

# USING MANAGED CARE TOOLS IN TRADITIONAL MEDICARE— SHOULD WE? COULD WE?

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## I

### INTRODUCTION

Since the early 1990s, policy analysts seeking important opportunities for reform in the Medicare program have looked at the experience of private markets and managed care in the private sector. Managed care organizations (“MCOs”), in general, and health maintenance organizations (“HMOs”), in particular, seem to have hit the wall in recent years in their ability to contain costs.<sup>1</sup> They have experienced a public backlash against many of their policies and procedures, resulting in marketplace, legislative, and legal reactions that have altered their operations.<sup>2</sup> Nevertheless, many policy analysts continue to look to managed care and competition among private health plans as the bases for structural reform of Medicare.

Proponents of market forces in health care often advocate both managed care and managed competition, but, although related, the concepts are quite different. For purposes of this discussion, we apply the term “managed care” to supply-side interventions meant to affect directly the efficiency and quality of health services delivery. In contrast, “managed competition” attempts to alter individuals’ demand for care among competing private insurers, thereby affecting provider behavior only indirectly.<sup>3</sup>

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1. Jon Gabel et al., *Job-based Health Insurance in 2001: Inflation Hits Double Digits, Managed Care Retreats*, HEALTH AFF., Sept./Oct. 2001, at 180, 181 (documenting recent inflationary trends in job-based health insurance and declining HMO enrollment).

2. See Frank A. Sloan & Mark A. Hall, *Market Failures and the Evolution of State Regulation of Managed Care*, 65 LAW & CONTEMP. PROBS. 169, 194 (2002) (reviewing any-willing-provider and freedom-of-choice laws). See also Richard Sorian & Judith Feder, *Why We Need a Patient's Bill of Rights*, 24 J. HEALTH POL. POL'Y & LAW 1137, 1138-43 (1999); Jill A. Marsteller et al., *The Resurgence of Selective Contracting Restrictions*, 22 J. HEALTH POL. POL'Y & LAW 1133, 1134 (1997) (describing the any-willing-provider and freedom-of-choice laws in fifty-one jurisdictions).

3. See Richard B. Saltman and Joseph Figueras, *Analyzing the Evidence on European Health Care Reforms*, HEALTH AFF., Mar./Apr. 1998, at 85, 102-04.

In discussions of Medicare reform and restructuring, most attention has been on putting the Medicare equivalent of managed competition into place. As initially articulated by Henry Aaron and Robert Reischauer, Medicare would be converted from a service reimbursement system to a premium support system in which Medicare would pay a defined sum toward the purchase of an insurance policy that provided a defined set of services.<sup>4</sup> For purposes of this discussion, a fundamental purpose of a premium support approach is to make beneficiaries price-sensitive in their choice among competing private plans and traditional fee-for-service (“FFS”) Medicare.<sup>5</sup> By migrating to lower-priced plans, beneficiaries would be exposed to private plans featuring managed care approaches to restraining costs and improving quality.

What has not gotten much attention in the debate over the desirability of premium support is how the traditional FFS program should be permitted to compete.<sup>6</sup> The program might remain a passive, unmanaged program. Accordingly, beneficiaries could avoid some or all managed care interventions by paying more out of their own pockets to remain in the traditional Medicare program. Alternately, the traditional program could become an active competitor that might be given greater authority to manage costs, using managed care approaches, and would be relieved of its social policy functions, such as supporting graduate medical education and providing a disproportionate share of hospital payments.<sup>7</sup> Under current premium support models, the issues related to the transformation of Medicare into an active purchaser permitted to use particular managed care interventions need to be addressed.

This article will first look at purchasing/managed care tools in the context of the traditional Medicare program. Then it will describe the general policy and administrative constraints that any regime of active purchasing would face. Some of these restraints narrow significantly the range of purchasing opportunities available in Medicare. Next, the article will propose a few purchasing techniques with which Medicare might proceed. Instead of compiling an exhaustive listing of managed care techniques that Medicare might adopt, as others have

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4. Henry J. Aaron & Robert D. Reischauer, *The Medicare Reform Debate: What Is the Next Step?*, HEALTH AFF., Winter 1995, at 8 (providing the rationale and proposal for converting Medicare from a service reimbursement system to a premium support system similar to developments in the private sector).

5. Under the most recent iteration of the premium support model, competing private health plans would set prices through negotiation with the federal government. The traditional fee-for-service program would set a national premium, and its members would pay the same amount regardless of where they lived. The government contribution to private plans would be a fixed percentage of the national premium up to a specified dollar limit. Payments to plans would be adjusted based on demographic and health status factors and adjusted for geographic location. Beneficiaries would pay, on average, a base percentage of the premium. In current proposals, this would be twelve percent. Those who chose plans that cost more than the government contribution would pay all of the extra cost themselves and those who picked a plan below the government contribution level would get a rebate. See Gail R. Wilensky, *Medicare Reform—Now is the Time*, 345 NEW ENG. J. MED. 458, 460 (2001).

6. See BETH C. FUCHS & LISA POTETZ, REFORMING MEDICARE: A FRAMEWORK FOR COMPARING INCREMENTAL AND PREMIUM SUPPORT APPROACHES 28-32 (1999) (discussing how the traditional fee-for-service program might function under a premium support framework).

7. See Aaron & Reischauer, *supra* note 4, at 26.

done,<sup>8</sup> the article will center on a few managed care techniques: those that have been the most controversial and are being abandoned by MCOs as well as those that pose the greatest policy and legal challenge to the Medicare program—the ones that are commonly criticized as threatening physician autonomy or interfering with the doctor-patient relationship. Finally, this article will review in detail the legal issues associated with Medicare's adoption of these approaches, first exploring statutory issues and then constitutional issues.

## II

### MANAGED CARE TOOLS IN THE CONTEXT OF THE TRADITIONAL MEDICARE PROGRAM

During the mid-1990s, when nearly one million Medicare beneficiaries per year were migrating from the traditional FFS program to risk-based HMOs,<sup>9</sup> and when HMOs were still demonstrating superiority over the traditional Medicare program in controlling spending,<sup>10</sup> policy analysts initiated discussions on the application of managed care techniques to the traditional program. These analysts recognized that premium support approaches, which moved Medicare away from defined benefits to defined government contributions, were politically controversial and therefore improbable in the near term.<sup>11</sup> Because Medicare beneficiaries are less price-sensitive than active employees given multiple choices,<sup>12</sup> analysts also thought that, under a politically acceptable premium support structure, most beneficiaries would likely choose to remain in traditional Medicare.<sup>13</sup>

Yet recently, many Medicare+Choice plans have withdrawn from the program, affecting more than 2.2 million beneficiaries.<sup>14</sup> At its peak in 1999, the Medicare+Choice risk program served about 6.3 million enrollees, over sixteen percent of Medicare beneficiaries. It now serves about five million enrollees, or about fourteen percent.<sup>15</sup> Given the uncertain future of Medicare's contracting

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8. See, e.g., Lynn Etheredge, *Reengineering Medicare: From Bill-Paying Insurer to Accountable Purchaser*, in CLARK C. HAVIGHURST ET AL., *HEALTH CARE LAW AND POLICY* 252 (2d ed. 1998); Peter D. Fox, *Applying Managed Care Techniques in Traditional Medicare*, *HEALTH AFF.*, Sept./Oct. 1997, at 44; Peter D. Fox, Lynn Etheredge, & Stanley B. Jones, *Addressing the Needs of Chronically Ill Persons Under Medicare*, *HEALTH AFF.*, Mar./Apr. 1998, at 144.

9. HEALTH CARE FINANCING ADMINISTRATION, *MEDICARE 2000: 35 YEARS OF IMPROVING AMERICANS' HEALTH* 29 (2000).

10. *Id.* at 31.

11. Robert A. Berenson, *Medicare+Choice: Doubling or Disappearing* (Nov. 28, 2001), at [http://www.healthaffairs.org/WebExclusives/Berenson\\_Web\\_Excl\\_112801.htm](http://www.healthaffairs.org/WebExclusives/Berenson_Web_Excl_112801.htm); Fox, *supra* note 8, at 45.

12. See Thomas Buchmueller, *The Health Plan Choices of Retirees Under Managed Competition*, 35 *HEALTH SERVICES RES.* 946, 968 (2000).

13. See Etheredge, *supra* note 8, at 253.

14. See Berenson, *supra* note 11, at W65, W66 (describing new approaches to paying Medicare+Choice plans given the current difficulties the program is experiencing).

15. Medicare Managed Care Contract (MMCC) Plans, Monthly Summary Report, available at <http://www.HCFA.gov/stats/mmcc0402.zip> (last visited Apr. 01, 2002). The Congressional Budget Office recently projected a sharp decline in future Medicare+Choice enrollment, down to only eight percent of beneficiaries in 2012. *Hearing on the Administration's FY 2003 Budget Proposals for Prescription Drugs Before the Senate Fin. Comm.*, 107th Cong. at 25 (2002) (statement of Dan L.

with private plans, it is even more important to examine whether the traditional program should be encouraged to adopt appropriate managed care techniques.<sup>16</sup>

In recent years, congressional attention has been given both to fundamental restructuring to promote price competition and to permitting Medicare to behave as a purchaser or managed care provider. In 2000, based upon the work of the Bipartisan Commission on the Future of Medicare, the Senate Finance Committee developed legislative options to “Modernize and Secure the Medicare Program for the 21st Century” that included both a premium support proposal and new authorities to permit the Health Care Financing Administration to use specific managed care tools.<sup>17</sup>

Although many Medicare reform advocates support both managed competition and managed care, the concepts are sufficiently different. It is possible to hold a view that, on the one hand, opposes premium support approaches because they lead to segmented insurance pools<sup>18</sup> and unnecessarily high administrative costs, and, on the other hand, supports using managed care tools in the traditional program in order to achieve improved program efficiency and quality of care.<sup>19</sup>

This analysis of how Medicare might adopt managed care techniques occurs at a time when many managed care organizations themselves are giving up some approaches that have made them distinctive. Their retreat comes in the face of consumer complaints about undue restrictions on provider choice and burdensome administrative requirements, and provider complaints about loss of

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Crippen, Director, Congressional Budget Office), available at <http://finance.senate.gov/hearings/testimony/030702dctest.pdf> (last visited May 1, 2002).

16. Writing in 1995, Lynn Etheredge emphasized how Medicare should evolve from a passive bill payer to an active purchaser of care by using purchasing techniques, including forms of selective, competitive contracting, capitation and risk-sharing arrangements, provider performance standards with payment incentives and penalties, high-cost case management, disease management, centers of excellence for certain specialized clinical problems, and consumer information and incentives. Etheredge, *supra* note 8, at 252-53. The National Academy of Social Insurance undertook a comprehensive assessment of Medicare that included a study panel on the fee-for-service system. NATIONAL ACADEMY OF SOCIAL INSURANCE, *MEDICARE: PREPARING FOR THE CHALLENGES OF THE 21ST CENTURY* (1999). In that report, Peter Fox contributed a paper suggesting that there were a number of managed care techniques that could be applied in traditional Medicare, developing a concept similar to Etheredge's suggestions of Medicare becoming an active purchaser. Peter D. Fox, *The Medicare Fee-For-Service System: Applying Managed Care Techniques*, in *MEDICARE: PREPARING FOR THE CHALLENGES OF THE 21ST CENTURY*, *supra*, at 185-206.

