

# ARTICLES

## NATIONAL COVERAGE POLICY UNDER THE MEDICARE PROGRAM: PROBLEMS AND PROPOSALS FOR CHANGE

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## I. INTRODUCTION

The Medicare program, a federal entitlement program providing health insurance for the aged, disabled and certain individuals with end-stage renal disease,<sup>1</sup> serves more than 30 million Americans and is the sole source of health insurance for most of these individuals.<sup>2</sup> The program has two components: (1) Part A hospital insurance, which pays for hospital and related services including skilled nursing and home health care;<sup>3</sup> and (2) Part B supplementary medical insurance, which pays for physician and other services provided chiefly on an out-patient basis.<sup>4</sup> In July 1988, Congress and the President enacted the Medicare Catastrophic Coverage Act of 1988 expanding Medicare benefits to include some new services for the treatment of catastrophic illness.<sup>5</sup> The Health Care Financing Administration (HCFA) within the Department of Health and Human Services (HHS) administers the Medicare program.<sup>6</sup>

The policies and procedures by which the Medicare program makes decisions about whether to cover certain items and procedures used in the medical care of beneficiaries under the Medicare program have become controversial in recent years. On April 29, 1987, pursuant to the settlement of a lawsuit,<sup>7</sup> HCFA issued a notice in the *Fed-*

1. All individuals who are eligible for Social Security, old age and disability insurance programs are eligible for Medicare. Social Security Act, 42 U.S.C. §§ 1395c, 1395o (1982 & Supp. III 1985). Eligibility for these programs is also extended to nearly all elderly individuals not covered under the Social Security program and certain other individuals with end-stage renal disease. 42 U.S.C. §§ 1395c, 1395i, & 1395o (1982 & Supp. III 1985). Enrollment in both Part A and Part B of the Medicare program is voluntary. 42 U.S.C. § 1395b (1982 & Supp. III 1985). There is no cost to enroll in Part A of the Medicare program, which is financed by the Social Security Wage Tax. 42 U.S.C. § 1395i (1982 & Supp. III 1985). To enroll in Part B, however, the eligible individual must pay monthly premiums. 42 U.S.C. §§ 1395c, 1395r, 1395s (1982 & Supp. III 1985).

2. Waldo, Levit & Lazenby, *National Health Expenditures, 1985*, 8 HEALTH CARE FIN. REV. 5 (Fall 1986).

3. 42 U.S.C. §§ 1395c-1395i (1982 & Supp. III 1985).

4. 42 U.S.C. §§ 1395j-1395w (1982 & Supp. III 1985).

5. The Medicare Catastrophic Coverage Act of 1988, Pub. L. No. 100-360; \_\_\_\_\_ Stat. \_\_\_\_\_ (1988) (to be codified at 42 U.S.C. §§ 1395).

6. The Department of Health and Human Services was created in 1980 out of the former Department of Health, Education and Welfare (HEW). Remarks at the Signing of the Bill Creating the Department of Health and Human Resources, 1 PUB. PAPERS 908 (May 14, 1980). HCFA was created in 1977 when President Carter consolidated the Medicare program from the Social Security Administration with the Medicaid program from the Public Health Service. Dep't of Health, Educ. & Welfare Reorganization Order, 42 Fed. Reg. 13,262 (1977).

7. *James v. Bowen*, [1985 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 34,534 (E.D. Cal. Feb. 15, 1988), *motion to dismiss denied* [1987-1 Transfer binder] Medicare & Medicaid Guide (CCH) ¶ 36,033 (E.D. Cal. Feb. 20, 1987) (Settlement Agreement and Release of claims).

*eral Register* publishing for the first time its procedures for making national coverage determinations pertaining to medical technologies and procedures.<sup>8</sup> In this notice, HCFA stated its intention to promulgate a rule establishing procedures and criteria for making such national coverage determinations.

The Administrative Conference of the United States has been concerned about the Medicare appeals system generally and in 1986 conducted a study and made recommendations on Medicare appeals.<sup>9</sup> The most controversial issues that emerged in that study were the problems with the process for making all types of coverage policy, including national coverage determinations regarding medical technologies and procedures. Regarding this particular process, the Conference urged HHS to reform its procedures for making national coverage decisions and introduce "more openness and regularity" into the process.<sup>10</sup> In 1987, out of concern that the national coverage policymaking process continues to need reform, the Conference commissioned this study of procedures by which HHS makes national coverage policy as well as the opportunities for administrative and judicial review of national coverage policy. The Administrative Conference has recently published a proposed recommendation for reforms in the national coverage policymaking process in the *Federal Register*.<sup>11</sup>

This study analyzes the process for making national coverage policy under the Medicare program from an administrative and constitutional law perspective and proposes recommendations for changes. Specifically, it addresses issues in two general areas: (1) promulgation and publication of national coverage policy, and (2) administrative and judicial review of national coverage policy. Regarding the first area, the study will address promulgation and publication of the procedures and criteria for making national coverage policy as well as specific national coverage policies. Regarding the second area, the study will look chiefly at issues posed by the Supreme Court's recent decision in *Bowen v. Michigan Academy of Family Physicians*<sup>12</sup> and by the Omnibus Budget Reconciliation Act of 1986, which expanded opportunities for

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8. Health Care Fin., Medicare Program, Procedures for Medical Services Coverage Decisions; Request for Comments, 52 Fed. Reg. 15,560 (Apr. 29, 1987) [hereinafter HCFA Notice].

9. Admin. Conference of U.S., Recommendation 86-5, Medicare Appeals, 1 C.F.R. §§ 305.86-5 (1987) [hereinafter Recommendation 86-5]; see also Kinney, *The Medicare Appeals System for Coverage and Payment Disputes: Achieving Fairness in a Time of Constraint*, 1 ADMIN. L.J. 1 (1987).

10. Recommendation 86-5, *supra* note 9.

11. The Report supported Conference Recommendation 87-8, National Coverage Determinations, 1 C.F.R. §§ 305.87-8 (1987); see Admin. Conference of the U.S., 52 Fed. Reg. 38,925 (1987) (Draft recommendation for Medicare's national coverage determinations); see also APPENDIX.

12. 476 U.S. 667 (1986); see *infra* notes 266-99 and accompanying text.

administrative and judicial review of coverage disputes but imposed significant restrictions as well.<sup>13</sup>

## II. BACKGROUND

### A. *The Current Medicare Coverage Policymaking Process*

#### 1. Statutory and Regulatory Definitions of Coverage

Coverage<sup>14</sup> is a concept that defines the amount and type of health care services for which the Medicare program will pay and determines the conditions upon which the Medicare program will pay for the services. The Medicare statute defines the scope of benefits broadly and defines in general terms the benefits for which the Medicare program will pay.<sup>15</sup> Specifically, Social Security Act § 1862(a)(1)(A) provides that the Medicare program will pay for health care services, not expressly excluded from coverage by statute, that are "reasonable and necessary" for the "diagnosis and treatment of disease or injury or to improve the functioning of a malformed body member."<sup>16</sup>

The basic statutory provision regarding coverage has remained unchanged since 1965.<sup>17</sup> Congress did not elaborate on this statutory lan-

13. Pub. L. No. 99-509, § 9341, 100 Stat. 2037 (1986) (to be codified at 42 U.S.C. § 1395); see *infra* notes 117-26 and accompanying text.

14. In a general insurance context, coverage is defined as the "amount and extent of risk covered by [an] insurer." BLACK'S LAW DICTIONARY 192 (abridged 5th ed. 1983).

15. 42 U.S.C. § 1395d (1982 & Supp. III 1985) (Part A); 42 U.S.C. § 1395k (1982 & Supp. III 1985) (Part B); see also 42 U.S.C. § 1395v (1982 & Supp. III 1985).

16. 42 U.S.C. § 1395y(a)(1)(A) (1982 & Supp. III 1985).

17. 42 U.S.C. § 1395y(a)(1)(A) (1982 & Supp. III 1985); see Hogan & Hartson, *Memorandum to Lewin & Associates, Inc. Re.: The Medicare Technology Assessment and Coverage Process*, reprinted in 2 LEWIN & ASSOCIATES, INC., A FORWARD PLAN FOR MEDICARE COVERAGE AND TECHNOLOGY ASSESSMENT 12-20 (1987) [hereinafter Hogan & Hartson].

Since 1965 Congress has extensively amended § 1395y which outlines coverage exclusions, but has never further defined the terms "reasonable and necessary." Most of the amendments to § 1395y pertain to coverage or exclusion of specific items, or impose coverage conditions on specific items. Some of the most important amendments include: exclusion of podiatry and optometry services (Social Security Amendments of 1967 (codified as amended at 42 U.S.C. §§ 1395y(a)(7), 1395y(a)(13) (1982 & Supp. III 1985)); exclusion of dental services (Omnibus Reconciliation Act of 1980 (codified as amended at 42 U.S.C. § 1395y(a)(12) (1982 & Supp. III 1985)); and exclusion of hospice services (Tax Equity and Fiscal Responsibility Act of 1982 (codified as amended at 42 U.S.C. § 1395y(a)(1)(C) (1982 & Supp. III 1985)). Also, in 1981, Congress required mandated coverage review of paid claims for home health services to monitor compliance with medical necessity requirements, and directed HHS to develop "utilization guidelines" for home health services as a means of containing escalating costs in home health service. Omnibus Budget Reconciliation Act of 1981 (codified as amended at 42 U.S.C. § 1395y(f) (1982)).

guage in the legislative history.<sup>18</sup> Rather, the Senate and House Committee reports only give examples of reasonable and necessary services:

For example, the bill would bar payment for health items or services that are not reasonable and necessary for the treatment of illness or injury or to improve the functioning of a malformed body member. Thus, payment could be made for the rental of a special hospital bed to be used by the patient in his home only if it was a reasonable and necessary part of a sick person's treatment. Similarly, such potential personal comfort items and services as massages and health lamp treatments would only be covered where they contribute meaningfully to the treatment of an illness or injury or the functioning of a malformed body member.<sup>19</sup>

Some statements in the legislative history regarding hospital benefits under Part A, however, clearly indicate that Congress contemplated covering and paying for new technologies and had drafted the statute broadly enough to assure such coverage in future years:

The reasonable cost of service ordinarily provided to inpatients by hospitals . . . , including new services and techniques as they are adopted in the future, would be paid for.<sup>20</sup>

HHS never promulgated regulations elaborating further the statutory coverage criteria of "reasonable and necessary" in section 1862(a)(1)(A). Rather, the applicable regulations<sup>21</sup> simply restate the statutory language.<sup>22</sup> However, HCFA has defined the term "reasonable and necessary" in the context of delineating when various types of Medicare benefits would be covered.

Regarding new or questionable medical technologies and procedures, the Social Security Administration, the predecessor to HCFA, did interpret these terms in a 1977 program instruction to fiscal intermediaries and carriers, stating that the Medicare program did not,

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18. See S. REP. NO. 404, 89th Cong., 1st Sess. 27 (1965), *reprinted in* 1965 U.S. CODE CONG. & ADMIN. NEWS 1943; H.R. REP. NO. 213, 89th Cong., 1st Sess. 41 (1965).

19. S. REP. NO. 404, 89th Cong., 1st Sess. 48 (1965), *reprinted in* 1965 U.S. CODE CONG. & ADMIN. NEWS 1943, 1989; *see also* H.R. REP. NO. 213, 89th Cong., 1st Sess. 41 (1965) (containing an identical provision).

20. S. REP. NO. 404, 89th Cong., 1st Sess. 27 (1965), *reprinted in* U.S. CODE CONG. & ADMIN. NEWS 1943, 1967-68; *see also* H.R. REP. NO. 213, 89th Cong., 1st Sess. 24 (1965) (containing a nearly identical provision).

21. 42 C.F.R. § 405.310(k)-(m) (1986).

22. In 1980, HCFA circulated a proposed rule within HHS establishing procedures for making national coverage policy, but HHS never published this proposed rule in the *Federal Register*. Mehlman, *Health Care Cost Containment and Medical Technology: A Critique of Waste Theory*, 36 CASE W. RES. 778, 863 n. 344 (1986); *see also* Memorandum from Howard Newman, Administrator of HCFA, to the Secretary of HHS (Sept. 24, 1980) (proposed rule for criteria and procedures for medical services coverage decisions under Medicare).

as a matter of policy, pay for a medical item or service considered to be "experimental or investigational" since they "have not generally been accepted by the professional medical community as effective and proven treatments for the conditions for which they are being used in particular cases."<sup>23</sup> More recently, HCFA stated that it interprets the phrase "reasonable and necessary" to mean that an item or procedure is safe and efficacious as well as widely accepted by the medical profession.<sup>24</sup>

HCFA has also defined the statutory terms of "reasonable and necessary" for other types of services and in other contexts. One example of such a definition of this statutory language is the manual provision defining coverage of physical therapy services provided as part of home health benefits. The MEDICARE HOME HEALTH MANUAL and the MEDICARE INTERMEDIARY MANUAL state that physical therapy services provided on a home basis are not "reasonable and necessary" unless the therapy can be expected to lead to significant improvement in the patient's condition.<sup>25</sup>

## 2. The Different Types of Medicare Coverage Policy

It is important to appreciate that there are different types of Medicare coverage policy. Specifically, there are three categories of coverage policy: (1) coverage policy of Medicare contractors; (2) national coverage determinations for medical technologies and procedures; and (3) national coverage policies that define the scope of specific Medicare benefits services and the conditions under which Medicare will pay for these benefits.

