . . FROM IDEA TO LAW (1969), available at <http://www.ssa.gov/history/corning.html>; THEODORE R. MARMOR, THE POLITICS OF MEDICARE 67-68 (2d ed. 2000).

19. *A Conversation With Tom Scully: 'Real Change' in System Won't Come Overnight*, MANAGED CARE, May 2002, at 36. See generally CMS, DHHS, *CMS/HCFA History*, at <http://cms.hhs.gov/about/history/default.asp> (last modified Sept. 24, 2003).

elderly, disabled, and low-income beneficiaries.<sup>20</sup>

*A. The Issue of National Health Insurance and the Development of Medicare*

The implementation of a national health insurance program for the elderly resulted from a compromise in the twentieth century political movement for comprehensive national health insurance.<sup>21</sup> To appreciate the current role that Medicare plays in the American health insurance system, it is necessary to have an understanding of the development and failures of the health insurance market leading up to Medicare's enactment. Government's increasing role in health care resulted from issues of increased costs, advances in medicine as well as social concerns for greater equity and the general welfare in light of the challenge of allocating scarce resources.<sup>22</sup>

Historically, there was no insurance for hospitalization until 1929, when Baylor Hospital offered a prepaid plan to Dallas schoolteachers.<sup>23</sup> Blue Cross plans followed this development by initially offering prepaid service benefits in a single facility; this evolved into "free choice" plans with access to several local facilities.<sup>24</sup> These Blue Cross plans were designed to protect hospital income by controlling the payment system and were assisted by state-enabling legislation that included tax exemptions.<sup>25</sup>

Commercial insurers eventually recognized a market for health insurance and developed cash indemnity plans in the 1930s that grew rapidly during the Second World War, aided by exemptions for health benefits from wage stabilization measures and the buying power of group purchasing.<sup>26</sup> Commercial insurers, who could rely on experience rating to define healthier beneficiary pools, soon had an advantage over Blue Cross and Blue Shield plans that relied on the less-healthy community rating premiums.<sup>27</sup>

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20. See CMS, DHHS, *CMS Programs*, at <http://cms.hhs.gov/about/programs.asp> (last modified Mar. 28, 2003).

21. See FEIN, *supra* note 18, at 54. See also STARR, *supra* note 18, at 369.

22. FEIN, *supra* note 18, at 2, 5.

23. *Id.* at 11. See also STARR, *supra* note 18, at 240 (noting that the political conditions and institutions of American society at the beginning of the twentieth-century reflected classic liberalism with a highly decentralized government and little direct regulation of social welfare). It was in reaction to this environment that the Progressive movement sought to strengthen the government's role in protecting social welfare. *Id.*

24. FEIN, *supra* note 18, at 14-15.

25. *Id.* at 16-17.

26. *Id.* at 20-24.

27. *Id.* at 28-31.

Reacting to the shortfalls of this free-market approach that left many uninsured, the first unsuccessful attempts at legislating comprehensive health insurance were made at the state level.<sup>28</sup> The federal Social Security legislation of the New Deal conspicuously lacked any health insurance provisions due to the opposition of organized medicine.<sup>29</sup> Subsequently, President Truman advocated comprehensive national health insurance, but by the early 1950s the Democratic efforts had shifted to obtaining catastrophic coverage only,<sup>30</sup> and eventually focused on coverage for the aged (as the most vulnerable population) by the end of the decade.<sup>31</sup> Opposition by organized medicine continued, and it was not until President Johnson's landslide victory in the 1964 election that there was enough political power to enact Medicare.<sup>32</sup>

What resulted as the original Medicare program was a richly complex, federally-defined benefit program with detailed entitlements, regulations, and payment methodologies.<sup>33</sup> In effect, the mechanics of a health insurance plan were codified into federal statutes.<sup>34</sup> Although aspects of Medicare have changed over the years, "its basic character, design, and structure have remained stable."<sup>35</sup> Medicare consists of three general sections: Part A, which covers inpatient hospital services; Part B, which covers physician services; and Part C, which currently provides for the Medicare+Choice (M+C) managed care option.<sup>36</sup> Medicare sets forth minimum coverage requirements for both inpatient and outpatient treatment, as well as skilled nursing facility, hospice, and home health care.<sup>37</sup> The program provides for specific rights concerning covered benefits requiring adequate notice of coverage denials; it also delineates appeal procedures to include judicial review after final agency action on a

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28. *Id.* at 34.

29. *Id.* at 42. *See also* STARR, *supra* note 18, at 255 (noting that organized labor and business interests also opposed health insurance).

30. FEIN, *supra* note 18, at 45, 51.

31. *Id.* at 54.

32. *Id.* at 63.

33. *See id.* at 69.

34. Interview with Sara Rosenbaum, Chair, Department of Health Policy and the Harold and Jane Hirsh Professor of Health Law and Policy, George Washington University, in Washington, D.C. (Mar. 7, 2003). *See generally* Timothy Stoltzfus Jost, *Private or Public Approaches to Insuring the Uninsured: Lessons from International Experience with Private Insurance*, 76 N.Y.U. L. REV. 419 (2001).

35. FEIN, *supra* note 18, at 69.

36. MEDICARE & YOU 2003, *supra* note 1, at 5. *See also* Zarabozo, *supra* note 2, at 65 (noting that Part C was introduced by the Balanced Budget Act of 1997). Medicare+Choice was changed to "Medicare Advantage" by the Medicare Act of 2003.

37. MEDICARE & YOU 2003, *supra* note 1, at 7.

set timeframe.<sup>38</sup> Moreover, it sets forth extensive regulations of safety standards, payment procedures, fiscal administration, provider participation, and peer review.<sup>39</sup> The extent of these regulations reflects the vast and complex environment of beneficiaries, providers, and administrators in which the Medicare programs operate.<sup>40</sup>

### B. *The Origins of Medicare Managed Care*

Since 1972, Medicare has offered the option of obtaining health services through managed care organizations, principally health maintenance organizations (HMOs).<sup>41</sup> The Nixon Administration approved amendments to the Medicare statute in 1972, allowing the program to contract with HMOs.<sup>42</sup> Additional statutes followed in 1973<sup>43</sup> and 1976,<sup>44</sup> designed to encourage HMO development with federal funding.<sup>45</sup> The 1972 amendments to the Social Security Act went beyond merely providing for reimbursement of prepaid medical services that had existed in Medicare since 1965, and introduced Medicare HMO enrollment and contracting.<sup>46</sup> The HMO Act of 1973 triggered the growth of managed care as a means of controlling rising health care costs by requiring employers with over twenty-five employees to offer an HMO insurance option if they provided conventional health insurance.<sup>47</sup>

HMOs arose as an alternative to the traditional fee-for-service healthcare system and as a means to manage costs through capitation payments and

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38. *Id.* at 49-50.

39. See CMS, DHHS, MEDICARE & MEDICAID PAPER-BASED MANUALS, available at <http://cms.hhs.gov/manuals/cmstoc.asp> (last visited Sept. 12, 2003).

40. See FEIN, *supra* note 18, at 70-71.

41. See Dana Gelb Safran et al., *Primary Care Quality in the Medicare Program: Comparing the Performance of Medicare Health Maintenance Organizations and Traditional Fee-for-Service Medicare*, 162 ARCHIVES OF INTERNAL MED. 757, 757 (2002). See generally AAHP, THE MEDICARE+CHOICE PROGRAM: WHAT YOU NEED TO KNOW 2 (May 2002), available at [http://www.aahp.org/template.cfm?section=Medicare\\_Payment](http://www.aahp.org/template.cfm?section=Medicare_Payment) [hereinafter AAHP, MEDICARE+CHOICE PROGRAM].

42. The Social Security Amendments of 1972, Pub. L. No. 92-603, 86 Stat. 1406 (1972). See generally Social Security Online, History Page, at <http://www.ssa.gov/history/1972amend.html> (last visited Sept. 12, 2003).

43. The Health Maintenance Organization Act of 1973, Pub. L. No. 93-222, 87 Stat. 914 (1973).

44. The Health Maintenance Organization Amendments of 1976, Pub. L. No. 94-460, 90 Stat. 1949 (1976).

45. JASON S. LEE, CONG. RESEARCH SERV., NO. 97-913 EPW, MANAGED HEALTH CARE: A PRIMER 4 (Sept. 1997), available at <http://countingcalifornia.cdlib.org/crs/pdf/97-913.pdf>.

46. Zarabozo, *supra* note 2, at 62.

47. ROSENBLATT ET AL., *supra* note 3, at 549.



resource allocation.<sup>48</sup> In a fee-for-service system, either the patient or the insurer pays the physician for covered care in accordance with the policy terms.<sup>49</sup> This creates a financial incentive for the physician to provide more, and possibly unnecessary, care based on an expectation of forthcoming reimbursement.<sup>50</sup> HMOs are defined by the use of fixed fees paid to a provider who assumes the responsibility and financial risk of providing any covered care that may be required for each enrollee.<sup>51</sup> HMO administrators review requested services in accordance with the plan provisions to minimize unnecessary procedures and use financial incentives and penalties with plan physicians to discourage excessive utilization.<sup>52</sup>

The purpose behind managed care is cost containment based on service rationing accomplished by risk-bearing organizational structures that deliver care.<sup>53</sup> In an HMO system, costs are controlled through several techniques, including limited provider selection and restraints on specialist access.<sup>54</sup> In return for adhering to network conditions, participating providers are ensured a more stable patient volume.<sup>55</sup> Primary care providers act as gatekeepers to control referrals to specialists and limit unnecessary treatment.<sup>56</sup> Incentive programs are also used to shift risk to physicians through either withholding a fee percentage or paying a bonus for cost-effective performance.<sup>57</sup> Thus, the incentive in an HMO system is to provide less care in order to control costs, not more.<sup>58</sup>

### C. *The Growth of Medicare Managed Care and Congressional Action*

Medicare participation in managed care was not significant until the 1990s when enrollment dramatically increased in Medicare HMOs.<sup>59</sup> The health care insurance industry failed to initially respond to the 1973 HMO Act due to regulatory requirements and limitations on reimbursement to

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48. *Pegram v. Herdrich*, 530 U.S. 211, 218-19 (2000) (citing ROSENBLATT ET AL., *supra* note 3, at 543-44, 546). See Jennifer L. Wright, *Unconstitutional or Impossible: The Irreconcilable Gap Between Managed Care and Due Process in Medicaid and Medicare*, 17 J. CONTEMP. HEALTH L. & POL'Y 135, 136 (2000); LEE, *supra* note 45, at 4.

49. *Pegram*, 530 U.S. at 218.

50. *Id.*

51. *Id.*

52. *Id.* at 219.

53. James W. Childs, *Comment: You May Be Willing, But Are You Able?: A Critical Analysis of "Any Willing Provider" Legislation*, 27 CUMB. L. REV. 199, 203 (1996-1997).

54. *Id.*

55. *Id.*

56. *Id.* at 203.

57. *Id.*

58. *Pegram v. Herdrich*, 530 U.S. 211, 219 (2000).

59. Safran et al., *supra* note 41, at 757.

include only actual reasonable costs, which thus limited HMO profit potential.<sup>60</sup> Not surprisingly, “[i]n 1979, there were 32 group practice prepayment plans (the pre-existing cost reimbursement option), 32 HMO cost contractors, and only 1 risk-sharing HMO.”<sup>61</sup> Therefore, in an attempt to develop the proper payment methodology for Medicare HMOs, Congress authorized demonstration projects for prospective payment and capitation payment methods.<sup>62</sup>

Congress revised the Medicare managed care program in 1982 as part of the Tax Equity and Fiscal Responsibility Act (TEFRA).<sup>63</sup> In an effort to “more favorably restructure the Medicare market to HMOs,”<sup>64</sup> TEFRA created new rules for HMOs participating in the Medicare managed risk contract program.<sup>65</sup> Significantly, TEFRA paid contracting HMOs on a full-risk basis and required savings to be passed on to beneficiaries in the form of increased benefits or reduced cost sharing, used for future benefits, or refunded to Medicare while also permitting HMOs the normal level of profit they received in private plans.<sup>66</sup> This program attracted beneficiaries through the variety of services covered, the availability of preventative health care, and the implementation of innovative disease management programs.<sup>67</sup> By the 1990s, the popularity of MCOs in general had grown substantially due to the increased benefits offered plus lower out-of-pocket costs.<sup>68</sup> Likewise, the TEFRA HMOs enjoyed early success with 161 of the 662 HMOs in the U.S. participating in Medicare by 1987.<sup>69</sup>

Despite its potential benefits, many participants see managed care as a complex and confusing system, which complicates efforts at reaching consensus on appropriate reforms.<sup>70</sup> Confidence in the HMO system also

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60. ROSENBLATT ET AL. (Supp. 2001-02), *supra* note 7, at 292.

61. Zarabozo, *supra* note 2, at 62.

62. *Id.* at 63.

63. Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982, Pub. L. No. 97-248, 96 Stat. 324 (1982).

64. ROSENBLATT ET AL. (Supp. 2001-02), *supra* note 7, at 292.

65. AAHP, MEDICARE+CHOICE PROGRAM, *supra* note 41, at 2. *See also* OIG, MEDICARE+CHOICE HMO EXTRA BENEFITS, *supra* note 17, at 6.

66. Zarabozo, *supra* note 2, at 63, noting that:

Under TEFRA, contracting HMOs or competitive medical plans (which were essentially HMOs that did not have a Federal qualification designation under the HMO Act of 1973) would be paid 95 percent of the AAPCC [average per capita cost—an estimate of the cost for an enrollee in traditional fee-for-service Medicare] on a full risk basis. The 5 percent differential recognized the presumed greater efficiency of HMOs and their ability to reduce program expenditures.

67. AAHP, MEDICARE+CHOICE PROGRAM, *supra* note 41, at 2.

68. *See* Safran et al., *supra* note 41, at 757.

69. Zarabozo, *supra* note 2, at 64.

70. Harry P. Cain II et al., Letter Report to the Administrator of the Health Care

suffers from instability, as seen in the late 1980s and early 1990s when large numbers of Medicare beneficiaries faced increased contract terminations as HMOs became more selective in the counties where they would offer plans.<sup>71</sup> Nonetheless, by the late 1990s, “74 percent of beneficiaries had at least one Medicare plan available in their area.”<sup>72</sup>

HMOs faced other criticism as well. Patient concerns over quality of care grew as a result of service rationing used by MCOs to contain costs.<sup>73</sup> In 1996, Medicare HMO beneficiaries who were denied care challenged the adequacy of the coverage denial process in *Grijalva v. Shalala*.<sup>74</sup> Both the Arizona District Court and the Ninth Circuit recognized constitutional due process requirements for adequate notice, a hearing, and expedited review in critical cases when Medicare HMOs deny coverage.<sup>75</sup> The Medicare statute did provide procedural protections for beneficiaries that enrolled in HMOs that were similar to the protections in fee-for-service Medicare.<sup>76</sup> The courts, however, agreed that the regulations regarding adverse HMO

Financing Administration on Developing an Information Infrastructure for the Medicare+Choice Program (June 22, 1998), available at <http://www.nap.edu/readingroom/books/choice> (“Research over the past 12 years has documented how poorly Medicare beneficiaries understand the differences between traditional and managed care Medicare.”); ROSENBLATT ET AL. (Supp. 2001-02), *supra* note 7, at 292 (illustrating the common perceptions of Medicare beneficiaries toward managed care with a dialogue between Hirsh Health Law Professor Sara Rosenbaum and her mother who noted concern over the Medicare shift to managed care with the assertion that even she, the mother of a health law professor, did not “have the slightest idea how to use managed care”); Frank Diamond, *Medicare+Choice: Uncertain Future for Unstable Program*, MANAGED CARE, Apr. 2002, at 34, available at <http://www.managedcaremag.com/archives/0204/0204.medicareplus.pdf> (“Medicare+Choice would still be more of a puzzle for the older group if for no other reason than that they have had much less experience with managed care than younger people who’ve dealt with it throughout their working lives.”); THOMAS RICE & KATHERINE A. DESMOND, THE HENRY J. KAISER FAMILY FOUND., AN ANALYSIS OF REFORMING MEDICARE THROUGH A “PREMIUM SUPPORT” PROGRAM 43, 44 (Feb. 2002), available at <http://www.kff.org/medicare/6015-index.cfm>; INST. OF MED., IMPROVING THE MEDICARE MARKET: ADDING CHOICE AND PROTECTIONS 85 (1996), available at <http://www.nap.edu/books/0309055350/html/R1.html>. See also OIG, MEDICARE+CHOICE HMO EXTRA BENEFITS, *supra* note 17, at 3 (noting that HMO marketing materials vary greatly and add to the potential for confusion).

