



SCHOOL OF LAW  
CASE WESTERN RESERVE  
UNIVERSITY

**Health Matrix: The Journal of Law-  
Medicine**

---

Volume 5 | Issue 1

---

1995

# Protecting Consumers and Providers Under Health Reform: An Overview of the Major Administrative Law Issues

Eleanor D. Kinney

Follow this and additional works at: <https://scholarlycommons.law.case.edu/healthmatrix>



Part of the [Health Law and Policy Commons](#)

---

## Recommended Citation

Eleanor D. Kinney, *Protecting Consumers and Providers Under Health Reform: An Overview of the Major Administrative Law Issues*, 5 Health Matrix 83 (1995)

Available at: <https://scholarlycommons.law.case.edu/healthmatrix/vol5/iss1/6>

This Symposium is brought to you for free and open access by the Student Journals at Case Western Reserve University School of Law Scholarly Commons. It has been accepted for inclusion in Health Matrix: The Journal of Law-Medicine by an authorized administrator of Case Western Reserve University School of Law Scholarly Commons.

# PROTECTING CONSUMERS AND PROVIDERS UNDER HEALTH REFORM: AN OVERVIEW OF THE MAJOR ADMINISTRATIVE LAW ISSUES

*Eleanor D. Kinney†*

## I. INTRODUCTION

**THE PRIVATE MARKET** has not been able to provide adequate and affordable health insurance for all Americans under age sixty-five. About 15% of Americans have no health insurance, and many more are underinsured.<sup>1</sup> Recent evidence suggests that the proportion of Americans covered under health insurance offered by employers has declined substantially in recent years from 64% in 1991 to 62.5% in 1992.<sup>2</sup> These gaps in health insurance coverage as well as the public's fear of losing employer-based health insurance were the precipitating factors in the call for health care reform in the 103d Congress.

President Clinton made comprehensive reform of the nation's health care system a key goal of his presidency. The President introduced a comprehensive health reform bill in the 103d Congress.<sup>3</sup> Senators and House members also introduced

---

\* Professor of Law and Director of the Center for Law and Health, Indiana University School of Law, Indianapolis. B.A., Duke University, 1969; University of Chicago, 1970; J.D., Duke University School of Law, 1973; M.P.H., University of North Carolina at Chapel Hill, 1979. The author wishes to thank Phyllis Bonds and Kurt Snyder for their help with this Article.

1. Sources of Health Insurance and Characteristics of the Uninsured, Employee Benefit Research Institute (EBRI) Issue Brief, No. 145, Jan. 1994, at 5. *See also* U.S. BIPARTISAN COMM'N ON COMPREHENSIVE HEALTH CARE, A CALL FOR ACTION, S. REP. NO. 113, 101st Cong., 2d Sess. (1990).

2. Employee Benefit Research Institute (EBRI) Issue Brief, *supra* note 1, at 6. *See also* Deborah Chollet, *Employer-Based Health Insurance in a Changing Work Force*, HEALTH AFF., Spring 1994, at 315.

3. American Health Security Act of 1993, H.R. 3600, S. 1757, 103d Cong., 1st Sess. (1993) [hereinafter Health Security Act of 1993].

innovative health reform proposals that were considered in tandem with the President's proposal.<sup>4</sup> At the close of the 103d Congress, several senators and House members introduced bills that promoted compromise among competing proposals.<sup>5</sup> (The major health reform bills of the 103d Congress are presented at Table 1.) The upcoming 104th Congress with its new Republican majorities in both chambers also may consider health reform legislation along the lines of the Republican bills of the 103d Congress (See Table 1). The President is likely to introduce a bill as well.

TABLE 1

## MAJOR HEALTH REFORM BILLS BEFORE THE 103D CONGRESS

## MANAGED COMPETITION PROPOSALS

The American Health Security Act of 1993, H.R. 3600, S. 1757, 103d Cong., 1st Sess. (1993) [hereinafter Health Security Act of 1993]. Sponsored by Rep. Gephardt, D-MO and Sen. Mitchell, D-ME for President Clinton.

The Managed Competition Act of 1993, H.R. 3222, S. 1579, 103d Cong., 1st Sess. (1993) [hereinafter Managed Competition Act of 1993]. Sponsored by Rep. Cooper, D-TN & Sen. Breaux, D-LA.

Health Equity and Access Reform Today Act of 1993, H.R. 3704, S. 1770, 103d Cong., 1st Sess. (1993) [hereinafter Health Equity and Access Reform Today Act of 1993]. Sponsored by Sen. Chafee, R-RI & Rep. Thomas, R-CA.

---

4. *Id.*; see, e.g., Health Equity and Access Reform Today Act of 1993, H.R. 3704, S. 1770, 103d Cong., 1st Sess. (1993) [hereinafter Health Equity and Access Reform Today Act of 1993]; Managed Competition Act of 1993, H.R. 3222, S. 1579, 103d Cong., 1st Sess. (1993) [hereinafter Managed Competition Act of 1993]; Consumer Choice Health Security Act of 1993, H.R. 3698, S. 1743, 103d Cong., 1st Sess. (1993) [hereinafter Consumer Choice Health Security Act]; Affordable Health Care Now Act of 1993, H.R. 3080, S. 1533, 103d Cong., 1st Sess. (1993) [hereinafter Affordable Health Care Now Act]; Comprehensive Family Health Access and Savings Act, H.R. 3918, S. 1807, 103d Cong., 1st Sess. (1993) [hereinafter Comprehensive Family Health Access and Saving Act of 1993].

5. See, e.g., Health Security Act, S. 2560, 103d Cong., 2d Sess. (1994) [hereinafter Mitchell Compromise Bill]; Health Security Act of 1994, S. 2357, 103d Cong., 2d Sess. (1994) [hereinafter Health Security Act of 1994]; Health Reform Consensus Act of 1994, H.R. 3955, 103d Cong., 2d Sess. (1994) [hereinafter Health Reform Consensus Act]; Bipartisan Health Care Reform Act of 1994, H.R. 5228, 103d Cong., 2d Sess. (1994) [hereinafter Bipartisan Health Care Reform Act].

## INCENTIVE PROPOSALS

Consumer Choice Health Security Act of 1993, H.R. 3698, S. 1743, 103d Cong., 1st Sess. (1993) [hereinafter Consumer Choice Health Security Act of 1993]. Sponsored by Sen. Nickles, R-OK & Rep. Stearns, R-FL.

Affordable Health Care Now Act of 1993, H.R. 3080, S. 1533, 103d Cong., 1st Sess. (1993) [hereinafter Affordable Health Care Now Act]. Sponsored by Rep. Michael, R-IL & Sen. Lott, R-MS.

Comprehensive Family Health Access and Savings Act, H.R. 3918, S. 1796, 103d Cong., 1st Sess. (1993) [hereinafter Comprehensive Family Health Access and Savings Act]. Sponsored by Sen. Gramm, R-TX and Rep. Santorum, R-CA.

## ALL-PAYER SYSTEM PROPOSALS

The American Health Security Act of 1993, H.R. 1200, S. 491, 103d Cong., 1st Sess. (1993) [hereinafter The American Health Security Act of 1993]. Sponsored by Rep. McDermott, D-WA & Sen. Wellstone, D-MN.

## COMPROMISE BILLS, SUMMER 1994

Health Security Act, S. 2357, 103d Cong., 2d Sess. (1994). Sponsored by Sen. Mitchell, ME-D [hereinafter Health Security Act of 1994].

S. 2374, 103d Cong., 2d Sess. (1994) [hereinafter Dole Compromise Bill]. Sponsored by Sen. Dole, R-KS.

Health Security Act, S. 2560, 103d Cong., 2d Sess. (1994) [hereinafter Mitchell Compromise Bill]. Sponsored by Sen. Mitchell, D-ME.

Health Reform Consensus Act of 1994, H.R. 3955, 103d Cong., 2d Sess. (1994) [hereinafter Health Reform Consensus Act]. Sponsored by Rep. Rowland, D-GA.

Bipartisan Health Care Reform Act of 1994, H.R. 5228, 103d Cong., 2d Sess. (1994) [hereinafter Bipartisan Health Care Reform Act]. Sponsored by Rep. Rowland, D-GA.

Three models of health reform approaches predominated in the proposals before the 103d Congress: managed competition, a single-payer system, and reform of the health insurance market through federal tax and other incentives. The managed competition approach leaves the current employer-based, private health insurance system in place, while reforming the private health insurance market. The incentive approach attempts

to expand coverage and accomplish insurance reform voluntarily by encouraging employers and consumers to purchase more cost-efficient health plans. The single-payer system model severs the link between employment and health insurance with a government social insurance program for health care expenses along the lines of the current Medicare program.

Some proposals before the 103d Congress were more regulatory in their approach, particularly with respect to mandating universal coverage and employer participation and setting health system expenditure limits, while other proposals relied on incentives and market forces to expand and finance coverage and contain costs. Proposals also varied in the allocation of authority among the federal government, state governments, and private organizations. Nevertheless, regardless of approach and emphasis, all health reform proposals before the 103d Congress would have fundamentally altered relationships between the consumers and providers of health care services and the employers, insurance companies, and governments that pay for these services. These new roles and responsibilities of the federal government, state governments, as well as new and existing private organizations implicate important administrative law issues.<sup>6</sup>

This Article focuses on the procedural issues raised by the various health reform proposals before the 103d Congress that are the primary concern of administrative law — rulemaking, adjudication, and judicial review. First, the Article reviews constitutional and administrative law principles that govern the current health care system and which would govern rulemaking and adjudication procedures and their judicial review in a reformed system absent explicit statutory change. Then, the Article critiques the provisions for rulemaking, adjudication, and

---

6. See ADMINISTRATIVE CONFERENCE OF THE UNITED STATES, ADMINISTRATIVE LAW ISSUES IN HEALTH CARE REFORM (1994) [hereinafter ADMINISTRATIVE LAW ISSUES IN HEALTH CARE REFORM]; Michael J. Graetz & Jerry L. Mashaw, *Praise Reform and Start The Litigation?*, 329 NEW ENG. J. MED. 1735 (1993) (stating that any enacted health care plan must provide administrative remedies sufficient to prevent federal courts from being overwhelmed by litigation); Rand E. Rosenblatt, *The Courts, Health Care Reform, and the Reconstruction of American Social Legislation*, 18 J. HEALTH POL. POL'Y & L. 439 (1993) (discussing new roles of the courts and agencies in implementing health care reform); Robert Pear, *Officials Predict Deluge of Suits On Health Plan*, N.Y. TIMES, Sept. 27, 1993, at A1, A14; Robert Pear, *U.S. Judges Warn of Health Lawsuits*, N.Y. TIMES, Aug. 16, 1994, at A13.

judicial review in the major health reform proposals before the 103d Congress and addresses how procedural arrangements might be designed to assure expeditious implementation of future health reform legislation while protecting the right of consumers, providers, and other affected persons.

## II. GOVERNING PRINCIPLES OF CONSTITUTIONAL AND ADMINISTRATIVE LAW

Any health reform proposal will be enacted in the context of existing principles of law that govern the procedures by which agencies conduct rulemaking and adjudication and also govern the way in which private parties, and government, can obtain judicial review of administrative rules and policies, as well as orders and decisions, or otherwise enforce provisions of health reform legislation. These principles of law accord important procedural rights and responsibilities to the federal government, states, and private parties. Consequently, if drafters of health reform legislation find the current arrangements established in these principles of law unsuitable for a reformed health care system, they must specify other arrangements in derogation of these principles of law in the health reform legislation. If, however, principles of constitutional law dictate, then drafters may not be able to change arrangements by legislation and must design the health reform around these constraints.

The applicable principles of procedural law will vary according to the type of health insurance plan involved. Consequently, it is crucial to understand the different ways in which most Americans obtain health insurance in the mix of public and private programs in the current health care system. Most Americans under age sixty-five are insured through private health insurance plans. The federal government provides health insurance to the aged and severely disabled through the Medicare program.<sup>7</sup> The federal and state governments, through the Medicaid program, provide health insurance for the poor on categorical cash assistance programs, and to other poor individuals with similar characteristics, including children, pregnant women, and the severely disabled.<sup>8</sup> The Health Care Financing Administration (HCFA) in the U.S. Department of Health and

---

7. 42 U.S.C. §§ 1395-1395cc (1988 & Supp. IV 1992).

8. *Id.* §§ 1396-1396(u).

Human Services (HHS) has federal responsibility for these programs. States administer the Medicaid program within federal requirements.<sup>9</sup> Medicare covers about thirty-four million people and Medicaid covers about twenty-four million people.<sup>10</sup>

The provision of health insurance for most Americans under age sixty-five is left primarily to the private market. Under private health insurance plans, the financing of health care is a matter of private contract between the insurer, the insured, and in most cases, the sponsor of the health insurance plan, such as employers or unions. Health plans are offered by private health insurance companies, Blue Cross and Blue Shield plans, health maintenance organizations, or managed care companies and sold to sponsors of health plans or offered to individuals. These plans vary from traditional indemnity insurance to prepaid health plans. Two-thirds of employers are self-insured and offer health plans to their employees without purchasing them on the private market.<sup>11</sup>

Private health insurance is regulated in several, often inconsistent ways. States regulate plans offered by commercial insurance companies, Blue Cross and Blue Shield Plans, and health maintenance organizations (HMOs). The Department of Labor (DOL), under the Employee Retirement Income Security Act of 1975 (ERISA),<sup>12</sup> regulates self-insured plans of employers and unions. ERISA preempts state law that might otherwise regulate self-insured and employee benefit plans. ERISA provides that employee benefit plans cannot be deemed as insurance and regulated under the state insurance code.<sup>13</sup> The upshot of this regulatory arrangement is that self-insured

---

9. *Id.* § 1396a (requiring state medical assistance programs to meet specific requirements before receiving federal approval).

10. Health Care Financing Admin., *Medicare and Medicaid Statistical Supplement*, HEALTH CARE FIN. REV. 15, 311 (Supp. 1992).

11. See U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, MEDICAL TESTING AND HEALTH INSURANCE 114 (1988). See also Alan I. Widiss & Larry Gostin, *What's Wrong with the ERISA "Vacuum"?: The Case Against Unrestricted Freedom for Employers to Terminate Employee Health Care Plans and to Decide What Coverage is to be Provided When Risk Retention Plans Are Established for Health Care*, 41 DRAKE L. REV. 635, 636, n.6 (1992).

12. Employment Retirement Income Security Act of 1974, Pub. L. No. 93-406, 88 Stat. 829 (1974), 29 U.S.C. §§ 1001-1461 (1988 & Supp. IV 1992).

13. *Id.* § 1144.

employer health plans are not covered by state insurance codes as are employer health plans that purchase health insurance.<sup>14</sup>

### A. Constitutional Protections

The Due Process Clauses of the Fifth and Fourteenth Amendments to the U.S. Constitution accord rights to procedural due process to individuals affected by adverse governmental action. For procedural due process protections to apply, there must be state action<sup>15</sup> and a protected interest.<sup>16</sup> Courts have consistently held that actions of providers, particularly physicians, in providing services do not constitute state action despite governmental support for such services or the provider.<sup>17</sup> Regarding the required interest, the Supreme Court has long recognized that beneficiaries of the Medicare and Medicaid programs have a protected property interest in these programs.<sup>18</sup> Providers do not have a recognized property inter-

---

14. See Mary Ann Bobinski, *Unhealthy Federalism: Barriers to Increasing Health Care Access for the Uninsured*, 24 U.C. DAVIS L. REV. 255 (1990) (discussing ERISA's preemption of many state attempts at regulating employee health plans).

15. See, e.g., *Flagg Bros., Inc. v. Brooks*, 436 U.S. 149 (1978) (holding that a state's acquiescence of a private action does not constitute state action); *Sniadach v. Family Fin. Corp.*, 395 U.S. 337 (1969) (holding that wage garnishment by states must follow due process procedures); *Burton v. Wilmington Parking Auth.*, 365 U.S. 715 (1961) (holding that action by a restaurant in a public building did not constitute state action merely because the state was a joint participant in the operation of the restaurant). See also Henry J. Friendly, *The Public-Private Penumbra — Fourteen Years Later*, 130 U. PA. L. REV. 1289 (1982) (discussing that more state involvement is required to produce a holding of constitutionality in a due process case); Morton J. Horwitz, *The History of the Public/Private Distinction*, 130 U. PA. L. REV. 1423 (1982) (describing the theoretical distinctions between public and private issues).

16. *Mathews v. Eldridge*, 424 U.S. 319 (1976) (establishing analysis for procedural due process requirements); *Goss v. Lopez*, 419 U.S. 565 (1975) (holding that the right to a public education is a protected interest); *Goldberg v. Kelly*, 397 U.S. 254 (1970) (ruling that welfare benefits constitute a protected interest).

17. See, e.g., *Blum v. Yaretsky*, 457 U.S. 991 (1982) (holding that actions by a nursing home cannot be considered state action simply because they did not give adequate notice to Medicaid recipients about transfers to lower levels of care); *Corum v. Beth Israel Medical Ctr.*, 373 F. Supp. 550, 555 (S.D.N.Y. 1974) (construing statute to compel hospitals to provide a reasonable amount of uncompensated services). But see *J.K. v. Dillenberg*, 836 F. Supp. 694 (D. Ariz. 1993) (holding that benefit decisions of a regional health authority managing mental health services under contract to a state Medicaid program could constitute state action).