17. STAFF OF SENATE FIN. COMM., 106TH CONG., *MAJOR OPTIONS TO MODERNIZE AND SECURE THE MEDICARE PROGRAM FOR THE 21ST CENTURY* (June 14, 2000), available at <http://finance.senate.gov/6-14opt.htm> (last visited Sept. 12, 2002).

18. Premium support models depend on the use of health status-based risk adjustment of payments to competing plans to counter the inherent incentive to cherry-picking. Aaron & Reischauer, *supra* note 4, at 16-17. Yet, progress in adopting risk adjustment in the Medicare+Choice program has been slow, both for technical reasons and because of political opposition by the managed care industry. This situation shows the divergence of the interests of managed care organizations and of market competition.

19. See Marilyn Moon & Karen Davis, *Preserving and Strengthening Medicare*, HEALTH AFF., Winter 1995, at 31 (arguing for the need to preserve and strengthen the integrity of the Medicare program, including improving the basic fee-for-service program).

clinical autonomy and increased hassles and compliance costs.<sup>20</sup> As noted earlier, legislatures and courts have responded to the backlash by putting limits on the use of some managed care tools.<sup>21</sup>

In many ways, MCOs that have responded to consumer preferences by voluntarily withdrawing many of their provider-side interventions now resemble the very indemnity insurance approaches they were designed to replace. They maintain broad provider networks, leaving providers alone to practice as they want, and paying claims and achieving profitability not by constraining costs, but rather by raising premiums over their actual cost increases in accordance with the health insurance underwriting cycle.<sup>22</sup> Indeed, some plans now actively advertise that they have abandoned specific components of managed care, including prior authorization, gatekeepers, and provider financial incentives.<sup>23</sup>

This retrenchment is taking place at a time when costs and premiums are rising faster than they have in a decade.<sup>24</sup> Some policy analysts have recognized the standard tools of managed care have achieved broad disrepute. Therefore, they predict that the next round of cost-cutting will focus on the consumer by emphasizing more price-sensitive health plan choices and increased patient cost-sharing.<sup>25</sup>

The various political and legal constraints applying to Medicare, and the lessons learned from the numerous mistakes MCOs made in executing their approaches, could cause Medicare to adopt some managed care purchasing techniques in a kinder and gentler, more effective fashion, despite its trend toward de-emphasizing its distinctiveness.

Although MCOs are withdrawing some of their cost-cutting tools,<sup>26</sup> they have also developed programs that attempt to improve quality while simultaneously promoting efficiency in an unobtrusive and voluntary manner. For example, some health plans and self-funded employers have added disease management programs that seem to achieve better health outcomes and reduce rates of

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20. See James C. Robinson, *The End of Managed Care*, JAMA, May 23–30, 2001, at 2622 (explaining the backlash to managed care and how consumerism is likely to develop in response).

21. Sloan and Hall, *supra* note 2, at 194.

22. Gabel et al., *supra* note 1, at 181.

23. A prominent example of managed care's retrenchment was United Health Group's decision to abandon utilization review, labeled by the Wall Street Journal as a "watershed event in the history of managed care." Carol Gentry, *UnitedHealth Move on Reviews is Seen as Industry Watershed*, WALL ST. J., Nov. 10, 1999, at B6. See CENTER FOR STUDYING HEALTH SYSTEM CHANGE, AN EMPTY TOOLBOX? CHANGES IN HEALTH PLANS' PRACTICES FOR MANAGING COSTS AND CARE (2001) (draft working paper for a survey of the changes managed care plans have made in the use of their various tools) (on file with author) [hereinafter CSHSC Draft].

24. Gabel et al., *supra* note 1, at 181.

25. For a general discussion of these issues, see Robinson, *supra* note 20, at 2625 (applied to Medicare, Robinson's reasoning would suggest a form of premium support).

26. While retrenchment has gotten the most attention, one should not over-emphasize the point. These tools are still used widely, though without fanfare. See CSHSC Draft, *supra* note 23.

hospitalization for sub-populations of enrollees with specific clinical problems, especially chronic diseases, such as congestive heart failure and diabetes.<sup>27</sup>

Most would view these kinds of initiatives, whether in private health plans or in traditional Medicare, as desirable program enhancements if they can be demonstrated to be cost-effective.<sup>28</sup> Much more controversial are managed care tools that have been the target of criticism from providers and consumers, including selective contracting, prior authorization, and gatekeeping.

### III

#### POLICY AND ADMINISTRATIVE CONSTRAINTS

The Medicare statute was a political compromise. On the one extreme were those who believed that Medicare should be a social insurance program covering all health care beneficiaries on a compulsory basis, financed by payroll taxes, with a public assistance program as a safety net. On the other extreme were those who supported only a public assistance program.<sup>29</sup> The legislative compromise that was achieved was based on the structure and function of existing private insurance. The program was designed to be a passive bill payer that did not try to influence how care was delivered. To assure this passive role, the first two sections of the legislation prohibit Medicare from interfering with the practice of medicine and from limiting beneficiaries' access to all providers who choose to participate in the program.<sup>30</sup>

Even with the health system changing in the private sector, Congress has generally not permitted the Centers for Medicare and Medicaid Services ("CMS") to use purchasing tools. This reluctance reflects not only political

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27. Medicare Program: Solicitation for Proposals for the Medicare Coordinated Care Demonstration, 65 Fed. Reg. 46466, 46467 (July 28, 2000). See also Thomas Bodenheimer, *Disease Management—Promises and Pitfalls*, 340 NEW ENG. J. MED. 1202, 1202 (1999). For documentation of the varying and disturbing levels of quality of care provided to Medicare beneficiaries, see Stephen F. Jencks et al., *Quality of Medical Care Delivered to Medicare Beneficiaries: A Profile at State and National Levels*, 284 JAMA 1670 (2000).

28. Given the facts that a small proportion of Medicare beneficiaries accounts for a major proportion of expenditures (in 1996, 12.1 percent of all beneficiaries accounted for 75.5 percent of fee-for-service program spending, Medicare Program, 65 Fed. Reg. at 46466), and that many of these beneficiaries are repeated high users with one or more chronic diseases, Medicare certainly has an interest in implementing disease management and other care-coordination programs. For the most part, these programs present substantial operational policy challenges but do not raise specific legal issues. We do discuss some aspects of high-cost case management which do raise some legal issues. See *infra* Part V.

29. See Robert J. Myers, *Why Medicare Part A and Part B, As Well As Medicaid?*, HEALTH CARE FIN. REV., Fall 2000, at 53, 53-54.

30. Sections 1801 and 1802, codified at 42 U.S.C. § 1395 (2001). Occasionally, Medicare has used its limited statutory authority to act less like a passive payer and more like a purchaser. A prominent example relates to designation of organ transplant centers. In a series of national coverage policy notices in the Federal Register, HCFA stated that organ transplants in adults were medically reasonable and necessary when performed on carefully selected patients in facilities that meet certain criteria. See Medicare Coverage Policy – Decisions. Re-Evaluation of Criteria for Medicare Approval of Transplant Centers (#CAG-00061N), available at <http://www.hcfa.gov/coverage/8b3%2Daa4.htm> (last visited March 10, 2002); see also National Coverage Policy for heart transplants, 52 Fed. Reg. 10,935 (Apr. 6, 1987); National Coverage Policy for liver transplants, 56 Fed. Reg. 15,006 (Apr. 12, 1991); National Coverage Policy for lung transplants, 60 Fed. Reg. 6,537 (Feb. 2, 1995).

opposition from the providers who might not do well under the regime of an active purchaser, but also important policy and operational concerns.

Perhaps the most important policy concern relates to the government's exercise of market power. Some providers are particularly dependent for revenues on Medicare patients—for example, for ophthalmologists, cardiovascular specialists and urologists, Medicare represents nearly half of total revenues.<sup>31</sup> Dialysis centers are almost totally dependent on Medicare revenues as a result of the creation of an end-stage renal disease benefit. Under these circumstances, with rare exceptions, Medicare has to pay at administered prices and cannot use its purchasing power to negotiate market rates because Medicare's large share of payments would distort the market.<sup>32</sup>

Medicare differs from traditional federal regulatory programs in that a transfer of resources to private individuals is not an incidental and undesirable result of the program, but rather the very reason for the program's existence.<sup>33</sup> Medicare, nevertheless, is subject to section 553 of the Administrative Procedures Act ("APA").<sup>34</sup> The APA and other procedural requirements limit agency discretion and create a lengthy decision-making process, certainly in contrast to private health plans.<sup>35</sup> Specific procedural requirements aside, there is a general expectation that a government purchasing program would treat providers fairly because of general notions of due process and equal protection, and because its participation is voluntary.<sup>36</sup>

Due to procedural restrictions that limit discretion and the national nature of the program, there has been an expectation of uniform treatment, such as similar treatment of providers and suppliers with similarly objective characteristics.<sup>37</sup> There is no expectation that uniform treatment can be applied within or across areas, however, because active purchasing is local.

It is important to note that the requirement of uniform national policies, particularly regarding payment formulas, results in vastly disproportionate aggregate payments across the country. This phenomenon became very notice-

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31. The American Medical Association's socioeconomic survey showed that ophthalmologists, cardiovascular specialists, and urologists received forty-nine percent, forty-seven percent, and forty-four percent of their revenues from Medicare. Interview with Sarah Thran, American Medical Association, in Chicago, Ill. (Nov. 7, 2001).

32. Medicare: Successful Reform Requires Meeting Key Management Challenges: United States General Accounting Office ("GAO"), Testimony of William J. Scanlon before the House Committee on the Budget, 106 Cong. at 3 (2001), available at <http://www.gao.gov/new.items/d011006t.pdf> [hereinafter Scanlon Testimony].

33. See Timothy Stoltzfuss Jost, *Recent Development: Health Care Symposium: Governing Medicare*, 51 ADMIN. L. REV. 39, 59 (1999).

34. *Id.* at 88. HCFA decided in 1971 to comply voluntarily with Section 553. *Id.* at 88 n.271. Congress codified this decision with respect to specified Medicare program regulations. *Id.* at 88 n.272.

35. Scanlon Testimony, *supra* note 32, at 3 (contrasting Medicare's ability to change program requirements with that of private plans).