71. Zarabozo, *supra* note 2, at 65.

72. *Id.*

73. See ROBERT WOOD JOHNSON FOUND., THE CHALLENGE OF MANAGED CARE REGULATION: MAKING MARKETS WORK? 3-4 (Aug. 2001); JILL A. MARSTELLER & RANDALL R. BOVBERG, THE URBAN INST., FEDERALISM AND PATIENT PROTECTION: CHANGING ROLES FOR STATE AND FEDERAL GOVERNMENT 2 (Aug. 1999), available at <http://www.urban.org/UploadedPDF/occa28.pdf>.

74. 946 F. Supp. 747 (D. Ariz. 1996), *aff’d*, 152 F.3d 1115 (9th Cir. 1998), *vacated by* 526 U.S. 1096 (1999).

75. See *Grijalva*, 152 F.3d at 1123.

76. *Id.* at 1117 (citing 42 U.S.C. § 1395mm(c) and 42 C.F.R. §§ 417.600-417.638).

coverage determinations failed to provide sufficient due process protections.<sup>77</sup> In particular the district court had found that the notices of coverage denials “were often illegible, failed to specify the reason for the denial, and failed to inform the beneficiary that he or she had the right to present additional evidence to the HMO.”<sup>78</sup>

While the district court opinion in *Grijalva* was on appeal, Congress enacted the Health Insurance Portability and Accountability Act of 1996 (HIPAA)<sup>79</sup> that included amendments to Medicare authorizing sanctions for Medicare risk contractors who failed to comply with the Medicare Act or federal regulations.<sup>80</sup> Additionally, the Department of Health and Human Services promulgated new rules concerning Medicare appeals of individual claims and expedited review for Medicare HMO enrollees.<sup>81</sup> Thus, as Medicare managed care grew and evolved, the regulatory framework governing MCO conduct and beneficiary protections developed as well.

In an effort to continue improvements in Medicare managed care delivery and address concerns about HMO abuses, Congress created the Medicare+Choice (M+C) program in 1997 as part of the Balanced Budget Act (BBA).<sup>82</sup> “[H]eralded as the most significant changes in private plan contracting in the history of Medicare,”<sup>83</sup> this initiative was based on a widespread expectation that Medicare would follow the general trend away from fee-for-service financing to a managed care structure.<sup>84</sup> Important changes set forth in the BBA included the types of plans that could participate, contracting standards, enrollment requirements, and payment rules.<sup>85</sup> In particular, the BBA introduced key adjustments to the capitation rates to account for health status (HMO enrollees tend to be healthier than fee-for-service Medicare beneficiaries), a payment floor for the lowest-paid counties, and a guaranteed two percent annual increase.<sup>86</sup> The BBA also provided for participation by medical savings account plans (on a demonstration basis), private fee-for-service plans (a defined contribution option with no premium limit), religious fraternal benefit plans, as well as

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77. *Id.* at 1118.

78. *Id.*

79. Health Insurance Portability and Accountability Act (HIPAA) of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996).

80. Gladieux, *supra* note 13, at 75.

81. *Id.*

82. Balanced Budget Act (BBA) of 1997, Pub. L. No. 105-33, 111 Stat. 251 (1997).

83. Zarabozo, *supra* note 2, at 65.

84. *Mass. Assoc. of Health Maint. Orgs. v. Ruthardt*, 194 F.3d 176, 184 (1st Cir. 1999) (citing H.R. Conf. Rep. No. 105-77, at 638 (1997), *reprinted in* 1997 U.S.C.C.A.N. 176, 259).

85. Zarabozo, *supra* note 2, at 65.

86. *Id.* at 65-66.

Preferred Provider Organizations (PPOs) and Provider Sponsored Organizations (PSOs).<sup>87</sup> As addressed in the next section, the impact of many of these provisions has been characterized as “more symbolic than practical.”<sup>88</sup>

The Balanced Budget Refinement Act of 1999 (BBRA)<sup>89</sup> and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA) of 2000<sup>90</sup> enacted further amendments to Medicare and Medicare+Choice. These changes included new procedures for appeals of Local Coverage Determinations and modifications to appeals of National Coverage Determinations.<sup>91</sup> Benefit mandates included requirements for preventative screenings and extended coverage for biennial pap smears and pelvic exams, as well as glaucoma, colonoscopy, and mammography screenings.<sup>92</sup> The laws also attempted to rectify certain funding shortfalls, although they fell short of permanently stabilizing the M+C program.<sup>93</sup> Overall, these additions to the already intricate Medicare regulatory scheme, particularly with respect to beneficiary appeal rights and benefit mandates, stand in stark contrast to the disparate regulation of the delivery of managed care under employee benefit plans in the private sector.

#### D. Medicare Managed Care Withdrawals

At the time the BBA was enacted in 1997, participation in Medicare managed care was projected to triple to thirty-five percent of those Medicare eligible by 2007.<sup>94</sup> One commentator went so far as to proclaim that “(f)ee-for-service Medicare is on death row.”<sup>95</sup> However, the M+C

87. *Id.* at 65.

88. *Id.* at 66.

89. Balanced Budget Refinement Act (BBRA) of 1999, Pub. L. No. 106-113, 113 Stat. 1501(a) (2000).

90. Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act (BIPA) of 2000, Pub. L. No. 106-554, 114 Stat. 2763 (2000).

91. See ROSENBLATT ET AL. (Supp. 2001-02), *supra* note 7, at 249.

92. See Peter W. Thomas & Jeremy Allen, Summary of Medicare, Medicaid, & SCHIP Benefits Improvement and Protection Act of 2000 (2001), at <http://www.ppsv.com/issues/givebackdoc.htm>.

93. AAHP, MEDICARE+CHOICE PROGRAM, *supra* note 41, at 4. See also LORI ACHMAN & MARSHA GOLD, THE COMMONWEALTH FUND, MEDICARE+CHOICE 1999-2001: AN ANALYSIS OF MANAGED CARE PLAN WITHDRAWALS AND TRENDS IN BENEFITS AND PREMIUMS 1, 13 (Feb. 2002), available at <http://www.cmfw.org> [hereinafter ANALYSIS OF MANAGED CARE PLAN WITHDRAWALS].

94. *Managed Medicare's Rapid Expansion*, MANAGED CARE, Aug. 1997, at 61, available at <http://www.managedcaremag.com/archives/9708/9708.managedmedicare.pdf>.

95. Andrew J. McCarthy, *The Competitive New World of Medicare Managed Care*, MANAGED CARE, Aug. 1996, at 28, available at <http://www.managedcaremag.com/archives/9608/MC9608.elderly.shtml>.

program now faces serious problems<sup>96</sup> and has not performed as well as expected.<sup>97</sup> In 1997, Medicare managed care participation peaked at six million (one in seven beneficiaries).<sup>98</sup> Since then, many HMOs have withdrawn from the M+C market due in part to limited increases in capitation payments and market variations nationwide, leaving large areas of the country without an M+C option.<sup>99</sup>

In addition to the provisions for an HMO option, the M+C program authorized both PPOs and PSOs as coordinated care plans (CCPs).<sup>100</sup> PPOs and PSOs are less restrictive forms of managed care.<sup>101</sup> Unlike an HMO, which relies on capitation payments, a PPO not only compensates providers on a traditional fee-for-service basis but also utilizes a network of providers who contract with the PPO to provide services to plan beneficiaries at discounted rates.<sup>102</sup> PPOs offer members the opportunity to seek care from providers outside the network if they are willing to pay additional fees. PSOs are cooperative ventures controlled and operated by the providers themselves in an effort to eliminate an intermediary insurer or managed care plan.<sup>103</sup> Together, PPOs and PSOs have emerged as the most popular

96. Diamond, *supra* note 70, at 28.

97. See Marsha Gold, *Medicare+Choice: An Interim Report Card*, 20 HEALTH AFF. 120, 132 (2001):

By almost any measure, the interim grade for the M+C program as of the start of 2001 must be judged a 'D' if not an 'F.' In contrast to the goal of expanded choice, the M+C program has reduced the range of choice that once existed, with existing plans withdrawing, few new participants entering from among the newly authorized types of options, no geographic redistribution of participants to develop choice where none existed (except for the private FFS plan option, which is too new to assess), and an increase rather than decrease in the inequities in benefits and offerings between higher- and lower-paid areas of the country.

98. Michael Levin-Epstein, *Medicare+Choice Reform: Hope, but No Quick Action Expected*, MANAGED CARE, Oct. 2001, available at [http://www.managedcaremag.com/archives/0110/0110.medicare\\_action.html](http://www.managedcaremag.com/archives/0110/0110.medicare_action.html).

99. Press Release, Statement of Tom Scully, Administrator, Centers for Medicare & Medicaid Services, Department of Health and Human Services, Medicare+Choice Plan Renewals and Nonrenewals (Sept. 25, 2002), at <http://cms.hhs.gov/media/press/release.asp?Counter=490> [hereinafter Scully Press Release]. See generally MEDPAC, REPORT TO THE CONGRESS: MEDICARE PAYMENT POLICY (Mar. 2002), available at [http://www.medpac.gov/publications/congressional\\_reports/Mar02\\_Entire%20report.pdf](http://www.medpac.gov/publications/congressional_reports/Mar02_Entire%20report.pdf); Marsha Gold & John McCoy, Mathematica Pol'y Research, Inc., *Medicare+Choice Withdrawals: Experiences in Major Metropolitan Areas*, OPERATIONAL INSIGHTS, Sept. 2002, at 2, at <http://www.mathematica-mpr.com/PDFs/opinsights8.pdf>.

100. Gold, *supra* note 97, at 125.

101. See LEE, *supra* note 45, at 21, 29 app.A (charting the characteristics of Managed Care Organizations).

102. *Id.* at 21.

103. *Id.* at 25.

structures for the delivery of managed health care in the private sector.<sup>104</sup> Their failure to materialize as viable alternatives in M+C has also hampered M+C's expansion.<sup>105</sup>

M+C withdrawals affected approximately 2.2 million Medicare beneficiaries between 1999 and 2002.<sup>106</sup> Furthermore, the program failed to realize the \$22.5 billion in savings expected between 1998 and 2002.<sup>107</sup> It appears clear that M+C is headed to a "day of reckoning,"<sup>108</sup> but whether

104. ROSENBLATT ET AL., *supra* note 3, at 552.

105. See Gold, *supra* note 97, at 135-36; NORA SUPER JONES, NAT'L HEALTH POLICY FORUM, ISSUE BRIEF NO. 758, MEDICARE+CHOICE: WHERE TO FROM HERE? 9 (Sept. 2000) ("While several PPOs were included initially, only one is operating as a M+C contractor today. Personal Choice 65, a PPO offered by Independence Blue Cross and Blue Shield (Pennsylvania), has approximately 14,000 enrollees."), available at <http://www.nhpf.org/index.cfm?fuseaction=Details&key=364>.

106. Gold & McCoy, *supra* note 99, at 1:

Recent withdrawals have been influenced by minimal Medicare capitation payment increases—only about 2 percent in most years—and by market-specific conditions. . . . includ[ing] local market history . . . trends in other lines of business, [and] state regulations (citation omitted).

....

Under current policy, it is likely that Medicare+Choice will continue to diminish nationally, with enrollment increasingly concentrated in those markets where conditions are most hospitable. Since markets vary, often in ways that federal policy can only marginally influence, a market-based insurance strategy like Medicare+Choice will almost always mean that plan choices vary substantially across the nation.

*Id.* at 2, 5. Cf. ANALYSIS OF MANAGED CARE PLAN WITHDRAWALS, *supra* note 93, at 1 & 14 fig.1 (showing bar graph of Medicare+Choice enrollment from 1985-2001); LORI ACHMAN & MARSHA GOLD, THE COMMONWEALTH FUND, TRENDS IN MEDICARE+CHOICE BENEFITS AND PREMIUMS, 1999-2002 (Nov. 2002) (noting that, in 2002, an estimated 536,000 M+C enrollees were affected), available at [http://www.cmwf.org/programs/medfutur/achman\\_trendsM+C\\_580.pdf](http://www.cmwf.org/programs/medfutur/achman_trendsM+C_580.pdf); TIMOTHY LAKE & RANDALL BROWN, HENRY J. KAISER FAMILY FOUND., MEDICARE+CHOICE WITHDRAWALS: UNDERSTANDING KEY FACTORS 14-17 (June 2002) (analyzing the decline in service areas covered by M+C contracts by percentage of existing M+C contracts and per M+C county), available at <http://www.kff.org/medicare/>; COLLEEN L. BARRY & JANET KLINE, THE COMMONWEALTH FUND, ISSUE BRIEF NO. 537, MEDICARE MANAGED CARE: MEDICARE+CHOICE AT FIVE YEARS 2 (Apr. 2002) (noting that, since 1999, the number of beneficiaries with an HMO available in their area has decreased from seventy-two percent to sixty-four percent), at [http://www.cmwf.org/programs/medfutur/barry\\_fiveyears\\_ib\\_537.pdf](http://www.cmwf.org/programs/medfutur/barry_fiveyears_ib_537.pdf); Timothy D. McBride & Keith J. Mueller, *Inequitable Access: Medicare+Choice Program Fails to Serve Rural America*, 7 RURAL POL'Y BRIEF 1, 1-2 (2002) (noting a thirty-five percent drop in enrollment of rural beneficiaries from October 1999 to October 2001), available at <http://www.rupri.org/publications/archive/pbriefs/PB2002-2/PB2002-2.pdf>; JONES, *supra* note 105, at 2 (noting that, in June and July 2000, sixty-five HMOs decided not to renew their M+C contracts and fifty-three reduced service areas, affecting more than 934,000 Medicare beneficiaries).

107. Diamond, *supra* note 70, at 28.

108. *Id.* at 35.

that day is upon us, or a few years hence, is debated by policymakers.<sup>109</sup>

Despite its failures, M+C remains a popular and less expensive alternative to traditional Medicare where available, especially for low-income seniors, because of increased benefits such as prescription drug coverage (currently not provided under Medicare until 2006 by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003) and lower out-of-pocket expenses (especially when compared to the cost of Medigap policies).<sup>110</sup> Without a M+C option, 1.5 million current M+C beneficiaries would have to rely on fee-for-service Medicare with no supplement, including forty-two percent of African-Americans now enrolled in M+C.<sup>111</sup> Because many low-income seniors cannot afford supplemental Medicare policies, they look to Medicare managed care to cover their needs.<sup>112</sup>

### *E. The Expansion of Prescription Drug Coverage in Medicare*

Driving the efforts of the 108th Congress to reform Medicare was the growing nationwide support for expanding drug coverage for seniors.<sup>113</sup> Both House and Senate Medicare reform bills passed in 2003 contained a prescription drug plan for Medicare beneficiaries that was included in the final legislation.<sup>114</sup> Underlying this massive expansion of a federal entitlement program was the premise that extensive federal regulation coupled with provisions for private competition for the delivery of Medicare services will create and sustain a viable market of participating providers.<sup>115</sup> However, whether a market will emerge to support such a program is far from certain.<sup>116</sup> Further, while the Medicare Prescription

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109. *Id.* (noting that Karen Ignagni, President of the AAHP, sees the day of M+C reckoning at hand, whereas Tom Scully, Administrator of the Centers for Medicare and Medicaid, sees the program's fate being decided in seven or eight years).

110. See OIG, *MEDICARE+CHOICE HMO EXTRA BENEFITS*, *supra* note 17, at 2.

111. AAHP, *supra* note 41, at 22.

112. Diamond, *supra* note 70, at 32. According to Tom Scully, "[t]he real comparable is Medicare+Choice versus Medicare plus medigap. A lot of the low-income people can't afford medigap." *Id.*

113. See William M. Welch, *GOP Takes Risk with Medicare Overhaul*, USA TODAY, June 16, 2003, at 9A.

114. See H.R. 1, 108th Cong. § 101 (2003); S. 1, 108th Cong. § 101 (2003); Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173 (2003).

115. See Amy Goldstein, *Prescription Drug Plan Faces Tests: Insurers' Participation Uncertain, Experts Say*, WASH. POST, June 30, 2003, at A1.

116. *Id.* ("According to policy specialists, industry lobbyists, Wall Street analysts and health care executives, not one company has said publicly that it would sign up for either of these new marriages with Medicare, and the willingness of insurers to take part remains an open question.").