18. *O'Bannon v. Town Court Nursing Ctr.*, 447 U.S. 773, 786-87 (1980) (holding that this interest does not confer a right to continued residence in a nursing home of one's choice).



est in Medicare or Medicaid payments.<sup>19</sup> Yet, a 1986 case, *Koerpel v. Heckler*,<sup>20</sup> ruled that a physician subject to losing participation in the Medicare program for violations of Medicare program requirements in an action by the HHS Inspector General did have a colorable liberty interest. It is likely that consumers and providers would have comparable interests in health care benefits and program participation respectively under new health reform legislation.

Further, whether an agency policy or decision is "legislative" or "adjudicative" in nature influences the available legal remedies in challenges to those policies and decisions. Legislative policies and decisions apply prospectively to large groups and are generally based on facts that pertain collectively to the group affected. Adjudicative decisions generally apply to specific individuals and generally pertain to past events and circumstances. The Supreme Court has ruled that due process protections are quite limited when legislative-type decisions are involved.<sup>21</sup>

Federal courts also have recognized that the Procedural Due Process doctrine requires specific procedures in the Medicare and Medicaid programs. Specifically, Medicare beneficiaries are entitled to effective notice of adverse government action, such as a claim or eligibility denial.<sup>22</sup> Similarly, Medicaid

---

19. *Id.* at 778; *St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872 (7th Cir. 1983), *cert. denied*, 465 U.S. 1022 (1984) (finding that governmental control over Medicare rates does not violate providers' due process rights by depriving them of property); *Geriatrics, Inc. v. Harris*, 640 F.2d 262, 264-65 (10th Cir. 1981), *cert. denied*, 454 U.S. 832 (1981) (holding that nursing home's unilateral hope that new provider agreements were to be executed for state Medicaid program did not constitute a protected property interest).

20. 797 F.2d 858 (10th Cir. 1986).

21. *See Bi-Metallic Inv. Co. v. Colorado*, 239 U.S. 441, 445 (1915) (stating that hearings and individual arguments regarding legislative matters are limited), *followed*, *U.S. v. Florida E. Coast Ry.*, 410 U.S. 224 (1973) (holding that the Administrative Procedure Act only requires "trial-type" hearings for rulemaking when the enabling act specifically specifies an on-the-record hearing); *Alaska Airlines v. Civil Aeronautics Board*, 545 F.2d 194 (D.C. Cir. 1976) (holding that no hearing is required for legislative fact-finding or rulemaking agency activities); *Assoc. of Nat'l Advertisers v. FTC*, 627 F.2d 1151, 1165, 1166 (D.C. 1979), *cert. denied*, 447 U.S. 921 (1984) (holding that when a proceeding is classified as rulemaking by an agency, due process does not demand rigorous hearing procedures).

22. *See, e.g., Gray Panthers v. Schweiker*, 652 F.2d 146 (D.C. Cir. 1980) (finding that due process mandates that Medicare recipients receive more protection of their benefits than notice and a "paper hearing"); *David v. Heckler*, 591 F. Supp. 1033 (E.D.N.Y. 1984) (finding that notice to recipients must be understood by the majority of beneficiaries who receive them to comply with due process requirements); *Dealy v. Heckler*, 616 F.

applicants and recipients are entitled to adequate notice of adverse decisions as a matter of procedural due process.<sup>23</sup> Medicare beneficiaries also are entitled to an informal hearing, which must be oral only when issues of witness veracity and credibility are involved.<sup>24</sup> The adjudicator must be unbiased but may be an employee of a private insurance company that administers the Medicare program.<sup>25</sup>

## B. The Law of Rule and Policy Making

According to administrative law theory, Congress or the legislature "delegates" legislative authority to agencies.<sup>26</sup> Generally, this delegation is an explicit grant of rulemaking authority in the enabling statute.<sup>27</sup> Under both federal and state law, rules that have legislative effect, so-called "legislative" or "substantive" rules, are distinguished by the procedure by which they were promulgated. The federal Administrative Procedure Act (APA)<sup>28</sup> and state administrative procedure acts<sup>29</sup> establish rulemaking procedures that control unless the agency's enabling statute provides otherwise.<sup>30</sup>

---

Supp. 880 (W.D. Mo. 1984) (finding that Medicare recipient was entitled to notice and fair and complete administrative hearing for reconsideration of benefits coverage).

23. See, e.g., *Ortiz v. Eichler*, 794 F.2d 889 (3d Cir. 1986) (holding that agencies revoking federally funded welfare benefits must articulate detailed reasons in pre-termination notices); *Easley v. Ark. Dep't of Human Serv.*, 645 F. Supp. 1535 (E.D. Ark. 1986) (holding that the HHS is constitutionally and statutorily required to notify Medicaid recipients of an adverse decision).

24. *Gray Panthers*, 652 F.2d at 172.

25. See *Schweiker v. McClure*, 456 U.S. 188, 197 (1982) (holding that there is a presumption of impartiality when the Secretary of HHS contracts with private insurance companies to determine coverage and pay for services and also to conduct some administrative appeal procedures); 42 U.S.C. §§ 1395h, u (1988 & Supp. IV 1992).

26. KENNETH C. DAVIS, 1 ADMINISTRATIVE LAW TREATISE § 3:1 (2d ed. 1978); JACOB STEIN ET AL., 1 ADMINISTRATIVE LAW § 3.03[1] (1993).

27. STEIN, *supra* note 26, at § 13.01.

28. 5 U.S.C. §§ 551-559 (1988 & Supp. V 1993).

29. See ARTHUR E. BONFIELD, STATE ADMINISTRATIVE RULEMAKING § 1.1.2 (1986) [hereinafter STATE ADMINISTRATIVE RULEMAKING].

30. See *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc.*, 435 U.S. 519 (1978) (establishing this principle as a matter of federal law).

## 1. The Federal Administrative Procedure Act (APA)

The federal APA sets forth requirements for legislative rulemaking under federal law.<sup>31</sup> Section 553 of the APA outlines the procedures that agencies must use to promulgate "substantive" rules having legislative effect. Informal rulemaking under section 553 basically requires publication of the text or substance of the proposed rulemaking and an opportunity for interested parties to comment through submission of written material.<sup>32</sup> The APA also provides for formal rulemaking using trial-type hearing and decision procedures in sections 556 and 557 of the APA,<sup>33</sup> when the enabling statute requires that the rulemaking be "on the record after opportunity for an agency hearing."<sup>34</sup> Section 553(c) invokes the evidentiary hearing and decision requirements of sections 556 and 557 of the APA.

Section 553(b)(3)(A) excludes interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice from section 553 rulemaking procedures. However, the Administrative Conference of the United States has recommended that agencies publish all interpretive rules of general applicability before promulgation and, if unfeasible, publish such rules and policy statements post-adoption to permit public comment irrespective of the requirements of the APA.<sup>35</sup> The question of what distinguishes a "legislative" rule from the other rules, for which section 553 rulemaking procedures are not required, is confounding, and has troubled agencies, courts, and scholars since the APA's enactment.<sup>36</sup> Thus,

---

31. 5 U.S.C. §§ 551-559 (1988 & Supp. V 1993). See ADMINISTRATIVE CONFERENCE OF THE UNITED STATES, A GUIDE TO FEDERAL AGENCY RULEMAKING 37-89 (2d ed. 1991) [hereinafter GUIDE TO FEDERAL AGENCY RULEMAKING].

32. 5 U.S.C. § 553(b), (c) (1988 & Supp. V 1993). See GUIDE TO FEDERAL AGENCY RULEMAKING, *supra* note 31, at 3-4, 47-48.

33. 5 U.S.C. §§ 556, 557 (1988 & Supp. V 1993).

34. 5 U.S.C. § 553(c) (1988 & Supp. V 1993). See *United States v. Florida E. Coast Ry.*, 410 U.S. 224 (1973) (holding that formal rulemaking provisions are only triggered when there is a specific statutory requirement for an oral hearing on the record).

35. Recommendations of the Administrative Conference of the United States, *Interpretive Rules of General Applicability and Statement of General Policy*, Recommendation No. 76-5 (1976).

36. See Robert A. Anthony, *Interpretive Rules, Policy Statements, Guidances, Manuals, and the Like — Should Federal Agencies Use Them to Bind the Public?*, 41 DUKE L.J. 1311 (1992) (discussing the practical problems with binding the public to non-legislative agency rulemaking); Michael Asimow, *Nonlegislative Rulemaking and Regulatory Reform*, 1985 DUKE L.J. 381 (1985) [hereinafter *Nonlegislative Rulemaking*] (describing the difficulty in distinguishing legislative from nonlegislative rules due to the

rules and policies promulgated without section 553 procedures are often challenged because they are "substantive" rules.<sup>37</sup>

Further, section 553(b)(3)(B) does not apply to legislative rules for which the agency can demonstrate that notice and comment procedures are "impracticable, unnecessary, or contrary to the public interest."<sup>38</sup> The rule becomes effective thirty days after final publication unless the agency can demonstrate that "good cause" necessitates that the legislative rule be effective even without use of notice and comment procedures.<sup>39</sup> In recent years, agencies have invoked these two "good cause" exemptions to issue legislative rules that are effective immediately without notice and comment proceedings.<sup>40</sup>

Regarding judicial review of rules and policies, if administrative review is available, challengers must exhaust administrative remedies before proceeding to court. The predominant model for judicial review of federal agency decisions is explicit authorization for judicial review and specification of the scope of review in the federal enabling act. If the statute is silent on availability of judicial review, the APA explicitly authorizes judicial review and sets forth procedures.<sup>41</sup> Further, the challenge must be brought under a federal procedural statute authorizing

---

notice and comment requirements for both); Michael Asimow, *Public Participation in the Adoption of Interpretive Rules and Policy Statements*, 75 MICH. L. REV. 520 (1977) [hereinafter *Public Participation*] (stating that the bright lines distinguishing interpretive rules and legislative rules policy statements have become "blurred and indistinct"); Kenneth C. Davis, *Administrative Rules — Interpretive, Legislative and Retroactive*, 57 YALE L.J. 919 (1948) (asserting that the distinction between legislative and interpretative rules is unclear).

37. See, e.g., Robert A. Anthony, *supra* note 36 (contending that federal agencies violate the APA and dishonor our system of limited government when they use nonlegislative documents such as "interpretive rules, policy statements, guidances, manuals, and the like" to bind the public); Michael Asimow, *Nonlegislative Rulemaking*, *supra* note 36 (contending that regulatory reform proposals at both the federal and state levels which require agencies to employ notice and comment procedures before adopting nonlegislative rules would discourage agencies from adopting nonlegislative rules and therefore dramatically disserve the public interest).

38. 5 U.S.C. § 553(b)(3)(B) (1988 & Supp. V 1993).

39. *Id.*

40. See Ellen R. Jordan, *The Administrative Procedure Act's "Good Cause" Exemption*, 36 ADMIN. L. REV. 113 (1984) (arguing good cause exceptions should be used only when formulating narrow solutions for the most significant and pressing problems and public reaction should be allowed after enactment); Catherine J. Lanctot, Note, *The "Good Cause" Exceptions: Danger to Notice and Comment Requirements Under the Administrative Procedure Act*, 68 GEO. L.J. 765, 771-77 (1980) (outlining the ways in which the courts have applied the good cause exceptions).

41. 5 U.S.C. §§ 702-706 (1988 & Supp. V 1993).

a cause of action, such as an action for injunctive or declaratory relief, or mandamus.<sup>42</sup>

It should be emphasized that the Supreme Court's decision in *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*<sup>43</sup> sharply limits judicial review of the content of agency policies where Congress has not directly addressed the issue specifically. *Chevron* limits the judicial inquiry to whether the agency's interpretation "is based on a permissible construction of the statute" and thus constitutes a reasonable policy choice.<sup>44</sup>

## 2. State Administrative Procedure Acts

Most states have state administrative procedure acts that establish rulemaking procedures for legislative rules which also govern if the enabling statute is silent. Many state APA rulemaking procedures are not always as streamlined as informal rulemaking under the federal APA. Many states impose oral hearing requirements for their informal rulemaking procedures.<sup>45</sup> Some allow for appeals by disappointed parties of rules to administrative law judges.<sup>46</sup> These additional procedures limit the ability of state agencies to promulgate rules expeditiously, an important factor to consider when imposing implementation obligations on states with respect to health reform. For example, such problems with state rulemaking procedures have posed difficulties for states and the federal government in the implementation of federal mandates in the Medicaid program.<sup>47</sup> Most state APAs do authorize the promulgation of

---

42. FED. R. CIV. P. 65 (injunctive relief); 28 U.S.C. §§ 2201-2202 (1988) (declaratory relief); 28 U.S.C. § 1361 (1988 & Supp. IV 1992) (mandamus).

43. 467 U.S. 837, 843 (1984) (holding where Congress is silent or ambiguous as to the scope of judicial review to be given to an agency's actions, courts must defer to an agency's interpretation if it is a permissible construction of the statute).

44. *Id.*; see Cass R. Sunstein, *Law and Administration After Chevron*, 90 COLUM. L. REV. 2071 (1990) (discussing the reach of *Chevron* and the scope of limitation on judicial review of agency policies).

45. See BERNARD SCHWARTZ, *ADMINISTRATIVE LAW* § 4.15 (3d ed. 1991); STATE ADMINISTRATIVE RULEMAKING, *supra* note 29, §§ 6.4-6.6.

46. See, e.g., MINN. STAT. ANN. §§ 14.14-14.25 (West 1988 & Supp. 1993); WASH. REV. CODE ANN. §§ 34.05.410-.479 (West 1990).

47. Recommendations of the Administrative Conference of the United States, *Rulemaking and Policymaking in the Medicaid Program*, Recommendation No. 90-8, 55 Fed. Reg. 53,269, 53,273 (1990) (recommending that Congress allow states to follow their own rulemaking procedures before complex Medicaid program changes occur on the state level). See Eleanor D. Kinney, *Rule and Policy Making for the Medicaid Program: A*

rules to have immediate effect on an emergency basis.<sup>48</sup> Also, most state APAs authorize the promulgation of rules on an expedited basis to implement federal mandates.<sup>49</sup> Generally, judicial review of state administrative rules is available.<sup>50</sup>

### C. The Law of Adjudication

Under the current health care system, there are a variety of systems for adjudicating a wide range of consumer, provider, and insurer disputes with government and other responsible entities. The pertinent law on the specific procedures for adjudicating disputes depends on the type of health insurance plan involved. Most disputes between private organizations, such as consumers and commercial health insurers, are currently resolved in state court. State courts adjudicate disputes under state regulated health insurance plans.

ERISA sets forth procedures for employer self-insured plans.<sup>51</sup> The Social Security Act sets forth procedures for adjudicating Medicare and, to a lesser extent, Medicaid program claims.<sup>52</sup> Neither the Social Security Act nor ERISA relies on the evidentiary hearing procedures set forth in the federal APA that otherwise apply when an enabling statute calls for an on-the-record hearing in an adjudicative proceeding.<sup>53</sup> Customarily, government benefit programs have not invoked APA procedures for evidentiary hearings in sections 556 and 557 probably due in part to the historical fact that constitutional protections were not accorded the "privilege" of government benefits until the 1970s.<sup>54</sup>

---

*Challenge to Federalism*, 51 OHIO ST. L.J. 855, 861-64 (1990) [hereinafter Kinney, *A Challenge to Federalism*] (noting that state procedures often create substantial delays in the implementation of new federal policy).

48. BERNARD SCHWARTZ, *supra* note 45, at § 4.15.

49. *Id.*

50. STATE ADMINISTRATIVE RULEMAKING, *supra* note 29, §§ 9.1-9.3.

51. See notes 59-73 *infra* and accompanying text.

52. See notes 74-99 *infra* (Medicare) and notes 100-10 (Medicaid) and accompanying text. See *Adjudicatory Procedures of the Dep't of Health and Human Services: Hearings before the Subcomm. on Administrative Law and Governmental Relations of the House of Rep. Comm. on the Judiciary*, 101st Cong., 1st Sess. (March 23, 1989 and June 27, 1989).

53. 5 U.S.C. § 554(c) (1988 & Supp. V 1993).

54. See, e.g., William V. Alstyn, *Cracks In "The New Property": Adjudicative Due Process in the Administrative State*, 62 CORNELL L. REV. 445, 445-46 (1977); Charles A. Reich, *The New Property*, 73 YALE L.J. 733 (1964) (discussing the effect of the growth of government on the historical conception of government benefits as privileges).

## 1. State Regulated Health Plans

For health plans regulated under state law, consumer and provider disputes are basically adjudicated in state courts as matters of state contract law as modified by state statutory and common law governing insurance.<sup>55</sup> An important common law theory for recovery in coverage disputes between beneficiaries and insurance companies are actions for "bad faith breach" of the insurance contract, which provides tort, as well as contract remedies, when insurers act in bad faith in rejecting a claim.<sup>56</sup> Some states have experimented with the use of alternative dispute resolution (ADR) techniques in lieu of trial in the common law tort system.<sup>57</sup> Under current law, the disposition of a matter by a state court is final unless a federal constitutional question is raised in the matter. Specifically, 42 U.S.C. section 1257 authorizes Supreme Court jurisdiction to hear final judgments of the highest court in a state to adjudicate the matter in question.<sup>58</sup> Consequently, lower federal courts do not have authority to review state agency decisions on state insurance law issues absent a specific congressional mandate to do so.