Most Medicare coverage policy is made by Medicare contractors, namely, fiscal intermediaries, carriers and peer review organizations, which process claims for the Medicare program and perform other

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23. Part A Intermediary Letter No. 77-4 and Part B Intermediary Letter, No. 77-5 (Jan. 1977), *reprinted in* [1976-77 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 28,152; *see also* Hogan & Hartson, *supra* note 17, at 16 (discussing a federal court decision denying Medicare coverage for the use of hyperbaric oxygen therapy in the treatment of senility because the procedure was experimental).

24. HCFA Notice, 52 Fed. Reg. 15,560, 15, 561-63 (1987) (requesting comments to proposed procedure for making coverage decisions). HCFA has defined "reasonable and necessary," albeit in other contexts. For example, the MEDICARE HOME HEALTH AGENCY MANUAL and the MEDICARE INTERMEDIARY MANUAL state that physical therapy services provided at one's home are not reasonable and necessary unless the therapy can be expected to lead to a significant improvement in the patient's condition. HEALTH CARE FIN. ADMIN., MEDICARE HOME HEALTH AGENCY MANUAL §§ 205.1(b)-(c) (1987); HEALTH CARE FIN. ADMIN., MEDICARE INTERMEDIARY MANUAL § 3118.1(b) (1987).

25. HEALTH CARE FIN. ADMIN., MEDICARE HOME HEALTH MANUAL § 205.1(b)-(c) (1987); HEALTH CARE FIN. ADMIN., MEDICARE INTERMEDIARY MANUAL § 3118.1(b)-(c) (1987).



functions described in greater detail below. But in certain cases, HCFA makes and publishes coverage policy on questions of national concern. According to the April 29th Notice, any policy affecting coverage that HCFA publishes in the MEDICARE COVERAGE ISSUES MANUAL,<sup>26</sup> HCFA rulings or other HCFA manuals<sup>27</sup> constitutes a national coverage determination.<sup>28</sup>

a. *Coverage Policy of Medicare Contractors*

Medicare contractors handle several hundred million claims annually of which a small proportion raise coverage questions.<sup>29</sup> In most cases, the coverage question involves a determination of whether an item or service was medically necessary for the individual or was furnished in an appropriate manner or setting.<sup>30</sup> In these cases, the Medicare contractor makes the coverage decision and follows any applicable national coverage policies.<sup>31</sup> In the case of hospital services, the fiscal intermediary or carrier is also bound by any decision of the PRO regarding medical necessity of an item or service.<sup>32</sup> If there is no applicable national coverage policy, Medicare contractors have considerable latitude in making coverage policies that apply to the Medicare claims within their jurisdiction even on questions involving new technologies.<sup>33</sup>

Medicare contractors, with HCFA's encouragement and, in the case of home health benefits, by statutory mandate,<sup>34</sup> often use computerized "screens" to identify claims for more conventional services in which the items or services provided exceed preset norms regarding duration, frequency or intensity of the utilization of such services.<sup>35</sup> These

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26. HEALTH CARE FIN. ADMIN., MEDICARE COVERAGE ISSUES MANUAL (1987), reprinted in 4 Medicare & Medicaid Guide (CCH) ¶¶ 27,201-27,221.

27. See *infra* notes 77-79 and accompanying text.

28. HCFA Notice, 52 Fed. Reg. 15,560, 15,561 (1987).

29. *Id.*

30. *Id.*

31. *Id.*

32. *Id.*

33. See DEMLO, HAMMONS, KUDER, RODGERS & LYNCH, DECISION-MAKING BY MEDICARE CONTRACTORS FOR COVERAGE OF MEDICARE TECHNOLOGIES, reprinted in OFFICE OF TECHNOLOGY ASSESSMENT, MEDICAL TECHNOLOGY AND THE COSTS OF THE MEDICARE PROGRAM, 196-97 (1982) [hereinafter DEMLO, HAMMONS]; LEWIN & ASSOCIATES, A FORWARD PLAN FOR MEDICARE COVERAGE AND TECHNOLOGY ASSESSMENT (1987); e.g., KNOX, *Heart Transplants: To Pay or Not to Pay*, 209 SCIENCE 570, 571 (1980) (illustrates the latitude given contractors in heart transplant coverage determinations). See generally MACRO SYSTEMS, INC., TECHNOLOGY ASSESSMENT AND COVERAGE DECISION-MAKING IN THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (1984).

34. 42 U.S.C. § 1395y(f) (1982).

35. See GOVERNMENT ACCOUNTING OFFICE, IMPROVING MEDICARE AND MEDICAID SYSTEMS TO CONTROL PAYMENTS FOR UNNECESSARY PHYSICIANS' SERVICES, H.R. DOC. NO. 16, 83d Cong., Sess. 16 (1983). See generally *Medicare Appeals Provisions:*

screens are adopted for a wide variety of benefits, primarily for physicians and suppliers services under Part B and home health and skilled nursing services under Part A. Little is known about how Medicare contractors use these screens, although in some cases it appears that Medicare contractors automatically deny claims for items or services exceeding the screens.<sup>36</sup>

b. *National Coverage Determinations for Medical Technologies and Procedures*

Since the inception of the Medicare program, HCFA and its predecessor, the Social Security Administration, have made approximately 200 national coverage determinations regarding medical technologies and procedures, although the number has been increasing in recent years.<sup>37</sup> These national coverage determinations are published in the MEDICARE COVERAGE ISSUES MANUAL<sup>38</sup> and sometimes as HCFA rulings or notices in the *Federal Register*. The MEDICARE COVERAGE ISSUES MANUAL also includes the "Screening List for Durable Medical Equipment" specifying various items of medical equipment that are covered or excluded under the Medicare program, and recently a list of covered ambulatory surgical procedures.<sup>39</sup>

c. *Other Types of National Coverage Policy*

Other types of national coverage policy define the scope of specific Medicare benefits, such as home health or skilled nursing home services, and the conditions under which the Medicare program will pay

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*Hearings Before the Senate Comm. on Finance*, 99th Cong., 1st Sess. 16 (1985) [hereinafter *Hearings on Medicare Appeals Provisions*]; *Issues Related to Medicare Contracting: Hearings Before the Subcomm. on Health of the House Comm. on Ways and Means*, 99th Cong., 2d Sess. 29 (1986).

36. See *Hearings on Medicare Appeal Provisions*, *supra* note 35.

37. LEWIN & ASSOCIATES, *supra* note 33, at 3.6.

38. See HEALTH CARE FIN. ADMIN., MEDICARE COVERAGE ISSUES MANUAL (1987), reprinted in 4 Medicare & Medicaid Guide (CCH) ¶ 27,201. The MANUAL also includes the "Screening List for Durable Medical Equipment," which specifies various items of medical equipment that are covered or excluded by Medicare.

Recently, the *Federal Register* printed a list of covered ambulatory surgical procedures. 52 Fed. Reg. 13,176 (1987) (List of Covered Surgical Procedures for Ambulatory Surgical Centers under Medicare), corrected, 52 Fed. Reg. 17,678 (1987), reprinted in 4 Medicare & Medicaid Guide (CCH) ¶ 27,211; see also HEALTH CARE FIN. ADMIN., MEDICARE CARRIERS MANUAL § 2100.1 (1987) (outlining criteria for coverage of durable medical equipment).

39. HEALTH CARE FIN. ADMIN., MEDICARE CARRIERS MANUAL § 22001. (1987) (outlining criteria for coverage of durable medical equipment); Health Care Fin. Admin., Medicare Program, Final Notice, List of Covered Surgical Procedures for Ambulatory Surgical Centers, 52 Fed. Reg. 13,176 (1987), corrected, 52 Fed. Reg. 17,678 (1987).

for these benefits. These national coverage policies are contained in HCFA manuals other than *Medicare Coverage Issues Manual* and are often not specifically identified as coverage policies.<sup>40</sup> Indeed, as has been demonstrated in the cases challenging Medicare coverage policy,<sup>41</sup> there are provisions in nearly all Medicare program manuals that influence the coverage of Medicare benefits.<sup>42</sup> One example of such coverage policies is the criteria for making coverage decisions regarding durable medical equipment contained in the *Medicare Carriers Manual*.<sup>43</sup> Specifically, covered durable medical equipment is "primarily and customarily used to serve a medical purpose" and "generally is not useful to a person in the absence of an illness or injury."<sup>44</sup>

It should be pointed out that, in the April 29th Notice, HCFA has defined national coverage determinations as including any coverage policy contained in "other HCFA manuals."<sup>45</sup> Thus, arguably, HCFA intends to have the coverage policymaking process described in the April 29th Notice apply to all coverage policy in addition to that concerning medical technologies and procedures. Further, this expansive definition suggests that HCFA intends that such coverage policy would be subject to the provisions limiting administrative and judicial review of national coverage determinations in the Omnibus Budget Reconciliation Act of 1986 discussed below.<sup>46</sup> HCFA has indicated its intention to interpret these provisions in this fashion in a recent court case.

### 3. Procedures for Making National Coverage Policy

#### *National Coverage Determinations for Medical Technologies and Procedures*

The current procedures for making national coverage determinations for medical technologies and procedures are relatively straightfor-

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40. See, e.g., HEALTH CARE FIN. ADMIN., MEDICARE CARRIERS MANUAL Ch. II (1987) (containing over 100 pages of program instructions defining coverage and limitations for a wide variety of outpatient medical services); HEALTH CARE FIN. ADMIN., MEDICARE INTERMEDIARY MANUAL Ch. II (1987) (containing over 100 pages of program instructions defining coverage and limitations for inpatient hospital, home health, skilled nursing home and hospice services). Other health insurance manuals contain similar coverage provisions.

41. See *infra* notes 266-99 & accompanying text.

42. See *infra* note 77-78 & accompanying text.

43. HEALTH CARE FIN. ADMIN., MEDICARE CARRIERS MANUAL § 2100.1 (1987). The Social Security Act includes as durable medical equipment wheelchairs, hospital beds and similar devices of a permanent nature used in the patient's home. 42 U.S.C. § 1395x(n) (1982 & Supp. III 1985).

44. HEALTH CARE FIN. ADMIN., MEDICARE CARRIERS MANUAL §§ 2100.1(C), 2100.1 (D) (1987).

45. HCFA Notice, 52 Fed. Reg. 15,561 (1987).

46. See *infra* notes 118-26 & accompanying text.

ward and have been described in the April 29th Notice.<sup>47</sup> The process for making these national coverage determinations is driven almost exclusively by the claims review process and thus is primarily reactive.<sup>48</sup> If a Medicare contractor has a question about whether a new procedure or technology should be covered, it may refer the question to the HCFA regional or national office.<sup>49</sup> In some cases, the HCFA regional office or national office may make an informal judgment which is then applied by the Medicare contractor.<sup>50</sup> In other cases, HCFA may decide to make a national coverage determination that applies in all future similar cases nationwide.<sup>51</sup>

The Special Coverage Issues Branch of the Division of Coverage Policy within the Bureau of Eligibility, Reimbursement and Coverage (BERC) in HCFA is responsible for making national coverage determinations regarding medical technologies and procedures and durable medical equipment. In most cases, BERC will simply make the national coverage determination if BERC staff feel that no significant medical question is involved and if the question is whether it is otherwise appropriate or authorized by statute to cover a questionable item or procedure.<sup>52</sup>

If BERC believes that a medical question is presented, then the question is referred to the HCFA Physicians Panel. This panel is an informal group comprised chiefly of physicians who work for HCFA. It was formed in 1980 to handle coverage questions of a medical nature "in-house" so that HCFA would not have to seek outside medical consultation from the Public Health Services (PHS) or other sources.<sup>53</sup> The Director of the PHS Office of Health Technology Assessment sits on this panel. The panel meets about once every six weeks, in private and without a published agenda, to make coverage policy.<sup>54</sup> HCFA estimates that the panel considers between 20 to 30 national coverage questions annually.<sup>55</sup> The panel makes a recommendation to BERC re-

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47. HCFA Notice, 52 Fed. Reg. 15,560, 15,561 (1987); *see also* LEWIN & ASSOCIATES, *supra* note 33; MACRO SYSTEMS, *supra* note 33; DEMLO, HAMMONS, *supra* note 33.

48. *See* LEWIN & ASSOCIATES, *supra* note 33; MACRO SYSTEMS, *supra* note 33; DEMLO, HAMMONS, *supra* note 33.

49. HCFA Notice, 52 Fed. Reg. 15,561 (1987); *see also* LEWIN & ASSOCIATES *supra* note 33; MARCO SYSTEMS, INC., *supra* note 33; Demlo, Hammond, Kuder, Roberts & Lynch, *supra* note 33.

50. *See supra* notes 33-34 and accompanying text.