Drug Benefit section of the Medicare Act of 2003 will provide some coverage where none existed, it falls short of an adequate solution to the drug coverage issue in the face of current market responses.<sup>117</sup> Both the final 2003 Medicare reform legislation and the 2003 House and Senate bills stopped short of the extensive coverage called for by many seniors,<sup>118</sup> which raises the issue of whether states should be free to mandate increased drug coverage or be blocked by federal preemption in the Medicare law.

### III. FAILURE TO CONSIDER PREEMPTION ISSUES WILL LEAD TO FUTURE PROBLEMS FOR MEDICARE PROGRAMS

The broad Medicare preemption provisions act as a check on many state initiatives aimed at managed care regulation and reform.<sup>119</sup> Even with such limits, the existing burdens on MCOs coupled with other market forces

117. See Harold Meyerson, *Medicare and the Missouri Compromise*, WASH. POST, July 10, 2003, at A23:

[W]ith U.S. employers cutting back on adequate and affordable health coverage, decent retirement plans and on-the-job education, either the role of the state must be beefed up or America will revert to its pre-New Deal, fend-for-yourself economy. When the market abdicates a necessary role, the nation needs a Democratic Party that's unafraid to argue for governmental responsibility.

*Id.*

118. See Helen Dewar & Amy Goldstein, *Medicare Bill Squeezes Through House at Dawn*, WASH. POST, Nov. 23, 2003, at A1 (discussing the final legislation):

To qualify for the prescription drug benefit, patients would pay a premium averaging \$35 a month, plus a \$250 annual deductible. The government would then pay 75 percent of a person's drug costs, to as much as \$2,250 a year. Coverage would end there unless someone's out-of-pocket costs exceed \$3,600 a year. The government would pay 95 percent of these "catastrophic" drug costs.

*Id.* Cf. Ceci Connolly, *For Struggling Seniors, Medicare Drug Plan's Proof Is in the Purse*, WASH. POST, June 26, 2003, at A1 (discussing the initial House and Senate provisions):

Both the House and Senate plans would require seniors to pay about \$35 in monthly premiums and an annual deductible of \$250 to \$275 before receiving any subsidy. The Senate plan would cover half of a person's annual drug expenditures between \$276 and \$4,500. The recipient would pay the next \$1,300 in prescription costs. If the person's total drug costs rose above \$5,800 in a year, subsidies would resume.

The House bill would offer retirees an 80 percent subsidy on drug bills between \$251 and \$2000 and no coverage for the next \$1,500 worth of medications. The "catastrophic coverage" would begin when costs reached \$3,501.

*Id.*; Daniel Altman, *Some Doubts About Logic of Senate Plan for Drug Aid*, N.Y. TIMES, June 14, 2003, at C1 (discussing Senate bill); Robert Pear, *Some Senators Fear Employers Will Drop Retiree's Drug Plans*, N.Y. TIMES, June 14, 2003, at A12 (noting that, according to some members of Congress, passage of the bill would result in curtailment of prescription drug coverage by employers).

119. See Mass. Assoc. of Health Maint. Orgs. V. Ruthardt, 194 F.3d 176, 184 (1st Cir. 1999).

have caused a decrease in the availability of M+C plans.<sup>120</sup> Although mandating increased benefits and network design certainly could improve the product from a beneficiary's perspective, such a goal becomes moot if providers withdraw from the market and there is no Medicare managed care option to regulate.<sup>121</sup>

The current M+C preemption scheme may represent the most appropriate and realistically achievable balance between provider<sup>122</sup> and beneficiary<sup>123</sup> needs. The Medicare regulations contain significant beneficiary protections<sup>124</sup> that parallel those addressed by state efforts at regulating MCOs.<sup>125</sup> In the realm of employer-sponsored health care plans, ERISA field preemption has created a legislative void<sup>126</sup> that will require federal action to increase beneficiary protections. In contrast, M+C express and conflict preemption provisions, coupled with extensive program regulations, set out a potentially viable managed care program<sup>127</sup> that could be successful with proper funding.<sup>128</sup> Given the Bush administration's emphasis on privatization of services and the challenges of providing

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120. See Scully Press Release, *supra* note 99.

121. Gladieux, *supra* note 13, at 101.

122. See Press Release, AAHP, AAHP Statement on Supreme Court Case of Rush Prudential HMO, Inc. v. Moran and State of Illinois (Jan. 16, 2002) (noting the importance of uniform regulations in the ERISA context in controlling the cost of benefit plans), available at [http://www.aahp.org/Content/NavigationMenu/About\\_AAHP/News\\_Room/Press\\_Releases/Default243.htm](http://www.aahp.org/Content/NavigationMenu/About_AAHP/News_Room/Press_Releases/Default243.htm).

123. See Richard Sorian & Judith Feder, *Why We Need a Patient's Bill of Rights*, 24 J. HEALTH POL. POL'Y & L. 1137, 1138 (1999).

124. See, e.g., 42 C.F.R. pt. 422, subpts. C, D, M, N (2003).

125. See FUCHS, *supra* note 13, at 28 tbl.1. Note that the Medicare Act of 2003, section 232, removes the conflict preemption provisions that exist under M+C and replaces them with a blanket express preemption scheme for the Medicare Advantage program.

126. Farrell, *supra* note 5, at 252.

127. See GERALDINE DALLEK, KAISER FAMILY FOUND., CONSUMER PROTECTIONS IN MEDICARE+CHOICE 18-19 (Dec. 1998), available at <http://www.kff.org/insurance/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=14673>.

128. See Scully Press Release, *supra* note 99 ("The Administration looks forward to working with Congress to preserve and improve Medicare+Choice . . ."). See also AAHP Press Release, *supra* note 2 ("Experience shows that when funded adequately by the federal government, Medicare+Choice offers seniors and disabled beneficiaries better benefits with lower out-of-pocket costs."); RICE & DESMOND, *supra* note 70, at 21 ("It is possible, however, that these trends will reverse if Congress pays HMOs considerably more money to treat Medicare beneficiaries."). But see ACHMAN & GOLD, *supra* note 93, at 13:

Experience to date suggests that increasing payments to health plans alone is not enough to solve the problems that plague Medicare managed care. . . . The trend suggests that policymakers should focus reform on Medicare's basic benefit package in order to provide the generous supplemental benefits common among managed care plans pre-BBA, instead of relying on more limited reform of the Medicare+Choice program.

prescription drug coverage for seniors,<sup>129</sup> M+C (now Medicare Advantage) could be the best option among imperfect choices for the future of public health insurance.<sup>130</sup> However, a push towards expanding premium support in Medicare may result in introducing new unregulated Medicare programs that will invite preemption challenges and problems akin to those seen under ERISA.

### *A. An Overview of Express and Implied Preemption Jurisprudence*

As Medicare continues to move toward the purchase of private insurance, whether in the form of managed care capitation payments, premium support, or other alternatives, the scope of federal limitations on state laws regulating health insurance have become increasingly important to Medicare beneficiaries. Federal preemption of state law occurs in two fundamental ways: "Congress expressly preempts state law when it attempts to define the extent to which a particular federal law will preempt state law"; and, "Congress impliedly preempts state law through federal legislation that occupies a field or conflicts with state law."<sup>131</sup> Evaluating the scope of federal express preemption requires courts to examine the meaning of statutory text, whereas implied preemption analysis involves an inference of Congressional intent to exclude state regulation in a particular area.<sup>132</sup> Conflict preemption considers the degree to which a state law is compatible with, or frustrates, the underlying objectives of a federal provision.<sup>133</sup> Furthermore, the existence of "an express preemption provision does not foreclose consideration of the implied preemption doctrines."<sup>134</sup> In the context of reformed Medicare managed care programs, the more limited the express federal preemption regulation is, the more litigation can be expected as states attempt to control the quality and content of the health care products purchased by Medicare when facing

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129. See President's Remarks in Grand Rapids, Michigan, 39 WEEKLY COMP. PRES. DOC. 119 (Jan. 29, 2003), available at <http://www.gpoaccess.gov/wcomp>; President's Remarks on Medicare Reform, 37 WEEKLY COMP. PRES. DOC. 1029 (July 12, 2001), available at <http://www.gpoaccess.gov/wcomp>.

130. But see Amy Goldstein, *Report Challenges Medicare Reform Bills; Budget Office Says Change Will Lead to Fewer Patients in Private Plans, Not More*, WASH. POST, July 23, 2003, at A2 (noting the Congressional Budget Office conclusion that the House and Senate reform bills passed in 2003 will fail to increase the number of elderly patients enrolled in private-sector alternatives to Medicare).

131. Karen A. Jordan, *The Shifting Preemption Paradigm: Conceptual and Interpretive Issues*, 51 VAND. L. REV. 1149, 1150-51 (1998).

132. *Id.* at 1151.

133. *Id.*

134. *Id.* at 1152.

only the more subjective implied preemption standards.<sup>135</sup>

### *B. Potential Preemption Problems in Unregulated Medicare Programs*

In order to avoid introducing current preemption problems experienced under ERISA-governed employer-sponsored health plans into any future Medicare programs, it is necessary for lawmakers to consider the complex issues of federalism involved.<sup>136</sup> State efforts at regulation in the ERISA context are complicated by inconsistent case law that has developed in the regulatory void caused by ERISA field preemption and insufficient federal regulation concerning private employee health plans.<sup>137</sup> In particular, the limited federal ERISA standards that do exist for information disclosure, coverage of benefits, and remedies for coverage disputes fall short of state and common law provisions.<sup>138</sup>

Two separate federal statutory provisions drive ERISA preemption. Section 514 of the Act preempts state laws that “relate to” an ERISA plan, thus affecting efforts to control plan design based on field preemption.<sup>139</sup> ERISA remedies are set forth in section 502, which expressly preempts any state law procedures concerning a challenge to a denial of benefits, provides only limited remedies to an aggrieved beneficiary, and preempts state efforts at increasing procedural safeguards.<sup>140</sup> An additional element of the

135. See ROBERT WOOD JOHNSON FOUND., *supra* note 73, at 3-4.; Greg Schwab, *State Regulation of Insurance Authority, Recent Developments, and Ohio Law*, MEMBERS ONLY, Feb. 12, 2001, at <http://www.lsc.state.oh.us/membersonly/124insurance.pdf>. See generally HEALTH INS. ASSOC. OF AM. (HIAA), *HEALTH INSURANCE LEGISLATION IN THE STATES: A REVIEW OF 2001 AND A FORECAST FOR 2002* (2001), available at [http://www.dmec.org/resources/files/state\\_review\\_forecast.pdf](http://www.dmec.org/resources/files/state_review_forecast.pdf) (summarizing legislation passed by various states); FUCHS, *supra* note 13, at 9-11.

136. See *Corp. Health Ins. v. Texas Dept. of Ins.*, 12 F. Supp. 2d 597, 616 n.7 (S.D. Tex. 1998). According to 5th Circuit Judge Vanessa Gilmore:

In light of the fundamental changes that have taken place in the health delivery system, it may be that the Supreme Court has gone as far as it can go in addressing this area and it should be for Congress to further define what rights a patient has when he or she has been negatively affected by an HMO's decision to deny medical care.

... If Congress wants the American citizens to have access to adequate health care, then Congress must accept its responsibility to define the scope of ERISA preemption and to enact legislation that will ensure every patient has access to that care.

*Id.*

137. See PATRICIA A. BUTLER, THE COMMONWEALTH FUND, *ERISA AND STATE HEALTH CARE ACCESS INITIATIVES: OPPORTUNITIES AND OBSTACLES 13-14* (Oct. 2000), available at [http://www.cmwf.org/programs/insurance/butler\\_erisa\\_411.pdf](http://www.cmwf.org/programs/insurance/butler_erisa_411.pdf).

138. ROSENBLATT ET AL., *supra* note 3, at 161.

139. See 29 U.S.C. § 1144(a) (2000).

140. See 29 U.S.C. § 1132 (2000). See also 29 U.S.C.A. § 1132 (West 2003).

ERISA preemption scheme is the insurance savings clause,<sup>141</sup> which is not included as an exception to the M+C (or Medicare Advantage) preemption provisions. While this clause permits state law to reach health plans covered by commercial insurance, the ERISA “deemer clause”<sup>142</sup> exempts the self-insured plans of the nation’s largest employers from state insurance laws by deeming their plans to not be in the business of insurance for the purpose of the savings clause.<sup>143</sup>

These provisions have created a regulatory vacuum where state laws are preempted but federal law has failed to fill the gap.<sup>144</sup> States generally cannot directly regulate private employer-sponsored health plans, mandate that employers even offer or pay for health insurance, tax private employer-sponsored health plans, or indirectly affect employer-sponsored health plans by imposing substantial costs on plans.<sup>145</sup> Furthermore, the favored status of self-insured plans and their freedom from state insurance regulation frustrates state efforts at implementing reforms that apply to all health plan beneficiaries.<sup>146</sup> In particular, beneficiaries face instability in benefits and coverage as a result of uncertain state laws concerning any-willing-provider laws, external review programs, stop-loss insurance, employer pay-or-play programs, employer health coverage tax credits, regulation of third party administrators, requirements that public health care access programs coordinate with employer-based coverage, payment of health care provider assessments to state agencies, and regulation of non-traditional providers.<sup>147</sup>

What has thus developed with ERISA-governed health plans is an environment where patient protections are not addressed by any uniform statute, and remedies for certain types of plan malfeasance are potentially available under state malpractice law while others are still preempted. While the harsh effect of the initially broad judicial interpretation of ERISA preemption has softened in the Supreme Court and some circuit courts,<sup>148</sup> beneficiaries of employer-sponsored health plans continue to face significant uncertainty as to the extent to which state law can protect their

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141. 29 U.S.C. § 1144(b)(2)(A).

142. 29 U.S.C. § 1144(b)(2)(B).

143. Farrell, *supra* note 5, at 264.

144. *Id.* at 265.

145. BUTLER, *supra* note 14, at 9 (noting that states generally are permitted to tax and regulate traditional insurers performing traditional insurance functions, multiple employer welfare arrangements such as jointly sponsored health coverage, and hospital rates charged to insurers; most importantly, from a beneficiary’s perspective, states may provide medical malpractice remedies for health plan negligence in the case of medical care delivery).

146. Farrell, *supra* note 5, at 265.

147. BUTLER, *supra* note 14, at 9.

148. ROSENBLATT ET AL. (Supp. 2001-02), *supra* note 7, at 100.

access to quality comprehensive health care. Left to the courts, ERISA preemption questions have not been answered consistently in either analysis or results.<sup>149</sup>

### C. Medicare+Choice as a Regulatory Model

The critical difference between ERISA and Medicare preemption is the ERISA regulatory vacuum and reliance on federal common law, as opposed to Medicare's explicit regulation of the terms of coverage, decision-making processes, certification requirements, and utilization management procedures, among other general regulations. Under M+C, the preemption provisions are supplemented with a detailed regulatory scheme concerning MCO M+C products.<sup>150</sup> The general test for Medicare preemption is whether a claim presented after exhaustion of administrative remedies per 42 U.S.C. §§ 405(g) and (h) "arises under" the Medicare Act.<sup>151</sup> The M+C statute contains additional specific provisions that generally preempt conflicting state laws<sup>152</sup> and specifically preempt state standards concerning benefit requirements, provider inclusion requirements, and coverage determinations (although modified in Medicare Advantage).<sup>153</sup> The CMS regulations contained in 42 C.F.R. Pt. 422 expound on these limitations.<sup>154</sup> However, CMS policy on general conflict preemption is to consider state law inconsistent with federal law only if adherence would prevent the plan or insurer from complying with a federal standard,<sup>155</sup> thus giving states more latitude to regulate certain aspects of Medicare-managed care plans under the Medicare "arises under" preemption standard than provided under ERISA's "relate to"<sup>156</sup> preemption standard.

149. Billee Elliott McAuliffe, *The Changing World of HMO Liability Under ERISA*, 22 J. LEGAL MED. 77, 79 (2001) (citation omitted).

150. ROSENBLATT ET AL. (Supp. 2001-02), *supra* note 7, at 473.

151. *Ardary v. Aetna Health Plans of Cal., Inc.*, 98 F.3d 496, 498-99 (9th Cir. 1996); *Freitag v. Sec. of Health & Human Res.*, No. CV-00-1095-HU, 2001 U.S. Dist. LEXIS 3307, at \*3 (D. Or. 2001); *Lifecare Hosps., Inc. v. Ochsner Health Plan, Inc.*, 139 F. Supp. 2d 768, 771 n.1 (W.D. La. 2001). *See also* *Foley v. Southwest Tex. HMO, Inc.*, 226 F. Supp. 2d 886, 893 (E.D. Tex. 2002) ("Any state law which has a connection with or reference to an employee benefit plan is generally preempted.")