## 2. Employer, Self-Insured Plans

For employer self-insured plans regulated under ERISA, administrative appeals procedures for consumers are set forth

---

55. See generally ROBERT E. KEETON & ALAN I. WIDISS, *INSURANCE LAW A GUIDE TO FUNDAMENTAL PRINCIPLES, LEGAL DOCTRINES, AND COMMERCIAL PRACTICES* (2d Ed. 1988) (discussing fundamental principles and legal doctrines that comprise the law of insurance); see also *Jordan v. Group Health Ass'ns*, 107 F.2d 239 (D.C. Cir. 1939) (discussing the applicability of insurance regulatory statutes to group health plans).

56. See, e.g., *Taylor v. Prudential Ins. Co. of America*, 775 F.2d 1457 (11th Cir. 1985) (addressing tort and contractual elements of a bad faith claim and dismissing the claim on summary judgment); *Sarchett v. Blue Shield of Cal.*, 729 P.2d 267, 277 (Cal. 1987) (finding bad faith breach by insurer who does not inform insured of right to peer review and arbitration after denial of benefits).

57. See generally STEPHEN B. GOLDBERG ET AL., *DISPUTE RESOLUTION* (1985) (discussing the growth of alternative dispute resolution since the 1960s).

Mandatory ADR has been upheld as constitutional in most judicial challenges. Dwight Golann, *Making Alternative Dispute Resolution Mandatory: The Constitutional Issues*, 68 ORE. L. REV. 487, 546 (1989) (stating that state courts have interpreted their constitutions consistently with federal due process doctrines to uphold the use of mandatory ADR).

58. See, e.g., *Thompson v. City of Louisville*, 362 U.S. 199 (1960) (finding that a state case raising a federal constitutional question falls under the jurisdiction of the Supreme Court); *Parker v. Illinois*, 333 U.S. 571 (1948) (holding that a claim of federal right may proceed to federal court unless the claimant waives his or her right by failing to follow state procedure).

in the ERISA statute.<sup>59</sup> Specifically, ERISA section 503 requires employee benefit plans to establish adequate notice procedures for denied benefits "written in a manner calculated to be understood by the participants" according to specifications in DOL regulations,<sup>60</sup> and to afford participants a reasonable opportunity for review of the claim denial decision before the appropriate named fiduciary of the decision denying the claim.<sup>61</sup> DOL regulations outline detailed requirements for notice, evidentiary hearings, and decisions of plans regarding denied claims.<sup>62</sup>

The ERISA statute provides broad opportunities for judicial review of plan decisions on claims and other matters, generally following consideration of the dispute by the plan under section 503.<sup>63</sup> Specifically, under ERISA section 502(a), a plan participant or beneficiary may sue in federal district court to recover benefits under the plan, to enforce participant rights under the plan, or to clarify rights to future benefits.<sup>64</sup> Relief may be accrued through benefits due, a declaratory judgment on entitlement to benefits, or an injunction against a plan ad-

---

59. 29 U.S.C. § 1132 (1988 & Supp. IV 1992).

60. 29 C.F.R. §§ 2560-2603 (1994).

61. 29 U.S.C. § 1133 (1988 & Supp. IV 1992). *See* Amato v. Bernard, 618 F.2d 559 (9th Cir. 1980) (stating that the intent of Congress in establishing these notice and hearing procedures before plans was to minimize litigation over consumer disputes with plans); Belasco v. W.K.P. Wilson & Sons, Inc., 833 F.2d 277 (11th Cir. 1987); Motley v. Metropolitan Life Ins. Company, 834 F. Supp. 1272 (D. Kan. 1993).

62. *See supra* note 60 and accompanying text.

63. *See, e.g.*, Zipf v. American Tel. and Tel. Co., 799 F.2d 889 (3d Cir. 1986) (holding that a participant in a federally regulated employee benefits plan who brought an action against an employer alleging she was discharged in order to prevent her from obtaining rights under the plan was not required to exhaust administrative remedies); Amato v. Bernard, 618 F.2d 559 (9th Cir. 1980) (holding that union member's claim against trustees of union pension trust and others was based purely on the interpretation or application of the terms of the plan rather than on statutory rights, and thus the claimant is required to exhaust the plan's claims procedure before filing suit); Riley v. Dow Corning Corp., 767 F. Supp. 735 (M.D.N.C. 1991) (holding that a wrongful discharge action was in bad faith); Vogel v. Independence Fed. Sav. Bank, 728 F. Supp. 1210 (D. Md. 1990) (holding that an employer had breached its fiduciary duty in terminating medical coverage even though it terminated coverage for all employees when family members of an insured employee under a group health plan brought an action against an employer, health insurer, and insurance agency alleging violations of ERISA and state law); Skrobacz v. International Harvester, 582 F. Supp. 1192 (N.D. Ill. 1984) (holding that exhaustion of administrative remedies is required when union members brought ERISA action against employer for alleged violations of collective bargaining agreement and for failure to pay required benefits under retirement plan).

64. 29 U.S.C. § 1132(a) (1988 & Supp. IV 1992).



ministrator's improper refusal to pay benefits.<sup>65</sup> In *Firestone Tire and Rubber Co. v. Bruch*, the Supreme Court ruled that federal district courts have de novo review under ERISA section 503 for plan denials of benefits.<sup>66</sup> ERISA remedies are exclusive, and ERISA preempts state common law remedies including actions for bad faith breach of contract for wrongful denial of claims.<sup>67</sup>

Provider disputes in plans regulated under ERISA are adjudicated as private contract claims under state law, as are provider disputes for state regulated health plans.<sup>68</sup> However, providers have sought to challenge plan decisions in health insurance cases with some very limited success.<sup>69</sup>

A most troubling development in the law of ERISA-regulated plans is the Supreme Court's decision upholding the right of an employer with a self-insured plan to limit benefits under its plan. Specifically, the Supreme Court in *McGann v. H & H Music Co.*<sup>70</sup> refused to reverse a federal appellate court decision upholding an employer's right to limit health insurance benefits for a particular condition such as AIDS, even though the employer had an employee with AIDS who sustained sharply reduced health insurance benefits as a result of this decision. Other federal appellate courts have rendered similar de-

---

65. *Id.* The Supreme Court has recently curtailed the ability of plan participants to obtain extra contractual damages, such as might be awarded in a common law bad faith claim. See *Mertens v. Hewitt Assocs.*, 948 F.2d 607 (9th Cir. 1991), *aff'd*, 113 S. Ct. 2063 (1993) (ruling that ERISA § 502(a)(3)(B)(i), an equitable relief authority, did not permit recovery of monetary damages). See also Richard Rouco, Comment, *Available Remedies Under ERISA Section 502(A)*, 45 ALA. L. REV. 631 (1994).

66. 489 U.S. 101 (1989); see Douglas Holdren, *Denial of Benefit Claims Under ERISA: The Rise and Fall of De Novo Review*, 36 VILL. L. REV. 1219 (1991).

67. See *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 47-51 (1987) (holding that common law actions for bad faith breach based upon improper processing of benefit claims are preempted by ERISA); see also *Metropolitan Life Ins. Co. v. Taylor*, 481 U.S. 58, 67 (1987) (holding that complaints for state causes of action in state court can be removed to federal court under ERISA). See generally E. Thomas Bishop & Paula Denny, *Hello ERISA, Good-Bye Bad Faith: Federal Pre-Emption of DTPA, Insurance Code, and Common Law Bad Faith Claims*, 41 BAYLOR L. REV. 267 (1989).

68. See *supra* notes 55-58 and accompanying text.

69. See David P. Kallus, *ERISA: Do Health Care Providers Have Standing to Bring a Civil Enforcement Action under Section 1132(a)?*, 30 SANTA CLARA L. REV. 173 (1990).

70. 742 F. Supp. 392 (S.D. Tex. 1990), *aff'd*, 946 F.2d 401 (5th Cir. 1991), *cert. denied*, *Greenberg v. H & H Music Co.*, 113 S. Ct. 482 (1992) (holding it is not illegal under ERISA for an employer to restrict possible AIDS claims in a discrimination suit nor a violation of rights under ERISA after the employer changed portions of a group medical plan, reducing the maximum benefits for AIDS patients from \$1 million to \$5000).

cisions permitting maximum employer flexibility in defining benefits and coverage under employer, self-insured plans.<sup>71</sup>

There is some question about the degree of flexibility that employers actually have to structure benefits and coverage particularly for existing employees with particular medical conditions in light of the Americans with Disabilities Act.<sup>72</sup> Recently, in *Carparts Distribution v. Automotive Wholesaler's Association of New England*, the First Circuit overruled the dismissal of a complaint in which an AIDS victim claimed that the health plan's restrictive coverage provision for AIDS-related medical expenses violated the Americans with Disabilities Act.<sup>73</sup> This case, while raising the issue only collaterally, does suggest that employers may not have as much latitude as before in crafting restrictive coverage provisions for specific illnesses in self-insured plans regulated under ERISA.

### 3. The Medicare Program

**BENEFICIARY APPEALS.** The Medicare statute specifies several administrative appeals systems for beneficiaries dissatisfied with determinations under Parts A and B of the Medicare program.<sup>74</sup> Under Medicare Part A, which funds inpatient hospital and related post-hospital services, beneficiaries may appeal a

---

71. See, e.g., *Owens v. Storehouse, Inc.* 773 F. Supp. 416 (N.D. Ga. 1991), *aff'd*, 984 F.2d 394 (11th Cir. 1993) (holding that an employer's unilateral modification of a health benefit plan could not support a claim for a violation of an ERISA statute preventing employers from discharging or harassing employees in order to keep them from obtaining benefits to which they are entitled); *Vogel v. Independence Fed. Sav. Bank*, 738 F. Supp. 1210, 1225 (D. Md. 1990) (requiring a plaintiff to demonstrate that employer had specific intent to violate ERISA in order to establish a prima facie case under ERISA § 510). See also Jeffrey R. Pettit, *Help! We've Fallen and We Can't Get Up: The Problems Families Face Because of Employment-Based Health Insurance*, 46 VAND. L. REV. 779 (1993).

72. Americans with Disabilities Act, Pub. L. No. 101-336, 104 Stat. 328 (1990) (codified at 42 U.S.C. §§ 12101-12213 (Supp. V 1993)).

73. 37 F.3d 12 (1st Cir. 1994) (holding that an association and trust could be an employer under Title I of the Americans with Disabilities Act (ADA) when a trade association member and employee brought a state court action to challenge a decision of a trade association and the administering trust for a health benefit plan that limited the lifetime benefits for illnesses related to AIDS); see also, Larry Gostin, *Update: The Americans with Disabilities Act and the U.S. Health System*, HEALTH AFF., Fall 1992, at 248.

74. 42 U.S.C. §§ 1395ff, 1395u (1988 & Supp. IV 1992); Eleanor D. Kinney, *The Medicare Appeals System for Coverage and Payment Disputes: Achieving Fairness in a Time of Constraint*, 1 ADMIN. L.J. 1, 39-53 (1986) [hereinafter Kinney, *The Medicare Appeals System*].

denied claim, after reconsideration by the intermediary,<sup>75</sup> to a Social Security administrative law judge (ALJ) if the amount in controversy is at least \$100, and the beneficiary then subsequently may appeal to the Social Security Appeals Council and seek judicial review.<sup>76</sup> For Part B, which pays for physician and other outpatient services, beneficiaries may appeal to a HCFA ALJ for claims involving at least \$500 and above, and following Appeals Council review, may obtain judicial review of claims involving \$1000 and above.<sup>77</sup> Smaller claims are adjudicated by the Medicare contractors.<sup>78</sup>

The Medicare appeals system for HMO beneficiaries is especially instructive for health reform.<sup>79</sup> The Medicare statute requires HMOs that contract with Medicare to "provide meaningful procedures" for hearing and resolving grievances between the HMO and Medicare members.<sup>80</sup> A Medicare enrollee who is "dissatisfied by reason of his failure to receive any health service to which he believes he is entitled and at no greater charge than he believes he is required to pay" has the right to administrative review for controversies over \$100 under the Social Security Act.<sup>81</sup> If the amount in controversy is \$1000 or above, the enrollee or HMO is entitled to judicial review under the Social Security Act.<sup>82</sup>

Medicare regulations distinguish between disputes to be handled under the "meaningful grievance procedures" and those subject to administrative and judicial review.<sup>83</sup> Specifically, only disputes that fall within the definition of an "initial determination" in the regulations, such as HMO determinations of non-coverage, are subject to administrative and judicial review. Upon making an "initial determination," the HMO must notify the affected Medicare enrollee of his or her right to

---

75. 42 C.F.R. § 405.710 (1993).

76. 42 U.S.C. § 1395ff (1988 & Supp. IV 1992).

77. *Id.* § 1395ff(b)(2)(B).

78. *Id.* § 1395u; 42 C.F.R. § 405.801 (1993).

79. 42 U.S.C. § 1395mm(c)(5) (1988 & Supp. IV 1992); 42 C.F.R. § 417.600-638 (1993). See Susan J. Stayn, *Securing Access to Care in Health Maintenance Organizations: Toward a Uniform Model of Grievance and Appeal Procedures*, 94 COLUM. L. REV. 1674, 1692-1701 (1994) (analyzing the Medicare HMO grievance and appeal process).

80. 42 U.S.C. § 1395mm(c)(5)(A) (1988 & Supp. IV 1992).

81. *Id.* § 1395mm(c)(5)(B).

82. *Id.*

83. 42 C.F.R. § 417 (1993).

seek reconsideration within sixty days of receipt of the notice.<sup>84</sup> After reconsideration by the HMO, the HMO must send a written explanation of an unfavorable decision for HCFA to reconsider the decision.<sup>85</sup> A dissatisfied Medicare enrollee can then appeal to a Social Security ALJ within sixty days of the decision, with subsequent Appeals Council and judicial review.<sup>86</sup>

**PROVIDER APPEALS.** The Provider Reimbursement Review Board (PRRB) adjudicates payment disputes of \$10,000 or more arising between institutional providers and the Medicare program.<sup>87</sup> The Secretary of HHS may reverse, affirm, or modify the Board's decision.<sup>88</sup> Judicial review is available in federal district court.<sup>89</sup> Hospitals also can appeal determinations of components of their rate formula under the Medicare prospective payment system to the recently created Medicare Geographic Classification Review Board.<sup>90</sup>

There are important limits on provider appeal rights under Medicare. Specifically, providers cannot appeal decisions regarding coverage of benefits accorded beneficiaries.<sup>91</sup> Nor can hospitals appeal components of the national prospective payment rate, including the establishment of Diagnosis Related Groups (DRGs), the methodology for classifying patient discharges, and appropriate weighing factors for DRGs.<sup>92</sup> The rationale for this preclusion is protecting the "necessity of maintaining a workable payment system."<sup>93</sup>

---

84. *Id.* § 417.608.

85. Currently, HCFA's reconsideration function is carried out by a contractor, Network Design Group (NDG). NDG is a private organization comprised of health professionals capable of reviewing medical records involved in disputes.

86. *See supra* notes 81-82 and accompanying text.

87. 42 U.S.C. § 1395oo(a) (1988 & Supp. IV 1992), 42 C.F.R. § 405.1835 (1993). The provider's fiscal intermediary adjudicates appeals under \$10,000. 42 C.F.R. § 405.1811 (1993). *See* Phyllis E. Bernard, *Social Security and Medicare Adjudications at HHS: Two Approaches to Administrative Justice in an Ever-Expanding Bureaucracy*, 3 HEALTH MATRIX 339, 412-20 (1993) (recommending the establishment of a Social Security court to help ease the burden federal courts will face when "baby boomers" become eligible to make claims on Social Security entitlement programs).

88. 42 U.S.C. § 1395oo(f)(1) (1988 & Supp. IV 1992).

89. *Id.*

90. Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-1239, § 6003(h)(3), 103 Stat. 2154-56 (codified at 42 U.S.C. § 1395 ww(d)(10) (Supp. IV 1992)).

91. 42 U.S.C. § 1395oo(g)(2) (1988 & Supp. IV 1992).

92. *Id.* § 1395oo(g).

93. H. REP. NO. 25, 98th Cong., 2d Sess. 143, pt. 1 (1983).

Further, physicians and suppliers of medical equipment have appeal rights under Part B only if they accept assignment of Part B benefits from beneficiaries.<sup>94</sup> Under the resource based relative value payment system for physicians, administrative and judicial review of the content of relative value scales used to establish payment rates for physicians is also precluded.<sup>95</sup> As with hospital payment, Congress created a congressional commission, the Physician Payment Review Commission, to review and comment on HCFA's payment rates and methodologies on physicians.<sup>96</sup>

**JUDICIAL REVIEW.** Judicial review for all disputes under Medicare are limited by the bar to federal question jurisdiction<sup>97</sup> in section 205(h) of the Social Security Act (SSA)<sup>98</sup> for all suits under the SSA except when brought in the context of claims for which administrative remedies have been exhausted.<sup>99</sup> This jurisdictional bar has served as an effective bar-

---

However, as a check on HCFA's authority to recalibrate DRGs and set hospital payment rates, Congress created the Prospective Payment Assessment Commission to monitor and evaluate HHS's performance in setting payment rates and, specifically, to analyze the hospital payment rates and DRGs independently of HHS and to advise HHS of its findings. 42 U.S.C. § 1395ww(e)(2) (1988 & Supp. IV 1992). See Eleanor D. Kinney, *Making Hard Choices Under the Medicare Prospective Payment System: One Administrative Model for Allocating Medical Resources Under a Government Health Insurance Program*, 19 IND. L. REV. 1151 (1986).