51. HCFA Notice, 52 Fed. Reg. 15,560, 15,561 (1987).

52. *See* LEWIN & ASSOCIATES, *supra* note 33, at 3.8.

53. *Id.* at 3.8.

54. Telephone interview with Barton McCann, M.D., Chief, Special Coverage Issues Branch, Office of Coverage Policy, Bureau of Eligibility, Reimbursement and Coverage, Health Care Fin. Admin. (May 3, 1987) [hereinafter McCann interview].

55. HCFA Notice, 52 Fed. Reg. 15,560 (1987).

garding coverage of the disputed item or service or whether to refer the coverage question to PHS for further medical evaluation.

Office of Health Technology Assessment (OHTA) coordinates the statutorily-mandated assistance of PHS to HCFA in making coverage policy.<sup>56</sup> The specific mandate of OHTA is to propose recommendations regarding whether specific technologies should be paid for by federal health insurance programs.<sup>57</sup> The criteria by which OHTA must assess a particular technology are broader than those used by HCFA,<sup>58</sup> and include the "safety, efficacy, and effectiveness" of the technology and, "as appropriate, the cost-effectiveness and the appropriate uses of the technology."<sup>59</sup> HCFA rarely asks OHTA to analyze the cost-effectiveness of new medical technology.<sup>60</sup>

The authorizing legislation for OHTA requires that it consult with the National Institutes of Health (NIH), the Food and Drug Administration (FDA) and other federal agencies in its assessment of a particular technology.<sup>61</sup> The most important federal technology assessment activities are the FDA's medical device approval procedures<sup>62</sup> and the NIH Consensus Conferences on medical treatment modalities.<sup>63</sup> If the NIH has already considered an item or procedure at issue in a coverage question, OHTA generally adopts the NIH position.<sup>64</sup> OHTA is

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56. The Public Health Service Act, 42 U.S.C. § 242c(e) (1982 & Supp. III 1985) provides:

(e)(1) The Center shall advise the Secretary respecting health care technology issues and make recommendations with respect to whether specific health care technologies should be reimbursable under federally financed health programs.

(2) In making recommendations respecting health care technologies, the Center shall consider the safety, efficacy, and effectiveness, and, as appropriate, the cost-effectiveness and appropriate uses of the technology.

(3) In carrying out its responsibilities under this section respecting health care technologies, the Center shall cooperate and consult with the National Institutes of Health, the Food and Drug Administration, and any other interested Federal departments or agencies.

57. *Id.*; see also DEP'T OF HEALTH & HUMAN SERVS., PUB. HEALTH SERVS., NAT'L CENTER FOR HEALTH SERVS. RESEARCH, PUBLIC HEALTH SERVICE PROCEDURES FOR EVALUATING HEALTH CARE TECHNOLOGIES FOR PURPOSES OF MEDICARE COVERAGE (Jul. 1983).

58. See 42 U.S.C. § 1395y(a)(1)(A) (1982 & Supp. III 1985) (providing that "no payment shall be made for items and services . . . which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to impair the function of a malformed body member").

59. 42 U.S.C. § 242c(e)(2) (1982 & Supp. III 1985).

60. LEWIN & ASSOCIATES, *supra* note 33, at 3.9.

61. 42 U.S.C. § 242c(e)(3) (1982 & Supp. III 1985).

62. See *infra* notes 140-48 and accompanying text.

63. See *infra* notes 150-52 and accompanying text.

64. Interview with Enrique Carter, M.D., Director, Pub. Health Serv. Office of Health Technology Assessment, Nat'l Center for Health Servs. Research (July 8, 1987) [hereinafter Carter interview]; Interview with Kathy Buto, Deputy Director, Bu-

less deferential to FDA approval of new medical devices; this situation has generated considerable criticism from health equipment manufacturers.<sup>65</sup>

BERC makes requests to OHTA in one of two forms: (1) an informal inquiry; or (2) a request for a full assessment regarding the safety and effectiveness.<sup>66</sup> For an informal inquiry, OHTA reviews the medical literature and consults with medical specialty groups and professional organizations to address specific questions of the HCFA Physicians Panel. OHTA is uncomfortable with this process, as it generally does not know how HCFA and the HCFA Physicians Panel use its advice in making coverage policy.<sup>67</sup>

A full assessment is a much more elaborate process. First, OHTA issues a notice in the *Federal Register* soliciting comments from interested parties. OHTA also consults extensively with other governmental agencies, medical specialty groups and professional organizations about the technology in question. Further, OHTA obtains information from commercial and industrial groups and specific manufacturers, and reviews published medical and scientific literature. OHTA relies heavily on the technology assessment activities of numerous private organizations,<sup>68</sup> and often confers informally and often with these organizations about coverage questions regarding new or questionable technologies.<sup>69</sup> OHTA collects data for its assessments from outside sources and does not engage in primary data collection efforts itself.<sup>70</sup> Moreover, the agency does not disclose its findings or decisions about the technology assessment in question until after HCFA actually publishes its coverage policy pertaining to the technology.<sup>71</sup>

In addition to preparing extensive reports on its assessments,<sup>72</sup>

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reau of Eligibility, Reimbursement and Coverage, Health Care Fin. Admin. (July 7, 1987) [hereinafter Buto interview].

65. See *infra* notes 219-37 and accompanying text.

66. HCFA Notice, 52 Fed. Reg. 15,562 (1987). Between 1981 and 1986, the number of informal inquiries was between 70 and 80, while the number of formal requests amounted to 125. Letter from Vincent A. Bucci, Vice President for Regulatory Affairs, Shiley Infusaid, Inc. to Eleanor D. Kinney (Nov. 30, 1987).

67. Carter interview, *supra* note 64.

68. LEWIN & ASSOCIATES, *supra* note 33, at 3.9.

69. Carter interview, *supra* note 64.

70. LEWIN & ASSOCIATES, *supra* note 33, at 3.9, 3.28-.29.

71. *Id.* at 3.9.

72. See, e.g., DEP'T HEALTH & HUMAN SERV., PUB. HEALTH SERV., NAT'L CENTER FOR HEALTH SERVS. RESEARCH, LIVER TRANSPLANTATION (1983); DEP'T HEALTH & HUMAN SERVS., PUB. HEALTH SERV., NAT'L CENTER FOR HEALTH SERVS. RESEARCH, CONTINUOUS POSITIVE AIRWAY PRESSURE FOR THE TREATMENT OF OBSTRUCTIVE SLEEP APNEA IN ADULTS (1986); DEP'T HEALTH & HUMAN SERVS., PUB. HEALTH SERV., NAT'L CENTER FOR HEALTH SERVS. RESEARCH, ANGLECHILK ANTI-REFLUX PROSTHESIS (1986); DEP'T HEALTH & HUMAN SERVS., PUB. HEALTH SERV., NAT'L CENTER FOR HEALTH SERVS. RESEARCH, SINGLE PHOTON ABSORPTIOMETRY

OHTA makes a recommendation on coverage.<sup>73</sup> HCFA, however, makes the final decision on a coverage question after reviewing OHTA recommendation.<sup>74</sup> HCFA may also re-evaluate an item or service that is already excluded or covered under the Medicare program: (1) if OHTA previously suggested re-evaluation of the item or service; (2) if OHTA learns of recent research advances; (3) if an item or service becomes obsolete; or (4) if interested parties submit evidence demonstrating that a re-assessment of the coverage determination is warranted.<sup>75</sup>

The procedures for making other types of national coverage policy that is not published in the *MEDICARE COVERAGE ISSUES MANUAL* are somewhat more obscure. The Office of Coverage Policy within BERC makes many of these policies, as do the offices within BERC that are responsible for reimbursement policy. The Health Standards and Quality Bureau makes most national coverage policies related to the peer review program. There are no established procedures for making these types of coverage policies, although HCFA sometimes consults with interested parties, especially providers, on an informal basis.

## B. *Background on the Medicare Program and the American Health Care System*

### 1. The Medicare Program

The Medicare program is a unique federal entitlement program. Three important features profoundly influence its coverage policymaking process and the problems inherent in this process as it exists at present: (1) the unique manner in which the program is administered; (2) the way in which the Medicare program pays for covered benefits; and (3) the procedures available to beneficiaries to appeal adverse coverage decisions.

#### a. *Administration*

HCFA contracts with private organizations to administer the claims of beneficiaries and payment to providers under the Medicare program.<sup>76</sup> For Part A, these organizations are called "fiscal intermediaries;" for Part B, they are referred to as "carriers." Collectively, these organizations, along with PROs, are known as Medicare

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FOR MEASURING BONE MINERAL DENSITY (1986); DEP'T HEALTH & HUMAN SERVS., PUB. HEALTH SERV., NAT'L CENTER FOR HEALTH SERVS. RESEARCH, FULLY AUTOMATED AMBULATORY BLOOD PRESSURE MONITORING OF HYPERTENSION (1986).

73. HCFA Notice, 52 Fed. Reg. 15,560, 15,562 (1987).

74. *Id.*

75. *Id.*

76. 42 U.S.C. §§ 1395h, 1395u (1982 & Supp. III 1985).

contractors. These contractors determine coverage for the particular treatment rendered to individual Medicare beneficiaries, and administer the actual payment of claims.

HHS retains overall policy control of both the administration and the review of claims, and has broadened the scope of this control over the years. To provide the requisite guidance to fiscal intermediaries, carriers and PROs, as well as to hospitals and other institutional providers, HCFA uses a massive compendium of multi-volume manuals; one manual is prepared and maintained for each organization and provider involved in the administration and provision of health care benefits.<sup>77</sup> In addition, HCFA publishes a specific manual on Medicare coverage.<sup>78</sup> Since September 1981, HCFA has also published rulings, generally administrative or judicial decisions, to clarify points of statutory and regulatory interpretation.<sup>79</sup>

The unique administrative structure for the Medicare program delegates enormous responsibility to private individuals and organizations in making coverage and payment decisions. Congress adopted this private approach to program administration for several reasons. First, the Department of Health, Education and Welfare (HEW) did not possess the requisite expertise to administer a massive health insurance program requiring the review of millions of medical decisions. Private insurance companies and Blue Cross and Blue Shield already possessed this requisite expertise.<sup>80</sup>

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77. The health insurance manuals published by HCFA include the following: MEDICARE HOSPITAL MANUAL (HIM-10); MEDICARE HOME HEALTH AGENCY MANUAL (HIM-11); MEDICARE SKILLED NURSING FACILITY MANUAL (HIM-12); MEDICARE INTERMEDIARIES MANUAL (HIM-13); MEDICARE CARRIERS MANUAL (HIM-14); MEDICARE PROVIDER REIMBURSEMENT MANUAL (HIM-15); MEDICARE RENAL DIALYSIS FACILITY MANUAL (HIM-29); and PRO MANUAL. HCFA constantly updates these manuals through "transmittals." For directives without ongoing effect, HCFA publishes program memoranda. 1 Medicare & Medicaid Guide (CCH) ¶ (1987).

HCFA gives each carrier and fiscal intermediary copies of these health insurance manuals, and distributes manuals to other organizations as needed. HCFA does not make these manuals generally available to the public or to providers because of the cost and need to be updated constantly. 42 C.F.R. § 401.112 (1986). Portions of the manuals that affect the public, are distributed to local Social Security Administration offices. *Id.* §§ 401.112, 401.130-132. Note that these manuals and other program directives are not promulgated pursuant to the notice-and-comment rulemaking requirements of the Administrative Procedure Act (APA), 5 U.S.C. § 553 (1982 & Supp. III 1985).

78. HEALTH CARE FIN. ADMIN., MEDICARE COVERAGE ISSUES MANUAL (1987), reprinted in 4 Medicare & Medicaid Guide (CCH) ¶ 27,201-27,221. This manual contains approximately 200 coverage policies pertaining to new or controversial medical technologies or procedures. The manual also contains a list of durable medical equipment for which HCFA has formulated a national coverage policy.

79. 42 C.F.R. § 401.108 (1987).

80. H.R. REP. NO. 213, 89th Cong., 1st Sess. 45-47 (1965); S. REP. NO. 404, 89th Cong., 1st Sess. 52-54 (1965), reprinted in 1965 U.S. CODE CONG. & ADMIN. NEWS 1943, 1992-95; S. LAW, BLUE CROSS - WHAT WENT WRONG? 31-50 (2d ed.



Second, Congress adopted this administrative approach to reflect the longstanding tradition of physician dominance in medical decision-making.<sup>81</sup> State laws and hospital accreditation standards require that physicians oversee the diagnosis and treatment of disease in hospitals.<sup>82</sup> Consistent with these legal requirements, the Medicare statute requires that physicians certify that services provided to individual beneficiaries are reasonable and necessary for the treatment of an illness or injury.<sup>83</sup>

Originally, physicians and hospitals opposed federal administration of the Medicare program for fear of government interference in the practice of medicine.<sup>84</sup> Indeed, providers were successful in preventing passage of the Medicare legislation for several years, and only offered their support when congressional committees and HEW introduced the concept of private administration into the proposed legislation.<sup>85</sup> The medical profession was adamant about the concept of private administration; Congress's ultimate accommodation of the medical profession is reflected in the legislative history.<sup>86</sup>

1976).