152. 42 U.S.C. § 1395w-26(b)(3)(A) (2000). *See also* 42 U.S.C.A. § 1395w-26(b)(3)(A) (West 2003). Note that the Medicare Act of 2003, section 232, removes the conflict preemption provisions that exist under M+C and replaces them with a blanket express preemption scheme for the Medicare Advantage program.

153. 42 U.S.C. § 1395w-26(b)(3)(B)(i)-(iii). *See also* 42 U.S.C.A. § 1395w-26(b)(3)(B)(i)-(iii).

154. *See, e.g.*, 42 C.F.R. § 422.402(a) (2003); 42 C.F.R. § 422.402(b)(1)-(3) (2003).

155. CMS, MEDICARE MANAGED CARE MANUAL, CMS PUB. 86, ch. 10, § 50 (2002), available at <http://www.cms.hhs.gov> [hereinafter MEDICARE MANAGED CARE MANUAL].

156. 29 U.S.C. § 1144(a) (2000).

The result in Medicare managed care programs is a statutory and regulatory apparatus that provides uniformity in the interest of MCO administration and cost containment, plus delineated protections for beneficiaries concerning the amount and type of care to be delivered. In particular, Medicare managed care plans must meet federal requirements with respect to disclosure requirements<sup>157</sup> (including disclosure of physician incentive plans),<sup>158</sup> participation procedures,<sup>159</sup> interference with medical treatment advice (the prohibition on gag clauses),<sup>160</sup> prompt payment requirements,<sup>161</sup> organization determinations (utilization reviews),<sup>162</sup> and grievance procedures.<sup>163</sup>

Furthermore, the M+C regulations specifically preempt state standards concerning benefit mandates (including cost sharing), direct access to provider requirements (whether in-plan or out-of-plan), appeals and grievances with respect to M+C coverage determinations, inclusion and treatment of providers (such as any willing provider laws), as well as requirements relating to content, design, and review of marketing materials.<sup>164</sup> While the M+C provisions are extensive, they do not exclude consistent state standards in many areas,<sup>165</sup> thus allowing states to impose increased protections for plan beneficiaries consistent with their needs to maintain a provider market. This has been restricted by the broader preemption provisions in the 2003 Medicare reform legislation,<sup>166</sup> making the scope of Medicare Advantage regulations even more critical to beneficiary protections in areas formerly subject to state law. ERISA, by contrast, lacks such extensive program guidance, forcing courts to resolve

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157. 42 C.F.R. § 422.111 (2003).

158. 42 C.F.R. § 422.210 (2003).

159. 42 C.F.R. § 422.202 (2003).

160. 42 C.F.R. § 422.206 (2003).

161. 42 C.F.R. § 422.520 (2003).

162. 42 C.F.R. § 422.566 (2003).

163. 42 C.F.R. § 422.564 (2003).

164. MEDICARE MANAGED CARE MANUAL, *supra* note 155, at § 40.

165. *See id.* at § 50 (noting that the following standards and procedures are subject to general preemption only if state law is inconsistent with M+C standards: market conduct examinations, timely payment of claims standards, enforcement actions, unfair claim settlement standards governing the process for determination of benefits as opposed to the benefits themselves, investigation of consumer complaints, utilization review programs and standards, quality assurance programs, adequacy of provider network, filing and review of policy forms and rate filings, credentialing procedures (other than those affected by specific preemption on provider participation), agent licensing, filing and review of provider contracts, enforcement of loss-ratio standards, and standards and enforcement of commission limitations).

166. *See* Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173, §232 (2003).

complex issues of coverage design, the coverage process and the reach of state medical malpractice law in the MCO context.

#### *D. State Efforts to Regulate Managed Care in Light of Federal Preemption Law*

As noted in Part II.B, the Health Maintenance Organization (HMO) Act of 1973<sup>167</sup> sparked the growth of the managed care industry and set forth minimum benefit requirements for HMOs to become federally qualified. However, neither federal nor state law directly regulated managed care quality of care issues.<sup>168</sup> The lack of federal regulation of HMO quality of care allowed the states latitude to act and in recent years they have imposed significant controls on the delivery of managed care.<sup>169</sup> Continued state action is certain, as current efforts appear to be reacting to public pressure “based on anecdotal evidence or political appeal, rather than scientific evidence of their impact on quality of care.”<sup>170</sup>

States have historically played a primary role in the regulation of health care and insurance.<sup>171</sup> In 1945 Congress passed the McCarran-Ferguson Act<sup>172</sup> to ensure continued state authority over the insurance industry in the wake of the 1944 Supreme Court decision in *United States v. South-Eastern Underwriters Ass’n*,<sup>173</sup> which recognized insurance as an element of interstate commerce subject to Federal Commerce Clause power.<sup>174</sup> Although the McCarran-Ferguson Act grants states broad powers to regulate insurance, Congress still reserved the right to supersede state law in that area.<sup>175</sup> Thus, there is the potential for conflict as states legislate in the face of federal law affecting health care.

In absence of uniform federal standards for MCOs, all states have enacted laws governing the delivery of managed care and regulating managed care products with regard to both program structure and beneficiary rights.<sup>176</sup> Many statutes are based on the National Association

167. Pub. L. No. 93-222, 87 Stat. 914 (1973) (codified as amended at 42 U.S.C. § 300e(b)(1)(A-D)(2003)).

168. *Id.* at 2-3.

169. *Id.* at 4 (noting that “[f]rom 1994 to 1999, more than 1,000 managed care laws were enacted by state legislatures.”).

170. *Id.* at 3.

171. FUCHS, *supra* note 13, at 6. See generally Schwab, *supra* note 135.

172. 15 U.S.C. §§ 1011-1015 (2000).

173. 322 U.S. 533 (1944).

174. *Id.* at 539-46; ROSENBLATT ET AL., *supra* note 3, at 656.

175. Schwab, *supra* note 135, at 3 (citing 15 U.S.C. § 1012(b)).

176. ROBERT WOOD JOHNSON FOUND., *supra* note 73, at 3; FUCHS, *supra* note 13, at 15-16, 28 tbl.1; JILL A. MARSTELLER & RANDALL R. BOVBJERG, *supra* note 73, at 2-3. See generally Sorian & Feder, *supra* note 124, at 1139-41.



of Insurance Commissioners' (NAIC) HMO Model Act.<sup>177</sup> Consumer reaction also motivated the implementation of a broad spectrum of laws that went beyond the scope of the HMO Model Act, as states responded to patient complaints concerning coverage denials and cost-cutting practices dubbed the "managed care backlash."<sup>178</sup> The various state statutes address issues such as access to services and providers, quality assurance, insolvency protections, beneficiary grievance procedures, utilization review, minimum hospital stay requirements, provider participation and choice, disclosure of plan information, and general consumer protection provisions.<sup>179</sup>

These laws can be grouped into three general categories for the purposes of preemption analysis. The first area involves coverage design issues such as benefit mandates, prompt payment issues, and provider participation requirements.<sup>180</sup> The second area deals with the integrity of the coverage process itself, involving issues such as utilization and external review requirements, as well as prohibitions on physician disclosures, also known as gag clauses.<sup>181</sup> The third area concerns medical malpractice liability.<sup>182</sup> Although states have enacted similar forms of MCO regulation, the standards nationwide are by no means uniform.<sup>183</sup> Thus, the current HMO market faces a complex and unorganized regulatory scheme that is likely to continue.<sup>184</sup>

In the area of coverage design, the Massachusetts prescription drug mandate<sup>185</sup> is illustrative of the challenges faced by states attempting to establish minimum health benefits for their citizens. Prescription drug coverage has been a paramount issue in the health care reform debate.<sup>186</sup> While the M+C program was established, in part, to encourage the

177. FUCHS, *supra* note 13, at 15-17.

178. *Id.* at 17; ROBERT WOOD JOHNSON FOUND., *supra* note 73, at 3, 4; MARSTELLER & BOVBJERG, *supra* note 73, at 2.

179. FUCHS, *supra* note 13, at 18-27.

180. *See generally* MARSTELLER & BOVBJERG, *supra* note 73.

181. *Id.* at 5. *See also* ROBERT WOOD JOHNSON FOUND., *supra* note 73, at 4.

182. MARSTELLER & BOVBJERG, *supra* note 73, at 6.

183. ROBERT WOOD JOHNSON FOUND., *supra* note 73, at 4.

184. *Id.*

185. *See* MASS. GEN. LAWS ANN. ch. 176K, § 4 (West 1998); MASS. REGS. CODE tit. 211, § 71.23(5) (1998).

186. *See* President's Remarks in Grand Rapids, Michigan, *supra* note 129, at 119; *Testimony on a Medicare Prescription Drug Benefit: Before the Senate Finance Committee*, 106th Cong. (2000), available at <http://www.cms.hhs.gov/media> (noting the significance of prescription drug coverage and the need for a plan as a part of traditional Medicare, as well as the concern that large employers are considering cutting back on drug plans and the expensive nature of Medigap insurance).

availability of prescription drug benefits in managed care plans, it stopped short of a comprehensive prescription drug mandate.<sup>187</sup> Due to perceived ambiguity in the M+C preemption scheme, the Massachusetts Commissioner of Insurance issued a bulletin in 1998 requiring providers to continue to offer full prescription drug coverage in M+C plans as required by the Massachusetts statutes until the scope of federal regulation was determined conclusively in court.<sup>188</sup> The First Circuit decided the resultant case in 1999, holding that the M+C provisions preempted the Massachusetts prescription drug mandate.<sup>189</sup> The impact of this decision reflects the dilemma faced by states when fulfilling their traditional role of regulating health care in the face of limitations posed by federal programs. This problem would be exacerbated if a new federal program fails to provide an adequate substitute for the preempted state benefit.

In addition to prescription drug coverage, state-mandated benefit laws address coverage for “mental health parity, clinical trials, contraceptives, diabetes, cancer screenings and infertility” among other benefits.<sup>190</sup> Application of these provisions to M+C plans have also been frustrated by federal law. For example, California’s extensive benefit requirements, (including cost-sharing requirements, requirements for inclusion or treatment of providers, coverage determinations, and the content of marketing materials related to health care service plans) were held preempted by the M+C section of the Social Security Act by a federal district court decision in 2001.<sup>191</sup> The implication of these experiences in Massachusetts and California is that where gaps exist in federal health care plan design and preemption, state law will increasingly attempt to fill the void.<sup>192</sup>

Coverage design also includes protections for provider participation under Any Willing Provider (AWP) laws. These statutes respond to provider concerns about the inclusiveness of plan provider panels.<sup>193</sup> In January 2003, the Supreme Court heard arguments in a challenge to

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187. See Gold, *supra* note 97, at 121. See also DALLEK, *supra* note 127, at 18.

188. Mass. Div. of Ins., Bulletin 98-07 (July 28, 1998), available at [http://www.state.ma.us/doi/Bulletins/bulletins\\_98\\_07.html](http://www.state.ma.us/doi/Bulletins/bulletins_98_07.html).

189. Mass. Assoc. of HMOs v. Ruthardt, 194 F.3d 176, 177 (1st Cir. 1999).

190. HIAA, *supra* note 135, at 4.

191. See Cal. Assoc. of Health Plans v. Zingale, No. 00-06803 RSWL (MCX), 2001 U.S. Dist. LEXIS 21497, at \*6 (C.D. Cal. Aug. 27, 2001).

192. See HIAA, *supra* note 135, at 4-5 (providing forecast of 2002 state legislative activity).

193. ROBERT WOOD JOHNSON FOUND., *supra* note 73, at 3. See generally Childs, *supra* note 53 (analyzing “any willing provider” legislation).

Kentucky's AWP law,<sup>194</sup> eventually upholding the Sixth Circuit decision.<sup>195</sup> The Kentucky statute required HMOs to permit patients to visit any physician willing to meet the HMO's conditions of participation.<sup>196</sup> HMOs opposed the requirements, which hampered their ability to control costs, while patients supported the greater provider choice that would result.<sup>197</sup> The Supreme Court's decision that the Kentucky statute survived federal preemption under ERISA may have a significant effect on one of the most widely implemented patient protection measures.<sup>198</sup>

Managed care plan providers have recently pushed for implementation of specific standards for prompt payment of claims.<sup>199</sup> Payment delays were a significant problem in Texas and were eventually addressed in the Texas HMO Act.<sup>200</sup> In 2002, their application to Medicare was challenged and held preempted by the federal district court in the Medicare context, but not the ERISA context.<sup>201</sup> Unlike California's general HMO success in the last five years, HMOs have been struggling in Texas and continue to suffer financially.<sup>202</sup> These problems have sparked continued activity from the Texas legislature in the area of prompt payment and other managed care reforms.<sup>203</sup>

With regard to the integrity of the coverage process, states have acted to require utilization and external review of coverage and treatment decisions.<sup>204</sup> In 2002, the Maryland high court reviewed that state's

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194. KY. REV. STAT. ANN. § 304.17A-110(3) (Banks-Baldwin 1995).

195. See *Ky. Ass'n of Health Plans, Inc. v. Miller*, 123 S. Ct. 1471, 1479 (2003). See also Charles Lane, *Court Hears Arguments on Ky. HMO Law*, WASH. POST, Jan. 15, 2003, at A6; Edward Walsh, *Supreme Court Sides with States on HMOs*, WASH. POST, Apr. 3, 2003, at A6.

196. Lane, *supra* note 195, at A6.

197. *Id.*

198. See ROBERT WOOD JOHNSON FOUND., *supra* note 73, at 9. But see Walsh, *supra* note 196 ("[T]here was disagreement over the practical effect [the Kentucky HMO decision] would have on the health care system. Some experts said it would have little immediate impact, in part because of the changes in the industry since the [sic] Kentucky enacted the law in 1994.").

199. HIAA, *supra* note 135, at 3.

200. TEX. INS. CODE ANN. § 20A.18B(c)(1) (Vernon 2002). See generally T. Daniel Hollaway, *The Truth About Texas' Prompt Payment Laws for Healthcare Providers*, at <http://www.houstonlaw.com/htmlversion/article5.htm> (last visited Oct. 28, 2003).

201. See *Foley v. S.W. Tex. HMO, Inc.*, 226 F. Supp. 2d 886, 907 (E.D. Tex. 2002).

202. Patricia V. Rivera, *HMOs on Life Support in Texas*, DALLAS MORNING NEWS, Jan. 27, 2002, at 1A.

203. *Id.*

204. HIAA, *supra* note 135, at 2. See generally KAREN POLLITZ ET AL., KAISER FAMILY FOUND., *ASSESSING STATE EXTERNAL REVIEW PROGRAMS AND THE EFFECTS OF PENDING FEDERAL PATIENT'S RIGHTS LEGISLATION* (last rev. May 2002), available at <http://www.kff.org/insurance/externalreviewpart2rev.pdf>

utilization and external review statute in the ERISA context.<sup>205</sup> It found that federal ERISA law did not preempt application of the statute, as the Maryland law was not in conflict with federal law.<sup>206</sup> A significant number of states have similar utilization and external review provisions,<sup>207</sup> which provide important protections<sup>208</sup> and recourse for patients denied care by a plan.<sup>209</sup> While current Medicare and M+C provisions address utilization and external review procedures,<sup>210</sup> HMO compliance with federal requirements has been found lacking.<sup>211</sup> Thus, there is impetus for continued state action in this area.<sup>212</sup>

States have also addressed the use of gag clauses to restrict provider disclosure of treatment options and provider financial incentives.<sup>213</sup> These statutes protect physicians and patients from HMO policies aimed at preventing discussion of treatment options not covered by the plan, as well as ensuring patient awareness of any cost-cutting incentives that may affect treatment recommendations.<sup>214</sup> Under current Medicare law, such clauses in provider contracts are prohibited.<sup>215</sup> In the absence of such provisions, the applicability of state requirements would pose a significant legal issue.

Finally, states have sought to expand health plan liability for medical malpractice.<sup>216</sup> Current Supreme Court jurisprudence indicates that certain claims against MCOs and their physicians may be subject to state law.<sup>217</sup> MCO malpractice liability depends on the nature of the claims raised, the characteristics of the managed care group purchaser, and the relation of

205. See *Conn. Gen. Life Ins. Co. v. Ins. Comm'r for Md.*, 810 A.2d 457, 457 (Md. 2002).

206. *Id.* at 435.