36. See *id.* at 53. *Infra* Part V.C. specifically deals with constitutional due process issues.

37. The one notable exception is coverage policy, where there is explicit recognition that there might well be local variations. THE LEWIN GROUP, REPORT 2: THE MEDICARE PAYMENT PROCESS AND PATIENT ACCESS TO TECHNOLOGY 30-31 (2000) [hereinafter LEWIN REPORT] (second article in a series of reports prepared by the Lewin Group for Advamed).

able because payments in the Tax Equity and Fiscal Responsibility Act of 1982 (“TEFRA”) risk contracting program, and now in the Medicare+Choice program, are based on spending levels in the traditional, FFS program at the county level, even though spending varies significantly.<sup>38</sup> Most of the difference in county-level spending probably represents practice style,<sup>39</sup> which the program is not able to influence, thus producing widely varying county payment rates across the country.<sup>40</sup>

A major barrier to adopting managed care cost-cutting techniques is the division of the Medicare budget between mandatory dollars to pay for services and discretionary dollars to pay for administration. Currently, Medicare spends less than two percent of program outlays on administration,<sup>41</sup> compared to over ten percent for private insurers.<sup>42</sup> Adopting virtually any managed care technique would involve increased spending on program administration, yet savings would accrue to the trust funds.<sup>43</sup>

Finally, the adoption of purchasing tools would face a series of practical, operational issues. Since Medicare is a national program, the organizational orientation of CMS is national, not local. Most of the staff works in Baltimore, while the rest are located in ten regional offices and have limited administrative authority. Much of the actual program administration is done through contractors, including fiscal intermediaries for Part A and carriers for Part B. Although these entities, based in insurance companies, offer the potential for the kind of local presence that purchasing would require, the services of these particular organizations have not been procured through a competitive process. While there is interest in contractor reform to give CMS broader contracting authority, the agency currently lacks experience in procuring the kind of expertise at the local level that many managed care techniques would require.

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38. 1997 PHYSICIAN PAYMENT REV. COMM’N (“PPRC”) ANN. REP. 29-31 (1997).

39. Aaron & Reischauer, *supra* note 4, at 17. Recently, Wennberg and his colleagues showed that the large geographic variation was traceable to the use of “supply sensitive” services, namely, physician visits, specialty consultations, and hospitalizations, especially in the last six months of life. Higher spending on such services does not result in more effective care or better health outcomes and does not represent patient preferences. John W. Wennberg et al., *Geography and the Debate over Medicare Reform* (Feb. 13, 2002), at [www.healthaffairs.org/WebExclusives/Wennberg\\_Web\\_Excl\\_021302.htm](http://www.healthaffairs.org/WebExclusives/Wennberg_Web_Excl_021302.htm).

40. See *Minnesota v. United States*, 102 F. Supp. 2d 1115, 1123-24 (D. Minn. 2000), *aff’d*, 273 F.3d 805 (8th Cir. 2001) (geographic differences in payments to counties under the Medicare+Choice program do not violate equal protection, because Congress’s policy was rationally related to legitimate objectives of cost-containment and expansion of options).

41. MEDICARE 2000, *supra* note 9, at 43.

42. See John K. Iglehart, *The Centers for Medicare and Medicaid Services*, 345 NEW ENG. J. MED. 1920, 1921 (2001).

43. A statutory exception to the separation of “mandatory trust fund spending from ‘discretionary’ administrative spending” was the Medicare Integrity Program, created under the Health Insurance Portability and Accountability Act, which earmarked mandatory funds for fraud and abuse activities and permitted savings from fraud recoveries to be retained for additional fraud detection activities and place the funds in a special account—the Health Care Fraud and Abuse Control Account. Social Security Act, as added by the Health Insurance Portability and Accountability Act, Pub. L. No. 104-191,

§ 1817(k) (1996).

These and other constraints restrain Medicare from becoming an active purchaser of care and selectively using managed care tools. Nevertheless, the experience among private health plans, both positive and negative, offers specific opportunities for Medicare. As we will make clear, both the experience of private plans and the constraints faced by Medicare would fashion how these tools might be best adapted to the Medicare environment.

#### IV

##### PURCHASING TECHNIQUES WITH WHICH MEDICARE MIGHT PROCEED

The ability to contract selectively with the licensed and available providers in a geographic area has been a hallmark of managed care.<sup>44</sup> The traditional prepaid group practices, such as Kaiser-Permanente, were opposed by organized medicine for many years precisely because they were closed-panel, alternative-delivery systems.<sup>45</sup> But even in open-panel, network-model HMOs that came to the forefront in the 1980s, selective contracting was a prominent tool used by the plans.<sup>46</sup> Some argue that the use of selective contracting is the key policy issue that must be addressed in considering the applicability of managed care techniques to a social insurance program such as Medicare, and that it is what really distinguishes managed care from good management by traditional payers.<sup>47</sup>

The basic premise of selective contracting is that MCOs can provide higher quality at lower cost by limiting the number and balancing the types of providers that plan enrollees may visit.<sup>48</sup> Theoretically, the health plan will have a smaller delivery system that can be more easily managed, and the plan can initially select providers who have reputations for quality and, over time, providers who have evidence to document higher quality and better efficiency than the average. Crucially important to those plans that negotiate payment rates in the market, selective contracting provides substantial negotiation leverage.<sup>49</sup> Even if a plan wants to establish a broadly inclusive network of available providers, the plausible threat of excluding providers permits plans to obtain more favorable payment rates, at least in those geographic areas where there is competition among providers.

Originally, even open-panel HMOs sought to market relatively small, manageable provider networks. Over time, they met with an unfavorable market reaction to restricted provider choice. Employers started demanding broad, almost universal, choice of provider to assuage employees who did not want

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44. See Joseph White, *Which 'Managed Care' for Medicare?*, HEALTH AFF., Mar. 1997, at 5, 73.

45. See PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 323-27 (1982).

46. See WALTER A. ZELMAN & ROBERT A. BERENSON, THE MANAGED CARE BLUES & HOW TO CURE THEM 69-72 (1988).

47. See generally Joseph White, *Targets and Systems of Health Care Cost Control*, 24 J. HEALTH POL. POL'Y & L. 653, 655, 676-82 (1999) (presenting the policy conflicts associated with making "coordinated payment," where "payment is coordinated broadly on standard terms across the community of providers," and selective contracting).

48. See Marsteller et al., *supra* note 2, at 1134.

49. See ZELMAN & BERENSON, *supra* note 46, at 69.

their choice of provider restricted. For their part, excluded providers were successful in some states in having legal restrictions placed on selective contracting, through any-willing-provider and freedom-of-choice laws.<sup>50</sup>

Despite the documented success of selective contracting in reducing costs,<sup>51</sup> there has been a broad retrenchment in its use. In their surveys of health system change in twelve communities, the Center for Studying Health System Change found that most health plans surveyed had steadily increased the number of physicians and hospitals with which they contracted, and, by 2000, few plans were actively constraining the size of their networks or excluding providers based on the efficiency of their practice patterns.<sup>52</sup> Reasons cited included growing consumer demand for provider choice, lack of reliable information on which to base selection, and difficulties demonstrating savings from limited-network products.

In short, the market has forced health plans into the same position as the authorizing statute has placed Medicare: They offer virtually all providers and do not selectively contract, except for relatively infrequent, highly specialized services. As noted, plans can still use the threat of non-contracting to negotiate lower payment rates than they otherwise might achieve. Medicare cannot use such leverage but, for most services, sets relatively aggressive administered prices.<sup>53</sup>

Some private plans that feel forced to contract with a broad array of providers nevertheless may profile providers for a number of reasons, including providing performance-based reimbursements and determining specialists from within the broader network to whom the HMO will refer certain kinds of cases.<sup>54</sup> Within an any-willing-provider system, Medicare similarly would have an interest in using financial incentives and consumer information to try to influence beneficiary choice of provider.

The Centers of Excellence provided a prototype for this area.<sup>55</sup> The program provided bundled Part A and Part B payments for certain expensive procedures, including coronary artery bypass graft ("CABG") surgery and hip and knee replacement surgery to designated hospitals, the Centers of Excellence, which were selected based on documented high outcomes associated with high

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50. See Marsteller et al., *supra* note 2, at 1134. See also Robert L. Ohsfeldt et al., *The Spread of Any Willing Provider Laws*, 33 HEALTH SERVICES RES. 1537, 1538 (1998).

51. See Jack Zwanginer et al., *The Effect of Selective Contracting on Hospital Costs and Revenues*, 35 HEALTH SERVICES RES. 849, 851 (2000) (demonstrating that hospitals in more competitive areas had a substantially lower rate of increase in costs and revenues, attributable to the growth of selective contracting).

52. CSHSC Draft, *supra* note 23.

53. See Moon & Davis, *supra* note 19, at 39.

54. See Peter R. Kongstvedt et al., *Using Data and Provider Profiling in Medical Management*, in THE MANAGED HEALTH CARE HANDBOOK 440-54 (Peter R. Kongstvedt ed., 4th ed. 2001) [hereinafter THE MANAGED HEALTH CARE HANDBOOK].

55. In response to concerns by those hospitals not receiving Centers of Excellence designations that they would be viewed by the public as not excellent, CMS recently agreed to change the name of the follow-up demonstration to Medicare Partnerships for Quality Services. See CMS website at <http://cms.hhs.gov/healthplans/research/mpqsdem.asp> (last visited Sept. 19, 2002).

volumes of services performed. In addition to receiving information about the quality differences, Centers were allowed to waive some or all of patient cost-sharing and could pay for transportation costs, given immunity from the Anti-Kickback Law.<sup>56</sup> Importantly, beneficiaries retained the choice of seeking care at any participating hospital according to standard statutory cost-sharing and other terms.

The first Centers demonstration cut program costs by ten percent for the 10,000 CABG surgeries performed, reduced expected mortality, and received higher patient satisfaction.<sup>57</sup> Nevertheless, provider groups have raised major concerns about a government program designating some providers as higher quality care providers than others and paying differentially.<sup>58</sup>

In summary, despite provider opposition to even government-made, quality-related designations, the Medicare program has an opportunity to use patient information, education, and relatively modest financial incentives to influence beneficiaries' choice of provider. Importantly, beneficiaries' freedom of choice of providers would be maintained, consistent with section 1802.

#### A. Prior Authorization

Prior authorization is a core activity of Utilization Management ("UM"), which the Institute of Medicine defined as:

a set of techniques used by or on behalf of purchasers of health care benefits to manage health care costs by influencing patient care decision-making<sup>59</sup> through case-by-case assessments of the appropriateness of care prior to its provision.

Utilization management approaches have been used in all types of insurance products, including indemnity plans. Using prior authorization programs is what distinguishes managed from unmanaged indemnity, so that its use in the traditional Medicare program might be expected.

Most of the studies examining the cost-effectiveness of utilization management programs that focused on inpatient care in the private sector took place in the mid- to late-1980s. A literature review performed in 1990 concluded that

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56. See Medicare-Medicaid Anti-Fraud and Abuse Amendments, Pub L. No. 95-142, 91 Stat. 1175 (1977) (codified as 42 U.S.C. § 1320a-7b(b)). Because most beneficiaries have a form of supplemental insurance, waiving cost-sharing would have attenuated value as an incentive.

57. *Medicare Reform: Modernization Requires Comprehensive Program View*, 107th Cong. 16 (2001) (testimony of William J. Scanlon, Director, Health Financing and Public Health Issues, General Accounting Division, before House Subcomm. on Health, Comm. on Energy and Commerce).

58. *Id.* at 17. See also Kristen Hallem, *Doctors Fear Excellence Designation; Medicare Center of Excellence Program*, 30 MODERN HEALTHCARE 30 (Dec. 18, 2000). An interesting commentary on the subject was offered by Tom Scully, then president of the Federation of American Health Systems and now Administrator of CMS. "The flaw of the fee-for-service system is that it has to pay every provider the same amount in every community. . . . That is the fundamental flaw of fee-for-service programs. Providers, obviously, do not like to hear that." Thomas Scully, *Comment on Joseph R. Antos Preparing for the Retirement of the Baby Boomers*, in *MEDICARE: PREPARING FOR THE CHALLENGES OF THE 21ST CENTURY* 257, 257 (Robert D. Reischauer et al. eds., 1998).