81. P. STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* 18-21 (1982); *see also* F. GRAD & N. MARTI, *PHYSICIANS' LICENSURE & DISCIPLINE* 54 (1979). Because the diagnosis and treatment of disease is a highly technical field and because the licensure requirements of all states require physicians to obtain extensive education and training before they are qualified to practice, it follows that only licensed physicians possess the requisite knowledge and, for the most part, legal authority to determine what services should be provided to specific patients. *Id.* at 60-61.

82. JOINT COMM'N ON ACCREDITATION OF HOSPITALS, *ACCREDITATION MANUAL FOR HOSPITALS* 109-27 (1987) (discussing medical staff standards); *see also* 42 U.S.C. § 1395bb (1982 & Supp. III 1985) (providing that hospitals that are accredited by the Joint Commission on Accreditation of Hospitals are deemed to comply with the Medicare program's condition of participation for providers under the Medicare program). *See generally* Jost, *The Joint Commission on Accreditation of Hospitals: Private Regulation of Health Care and the Public Interest*, 24 B.C.L. REV. 835 (1983).

83. 42 U.S.C. §§ 1395g(a), 1395l(a) (1982 & Supp. III 1985). The Medicare statute defines "physician" broadly to include osteopathic physicians, optometrists, podiatrists, dentists and chiropractors practicing within the scope of their license. 42 U.S.C. § 1395x(r) (1982 & Supp. III 1985).

84. *See generally* J. FEDER, *MEDICARE: THE POLITICS OF FEDERAL HOSPITAL INSURANCE* 1 (1977); H. SOMERS & A. SOMERS, *MEDICARE AND THE HOSPITALS: ISSUES AND PROSPECTS*, 1-6 (1967); Wolkstein, *Medicare 1971: Changing Attitudes and Changing Legislation*, 35 J.L. & CONTEMP. PROBS. 697, 698-99 (1970); *Twenty Years of Medicare and Medicaid*, HEALTH CARE FIN. REV. 121-23 (Supp. 1985).

85. Wolkstein, *supra* note 84; S. LAW, *supra* note 80, at 32-33.

86. *E.g.*, the Senate Finance Committee Report states:

The committee's bill provides a considerable role for the participation of private organizations in the administration of both the hospital insurance plan and the supplementary plan.

...

The committee believes that medical benefits under the supplementary plan (Part B) should be administered by the private sector. Private insurers, group health plans, and voluntary medical insurance plans have great expe-

The third reason Congress adopted a private administrative structure for the Medicare program was to assure complete autonomy to the physician both in the practice of medicine and in setting policy affecting medical practice generally. Congress and HEW adopted the principle of physician autonomy in the practice of medicine for the Medicare program and Congress specifically retained this principle as a general policy in the Medicare statute itself:

Nothing in this title shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person.<sup>87</sup>

In designing the Medicare program, Congress and HEW were also concerned about controlling the costs of the program and ensuring that Medicare beneficiaries received only those services that were medically necessary. Because of the policy of physician autonomy in the care of Medicare beneficiaries, and because only physicians possessed the requisite expertise to make decisions about medical necessity, Congress placed the regulatory function for accomplishing this objective in the control of physicians. Initially, Congress required that hospitals and skilled nursing facilities establish utilization review committees, staffed by physicians, to review the admissions, durations of stay and professional services provided to Medicare beneficiaries. The purpose of the review was to assess medical necessity, and to determine whether the institution was making the most efficient use of available health facilities and services.<sup>88</sup> There was no utilization review requirement for

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rience in reimbursing physicians.

S. REP. NO. 404, *reprinted in* 1965 U.S. CODE CONG. & ADMIN. NEWS 1943, 1992-94; *see also* H.R. Rep. No. 213, 89th Cong., 1st Sess. 42-43 (1965).

87. 42 U.S.C. § 1395 (1982 & Supp. III 1985). The Senate Finance Committee Report reiterates this policy:

The bill specifically prohibits the Federal Government from exercising supervision or control over the practice of medicine, the manner in which medical services are provided, and the administration or operation of medical facilities. . . . The responsibility for, and the control of, the care of the beneficiaries rests with the hospitals, extended care facilities, the beneficiaries' physicians, etc.

S. REP. NO. 404, 89th Cong., 1st Sess. 54 (1965), *reprinted in* 1965 U.S. CODE CONG. & ADMIN. NEWS 1943, 1965.

The Senate Finance Committee explained further that "the physician is to be the key figure in determining utilization of health services—and provides that it is a physician who is to decide upon admission to a hospital, order tests, drugs and treatments, and determine the length of stay." *Id.* at 40-41, 1965 U.S. CODE CONG. & ADMIN. NEWS at 1986-87.

88. 42 U.S.C. §§ 1395f(a)(6), 1395x(k) (1982 & Supp. III 1985).

Part B.<sup>89</sup> In 1972, Congress concluded that the utilization review programs had not proved effective. Congress enacted the Professional Standards Review Program, which set up external organizations to conduct utilization review for health care facilities serving Medicare beneficiaries.<sup>90</sup> Following the antiregulatory lead of the newly-elected Reagan Administration, however, Congress repealed this program in 1981.<sup>91</sup>

One year later, Congress enacted the Peer Review Improvement Act,<sup>92</sup> which required HCFA to contract with PROs, private, physician-dominated organizations, to determine whether hospital services provided to Medicare beneficiaries are medically necessary and provided in an appropriate setting.<sup>93</sup> In 1983, Congress assigned PROs important monitoring functions under the prospective payment system for hospitals, including the review of admissions, discharges and selected categories of cases as well as the responsibility to deny coverage where services were neither medically necessary nor provided in an appropriate setting.<sup>94</sup> PROs are also authorized to handle all beneficiary requests for reconsideration of adverse coverage decisions for inpatient hospital services.<sup>95</sup>

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89. The history of utilization review under the Medicare program is important because the basic failure of the medical profession to assume responsibility for effective utilization review put tremendous pressure on HHS and its fiscal intermediaries and carriers to use coverage policy as a means of controlling excess utilization of services by defining acceptable utilization through coverage policy. *See* J. FEDER, *supra* note 75, at 42; S. LAW, *supra* note 71, at 122; *see also* Havighurst & Blumstein, *Coping with Quality/Cost Trade-Offs in Medical Care: The Role of PSROs*, 70 NW. U.L. REV. 6 (1975).

90. Social Security Amendments of 1972 (codified as amended at Social Security Act § 1151), *repealed by* Peer Review Improvement Act of 1982, Pub. L. No. 97-248, 143, 96 Stat. 324, 382 (1982) (codified as amended at 42 U.S.C. §§ 1320c to 1320c-12 (1982 & Supp. III 1985)). *See generally* A. GOSFIELD, *PSROs: THE LAW AND THE HEALTH CONSUMER* (1975).

91. *See Professional Standards Review Organization (PSRO) Program: Hearings Before the Subcomm. on Oversight and the Subcomm. on Health of the House Ways and Means Comm.*, 97th Cong., 1st Sess. 25-27 (1981) (statement of Carolyne Davis, Administrator of HCFA); *Proposed Phaseout of PSROs and Utilization Review Requirements: Hearings Before the Subcomm. on Health of the Senate Comm. on Finance*, 97th Cong., 1st Sess. 15 (1981) (statement of Carolyne Davis, Adm'r of HCFA).

92. Pub. L. No. 97-248, 96 Stat. 324 (1982) (codified as amended at 42 U.S.C. §§ 1320c to 1320c-12 (1982 & Supp. III 1985)).

93. *Id.*

94. 42 U.S.C. § 1395cc(a)(1)(F) (1982 & Supp. III 1985); *see also* H.R. REP. NO. 47, 98th Cong., 1st Sess. 197, *reprinted in* 1983 U.S. CODE CONG. & ADMIN. NEWS 143, 487.

95. *See infra* note 110 and accompanying text.

b. *Payment*

Originally, Congress and HEW left to providers and insurance companies the determination of price and payment method for services furnished to Medicare beneficiaries. In the Social Security Amendments of 1965, Congress stated only that it would pay institutional providers the "reasonable cost"<sup>96</sup> and physicians the "reasonable charge"<sup>97</sup> of covered services. By statute, these costs and charges were to be calculated according to methods that health insurance companies already used.<sup>98</sup> This halcyon state of affairs lasted only a few years, until the cost and volume of services provided to Medicare beneficiaries exploded.<sup>99</sup>

HEW recognized almost immediately that the costs of the Medicare program would greatly exceed initial projections.<sup>100</sup> Over the following years, total Medicare expenditures rose from \$4.6 billion in 1967 to \$62.9 billion in 1984.<sup>101</sup> This development helped fuel the extraordinary inflation in health care costs reflected in part in the increase in percentage of the gross national product devoted to health care from approximately 6 percent in 1965 to 10.7 percent in 1985.<sup>102</sup>

Since 1971, Congress, with input from HHS, has enacted and continues to consider major changes in the methods for paying providers under the Medicare program. A complete history of these reforms is beyond the scope of this analysis, but some key reforms are noteworthy because of their implications for the Medicare coverage policymaking process. In the Social Security Amendments of 1983, for example,

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96. 42 U.S.C. § 1395x(v)(1) (1982 & Supp. III 1985)).

97. 42 U.S.C. § 1395u(b)(3)(f) (1982 & Supp. III 1985)).

98. 42 U.S.C. § 1395v(b)(3)(F), 1395x(v)(1) (1982 & Supp. III 1985); see S. REP. NO. 404, 89th Cong., 1st Sess. 8 (1965), reprinted in 1965 U.S. CODE CONG. & ADMIN. NEWS 1943, 1949; H.REP. NO. 213, 89th Cong., 1st Sess. 37-38 (1965); see also J. FEDER, *supra* note 75, at 2.

99. See *Proposed Medicare Reimbursement Formula: Hearings Before The Senate Comm. on Finance*, 89th Cong., 2d Sess. 22 (1966); *Staff of Senate Comm. on Finance, Medicare and Medicaid: Problems, Issues, and Alternatives*, 91st Cong., 1st Sess. 140-43 (Comm. Print 1970); M. FELDSTEIN & A. TAYLOR, *THE RAPID RISE OF HOSPITAL COSTS* (1977); M. ZUBKOFF, I. RASKIN & R. HANFT, *HOSPITAL COST CONTAINMENT, SELECTED NOTES FOR FUTURE POLICY* (1978); Davis, *Hospital Costs and the Medicare Program*, 36 SOC. SEC. BULL. 18 (1973); Wolkstein, *supra* note 84.

100. *Reimbursement Guidelines for Medicare: Hearing Before the Senate Comm. on Finance*, 89th Cong., 2d Sess. 1 (1966); *Staff of Senate Comm. on Finance, Medicare and Medicaid: Problems, Issues, and Alternatives*, 91st Cong., 1st Sess. 140-43 (Comm. Print 1970).

101. Gornick, Greenberg, Eggers & Dobson, *Twenty Years of Medicare and Medicaid: Covered Populations, Use of Benefits, and Program Expenditures*, HEALTH CARE FIN. REV. (Supp. 1985). During this period, Part A expenditures rose from \$3.4 billion to \$43.3 billion, and Part B expenditures rose from \$1.2 billion to \$19.7 billion. *Id.* at 43.

102. Waldo, Levit & Lazenby, *supra* note 2, at 1.

Congress established the prospective payment system for hospitals.<sup>103</sup> This system pays hospitals a fixed price, based on diagnosis, for each Medicare case irrespective of costs incurred. The prospective payment system provides strong incentives for hospitals to treat Medicare beneficiaries in a cost-effective manner: hospitals may retain savings but are at risk for costs exceeding the price per case.<sup>104</sup> Furthermore, Congress is currently considering payment methodology reforms for physicians and suppliers under Part B of the Medicare program.<sup>105</sup> All of the proposed reforms would depart from the current practice of paying the reasonable charge for a particular service,<sup>106</sup> thus creating additional incentives for physicians to provide care in a more cost-efficient manner.

Under the reforms, coverage of costly new medical technologies and the items and services used in the care of patients will be critical factors in determining payment rates under any formula.<sup>107</sup> Indeed, the prospective payment system has already changed the way hospitals view the acquisition of new medical technology to one of more cautious consideration of the impact the technology will have on the hospitals' financial performance.<sup>108</sup>

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103. 42 U.S.C. § 1395ww (1982 & Supp. III 1985).

104. H.R. REP. NO. 25, 98TH CONG., 1ST SESS. 132 (1983), reprinted in 1983 U.S. CODE CONG. & ADMIN. NEWS 143, 351; SEC'Y OF THE DEP'T. OF HEALTH & HUMAN SERVS., REPORT TO CONGRESS ON HOSPITAL PROSPECTIVE PAYMENT FOR MEDICARE 101-10 (1982). See generally *Hospital Prospective Payment System: Hearings Before the Subcomm. on Health of the Senate Comm. on Finance*, 98th Cong., 1st Sess. 6 (1983); *Medicare Hospital Prospective Payment System: Hearings Before the Subcomm. on Health of the House Comm. on Ways and Means*, 98th Cong., 1st Sess. 10 (1983).