207. See HIAA, *supra* note 135, at 2.

208. David Dranove & Kathryn E. Spier, *A Theory of Utilization Review* (Ctr. For the Study of Ind. Orgs., Working Paper No. 0013, Oct. 18, 2000) (using an economic analysis to conclude that utilization review does improve patient welfare), at <http://www.csio.econ.nwu.edu/Papers/2000>.

209. Tracy E. Miller, *Center Stage on the Patient Protection Agenda: Grievance and Appeal Rights*, 26 J.L. MED. & ETHICS 89, 89 (1998).

210. See 42 C.F.R. §§ 417.101-.126 (2003); 42 C.F.R. §§ 422.564, .566.

211. Miller, *supra* note 209, at 90.

212. See generally Alexander S. Wylie, *California's Managed Care Reform Moves to a New Level*, 31 McGEORGE L. REV. 534 (2002) (discussing California's recent efforts at managed care utilization and external review reform).

213. FUCHS, *supra* note 13, at 27.

214. *Id.*

215. 42 C.F.R. §§ 422.206(a) (2003); 42 C.F.R. § 422.210(b) (2003). See generally Douglas A. Hastings, *Patient Rights Meet Managed Care: Understanding the Underlying Conflicts*, 31 J. HEALTH L. 241 (1998).

216. HIAA, *supra* note 135, at 1 (noting that, in 2001, health plan liability was introduced in twenty-six states).

217. ROSENBAUM, *supra* note 7, at 2.

state and federal law concerning those purchasers.<sup>218</sup> The central issue is whether the injury resulted from a treatment-related coverage decision, in which case it would be preempted under ERISA and Medicare, or from the quality of care provided, in which case it would likely be subject to state law.<sup>219</sup> Whether Congress will act to alter this current effect of federal preemption remains unclear,<sup>220</sup> but it, too, is a vital consideration for any reformed federal healthcare program.

### *E. Preemption Issues Affecting Coverage Design*

In the area of coverage design, lack of clear ERISA preemption standards has created uncertainty in the ability of states to regulate ERISA plans. The Supreme Court has interpreted the Supremacy Clause<sup>221</sup> to require federal preemption of state law by express provision, by implication, or by a conflict between federal and state law.<sup>222</sup> The early Supreme Court ERISA cases applied a broad interpretation of the scope of ERISA express and implied preemption.<sup>223</sup> The lower courts generally followed this unregulated market approach as well.<sup>224</sup> Thus, states were frustrated by ERISA in their attempts to set minimum statewide benefit mandates.<sup>225</sup> For example, in *Shaw v. Delta Air Lines, Inc.*,<sup>226</sup> the Supreme Court analyzed the meaning of the statutory definition of ERISA preemption as applied to New York's pregnancy benefit legislation and found that law preempted. The ERISA statute provides that preemption is triggered when state laws "relate to"<sup>227</sup> an ERISA plan. The Court in *Shaw* interpreted the "relate to" provision to mean "a connection with or reference to such a plan" and found the requirement in New York's Disability Benefits Law (for payment of sick-leave benefits to pregnant employees who could not work) to affect plan structure and thus held it related to the plan.<sup>228</sup> As a result, the

218. *Id.*

219. *See id.*

220. *Id.*

221. U.S. CONST. art. VI.

222. N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 654 (1995). *See generally* Jordan, *supra* note 131, at 1155-56 (noting the distinction between express preemption based on statutory language, and implied preemption comprised of both field preemption, which is based on Congressional intent to occupy a particular area with federal law, and conflict preemption, where state law contradicts federal law).

223. ROSENBLATT ET AL. (Supp. 2001-02), *supra* note 7, at 100.

224. *Id.*

225. *See* BUTLER, *supra* note 137, at 3; FUCHS, *supra* note 13, at 7.

226. 463 U.S. 85, 108 (1983).

227. 29 U.S.C. § 1144(a) (2000).

228. *Shaw*, 463 U.S. at 96-97.

Supreme Court established a standard of preemption of claims that included even those claims not specifically designed to affect ERISA plans, as well as claims that may have had only an indirect effect on such plans.<sup>229</sup> Thus, ERISA displaces not only state laws that may conflict with federal regulations, but state laws that may otherwise be compatible with federal provisions, even though once preempted there is no federal regulation on point to fill the void.<sup>230</sup>

The broad reading of ERISA Section 514's preemption language was continued in another early benefit mandates case. In *Metropolitan Life Insurance Co. v. Massachusetts*, the Supreme Court upheld Massachusetts' mental health benefit requirement as a law regulating insurance.<sup>231</sup> However, this was only a partial victory for state authority because the statute still would not reach beneficiaries of self-insured plans based on the ERISA deemer clause, limiting the scope of potential state protection for a significant number of individuals.<sup>232</sup> In subsequent cases, courts held ERISA preempted claims based on common law or state statute if they "expressly refer to ERISA plans, or are essentially claims for plan benefits, claims of improper administration of the plan, claims that depend on the existence of an ERISA plan, or claims that affect the provision of benefits under a plan."<sup>233</sup> The result of the Supreme Court's attempt at clarifying the ambiguous "relate to" statutory language in cases such as *Shaw* and *Metropolitan Life* was "doctrinal confusion and 'chaos' in the lower courts."<sup>234</sup>

The impact of the initial breadth of ERISA preemption of state law was tempered by a shift in Supreme Court jurisprudence in 1995. In *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Insurance Co.*,<sup>235</sup> the Court reined in its expansive reading of the "relate to" standard by looking beyond the common sense textual meaning to Congressional purposes underlying ERISA and the general presumption against preemption of areas of traditional state legislation.<sup>236</sup> Under this narrower

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229. Karla S. Bartholomew, *ERISA Preemption of Medical Malpractice Claims in Managed Care: Asserting a New Statutory Interpretation*, 52 VAND. L. REV. 1131, 1143 (1999).

230. Farrell, *supra* note 5, at 261.

231. 471 U.S. 724, 757 (1985).

232. See FUCHS, *supra* note 13, at 7.

233. Farrell, *supra* note 5, at 262.

234. Bartholomew, *supra* note 229, at 1133 (citing Catherine L. Fisk, *The Last Article About the Language of ERISA Preemption? A Case Study of the Failure of Textualism*, 33 HARV. J. ON LEGIS. 35, 60-82 (1996)).

235. 514 U.S. 645 (1995).

236. ROSENBLATT ET AL. (Supp. 2001-02), *supra* note 7, at 100.

approach, state laws “will not be preempted because they relate to employer health plans unless they have a direct economic effect that essentially binds plan administrators to particular benefits structures.”<sup>237</sup> The trend in Supreme Court jurisprudence, as evidenced by *Travelers Insurance*, indicates a greater tolerance for state legislation addressing certain aspects of managed care plans. However, the extent of state authority over an employer-sponsored health benefits plan still remains unclear, as courts remain divided on the scope of ERISA preemption.<sup>238</sup>

This division is highlighted in the context of applying ERISA to AWP laws, where courts have split on the issue of preemption.<sup>239</sup> The basic legal framework created by ERISA promotes a free-market environment for MCOs to contract with providers, which raises significant issues concerning the ability of MCOs to control costs.<sup>240</sup> Utilization profiles provide an economic snapshot of provider cost efficiency that can influence the inclusion or exclusion of particular providers as MCOs form and maintain networks.<sup>241</sup> Proponents of AWP laws point to a need to insulate physicians from arbitrary exclusion from networks and to protect the ability of beneficiaries to have meaningful choice in provider selection.<sup>242</sup> Opponents have argued such efforts reflect the desire of physicians to protect their income levels despite the need for MCOs to control escalating health care costs through selective contracting.<sup>243</sup>

In *Stuart Circle Hospital Corp. v. Aetna Health Management*,<sup>244</sup> decided two years before *Travelers Insurance*, the Fourth Circuit applied a broad preemption analysis to find that Virginia’s Preferred Provider Organization AWP law did relate to employee benefit plans covered under ERISA, but was saved as an insurance regulation.<sup>245</sup> However, a year after *Travelers Insurance* relaxed the sweep of ERISA preemption, the Fifth Circuit struck down a Louisiana AWP law that went beyond regulation of insurance in an effort to reach self-insured employer plans.<sup>246</sup> Washington State was able to avoid the fate of the Louisiana AWP law by drafting a provider mandate

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237. Farrell, *supra* note 5, at 266.

238. ROSENBLATT ET AL. (Supp. 2001-02), *supra* note 7, at 100-01 (noting the commitment to unregulated markets in the Fourth and Fifth Circuits in contrast to the general trend toward a more regulatory and less market-deferential approach).

239. Farrell, *supra* note 5, at 270.

240. ROSENBLATT ET AL. (Supp. 2001-02), *supra* note 7, at 403.

241. *Id.* at 402.

242. Childs, *supra* note 53, at 200, 205.

243. *Id.* at 200, 206.

244. 995 F.2d 500 (4th Cir. 1993).

245. *Id.* at 502.

246. See *Cigna Healthplan of La., Inc. ex rel. Ieyoub v. Louisiana*, 82 F.3d 642, 645 (5th Cir. 1996); Farrell, *supra* note 5, at 270.

## Impact of Medicare Preemption on State Laws

statute<sup>247</sup> more limited in scope that avoided reference to an ERISA plan. This statute was upheld in 1999 by *Washington Physicians Service Assoc. v. Gregoire*.<sup>248</sup> The *Gregoire* court characterized HMOs as insurers<sup>249</sup> yet other cases in both the Fifth and Eighth Circuits have since struck down AWP laws based on the conclusion that the HMOs involved were not insurers.<sup>250</sup>

The issue of ERISA preemption of state AWP laws was heard by the Supreme Court in January 2003,<sup>251</sup> on appeal from the Sixth Circuit's decision in *Kentucky Ass'n of Health Plans v. Nichols*.<sup>252</sup> The Kentucky statutes at issue prohibited discrimination against any provider willing to meet plan conditions of participation within the plan's geographic coverage area, and specifically regulated plan interaction with chiropractors.<sup>253</sup> The district court found that the laws both referred to and had a connection with ERISA covered employee benefit plans,<sup>254</sup> but were saved from ERISA preemption as insurance regulations.<sup>255</sup> The Sixth Circuit agreed with the district court's finding that "the AWP statutes did more than just indirectly affect the cost of ERISA plans; the AWP statutes mandated benefit structures."<sup>256</sup> Furthermore, the court characterized HMOs fundamentally as insurers; thus, the Kentucky laws still fell within the ERISA insurance savings provision.<sup>257</sup> However, in a strong dissent Judge Kennedy noted that, because Kentucky's AWP laws merely regulated the "business of insurers" by structuring their provider networks irrespective of the risks underwritten, they should not qualify for the protection of ERISA's insurance savings clause that deals with the "business of insurance" (i.e.,

247. See BUTLER, *supra* note 14, at 23 ("Along with requiring managed care and other insurance plans to cover specific services in their policies, most states have long mandated that insurers pay certain categories of providers—such as chiropractors and optometrists—if they render covered services.").

248. 147 F.3d 1039, 1042-43 (9th Cir. 1998). See ROSENBLATT ET AL. (Supp. 2001-02), *supra* note 7, at 418.

249. *Gregoire*, 147 F.3d at 1046.

250. See BUTLER, *supra* note 14, at 24 & n.87 (citing *Tex. Pharmacy Assoc. v. Prudential Ins. Co.*, 105 F.3d 1035 (5th Cir. 1997); *Prudential Ins. Co. v. Nat'l Park Med. Ctr.*, 154 F.3d 812 (8th Cir. 1998)).

251. Lane, *supra* note 195, at A6.

252. 227 F.3d 352 (6th Cir. 2000), *aff'd sub nom. Ky. Assoc. of Health Plans, Inc. v. Miller*, 123 S. Ct. 1471 (2003).

253. *Id.* at 355.

254. *Id.* at 358.

255. *Id.* at 355.

256. *Id.* at 362.

257. *Id.* at 365 ("The only distinction between an HMO (or HCSC) and a traditional insurer is that the HMO provides medical services directly, while a traditional insurer does so indirectly by paying for the service." (citations omitted)).



allocating risk between the insurer and insured).<sup>258</sup>

The Supreme Court disagreed with the *Nichols* dissent and upheld the Sixth Circuit.<sup>259</sup> The ruling was a setback for the MCO industry, which views AWP laws as a significant impediment to a vital cost-saving feature of managed care.<sup>260</sup> At oral argument, Justice Scalia noted that the proposition that Kentucky's AWP law regulated insurance was at odds with the rule in *Group Life & Health Ins. v. Royal Drug*,<sup>261</sup> which focused on risk allocation as the primary element of insurance.<sup>262</sup> Even though the Sixth Circuit's decision in *Nichols* was upheld and some AWP laws may escape ERISA preemption, the fate of all AWP laws remains unclear. Statutes that reach beyond the protection of the ERISA insurance savings clause are in jeopardy, and self-insured plans that remain free from state AWP requirements can still exclude willing providers from their networks.<sup>263</sup> While, in *Miller*, the Supreme Court attempted to provide some clarity on the AWP issue, ERISA jurisprudence as a whole will continue to be problematic absent Congressional action.<sup>264</sup>

The absence of an insurance savings clause in M+C does not create an AWP issue in the current M+C program because provider participation is addressed by CMS regulations.<sup>265</sup> That of course would change if a new Medicare premium support program did not also address AWP and other plan design issues in the continued absence of an insurance savings clause in Medicare. At present, the boundaries of M+C preemption concerning program design are more defined<sup>266</sup> than in the less regulated ERISA context. As a result, states have been largely unsuccessful in attempts to avoid preemption of mandatory benefit programs as applied to Medicare

258. *Nichols*, 227 F.3d at 380-81 (Kennedy, J., dissenting).

259. See *Ky. Assoc. of Health Plans, Inc. v. Miller*, 123 S. Ct. 1471 (2003). See also Edward Walsh, *Supreme Court Sides with States on HMOs*, WASH. POST, Apr. 3, 2003, at A6.

260. See Lane, *supra* note 195, at A6 (quoting Robert N. Eccles, attorney for the Kentucky Association of Health Plans: "any willing provider' laws increase the cost of providing HMO benefits by 15 percent, thus defeating the purpose of an institution that won predominance in American health care because it saved employers money on health benefits for their employees.").

261. 440 U.S. 205 (1979).

262. See Lane, *supra* note 195, at A6 (quoting Justice Scalia: "I want some rule of law that we can adhere to. I thought we had one in *Royal Drug*.").

263. Farrell, *supra* note 5, at 270.

264. See *Nichols*, 227 F.3d at 383 (Kennedy, J., dissenting: "I agree with the Eighth Circuit's observation in *Prudential Ins. Co.* that, 'it is for Congress, not the courts, to reassess ERISA in light of modern insurance practices and the national debate over health care.'" (citation omitted)).

265. See generally 42 C.F.R. § 422 (2003).

266. See generally MEDICARE MANAGED CARE MANUAL, *supra* note 155.

managed care plans.<sup>267</sup>

In *Massachusetts Association of HMOs v. Ruthardt*,<sup>268</sup> the Massachusetts prescription drug mandate was held preempted along with all other state benefit requirements.<sup>269</sup> The Massachusetts Commissioner of Insurance had attempted to enforce a state law requiring supplemental providers to offer at least one plan that included unlimited outpatient prescription drug coverage.<sup>270</sup> The First Circuit did not accept Massachusetts' argument that the mandatory prescription drug benefit requirement should be analyzed under the M+C conflict preemption provisions. The State argued that because prescription drugs were not "covered benefits" under the M+C program, the Massachusetts requirement for additional benefits was not inconsistent with federal law.<sup>271</sup> In rejecting that position, the court focused on the three enumerated areas of benefit requirements, inclusion and treatment of providers, and coverage determinations as expressly preempted based on M+C statutory provisions.<sup>272</sup>

In reaching that conclusion, the *Ruthardt* court noted that express preemption analysis includes a determination of the scope of the preemption derived from Congressional intent.<sup>273</sup> The court supported its analysis of Congressional intent with a review of the legislative history surrounding the M+C preemption provisions.<sup>274</sup> It noted the absence of any indication that Congress sought to limit federal preemption of state benefit requirements to those in direct conflict with federal law, and in fact intended for the federal government alone to establish the "covered benefits" under M+C.<sup>275</sup> Congress had, in fact, considered provisions allowing states to impose more stringent benefit mandates than those now contained in the federal program, but that language was eliminated by the conference committee.<sup>276</sup> The court concluded that the M+C preemption scheme established a rule of general conflict preemption in the first section of the statute, and per se preemption of the three enumerated areas in the

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267. See M. Alexander Otto, *M+C Plans Harness Preemption Clause to Duck Prompt Pay Rules*, 13 BNA'S MEDICARE REP. 254 (2002), available at <http://subscript.bna.com/SAMPLES/mcr.nsf>.