59. See INSTITUTE OF MEDICINE, *CONTROLLING COSTS AND CHANGING PATIENT CARE: THE ROLE OF UTILIZATION MANAGEMENT* 2-3 (Bradford H. Gray & Marilyn J. Field eds., 1989). The terms "utilization review" and "utilization management" are often used interchangeably. The latter term connotes a somewhat broader set of activities, of which utilization review is a core activity.

both utilization review programs which focused on hospital use and prior authorization programs did reduce inpatient utilization and expenditures.<sup>60</sup> Based on early successes, programs were expanded first to outpatient surgical procedures and then even to routine ambulatory referrals from one physician to another.<sup>61</sup>

Although much medical review is required to determine that services provided are medically necessary in the Medicare program, most of the activity performed by the Part A and Part B contractors, the intermediaries and carriers, and by the Peer Review Organizations (“PROs”) is retrospective.<sup>62</sup> When reviews are done—prior to services being rendered, prior authorization and concurrent review, or after the fact, retrospective review—is a major difference between managed care utilization review (“UR”) and Medicare UR.<sup>63</sup>

There are good reasons to perform prior authorization rather than rely on after-the-fact review of cases for appropriateness. Most importantly, prior authorization removes the need to deny payment after resources have been committed.<sup>64</sup> If the only option is to deny payment for services found not to be medically necessary, as it is under the Medicare statute, retrospective denial would expose beneficiaries to extraordinary financial liability. Accordingly, medical reviewers are more likely to invent a rationale for a retrospective approval for a procedure or admission that they would have denied under a prior authorization regime.<sup>65</sup> Also, retrospective review exposes patients to possibly harmful interventions that might have been avoided if they had been subjected to prior authorization.<sup>66</sup>

Of course, prior authorization, especially when broadly applied, is viewed as highly intrusive by physicians<sup>67</sup> and has been abandoned by some insurance companies.<sup>68</sup> It was also abandoned in Medicare after making a brief appear-

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60. See Thomas M. Wickizer, *The Effect of Utilization Review on Hospital Use and Expenditures: A Review of the Literature and an Update on Recent Findings*, 47 MED. CARE REV. 327 (1990).

61. See Kongstvedt et al., *Managing Basic Medical-Surgical Utilization*, *supra* note 54, at 294-330.

62. U.S. GENERAL ACCOUNTING OFFICE, *MEDICARE: FEDERAL EFFORTS TO ENHANCE PATIENT QUALITY OF CARE* 27 (1996) [hereinafter *GAO FEDERAL EFFORTS*]; U.S. GENERAL ACCOUNTING OFFICE, *MEDICARE: INADEQUATE REVIEW OF CLAIMS PAYMENTS LIMITS ABILITY TO CONTROL SPENDING* (1994) [hereinafter *GAO INADEQUATE REVIEW*].

63. See U.S. GENERAL ACCOUNTING OFFICE, *MEDICARE: IMPROVEMENTS NEEDED IN THE IDENTIFICATION OF INAPPROPRIATE CARE* 3, 17 (1989) [hereinafter *GAO MEDICARE*].

64. *Id.* at 18.

65. *Id.* at 32.

66. *Id.* at 18.

67. *Id.* at 18. See also Eve A. Kerr et al., *Associations Between Primary Care Physician Satisfaction and Self-Reported Aspects of Utilization Management*, 35 HEALTH SERVICES RES. 333, 333 (2000).

68. CSHSC Draft, *supra* note 23. Patients and consumer advocates have also complained about prior authorization as an intrusion into the doctor-patient relationship and the claim that clerks or bean counters were overruling physicians' clinical decisions. *GAO FEDERAL EFFORTS*, *supra* note 62, at 27 (describing the categories involved in individual case review by the PROs in the fifth scope of work; prior authorization of specified hospitalization services was no longer a category). In reporting on structured interviews with consumer representatives, Singer and Bergthold reported that “consumers interviewed were unaware that both the National Committee for Quality Assurance (“NCQA”) and the Knox-Keene Act, which regulates managed care plans in California, require that only licensed physicians can make medical necessity decisions or denials, and that NCQA audits compliance with

ance in the program in the mid- to late 1980s.<sup>69</sup> As an example of prior authorization, under the third Scope of Work<sup>70</sup> contracts, PROs were required to perform prospective reviews for ten medical and surgical procedures, such as cataract extractions and carotid endarterectomies.<sup>71</sup>

By the early 1990s, the Health Care Financing Administration abandoned PRO prior authorization<sup>72</sup> and presaged what would happen in private plans, namely, a marked backlash by physicians and patients, which has led many private plans to abandon prior authorization in part or completely.<sup>73</sup>

What went wrong? Certainly, some of the problem was related to blind adherence to fragments of evidence of appropriateness that led to the drive-through-deliveries phenomenon, which quite effectively aligned the interest of the public with those of physicians.<sup>74</sup> Health plans lost the moral high ground they might have claimed for trying to reduce unnecessary and possibly harmful hospitalizations and procedures. Instead, they became easy targets for caricature and ridicule.

Another major execution problem resulted from the assumption of health plan and benefit consultants that, if some prior authorization is good, more must be better. Prior authorization requirements became commonly applied not only to high-cost, relatively rare hospitalizations, but also to routine, common ambulatory care encounters,<sup>75</sup> dramatically raising administrative costs and the amount of intrusion into clinical practice. Also, prior authorization programs typically treated all providers the same, which Medicare arguably has to do, but private plans did not. The technique was not targeted to problem providers, based on utilization management profiling, but rather applied with a broad brush, thereby arousing the ire of potential physician allies in health plan

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these requirements.” Sara J. Singer & Linda A. Bergthold, *Prospects for Improved Decision Making About Medical Necessity*, HEALTH AFF., Jan./Feb. 2001, at 200, 201.

69. Katherine N. Lohr & A.J. Walker, *The Utilization and Quality Control Peer Review Organization Program*, in MEDICARE: A STRATEGY FOR QUALITY ASSURANCE 413-414 (Katherine N. Lohr ed., 1990) (conducting a complete review of the origins and activities of the PRO program from inception until the summer of 1989). A focus on utilization review through the peer review organizations complemented implementation of the hospital prospective per case payment system (“PPS”), which went into effect in 1985. The per case payment system has an incentive for inappropriate hospitalization of low acuity patients.

70. Scope of Work refers to contract cycles that initially were for two years and that in the Omnibus Budget Reconciliation Act of 1987 were extended to three years. Pub. L. No. 100-203, 101 Stat. 1330. Thus, the third Scope of Work was developed in which one-fourth of the PROs began the contract cycle on October 1, 1988 and the remaining PROs on April 1, 1989. Lohr & Walker, *supra* note 69, at 345.

71. GAO MEDICARE, *supra* note 63, at n.61.

72. GAO FEDERAL EFFORTS, *supra* note 62, at 27.

73. The CSHSC survey found that, prior to 1998, nearly all HMO and PPO products in the twelve surveyed communities required patients to obtain prior authorization from the plan for many inpatient and outpatient procedures. From 1998 until their interviews in 2000-01, sixteen of forty-eight plans eliminated selected prior authorization requirements. See CSHSC Draft, *supra* note 23.

74. Technically, a two-day limit on hospital stay after pregnancy is called concurrent review, not prior authorization. They are complementary procedures in utilization management. GAO MEDICARE, *supra* note 63, at 17.

75. Kongstvedt et al., *supra* note 61, at 294-330.

networks who might have supported prior authorization if targeted to address problematic performance.

Given the backlash to prior authorization performed by the PROs in the 1980s and the current backlash toward its use by private plans, why would Medicare ever consider reinstating prior authorization? Because that is where the money is. Of note, the CSHSC study discussed earlier shows that the majority of health insurance products have maintained their utilization management requirements in the face of opposition from providers, patients, and even political candidates.<sup>76</sup> It is important to note that capitated, at-risk medical groups in California adopted the very techniques of utilization management—including prior authorization—to manage their own risk about which physicians complained when performed by insurance companies and third-party administrators.<sup>77</sup>

When performed by Medicare, prior authorization should be narrowly applied and targeted, unlike the general approach that has been used by many health insurers. Given the checkered history of prior authorization, Medicare should only apply prior authorization to procedures that meet most or all of the following criteria: (1) have high unit cost; (2) are infrequently performed; (3) are elective, such that the time to conduct external review would not affect outcomes; (4) rely on clinical judgment based largely on objective, easily retrievable information; (5) have associated evidence of or reason to expect significant variations in use; and (6) would benefit from a review process focused on quality, as well as costs.

Although these criteria might seem to eliminate almost everything from consideration, the dissemination of expensive, new diagnosis and treatment technology offers opportunities beyond what can be provided by the new approaches in determining what new technologies and services are reasonable and necessary.<sup>78</sup> In addition, Medicare should utilize profiling to foster better provider relations and lower administrative costs. Through the use of profiling, Medicare should, over time, be able to exempt from prior authorization

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76. See CSHSC Draft, *supra* note 23.

77. Eve A. Kerr et al., *Managed Care and Capitation in California: How Do Physicians at Financial Risk Control Their Own Utilization?*, 127 ANNALS INTERNAL MED. 500, 500-04 (1995).

78. LEWIN REPORT, *supra* note 37, at 34. A good candidate for prior authorization would be the recently approved ocular photodynamic therapy for age-related macular degeneration ("AMD"), the leading cause of blindness in adults over fifty. National Institutes of Health, *Recruitment Begins for Study on Age-Related Macular Degeneration*, available at <http://www.nih.gov/news/pr/jul99/nei-07.htm> (Jul. 7, 1999) [hereinafter NIH, *Recruitment*]. The NIH has estimated that 1.7 million adults over sixty-five have AMD. *Id.* Verteporfin was approved by the Food and Drug Administration in April 2000, based on studies showing efficacy for delaying deterioration in vision AMD. *Id.* Later in 2000, it received a positive National Coverage Decision by Health Care Financing Administration. Medicare Coverage Policy Decisions—Ocular Photodynamic Therapy with Verteporfin, available at <http://www.hcfa.gov/coverage/8b3-ee.htm> (last visited May 1, 2002). If used for the nearly 200,000 Medicare beneficiaries that, under current FDA-approved indications, can benefit from the therapy, Medicare would spend \$2.5 billion dollars for beneficiaries who currently have the diagnosis and another \$250 million per year for the 20,000 new cases of wet macular degeneration that develop each year. From this estimate, one can see the scale of spending if used for some portion of the large majority of patients with "dry" AMD.

requirements those physicians who consistently meet the relevant clinical appropriateness criteria.

### B. Gatekeeper/Case Management Programs

The use of primary care physicians as gatekeepers is another core component that has characterized much of managed care, particularly, but not exclusively, HMOs.<sup>79</sup> As with other managed care tools, gatekeeping can serve multiple functions. These include containing costs by restricting referrals to specialists, increasing access to primary and specialty care, or improving coordination of care by generalists.<sup>80</sup>

Indeed, the terminology used to describe gatekeeping reflects not only the primary purpose of the intervention, but also its political viability. For example, although gatekeeper programs used by state Medicaid agencies were designed to alter utilization patterns of Medicaid beneficiaries as well as provide them a medical home,<sup>81</sup> the terminology changed by the early 1990s to primary care case management (“PCCM”), presumably because of the pejorative connotation of gatekeeping.