105. *Proposals to Modify Medicare's Physician Payment System, Hearing Before the Subcomm. on Health of the Senate Comm. on Finance*, 99th Cong., 2d Sess. 13 (1986); *Medicare Reimbursement for Physicians Services: Hearings Before the Subcomm. on Health of the House Comm. on Ways and Means*, 99th Cong., 2d Sess. 21 (1981); OFFICE OF TECHNOLOGY ASSESSMENT, PAYMENT FOR PHYSICIAN SERVICES: STRATEGIES FOR MEDICARE (1986); PHYSICIAN PAYMENT REVIEW COMM'N, MEDICARE PHYSICIAN PAYMENT: AN AGENDA FOR REFORM (1987).

106. 42 U.S.C. § 1395u (1982 & Supp. III 1985).

107. See LEWIN & ASSOCIATES, *supra* note 33, at 2.1, 4.1-20.

108. See Anderson & Stenberg, *To Buy or Not To Buy: Technology Acquisition Under Prospective Payment*, 311 NEW ENG. J. MED. 182 (1984); Ball, *Prospective Payment: Implications for Medical Technology*, 100 ANNALS OF INTERNAL MED. 606 (1984); Garrison & Wilensky, *Cost Containment and Incentives for Technology*, 5 HEALTH AFF. 46 (1986); see also Merrill, *Will Payment Control Technology Diffusion?*, HOSP., July 5, 1987 at 46. In fact, Senator David Durenberger of Minnesota was so concerned that the prospective payment system would constrain hospitals from providing new lifesaving technologies in certain cases that he introduced a bill to authorize coverage of and payment for such technologies outside the prospective payment system. Since its introduction, Congress has taken no action on this bill. HEALTH CARE INNOVATION ACT OF 1987, S. REP. NO. 897, 100th Cong., 1st Sess. 10, 133 CONG. REC. S4368 (daily ed. Apr. 1, 1987).

### c. Appeals

The Medicare statute authorizes administrative and judicial review for beneficiaries who choose to challenge adverse decisions regarding coverage of and payment for their Medicare benefits.<sup>109</sup> Specifically, beneficiaries of skilled nursing home and home health services under Part A are entitled to administrative review before an administrative law judge (ALJ) within the Social Security Administration for claims over \$100 and judicial review of claims exceeding \$1000.<sup>110</sup> For inpatient hospital services under Part A, beneficiaries may obtain administrative review before an ALJ of PRO coverage decisions on claims exceeding \$200 and judicial review of claims exceeding \$2000.<sup>111</sup>

Congress has significantly limited the ability of providers under Part A to challenge the coverage of Medicare benefits accorded individual beneficiaries. Specifically, the Provider Reimbursement Review Board, created in 1972 for administrative review of provider payment disputes,<sup>112</sup> has no jurisdiction to hear coverage issues.<sup>113</sup> Further, statutory provisions that authorize providers and beneficiaries to waive liability for noncovered services are limited in scope. Providers may only challenge the validity of a Medicare contractor's decision on waiver of liability, rather than the underlying coverage determination on which the waiver of liability decision was based.<sup>114</sup>

Beneficiaries only recently obtained the right to administrative and judicial review of coverage decisions regarding benefits under Part B. Previously, beneficiaries and providers (who accepted assignment of the Medicare claim) were only entitled to a hearing before the Medicare contractor.<sup>115</sup> After years of pressure from beneficiaries, the American Bar Association and other groups, Congress concluded that the increased sophistication and large monetary amount of Part B claims justified reconsideration of the preclusion.<sup>116</sup> Thus, Congress established

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109. 42 U.S.C. §§ 1395ff, 1320c-4 (1982 & Supp. III 1985).

110. 42 U.S.C. §§ 1395ff(b)(1)(C), 1395ff(b)(2) (1982 & Supp. III 1985).

111. 42 U.S.C. § 1320c-4 (1982 & Supp. III 1985).

112. 42 U.S.C. §§ 1395oo (1982 & Supp. III 1985).

113. 42 U.S.C. §§ 1395oo(g) (1982 & Supp. III 1985).

114. 42 U.S.C. §§ 1395pp(d) (1982); *see Hearings on Medicare Appeals Provisions, supra* note 35, at 48-49. HCFA had also prohibited providers from representing beneficiaries in coverage and other appeals, but Congress overturned this policy in the Omnibus Budget Reconciliation Act of 1986. Pub. L. No. 99-509, § 9313(a), 100 Stat. 2037 (1986) (to be codified at 42 U.S.C. § 1395ff(b)(1); *see Home Health Care, Inc. v. Bowen*, 639 F. Supp. 1124 (D.D.C. 1986) (invalidating the manual provisions prohibiting provider representation of beneficiaries on grounds that the provision was a legislative rule not promulgated under § 553 of the Administrative Procedure Act, 5 U.S.C. § 553 (1982 & Supp. III 1985)).

115. 42 U.S.C. § 1395u(c)(7) (1982 & Supp. III 1985).

116. *See, e.g., Hearings on Medicare Appeals Provisions; Am. Bar Ass'n, Report and Recommendations from the American Bar Association House of Delegates*

administrative and judicial review of Part B claims by passing the Omnibus Budget Reconciliation Act of 1986.<sup>117</sup>

In the Omnibus Budget Reconciliation Act, Congress imposed significant limitations on the administrative and judicial review of national coverage determinations.<sup>118</sup> The law contains three critical provisions. First, an administrative law judge may not review the validity of national coverage determinations in administrative appeals.<sup>119</sup> Congress enacted this restriction to preclude ALJs from overturning national coverage determinations that had been made on the basis of medical evidence and expertise.<sup>120</sup> Second, the Act provides that national coverage determinations cannot be held unlawful on grounds that HHS did not comply with Chapter V of the APA or Social Security Act § 1871(b)<sup>121</sup> regarding publication in the *Federal Register* or providing the requisite opportunity for public comment.<sup>122</sup> Congress adopted this provision because it concluded that current procedures for making national coverage determinations offer sufficient opportunities for input from medical groups and the public, without assessing certain APA

(Aug. 6, 1980), *reprinted in* [1980 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 30,608. Note that the Supreme Court specifically upheld this statutory preclusion of administrative and judicial review of Part B claims. *See United States v. Erika, Inc.*, 456 U.S. 201 (1982); *cf. Schweiker v. McClure*, 456 U.S. 188 (1982).

117. Pub. L. No. 99-509, § 9341(a)(2)(D), 100 Stat. 2037 (1986) (to be codified at 42 U.S.C. § 1395ff).

118. Pub. L. No. 99-509, § 9341a, 100 Stat. 2037 (1986) (to be codified at 42 U.S.C. § 1395ff). This statute provides in pertinent part:

(3) Review of any national coverage determination under section 1862(a)(1) respecting whether or not a particular type or class of items or services is covered under this title shall be subject to the following limitations: (A) Such a determination shall not be reviewed by any administrative law judge. (B) Such a determination shall not be held unlawful or set aside on the ground that a requirement of chapter 5 of title 5, United States Code [Chapter 5 of the Administrative Procedure Act], or section 1871(b), relating to publication in the Federal Register or opportunity for public comment, was not satisfied. (C) In any case in which a court determines that the record is incomplete or otherwise lacks adequate information to support the validity of the determination, it shall remand the matter to the Secretary for additional proceedings to supplement the record and the court may not determine that an item or service is covered except upon review of the supplemental record.

*Id.*

119. Pub. L. No. 99-509, § 9341(a)(1)(D), 100 Stat. 2037 (1986) (to be codified at 42 U.S.C. § 1395ff).

120. H.R. REP. NO. 727, 99th Cong., 2d Sess. 95 (1986), *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS 3607, 3685.

121. *See, e.g.*, 5 U.S.C. §§ 500-504, 551-559, 571-576 (1982 & Supp. III 1985); 42 U.S.C. § 1395hh(b) (1982 & Supp. III 1985).

122. Pub. L. No. 99-509, § 9341, 100 Stat. 2037 (1986) (to be codified at 42 U.S.C. § 1395ff).

requirements.<sup>123</sup>

Coverage determinations of national applicability could not be overturned solely on the grounds that they were not issued in accordance with the notice and comment procedures of the Administrative Procedure Act, as amended. The process used by the Secretary in making such determinations, including the role of the National Center for Health Services Research and Health Care Technology Assessment, is designed to assure consultation with the scientific and medical community and the general public. If that process is adhered to, the further procedure of publishing proposed and final regulations does not seem essential.<sup>124</sup>

Finally, the Omnibus Budget Reconciliation Act requires that when a court determines that the record is incomplete or otherwise lacks adequate information to support the validity of a national coverage determination, the court must remand the case to HHS. The court itself may not determine that a national coverage determination is invalid except upon review of a supplemental record.<sup>125</sup> Here, Congress sought to preclude courts from reversing national coverage determinations made on the basis of medical evidence and expertise without according HHS an opportunity to reconsider its determination.<sup>126</sup>

#### d. *Conclusory Observations*

In sum, the architects of the Medicare program crafted a markedly singular approach to defining the program benefit than other government benefit programs. Under the program, physicians and insurance companies play a major role both in developing coverage policy that defines specific benefits under the program, and in determining which of these benefits should be accorded individual beneficiaries. Although HHS has assumed a more aggressive role in formulating coverage policy in recent years, the agency still relies heavily on insurance companies to make most coverage decisions and coverage policy, and on physicians for their expertise in formulating specific coverage policies.<sup>127</sup>

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123. See *infra* note 494 and accompanying text.

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

125. Pub. L. No. 99-509, § 9341(1), 100 Stat. 2037 (1986) (to be codified at 42 U.S.C. § 1395ff).

126. H.R. REP. NO. 727, 99th Cong., 2d Sess. 95-96 (1986), *reprinted in* 1986 U.S. CODE CONG. & ADMIN. NEWS 3607, 3685-86.

127. See *supra* notes 29-36 and accompanying text. HHS has traditionally paid little attention to the process for making national coverage policy—an understandable situation given the fact that the Medicare program was established before the so-called “due process revolution” of the 1970s, in which the Supreme Court acknowledged that recipients of government programs had a property or “entitlement” interest in the benefits of the program. See *also* *Goldberg v. Kelly*, 397 U.S. 254 (1970).



Nevertheless, this unique approach to defining public entitlement interests of beneficiaries under the Medicare program is somewhat at odds with the typical government entitlement program. Specifically, in a conventional entitlement program the entitlement interest is defined by law, as are the conditions upon which the benefit will be conferred. Even in programs such as Social Security Disability Insurance, in which entitlement to cash assistance is based on a medical determination of disability, the statute and regulations fix the level and amount of benefits once the medical determination of eligibility has been made. In the Medicare program, on the other hand, the decisions concerning the level and amount of benefits and whether particular conditions for eligibility have been met are medical decisions made primarily by physicians.<sup>128</sup>

## 2. Impact of Developments in Medical Technology on the Medicare Program

In the early 1970s, the Medicare program became more concerned with coverage policy for two reasons. First, unanticipated inflation in Medicare expenditures threatened the solvency of the Medicare program and the ability of the federal government to maintain a balanced budget.<sup>129</sup> Second, the rapid development of costly new technologies aggravated this inflation.<sup>130</sup>

The serious and unexpected cost of inflation in the health care system prompted policymakers to scrutinize Medicare coverage policies more closely to ascertain where cost savings could be achieved. When utilization review proved ineffective in controlling costs attributed to medically unnecessary care or care provided in an inappropriate setting, the Medicare program encouraged fiscal intermediaries and carriers to deny payment for these claims.<sup>131</sup> As a result, Medicare has basi-

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128. See *supra* notes 81-83 and accompanying text.

129. See *supra* notes 99-102 and accompanying text.

130. See *infra* notes 132-37 and accompanying text.

131. J. FEDER, *supra* note 84, at 41. For example, in 1972, HHS redefined the concepts of covered "skilled nursing care" more narrowly and noncovered "custodial" care more broadly in its health insurance manuals and regulations to reduce expenditures for skilled nursing facilities, and encouraged Medicare contractors to deny coverage of claims on a retroactive basis through aggressive application of these coverage policies. See S. LAW, *supra* note 80, at 125-30; Adler & Brown, *Who Reviews the Reviewers?: A Retrospective Study of Medicare Determinations*, 302 NEW ENG. J. MED. 842 (1980) (a study of denial patterns in one rehabilitation hospital); Butler, *An Advocate's Guide to the Medicare Program*, 8 CLEARINGHOUSE REV. 831, 837 (1975); Loeser, Dickstein & Schiavone, *Medicare Coverage in Nursing Homes—A Broken Promise*, 304 NEW ENG. J. MED. 353 (1982); Wilson, *Benefit Cutbacks In The Medicare Program Through Administrative Agency Fiat Without Protections: Litigation Approaches On Behalf of Beneficiaries*, 16 GONZ. L. REV. 533, 550-51 (1981).

The result of this approach to medically unnecessary care was that through retro-

cally transformed its coverage policy into a strategy for cost containment—in a manner probably not contemplated by the architects of the Medicare program.