94. 42 U.S.C. § 1395u(b)(3)(B)(1) (1988 & Supp. IV 1992).

95. Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, § 6102, 103 Stat. 2106, 2184 (codified at 42 U.S.C. § 1395w-4(1)(1)(B) (Supp. IV 1992)).

96. 42 U.S.C. § 1395w-1 (Supp. IV 1992).

97. 28 U.S.C. § 1331 (1988 & Supp. IV 1992).

98. 42 U.S.C. § 405(h) (1988 & Supp. IV 1992).

99. In its 1975 decision, *Weinberger v. Salfi*, 422 U.S. 749 (1975), the Supreme Court held that federal courts do not have federal jurisdiction to hear constitutional challenges to the Social Security Act, except in the context of claims that have proceeded through all administrative remedies. Later in *Heckler v. Ringer*, 466 U.S. 602, 612-15 (1984), the Supreme Court ruled that § 205(h) expressly precluded federal question jurisdiction for direct challenges under the Medicare provisions of the SSA. In its 1986 decision, *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 674-78 (1986), the Supreme Court ruled that SSA § 205(h) did not bar challenges to HHS policies prescribing the method of calculating payment of Part B claims. After this decision, Congress authorized administrative and judicial review of Part B claims in a manner comparable to Part A claims. See 42 U.S.C. § 1395ff (1988 & Supp. III 1991). Several courts have since ruled that Part B claims, including challenges to policy, fall within *Ringer* and that *Michigan Academy* no longer governs Part B appeals. See, e.g., *Abbey v. Sullivan*, 978 F.2d 37 (2d Cir.), *reh'g denied*, No. 92-6055 (2d Cir. 1992) (holding that Medicare claimant was not entitled to mandamus relief because not all administrative remedies were exhausted); *National Kidney Patients Ass'n v. Sullivan*, 958 F.2d 1127, 1130 (D.C. Cir. 1992), *cert. denied*, 113 S. Ct. 966 (1993) (holding that the District Court lacked jurisdiction to preliminarily enjoin HHS and that the Department could apply its recoupment procedures in

rier to federal court for both Medicare beneficiaries and providers and has limited adjudication of disputes to administrative tribunals created under the SSA.

#### 4. The Medicaid Program

Under the Medicaid statute, state Medicaid plans must provide for an opportunity for a fair hearing before the state agency for individuals whose claims are either denied or not acted on with reasonable promptness, or where the agency otherwise acted erroneously.<sup>100</sup> States must maintain a hearing system that provides for a hearing before the state Medicaid agency, or an evidentiary hearing at the local level, with a right of appeal to a state agency hearing.<sup>101</sup> The hearings provided under the state's hearing system must meet the due process standards in *Goldberg v. Kelly*,<sup>102</sup> and additional standards specified in the regulations.<sup>103</sup>

Medicaid HMOs are all required to maintain "an internal grievance procedure," approved by the state Medicaid agency, which provides for prompt resolution of disputes, and "the participation of individuals with authority to require corrective action."<sup>104</sup> Otherwise, HMO appeal procedures are the state "fair hearing" procedures described above.<sup>105</sup> Provided that states meet these minimal requirements, states have considerable latitude to structure appeal procedures for their Medicaid programs.

**JUDICIAL REVIEW.** The SSA is silent on the availability of judicial review for decisions of state Medicaid agencies in adjudications of disputes with consumers and providers over claims. Consequently, claimants are left with the avenues for judicial review under relevant federal and state law.<sup>106</sup>

---

seeking refund of overpayments made to health care services provider under injunction). *But see* Griffith v. Bowen, 678 F. Supp. 942, 945 (D. Mass. 1988) (specifically holding that *Michigan Academy* still governs Part B appeals).

100. 42 U.S.C. § 1396a(a)(3) (1988 & Supp. IV 1992); 42 C.F.R. § 431.200-250 (1993).

101. 42 C.F.R. § 431.205 (1993).

102. 397 U.S. 254 (1970) (holding that a welfare recipient was entitled to an oral pretermination hearing).

103. 42 C.F.R. § 431.205(d) (1993).

104. *Id.* § 434.32(c).

105. *See supra* notes 100-03 and accompanying text.

106. *See* part III.D.

Traditionally, Medicaid claimants and providers were severely hampered in their access to federal courts because of the prohibitions of the Eleventh Amendment and limits on challenges under section 1983.<sup>107</sup> However, Medicaid providers and beneficiaries obtained an important victory in terms of opening up judicial challenge to state Medicaid program policies in *Virginia Hospital Association v. Wilder*.<sup>108</sup> In this case, the Supreme Court held that the Boren Amendment<sup>109</sup> creates a right, enforceable in a private cause of action by health care providers, for declaratory and injunctive relief under section 1983 to have states adopt reasonable and adequate rates.

#### D. Statutory and Constitutional Law Pertaining to Judicial Review

The law of judicial review of the policies and decisions of administrative agencies is fairly straightforward in the current health care system. If the matter arises in the context of a health insurance program, such as decisions regarding coverage and payment of claims, the availability of judicial review depends on the sponsor of the claimant's health insurance plan. Judicial review of claim disputes under governmental health insurance programs is discussed above. Other challenges over governmental actions regarding health-related matters are governed by the body of federal and state procedural and constitutional law outlined below. Regarding judicial review of agency actions generally, the Federal APA as well as most state administrative procedure acts provide a mechanism for judicial

---

107. Civil Rights Act of 1871 § 1, 42 U.S.C. § 1983 (1988). See, e.g., Kinney, *A Challenge to Federalism*, *supra* note 47; Rand E. Rosenblatt, *Statutory Interpretation and Distributive Justice: Medicaid Hospital Reimbursement and the Debate over Public Choice*, 35 St. Louis U. L. J. 793 (1991).

108. 496 U.S. 498 (1990). See note 109 *infra* and accompanying text.

109. 42 U.S.C. § 1396a(a)(13)(A) (1988 & Supp. IV 1992).

In the 1980s, Congress revised federal requirements for state payment methodologies for institutional providers, enabling states to depart from cost reimbursement to more efficient payment methodologies based on the criterion that payment rates be "reasonable and adequate" to meet the costs of "efficiently and economically operated facilities." *Id.* In the Omnibus Reconciliation Act of 1980, Pub. L. No. 96-499, § 962(b), 94 Stat. 2651 (1980), Congress established this standard for nursing homes. The following year, Congress extended this requirement for hospitals. Omnibus Budget Reconciliation Act of 1981, Pub. L. No. 97-35, § 2173, 95 Stat. 357, 808-09 (1981).

review unless the enabling legislation explicitly precludes review.<sup>110</sup>

### 1. De Novo Review in State Court

Under current law, assuming there is no state or federal administrative review or mandatory ADR, consumers can bring state causes of action arising in contract, tort, or other areas of state law in state court. State constitutions, as well as statutory and common law, govern the degree to which state legislatures can foreclose such state claims. State courts also have authority to hear federal claims unless explicitly barred by federal statute. Furthermore, Congress, under the Supremacy Clause of the U.S. Constitution, can require state courts to adjudicate federal claims and has indeed done so in some instances.<sup>111</sup>

### 2. De Novo Review in Federal Court

SUITS AGAINST GOVERNMENTS AND OFFICIALS AND OTHER INDIVIDUALS ACTING UNDER COLOR OF STATE LAW. Ostensibly, the Eleventh Amendment of the U.S. Constitution prohibits suits in federal court against state governments by the state's own citizens or citizens of other states. The Supreme Court has developed several theories that permit review of actions by state governments and their personnel in federal court.<sup>112</sup> The Supreme Court ruled that the Eleventh Amendment does not bar suits against state officers for declaratory and injunctive relief that seek to compel state officials to implement federal policies prospectively<sup>113</sup> or from implementing

---

110. *See, e.g.*, 5 U.S.C. §§ 701-06 (1988 & Supp. V 1993).

111. *See, e.g.*, *Howlett v. Rose*, 496 U.S. 356, 367-72 (1990) (holding that while the state court may not refuse to hear a federal claim, it may apply its own procedural rules to the claim); *Taffin v. Levitt*, 493 U.S. 455 (1990) (holding that state courts have concurrent jurisdiction over RICO Act claims); *Felder v. Casey*, 487 U.S. 131 (1988) (stating that civil rights victims seeking redress in state courts must comply with federal requirements); *Wallace v. Robinson*, 914 F.2d 869 (7th Cir. 1990) (showing that a federal civil rights claim may be heard in a state court).

112. E. CHEMERINSKY, *FEDERAL JURISDICTION* § 7.4-6 (1989).

113. *See, e.g., Wilder*, 496 U.S. at 516-17; *Edelman v. Jordan*, 415 U.S. 651 (1974).



state policies.<sup>114</sup> Clearly, actions for damages against states and state officials are barred.<sup>115</sup>

A state may waive its Eleventh Amendment protection although the Supreme Court has ruled that the fact that a state participates in a federally-funded program does not constitute such waiver.<sup>116</sup> Congress can abrogate the Eleventh Amendment immunity but must make its intent to do so "unmistakably clear in the language of the statute."<sup>117</sup> In 1975, Congress briefly required states to amend their Medicaid state plans to permit suits by hospitals for damages in federal court but repealed the requirement the next year out of concern over fiscal constraints.<sup>118</sup>

More importantly, section 1983<sup>119</sup> creates a private cause of action against any person who, under color of state law, abridges rights created by the Constitution and laws of the United States. As pointed out above, the Supreme Court, in *Wilder v. Virginia Hospital Association*,<sup>120</sup> ruled that the Boren Amendment<sup>121</sup> created a federal cause of action under section 1983 to challenge state compliance with federal statutory criteria for provider payment. The Court focused on whether

---

114. *Ex Parte Young*, 209 U.S. 123, 125 (1908) (holding that a suit brought by a stockholder against a corporation to enjoin the directors and officers from complying with the provisions of a state statute alleged to be unconstitutional was not barred by the Eleventh Amendment). See CHEMERINSKY, *supra* note 112, at § 7.6.

115. *Quern v. Jordan*, 440 U.S. 332, 341 (1979) (holding that the Civil Rights Act of 1871 did not abrogate the Eleventh Amendment immunity of the states in a class action suit for failure of the Illinois Department of Public Aid to process applications for assistance under the aid to the aged, blind, and disabled program on a timely basis); *Edelman*, 415 U.S. at 663 (holding that the Eleventh Amendment barred the retroactive payment of benefits found to have been wrongfully withheld in a class action suit against Illinois officials who were administering the federal-state programs of aid to the aged, blind, and disabled, and who were charged with violating federal law and denying equal protection of the laws by following state regulations that did not comply with federal time limits for aged, blind, and disabled applications).

116. *Florida Dep't of Health and Rehab. Servs. v. Florida Nursing Home Ass'n*, 450 U.S. 147 (1981) (holding that the Eleventh Amendment barred the federal court from ordering the state to reimburse nursing homes for the amounts they would have received if federal regulations had been promulgated in a timely manner); *Edelman*, 415 U.S. at 673.

117. *Hoffman v. Connecticut Dep't of Income Maintenance*, 492 U.S. 96, 101 (1989) (holding that Congress did not abrogate the Eleventh Amendment immunity of states by enacting a bankruptcy statute).

118. Act of Dec. 31, 1975, Pub. L. No. 94-182, § 111, 89 Stat. 1051, *repealed by*, Act of Oct. 18, 1976, Pub. L. No. 94-552, § 2, 90 Stat. 2540 (codified at 42 U.S.C. § 1396) (1988 & Supp IV 1992). See S. REP. No. 1240, 94th Cong., 2d Sess. 3 (1976).

119. Civil Rights Act of 1871 § 1, 42 U.S.C. § 1983 (1988).

120. *Wilder*, 496 U.S. at 524.

121. See *supra* note 109 and accompanying text.

the provision in question was intended to benefit the plaintiff and, if so, whether the statute “reflects merely a ‘congressional preference’ for a certain kind of conduct rather than a binding obligation on the governmental unit,” as well as whether the plaintiff’s interest was “too vague and amorphous,” and thus “beyond the judiciary’s competence to enforce.”<sup>122</sup>

However, later in *Suter v. Artist M.*,<sup>123</sup> the Supreme Court ruled that the children beneficiaries under a federal grant-in-aid program did not have a federal cause of action under section 1983 to enforce statutory obligations of state officials under the federal statute. The Court did not apply the test enunciated in *Wilder*, but rather focused on the statutory language to determine whether Congress had “unambiguously confer[red] upon the child beneficiaries of the Act a right to enforce the requirement that the State make ‘reasonable efforts.’ ”<sup>124</sup>

Subsequent appellate court decisions have sought to reconcile *Suter* and *Wilder*.<sup>125</sup> After *Suter*, appellate courts have focused carefully on the specific statutory provision in question to determine whether the statute merely reflects a congressional preference or binding obligation. If the statute does not clearly compel the state to take some action regarding plaintiffs, as opposed to a generalized obligation to submit a plan or plan amendment, courts are unlikely to find that the statute creates an enforceable right under section 1983.

**SUITS AGAINST THE FEDERAL GOVERNMENT AND FEDERAL OFFICIALS.** Under the principle of sovereign immunity, the United States government may not be sued unless federal legislation specifically authorizes suit. Three major statutes waive the federal government’s sovereign immunity: (1) the federal

---

122. *Wilder*, 496 U.S. at 509.

123. 112 S. Ct. 1360, 1370 (1992).

124. *Id.* at 1367.

125. See, e.g., *Procopia v. Johnson*, 994 F.2d 325, 331-32 (7th Cir. 1993) (stating that it was “prudent and possible to synthesize the teachings of *Suter* and the court’s prior precedents”); *Clifton v. Schafer*, 969 F.2d 278 (7th Cir. 1992) (stating that *Wilder* simply held that health care providers could sue to enforce their right to a state plan that does not violate the Boren Amendment, whereas *Suter* requires only that the state adopt a plan that provides “for a system of hearings” to determine whether payments to providers are reasonable and adequate); *Stowell v. Ives*, 976 F.2d 65 (1st Cir. 1992) (denying a federal cause of action to enforce state compliance because the statute did not impose a direct obligation on the state).

APA which allows suits for injunctive relief;<sup>126</sup> (2) the Federal Tort Claims Act which allows suits for negligence by federal employees;<sup>127</sup> and (3) the Tucker Act which allows suits for breach of contract and other monetary claims not arising in tort.<sup>128</sup>

No federal statute comparable to section 1983 provides a cause of action for relief against federal officers who violate the U.S. Constitution. Nevertheless, the Supreme Court has ruled that federal officers may be sued for injunctive relief to prevent future infringements of federal law.<sup>129</sup> Further, in *Bivens v. Six Unknown Named Agents of Federal Bureau of Narcotics*,<sup>130</sup> the Supreme Court inferred a cause of action for damages directly from constitutional provisions.

### III. ADMINISTRATIVE LAW ISSUES IN PROPOSED HEALTH REFORM LEGISLATION

The chief concern of administrative law is enabling private parties affected by decisions and policies of government agencies to influence or, when necessary, challenge those decisions or policies. Further, administrative law is concerned with the procedures by which government discharges its responsibilities and relates to affected private parties. The major procedural issues are: (1) making rules and policy; (2) adjudicating disputes; and, (3) providing judicial review to enforce governmental compliance with constitutional, common law, and statutory requirements.

The core value in designing ideal administrative procedures for a reformed health care system is the degree to which private parties can challenge policies, decisions or other agency actions that affect them without compromising the integrity of the health reform system or its expeditious implementation. Administrative procedures in any health reform proposal should be measured against this core value.

---

126. 5 U.S.C. § 702 (1988 & Supp. V 1993).

127. 28 U.S.C. §§ 1346, 2671-2678, 2680 (1988 & Supp. IV 1992).

128. *Id.* §§ 1346(a), 1491. See generally CHEMERINSKY, *supra* note 112, at § 9.2.

129. See, e.g., *Larson v. Domestic & Foreign Commerce Corp.* 337 U.S. 682, 689-90 (1949); see CHEMERINSKY, *supra* note 112, at § 9.1.

130. 403 U.S. 388 (1971) (inferring a cause of action under the Fourth Amendment).

The resolution of procedural issues for health reform is informed by three crucial "structural" issues raised by the overall design of a given health reform. The key structural issues are: (1) the allocation of responsibilities between the federal government and the states; (2) the design and powers of the various organizations and agencies with responsibilities for health reform; and (3) the way in which reforms relate to existing public health insurance programs including the Medicare and Medicaid program. Clearly, the allocation of power to implement and operate health reform between the federal government and states, as well as the organizational characteristics of responsible agencies, will influence the appropriate administrative procedures for making rules and policies, adjudicating disputes, and enforcing governmental compliance with health reform legislation and constitutional requirements through judicial review.

### A. Structural Issues

Most of the comprehensive health reform proposals before the 103d Congress would have dramatically altered the structural characteristics of the American health care system. Managed competition proposals would have created new organizations and agencies and vested additional powers in the federal government and the states to oversee reforms in the health insurance market and execute other programmatic responsibilities. Proposals with incentive approaches would have endeavored to achieve comparable health system efficiencies and enhanced access through voluntary action encouraged by tax code and other changes. The single-payer proposals would have eliminated private health insurance altogether, and substituted a federal program with, in some cases, options for states to offer their own program within federal guidelines. These structural issues are important from an administrative law perspective for they delineate the authority of responsible agencies, and consequently influence the procedures that these agencies will use to make rules and policy, adjudicate disputes, and enforce program requirements.