Gatekeeping is not unique to the United States or to managed care, as it is widely used in European health systems, both in FFS and capitated arrangements.<sup>82</sup> Nevertheless, the mandatory enrollee assignment to a primary care physician who approves referrals has been a prominent source of resentment against MCOs. As with prior authorization programs, many plans have withdrawn their gatekeeping programs.<sup>83</sup>

There is evidence of a decrease in costs and specialty utilization within health plans that use primary care gatekeeping, particularly among groups of patients who might otherwise have relatively high rates of specialty utilization.<sup>84</sup> Nevertheless, although many of the studies comparing the performance of generalists and specialists have methodological flaws, the literature does suggest that generalists lag behind specialists in using recommended diagnostic and treatment modalities.<sup>85</sup>

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79. ZELMAN & BERENSON, *supra* note 46, at 76-78.

80. See Timothy G. Ferris et al., *Leaving Gatekeeping Behind: Effects of Opening Access to Specialists for Adults in a Health Maintenance Organization*, 345 NEW ENG. J. MED. 1312, 1312 (2001) (finding in a capitated, multispecialty group practice little evidence of changing use of specialty services in the first eighteen months after elimination of gatekeeping).

81. See Robert E. Hurley et al., *Gatekeeper Effects on Patterns of Physician Use*, 32 J. FAM. PRAC. 167, 167 (1991).

82. See Juan Guervas et al., *Primary Care, Financing and Gatekeeping in Western Europe*, 11 FAM. PRAC., 307, 307-17 (1994).

83. CSHSC Draft, *supra* note 23.

84. See Ferris et al., *supra* note 80, at 1312 for a comprehensive literature review of the effects of gatekeeping.

85. See Sloan & Hall, *supra* note 2, at 170 n.3 (concluding that specialists tend to outperform generalists in their field of expertise. The authors also conclude that no studies demonstrate that this theoretical flaw of gatekeeping has resulted in worse outcomes or process measures for HMO enrollees).

Seniors and disabled beneficiaries appear to be an ideal population for a primary care physician functioning as a care coordinator because they have more chronic diseases than the relatively healthy population or those Medicaid beneficiaries required to be in PCCM programs. The general backlash to gate-keeping, however, and the concern about primary care physicians handling clinical problems beyond their expertise would seem to preclude consideration of a mandatory, primary care gatekeeper requirement in Medicare.<sup>86</sup>

Many health plans, as well as the Medicare PACE program,<sup>87</sup> have utilized non-physician, case-management programs for patients with a single catastrophic illness or multiple debilitating, chronic diseases. Case management has been defined as “a collaborative process which assesses, plans, implements, coordinates, monitors, and evaluates the options and services required to meet an individual’s health needs, using communication and available resources to promote quality, cost-effective care.”<sup>88</sup>

CMS is currently conducting a demonstration of case management and disease management programs that are targeted to the small population of beneficiaries that are responsible for a major proportion of Medicare expenditures.<sup>89</sup> As noted earlier, targeted case-management and disease-management programs would be useful in a modernized Medicare program if proven to be cost-effective. There should be little policy or legal concern for targeting those who can benefit from these programs. Similarly, if beneficiary participation in these programs were voluntary, there should be little problem with restricting freedom of choice in Medicare+Choice plans or hospice.

There is another issue relevant to case management, which should be noted. In addition to coordinating services and educating and monitoring patients, case managers in MCOs typically have authority to provide individual patients off-policy benefits, allowing them discretion in instances where treatment goals may be achieved in a more cost-effective manner.<sup>90</sup> The question whether Medicare could approve non-statutory benefits on a case-by-case basis will be considered later.

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86. As an alternative, the agency could promote the desirability of seniors voluntarily choosing to have a primary care physician be the source of primary care and to help care coordination among specialists.

87. 42 U.S.C. § 1395eee (2000).

88. Catherine M. Mullahy, *Case Management and Managed Care*, in THE MANAGED HEALTH CARE HANDBOOK, *supra* note 54, at 371.

89. *See supra* note 27 and accompanying text.

90. *See* Mullahy, *supra* note 88, at 373.

## V LEGAL ISSUES

### A. The Current Statutory Scheme for Medicare Providers and Patients

Under the current statutory scheme, Medicare beneficiaries have the right to choose any qualified provider.<sup>91</sup> In a corresponding manner, virtually any licensed healthcare provider has the opportunity to participate in this lucrative federal program.

In addressing provider participation, the current statute makes a distinction between health care facilities and individual physicians. For health care facilities, which are referred to as providers, the statute and regulations establish a system of provider agreements.<sup>92</sup> The Secretary of Health and Human Services is essentially required to enter into an agreement with any entity that requests participation and meets the applicable conditions of participation.<sup>93</sup> Although providers may terminate their agreements without cause, the grounds on which the Secretary may refuse to enter into an agreement, terminate an agreement, or refuse to renew an agreement are extremely limited.<sup>94</sup> Individual physicians enjoy an even more privileged status under the Medicare statute, since they are not subject to the above-described system of provider agreements and conditions of participation. In effect, the Medicare statute permits anyone who is licensed or authorized to practice medicine by the laws of a state to treat Medicare beneficiaries and to receive compensation for doing so.<sup>95</sup>

Notwithstanding the beneficiary's free choice of provider, the Secretary of Health and Human Services has authority to exclude an individual physician, as well as a facility, from participation in the program for statutorily specified reasons.<sup>96</sup> Exclusion is mandatory for certain conduct, such as conviction of a program-related crime.<sup>97</sup> In addition, the Secretary has the discretion to exclude an individual or facility for other specified conduct, such as providing patients with services that are "substantially in excess of the needs of such patients or of a quality which fails to meet professionally recognized standards of health care."<sup>98</sup> At least theoretically, the Secretary already has the statutory authority to exclude physicians and institutions on the grounds of inadequate quality and excessive utilization. Except in the most egregious cases, however, it is difficult

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91. See Social Security Act § 1802, 42 U.S.C. § 1395a(a) (2000).

92. See 42 U.S.C. § 1395cc (2000); 42 C.F.R. § 489.10.

93. See *id.*

94. See 42 U.S.C. § 1395cc(b); 42 C.F.R. § 489.12.

95. See 42 U.S.C. § 1395x(r) (defining "physician"). The statute does include the concept of "participating physician," but merely refers to the routine acceptance of assignment, and even non-participating physicians have the right to be compensated by the program for treating Medicare patients. See 42 U.S.C. § 1395u(b). Therefore, in this article, the term "participation" is used in the broader sense of treating Medicare beneficiaries and receiving payment from the Medicare program.

96. See 42 U.S.C. § 1320a-7 (2000).

97. See 42 U.S.C. § 1320a-7(a)(1).

98. 42 U.S.C. § 1320a-7(b)(6)(B). See also 42 C.F.R. § 1001; 42 C.F.R. § 489.54.

to exclude physicians and institutions from participation in the program on those grounds.<sup>99</sup>

As corollaries to the free choice of provider, the current statutory scheme requires uniformity in payment to providers and in cost-sharing by beneficiaries. For each type of provider, the statutes set forth a single methodology to determine the payment for services rendered, such as prospective payment for hospital services and fee schedules for physicians. Within each category of provider, the amount of payment may vary based on the service performed or the patient's diagnosis. The statutes do not, however, include any mechanism to pay a retrospective bonus or a higher prospective rate for services of greater quality and efficiency. Similarly, the statutes delineate the responsibility of the beneficiary for co-payments and deductibles, but do not permit any differentiation in cost-sharing on the basis of the beneficiary's choice of provider. The statutes also require uniformity of benefits and administration of benefits for all eligible beneficiaries. This prevents the use of flexible case management, voluntary negotiation of off-policy benefits, and targeting of particular services, providers, and geographic areas for prior authorization or other types of more intensive utilization review.

Finally, the statutes include an explicit prohibition in section 1801 against any federal interference with the practice of medicine or the operation of any health care facility.<sup>100</sup> Despite the broad language of that statute, it has not been interpreted as a significant limitation on federal authority. First, courts have recognized that section 1801 must be read *in pari materia* with other provisions of the Medicare law, including the provisions on cost containment<sup>101</sup> and qualifications of providers.<sup>102</sup> Second, courts have reasoned that Congress intended to

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99. See William H. Dow & Dean M. Harris, *Exclusion of International Medical Graduates from Federal Health-Care Programs*, 40 MED. CARE 68, 69 (2002) (concluding that data on exclusion of physicians from Medicare indicates that only a small percentage of those exclusions is explicitly based on quality of care or efficiency).

The any-willing-provider ("AWP") concept and the beneficiary's free choice of provider may make it more difficult for the program to exclude physicians and institutions for cause, such as a failure to meet appropriate standards of quality and utilization. Although the current statute only gives beneficiaries the right to select a "qualified" provider and includes clear authority to exclude physicians and institutions for cause, 42 U.S.C. § 1395a(a) (2000), there is an understandable reluctance to exclude all but the worst performers from a system in which virtually everyone is allowed to participate.

In addition, the AWP concept prevents the Medicare program from terminating providers for business reasons, such as eliminating low-volume providers in the interest of administrative efficiency.

100. Codified at 42 U.S.C. § 1395. Specifically, this section provides that

[n]othing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person. *Id.*

101. See *Home Health Care, Inc. v. Heckler*, 717 F.2d 587, 590 (D.C. Cir. 1983). See also *Mount Sinai Hosp., Inc. v. Weinberger*, 517 F.2d 329, 344 (5th Cir. 1975) (concluding that a system of immediate claims review was created by the same Congress that adopted § 1801).

102. See *Rasulis v. Weinberger*, 502 F.2d 1006, 1010 (7th Cir. 1974) (discussing qualifications of physical therapists).

encourage physicians to practice in a cost-effective manner, and, therefore, encouraging physicians to consider financial issues in their treatment decisions does not constitute federal supervision or control.<sup>103</sup> In light of these decisions, section 1801 does not prevent the Medicare program from imposing restrictions and limitations on the payment of providers,<sup>104</sup> nor does that statute prevent the Secretary from using payment mechanisms that give financial incentives to providers.<sup>105</sup>

#### B. Proposed Statutory and Regulatory Changes<sup>106</sup>

In addition to the inherent power of Congress to amend its own prior acts, Congress explicitly reserved the right to amend or repeal any part of the Social Security Act, which would include the Medicare provisions in Title XVIII of that Act.<sup>107</sup> In order to implement the reforms proposed in this article, it would be necessary to amend section 1802,<sup>108</sup> which guarantees the free choice of any qualified provider, as well as the corresponding provisions on participation by physicians and facilities.

This article does not propose to amend section 1802 to replace the existing any-willing-provider (“AWP”) system with a process of selective contracting.

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103. See *Home Health Care*, 717 F.2d at 590-91; *Rasulis*, 502 F.2d at 1010; *Pleasantview Convalescent & Nursing Ctr., Inc. v. Weinberger*, 565 F.2d 99, 103 (7th Cir. 1976).