The second reason for the emerging interest in coverage policy in the early 1970s was the virtual explosion of advances in medical technology during this period, especially in the area of biomedical research.<sup>132</sup> In addition, progressive albeit expensive types of medical equipment were marketed during the seventies, such as the computerized tomography scanner<sup>133</sup> for the diagnosis and treatment of disease and the maintenance of life.<sup>134</sup> These developments precipitated extensive press coverage,<sup>135</sup> resulting in public and political pressure to make

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active claims denial, beneficiaries, rather than the Medicare program and providers, bore the cost of uncovered and unnecessary medical care, thus preventing the provision of such services in the first place. See S. LAW, *supra* note 80, at 49. Congress has since endeavored to mitigate this burden through enactment of a so-called “waiver of liability” policy, which requires the Medicare program to pay for uncovered services that the beneficiary and/or provider believed in good faith were covered. 42 U.S.C. § 1395pp (1982 & Supp. III 1985)).

132. See Banta & Behney, *Policy Formation and Technology Assessment*, 59 MILBANK MEMORIAL FUND Q. 445, 453 (1981); Iglehart, *The Cost and Regulation of Medical Technology: Future Policy Decisions*, 55 MILBANK MEMORIAL FUND Q. 25, 50-52 (1977).

Since World War II, the federal government has supported over half the biomedical research conducted in this nation. In 1985, total national expenditures for biomedical research were \$13.1 billion, of which the federal government spent 50% (\$6.8 billion), industry spent 38% (\$4.9 billion) and other sources, e.g., state governments and private, nonprofit organizations, spent 11% (\$1.3 billion). DEP'T HEALTH & HUMAN SERVS., PUBLIC HEALTH SERV., NATIONAL INSTITUTES OF HEALTH, NIH DATA BOOK 4-5 (1987). See generally Fredrickson, *Health and the Search for New Knowledge*, 106 DAEDALUS 159, 160 (1977).

133. The computerized tomography (CT) scanner epitomized the relationship between costly technological equipment and health system costs in the minds of many policymakers. This medical device, manufactured in Great Britain, takes extraordinarily effective noninvasive impressions of the head and body, but costs over \$1 million. Soon after its introduction on the market, most hospitals and even some physicians, sought to purchase the CT scanner. Iglehart, *supra* note 132, at 30-35.

134. *Id.*; see also P. STARR, *supra* note 81, at 338-47. Most of the new medical technologies, e.g., renal dialysis or transplantation, are “halfway” technologies that do not cure disease but sustain the patient and prolong life. These technologies tend to increase health care system costs. See, e.g., Rettig, *Medical Technology in a Changing Health Care Environment*, in CHARTING THE FUTURE OF HEALTH CARE (Am. Enterprise Inst. ed. 1987); Rosenthal, *Anticipating the Costs and Benefits of New Technology: A Typology for Policy in Dep't of Health, Educ. & Welfare*, in MEDICAL TECHNOLOGY: THE CULPRIT BEHIND HEALTH CARE COSTS? 78-87 (1977); Schwartz & Joskow, *Medical Efficacy Versus Economic Efficiency: A Conflict in Values*, 299 NEW ENG. J. MED. 1462 (1978); Smits, *The Clinical Context of Technology Assessment*, 9 J. OF HEALTH POL., POL'Y & POL. 31, 33 (1984).

135. See, e.g., Cherry, *Medical Technology: The New Revolution*, N.Y. Times, Aug. 5, 1979, § 6 (Magazine), at 12; Ebert, *The New Technology—How Far, How Fast?*, Am. Med. News, June 28, 1976, at 2.

these new medical technologies economically available to Medicare beneficiaries and the consensus among scholars and policymakers that new technology was a very important factor in the inflation in Medicare costs.<sup>136</sup> Ultimately, these extraordinary developments in medical

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136. Gaus & Cooper, *Technology and Medicare: Alternatives for Change* (Background paper for Conference on Health Care Technology and Quality of Care, Boston University Health Policy Center, Nov. 1976); L. RUSSELL, *TECHNOLOGY IN HOSPITALS: MEDICAL ADVANCES ON THEIR DIFFUSION* (1979); see also NATIONAL ACADEMY OF SCIENCE, *MEDICAL TECHNOLOGY AND THE HEALTH CARE SYSTEM: A STUDY OF THE DIFFUSION OF EQUIPMENT-EMBODIED TECHNOLOGY* (1979); DEP'T HEALTH & HUMAN SERVS., HEALTH RESOURCES ADMIN., *HEALTH CAPITAL ISSUES* (1981); DEP'T HEALTH, EDUC., & WELFARE, HEALTH RESOURCES ADMIN., *CAPITAL FORMATION IN HEALTH CARE FACILITIES* (1979). In addition to several HEW conferences on the subject, see DEP'T OF HEALTH, EDUC., & WELFARE, NATIONAL CENTER FOR HEALTH SERVS., RESEARCH, *MEDICAL TECHNOLOGY* (Research Proceedings Series, Sept. 1979); NATIONAL CENTER FOR HEALTH SERVS., RESEARCH AND DEVELOPMENT, *TECHNOLOGY AND HEALTH CARE SYSTEMS IN THE 1980s* (Conference Series, Jan. 1972).

Several scholars documented the relationship between the dissemination of medical technology and increased costs in the Medicare program. See, e.g., Blendon & Altman, *The Hidden Cost of "Little Ticket" Advances*, BUSINESS AND HEALTH, July/Aug. 1984 at 12; Debakey & Debakey, *The Ethics and Economics of High-Technology Medicine*, 9 COMPREHENSIVE THERAPY 6 (1983); Fineberg, *Life, Death . . . and Dollars*, THE SCIENCES, Dec. 1978 at 30; Hellerstein, *Overdosing on Medical Technology*, 88 TECHNOLOGY REV. 13 (1983); Moloney & Rogers, *Medical Technology—A Different View of the Contentious Debate Over Costs*, 301 NEW ENG. J. MED. 1413 (1979); Schroeder, *Curbing the High Costs of Medical Advances*, BUSINESS AND HEALTH, July/Aug. 1984 at 7; Williams & Banta, *Improving The Use of Medical Technology*, 1 HEALTH AFF. 86 (Spring 1982). Other scholars argued that Medicare coverage policy should address this relationship more directly. See Fineberg & Hiatt, *Evaluation of Medical Practices: The Case for Technology Assessment*, 301 NEW ENG. J. MED. 1086 (1979); Greenberg & Derzon, *Determining Health Insurance Coverage of Technology: Problems and Options*, 119 MED. CARE 967 (1981); Hellinger, *Controlling Costs by Adjusting Payment for Medical Technologies*, 19 INQUIRY 34 (1982); Schroeder, *Medical Technology and Academic Medicine: The Doctor-Producers' Dilemma*, 56 J. MED. EDUC. 634 (1981). See generally R. EGDAHL & P. GERTMAN, *TECHNOLOGY AND THE QUALITY OF HEALTH CARE* (1978). One scholar estimated that one-third of the annual cost of hospital services can be attributed to the growth in the so-called "intensity" of services used in the average hospital stay—primarily a result of the use of more sophisticated medical technology. Blumenthal, *Federal Policy Toward Health Care Technology: The Case of the National Center*, 61 MILBANK MEMORIAL FUND 584, 588 (1983) (citing P. JOSKOW, *CONTROLLING HOSPITAL COSTS: THE ROLE OF GOVERNMENT REGULATION* (1981)); see also Warner, *Effects of Hospital Cost Containment on the Development and Use of Medical Technology*, 56 MILBANK MEMORIAL FUND Q. 187 (1978).

Indeed, Medicare's ultimate decision to cover the cost of renal dialysis for persons afflicted with terminal kidney disease is a dramatic illustration of how public pressure affects coverage policy. In the 1960s, physician investigators perfected the process of kidney dialysis to cleanse the body of metabolic waste, a process which the kidneys can no longer accomplish. But kidney dialysis was prohibitively expensive for most Americans with terminal kidney disease, and few kidney dialysis machines were available. See Rettig, *The Policy Debate on Patient Care Financing for Victims of End-Stage Renal Disease*, 40 L. & CONTEMP. PROB. 196 (1976); Iglehart, *supra* note 132, at 48,

technology resulted in the development of more complex coverage questions for the Medicare program.<sup>137</sup>

a. *Congressional Action and Legislation*

During the 1970s, Congress was especially aggressive in addressing the relationship between the inflationary costs of new technology and health care. Many of the programs created by Congress during this period now play a key role in determining Medicare coverage policy that pertains to new or questionable medical technologies.<sup>138</sup> In 1976,

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49-50. Physicians and hospitals were placed in an ethically awkward position, forced to choose among patients who might benefit from this expensive, lifesaving procedure. *See, e.g., Kidney Treatment Called Arbitrary*, N.Y. Times, June 30, 1975, § 6 (Magazine), at 55. As a result, Congress mandated that individuals with end-stage renal disease must be eligible for Medicare. 42 U.S.C. § 1395y(b) (1982 & Supp. III 1985); *see also* Iglehart, *supra* note 132, at 47-50.

137. In the early years of the Medicare Program, national coverage policies concentrated on definitional issues about the appropriateness of the setting for inpatient care. *See* HEALTH CARE FIN. ADMIN., HEALTH CARE FIN. ADMIN. RULINGS ON MEDICARE, MEDICARE PROFESSIONAL STANDARDS REVIEW AND RELATED MATTERS (four volumes published Jan. 1979, Apr. 1979, Apr.-Dec. 1979, Jan.-Sept. 1980). In the 1980s, the national coverage policies focused more on coverage of new or questionable technologies, such as heart transplants and bilateral carotid body resection. *See, e.g., Medicare Program*, 45 Fed. Reg. 71,426 (1980) (discussing exclusion from Medicare coverage of bilateral carotid body resection to relieve pulmonary distress).

The most controversial coverage issue to date concerned heart transplants. In 1980, HHS Secretary Patricia Roberts Harris deferred coverage of heart transplants and commissioned a thorough study of the question. *Medicare Program*, 45 Fed. Reg. 52,296 (1980) (discussing exclusion of heart transplantation procedures from Medicare coverage); *see* BATTELLE HUMAN AFFAIRS RESEARCH CENTERS, NATIONAL HEART TRANSPLANTATION STUDY: FINAL REPORT (1984). In 1987, following this study, HHS authorized Medicare coverage of heart transplants in selected institutions having specialized resources. *Medicare Program*, 52 Fed. Reg. 10,935 (1987) (discussing criteria for Medicare coverage of heart transplants). *See generally* Cassells, *Heart Transplantation: Recent Policy Developments*, 315 NEW ENG. J. MED. 1365 (1986); Knox, *supra* note 33.

138. In 1974, concerned that there was excessive and irrational distribution of health care technology in the health care system, Congress enacted the National Health Planning and Resources Development Act of 1974 to require states to conduct health planning and capital expenditure review activities. Pub. L. No. 93-641, 88 Stat. 2225 (1974) (codified as amended at 42 U.S.C. §§ 300k-1 to 300n-6 (Supp. II 1982), *repealed by* Pub. L. No. 99-660, 100 Stat. 3799 (1987)); B. LEFKOWITZ, HEALTH PLANNING: LESSONS FOR THE FUTURE (1983); I INST. OF MED., HEALTH PLANNING IN THE UNITED STATES: SELECTED POLICY ISSUES 12 (1981). This statute required states to approve all proposed capital investment for medical equipment exceeding \$150,000, and required the federal government to set standards for the distribution of certain equipment throughout the nation. The Reagan Administration opposed the federally-mandated health planning and capital expenditure review programs. Consequently, in 1986 Congress repealed the National Health Planning and Resources Development Act of 1974. Many states have elected to retain capital expenditure review programs, and some states continue to review investment in new medical equipment. *See generally*

the relatively new Congressional Office of Technology Assessment (OTA) expanded its mission to include assessment of medical technologies.<sup>139</sup>

To address the specific problems posed by the rapid development of new medical equipment and the concern that many devices were ineffective or even harmful,<sup>140</sup> Congress enacted the Medical Device Amendments of 1976.<sup>141</sup> The law created a review process within FDA to regulate the safety and effectiveness of medical devices.<sup>142</sup> Regulating virtually all medical equipment,<sup>143</sup> this legislation establishes a three-tiered classification scheme that determines the scope of review for a medical device before it is marketed.<sup>144</sup> Class I devices pose minimal risk and need no formal review before marketing. Class II devices are similar to existing devices for which sufficient information exists to establish performance standards, thereby making formal premarket testing unnecessary. Class III devices are those for which insufficient information exists to devise performance standards adequately, and thus require premarket testing under FDA supervision.<sup>145</sup> If a manufacturer believes that a new device is "substantially equivalent" to a device in commercial distribution before the Medical Device Amendment of 1976 or to a Class I or Class II device,<sup>146</sup> it must notify FDA

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Simpson, *Full Circle: The Return of CON Regulation of Health Facilities to State Control*, 19 IND. L. REV. 1025 (1986).