268. 194 F.3d 176 (1st Cir. 1999).

269. *Id.* at 185.

270. *Id.* at 177, 178.

271. *Id.* at 180.

272. *Id.*

273. *Id.* at 179.

274. *Ruthardt*, 194 F.3d at 184.

275. *Id.* (citing H.R. Conf. Rep. No. 105-77, at 638, reprinted in 1997 U.S.C.C.A.N. 176, 259).

276. *Id.* at 184-85.

second section.<sup>277</sup> Thus, under the First Circuit's analysis the scope of M+C preemption of state benefit mandates is complete, whether or not the state law conflicts with M+C benefits or merely seeks to augment them.

Likewise in *California Ass'n of Health Plans v. Zingale*,<sup>278</sup> the U.S. District Court for the Central District of California granted summary judgment in favor of the California Association of Health Plan's motion challenging the applicability of 122 provisions of the California Health & Safety Code on M+C preemption grounds.<sup>279</sup> The Court's August 2001 ruling held that "[a]ll California State standards relating to benefit requirements (including cost-sharing requirements), requirements relating to the inclusion or treatment of providers, coverage determinations (including related appeals and grievance procedures) and marketing materials [that] may concern M+C plans in California" were superceded by the M+C preemption provisions.<sup>280</sup> The *Zingale* ruling thus reinforces the principle contained in the First Circuit's holding in *Ruthardt* that the M+C express preemption provisions preempt all state standards relating to benefit requirements in M+C plans.

Medicare+Choice preemption has also been recently addressed in the context of state efforts to regulate prompt payment of providers by participating plans. In a July 2002 decision the Texas District Court reviewed provider prompt payment claims in both the ERISA and Medicare contexts.<sup>281</sup> In noting a distinction between ERISA and M+C preemption provisions, the *Foley* court held that state law claims for prompt payment were not completely preempted by ERISA section 502 and thus remanded them to state court for an ERISA section 514 determination.<sup>282</sup> In the ERISA context, the plaintiff providers were seen as neither plan participants

277. See *id.* at 183. According to the first section of the statute: "The standards established under this subsection shall supercede any State law or regulation (including standards described in subparagraph (B)) with respect to M+C plans which are offered by M+C organizations under this part to the extent such law or regulation is inconsistent with such standards." See 42 U.S.C. § 1395w-26(b)(3)(A) (2000). See also 42 U.S.C.A. § 1395w-26(b)(3)(A) (West 2003). According to the second section of the statute: "State standards relating to the following are superceded under this paragraph: (i) Benefit requirements (including cost-sharing requirements); (ii) Requirements relating to inclusion or treatment of providers; (iii) Coverage determinations (including related appeals and grievance processes); [and] Requirements relating to marketing materials and summaries and schedules of benefits regarding a Medicare+Choice plan." See 42 U.S.C. §1395w-26(b)(3)(B)(i)-(iv). See also 42 U.S.C.A. §1395w-26(b)(3)(B)(i)-(iv).

278. See 2001 WL 1334987 (C.D. Cal. Aug. 29, 2001). See generally Wylie, *supra* note 212, for a discussion of California's recent managed care reform efforts.

279. Otto, *supra* note 267, at 254.

280. *Zingale*, 2001 WL 1334987, at \*1.

281. *Foley v. S.W. Tex. HMO, Inc.*, 226 F. Supp. 2d 886, 890 (E.D. Tex. 2002).

282. *Id.* at 895.

nor beneficiaries, and even if the court were to hold that the law related to ERISA, it would be saved as an insurance regulation.<sup>283</sup>

However, in *Foley*, claims for services under Medicare did arise under the Medicare Act requiring exhaustion of administrative remedies.<sup>284</sup> Under a Medicare analysis, the court found the breach of contract claim under the prompt payment law to be inextricably intertwined with the Medicare Act, and thus preempted as a claim “arising under” the Act.<sup>285</sup>

The *Foley* case highlights the contradictions in current federal regulation of managed care providers caused by varying limits on federal preemption and pointing to the need for a more uniform vision of managed care regulation. Thus, the ability of states to mandate aspects of coverage design is uncertain in the ERISA context, with courts applying varying degrees of the “relate to” analysis to either uphold or preempt specific measures, with many statutes surviving to apply to some, but not all, employer-sponsored plans based on the application of the ERISA insurance savings clause. In the Medicare context, however, the “arises under” standard plus the M+C preemption provisions have thus far yielded more predictable results in a program with a far more comprehensive regulatory scheme. What occurs in the ERISA context is a frustrating negation of state law with inadequate federal regulation of managed care providers to fill the void. However, under Medicare the landscape is markedly different. While the express preemption of benefit mandates in M+C trumps many state requirements, the extensive M+C regulations provide essential beneficiary protections absent in ERISA-governed health plans and clearly leave certain areas to the states to regulate.

#### *F. Preemption Issues Affecting the Coverage Process*

While ERISA mandates that MCOs implement some mechanism for internal review of benefit denials<sup>286</sup> and provides a right to judicial review of a denial of covered benefits,<sup>287</sup> it sets forth no standards for such review. Furthermore, ERISA does not address any requirement for external review, and thus beneficiaries are left with the provisions of ERISA section 502 and limited judicial review of coverage determinations.<sup>288</sup> In the context of the integrity of the coverage process itself, ERISA jurisprudence under section

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283. *Id.* at 897-98.

284. *Id.* at 905.

285. *Id.* at 905-06.

286. *See* 29 U.S.C. § 1133(2) (2000).

287. *See* 29 U.S.C. § 1132(a)(1)(B) (2000). *See also* 29 U.S.C.A. § 1132(a)(1)(B) (West 2003).

288. ROSENBLATT ET AL. (Supp. 2001-02), *supra* note 7, at 445.

502 reflects tension concerning the issue of whether a claim is characterized as one of quality versus quantity of care.<sup>289</sup> The practical result of ERISA section 502 preemption is that the legal remedies available to plan beneficiaries are generally limited to enforcement of benefits due under the terms of the plan contract.<sup>290</sup> That limitation on beneficiary protection from employer-sponsored health plan malfeasance is compounded by the ineffective structure of state health insurance regulatory enforcement and the absence of U.S. Department of Labor intervention in ERISA plan regulation and supervision.<sup>291</sup>

Early state tort and contract challenges to employer-sponsored plan coverage decisions were viewed as difficult questions by the courts and held by some as saved from ERISA preemption as laws regulating insurance.<sup>292</sup> This lower court analysis met with a harsh rule set forth by the Supreme Court's unanimous 1987 opinion in *Pilot Life Insurance Co. v. Dedeaux*.<sup>293</sup> In a tragic case, the plaintiff Everate W. Dedeaux challenged Pilot Life's repeated termination and reinstatement of his disability benefits on state law bad faith breach of contract, breach of fiduciary duty and fraud theories.<sup>294</sup> The Supreme Court's denial of these claims on preemption grounds focused on the detailed provisions of ERISA section 502(a) as reflecting Congressional intent to set forth:

[A] comprehensive civil enforcement scheme that represents a careful balancing of the need for prompt and fair claims settlement procedures against the public interest in encouraging the formation of employee benefit plans. The policy choices reflected in the inclusion of certain remedies and the exclusion of others under the federal scheme would be completely undermined if ERISA-plan participants and beneficiaries were free to obtain remedies under state law that Congress rejected in ERISA.<sup>295</sup>

Although *Pilot Life* held that pure eligibility decisions fall within ERISA preemption, the issue of mixed eligibility and treatment decisions remained unresolved.<sup>296</sup> That issue was addressed in 1992 by *Corcoran v. United*

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289. BUTLER, *supra* note 14, at 83.

290. ROSENBLATT ET AL. (Supp. 2001-02), *supra* note 7, at 96.

291. *Id.* at 97.

292. *Id.* at 112.

293. 481 U.S. 41 (1987).

294. *Id.* at 43.

295. *Id.* at 54. See generally ROSENBLATT ET AL., *supra* note 3, at 173-77 (discussing the legislative history of the ERISA preemption provisions).

296. See BUTLER, *supra* note 14, at 25.

*Healthcare, Inc.*<sup>297</sup> The Fifth Circuit upheld a dismissal of a wrongful death claim that arose from a South Central Bell health plan denial of inpatient hospitalization for a high-risk pregnancy.<sup>298</sup> United Healthcare, the plan administrator, conducted a utilization review of Mrs. Corcoran's request for inpatient treatment due to complications with her pregnancy and authorized limited home nursing care instead.<sup>299</sup> Mrs. Corcoran's fetus went into distress and died during a time when no nurse was present.<sup>300</sup> The court wrestled with the characterization of the MCO utilization review process as either a determination of benefits under the plan or a medical treatment decision.<sup>301</sup> The court concluded that, "United makes medical decisions as part and parcel of its mandate to decide what benefits are available under the Bell plan," and that the holding of *Pilot Life* preempted any state law claims concerning plan benefits.<sup>302</sup> As a result, the *Corcoran* decision has been described as representing "one of the nightmare scenarios of utilization review of managed care that commentators have been forecasting for years."<sup>303</sup> This is due to the "perverse incentive" that ERISA preemption has created for MCOs to "make medically unsupportable and dangerous utilization review decisions in complex cases" with no likelihood of facing any successful claim for damages.<sup>304</sup>

In contrast to *Corcoran's* denial of a claim under ERISA based on the Fifth Circuit's characterization of the suit as a demand for benefits, the Third Circuit in *Dukes v. U.S. Healthcare, Inc.* did not find preemption where the claim was viewed as dealing with the quality of treatment, not a withholding of benefits.<sup>305</sup> In a wrongful death action arising from a failure to perform blood tests to detect low blood sugar, the plaintiff's state malpractice claim was challenged by the defendant HMO as a preempted claim for benefits under an ERISA plan<sup>306</sup> where the medical care received was itself the plan benefit.<sup>307</sup> As in *Pilot Life*, Congressional intent was cited as a basis for the decision, but with a different focus.<sup>308</sup> The court viewed the purpose of ERISA section 502 as to ensure availability of

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297. 965 F.2d 1321 (5th Cir. 1992).

298. *Id.* at 1322.

299. *Id.* at 1324.

300. *Id.*

301. *Id.* at 1329-30.

302. *Id.* at 1332.

303. ROSENBLATT ET AL., *supra* note 3, at 1011.

304. *Id.* at 1046.

305. *See* 57 F.3d 350, 351-52 (3d. Cir. 1995).

306. *Id.* at 352-53.

307. *Id.* at 356.

308. *See id.* at 357; Bartholomew, *supra* note 229, at 1158.

promised benefits, but not to create a federal scheme to control the quality of those benefits.<sup>309</sup> The court noted that, “[q]uality control of benefits, such as the health care benefits provided here, is a field traditionally occupied by state regulation and we interpret the silence of Congress as reflecting an intent that it remain such.”<sup>310</sup> The *Dukes* court also distinguished the role of the HMO in *Corcoran*, which conducted the utilization review to determine benefit coverage, from the broader role of the HMO in *Dukes*, which also arranged for medical treatment of the plan participants.<sup>311</sup> After *Dukes*, courts struggled with characterization analysis as they attempted to distinguish between cases raising issues of denial of benefits or challenges to the quality of care.<sup>312</sup>

In 2000, the Supreme Court attempted to clarify the quality-quantity issue highlighted in *Corcoran* and *Dukes*. In *Pegram v. Herdrich*, the Court held that mixed decisions involving medical judgment and plan coverage are outside ERISA and, therefore, subject to state malpractice law.<sup>313</sup> Justice Souter wrote that Congress did not intend that treatment decisions made by an HMO’s physician employees be considered fiduciary acts within the meaning of ERISA provisions.<sup>314</sup> He further noted that to find otherwise would mean “nothing less than elimination of the for-profit HMO,”<sup>315</sup> which would clearly run afoul of express Congressional intent.<sup>316</sup>

While *Pegram*’s holding opened the door for certain state medical malpractice claims against mixed eligibility and treatment decisions by plan administrators, the reach of *Pegram* has been widely debated by legal scholars.<sup>317</sup> It does appear that, without so stating, *Pegram* has overruled the *Corcoran* holding that mixed eligibility and treatment decisions were claims for benefits under the plan. However, other state law claims such as fraud and breach of contract remain foreclosed, so that the harsh result seen in *Pilot Life* in the context of a denial of benefits may reoccur. Although there are limits to ERISA plan immunity from state law claims, such as the *Unum Life Insurance Co. of America v. Ward* decision upholding applicability of California’s notice-prejudice rule to an ERISA section 502 claim for disability benefits,<sup>318</sup> the scope of ERISA preemption of state laws

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309. *Dukes*, 57 F.3d at 357.

310. *Id.*

311. *See id.* at 359-61.

312. Bartholomew, *supra* note 229, at 1158-59 & nn.198-99.

313. *Pegram v. Herdrich*, 530 U.S. 211, 237 (2000).

314. *Id.* at 231.

315. *Id.* at 233.

316. *See id.*

317. ROSENBAUM, *supra* note 7, at 13.

318. *See Unum Life Ins. Co. of Am. v. Ward*, 526 U.S. 358, 373 (1999).

that affect the integrity of the coverage process, apart from medical malpractice actions, remains broad.<sup>319</sup>

Concerns over the quality of internal plan utilization review decisions are augmented by significant state efforts to improve access to independent external review of plan treatment decisions.<sup>320</sup> In *Rush Prudential HMO, Inc., v. Moran*,<sup>321</sup> the Supreme Court affirmed the Seventh Circuit's decision upholding an Illinois mandatory external review statute as saved from ERISA preemption as a law regulating insurance.<sup>322</sup> In so doing, it resolved a split between the Seventh Circuit and the Fifth Circuit, which had held in *Corporate Health Insurance v. Texas Department of Insurance* that a similar external review mandate in the Texas HMO Act created an additional administrative regime governing coverage decisions, and was therefore preempted as being in direct conflict with the provisions of ERISA section 502.<sup>323</sup> The *Moran* court clarified the status of an HMO as fulfilling dual roles by providing health care as an insurer,<sup>324</sup> and found the Illinois external review law imposed no new obligation or remedy, but instead appeared more like a requirement for a second-opinion than an arbitration scheme.<sup>325</sup> In reaching that determination, Justice Souter employed "qualifiers, legal parsing, and other techniques for navigating legally rocky waters"<sup>326</sup> to set forth a test based on the characterization of a state insurance law as being content-focused rather than remedial (which would fail a *Pilot Life* preemption analysis).<sup>327</sup> Thus, under a *Moran* analysis, a state external review law will be saved as regulating insurance if it is designed to interpret the content of the plan contract and neither expands ERISA remedies nor unduly burdens ERISA plan administration.<sup>328</sup>

In a strong dissent, Justice Thomas maintained that the Illinois external review provision was nothing short of an additional arbitration requirement that ought to be preempted based on conflict preemption grounds.<sup>329</sup> His arguments echo those of Judge Posner dissenting in the lower court's

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319. BUTLER, *supra* note 14, at 23.

320. POLLITZ ET AL., *supra* note 204, at 1.

321. 536 U.S. 355 (2002).

322. *Id.* at 387.

323. *See Corp. Health Ins., Inc. v. Tex. Dept. of Ins.*, 215 F.3d 526, 537 (2000).

324. *Moran*, 536 U.S. at 367.

325. *Id.* at 386.

326. RAND E. ROSENBLATT ET AL., LAW AND THE AMERICAN HEALTH CARE SYSTEM 21 (Supp. 2002-03).

327. *Id.* at 22.

328. *Id.*

329. *Moran*, 536 U.S. at 395, 401 (Thomas, J., dissenting).



decision.<sup>330</sup> Judge Posner noted that the Illinois law added “heavy new procedural burdens to ERISA plans”<sup>331</sup> that would have several adverse effects on the delivery of quality managed care. First, he noted that “[p]iling on costs in the administration of ERISA plans will shrink benefits and deter some employers from offering health insurance at all.”<sup>332</sup> Second, the majority position “invites states to evade the preemptive force of ERISA simply by deeming its regulations of ERISA plans to be plan terms.”<sup>333</sup> Finally, Judge Posner highlights an inherent contradiction in the majority’s reasoning:

If the statute merely regulates insurance and therefore is not preempted, how can it be part of an ERISA plan and enforceable in federal court? If, on the other hand, the requirement imposed by the statute is and must be incorporated into the plan, then Illinois has done more than merely regulate the contents of an insurance policy. It has regulated the contents of an ERISA plan—which means that its law is preempted.<sup>334</sup>

Thus, in the absence of a unified federal vision for the regulation of managed care, the courts will wrestle with the vague language of the ERISA statute in an attempt to find workable solutions to complex federalism issues. Unfortunately, the results dictated by federal common law may not comport with the best interests of either the MCO industry or plan beneficiaries, and ought instead to be driven by explicit legislative guidance that addresses the needs of both MCOs and beneficiaries.