For example, in a challenge by the American Medical Association to the validity of the Secretary's regulations on the Maximum Allowable Cost (“MAC”) of prescription drugs, the district court held that the regulations would not constitute federal supervision of medical practice, even if the regulations would affect the prescribing habits of physicians. *AMA v. Mathews*, 429 F. Supp. 1179, 1201-03 (N.D. Ill. 1977). The court reasoned that the effect on medical practice would be merely “incidental,” and that having an impact on unnecessary medical care was intended by Congress “as a permissible by-product of cost controls.” *Id.* at 1202-03. At least theoretically, the court recognized that Section 1801 could prevent some mechanisms of cost control that go too far in limiting professional judgment, but those mechanisms would be permissible so long as there was “an informed medical decision that the incurred costs are necessary in the efficient delivery of health services.” *Id.* at 1202. But see *AMA v. Weinberger*, 522 F.2d 921, 925 (7th Cir. 1975) (upholding preliminary injunction against enforcement of Medicare regulation on immediate utilization review, in part because a direct influence on doctors' decisions would violate Section 1801).

104. See *Heckler*, 717 F.2d at 591; *Mathews*, 429 F. Supp. at 1201-02. See also *Mount Sinai*, 517 F.2d at 344 (recouping funds paid by the program for unnecessary care would not violate Section 1801, despite the claimed chilling effect on professional judgment). *Accord Szekely v. Florida Med. Ass'n*, 517 F.2d 345, 350 (5th Cir. 1975). Moreover, courts have specifically rejected the contention that refusing to pay for a particular method of delivering services is tantamount to prohibiting that method of delivery. See *Home Health Care*, 717 F.2d at 591.

105. In addition, some aspects of medical practice and facility operation would be beyond the scope of Section 1801 on the ground that they constitute business decisions rather than professional judgment. See *Pleasantview*, 565 F.2d at 103.

In a totally different approach to Section 1801, the California Court of Appeals held that this federal statute was intended to preserve state and local control over health care licensure and to avoid federal preemption in that area. *Bell v. City of Mountain View*, 66 Cal. App. 3d 332, 340 (1977).

106. For the reasons discussed above, it would not be necessary to amend or repeal Section 1801, because that statute has not been interpreted to impose any significant limitation on the authority of the government.

107. 42 U.S.C. § 1304. As part of the Social Security Act, Title XVIII on Medicare is subject to the general provisions in Title XI, including § 1304.

108. See *supra* note 91 and accompanying text.

For the reasons discussed above,<sup>109</sup> it would not be advisable for Medicare to contract exclusively with some providers to the total exclusion of others, except perhaps for a few non-professional commodities such as durable medical equipment. Instead, section 1802 and the corresponding sections on provider participation should be amended to authorize financial incentives for beneficiaries to select the highest quality and most efficient providers, while continuing to permit beneficiaries' choice of any qualified provider. Under this alternative, the revised section 1802 would still guarantee the beneficiary's freedom of choice. The revised section, however, would explicitly acknowledge that the beneficiary may incur lower co-payments for selecting a preferred provider, and would explicitly acknowledge that the provider selected by the beneficiary would not necessarily be paid the same as all other qualified providers.<sup>110</sup>

To implement the proposed system of contracting at differential rates with preferred and non-preferred providers, it would also be necessary to amend the current statutory provisions that effectively require all providers to be paid on equal terms. At least theoretically, statutory provisions requiring specific payment methodologies for each category of provider could be replaced with a broad grant of authority to the Secretary to procure services for Medicare beneficiaries on such terms, and with such variations in terms, as are deemed to be in the best interest of the program and its beneficiaries.<sup>111</sup> A less radical and more politically realistic approach would be to retain the existing payment methodologies in the statutes, while adding statutory authorization for the Secretary and his agents to enter into contracts on different terms of payment, on either a national or local basis, with physicians and facilities who are willing to enter into contracts on an alternative basis. To impose limits on local intermediaries and carriers, the Secretary could issue general guidelines for alternative contracting, with local agents negotiating alternative arrangements within those parameters. If those alternative contracts were voluntary, they would be less problematic from a legal and political perspective.

In amending the statute, Congress should not permit the Medicare program to terminate providers without cause, as is permitted by contract in some private managed care plans.<sup>112</sup> That approach would be inadvisable for a program

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109. See *supra* notes 45-59 and accompanying text.

110. Conforming changes would also be required to the statutes on co-payments and deductibles.

111. Jost, *supra* note 33, at 66 ("Congress has not been content to establish the broad framework of the Medicare program, but has in many respects micromanaged programmatic detail as well."); see also U.S. GENERAL ACCOUNTING OFFICE, MEDICARE: TWENTY-FIRST CENTURY CHALLENGES PROMPT FRESH THINKING ABOUT PROGRAM'S ADMINISTRATIVE STRUCTURE 14 (2000) ("micromanagement of Medicare").

112. Theoretically, the Medicare statute could be amended to specify that (i) all provider agreements will expire by their own terms after a limited period of time; (ii) the Secretary may terminate any provider agreement without cause upon adequate notice; and (iii) the Secretary may refuse to renew an agreement without cause. In addition, the statute could be amended to explicitly state that the Secretary has no obligation to enter into an agreement with any individual or entity, and that the Secretary has the discretion to enter into contracts on a selective, exclusive, or differential basis for the benefit of the program and its beneficiaries. Finally, the statute could also be amended to bring physicians into a system of written contracts that have limited duration and are terminable without

such as Medicare that relies on the public for both financial and political support. In addition, termination without cause can be used as a subterfuge to avoid the need for legal proceedings and legal justification in situations that are really terminations for cause.<sup>113</sup> Therefore, the Medicare statute should continue to require cause to terminate or refuse to renew providers, but the exclusion of providers on grounds of quality and efficiency might be enhanced through the use of objective standards and clinical practice guidelines.<sup>114</sup>

Moreover, the statute should be amended to provide greater flexibility in benefits and in the administration of benefits. Specifically, Congress should grant the Secretary statutory authority to use prior authorization in those situations in which the Secretary considers it to be useful and appropriate. This change would allow the Secretary and his agents to tailor the use of prior authorization to particular services, providers, and geographic areas. The statute should also be amended to permit the Medicare program to use modern methods of case management, and to provide off-policy benefits by voluntary negotiation with the beneficiary, provided that the cost to the program for the off-policy benefit is not anticipated to exceed the amount that would have been paid for the standard benefit.<sup>115</sup>

In addition to amending the laws on provider participation, payment, and benefits, it would be necessary to amend the laws on Medicare fraud and abuse

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cause. However, as stated above, we think that these types of changes would be inappropriate for the Medicare program.

113. In the analogous context of de-participation without cause by private managed care plans, a few courts have allowed the aggrieved physician to argue that the purpose of termination violated public policy. See, e.g., *Potvin v. Metro. Life Ins. Co.*, 22 Cal. 4th 1060, 1073 (2000) (“We therefore agree with Potvin that the ‘without cause’ termination clause is unenforceable to the extent it purports to limit an otherwise existing right to fair procedure under the common law.”); *Harper v. Healthsource N.H., Inc.*, 674 A.2d 962, 964 (N.H. 1996) (holding that a managed care organization’s contractual right to terminate a physician without cause could not be exercised for a reason that is contrary to the public policy of the State).

114. In addition to recommending that the ability of the program to terminate providers for lack of quality or efficiency be enhanced, some commentators have recommended that Congress impose more stringent conditions of participation or authorize the Secretary to impose higher conditions of participation by means of regulation. For example, Lee Newcomer has suggested that Medicare’s conditions of participation should require hospitals to use a computerized order entry system. Lee N. Newcomer, *Medicare Pharmacy Coverage: Ensuring Safety Before Funding*, HEALTH AFF., Mar. 2000, at 59; see also Etheredge, *supra* note 8. However, that approach could be difficult to implement. Under 42 U.S.C. § 1395bb, the vast majority of hospitals are “deemed” to comply with Medicare certification requirements on the basis of their accreditation by the Joint Commission on Accreditation of Healthcare Organizations (“JCAHO”). See U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL, *The External Review of Hospital Quality: The Role of Medicare Certification* 1, 6 (1999) (only twenty percent of participating hospitals are non-accredited and undergo the governmental survey and certification process). Moreover, there are currently no conditions of participation in existence for physicians, and, therefore, it would be difficult at this point to establish a complete set of meaningful requirements.

115. In addition, Clark Havighurst has raised the possibility of permitting the Medicare program to pay the amount of the standard benefit for patients who select a non-traditional, experimental, or unapproved treatment, rather than denying all payment for the chosen procedure. That idea deserves serious consideration, and would require the same type of statutory change discussed above. Interview with Clark Havighurst, Professor of Law, Duke University Law School, in Durham, N.C. (Aug. 29, 2001).

in order to permit new types of financial arrangements and incentives that encourage selection of cost-effective providers. For example, in order to encourage beneficiaries to seek care from a cost-effective provider or a Center of Excellence that is distant from the beneficiary's home, it may be necessary for the provider to pay the transportation expenses of the beneficiary and his family. On its face, that type of payment would constitute remuneration for the purpose of encouraging the beneficiary to obtain treatment at a particular facility, and would violate the Anti-Kickback Law.<sup>116</sup> In order to provide the flexibility for this type of beneficial incentive, the Anti-Kickback Law could be amended, or the Secretary could use his existing statutory authority to establish safe harbors by means of formally adopted rules.<sup>117</sup>

The proposed reforms would also require changes to other statutes that are not part of the Medicare law. Statutes and regulations that protect the privacy of patient information should be carefully reviewed and amended as necessary because they may prevent the use or disclosure of information that is needed for effective case management.<sup>118</sup> In addition, since beneficiaries will be encouraged to select providers on the basis of quality and efficiency, they will need the information that will enable them to make informed choices about their providers. Therefore, laws that currently prevent the public release of data on the quality of health care services should be amended to permit broader disclosure to the public.<sup>119</sup>

Under the proposed reforms, the Medicare program will publicly characterize some providers as non-preferred or less-preferred, because of their alleged lack of quality or efficiency. In communicating with their current and potential patients, providers should be allowed to rebut those negative statements by the Medicare program, albeit at the provider's own expense. For example, if the Medicare program identifies a physician as a non-preferred provider because of the physician's high mortality rate, the physician ought to have the right to place an advertisement in the local newspaper to the effect that his high mortality rate is the result of treating patients who are more acutely ill than the average. Similarly, if a physician is designated as non-preferred because of alleged inefficiency, that physician should have the right to publicly respond that she provides services of higher quality, in order to encourage patients to

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116. *See supra* note 56.

117. 42 U.S.C. § 1320a-7b(b)(3)(E).

118. *See, e.g.*, Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82462 (Dec. 28, 2000). That final rule, which was issued pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, § 264, 110 Stat. 1936, is applicable to uses and disclosures of patient information by the Medicare program. *See* 65 Fed. Reg. at 82799 (including the Medicare program within the definition of "health plan" and therefore within the definition of "covered entity" for purposes of that rule). *See also* U.S. GENERAL ACCOUNTING OFFICE, MEDICARE: SUCCESSFUL REFORM REQUIRES MEETING KEY MANAGEMENT CHALLENGES 14 (2001) (stating that privacy of data may hinder targeted disease management).