139. OFFICE OF HEALTH TECHNOLOGY ASSESSMENT, DEVELOPMENT OF MEDICAL TECHNOLOGY: OPPORTUNITIES FOR ASSESSMENT vii (1976); *see also* OFFICE OF HEALTH TECHNOLOGY ASSESSMENT, ABSTRACTS OF CASE STUDIES IN THE HEALTH TECHNOLOGY CASE STUDY SERIES (1983); OFFICE OF HEALTH TECHNOLOGY ASSESSMENT, ABSTRACTS OF CASE STUDIES IN THE HEALTH TECHNOLOGY CASE STUDY SERIES (1986); Banta & Behney, *supra* note 132, at 450-51; Iglehart, *supra* note 132, at 30-31.

140. *See* H.R. REP. NO. 853, 94th Cong., 2nd Sess. 7-8 (1976); *see also* S. REP. NO. 33, 94th Cong., 1st Sess. 18, *reprinted in* 1976 U.S. CODE CONG. & ADMIN. NEWS 1970.

141. Pub. L. No. 94-295, 90 Stat. 539 (1979) (codified as amended at the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, 360c-k (1982 & Supp. III 1985)).

142. *Id.* The legislative history further explains the statutory purpose of the FDA medical device approval process as assuring "the reasonable safety and effectiveness of medical devices intended for human use." H.R. REP. NO. 1090, 94th Cong., 2d Sess. 51, *reprinted in* 1976 U.S. CODE CONG. & ADMIN. NEWS 1103; *see also* Hogan & Hartson, *supra* note 17, at 56-84 (outlining the FDA approval process for medical devices in detail).

143. *See* 21 U.S.C. § 321(h) (1982 & Supp. III 1985) (including in the definition of medical device almost every conceivable piece of equipment used in the treatment of illness or injury).

144. 21 U.S.C. § 360c-e (1982 & Supp. III 1985).

145. 21 U.S.C. § 360c (1982 & Supp. III 1985).

146. If the comparable device was never classified because it was marketed before the Amendment was passed, the manufacturer need only show that the new device is "substantially equivalent." *Id.*

and, upon FDA concurrence, the manufacturer may market the device within ninety days of notification.<sup>147</sup> For a Class III device, however, the manufacturer must submit a premarket approval application and go through extensive testing of its safety and effectiveness.<sup>148</sup> Three criteria for approval of premarket applications include: (1) that the product has been assured to be safe and effective for use as contemplated in the label; (2) that the label is not false and misleading; and (3) that the device meets any applicable performance standards.<sup>149</sup>

b. *Technology Assessment in HEW*

In 1977, the National Institutes of Health (NIH) acknowledged its strong influence on the development and diffusion of new medical technology through funding of biomedical research,<sup>150</sup> and established the Office of Medical Applications Research to conduct Consensus Development Conferences to evaluate both new and established medical technologies.<sup>151</sup> In these conferences, NIH convenes leading experts in the field to develop conclusions about the efficacy of the modalities procedures or technologies used in the treatment of a specific disease.<sup>152</sup>

In the late seventies, Congress briefly established a specific medical technology assessment function within HEW by creating the National Center for Health Care Technology within the Public Health Service.<sup>153</sup> The statutory mandate of the Center was to advise Medi-

147. 21 U.S.C. § § 360(k) (1982 & Supp. III 1985); see Hogan & Hartson, *supra* note 17, at 57-58, 63-71 (explaining the history and structure of the premarket notification process).

148. 21 U.S.C. § 360e(b) (1982 & Supp. III 1985); see also Hogan & Hartson, *supra* note 17, at 71-85.

149. 21 U.S.C. § 360e(d)(2) (1982 & Supp. III 1985).

150. In a relatively unsystematic but consistent fashion, basic biomedical research funded by NIH has provided the requisite knowledge for the development of new medical technologies by private industry, i.e., new drugs and medical equipment. See OFFICE OF HEALTH TECHNOLOGY ASSESSMENT, DEVELOPMENT OF MEDICAL TECHNOLOGY: OPPORTUNITIES FOR ASSESSMENT 67-88 (1976); Comroe & Dripps, *Scientific Basis for the Support of Biomedical Science*, 192 SCIENCE 105 (1976); Fineberg, *Technology Assessment: Motivation, Capability, and Future Directions*, 23 MED. CARE 663 (1985); Frederickson, *supra* note 132; Perry, *Diffusion of New Technologies*, 1 J. HEALTH CARE TECHNOLOGY 73 (1984).

151. See Greenberg, *Health Care Technology: A Small Office vs. a Big Problem*, 302 NEW ENG. J. MED. 243 (1980); Perry & Kalberer, *The NIH Consensus-Development Program and the Assessment of Health Care Technologies: The First Two Years*, 303 NEW ENG. J. MED. 169 (1980); see also DEP'T HEALTH & HUMAN SERVICES, NATIONAL INSTITUTES OF HEALTH, GUIDELINES FOR THE SELECTION AND MANAGEMENT OF CONSENSUS DEVELOPMENT CONFERENCES (1986).

152. See Greenberg, *supra* note 151; see also Bernstein, *National Institutes of Health Consensus Development Program*, 48 CONN. MED. 513 (1984); Mullan & Jacoby, *The Town Meeting For Technology: The Maturation of Consensus Conferences*, 254 J.A.M.A. 1068 (1985).

153. Pub. L. No. 95-623, 92 Stat. 3443 (1978) (codified as amended in scattered

care and other federal health insurance programs on coverage of new technologies. Although the Center had no regulatory function, it was authorized to conduct assessments of new technologies as needed.<sup>154</sup> The statute specified criteria for the Center to consider in its technology assessments, including "the safety, effectiveness, and cost effectiveness of, and the social, ethical, and economic impact of health care technologies."<sup>155</sup> The Center was poorly funded during its brief existence, although it did conduct some major technology assessments before it closed in 1982.<sup>156</sup> Upon its closure, HHS retained a technology assessment function and continued to rely on this statutory language as authority for purposes of resolving Medicare coverage issues in valuing medical technologies.<sup>157</sup>

### 3. Developments in the 1980s

Following the election of Ronald Reagan, American health policy shifted to the right. The new President was not ideologically committed to the existing regulatory strategies for cost containment and utilization review that Congress and HHS had conceived during the 1970s.<sup>158</sup> Rather, the Reagan Administration's health policy focused on making government health insurance programs more prudent purchasers of health care services through payment reforms such as the prospective payment system for hospitals, promoting competition in the market for health care services and deregulating the health care industry wherever possible.<sup>159</sup> In 1981, the Reagan Administration disbanded the National Center for Health Care Technology, maintaining that a federal role in technology assessment should be de-emphasized.<sup>160</sup> The Center

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sections of 42 U.S.C. (1982 & Supp. III 1985)); see Blumenthal, *supra* note 136; Greenberg, *supra* note 151; Perry, *The National Center for Health Care Technology*, 245 J.A.M.A. 2510 (1981) [hereinafter Perry, *The National Center*]; Perry, *The Brief Life of the National Center for Health Care Technology*, 307 NEW ENG. J. MED. 1095 (1982) [hereinafter Perry, *The Brief Life*].

154. 42 U.S.C. § 242n (1982 & Supp. III 1985).

155. *Id.*

156. See Blumenthal, *supra* note 136; Greenberg, *supra* note 151; Perry, *The Brief Life*, *supra* note 153; Perry, *The National Center*, *supra* note 153.

157. Carter Interview, *supra* note 64.

158. Wing, *American Health Policy in the 1980's*, 36 CASE W. RES. 608 (1986); see also Comment, *Reagan Administration Health Legislation: The Emergence of a Hidden Agenda*, 20 HARV. J. ON LEGIS. 573 (1983).

159. See H.R. DOC. NO. 24, 98th Cong., 1st Sess. 34 (1983); *Proposals to Stimulate Competition in the Financing and Delivery of Health Care, 1981 Hearings Before the Subcomm. on Health of the Comm. on Ways and Means of the House of Representatives*, 97th Cong., 1st Sess. 1 (1981); *Medicare Reimbursement to Competitive Medical Plans, Hearing Before the Special Comm. on Aging*, 97th Cong., 1st Sess. 12 (1981); Enthoven, *The Competition Strategy: Status and Prospects*, 304 NEW ENG. J. MED. 109 (1981).

160. See Greenberg, *supra* note 151; Perry, *The Brief Life*, *supra* note 153;

always had critics in the medical profession and the health equipment industry who contended that the Center represented an inappropriate federal intrusion into the process of developing and marketing new medical technologies.<sup>161</sup> Nevertheless, PHS continued to review technologies in order to advise HCFA on coverage of new technologies.<sup>162</sup>

Besides promoting the deregulation of the health care system, Congress and HHS inaugurated important reforms in Medicare's coverage and payment procedures in the 1980s. In 1982, Congress established the peer review program as a means of aggressive utilization review of hospital services to Medicare beneficiaries in light of the anticipated movement to prospective payment.<sup>163</sup> Congress also created the Prospective Payment Assessment Commission (ProPAC) within OTA to work with HHS and Congress in updating the prospective payment rates and recalibrating the Diagnosis Related Groupings (DRGs) upon which the price per Medicare case is established.<sup>164</sup> This updating process involves consideration of the cost and efficacy of new medical technologies affecting the cost of care for illnesses included within a DRG, as well as whether the new technology or procedure should be covered by Medicare. Thus, ProPAC engages in some technology assessments in its analysis of how to modify the DRGs.<sup>165</sup>

Nevertheless, the concerns of congressional policymakers and the health care community about the safety and efficacy of new technologies never dissipated and, in the early 1980s, there were pressures from

Perry, *The National Center*, *supra* note 153.

161. *Id.*

162. Carter Interview, *supra* note 64; *see also* Iglehart, *Another Chance for Technology Assessment*, 309 NEW ENG. J. MED. 509 (1983).

163. *See supra* notes 93-95 and accompanying text.

164. 42 U.S.C. §§ 1395(d)(2)(B), 1395(b)(3)(B) (1982 & Supp. III 1985). DRGs were initially developed by a team of Yale researchers for utilization review purposes. DRGs group patients primarily by principal (admitting) diagnoses, which are themselves categorized by body system into 23 major diagnostic categories (MDCs). These groupings are then broken down into 467 further categories by considering principal and secondary diagnoses, whether a surgical procedure was performed and, where relevant, by considering age, gender and discharge status. The purpose of this analysis is to yield groups of hospital patients, each covered by a distinct DRG, which require approximately the same consumption of medical resources. B. FURROW, S. JOHNSON, T. JOST & R. SCHWARTZ, *HEALTH LAW* 456-57 (1987).

165. PROSPECTIVE PAYMENT ASSESSMENT COMM'N, REPORT AND RECOMMENDATIONS TO THE SECRETARY, DEP'T OF HEALTH & HUMAN SERVS., 23, 32-35 (1985); PROSPECTIVE PAYMENT ASSESSMENT COMM'N, REPORT AND RECOMMENDATIONS TO THE SECRETARY DEP'T OF HEALTH AND HUMAN SERVS. 16, 26-29 (1986); PROSPECTIVE PAYMENT ASSESSMENT COMM'N, TECHNICAL APPENDIXES TO THE REPORT AND RECOMMENDATIONS TO THE SECRETARY, DEP'T OF HEALTH & HUMAN SERVS. 83 (1986); PROSPECTIVE PAYMENT ASSESSMENT COMM'N, TECHNICAL APPENDIXES TO THE REPORT AND RECOMMENDATIONS TO THE SECRETARY DEP'T OF HEALTH & HUMAN SERVS. 15, 29-31, 127-36 (1987). *See generally* Foote, *Assessing Medical Technology Assessment*, 65 MILBANK MEMORIAL FUND Q. 59 (1987).



the private sector as well as from Congress for enhanced medical technology assessment activities.<sup>166</sup> In the early 1980s, several influential physicians and other commentators suggested changes in Medicare's technology assessment process. Specifically, they proposed the creation of an independent, nonregulatory, nonprofit institute to collect, analyze and disseminate data on new medical procedures. In addition, the proposed institute would support clinical trials of selected technologies.<sup>167</sup> In 1982, the Institute of Medicine, responding to these suggestions,<sup>168</sup> established a committee to study the feasibility of a public-private consortium to conduct technology assessments and, in cooperation with the National Library of Medicine, to create a clearinghouse for information on medical technology assessments.<sup>169</sup>

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166. In the early 1980s, several medical professional groups initiated medical technology assessment efforts. Foote, *supra* note 155; Iglehart, *Another Chance for Technology Assessment*, 309 NEW ENG. J. MED. 509 (1983) [hereinafter *Another Chance*]. The AMA established its Diagnostic and Therapeutic Technology Assessment (DATTA) in 1982. AM. MED. ASS'N, DATTA: AN AMA PROGRAM IN MEDICAL TECHNOLOGY ASSESSMENT (1987); Jones, *The American Medical Association's Diagnostic and Therapeutic Technology Assessment Program*, 250 J.A.M.A. 387 (1983). It was also during this period that the American College of Physicians inaugurated its Clinical Efficacy Assessment Project. Other medical specialty societies have since established comparable programs. See, e.g. AM. COLLEGE OF PHYSICIANS, CLINICAL EFFICACY ASSESSMENT PROJECT: PROCEDURAL MANUAL (1986); AM. COLLEGE OF PHYSICIANS, CLINICAL EFFICACY ASSESSMENT PROJECT, RECOMMENDATIONS 1981-86 (1987); see also LEWIN & ASSOCIATES, *supra* note 33, at Appendix B. In addition, the Blue Cross and Blue Shield Association, working with the American College of Physician, developed its Medical Necessity Program to assess costly, but commonly used, technologies for purposes of determining coverage policies for its own health insurance programs. Letter from Susan Gleason, Executive Director, Technology Management, Blue Cross and Blue Shield Association to Eleanor D. Kinney (Aug. 10, 1987); see LEWIN & ASSOCIATES, *supra* note 33, at B23-B25; see also Centor, Meier & Dalton, *Throat Cultures and Rapid Tests for Diagnosis of Group A Streptococcal Pharyngitis*, 105 ANNALS INTERNAL MED. 892 (1986); Goldberger & O'Konski, *Utility of the Routine Electrocardiogram Before Surgery and on General Hospital Admission*, 105 ANNALS INTERNAL MED. 552 (1986); Raffin, *Indications for Arterial Blood Gas Analysis*, 105 ANNALS INTERNAL MED. 390 (1986); Sox, *Probability Theory in the Use of Diagnostic Tests*, 104 ANNALS INTERNAL MED. 60 (1986); Tape & Mushlin, *The Utility of Routine Chest Radiographs*, 104 ANNALS INTERNAL MED. 663 (1986). Other Blue Cross and Blue Shield plans, as well as commercial health insurance companies, have begun similar programs of varying degrees of sophistication. See LEWIN & ASSOCIATES, INC. *supra* note 33, at B22-B29.