There are several key issues left unanswered in the wake of the *Moran* decision. For instance, *Moran* does not provide the answer to whether federal external review standards, such as those that passed both the House and Senate in 2001 as part of the Patients’ Bill of Rights legislation, would completely preempt state external review law.<sup>335</sup> There is proposed legislation to clarify the extent of ERISA preemption based on the *Moran* holding. The legislation would give states the ability to write external review laws for fully-insured plans, permitting a state to have a more (but not less) stringent external review provision than the federal law and

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330. See *Moran v. Rush Prudential HMO, Inc.*, 230 F.3d 959, 973-74 (7th Cir. 2000) (Posner, J., dissenting).

331. *Id.* at 973.

332. *Id.* at 973-74.

333. *Id.* at 974.

334. *Id.*

335. See POLLITZ ET AL., *supra* note 204, at 29 nn. 21-22 (noting that the House version, H.R. 2563, exempted external review requirements from its preemption provisions, whereas the Senate version, S. 1052, included a provision that would preempt state external review measures).

ensuring that ERISA does not preempt a state cause of action arising from an insurer's determination of medical necessity.<sup>336</sup> However, many state causes of action will still be preempted by ERISA, limiting beneficiary recourse for plan malfeasance such as fraud and bad faith breach of contract.

How the lower courts will interpret *Moran* is also significant. In *Connecticut General Life Insurance Co. v. Insurance Commissioner for Maryland*, decided in November 2002, the Maryland Court of Appeals (the state's highest court) applied the *Moran* reasoning to a much broader state law than the Illinois law requiring a second opinion, which was at issue in *Moran*.<sup>337</sup> The Maryland law<sup>338</sup> went beyond mandating independent review by creating an administrative appeal to the State Insurance Commissioner, who may not only order provision of care but payment as well.<sup>339</sup> Additionally, the state has the authority under the Maryland statute to impose fines.<sup>340</sup> It appears that the breadth of the Maryland statute should trigger preemption under the provisions of ERISA section 502. However, the Maryland Court of Appeals characterized the law as a mere additional layer of external review, and not as a conflicting benefit enforcement regime.<sup>341</sup> Because the court viewed the statute as a law regulating insurance, it was thus held as saved by the ERISA insurance savings clause.<sup>342</sup>

In the M+C context, the Maryland external review law at issue in *Connecticut General* would appear to be preempted under a Medicare preemption analysis on two grounds. First, the M+C statute lacks any insurance savings clause. Second, the conflict between the M+C external review requirements and what can be described as an alternate benefit enforcement system set forth in the Maryland statute argues in favor of preemption based on the Medicare "arises under" analysis.

While Medicare managed care program contains no insurance savings clause, it does provide for an extensive review and appeals process.<sup>343</sup> This

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336. See H.R. 596, 108th Cong. § 2 (2003). See also Press Release, Representative Charlie Norwood, Norwood Introduces the Patient Protection & ERISA Clarification Acts (Feb. 5, 2003), available at <http://www.house.gov>.

337. See *Conn. Gen. Life Ins. Co. v. Ins. Comm'r for Md.*, 810 A.2d 425, 435 (Md. 2002).

338. MD. CODE ANN., INS. §§ 10A, 10B, 10C (2003).

339. *Conn. Gen. Life Ins. Co.*, 810 A.2d at 427.

340. *Id.*

341. *Id.* at 433-34.

342. *Id.* at 433.

343. See 42 U.S.C. § 1395w-22(g)(1)-(4) (2000). See also 42 U.S.C.A. § 1395w-22(g)(1)-(4) (West 2003); ROSENBLATT ET AL. (Supp. 2001-02), *supra* note 7, at 471.

forecloses state regulation of these procedures while providing uniform federal requirements for all MCOs that provide Medicare managed care services. These provisions include procedures for basic and expedited review of coverage decisions, as well as an external review provision for reconsideration by an independent organization under contract.<sup>344</sup> Adverse reconsiderations are subject to appeal to the Secretary of Health and Human Services per the general Medicare appeals process.<sup>345</sup> Additional protections are contained in proposed changes to the CMS regulations in response to the settlement of a class action challenge in *Grijalva* concerning inadequate notice of denial, termination, and reduction of coverage by Medicare contracted MCOs.<sup>346</sup> Additional proposed changes to the general Medicare grievance and appeals process contained in 42 U.S.C. § 405 have also been published.<sup>347</sup>

The effect of Medicare preemption on claims for coverage determinations was addressed by the Supreme Court in *Heckler v. Ringer*.<sup>348</sup> The *Heckler* Court held that claims against the Secretary of Health and Human Services for failure to cover a particular procedure were inextricably intertwined with claims for benefits because, at bottom, they were claims for reimbursement for a medical procedure.<sup>349</sup> Thus, the Medicare provisions for administrative review of coverage denials foreclose other avenues of redress.<sup>350</sup> This mirrors the result in *Pilot Life* under an ERISA section 502 analysis.

As Congress considers the structure of a premium support program for Medicare it must also provide similar protections, or face a regulatory void in the absence of an ERISA-like insurance savings clause. In his dissent in *Moran*, Justice Thomas noted that the state law at issue in effect provided an additional remedy to that established by ERISA section 502, and that it frustrated Congress' goal of creating an exclusive and uniform remedial

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344. See § 1395w-22(g)(1)-(4).

345. 42 U.S.C. § 1395w-22(g)(5); 42 U.S.C. § 405(g) (2000). See also 42 U.S.C.A. § 1395w-22(g)(5) (West 2003).

346. See Medicare Program: Improvements to the Medicare+Choice Appeal and Grievance Procedures, 66 Fed. Reg. 7593, 7593 (proposed Jan. 24, 2001) (citing *Grijalva v. Shalala*, 946 F.Supp. 747 (D. Ariz. 1996), *aff'd*, 152 F.3d 1115 (9th Cir. 1998), *vacated by* 526 U.S. 1096 (1999), which held that coverage decisions by Medicare contracted providers constituted state action triggering Constitutional procedural due process protections, including adequate notice and a hearing). See generally Wright, *supra* note 48; Gladieux, *supra* note 13 (concerning due process issues in Medicare).

347. Medicare Program: Improvements to the Medicare Claims Appeal Procedures, 67 Fed. Reg. 69312 (proposed Nov. 15, 2002).

348. 466 U.S. 602 (1984).

349. *Id.* at 614.

350. *Id.* at 614-15.

scheme.<sup>351</sup> He pointed to increased financial and administrative burdens in complying with conflicting directives among the states, and the potential disincentive to the formation of employee health benefit plans.<sup>352</sup> These potential consequences should be paramount considerations in the design of new Medicare managed care programs and the maintenance of an adequate Medicare preemption mechanism.

### G. Preemption and Remedies: State Medical Malpractice Claims

The final area to address concerning the reach of federal preemption of state law affecting managed care is that of medical malpractice claims.<sup>353</sup> As Medicare moves toward increased use of managed care, the scope and importance of preemption of state law malpractice claims will continue to grow as more beneficiaries are affected.<sup>354</sup> While access to state courts to seek remedies for inadequate care may appeal to patients' rights advocates, "[i]ncreased liability will produce higher health care and health insurance costs. . . . [which] ultimately will be passed on to the consumer."<sup>355</sup>

It is ironic that *Pegram* was initially viewed by the press and the managed care industry as a great victory for MCOs that validated HMO incentive structures for rationing care.<sup>356</sup> While relieved of the threat of claims of breach of fiduciary duty, MCOs now face increased exposure to state law malpractice claims.<sup>357</sup> The *Pegram* decision addresses significant concerns for ERISA plan enrollees faced with a denial of care based on a mixed eligibility and coverage analysis. The tension in *Pegram*, which centers on denial of fiduciary claims against mixed treatment decisions while sustaining viability of state law malpractice claims for the negative consequences of such decisions,<sup>358</sup> is of particular importance to those who lack resources to pay for necessary care refused by a plan. Increased availability of state law malpractice claims against ERISA plans adds a significant mechanism to ensure the availability and quality of treatment options in employer-sponsored health plans.

The impact of *Pegram* is reflected in the recent Second Circuit opinion in

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351. *Moran*, 536 U.S. at 400-01.

352. *Id.*

353. *See generally* ROSENBAUM, *supra* note 7.

354. *Id.* at 18.

355. McAuliffe, *supra* note 149, at 106.

356. *See* Thomas R. McLean & Edward P. Richards, *Managed Care Liability for Breach of Fiduciary Duty After Pegram v. Herdrich: The End of ERISA Preemption for State Law Liability for Medical Care Decision Making*, 53 FLA. L. REV. 1, 2 (2001).

357. *Id.* at 4.

358. *Pegram v. Herdrich*, 530 U.S. 211, 236-37.

*Cicio v. Vytra Healthcare*.<sup>359</sup> The issue of whether a state law medical malpractice claim concerning a MCO's utilization review decision is preempted by ERISA section 514 and beyond the reach of state tort law was one of first impression for the Second Circuit.<sup>360</sup> Mr. Cicio suffered from multiple myeloma and his treating oncologist sought insurance approval for treatment using a double stem cell transplant procedure.<sup>361</sup> The court noted that the HMO medical director's denial of the request could have been based on whether such treatment was appropriate to Mr. Cicio's particular condition (a medical decision) or whether the treatment in general was experimental (a coverage decision).<sup>362</sup> Characterizing the process of prospective utilization review as "quasi- medical in nature,"<sup>363</sup> the court reviewed the shift in ERISA preemption jurisprudence away from its earlier breadth, noting ERISA's stated purpose of the protection of contractually defined benefits.<sup>364</sup>

The *Cicio* court then turned to the Supreme Court's reasoning in *Pegram*, "albeit in dicta,"<sup>365</sup> to infer the availability of state law malpractice actions "based on at least some varieties of utilization review decisions."<sup>366</sup> The Second Circuit concluded that state law concerning the quality of medical decision-making might therefore be implicated by mixed eligibility and treatment decisions, but did not reach the issue of whether an actual malpractice claim was available under New York law.<sup>367</sup>

In dissent, Judge Calabresi characterized the majority *Cicio* opinion as "a band-aid on a gaping wound"<sup>368</sup> that may provide justice to Mr. Cicio, but that failed to follow other Supreme Court precedent and the structure of ERISA itself.<sup>369</sup> In particular he noted the intent of ERISA's drafters to balance "the need for prompt and fair claims settlement procedures against the public interest in encouraging the formation of employee benefit plans."<sup>370</sup> The consequence of the majority's analysis, he argued, would be to "complicate ERISA and create anomalous results. . . . [where] providers will increasingly have to face that very patchwork of liability risks—

359. 321 F.3d 83 (2d Cir. 2003).

360. *Id.* at 97-98.

361. *Id.* at 86-87.

362. *Id.* at 91.

363. *Id.* at 98.

364. *Id.* at 99.

365. *Cicio*, 321 F.3d at 100.

366. *Id.* at 101.

367. *Id.* at 91-92.

368. *Id.* at 106 (Calabresi, J., dissenting).

369. *Id.*

370. *Id.* at 106-07 (quoting *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 54 (1987)).

differing from state to state—that ERISA’s preemptive scheme was meant to avoid.”<sup>371</sup> Judge Calabresi concluded by noting that beneficiaries who face consequential damages as a result of non-medically based wrongful coverage decisions still have no recourse.<sup>372</sup> These points, when considered with the dissents of Justice Thomas and Judge Posner in the *Moran* cases, highlight the difficulties faced by beneficiaries and MCOs alike under the current federal common law interpretation of the scope of preemption in the ERISA context.

Medicare preemption is similar to ERISA in the applicability of state medical malpractice law. In *Ardary v. Aetna Health Plans of California*, state law claims for malpractice were held not to arise under the Medicare statute.<sup>373</sup> The court focused on the nature of the Ardarys’ claims for negligence in the failure to authorize an airlift subsequent to Cynthia Ardary’s heart attack.<sup>374</sup> The court noted that the claims arose under state common law, and not the Medicare Act.<sup>375</sup> Furthermore, the claims were not “inextricably intertwined” with the Act because they were not at bottom seeking to recover benefits.<sup>376</sup>

*Ardary* was recently followed by the Ninth Circuit in *Hofler v. Aetna U.S. Healthcare of California*.<sup>377</sup> The plaintiff pled only state causes of action arising out of the Medicare HMO’s alleged failure to treat Mr. Hofler’s esophageal cancer.<sup>378</sup> The court found that the reasoning in *Ardary* (decided prior to the BBA of 1997) was applicable to MCOs under the M+C program as well.<sup>379</sup> Thus, like ERISA section 502 civil enforcement remedies, the Medicare appeal procedures do not completely replace state law claims dealing with quality of care and vice coverage.

However, the availability of state claims is broader under Medicare. While *Pegram* exposed MCOs to state law malpractice claims, it dealt only with mixed eligibility and treatment decisions.<sup>380</sup> In the Medicare context, state tort actions are available for willful misconduct, fraud, and emotional distress in addition to medical malpractice negligence, as the California Supreme Court discussed in its reasoning in *McCall v. Pacificare of*

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371. *Cicio*, 321 F.3d at 107.

372. *Id.* at 110.

373. *Ardary v. Aetna Health Plans of Cal., Inc.*, 98 F.3d 496, 502 (9th Cir. 1996).

374. *Id.* at 499-500.

375. *Id.*

376. *Id.* at 500 (citing *Heckler v. Ringer*, 466 U.S. 602, 614 (1984)).

377. *See Hofler v. Aetna U.S. Healthcare of Cal., Inc.*, 296 F.3d 764 (9th Cir. 2002).

378. *Id.* at 766.

379. *Id.* at 770.

380. *See Pegram*, 530 U.S. at 231.

*California*.<sup>381</sup> In that case, the court reiterated that the M+C provisions expressly preempted state laws affecting mandated benefits, inclusion of providers, and coverage determinations in M+C plans.<sup>382</sup> The availability to Medicare beneficiaries of the other causes of action, which are broader than the exception for ERISA plan mixed-eligibility decisions created by *Pegram*, is of particular importance to seniors who are generally in poorer health and who lack the financial resources to independently obtain care denied by a plan.<sup>383</sup>

An analysis of medical malpractice tort reform proposals is beyond the scope of this article. However, limits on malpractice remedies need to be an integral consideration in the reform of Medicare managed care programs. Current law provides managed care beneficiaries access to state courts to seek redress for Medicare plan negligence, and increasingly ERISA plans are facing liability as well. Caps on tort recoveries would have bittersweet results. Reducing malpractice costs may enable plans to reduce premiums, provide greater coverage, and offer broader benefits.<sup>384</sup> Capping damages, however, could effectively revoke a practical remedy for many severely injured beneficiaries by making litigation financially impractical for plaintiffs' attorneys to pursue, and "a right without an effective remedy is no right at all."<sup>385</sup> Based on the general support for some level of medical malpractice tort reform shown in the 107<sup>th</sup> and 108<sup>th</sup> Congresses, coupled with the Bush Administration's emphasis on such reform,<sup>386</sup> the role of managed care malpractice remedies should also be a paramount concern in the development of new Medicare managed care plans.

#### IV. MEDICARE REFORM IN LIGHT OF PREEMPTION CONSIDERATIONS

There is widespread agreement that the method for financing American health care needs reform, but great disparity in the nature of reforms proposed.<sup>387</sup> The current structure of the health care system in this country

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381. 21 P.3d 1189 (Cal. 2001).

382. *Id.* at 1198.

383. *See* FEIN, *supra* note 18, at 53.

384. President's Remarks in Grand Rapids, Michigan, *supra* note 129, at 5. *See* Robert Pear, *White House and Senate Hit Impasse on Patient's Rights*, N.Y. TIMES, Aug. 2, 2002, at A17.

385. Pear, *supra* note 384, at A17 (quoting Senator Edward Kennedy in opposition to damage limits for serious medical injuries).