#### 1. Allocation of State and Federal Responsibilities

Many proposals before the 103d Congress, regardless of approach, would have accorded states the opportunity to as-

sume considerable responsibility for the implementation of health reform.<sup>131</sup> Interestingly, proposals from Democrats including President Clinton tended to provide for a more distinct state role in health reform than those from Republicans. Indeed, the President's proposal actually permitted states to establish independent single-payer systems.<sup>132</sup> The strong state focus reflects recognition of the innovative leadership that many states have exhibited in health reform during the 1980s.<sup>133</sup> The major role for states in health reform also poses important federalism issues.

Further, most proposals before the 103d Congress, regardless of the role for states, would have established oversight responsibilities for HHS for the Medicare and Medicaid programs and other public health functions and the DOL for health plans regulated under ERISA. Further, many proposals from across the political spectrum called for independent federal agencies to make national policy affecting the reformed health care system.<sup>134</sup>

The most important federalism issue from a procedural perspective is whether a health reform proposal that requires states to conduct various functions meets the requirements of the Tenth Amendment of the U.S. Constitution as delineated in the Supreme Court's decision in *New York v. United States*.<sup>135</sup> *New York v. United States* held that the Tenth Amendment prohibits Congress from requiring states to comply with orders falling outside Congress' enumerated powers. However, in light of *New York v. United States*, federal legislation can give states the option of not participating in the reformed system and making health reform completely a federal respon-

---

131. See, e.g., Health Security Act of 1993 §§ 1200-1224; Consumer Choice Health Security Act of 1993 § 131.

132. Health Security Act of 1993 §§ 1200-1224.

133. See Deborah L. Rogel & W. David Helms, *State Models: An Overview*, HEALTH AFF., Summer 1993, at 27 (tracking several states in their efforts to implement health reform legislation).

134. See note 144 *infra* and accompanying text.

135. 112 S. Ct. 2408 (1992).

sibility.<sup>136</sup> Many health reform proposals before the 103d Congress provided states with such an option.<sup>137</sup>

A crucial issue in locating authority is whether the state or the federal government has ultimate financial liability for the health care services, as well as increases in expenditures for services. Specifically, if states are liable for increases in health care expenditures or health insurance premiums, they should be accorded the requisite authority to regulate the institutions, such as providers and insurers, in the health care system that generate excess expenditures or premiums. Clearly, the degree to which the federal government or states have ultimate financial responsibility for the provision of health care services to subsidized groups, such as the poor and near poor, as well as the employees of marginal small businesses, the greater degree of interest the states and the federal government, respectively, will have in the formulation of policy and the adjudication of disputes. Further, states will be especially concerned about unfunded federal mandates that they will be responsible to implement and finance.<sup>138</sup>

## 2. Organizational Arrangements

In addition to responsibilities accorded to HHS and DOL, most health reform proposals before the 103d Congress called for the creation of new government agencies and quasi-public organizations to implement and operate aspects of the health reform legislation.<sup>139</sup> Many of these agencies and organizations were unique in their structure, whereas some had fairly strong regulatory responsibilities that were controversial given their unique organizational characteristics.<sup>140</sup>

Several health reform proposals called for creation of quasi-public organizations, to consolidate insurance purchasing power and, to varying degrees, to perform other regulatory

---

136. See Candice Hoke, *Constitutional Impediments to National Health Reform: Tenth Amendment and Spending Clause Hurdles*, 21 HASTINGS CONST. L.Q. 489, 550-73 (1994).

137. See, e.g., Health Security Act of 1993 § 1521-1524; Health Equity and Access Reform Today Act of 1993 §§ 1441-1444; Mitchell Compromise Bill §§ 1421-1424.

138. See Edward A. Zelinsky, *Unfunded Mandates, Hidden Taxation, and The Tenth Amendment; Public Choice, Public Interest, and Public Services*, 46 VAND. L. REV. 1355 (1993).

139. See *infra* notes 141 & 144 and accompanying text.

140. See *infra* notes 141-46 and accompanying text.

functions for the private health insurance market.<sup>141</sup> One of the most controversial aspects of the managed competition proposals before the 103d Congress was the design and authority of agencies with responsibilities for regulating the private health insurance market. For example, health alliances under the President's proposal, in addition to consolidating purchasing power in the private health insurance market, also administered budgetary limits on health expenditures.<sup>142</sup> Under the Chafee and Cooper bills, individual and employer participation was voluntary and these organizations had minimal regulatory responsibilities.<sup>143</sup> However, to the extent that participation in these entities is voluntary, these entities would be less able to accomplish genuine reform of the private health insurance market.

Many proposals before the 103d Congress called for the creation of independent federal agencies to set uniform standards and perform other oversight functions for the reformed system.<sup>144</sup> These federal agencies under most proposals would have had similar responsibilities, including establishing the standard benefit package, national data standards, clinical practice guidelines, and national coverage policy.<sup>145</sup> These re-

---

141. See, e.g., Health Security Act of 1993 §§ 1321-1397 (health alliances); Managed Competition Act of 1993 §§ 1101-1108 (health plan purchasing cooperatives); Health Equity and Access Reform Today Act of 1993 §§ 1141-1145 (health insurance purchasing cooperations).

142. Health Security Act of 1993 § 1300.

143. See, e.g., Health Equity and Access Reform Today Act of 1993 §§ 1141-1145; Managed Competition Act of 1993 §§ 1101-1108.

144. See, e.g., Health Security Act of 1993 §§ 1201-1217 (National Health Benefits Board), §§ 1501-1506 (National Health Board); Health Equity and Access Reform Today Act of 1993 § 1311-1315 (Benefits Commission); Managed Competition Act of 1993 §§ 1301-1313 (Health Care Standards Commission). See also Affordable Health Care Now Act § 1108 (Office of Private Health Care Coverage within HHS).

145. See, e.g., Health Security Act of 1993 §§ 401, 1503; Health Equity and Access Reform Today Act of 1993 § 1312; Managed Competition Act of 1993 §§ 1301-1312.

These federal oversight agencies essentially would assume functions that HHS currently performs regarding Medicare coverage policy, medical practice guidelines, and other policy issues. Currently, HCFA makes coverage decisions based on referrals from Medicare contractors. HCFA may refer an issue to the Public Health Service (which makes recommendations) upon consultation with the Food and Drug Administration (which approves certain medical devices and the National Institutes of Health. The Public Health Service then makes recommendations on whether federal health insurance programs should pay for specific health care technologies. 42 U.S.C. §§ 2992-2(d)(3), 242(c)(e) (1988 & Supp. IV 1992). The Agency for Health Care Policy and Research (AHCPR) has direct responsibility for sponsoring the development of clinical practice guidelines, as well as enhancing the quality, appropriateness, and effectiveness of health care services through research and the promotion of improvements in clinical practice. Omnibus Budget Reconcili-

sponsibilities involve very different types of issues and should be executed through processes that elicit the best information for decision making from a scientific and equity perspective. Under the President's proposal, a National Health Board also would have implemented the national budget for health care spending through the alliances — a controversial function that distinguished the President's proposal from other managed competition proposals.<sup>146</sup>

Some health reform proposals even call for private organizations to assist in the policy-making function. For example, several proposals would have the National Association of Insurance Commissioners (NAIC) or the private accrediting organizations such as the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) to suggest policy and standards for various state responsibilities under health reform.<sup>147</sup> The structure of many of the organizations called for under various health reform proposals, especially when coupled with unique regulatory authority, may implicate the delegation doctrine in constitutional law.<sup>148</sup> This problem was potentially greatest with the alliances under the President's proposal as these alliances had extraordinary responsibilities that customarily reside in government agencies, such as implementation of the national budget on health care spending.

The Administrative Conference of the United States has recommended that private regulation be used when both the responsible agency and the private organization have the organizational ability in terms of expertise, experience, and author-

---

ation Act of 1989, § 6103, *reprinted in* 1989 U.S.C.C.A.N. 2101, 2104 (codified at 42 U.S.C. § 299).

146. Health Security Act of 1993 §§ 1501-1506.

147. *Id.* § 4307(d). *See, e.g.*, Health Equity and Access Reform Today Act of 1993 § 1102; Consumer Choice Health Security Act § 118; Affordable Health Care Now Act of 1993 §§ 1102(a)(1)(F), 1103(a)(1), 1106(a)(1) (1993).

148. *See, e.g.*, *Touby v. United States*, 500 U.S. 160 (1991) (holding that Congress may delegate power to a coordinate branch, so long as it sets forth standards to which the agency must conform); *Skinner v. Mid-America Pipeline Co.*, 490 U.S. 212 (1989) (holding that a delegation of Congress' taxation power to the Department of Transportation was permissible); *Mistretta v. United States*, 488 U.S. 361 (1989) (holding that Congress did not delegate excessive legislative powers in creating the U.S. Sentencing Commission). *See also* Peter H. Aranson et al., *A Theory of Legislative Delegation*, 68 CORNELL L. REV. 1 (1982) (discussing the modern delegation doctrine).



ity to implement the regulatory assignment effectively.<sup>149</sup> Also, the private organization should have fair and democratic procedures for the development of regulatory standards and the responsible agency has access to applicable records of the private organization.<sup>150</sup>

In general, however, the delegation doctrine is quite permissive and has sanctioned the delegation of many public functions, such as the establishment of criteria and standards for government regulatory programs<sup>151</sup> to private organizations.<sup>152</sup> The rationale for such delegation is that private bodies have unique expertise or capabilities that do not reside in government.<sup>153</sup> The problem with delegation comes when Congress delegates quasi-public organizations more proactive responsibilities without sufficient statutory standards or direction.<sup>154</sup>

### 3. Relations of Health Reform with Existing Programs

A major issue for all health reform proposals is what to do with government health insurance programs, such as the health insurance programs for military dependents and veterans, as well as the Medicare and Medicaid programs. Medicare and Medicaid are especially crucial since they cover nearly fifty-eight million Americans including the elderly, the severely disabled and some poor.<sup>155</sup> Both programs present real but different challenges for health reformers. Medicare is a popular program serving the elderly and severely disabled, and these

---

149. Recommendations of the Administrative Conference of the United States, *The Use of Audited Self-Regulation as a Regulatory Technique*, Recommendation No. 94-1, 59 Fed. Reg. 44,701, 44,701 (1994).

150. *Id.*

151. See DOUGLAS C. MICHAEL, *FEDERAL AGENCY USE OF AUDITED SELF-REGULATION AS A REGULATORY TECHNIQUE* (1993); Eleanor D. Kinney, *Government as a Substitute for Direct Regulation in Private Accreditation of Public Health Insurance Programs*, 57 LAW & CONTEMP. PROBS. 47 (1994) [hereinafter *Private Accreditation*].

152. See, e.g., Harold I. Abramson, *A Fifth Branch of Government: The Private Regulators and their Constitutionality*, 16 HASTINGS CONST. L.Q. 165 (1989); Harold J. Krent, *Fragmenting the Unitary Executive: Congressional Delegations of Administrative Authority Outside the Federal Government*, 85 NW. U. L. REV. 62 (1990).

153. See Kinney, *Private Accreditation*, *supra* note 151.

154. See, e.g., *United States v. Schechter Poultry Corp.*, 295 U.S. 495 (1935) (invalidating the National Industry Recovery Act because it impermissibly delegated legislative functions to the President); *Panama Refining Co. v. Ryan*, 293 U.S. 388, 392 (1935) (invalidating the National Industrial Recovery Act as an improper delegation of legislative authority to the President).

155. See note 10 *supra* and accompanying text.

constituencies have successfully pressed policy makers to retain the independence of the Medicare program in any new system. And, at least two health reform proposals before the 103d Congress called for expanding Medicare to all Americans in a single-payer system.<sup>156</sup>

Medicaid is a horse of a different color. Medicaid is the only public health insurance program that taps state revenues for its financing, but also serves an expansive population compared to other societal groups.<sup>157</sup> Historically, Medicaid, which is jointly administered by the federal government and states, has been a controversial program because of the pressures of escalating program expenditures on the budgets of the federal and particularly state governments. Consequently, state health reformers resisted incorporating the expensive Medicaid population into reformed systems in ways that would increase state financial liability.<sup>158</sup>

Under most managed competition proposals before the 103d Congress, including the President's, the Medicare program would have remained intact but with streamlined billing and claims administration procedures.<sup>159</sup> Most managed competition proposals would have incorporated the Medicaid program into the private health insurance system over a period of years.<sup>160</sup> Under the single-payer proposals, Medicare and Medicaid would be incorporated into the single-payer system.<sup>161</sup> As no health reform completely eliminated the Medi-

---

156. The American Health Security Act of 1993, H.R. 1200, S. 491, 103d Cong., 1st Sess. (1993)[hereinafter *The American Health Security Act of 1993*].

157. Deborah Chollet, *Employer-Based Health Insurance In A Changing Work Force*, HEALTH AFF., Spring 1994, at 315 (discussing the employees and their families working in various industries who are insured under the Medicaid program).

158. Adam Clymer, *The Nation: In the Arithmetic of Health Care, It Pays to Aim for 100%*, N.Y. TIMES, July 24, 1994, § 4, at 16; Robert Pear, *The Health Care Debate: The States; A Promise on Coverage; A Hint on Abortion*, N.Y. TIMES, July 18, 1994, at A12; Robert Pear, *The Health Care Debate: The States; Governors Oppose Key Dole Proposal on a Health Plan*, N.Y. TIMES, July 17, 1994, § 1, at 1.

159. Health Security Act of 1993 §§ 4101-4141; Affordable Health Care Now Act of 1993 §§ 2401-2411; Managed Competition Act of 1993 §§ 2201-2208; Consumer Choice Health Security Act of 1993 §§ 201-206; Health Equity and Access Reform Today Act of 1993 §§ 6111-6139.

160. Health Security Act of 1993 §§ 4201-4251; Health Equity and Access Reform Today Act of 1993 § 6031; Comprehensive Family Health Access and Savings Act §§ 901-902 [hereinafter *Comprehensive Family Health Access and Savings Act*].

161. See, e.g., *The American Health Care Act of 1993* § 106.

care and Medicaid programs, all proposals raised questions about the coordination of health reform with these programs.

### B. Rule and Policy Making

All health reform proposals before the 103d Congress would have required responsible government agencies and private organizations to make a wide variety of rules and policies to implement the health reform legislation.<sup>162</sup> Most health reform proposals required rulemaking to implement the major programmatic functions of the health reform legislation including defining benefits and coverage, defining eligibility and enrollment in health plans, regulating health plans and their participating providers, assuring the quality of health care services, evaluating plan and provider performance, regulating the private health insurance market, paying health plans and providers, financing health benefits, controlling fraud and abuse, collecting and managing data, and enforcing cost controls, if any.

The procedures by which rules are made as well as the sponsorship of rules are crucial determinants of their legal effect. If the sponsor is a government agency, it must use rule and policy-making procedures delineated in the agency's enabling act or the applicable administrative procedure act to promulgate rules having legal effect.<sup>163</sup> If the sponsor is a private organization, it must use corporate policy-making procedures or contracts to make legally binding policy.<sup>164</sup>

Other than to specify subject matters on which agencies should promulgate rules and standards, health reform proposals before the 103d Congress were not very specific about procedures to be invoked in making rules and policies for health reform. Several proposals called for the use of interim final rules to permit expeditious implementation of health reform legislation.<sup>165</sup> In specific instances, several bills called for the reliance

---

162. Eleanor D. Kinney, *Rule and Policy Making Under Health Reform*, in *ADMINISTRATIVE LAW ISSUES IN HEALTH CARE REFORM* (1994) (not paginated).

163. CHARLES H. KOCH, JR., 1 *ADMIN. LAW AND PRACTICE* § 3.52, at 171-72 (1985).

164. HARRY G. HENN & JOHN R. ALEXANDER, *LAW OF CORPORATIONS AND OTHER BUSINESS ENTERPRISES* § 133 (3d ed. 1993).

165. *See, e.g.*, Health Security Act of 1994 § 1102(b); Health Security Act of 1993 § 1911; Dole Compromise Bill § 201.

on standards established by private organizations such as the NAIC<sup>166</sup> or private accreditation bodies.<sup>167</sup>

Any health reform proposal, particularly if it imposes responsibilities on states, will encounter three major challenges in rule and policy making. First, responsible agencies will have to implement rules and policies quickly to get the health reform up and running. Second, responsible agencies will have to make rules and policies on subjects that are highly controversial and require medical and technical expertise in an environment where cost constraints are paramount. Third, state rule and policy-making responsibilities may be too burdensome for the rulemaking procedures of some states. These challenges are discussed in greater detail below.

### 1. Promulgating Rules and Policy Expeditiously

The task of crafting and properly promulgating all the requisite rules and policy to implement health reform legislation is great. It is especially challenging to do so and still get the appropriate public input necessary to achieve sound policy and avoid subsequent judicial challenges from affected individuals and interest groups. However, there are some strategies that might achieve these two important goals.