119. *See, e.g.*, Health Care Quality Improvement Act, 42 U.S.C. § 11137(b) (discussing confidentiality of information in the National Practitioner Data Bank); Social Security Act, 42 U.S.C. § 1395bb(c) (discussing confidentiality of JCAHO survey results provided to the Secretary for the purpose of participation in the Medicare program).

pay the higher co-payments for her supposedly non-preferred services. At the present time, public statements by health care professionals about the quality of their services may be prohibited by state licensing laws and the ethical rules of professional associations, on the theory that advertisement of professional quality is inherently misleading.<sup>120</sup> Therefore, it may be necessary to modify these restrictions to some extent, or at least to influence their enforcement, in order to permit the type of communication described above.

Inevitably, there are other statutes that would require amendment to implement the proposed reforms, and the above is only an attempt to identify the most important of the necessary amendments. If the political barriers could be overcome, Congress could make all of the necessary changes or require those changes to be made by the Secretary. Therefore, the remaining issue is the extent to which the United States Constitution may limit or influence any statutory reform of the Medicare program.

### C. Constitutional Issues in Implementing the Proposed Reforms

As currently structured, the open system of Medicare participation raises few constitutional issues. Every qualified provider has the opportunity to participate with payment on uniform terms, and every beneficiary has the opportunity to choose any qualified provider with uniformity of cost-sharing.<sup>121</sup> The government has no constitutional obligation to include unqualified providers as

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120. See, e.g., *California Dental Ass'n v. FTC*, 526 U.S. 756, 760, 760 n.1 (1999); CAL. BUS. & PROF. CODE §§ 651,1680 (West 1990) (restricting advertisements of "professional superiority").

With regard to antitrust law, in general, it would not be necessary to amend the law, nor would it be necessary to create any new statutory immunity, in order to implement the reforms that we propose. Participating in value purchasing would not require anyone to violate the antitrust laws, and the proposed statutory changes would not result in an implied repeal of the antitrust laws. See *Nat'l Gerimedical Hosp. v. Blue Cross*, 452 U.S. 378, 393 n.18 (1981). See generally William M. Sage & Peter J. Hammer, *Competing on Quality of Care: The Need to Develop a Competition Policy for Health Care Markets*, 32 U. MICH. J.L. REFORM 1069, 1087 (1999). In fact, the reformed market for Medicare services would be more competitive than the existing market, because providers would compete among themselves for preferred status, and beneficiaries would be able to choose their optimal levels of cost and quality.

Some commentators have expressed concern about the tremendous purchasing power of the Medicare program. See, e.g., Fox, *supra* note 8, at 46. However, that purchasing power does not create an antitrust problem, for several reasons. First, a federal agency such as CMS is not subject to federal antitrust law, even as a value purchaser, and neither are its employees who act in their official capacities. See *Rex Sys., Inc. v. Holiday*, 814 F.2d 994, 997 (4th Cir. 1987) (collecting cases). Second, in purchasing services at the lowest possible price, a third-party payor with market power does not violate antitrust law by acting unilaterally in an economically rational manner. *Kartell v. Blue Shield*, 749 F.2d 922 (1st Cir. 1984). Finally, existing antitrust laws would be available to remedy any attempt to interfere with the operation of the more competitive market, to address any spillover effects from the lawful activities of intermediaries and carriers, and to prevent any unlawful collaboration by purchasers or providers. See, e.g., Clark C. Havighurst, *Antitrust Issues in the Joint Purchasing of Health Care*, 1995 UTAH L. REV. 409, 432 n.66 (1995) (stating that "[a]n antitrust issue might arise, however, if joint purchasers act in concert with other large buyers such as Blue Cross and Medicare—for example, by following Medicare's lead in setting fee schedules for physicians or DRG allowances for hospitals.").

121. See *supra* notes 91-100 and accompanying text. Although beneficiaries enrolling in a managed care plan under Part C of Medicare may be subject to restrictions on choice of provider, enrollment in Part C is voluntary, and all beneficiaries have the opportunity to remain in the traditional fee-for-service Medicare program with free choice of provider.

vendors in a federal payment program, so long as the government complies with the requirements of procedural due process in excluding or terminating those providers. Moreover, it is clear that beneficiaries have no constitutional right to financial support from the government for services rendered by unqualified practitioners and facilities.<sup>122</sup>

The constitutional issues would become more complex and more interesting if the Medicare program were changed along the proposed lines. Under these revisions, some qualified providers would be compensated on less favorable terms than their competitors, and their patients would be given financial incentives to switch to a different provider. These reforms could cause significant financial losses for particular providers, especially if other third-party payors follow Medicare's lead and treat those same providers in a less favorable manner.<sup>123</sup> In addition, co-payments and deductibles would be different for some beneficiaries. Although these changes could raise theoretical issues of due process and equal protection, the constitutional limitations on the power of government would not prevent the type of reform that we propose.

These limitations include substantive due process, takings without just compensation, equal protection, and procedural due process. Although each doctrine is addressed separately, the unifying theme in analyzing these issues is the nature of the Medicare program as an endeavor that is voluntary for the providers and for the government. Providers who elect to participate in the Medicare program will feel aggrieved but will have little legal right to complain about their rate of payment or the program's use of prior authorization, because participation is purely voluntary for the provider.<sup>124</sup> For their part, Medicare beneficiaries will have limited rights to object to restrictions imposed by the government, such as prior authorization or case management, because the beneficiaries are participating in a social welfare program that is not constitutionally mandated.

Thus, the proposed changes would not deprive beneficiaries or providers of any of the liberties protected by the Due Process Clause of the Fifth Amendment.<sup>125</sup> The scope of liberty protected by the Due Process Clause includes the right to make personal choices in matters of marriage, reproduction, education of children, and similar issues of family life.<sup>126</sup> The Constitution, however, does not provide a right for beneficiaries to receive financial support in using the

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122. In describing the rights of a beneficiary under the analogous Medicaid program, the Supreme Court explained that, "while a patient has a right to continued benefits to pay for care in the qualified institution of his choice, he has no enforceable expectation of continued benefits to pay for care in an institution that has been determined to be unqualified." *O'Bannon v. Town Court Nursing Ctr.*, 447 U.S. 773, 786 (1980).

123. See Fox, *supra* note 8, at 46.

124. See, e.g., *Ass'n of Am. Physicians & Surgeons v. Mathews*, 395 F. Supp. 125, 134 (N.D. Ill.), *aff'd*, 423 U.S. 975 (1975) ("Underlying the constitutionality of the challenged legislation is the basic premise that each individual physician and practitioner has the ability to choose whether or not to participate in the program.").

125. U.S. CONST. amend. V.

126. See *Roe v. Wade*, 410 U.S. 113, 152-53 (1973).

provider of their choice, even if the provider is fully qualified to render those services. As seen in the abortion funding cases, the right to choose particular health care services, even where that right is protected by the Constitution, does not include the right to receive government funds to pay for the services that are chosen.<sup>127</sup> Thus, although Medicare beneficiaries may have the right to obtain health care services from any providers who are willing to treat them, they do not have a constitutional right to require the Medicare program to pay for the services rendered by those providers. Moreover, because the government is not constitutionally required to provide or support a system of health insurance for persons who are elderly or disabled,<sup>128</sup> the government does not deprive beneficiaries of liberty by imposing restrictions on the services for which it voluntarily chooses to pay.<sup>129</sup>

In a reformed Medicare program, restrictions imposed on some beneficiaries but not others would not constitute a denial of equal protection.<sup>130</sup> Distinguishing between beneficiaries on the basis of their choice of provider would not interfere with fundamental rights or discriminate on the basis of suspect classifications, and could be easily justified as rationally related to the legitimate governmental objectives of reducing cost and promoting quality in the Medicare program.<sup>131</sup> For the same reasons, it would not violate the requirements of equal protection to treat some practitioners and facilities differently from others on the basis of their efficiency and quality, because that would not implicate

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127. *Harris v. McRae*, 448 U.S. 297, 316-18 (1980) (“Although the liberty protected by the Due Process Clause affords protection against unwarranted government interference with freedom of choice in the context of certain personal decisions, it does not confer an entitlement to such funds as may be necessary to realize all the advantages of that freedom.”). Moreover, the Court upheld the government’s use of financial incentives to influence the beneficiary’s decision. *See id.* at 325; *see also* LAURENCE H. TRIBE, *AMERICAN CONSTITUTIONAL LAW* 782 (2d ed. 1988) (“The Supreme Court held . . . that the government is even free to influence an indigent pregnant woman’s constitutionally protected reproductive choice.”).

128. In discussing the analogous due process clause of the Fourteenth Amendment, the Supreme Court stated that, “[a]s a general matter, a State is under no constitutional duty to provide substantive services for those within its border.” *Youngberg v. Romeo*, 457 U.S. 307, 317 (1982).

129. *See, e.g., Harris*, 448 U.S. at 316-17 (“Congress has opted to subsidize medically necessary services generally, but not certain medically necessary abortions.”); *Maher v. Roe*, 432 U.S. 464, 469 (1977) (“The Constitution imposes no obligation on the [government] to pay the pregnancy-related medical expenses of indigent women, or indeed to pay any of the medical expenses of indigents.”).

130. Even without an explicit Equal Protection Clause in the Fifth Amendment, the Supreme Court has applied a similar analysis to the federal government under the Due Process Clause of the Fifth Amendment. *See Bolling v. Sharpe*, 347 U.S. 497 (1954).

131. *See, e.g., Legion v. Richardson*, 354 F. Supp. 456, 459 (S.D.N.Y. 1973), *aff’d*, 414 U.S. 1058 (1973) (rejecting equal protection claim by class of Medicare and Medicaid beneficiaries, where classifications were not based on suspect grounds, because there was a rational basis for the statutory classifications); *Minnesota ex rel. Hatch v. United States*, 102 F. Supp. 2d 1115, 1123-24 (D. Minn. 2000), *aff’d sub nom. Minn. Senior Fed’n v. United States*, 273 F. 3d 805 (8th Cir. 2001) (holding that geographic differences in the Medicare+Choice program do not violate equal protection, because the decision of Congress was rationally related to its legitimate objectives of cost-containment and expansion of options); *see also Harris*, 448 U.S. at 322-24 (rejecting equal protection claim where the challenged statute did not violate a substantive right, was not based on a suspect classification, was facially neutral, there was no evidence of intentional discrimination, and was rationally related to a legitimate governmental interest).

suspect classifications or interfere with fundamental rights, and would be justified as rationally related to legitimate governmental goals.

Even if providers are qualified to furnish covered services, the liberty protected by the Due Process Clause does not include a right to participate as vendors in a federal payment program,<sup>132</sup> nor a right to be compensated with federal funds.<sup>133</sup> Because providers have no constitutional right to participate in the Medicare program at all, they could not complain that they have been deprived of liberty if they are only allowed to participate subject to conditions that they view as burdensome.