386. *See* Robert Pear, *The 2002 Election: Health Care; Republicans Plan to Push Through Prescription Drug Coverage for the Elderly*, N.Y. TIMES, Nov. 10, 2002, at 30. *See also* Helen Dewar, *GOP Senators' Agenda Dovetails with Bush's; Debate Lingers on Tax Cut, Drug Benefit*, WASH. POST, Feb. 15, 2003, at A4. *See generally* President's Remarks in Grand Rapids, Michigan, *supra* note 129.

387. *See* Soriano & Feder, *supra* note 123, at 1143. *See also* Goldstein & Milbank, *supra*

can be described as a “big, lumbering battleship that’s difficult to turn.”<sup>388</sup> The last major attempt at health care reform made during the Clinton Administration died in 1994 without success.<sup>389</sup> The same conditions concerning cost, access, and equity that motivated the Clinton health care reform efforts returned to challenge the current Republican Administration and Congress, resulting in the 2003 Medicare reform legislation.<sup>390</sup>

In 1999, the National Bipartisan Commission on the Future of Medicare considered a premium support model as a change to the existing Medicare system.<sup>391</sup> Although the proposal, championed by Democratic Senator John B. Breaux of Louisiana, failed to gain the votes required to become the official Commission recommendation, President George W. Bush, as well as many conservative legislators in the 108th Congress, successfully pushed for its inclusion in the final 2003 Medicare reform legislation.<sup>392</sup> Premium support is designed to provide a set amount of government contribution towards the purchase of a private health plan.<sup>393</sup> It differs from a defined contribution approach, however, which would expose beneficiaries to the full amount of a premium cost increase if the government did not also increase the size of its contribution.<sup>394</sup> In premium support, the amount of federal contribution is not set in advance, but is linked to the bids of participating plans and the traditional Medicare program, thus allowing for an automatic increase of federal coverage to address health care cost inflation.<sup>395</sup> Thus, premium support payments would be tied to premium growth and size, rather than remaining fixed. As costs rise, beneficiaries in a premium support system would incur only a fraction of the total increase in their premiums.<sup>396</sup>

Advocates of premium support assert it will control federal expenditures and increase savings from competition among plans by providing

note 2, at A1.

388. Levin-Epstein, *supra* note 98, at 4 (quoting Marianne Miller, Director of Federal Regulatory Affairs and Policy Development, Health Insurance Association of America).

389. Peter Swenson & Scott Greer, *Foul Weather Friends: Big Business and Health Care Reform in the 1990’s in Historical Perspective*, 27 J. HEALTH POL. POL’Y & L. 605, 627 (2002), available at <http://muse.jhu.edu>.

390. Ronald Brownstein, *It’s the Republicans’ Turn to Find a Health Care Cure*, L.A. TIMES, Dec. 28, 2002, at A1.

391. See NAT’L BIPARTISAN COMM’N, *supra* note 10, at 1. See generally RICE & DESMOND, *supra* note 70, at v.

392. See Ronald Brownstein, *Bush, Frist Share Vision to Reshape Their Party*, L.A. TIMES, Dec. 22, 2002, at A1. See generally H.R. 1, 108th Cong. (2003); S. 1, 108th Cong. (2003).

393. See RICE & DESMOND, *supra* note 70, at v.

394. *Id.* at 2.

395. *Id.*

396. *Id.*



beneficiaries a subsidy towards the choice of a private plan.<sup>397</sup> They point to the California Public Employees' Retirement System (CalPERS), which is a defined contribution system, and the Federal Employees Health Benefits Program (FEHBP), which is a premium support system, as successful models.<sup>398</sup> A premium support program, it is argued, would also save funds previously lost through the past practice of overpaying HMOs for providing Medicare services.<sup>399</sup>

The premium support proposal does face criticism.<sup>400</sup> Some Democrats have raised the issue that the program would push many seniors out of traditional fee-for-service Medicare, and unwillingly into managed care, based on the resulting higher fee-for-service Medicare premiums expected as a consequence of any new premium support system.<sup>401</sup> Both MCOs and beneficiaries have concerns that the competitive pricing of premium support program plans will reduce the amount of benefits offered at a zero premium level.<sup>402</sup> This raises the issue of whether states will be able to step in and mandate minimum benefits for such a program, or whether state action should or would be preempted by federal law. Thus, the scope of federal preemption has a key role to play in a premium support program. Given the current conservative focus on privatizing the delivery of Medicare services, premium support has become an important part of Medicare reform.<sup>403</sup>

The 107th Congress saw comprehensive Medicare reform based on a premium support model proposed by Senators John Breaux and Bill Frist (the current Senate Majority Leader from Tennessee).<sup>404</sup> Under that plan, which has been referred to as Breaux-Frist I (BF-I), the existing Medicare programs would be replaced by a system of competing plans (including a CMS-sponsored fee-for-service option).<sup>405</sup> Beneficiaries would elect either a standard or a high option plan (that would include prescription drugs and stop-loss coverage—a cap on out-of-pocket patient co-payments) and pay the difference between the plan bid and the Medicare contribution

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397. See S. 357, 107th Cong. § 2 (2001). See also Press Release, Senator John Breaux, National Bipartisan Commission on the Future of Medicare, Medicare Reform: It's Time Has Come 2 (Mar. 4, 1999), available at <http://medicare.commission.gov>.

398. RICE & DESMOND, *supra* note 70, at 3.

399. *Id.* at 4.

400. Brownstein, *supra* note 392, at 1.

401. *Id.*

402. Diamond, *supra* note 70, at 35.

403. See Brownstein, *supra* note 392, at 1.

404. See S. 357, 107th Cong. § 2 (2001). See also Press Release, Senator John Breaux, Nat'l Bipartisan Comm'n on the Future of Medicare, *supra* note 397; RICE & DESMOND, *supra* note 70, at 9.

405. RICE & DESMOND, *supra* note 70, at 9.

amount.<sup>406</sup> Medicare enrollees would be able to choose either a private or CMS-sponsored plan under the Breaux-Frist model.<sup>407</sup>

Noting the composition of the 108th Congress and the goals of the current administration, significant progress in Medicare reform was anticipated and achieved this term.<sup>408</sup> It met expectations that it would include a prescription drug benefit in all Medicare programs and an increased reliance on privatization. The Bush Administration had announced a proposed general framework for Medicare reform on March 4, 2003, when the President spoke before the American Medical Association, who so vehemently opposed Medicare forty years ago.<sup>409</sup> The President's proposal contained three options: retention of traditional fee-for-service Medicare with an added prescription drug discount at no additional premium; Enhanced Medicare modeled after the FEHBP to include a drug benefit and preventative care; and, Medicare Advantage as a continuation of the Medicare+Choice HMO option.<sup>410</sup> The basic elements of these proposals are contained in the House and Senate reform bills passed in the summer of 2003, and ultimately included in the final reform legislation.<sup>411</sup>

Until the passage of the 2003 Medicare reform legislation, proposals for Medicare reform had not adequately addressed the scope of federal preemption and the ability of states to regulate these new Medicare premium support products. In its report, the National Bipartisan Commission on the Future of Medicare did not discuss the role of preemption in a reformed Medicare system.<sup>412</sup> In BF-I, section 2203 only addressed the “[c]ontinuation of [b]eneficiary [p]rotections and [o]ther [q]ualifications for Medicare [p]lans” in broad terms of participating plans meeting the Medicare+Choice plan requirements for benefits and beneficiary protections.<sup>413</sup> However, the new preemption provisions

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406. *Id.*

407. *Id.* at 10.

408. Interview with Tom Scully, Administrator, CMS, DHHS, in Washington, D.C. (Feb. 19, 2003). See also Greg Pierce, *Inside Politics*, WASH. TIMES, Mar. 10, 2003, at A6 (quoting Tommy Thompson, Secretary of Health and Human Services as stating that, “‘Medicare, Medicaid, liability insurance and [coverage for] the uninsured,’ and welfare reform are the best bets for passing Congress this year.”).

409. President's Remarks to the AMA National Advocacy Conference, *supra* note 11. See also President's Framework to Modernize and Improve Medicare Fact Sheet, *supra* note 11, at <http://www.whitehouse.gov/news/releases/2003/03/print/20030304-1.html>.

410. President's Framework to Modernize and Improve Medicare Fact Sheet, *supra* note 11, at 2-3.

411. See H.R. 1, 108th Cong. (2003); S. 1, 108th Cong. (2003); Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173 (2003).

412. See generally NAT'L BIPARTISAN COMM'N, *supra* note 10.

413. See S. 357, 107th Cong. § 2203 (2001).

contained in the Medicare Advantage program specifically expand the scope of the Medicare managed care preemption scheme.<sup>414</sup> Absent a continuation of this comprehensive federal preemption scheme in future Medicare managed care programs, the door is open for significant state action regarding such plans, which invites legal challenges to any state efforts at controlling plan structure and operation.

Thus, preemption in the ERISA context fails to meet the needs of a uniform regulatory system, as noted by Justice Thomas in the *Moran* dissent.<sup>415</sup> Beneficiaries are left with minimal protections when faced with a denial of coverage decision, although Supreme Court decisions such as *Pegram* open avenues for state law malpractice claims in mixed treatment and benefit decision cases. Leaving the issue of the scope of preemption for the courts to resolve fails to provide a reliable regulatory structure to address the needs of MCOs and beneficiaries alike. Reforming ERISA's preemption provisions, while frequently debated in Congress, has proven to be a more of an aspiration than a reasonable prospect.<sup>416</sup>

Preemption under M+C is less complex, and even more straightforward under Medicare Advantage. Under M+C, states were free to regulate in areas that did not conflict with federal provisions. The enumerated areas of benefit mandates, provider participation, and coverage determinations were clearly preempted. Medicare Advantage preemption expanded the scope of federal preemption to almost all areas of state regulation. However, unlike ERISA plans, the areas of benefit design and coverage process in Medicare managed care are addressed by extensive federal regulations. Furthermore, because state malpractice claims do not arise under the Medicare Act, they are available to Medicare beneficiaries.

If Congress were to alter the preemption provisions contained in the Medicare managed care programs, the issues seen under ERISA would likewise arise in the Medicare managed care context. The forces of preemption and federal regulation create tension with respect to the market for Medicare products. The more Congress pursues unregulated premium support options, the more preemption issues will arise, unless broad preemption provisions are maintained. With the Administration's proposal to implement premium support under Enhanced Medicare,<sup>417</sup> and its introduction through demonstration projects by the 2003 Medicare reform

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414. See Medicare Prescription Drug, Improvement and Modernization Act of 2003 § 232.

415. *Rush Prudential HMO, Inc., v. Moran*, 536 U.S. 355, 400-01 (2002) (Thomas, J., dissenting).

416. ROSENBLATT ET AL. (Supp. 2001-2002), *supra* note 7, at 102.

417. President's Remarks to the AMA National Advocacy Conference, *supra* note 11.

## Impact of Medicare Preemption on State Laws

legislation,<sup>418</sup> the focus on increasing the delivery of health care to Medicare enrollees through private insurance plans has been magnified.

The success of continued managed care reform in Medicare will depend in large degree on the public perception of the program.<sup>419</sup> The lessons of the Clinton Administration health care reform efforts, which boasted of the boldness and scope of their vision for a new health system, were not lost on the Bush Administration.<sup>420</sup> House Energy and Commerce Chair Billy Tauzin's (R-La.) comment, now oft-quoted, captures a popular sentiment: "[y]ou couldn't move my own mother out of Medicare [and into a private, supplemental Medicare plan] without a bulldozer. She trusts it, believes in it. It's served her well."<sup>421</sup> Other criticisms of the Bush proposal include "less security, fewer guaranteed benefits and more financial risk for beneficiaries."<sup>422</sup> However, in light of the economic realities facing Medicare financing,<sup>423</sup> the reliance on fee-for-service Medicare to fulfill the Great Society promise of comprehensive health care for the elderly appears increasingly unrealistic. Managed care, whether in the form of a capitated-payment HMO, or premium support PPO, may provide the only realistic means to control costs while guaranteeing minimum benefits for many enrollees,<sup>424</sup> especially lower-income seniors unable to afford higher premiums or supplemental Medigap insurance.

Allowing states great latitude to regulate managed care products purchased by the federal government invites challenges to a uniform Medicare system and drive plans away from Medicare product markets.<sup>425</sup> Many state laws may have been enacted out of political expediency or in reaction to extreme cases rather than considered analysis based on studies of their impact and effectiveness in other jurisdictions.<sup>426</sup> The cumulative impact of these varied state laws on the managed care market must be an

418. See Medicare Prescription Drug, Improvement and Modernization Act of 2003.

419. HENRY J. KAISER FAMILY FOUND., *Success of Bush's Medicare Reform Outline Hinges on Public Perception of Managed Care*, KAISER DAILY HEALTH POL'Y REP. 1 (Mar. 11, 2003), available at <http://www.kaisernetwork.org> [hereinafter *Success of Bush's Medicare Reform Outline*].

420. Robin Toner & Robert Pear, *Bush Proposes Major Changes in Health Plans*, N.Y. TIMES, Feb. 24, 2003, at A1 (surmising that President Bush is mindful of voter anxiety about major changes in health care).

421. See *Success of Bush's Medicare Reform Outline*, *supra* note 419, at 1.

422. Toner & Pear, *supra* note 419, at A1.

423. See *Success of Bush's Medicare Reform Outline*, *supra* note 419, at 2 (noting that Medicare currently accounts for 2.5% of the GDP and is expected to grow to 4.5% by 2030).

424. Toner & Pear, *supra* note 420, at A1.

425. See AAHP, *supra* note 41, at 14 (noting the AAHP proposition that M+C preemption should be clarified to explicitly preempt "all state laws except state licensing laws or state laws relating to plan solvency.").

426. ROBERT WOOD JOHNSON FOUND., *supra* note 73, at 8.

important consideration in policy and program development.<sup>427</sup>

Congress must also consider the weakness of the Medicare products market. It is not clear that there is a strong market for private retirement health care plans, as indicated by the current rash of M+C plan withdrawals.<sup>428</sup> While increased federal regulation will curb preemption problems, it may also negatively impact the market, as has been seen with M+C and the issue of rate controls.<sup>429</sup> Thus, a balance between state and federal goals in guaranteeing patient rights and quality of care, and MCO requirements for uniform regulations and cost controls, must be a fundamental consideration of future Medicare reform proposals.

## V. CONCLUSION

The role of federal preemption of state law will continue to have a significant influence on the quality and quantity of health care delivered under Medicare programs. The broad scope of Medicare managed care preemption will continue to frustrate state attempts at regulating benefits and network processes (including prompt payment, utilization, and external review provisions). Medicare managed care programs provide an important coverage option, especially for low-income beneficiaries. Unlike the regulatory void faced under ERISA, the Medicare managed care regulations provide essential protections to beneficiaries in these areas. Medical malpractice suits against HMOs participating in Medicare managed care will remain a viable, but generally less desirable, means to guarantee health care quality. Recognizing the unlikelihood of the development of an integrated and comprehensive federal health care system in the near future, further reform of the current health care framework, including implementation of premium support options, must consider the impact of federal preemption to avoid the creation of problems already experienced in the current ERISA patchwork federal preemption scheme.

Medicare managed care has avoided most of these conflicts by either allowing states increased latitude to protect patients' rights and benefits in certain areas that do not conflict with federal requirements, or by imposing protections through federal legislation and regulation. Although states have traditionally regulated the provision of health care, the nature of managed care delivery requires a uniform regulatory environment to control costs and to ensure that providers continue to service the managed care market. Creating new Medicare plans without comprehensive preemption

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427. *Id.* at 11.

428. *See generally* Gold & McCoy, *supra* note 99.

429. ACHMAN & GOLD, *supra* note 93, at 1.

provisions, coupled with extensive regulation of plan structure and coverage process, would invite the complexities and frustrations facing ERISA plan beneficiaries. A reformed federal health care system must maintain a logical preemption scheme in order to ensure a viable managed care option for Medicare and avoid the problems experienced under ERISA. The new broader preemption provisions under Medicare Advantage will further limit state efforts at controlling the delivery of managed care. However, the better choice for a reformed Medicare managed care program may be reliance on a thorough preemption scheme concerning plan benefits, while deferring to state law on the regulation of Medicare managed care network organization and delivery of services.<sup>430</sup> Ultimately, a failure to maintain a proper preemption balance will lead to unnecessary and costly litigation as the means to define the scope of federal preemption and its impact on state laws affecting Medicare programs.

“The underlying tension . . . continues today—between a medical care system geared toward expansion and a society and state requiring some means of control over medical expenditures.”<sup>431</sup>

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430. Interview with Sara Rosenbaum, *supra* note 34.

431. STARR, *supra* note 18, at 380.