Specifically, responsible agencies should carefully consider whether rules need to be legislative and thus made pursuant to more time-consuming statutory rulemaking procedures. Certainly, agencies should steer clear of formal, trial-type procedures, if possible, and use them only if it is necessary to adjudicate complex, technical facts.<sup>168</sup> Further, interpretative rules or program guidance, which need not be promulgated according to statutory procedures, may be sufficient to inform the public of their responsibilities under the legislation. One intractable problem with interpretative rules, however, is their susceptibility to procedural challenges on grounds that they are invalid as they are actually legislative rules.<sup>169</sup>

---

166. See *supra* note 147 and accompanying text.

167. See, e.g., Health Security Act of 1994 § 1501(b)(4), Dole Compromise Bill § 201(a).

168. See Recommendations of the Administrative Conference of the United States, Procedures for the Adoption of Rules of General Applicability, Recommendation No. 72-5 (1972).

169. See *supra* note 37 and accompanying text.

One approach is the use of interim final rulemaking authority under the good cause exception of the federal APA and comparable provisions of state APAs.<sup>170</sup> Several proposals before the 103d Congress called for widespread use of interim final rules for agencies in establishing the reformed health system.<sup>171</sup> This practice, although unpopular with consumers and providers, has been upheld by courts.<sup>172</sup> For example, in *Coalition of Michigan Nursing Homes, Inc. v. Dempsey*,<sup>173</sup> HHS had invoked the "good cause" exception in a regulation pertaining to Medicaid state plan amendments on grounds that to proceed with a thirty day notice and comment period was impractical given the legislatively imposed time limits. The court stated that meeting such deadlines was a clear example of impracticability and satisfied the requirement for good cause.<sup>174</sup>

Another excellent strategy for expeditious rulemaking is to borrow heavily from applicable standards that private organizations such as the NAIC or the JCAHO have developed, particularly if the standards have been made in a democratic procedure that assures the input of respected experts and opinion leaders.<sup>175</sup> Use of such private standards is also an effective way to enhance public confidence in the rules and policy as well as public support for the health reform legislation. As discussed above, the Administrative Conference of the United States has recommended use of private standards when they have been developed in an open and democratic process.<sup>176</sup>

Congress also can establish a special statutory rulemaking procedure in the enabling statute that is more expeditious than notice and comment rulemaking procedures under the APA to make legislative rules in specific areas. Or Congress can insulate certain interpretative rules from procedural challenges. For

---

170. See *supra* notes 48-49 and accompanying text.

171. See *supra* note 165 and accompanying text.

172. See, e.g., *Philadelphia Citizens in Action v. Schweiker*, 669 F.2d 877 (3rd Cir. 1982) (calling for the dispensing of the HHS's notice and comment procedure in promulgating rules); *Universal Health Services of McAllen v. Sullivan*, 770 F. Supp. 704 (D.C. Cir. 1991) (holding that interim final rules can become effective immediately without notice and comment if made with good cause); *Petry v. Block*, 737 F.2d 1193, 1200-03 (D.C. Cir. 1984) (upholding interim final rule mandating reductions in administrative reimbursement to Child Care Food Program within 60 days after enactment of enabling legislation).

173. 537 F. Supp. 451 (E.D. Mich. 1982).

174. *Id.*

175. See sources cited *supra* note 151.

176. See notes 149-50 *supra* and accompanying text.

example, Congress recognized that the special policy-making process for making national coverage policy under the Medicare program is designed to tap medical expertise and exempted that process from procedural challenges for failure to follow legislative rulemaking procedures under the federal APA.<sup>177</sup> Congress concluded that the procedures for making national coverage determinations specifically solicited medical input and the need to preserve the scientific integrity of national coverage policy made APA procedures unnecessary.<sup>178</sup> However, the Administrative Conference of the United States opposed this approach in its recommendation on Medicare national coverage policy.<sup>179</sup>

Regarding limiting judicial challenge, Congress may want to consider limiting or even precluding judicial review of certain rules and policies although such limitations and preclusions should be used sparingly. For example, statutory pre-enforcement review can "smoke out" judicial challenges to promulgated rules and settle their validity.<sup>180</sup> Some statutes, particularly in the environmental area,<sup>181</sup> actually preclude judicial review of a rule in an enforcement proceeding because pre-enforcement review is available.<sup>182</sup> Negotiated rulemaking in which all parties with substantial interests at stake participate in negotiating the content of the rule are expressly designed to reduce subsequent judicial challenge.<sup>183</sup>

---

177. 42 U.S.C. § 1395ff(b)(3) (1988 & Supp. V 1993).

178. H.R. REP. No. 1012, 99th Cong., 2d Sess. 350-51 (1986).

179. Recommendations of the Administrative Conference of the United States, National Coverage Determinations Under the Medicare Program, Recommendation No. 87-8, 52 Fed. Reg. 49,141, 49,144 (1987). See Kinney, *National Coverage Policy Under the Medicare Program: Problems and Proposals for Change*, 32 ST. LOUIS U. L.J. 869 (1988).

180. See GUIDE TO FEDERAL AGENCY RULEMAKING, *supra* note 31, at 310-17.

181. See *id.* at 313 n.126.

182. See Paul Verkuil, *Congressional Limitations on Judicial Review of Rules*, 57 TULANE L. REV. 733 (1983). See Recommendations of the Administrative Conference of the United States, Judicial Review of Rules in Enforcement Proceedings, Recommendation No. 82-7, 47 Fed. Reg. 58,207, 58,208 (1982).

183. Negotiated Rulemaking Act of 1990, Pub. L. No. 101-648, 104 Stat. 4969 (1990), 5 U.S.C. §§ 581-90 (1988 & Supp. V 1993). See Recommendations of the Administrative Conference of the United States, Procedures for Negotiating Proposed Regulations, Recommendation No. 85-5, 50 Fed. Reg. 52,893, 52,894 (1985), Recommendation No. 82-4, 47 Fed. Reg. 30,701, 30,708 (1982). See also ADMINISTRATIVE CONFERENCE OF THE UNITED STATES, NEGOTIATED RULEMAKING SOURCEBOOK: FEDERAL AGENCY USE OF ALTERNATIVE DISPUTE RESOLUTION (1990) [hereinafter ADMINISTRATIVE CONFERENCE OF US SOURCEBOOK]; Philip Harter, *Negotiating Regulations: A Cure for the Malaise?*, 71 GEO. L.J. 1 (1982); Henry Perritt, *Administrative Alternative Dispute Resolution: The*

In some limited cases, it may be well to limit the subject matter and scope of judicial review. For example, Congress has precluded judicial review of certain elements of the payment methodologies that Medicare uses to pay hospitals and physicians because of the need to maintain the rate setting systems for these providers.<sup>184</sup> However, Congress has also established elaborate procedures for the establishment of these rates with a dialogue between specially created expert congressional commissions and HHS that permits considerable public input at the inception of the rate setting process.<sup>185</sup>

Finally, it also will be important to get rules and policy right the first time. The Supreme Court has emphatically limited the use of retroactive rules in the Medicare program.<sup>186</sup> To meet this challenge, Congress and state agencies need to give thought to the type of public input and advice they need to develop good rules and policy, and then design rulemaking procedures that accomplish these objectives. Responsible agencies should make every effort to identify the type of input such as medical expertise needed for making sound policy in designing a rulemaking process that will obtain the requisite technical input and accommodate legitimate interests. With these efforts, the agency can reduce subsequent judicial challenges that will delay implementation of the health reform legislation.

## 2. Controversial Subject Areas

There are two subject areas that will require rules under any health reform proposal and that promise to be especially controversial. The first issue is the delineation of benefits and their coverage. The second is the definition of the quality of health care services and the measures and methods by which quality will be determined. The proper delineation of policy in both fields is highly dependent on medical expertise and goes to the core of public and professional concern about the health

---

*Development of Negotiated Rulemaking and Other Processes*, 14 PEPP. L. REV. 863 (1987).

184. 42 U.S.C. § 1395ww(d)(7) (hospitals); § 1395w-4(i)(1) (physicians) (1988).

185. See Kinney, *Making Hard Choices*, *supra* note 93.

186. *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204 (1988) (holding that a rule retroactively establishing the Medicare wage schedules was invalid); *Health Ins. Ass'n of Am. v. Shalala*, 23 F.3d 412, 423 (D.C. Cir. 1994) (holding that interpretative rules may not be retroactive).

care system — the availability of all necessary health care services of high quality.

Coverage, which defines the amount, duration, and scope of benefits, as well as the medical necessity or appropriateness of services, raises difficult questions about the availability of high technology care for catastrophic illness, the continued search for more and better cures for serious illness, and even access to unorthodox medical services. Not surprisingly, coverage policy has been controversial for private health insurers and HMOs,<sup>187</sup> as well as for the Medicare and Medicaid programs.<sup>188</sup> In addition to objecting to the content of Medicare coverage policy, the medical profession and medical device manufacturers have objected to the closed procedures by which HCFA makes Medicare coverage policy.<sup>189</sup>

One of the greatest challenges for any government sponsored health reform initiative is selecting and/or promulgating the standards, criteria, and methods to be used in measuring and monitoring the quality of care provided in a reformed health care system.<sup>190</sup> Clearly, any standards, criteria, and methods must reflect a broad consensus, both within the medical profession and among consumers, as to what constitutes good quality health care. Also, the level of detail involved in this task is staggering as is the degree of technical medical expertise required to create sound policy in the quality assurance field. Further, the challenge of rule and policy making in the quality assurance and improvement area will be especially great because of the increased interest and concern of consum-

---

187. Frank P. James, *The Experimental Treatment Exclusion Clause: A Tool for Silent Rationing of Health Care?*, 12 J. LEGAL MED. 359 (1991) (discussing the controversy of surrounding the exclusion of experimental treatment from coverage); David Mechanic, *Professional Judgment and the Rationing of Medical Care*, 140 U. PA. L. REV. 1713 (1992) (discussing the inevitability of more stringent health care rationing); Julia F. Costich, Note, *Denial of Coverage for "Experimental" Medical Procedures: The Problem of De Novo Review under ERISA*, 79 KY. L.J. 801 (1990-91) (discussing the de novo standard of review for the denial of health benefits under ERISA and the use of the adversary system as a forum of decision making).

188. See Eleanor D. Kinney, *National Coverage Policy Under the Medicare Program*, *supra* note 179; see also Recommendation No. 87-8, *supra* note 179.

189. Kinney, *National Coverage Policy Under the Medicare Program*, *supra* note 179, at 904-14.

190. See Timothy S. Jost, *Health System Reform: Forward or Backward with Quality Oversight*, 271 JAMA 1508 (1994) (pointing out problems with the regulation of quality under health reform).



ers in determining quality.<sup>191</sup> Clearly, the enforcement of quality measures in the Medicare program has been a controversial undertaking.<sup>192</sup>

The current theories of coverage and quality assurance are informed by health services research on the effectiveness or "outcomes" of specific medical procedures.<sup>193</sup> In recent years, third party payers have used outcomes research on costly and widely used medical procedures to define the content of medically necessary and appropriate care through development of medical practice guidelines, clinical standards, and quality assurance measures.<sup>194</sup> The theory behind using outcomes research in this way is that cost savings can be achieved and

191. See Marc A. Rodwin, *Patient Accountability and Quality of Care: Lessons from Medical Consumerism and the Patients' Rights, Women's Health and Disability Rights Movements*, 20 AM. J. LAW & MED. 147 (1994) (emphasizing the role of consumers in defining quality health care).

192. See Alice G. Gosfield, *Value Purchasing in Medicare Law: Precursor to Health Reform*, 20 AM. J. LAW & MED. 169 (1994) (analyzing the Medicare experience in the quality assurance field); Timothy S. Jost, *Administrative Law Issues Involving the Medicare Utilization and Quality Control Peer Review Organizations (PRO) Program: Analysis and Recommendations*, 50 OHIO ST. L.J. 1 (1989). See also Recommendations of the Administrative Conference of the United States, *Peer Review and Sanctions in the Medicare Program*, Recommendation No. 89-1, 54 Fed. Reg. 28,964, 28,965 (1989).

193. See Robert H. Brook & Kathleen M. Lohr, *Efficacy, Effectiveness, Variations, and Quality: Boundary Crossing Research*, 23 MED. CARE 710, 713-14 (1985) (describing differences in medical services research outcomes); Mark Chassin, *Standards of Care in Medicine*, 25 INQUIRY 436, 437-38 (1988); David M. Eddy, *Variations in Physician Practice: The Role of Uncertainty*, HEALTH AFF., Summer 1984, at 74, 80-82 (discussing the difficulties posed by uncertainty in outcomes research); John E. Wennberg, *Commentary: On Patient Need, Equity, Supplier-Induced Demand, and the Need to Assess the Outcomes of Common Medical Procedures*, 23 MED. CARE 512, 520 (1985) (describing outcomes research by the National Center for Health Services (NCHS) and Health Care Technology Assessment (HCTA)); John E. Wennberg, *Dealing with Medical Practice Variations: A Proposal for Action*, HEALTH AFF., Summer 1984, at 6, 20-21 (discussing proposals for the improvement of outcomes research).

194. Mark Chassin, *supra* note 193, at 437-38; Eleanor D. Kinney, *Report of the Medical Guidelines Panel*, in RAND INSTITUTE FOR CIVIL JUSTICE, HEALTH CARE DELIVERY AND TORT SYSTEMS ON A COLLISION COURSE 46, 53-54 (1992) (outlining the historical development of medical practice guidelines and their implications in the medical liability system).

In 1989, Congress charged the Agency for Health Care Policy and Research to support outcomes research on outcomes of specific medical procedures and to sponsor development of medical practice guidelines based on this research. Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, § 6103, 103 Stat. 2189 (1989) (codified as amended at 42 U.S.C. § 299). HCFA has engaged in a similar initiative before establishment of AHCPR. See William L. Roper et al., *Effectiveness in Health Care: An Initiative to Evaluate and Improve Medical Practice*, 319 NEW. ENG. J. MED. 1197 (1988) (describing the federal effort in this regard).

quality improved by limiting coverage of such health care services that do not have a significant impact.<sup>195</sup>

Under most health reform proposals, an independent federal agency has broad authority to establish policy that defines and updates the national benefit package and its coverage policy.<sup>196</sup> Further, most proposals have a general standard that medical care must meet to be a covered benefit, such as "medically necessary" or "medically appropriate."<sup>197</sup> Prevailing definitions of coverage, such as "medically necessary," "experimental," and "investigational," have been interpreted extensively by both state and federal courts, and thus have specific legal meanings that may persist under the new system.<sup>198</sup>

Most health reform proposals before the 103d Congress also gave federal and state agencies important responsibilities to monitor the quality of health care that health plans and providers accorded consumers under the reformed health care system.<sup>199</sup> Some proposals even called for the creation of special agencies with quality assurance responsibilities. For example, under Senator Mitchell's compromise bill, the Secretary of HHS had responsibility for a performance-based system of quality management and improvement that included establishing a National Quality Council, with explicit rulemaking authority, to oversee a program of quality management and im-

---

195. See, e.g., David M. Eddy & John Billings, *The Quality of Medical Evidence: Implications for Quality of Care*, HEALTH AFF., Spring 1988, at 19, 29-31 (arguing in support for improvement of evidence and procedures used in outcomes research); John E. Wennberg, *Improving the Medical Decision-Making Process*, HEALTH AFF., Spring 1988, at 99, 104-05 (discussing how the NCHS and HCTA are conducting outcomes research that will provide for a higher quality and medical care and create more certainty in medical practices and guidelines). See also Arnold M. Epstein, *The Outcomes Movement — Will It Get Us Where We Want to Go?*, 323 NEW ENG. J. MED. 266 (1990) (discussing the viability of using outcomes research to develop standards of medical treatment).

196. See *supra* note 144 and accompanying text.

197. See, e.g., Health Security Act of 1993 § 1411; Health Equity and Access Reform Today Act of 1993 § 1301(b); Managed Competition Act of 1993 § 1302(b); Consumer Choice Health Security Act of 1993 § 112; Affordable Health Care Now Act § 1102; Dole Compromise Bill § 201(a); Mitchell Compromise Bill § 1213.

198. See LINDA A. BERGTHOLD & WILLIAM M. SAGE, MEDICAL NECESSITY, EXPERIMENTAL TREATMENT AND COVERAGE DECISIONS: LESSONS FROM NATIONAL HEALTH REFORM. NATIONAL INSTITUTE OF HEALTH CARE MANAGEMENT ISSUES PAPER (Oct. 1994); Mark A. Hall & Gerald F. Anderson, *Health Insurer's Assessment of Medical Necessity*, 140 U. PA. L. REV. 1637 (1992); Kinney, *National Coverage Policy Under the Medicare Program*, *supra* note 179.

199. See, e.g., Health Security Act of 1993 §§ 5001-5123; Health Equity and Access Reform Today Act of 1993 §§ 3001-3315; Managed Competition Act of 1993 §§ 501-504.

provement.<sup>200</sup> Senator Dole's compromise bill called for the establishment of the Agency for Quality Assurance and Consumer Information within HHS to supervise a quality assurance program.<sup>201</sup> Included among its duties was development of minimum guidelines for health care quality measures.<sup>202</sup>

Under health reform, several proposals call for the responsible federal agency to conduct outcomes research and develop medical practice guidelines and coverage policy based on that research.<sup>203</sup> The medical profession, health care institutions, drug device manufacturers, and patients will be vitally interested in the content of medical practice guidelines that will ultimately dictate coverage policy under the reformed system.<sup>204</sup> While notice and comment rulemaking procedures under the APA may not be necessary or even desirable to use in developing medical practice guidelines and similar policy, some thought should be accorded to designing a process for developing policy in this area in an expeditious fashion that accommodates legitimate interests. Reviewing the experience of the Medicare program in this area also would be instructive.<sup>205</sup>

### 3. Adequacy of State Rulemaking Procedures

Most health reform proposals accord states various responsibilities for implementation.<sup>206</sup> In so doing, the proposals are relying on state rulemaking procedures and other state policy making procedures — existing or invented — to provide consumer and provider input.<sup>207</sup> Are these procedures adequate, particularly in view of the need to promulgate a large volume of rules and policies in a short period of time?