Several courts have relied on the voluntary nature of Medicare participation to reject claims by providers that unfavorable terms of payment constitute a taking without just compensation.<sup>134</sup> Although courts in these cases have ordinarily focused on the voluntary nature of participation, it is also questionable whether health care providers have any property that could be taken by governmental action to limit Medicare reimbursement. Despite the expanded view of property in the context of procedural due process,<sup>135</sup> the Constitution does not prevent Congress from changing the law in ways that frustrate long-standing expectations based on the prior law.<sup>136</sup> For example, Congress may change or eliminate benefits under the Social Security program at any time, despite the contributions and expectations of the recipients.<sup>137</sup> Since Congress may change

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132. We are not recommending that qualified providers be totally excluded from participation. The legal implications of exclusion, however, provide a useful framework for understanding the implications of differential treatment with regard to rates of payment and beneficiary cost-sharing.

133. See *Ass'n of Am. Physicians & Surgeons v. Mathews*, 395 F. Supp. 125 (N.D. Ill. 1975), *aff'd*, 423 U.S. 975 (1975) (rejecting claim that federal legislation for Professional Standards Review violates the physicians' right to practice); *Rasulis v. Weinberger*, 502 F.2d 1006, 1010 (7th Cir. 1974) (upholding Medicare regulation that established conditions for physical therapists, because "[i]t merely provides standards for the dispensation of federal funds.").

134. See *Garelick v. Sullivan*, 987 F.2d 913, 917 (2d Cir. 1993), *cert. denied*, 510 U.S. 821 (1993) ("All court decisions of which we are aware that have considered takings challenges by physicians to Medicare price regulations have rejected them in the recognition that participation in Medicare is voluntary."); *St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875 (7th Cir. 1983), *cert. denied*, 465 U.S. 1022 (1984) (rejecting claim under Fifth Amendment just compensation provision, despite the practical necessity of Medicare participation); *Pharmacist Political Action Comm. v. Harris*, 502 F. Supp. 1235, 1243 (D. Md. 1980) ("There is no compulsion to participate in the program."). The federal government's use of financial incentives for providers without direct regulatory compulsion is analogous to its use of incentives for state governments under the spending power of Congress. See *generally* *South Dakota v. Dole*, 483 U.S. 203, 207 (1987).

135. See *generally* *Goldberg v. Kelly*, 397 U.S. 254 (1970); Charles A. Reich, *The New Property*, 73 *YALE L.J.* 733 (1964).

136. See *Atkins v. Parker*, 472 U.S. 115, 129 (1985) ("Before the statutory change became effective, the existing property entitlement did not qualify the legislature's power to substitute a different, less valuable entitlement at a later date.").

137. See *U.S. R.R. Ret. Bd. v. Fritz*, 449 U.S. 166, 174 (1980) ("There is no claim here that Congress has taken property in violation of the Fifth Amendment, since railroad benefits, like social security benefits, are not contractual and may be altered or even eliminated at any time."). *But see* LAWRENCE H. TRIBE, *AMERICAN CONSTITUTIONAL LAW* 627-28 (2d ed. 1988) (criticizing the Court's analysis in *Fritz*). See also *Flemming v. Nestor*, 363 U.S. 603, 608-611 (1960) (describing the interest of a Social Security beneficiary as a "noncontractual benefit under a social welfare program"). Recently, the Supreme Court concluded that providers participating in the Medicare program also receive benefits, and not merely compensation for services rendered. *Fischer v. United States*, 529 U.S. 667, 680 (2000).

or eliminate the interest of a Social Security or Medicare beneficiary without violating the Constitution, Congress could also change the Medicare program in ways that subjected providers to less desirable and more burdensome terms.<sup>138</sup>

In some cases, providers may be able to assert valid claims on the basis of procedural due process. Even if those claims were successful, they would not create a barrier to reform. First, it is questionable whether providers have a constitutionally protected property right or liberty interest in continued Medicare participation.<sup>139</sup> Although some courts have recognized a property interest in continued participation,<sup>140</sup> others have flatly rejected it.<sup>141</sup> Some courts that have denied the existence of a property interest have held that providers nevertheless did have a liberty interest in continued participation because the provider's change of status was accompanied by an allegation that would damage the provider's reputation.<sup>142</sup>

Even if providers have a constitutionally protected interest, that would not necessarily create an entitlement to continued program participation. Rather, it would merely entitle providers to an appropriate type of procedure in connection with their change in status.<sup>143</sup> Moreover, that procedure may be limited by the circumstances, and might not have to be conducted before the provider's change in status.<sup>144</sup> Finally, at any hearing to which the provider is entitled, the issue to be decided would not be a constitutional question. Rather, the issue at such a hearing would be whether the Medicare program had violated the provider's rights, as defined by the Medicare statute and any applicable contract.<sup>145</sup>

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138. See also *O'Bannon v. Town Court Nursing Ctr.*, 447 U.S. 773, 798 (1980) (Blackmun, J. concurring) (recognizing that government has the power to completely eliminate the public programs under which individuals are claiming to have rights).

139. See *Midwest Family Clinic, Inc. v. Shalala*, 998 F. Supp. 763, 770 (E.D. Mich. 1998) ("Courts are in disagreement as to whether such a property interest exists."). See generally Eleanor D. Kinney, *Protecting Consumers and Providers Under Health Reform: An Overview of the Major Administrative Law Issues*, 5 HEALTH MATRIX 83, 89-90 (1995).

140. See, e.g., *Patchogue Nursing Ctr. v. Bowen*, 797 F.2d 1137, 1144-45 (2d Cir. 1986); *Ram v. Heckler*, 792 F.2d 444, 447 (4th Cir. 1986). See also *Cathedral Rock, Inc. v. Shalala*, 223 F.3d 354, 364 (6th Cir. 2000) (recognizing, implicitly, a protected property interest by considering the type of process that was due).

141. See, e.g., *Erickson v. U.S.*, 67 F.3d 858, 862-63 (9th Cir. 1995); *Geriatrics, Inc. v. Harris*, 640 F.2d 262, 265 (10th Cir. 1981), *cert. denied*, 454 U.S. 832 (1981).

142. See, e.g., *Erickson*, 67 F.3d at 862-63; see generally *Paul v. Davis*, 424 U.S. 693, 701-09 (1976).

143. See *Perry v. Sindermann*, 408 U.S. 593, 603 (1972) ("Proof of such a property interest would not, of course, entitle him to reinstatement").

144. See *Cathedral Rock*, 223 F.3d at 364-65 (citing decisions that providers were not entitled to pre-termination hearings). See also *Erickson*, 67 F.3d at 863; *Patchogue*, 797 F.2d at 1145-46.

145. See *Perry*, 408 U.S. at 602 ("If it is the law of Texas that a teacher in the respondent's position has no contractual or other claim to job tenure, the respondent's claim would be defeated.").

As discussed above, we are not proposing that the Medicare statute be amended to permit termination of providers *without cause*. However, if a revised Medicare statute and any applicable contract permitted the Secretary to terminate or refuse to renew a provider's agreement *without cause*, then the provider would not have a constitutionally protected interest, and would not be entitled to a hearing as a matter of procedural due process. Under those circumstances, even if the provider claimed that the Secretary's action was taken for the purpose of infringing the provider's First Amendment right to freedom of speech, the provider would have to pursue that claim by filing an action in federal court, rather than in a due process hearing. See *Perry*, 408 U.S. at 597.

Under these circumstances, the nature of any required due process hearing would depend on the type of governmental action challenged by the provider. For example, if all low-volume providers were terminated in the interest of administrative efficiency, a terminated provider would be entitled to some type of hearing, but that hearing would be limited to an examination of the provider's historical volume.<sup>146</sup> Obviously, the hearing would be more complex if the provider were terminated for cause on the basis of inadequate quality or excessive utilization. However, that would be fairly unusual, and would be no different than the existing, detailed process for exclusion of providers on those grounds.<sup>147</sup> Reducing a physician's payment status from preferred to non-preferred would also require a hearing on complex issues of fact, but it is reasonable to require that procedure in light of the important interests at stake. Ultimately, even if providers were to succeed on specific claims of procedural due process, that would not create a significant problem for the Medicare program, nor would it interfere with the progress of reform.<sup>148</sup>

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146. Although we are not proposing a widespread system of competitive bidding, it might be appropriate in the case of standardized commodities such as durable medical equipment. Under those circumstances, if an aggrieved provider had lost in a process of competitive bidding, then the provider would have a right to protest the government's award of that contract to a competitor, in a manner similar to that for defense procurement or public works projects.

147. See 42 C.F.R. § 1001.2007 (providing for appeal of exclusions by OIG); 42 C.F.R. § 1001.2003 (allowing written requests for a hearing to challenge an exclusion by OIG); 42 C.F.R. § 1005 (specifying procedures for appeals of exclusions).

With regard to the specific purchasing activities proposed in this article, the conduct of Medicare intermediaries and carriers, as agents of the federal government, should be treated as federal action and should be subject to the requirements of the Fifth Amendment. Therefore, it is not necessary to analyze whether these particular functions constitute governmental action under the principles set forth in *American Mfrs. Mut. Ins. Co. v. Sullivan*, 526 U.S. 40 (1999). However, other types of activities by Medicare intermediaries and carriers may require a detailed analysis to determine whether they constitute governmental action. See *Grijalva v. Shalala*, 152 F.3d 1115 (9th Cir. 1998), *vacated and remanded*, 526 U.S. 1096 (1999) (remanding for further consideration in light of *Sullivan*, Sections 4001 and 4002 of the Balanced Budget Act of 1997, and the HHS regulations that implement those statutory provisions). See generally Jody Freeman, *The Private Role in Public Governance*, 75 N.Y.U. L. REV. 543, 622 n.321 (2000).

Even if the conduct of Medicare intermediaries and carriers is deemed to be federal action for constitutional purposes, the Supreme Court has recently held that private organizations engaged in federal action are not subject to an implied private right of action for monetary damages for alleged violations of constitutional rights. See *Corr. Servs. Corp. v. Malesko*, 534 U.S. 61 (2001) (refusing to extend *Bivens v. Six Unknown Fed. Narcotics Agents*, 403 U.S. 388 (1977) to a claim against a private contractor for the federal Bureau of Prisons). That recent decision would alleviate concern about one type of potential liability for purchasing decisions in a reformed Medicare program.

148. The burden on the Medicare program is also limited somewhat by the requirement to exhaust administrative remedies and the channeling of judicial review. See, e.g., *Shalala v. Ill. Council on Long-Term Care, Inc.*, 529 U.S. 1 (2000); Jost, *supra* note 33, at 66 ("Congress has withheld from the courts jurisdiction over large areas of coverage and payment policy."); David A. Hyman, *Accountable Managed Care: Should We Be Careful What We Wish For?*, 32 U. MICH. J. L. REFORM 785, 798 (1999) ("Congress has quite deliberately insulated broad aspects of the Medicare program from judicial review.").

## VI

## CONCLUSION

This article has considered whether the most controversial tools of managed care, including selective contracting, gatekeeping, and prior authorization, should be adopted in the Medicare program. On policy and practical political grounds, it does not recommend selective contracting or gatekeeping. Prior authorization should be targeted much more narrowly than is common practice by MCOs. Nevertheless, Medicare should be granted the authority to have preferred providers and case management programs that could treat providers differently and could permit certain beneficiaries to receive additional, off-policy benefits. These managed care tools would need to be expressly provided for in statutes and do not raise major constitutional issues.