Rulemaking under the Medicaid program became especially controversial in the 1980s when Congress legislated dra-

200. Mitchell Compromise Bill §§ 1401, 5001.

201. Dole Compromise Bill § 211.

202. *Id.* § 211(b)(3).

203. Health Security Act of 1993 § 5312; Managed Competition Act of 1993 § 5301; Health Equity and Access Reform Today Act of 1993 §§ 3003-3005; Health Reform Consensus Act of 1994 § 3109.

204. See AMERICAN MEDICAL ASSOCIATION, A PARTNERSHIP FOR HEALTH CARE REFORM: NEGOTIATIONS AND THE MEDICARE PROGRAM (Feb. 1993) (proposing negotiated rulemaking for Medicare coverage policy).

205. See *supra* notes 79-86 and accompanying text.

206. See *supra* note 131 and accompanying text.

207. See STATE ADMINISTRATIVE RULE MAKING, *supra* note 29, at § 64.2 (discussing the public's right to participate in the proposed rules).

matic changes in the Medicaid program that were opposed by the Republican administrations and HHS dallied in promulgating the requisite regulations to implement the legislative changes.<sup>208</sup> Congress often mandated that states implement legislative changes whether or not the federal government promulgated regulations.<sup>209</sup> This practice caused great problems for states and generated a recommendation from the Administrative Conference of the United States to restrict such practices.<sup>210</sup>

### C. Adjudicating Consumer, Provider, and Payer Disputes

Invariably, disputes will arise between responsible agencies and the individuals and organizations affected by health reform legislation.<sup>211</sup> Reviewed below are the provisions in the major health reform proposals of the 103d Congress that addressed adjudication of consumer and provider disputes, as well as the major issues to be addressed in designing an administrative appeals system.

#### 1. Consumer Disputes

Consumers will inevitably have individual disputes under any health reform legislation that will require forums for adjudication and resolution.<sup>212</sup> Most disputes will arise in the context of claims and include coverage of services, liability for provided services that are not covered benefits,<sup>213</sup> co-insurance issues, and payment issues. Important consumer disputes also

---

208. See Robert Pear, *U.S. Laws Delayed by Complex Rules and Partisanship*, N.Y. TIMES, March 31, 1991, at A1, A14 (criticizing the slowness of officials in publishing the rules implementing changes in the Medicaid program).

209. See *Federal and State Coordination: Medicaid — State Plans and Financing in Project: Federal and State Coordination: A Survey of Administrative Law Schemes*, 46 ADMIN. L. REV. 481 (1994) (detailing the extensive federal-state coordination necessitated under the Medicaid program).

210. Recommendation No. 90-8, *supra* note 47. See Kinney, *A Challenge to Federalism*, *supra* note 47, at 875-82 (summarizing the vast number of changes to the Medicaid program mandated by Congress since 1981).

211. Timothy S. Jost, *Administrative Adjudication Issues in Health Reform* in ADMINISTRATIVE LAW ISSUES IN HEALTH CARE REFORM, *supra* note 6 (not paginated).

212. See Margaret G. Farrell, *Resolving Patient Disputes under Health Reform*, J. L. & HEALTH (forthcoming 1995).

213. This issue pertains to the problem solved by the waiver of liability rules under the Medicare program in which beneficiaries are only liable to pay for services if they had reason to know that the services were not covered. See 42 U.S.C. § 1395pp (1988 & Supp. IV 1992).

will arise independently of claims and will involve not only health plans, but also providers and responsible agencies and organizations charged with regulatory responsibilities under the reformed system.

Regardless of approach, a government-sponsored health reform system necessarily must have a system of "mass justice" for adjudicating disputes the consumers have with responsible agencies that provide and/or pay for their health care services. Such a system would be comparable to the "mass justice" systems established under the Social Security Disability and other federal entitlement programs.<sup>214</sup> As such, an adjudication system for a reformed health care system raises all the issues of achieving due process with meaningful hearings at a minimal cost.<sup>215</sup> The development of the law of due process since *Mathews v. Eldridge*,<sup>216</sup> has stressed flexibility in the design of hearing procedures, and has basically concluded that oral hearings are required only when the credibility and veracity of witnesses regarding disputed adjudicative facts are at issue.<sup>217</sup> Consequently, there is great opportunity for innovation in the design of hearing procedures for a reformed health reform system.

#### a. The Bills

Most bills before the 103d Congress were not very specific about systems for resolving consumer disputes, although they included some noteworthy approaches. Specifically, the Cooper bill would have required that health plan purchasing cooperatives establish a complaint process for consumers regarding the performance of their duties<sup>218</sup> and that health plans establish "effective" procedures for hearing and resolving grievances be-

---

214. See, e.g., M. DONNA PRICE COFER, *ADMINISTERING PUBLIC ASSISTANCE: A CONSTITUTIONAL AND ADMINISTRATIVE PERSPECTIVE* (1982); JERRY L. MASHAW, *BUREAUCRATIC JUSTICE: MANAGING SOCIAL SECURITY DISABILITY CLAIMS* (1983); Kinney, *The Medicare Appeals System*, *supra* note 74.

215. See, e.g., JERRY L. MASHAW, *DUE PROCESS IN THE ADMINISTRATIVE STATE* (1984); Henry Friendly, *Some Kind of Hearing*, 123 U. PA. L. REV. 1267 (1975); Jerry L. Mashaw, *Administrative Due Process: The Quest for a Dignitary Theory*, 61 BU L. REV. 885 (1981); Lawrence Tribe, *Structural Due Process*, 10 HARV. C.R.-CL. L. REV. 269 (1975); William Van Alstyne, *supra* note 54.

216. 424 U.S. 319 (1976).

217. BERNARD SCHWARTZ, *supra* note 45, § 5.24-5.27 (1991).

218. Managed Competition Act of 1993 §§ 1107-1108.

tween the plan and enrolled individuals according to procedures of the federal oversight commission.<sup>219</sup> One bill for a single-payer system would have required that ombudsmen at the state level register consumer complaints about the operation of the state program and resolve complaints between consumers and providers.<sup>220</sup>

The Chafee bill would have required that each state program develop a binding arbitration process for the adjudication disputes over coverage and utilization of services.<sup>221</sup> Further, a health plan official who maintained that an item or service was not necessary or appropriate must have so demonstrated in the arbitration proceeding by a preponderance of available scientific evidence.<sup>222</sup> A health plan also must have maintained documentation to support its utilization and coverage decisions.<sup>223</sup>

The President's bill outlined the most detailed procedures for adjudicating disputes under health reform.<sup>224</sup> Health plans were required to have a benefit claims dispute procedure.<sup>225</sup> Claims were the event that triggered the appeal and were defined as a "claim for payment or provision of benefits" or "a request for preauthorization of items or services" submitted to a health plan.<sup>226</sup> Further review would be before a "complaint review office" in the regional alliance.<sup>227</sup> States would establish a complaint review office for each regional alliance and would select one of these offices to serve corporate alliances operating in the state.<sup>228</sup> Administrative review before the alliance complaint review office would be the exclusive means of review for plans maintained by corporate alliances.<sup>229</sup> At the alliance complaint review office level, claimants would elect whether to proceed directly to a court of competent jurisdiction without

---

219. *Id.* § 1207. See Jost, *Administrative Adjudication Issues*, *supra* note 211, at 7.

220. Health Security Act of 1993 § 405(b)(1)(I). See Jost, *Administrative Adjudication Issues*, *supra* note 211, at 7.

221. Health Equity and Access Reform Act Today §§ 1113(d), 1407. See Jost, *Administrative Adjudication Issues*, *supra* note 211, at 7.

222. Health Equity and Access Reform Act Today § 1407. See Jost, *Administrative Adjudication Issues*, *supra* note 211, at 7.

223. Health Equity and Access Reform Act Today § 1301(d)(4). See Jost, *Administrative Adjudication Issues*, *supra* note 211, at 7.

224. Health Security Act of 1993 §§ 5201-5243.

225. *Id.* § 5201.

226. *Id.* § 5201(a)(1).

227. *Id.* §§ 5202-5204.

228. *Id.* § 5202.

229. *Id.* § 5202(d).

further administrative review, ADR procedures, such as mediation, maintained by the complaint review office,<sup>230</sup> or have an oral hearing before the complaint review office. Claimants could appeal the determination of the complaint review office to a Federal Health Plan Review Board in DOL.<sup>231</sup> Judicial review of this board's decisions would have been available for amounts in controversy exceeding \$10,000.<sup>232</sup>

Senator Mitchell's compromise bill showed some development in the appeal procedures over the President's original bill. The provisions regarding preliminary appeals at the plan level were much the same as the President's bill, although with important differences.<sup>233</sup> One key difference was an expanded definition of "claim" to include the "denial, reduction or termination of any service or request for a referral or reimbursement."<sup>234</sup> Another change was a shorter time period for the health plan's first choice of a disposition of claim.<sup>235</sup> The other major change was the location of the complaint review office that hears initial appeals from a health alliance to an entity the state designated for each community-rating area.<sup>236</sup>

The Mitchell bill called for a more streamlined hearing process than the President's bill. Specifically, the Mitchell bill permitted the claimant to make three elections upon filing a complaint: (1) proceed directly to a court of competent jurisdiction without further administrative process, (2) submit to alternative dispute resolution, or (3) proceed with an administrative hearing before the complaint review office.<sup>237</sup> Regarding the first option, the Mitchell bill did not require claimants under ERISA-regulated health plans to proceed with ERISA

---

230. *Id.* §§ 5211-5215.

231. *Id.* § 5205.

232. *Id.* § 5205(e).

233. Mitchell Compromise Bill § 5501. *See* Health Security Act of 1993 (Senate version) § 5201(a).

234. Mitchell Compromise Bill § 5501. *See* Health Security Act of 1993 (Senate version) § 5201(a).

235. Mitchell Compromise Bill § 5501. *See* Health Security Act of 1993 (Senate version) § 5201(b)(1).

236. Mitchell Compromise Bill § 5502(a). *See* Health Security Act of 1993 (Senate version) § 5202(a).

237. Mitchell Compromise Bill § 5503(a).

administrative review as did the President's bill.<sup>238</sup> The second option regarding use of alternative dispute resolution was virtually the same in the bills of the President and Senator Mitchell.<sup>239</sup>

Regarding administrative review, the procedures for administrative review under option three of the Mitchell bill were the same as the President's bill except that the Mitchell bill required the hearing officer to render a decision within 120 days of the assignment of the complaint.<sup>240</sup> The Mitchell bill did not require additional administrative review before the Federal Health Plan Review Board, as did the President's bill.<sup>241</sup> Rather, the Mitchell bill would have authorized claimants to proceed directly to court to obtain appropriate relief including the provision of disputed benefits.<sup>242</sup> The Mitchell bill provided that in such enforcement proceedings, the court could not review an administrative order in favor of the complainant.<sup>243</sup>

## b. Design Issues

**PRELIMINARY GRIEVANCE PROCEDURE.** In general, health plans need some kind of grievance procedure to handle complaints of individual consumers over claims and other matters, particularly if the health plan is executing public responsibilities under health reform legislation. As stated above, many health reform proposals required such a procedure.<sup>244</sup> The grievance process should commence with a very informal meeting led by responsible plan personnel with authority to make requisite decisions in order to correct mistakes or obtain medical or other information that can resolve the dispute.<sup>245</sup> In this meeting, the plan representative should try to resolve the dispute and would advise the consumer of future steps in the appeals process. The health plan would provide the consumer with a written decision and notice of further appeal steps. It is

---

238. Mitchell Compromise Bill § 5503(a)(1). See Health Security Act of 1993 (Senate version) § 5203(a)(1).

239. Mitchell Compromise Bill §§ 5511-5515.

240. Mitchell Compromise Bill § 5504(c)(4). See Health Security Act of 1993 (Senate version) § 5204(d)(1).

241. See Health Security Act of 1993 (Senate version) § 5205.

242. Mitchell Compromise Bill § 5504(d)(2).

243. *Id.* § 5504(f)(2).

244. See *supra* notes 218-20 and accompanying text.

245. See Stayn, *supra* note 79.



noteworthy that the Medicare HMO appeals process, described above, required Medicare HMOs to have grievance procedures for final authority over such matters as disputes over choice of physicians or specialists or conflicts with HMO employees.<sup>246</sup>

### c. Subsequent Appeal Procedures

A threshold question is whether health reform legislation should specify an appeal procedure above the plan grievance procedure at all. If the legislation is silent, consumers will be able to pursue remedies in state and federal courts under the law of judicial review discussed above.<sup>247</sup>

A second threshold question is whether appeals should go through an administrative system, a form of ADR, or a court. Presumably an administrative adjudication system will have more expertise to adjudicate appeals expeditiously compared to a court. ADR endeavors to resolve disputes between parties without recourse to courts or even administrative tribunals.<sup>248</sup> As indicated above, the President's bill permitted ADR as an option for administrative review, and the Chafee bill required binding arbitration for consumer disputes with health plans over coverage and utilization of services.<sup>249</sup>

However, use of ADR is not without controversy.<sup>250</sup> An important concern about ADR methods pertains to issues involving medical expertise, such as coverage denial disputes, because of the disparate and inferior position of the consumer vis-à-vis the health plan and the potential for compromising the consumer's interest unfairly, particularly if the consumer is not represented by counsel.

Nevertheless, there is room for creativity in the design of administrative hearing procedures under health reform. Indeed, it may be desirable to give consumers the option of selecting hearing formats that are the most comfortable forum from their perspective. Suggested options include "paper" or "on-the-record" reviews, telephone hearings, or oral hearings before

---

246. See *supra* notes 74-86 and accompanying text.

247. See *supra* part II.C.

248. See STEPHEN B. GOLDBERG ET AL., *DISPUTE RESOLUTION* (2d Ed. 1992); ADMINISTRATIVE CONFERENCE OF U.S. SOURCEBOOK, *supra* note 183.

249. See *supra* notes 221-22, 230, 237 and accompanying text.

250. Harry T. Edwards, *Alternative Dispute Resolution: Panacea or Anathema?*, 99 HARV. L. REV. 668 (1986).

a senior plan representative. In any event, hearing formats should be as informal as possible to permit expeditious adjudication without counsel, although a consumer may be represented by counsel at any point.

**THE DEFINITION OF AN APPEALABLE EVENT.** A key issue for any proposal is the definition of the event that triggers the appeal. No other issue has generated greater concern from consumer groups in the debate over health reform.<sup>251</sup> The various health reform proposals do not address the issue adequately. For example, under the President's proposal, procedures for adjudicating coverage and payment disputes are activated by an appeal on a "claim."<sup>252</sup> As noted above, the Mitchell bill expanded the definition of claim to address this concern.<sup>253</sup>

A key question is whether the definition of "claim" is expansive enough to include decisions of HMOs and other pre-paid health plans to terminate or not provide requested services. In such health plans, consumers customarily do not submit claims for coverage and payment of specific services. Consequently, such consumers might be unable to challenge a provider decision to terminate or withhold services. Another mechanism, such as an initial determination concept, could be used to activate the appeals mechanism used for prepaid health plans, as is the case with Medicare HMOs.<sup>254</sup>

A crucial problem is how to identify an appealable event in the reality of medical practice that requires physicians to choose among an array of treatment modalities for many medi-

---

251. See, e.g., *Testimony before the Subcomm. on Health for Families and the Uninsured Comm. on Finance of the U.S. Senate*, 103d Cong., 2d Sess. (April 29, 1994) (statement of Alfred J. Chiplin, Jr., representing Coalition for Consumer Protection and Quality in Health Care Reform) (discussing due process rights of notice, appeal, and grievance rights as essential in any health care plan); *On Access to Justice, Discrimination and Health Care Reform: Testimony before the Health and Environment Subcomm. of the Energy and Commerce Comm. of the U.S. House of Rep.*, 103d Cong., 2d Sess. (Jan. 31, 1994) (statement of Rand E. Rosenblatt, co-chair of Society of American Law Teachers Comm. on Access to Justice in Health Care Reform) (arguing Clinton's health care reform plan does not provide an adequate system by which consumers in HMOs may be notified when a claim has been appealed); COALITION FOR CONSUMER PROTECTION AND QUALITY IN HEALTH CARE REFORM, WHITE PAPER ON CONSUMER DUE PROCESS PROTECTIONS 1-6 (1993) (examining consumer due process rights under a national health care system); THE CENTER FOR MEDICARE ADVOCACY, POSITION PAPER ON THE REMEDIES AND ENFORCEMENT PROVISIONS IN HR 3600/S 1757 (1994). See also Jost, *Administrative Adjudication Issues*, *supra* note 211, at 14.

252. See *supra* notes 225-26 and accompanying text.

253. See *supra* note 234 and accompanying text.

254. 42 C.F.R. § 417.606 (1993).

cal problems. Conceivably, every decision that a physician makes could trigger an appeal. Clearly, such eventuality would impede a frank and open physician-patient relationship required for a sound therapeutic environment. Further, would not physicians have great incentives to proscribe the most intensive services in order to limit litigation as is the concern about physicians practicing "defensively" to avoid malpractice litigation and liability? Further, how would administrative appeals over claims be distinguished from medical malpractice claims when both would be predicated on decisions of physicians?

Another crucial issue is the point at which determinations of medical appropriateness or necessity blend with clinical decision making. For example, a physician may decide that, although a service is covered, it is not medically necessary or appropriate in his/her clinical judgment for a given patient. In a capitated system, incentives exist for physicians to make clinical judgments that limit the provision of covered benefits. This issue is compounded when a health plan makes a corporate decision, presumably to be more competitive from a cost perspective, to define, as a matter of corporate policy, medical necessity for particular conditions at levels less than is customarily provided under current practice. Such policies would presumably be based on clinical practice guidelines and be accompanied by efforts to get plan subscribers to agree by contract to accept the medical practice guideline as the applicable standard of care for malpractice purposes.

CHALLENGES TO NATIONAL POLICIES, STANDARDS, AND DECISIONS. As part of challenges to claims or other issues under health plans, individual consumers may want to challenge national or state policies and standards that constitute the legal bases of adverse decisions. Most likely, coverage policies, utilization review standards, and underlying medical practice guidelines would be objects of such challenges. To the extent that these policies are state-wide, it would not be wise for adjudicators in claim disputes to be able to invalidate these policies without some opportunity to defend these policies by the responsible state or federal agency. The responsible agency should have some opportunity to defend or refine the challenged policy or standard through augmentation of the record in the claim proceeding or referral of the validity question to a more centralized tribunal with a statewide or national perspective.

It is noteworthy that Congress created an explicit bar to procedural challenges to the Medicare national coverage determinations in 1986, on grounds that current procedures of making national coverage determinations and the need to preserve the scientific integrity of national coverage policy made APA procedures unnecessary.<sup>255</sup> Congress also required courts to remand contested national coverage policies to the Secretary of HHS for amplification of the record.<sup>256</sup> Courts have generally upheld HCFA national coverage determinations, according great deference to HHS and its expert decision-making process.<sup>257</sup> However, in 1987, the Administrative Conference of the United States recommended changes regarding policy making for national coverage policy.<sup>258</sup> Blocking consumer access to adjudicating disputes, as Congress did with Medicare national coverage policy, seems less desirable than forging an adjudication mechanism that permits presentation of disputes and seeks resolution of disputes.

## 2. Provider Disputes

There are three categories of anticipated individual provider disputes under health reform — payment, coverage, and plan selection. The degree to which new arrangements for provider appeals may be necessary is dependent on how much health reform legislation changes the current way in which providers are organized and paid. A threshold issue is whether to create a separate appeals system, independent of state or federal court, for providers to bring disputes with health plans, organizations responsible for regulating the insurance market, or other parties.

---

255. See *supra* note 178 and accompanying text.

256. 42 U.S.C. § 1395ff(b)(3)(C) (1988 & Supp. IV 1992).

257. See, e.g., *Friedrich v. Secretary of HHS*, 894 F.2d 829 (6th Cir. 1990) (holding that the HHS is to create national standards to ensure uniformity and equality in the administration of Medicare); *Goodman v. Sullivan*, 891 F.2d 449 (2d Cir. 1989) (holding that the Secretary of HHS may regulate the Medicare program by enacting regulations concerning Medicare reimbursement); *Wilkins v. Sullivan*, 889 F.2d 135 (7th Cir. 1989) (deferring to the HHS Secretary's authority to interpret Medicare statutes).

258. Recommendation No. 87-8, *supra* note 179. See Kinney, *National Coverage Policy*, *supra* note 179.

### a. The Bills

Most bills before the 103d Congress did not provide for a separate appeals system for provider disputes. Presumably, bill sponsors assumed that provider disputes over payment and selection would be private, contractual matters between providers and payers that could generally be resolved in state court as they are now. However, important issues remain about provider disputes, namely the treatment of coverage and other policies that have national policy implications, as well as remedies for providers that have been excluded from regulated health plans.

The Mitchell bill, however, addressed provider appeals and explicitly provided "due process" for health care providers.<sup>259</sup> Specifically, the bill required health plans to use "publicly available standards for contracting with health care providers," as well as a "publicly available process" for dismissing providers or not renewing their contracts.<sup>260</sup> The hearing would be conducted by the provider's peers within the health plan and included, with the mutual consent of the provider and health plan, a plan enrollee.<sup>261</sup>

### b. Design Issues

WHETHER TO HAVE A SEPARATE PROVIDER APPEALS SYSTEM. A crucial threshold issue is whether even to have a separate appeals system for provider disputes over payment and other issues. Further, should such an appeals system hear disputes over non-payment issues? Specifically, providers may want to challenge coverage and other decisions and policies of health plans and payers, particularly if denied payment for services already provided and precluded from recovering payment from patients. Providers also may want to challenge an adverse health plan coverage policy or even governing medical practice guidelines prospectively on behalf of patients, particularly when organized provider groups believe that coverage policy is inconsistent with good medical practice.

An important issue is whether providers should have rights to challenge coverage policy at all, and if so, in what forum

---

259. Mitchell Compromise Bill § 5516.

260. *Id.*

261. *Id.* § 5516(c).

should such challenges be heard. It is noteworthy that under the Medicare program, providers cannot bring challenges to coverage policies on behalf of patients, except when contesting adverse waiver of liability decisions.<sup>262</sup> If providers are able to challenge coverage policy facially or in associated payment disputes, some mechanism should be available to refer coverage issues of national importance to the state and/or federal oversight or other responsible agency in order to maintain consistent policy coverage in the state or nationwide.

ADJUDICATION OF PROVIDER DISPUTES OVER SELECTION BY HEALTH PLANS. Provider disputes over health plan selection policies and practices may be more prevalent than payment disputes. Many states now have "any willing provider" laws that prohibit health insurers from excluding providers willing to meet plan contract terms from participating in any state regulated health insurance plans.<sup>263</sup> However, these statutes would probably be preempted by federal health reform legislation in order to permit health plans to contract with specific providers and achieve discounts needed in cost savings.<sup>264</sup>

Disappointed providers already have existing remedies under the federal civil rights and antitrust laws respectively, if selection policies and practices constitute proscribed discrimination or oppressive economic conduct.<sup>265</sup> Nearly all states have civil rights and antitrust laws that could govern such practices as well.<sup>266</sup> Further, case law in some states essentially es-

---

262. 42 U.S.C. § 1395ff(a)(d) (1988 & Supp. IV 1992).

263. Thomas L. Greaney, *Competitive Reform in Health Care: The Vulnerable Revolution*, 5 YALE J. REG. 179, 195-89 (1988) (discussing state "any willing provider" laws).

264. See, e.g., Health Security Act of 1993 § 1407; Health Equity and Access Reform Today Act of 1993 § 1432; Managed Competition Act of 1993 § 1222; Consumer Choice Health Security Act of 1993 § 141; Affordable Health Care Now Act of 1993 § 1203; Comprehensive Family Health Access and Savings Act § 1101; Health Reform Consensus Act § 1203; Dole Compromise Bill § 201(a); Health Security Act of 1994 § 1511; Bipartisan Health Care Reform Act § 6102.

265. See generally JULIAN O. VON KALINOWSKI, BUSINESS ORGANIZATIONS: STATE ANTITRUST AND TRADE REGULATION LAWS, chs. 16L, 16M (1994 & Supp. 1994) (discussing provider rights and remedies under state antitrust laws).

266. See generally James F. Blumstein & Frank A. Sloan, *Antitrust and Hospital Peer Review*, 51 LAW & CONTEMP. PROBS. 7 (1988) (outlining the application of antitrust law to hospital peer review decisions regarding physicians); Clifford D. Stromberg, *Health Care Provider Networks: Antitrust Issues and Practical Suggestions*, in DEVELOPMENTS IN ANTITRUST HEALTH CARE LAW 73, 84-86 (Phillip A. Droger et al. eds., A.B.A. Section of Antitrust Law, 1990) (outlining protections under federal antitrust laws for physicians in networks).

establishes due process requirements for physicians and, to a lesser extent, other health professionals, who are excluded or terminated from the medical staff of hospitals.<sup>267</sup> While these due process rights will not automatically apply to health plan decisions to exclude or terminate physicians, state courts may find this body of case law analogous to the situation physicians face under a reformed health care system.

#### D. Judicial Review

A central issue is the degree to which consumers and providers may challenge decisions and policies under health reform legislation in state and/or federal court. To many consumers and providers, judicial review is perceived as the ultimate forum for assuring accountability of government or corporate actors.<sup>268</sup> If the federal enabling legislation does not address avenues for judicial review of responsible agency action, existing law may cause undesirable consequences, such as making federal causes of action out of disputes that customarily would be handled in state court.<sup>269</sup> As outlined above,<sup>270</sup> affected parties have rights under existing law and, to varying degrees, under some health reform proposals to force the federal government and states to comply with pertinent legislative requirements as well as the constitutions of the states and federal government.

The policies and decisions of any federal oversight agencies clearly will generate opposition and judicial challenge. As indicated above, these federal oversight agencies will be making policies and decisions about a wide variety of issues that will dramatically affect the range and quality of health care services that consumers receive and the payment that the providers receive for providing these services.<sup>271</sup>

Affected parties also will have concerns about policies and decisions of states as they develop and implement state plans

---

267. BARRY R. FURROW ET AL., *THE LAW OF HEALTH CARE ORGANIZATIONS AND FINANCE* 154-55, n.2 (1991).

268. See Rosenblatt, *supra* note 6.

269. Graetz & Mashaw, *supra* note 6; Sallyanne Payton, *Federal Jurisdictional and Administrative Law Implications of National Health Care Reform* in *ADMINISTRATIVE LAW ISSUES IN HEALTH CARE REFORM*, *supra* note 6; Robert Pear, *U.S. Judges Warn of Health Lawsuits*, N.Y. TIMES, August 16, 1994, at A13; Robert Pear, *Officials Predict Deluge of Suits on Health Plan*, N.Y. TIMES, Sept. 27, 1993 at A1, A14.

270. See *supra* part II.C.

271. See *supra* notes 144-45 and accompanying text.

called for under several health reform proposals.<sup>272</sup> Likely issues to be disputed are selection of organizations to regulate the insurance market, boundaries of regulatory areas, selection of health plans, regulation of health plans, and state compliance with federal requirements generally. An analogue for disputes over state plan elements are challenges to state plans for the Medicaid program.<sup>273</sup> Because these policies and decisions involve actions by state officials arising under federal law, section 1983 may provide a cause of action to consumers to challenge the state plan.<sup>274</sup>

### 1. The Bills

Most health reform proposals before the 103d Congress did not specifically address the rights to judicial review in state and/or federal court for affected parties to challenge policies and decisions of responsible agencies under the health reform legislation. Thus, these proposals left consumers, providers, insurers, and other affected parties with the existing rights to judicial review with associated remedies under current law.<sup>275</sup>

Only the bills of President Clinton and Senator Mitchell were specific about the remedies available for consumers, providers, and other affected parties.<sup>276</sup> The President's bill contained extensive provisions providing for judicial enforcement of plan provisions in federal and state courts. Specifically, the President's proposal authorized private rights of action to enforce state responsibilities as well as private rights of action to enforce responsibilities of alliances.<sup>277</sup> The President's proposal required that facial constitutional challenges to the health reform legislation be brought within one year of enactment, and further provided for an expedited procedure for judicial review.<sup>278</sup> Finally, the President's proposal explicitly provided

---

272. See *supra* note 131 and accompanying text.

273. See Kinney, *A Challenge to Federalism*, *supra* note 47.

274. See *supra* notes 119-25 and accompanying text.

275. See *supra* part II.C.

276. Health Security Act of 1993 §§ 5231-5243; Mitchell Compromise Bill §§ 5531-5543.

277. Health Reform Act of 1993 §§ 5235, 5237. The bill also accorded private rights of action to enforce federal responsibilities regarding operating the health reform in a non-participating state. *Id.* § 5236.

278. *Id.* § 5241.



that existing judicial rights and remedies under current law were not preempted.<sup>279</sup>

However, the President's proposal provided only states and alliances, but not consumers or providers, with a cause of action to review federal action and thus insulated such matters as national benefits and coverage policy from judicial review.<sup>280</sup> Further, the bill expressly precluded judicial review of any determination of the National Health Board regarding cost containment policy.<sup>281</sup> These limitations, combined with the widespread use of interim final rules to implement elements of the reformed system, could have compromised the legitimate interests of consumers and providers in influencing the rules and policies that would have affected them greatly under the health reform legislation.

The enforcement provisions of the Mitchell bill were quite similar to the President's.<sup>282</sup> Like the President's bill, the Mitchell bill accorded consumers broad rights to bring actions against state officials explicitly under section 1983 and without regard to exhaustion of available administrative remedies.<sup>283</sup> Further, like the President's bill, the Mitchell bill expressly preserved existing rights and remedies, and included some interesting provisions.<sup>284</sup> Specifically, the Mitchell bill provided explicitly for enforcement of consumer protections established in other parts of the bill.<sup>285</sup> It also expanded the remedies against health plans available to essential community providers as compared to the President's bill.<sup>286</sup>

## 2. Design Issues

The major issue regarding the range of judicial remedies accorded affected parties in designing health reform legislation is to determine the degree to which judicial remedies, particularly in federal court, are desirable given the need for expeditious implementation of health reforms. Further, to what extent

---

279. *Id.* § 5243.

280. *Id.* § 5231.

281. *Id.* § 5232.

282. Mitchell Compromise Bill § 5531-5543. *See* Health Security Act of 1993 §§ 5231-5243.

283. Mitchell Compromise Bill § 5534. *See* Health Security Act of 1993 § 5235.

284. Mitchell Compromise Bill § 5543. *See* Health Security Act of 1993 § 5243.

285. Mitchell Compromise Bill § 5536.

286. *Id.* § 5539. *See* Health Security Act of 1993 § 5240.

are state and particularly federal judicial remedies desirable, given the need of the state and federal governments, insurance purchasing cooperatives, and health plans to implement the health reforms? On the other hand, preclusion of judicial remedies cuts off important consumer rights, particularly to those who are poor and often not well-represented in the political process.<sup>287</sup>

A crucial question regarding suits against insurance purchasing cooperatives and health plans is whether they are public or private bodies subject to suit in federal court. If their actions are deemed to be state action for purposes of procedural due process and section 1983, then challengers have procedural due process rights that may enable them to bring challenges in federal court under section 1983. If health insurance purchasing cooperatives and health plans are not state actors, then challengers are left with causes of action in state court under tort, contract and other state laws.

As many decisions and policies of responsible agencies will be legislative in nature, challengers will not have due process rights to hearings as they would with respect to adjudicative decisions.<sup>288</sup> However, to the extent that legislative-type decisions and policies are involved, the federal enabling legislation should require states to provide legislative-type hearings at which consumers and their advocates may express their views about the content of policies and decisions that are ultimately adopted in the state plan.

For disputes that concern policies and decisions of a more legislative nature, the federal enabling legislation can provide mandated input from all interested constituencies into the policy-making and decision-making processes. Such procedures could involve public hearings and ombudsman offices. An innovative approach is negotiated rulemaking, which brings all parties to the table in a rulemaking procedure and involves their contribution in a structured process before publication of the proposed rule.<sup>289</sup>

---

287. See Rosenblatt, *supra* note 6.

288. See *supra* note 21 and accompanying text.

289. See *supra* note 183 and accompanying text.

#### IV. CONCLUSION

In sum, there are various procedural options that can be employed to protect the rights of consumer and providers under any health reform legislation, regardless of its approach or ideological focus. For example, it is crucial to consider all the interrelationships among all procedural arrangements for rule and policy making, disputes adjudication, and judicial review in the health reform proposals, because the appropriateness of a particular procedures may well depend on whether procedural arrangements in other areas ameliorate what might be a harsh provision from the perspective of consumers, providers, or other affected parties. For example, a preclusion of judicial review of a particular policy may be much more palatable if ample opportunity is accorded to affected parties in the development of the policy. On the other hand, rules and policies made in expedited procedures that short circuit public input ought to be subject to subsequent challenge through administrative or judicial review.

Finally, when it comes to the resolution of disputes, it is crucial to look at the type of factual and legal issues involved in the dispute in selecting the dispute resolution methodologies. Disputes over policy should be confined to the rule and policy-making processes and kept out of courts when possible, given the limited scope of review of policy, particularly at the federal level, existing under current law.<sup>290</sup> Consumer disputes over claims should be resolved through expeditious procedures that emphasize immediate and satisfactory resolution as offered by some ADR techniques. Further, all dispute resolution and policy-making processes must have adequate mechanisms for ensuring access to accurate, unbiased, and timely input from medical experts, other experts, and consumers.

Perhaps most importantly, the specific features of the procedure are less important than whether the options preserve the core value of providing consumers and providers avenues to influence policies that affect them generally and challenge decisions that affect them individually without compromising the integrity of the health reform system or its expeditious implementation.

---

290. See *supra* notes 31-40 and accompanying text.