167. See, e.g., Banta & Behney, *supra* note 132; Bunker, Fowles & Schafartzick, *Evaluation of Medical-Technology Strategies: Proposal for an Institute for Health-Care Evaluation*, 306 NEW ENG. J. MED. 687 (1982); Rehlman, *Assessment of Medical Practices: A Simple Proposal*, 303 NEW ENG. J. MED. 153 (1980) [hereinafter Rehlman, *Assessment*]; Rehlman, *An Institute for Health-Care Evaluation*, 306 NEW ENG. J. MED. 669 (1982) [hereinafter Rehlman, *Institute*].

168. See also Rehlman, *Assessment*, *supra* note 167; Rehlman, *Institute*, *supra* note 167.

169. See Brandt, *Technology Assessment, A Private-Public Partnership*, 99 PUB.

#### 4. The Health Promotion and Disease Prevention Amendments

The Health Promotion and Disease Prevention Amendments of 1984 re-established a formal technology assessment function in HHS by expanding the responsibilities of the National Center for Health Services Research. Pursuant to the Amendments, the Center was renamed the National Center for Health Services Research and Health Care Technology Assessment.<sup>170</sup> The Amendments also established the National Advisory Council on Health Care Technology Assessment, composed of officials in other branches of HHS and the federal government as well as outside experts in medicine, engineering, science, law, ethics, economics and management, to advise the Secretary of HHS on developing criteria and methods for making decisions about coverage under the Medicare and federal health insurance programs.<sup>171</sup>

In addition, the Health Promotion and Disease Prevention Amendments of 1984 authorize federal support to the Institute of Medicine to encourage creation of the Council on Health Technology, whose task would be to promote the development and application of appropriate health care technology assessments, to review existing health care technologies to identify obsolete or inappropriately-used technologies, and to fund private sector initiatives in technology assessment.<sup>172</sup>

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HEALTH REP. 329 (1984); Iglehart, *supra* note 166; Marwick, *Legislation Expands Federal Role in Medical Technology Assessment*, 252 J.A.M.A. 3235 (1984). The Institute also conducted a study in 1985, which has been influential in shaping the current debate over how best to conduct technologies assessment from a technical perspective. INST. OF MED., *ASSESSING MEDICAL TECHNOLOGIES* (1985).

170. Pub. L. No. 98-551, 98 Stat. 2815 (1984) (codified as amended at 42 U.S.C. § 242c (1982 & Supp. III 1985)); *see also Health Care Technology Assessment: Hearings Before the Senate Comm. on Labor and Human Resources*, 98th Cong., 2d Sess. 67 (1984); *Health and the Environment, Part 4: Hearings Before the Subcomm. on Health and the Environment of the House Energy and Commerce Comm.*, 98th Cong., 2d Sess. (1984).

171. Marwick, *supra* note 169. Representatives from the Federal government include the Director of NIH, the Chief Medical Director of the Veterans Administration, the Assistant Secretary for Health and Environment of the Defense Department, the Director of the Centers for Disease Control and a representative from HCFA. Pub. L. No. 98-551, 98 Stat. 2815 (1984) (codified as amended at 42 U.S.C. § 242n (1982 & Supp. III 1985)). This council is currently reviewing HCFA coverage policymaking process as it relates to new technologies, and will publish its report in early 1988.

172. *Id.* (codified at Pub. L. No. 98-551, 98 Stat. 2815 (1984), 42 U.S.C. § 242n (1982 & Supp. III 1985)). The Institute and its Council are currently developing a technology assessment initiative to coordinate technology assessment activities in the public and private sectors.

### III. CRITIQUES OF THE MEDICARE COVERAGE POLICYMAKING PROCESS

#### A. *Summary of Critiques*

Criticism of the Medicare coverage policymaking process in recent years has taken various forms, yet sounded some common themes. In 1986, the Administrative Conference of the United States conducted an examination of the Medicare appeals system that resulted in recommendations for reform, particularly dealing with the issue of publication.<sup>173</sup> That issue also arose in the comments to the April 29th Notice by individuals and interest groups, many of whom also commented on the lack of accountability that flows from the absence of publication in the various coverage policymaking processes. Both HHS and OTA have conducted studies of Medicare coverage policymaking process which address these and other concerns. Several additional studies are now underway.

Some of the most vocal criticism has arisen in the context of litigation by beneficiaries and, to a lesser extent, by providers. Several courts have invalidated Medicare coverage policies on the very grounds raised in the comments to the April 29th Notice, and have joined the criticism expressed in studies by the Administrative Conference of the United States and other commentators.<sup>174</sup> Finally, Congress has recently exhibited concern about the publication of coverage and other HCFA policies. In the House budget legislation, there is a provision requiring HCFA to publish such policies.<sup>175</sup>

#### 1. The Administrative Conference of the United States

Following its study of the Medicare appeals system in 1986, the Administrative Conference of the United States recommended reforms in the process by which HHS makes national coverage policy. Responding to comments from diverse interest groups,<sup>176</sup> the Conference

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173. This issue also arose pursuant to the 1987 publication of HCFA's 1987 Notice in the *Federal Register*. See *supra* notes 9-11 and accompanying text. Both HHS and OTA have conducted studies of the Medicare coverage policymaking process, addressing this and other concerns. Several additional studies are currently underway.

174. See *infra* notes 269-99 and accompanying text.

175. H.R. 3545, 100th Cong., 1st Sess., 133 CONG. REC. 8980 (1987).

176. Letter from Gordon Schatz, Assistant General Counsel of the Health Industry Manufacturers Association to Jeffrey Lubbers, Research Director of the Administrative Conference of the United States (Nov. 7, 1986) [hereinafter Schatz letter] (commenting on recommendations to improve the Medicare appeals system by avoiding lack of clarity, apparent duplication and delay in coverage decisions); Letter from John B. Reiss of Dechart Price & Rhoads to Jeffrey Lubbers (Nov. 6, 1986) [hereinafter Reiss letter] (commenting on recommendations to improve the Medicare appeals system); Letter from William Dombi, Attorney for Legal Assistance to Medicare Patients to Deborah Ross, Staff Attorney of the Administrative Conference of the United States

made several recommendations to improve publication of Medicare coverage policies.<sup>177</sup> The Conference urged HCFA to make accessible all standards, guidelines and policies used in coverage decisions, and to allow for public comment on coverage policy if a particular policy has a "substantial impact on the public."<sup>178</sup> The Conference also recommended that HCFA or Congress should require Medicare contractors to publish and make accessible all "insurance industry rules or other screening devices" used in making coverage decisions.<sup>179</sup> Finally, the Conference recommended specific reforms in the process for making national coverage policy.

## 2. The April 29th Notice

In response to HCFA's April 29th Notice, approximately twenty individuals and interest groups submitted comments, including those who represent beneficiaries, physicians, hospitals, health equipment manufacturers and states that follow Medicare coverage decisions in making coverage policy for their Medicaid programs.<sup>180</sup> These comments reflect the most current concerns about the Medicare coverage policymaking process and are summarized below.

### a. *Beneficiary Concerns*

Beneficiaries and their advocacy groups are profoundly critical of the Medicare coverage policymaking process.<sup>181</sup> Beneficiaries are most

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(Oct. 28, 1986) (comments on recommendations regarding the Medicare appeals system); Letter from Alfred Chiplin, Jr., Staff Attorney of the National Senior Citizens Law Center to William Bush of the Administrative Conference of the United States (Nov. 17, 1986) [hereinafter Chiplin Letter] (commenting on a draft of the Medicare appeals system).

177. See Admin. Conference of U.S. Interpretive Rules of General Applicability and Statements of General Policy, 1 C.F.R. §§ 305.76-5 (1987). The Conference suggested that HHS invite comments for all changes in policy that have a substantial impact on the public.

178. Admin. Conference of the U.S. Medicare Appeals, 1 C.F.R. § 305.86-5 (1987). This applies to both Parts A and B.

179. *Id.*

180. Medicaid is a joint federal-state program requiring states to submit and have approved a state plan for medical assistance to the Secretary of HHS in order to qualify for federal funding. 42 U.S.C. § 1396a(a)(10) (1982 & Supp. III 1985). Medicaid is financed out of federal revenues from general appropriations that match state expenditures for the Medicaid program. 42 U.S.C. §§ 1396, 1396(a) (1982 & Supp. III 1985).

181. Letter from Cyril Brickfield, Executive Director of the American Association of Retired Persons to the Health Care Financing Administration (HCFA) of the Department of Health and Human Services (June 26, 1987) [hereinafter Brickfield letter] (commenting on procedures for Medicare services coverage decisions); Letter from Judith Waxman, Managing Attorney of the National Health Law Program, Inc. to HCFA (June 25, 1987) [hereinafter Waxman letter] (commenting on Medicare cov-

concerned with national coverage policy, where sophisticated scientific expertise is not necessary to make the coverage decision, as is the case with limits on coverage of home health benefits, for example, or conventional items of durable medical equipment.<sup>182</sup> Also, several handicapped individuals and advocacy groups criticized Medicare coverage policy for devices used by handicapped individuals. These individuals and groups protested repeatedly that the particular needs of handicapped individuals are not well understood by HCFA.<sup>183</sup> Many of the devices used by handicapped persons represent new and dramatic advances over conventional devices for the same purpose.<sup>184</sup> Yet HCFA declines coverage of many of these devices on the basis of criteria stated in the *Medicare Carriers Manual* that the Medicare program covers the least expensive device that will accomplish the intended purpose and only equipment that is primarily medical in nature.<sup>185</sup> The result of this policy is that the handicapped are often denied benefits of the advances in technologies that overcome disabilities.

Beneficiaries are also concerned about coverage policy made locally by Medicare contractors and the HCFA regional office.<sup>186</sup> The handicapped, in particular, expressed objections to the use of unpublished utilization screens and other policies by Medicare contractors defining frequency, intensity and duration of services for the handi-

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erage determinations process); Letter from Jeffrey Spitzer-Resnick, Director of the Access for Senior Citizens Project of the Center for Public Representation and Catherina A. Lemmer, legal intern to HCFA (June 26, 1987) [hereinafter Spetzer-Resnick letter] (commenting on Medicare coverage decisions).

182. Letter from Sally Hart Wilson & Alfred J. Chiplin, Jr., Staff Attorneys of the National Senior Citizens Law Center to HCFA (June 18, 1986) (commenting on Medicare coverage determinations process).

183. Letter from Steven White, Ph.D., Director of the Reimbursement Policy Division of the American Speech-Language-Hearing Association to William Roper, M.D. Administrator of HCFA (June 8, 1987) [hereinafter White letter] (commenting on procedures for medical services coverage decisions under the Medicare Program); Letter from Albert M. Cook, Ph.D., Director of the Assistive Device Center to HCFA (June 24, 1987) (commenting on Medicare coverage determination procedures); Letter from Joel D. Myerberg, Chairman of the Maryland Advisory Council for Handicapped Individuals to HCFA (June 23, 1987) (commenting on Medicare's procedures for medical services coverage decisions); Letter from C. Gerald Warren, M.P.A., President of RESNA, Association for the Advancement of Rehabilitation Technology to HCFA (June 23, 1987) (commenting on Medicare procedures for coverage determinations); Letter from Mary Binion, Consultant to the Ohio Resource Center for Low Incidence and Severely Handicapped to HCFA (June 26, 1987) [hereinafter Binion letter] (commenting on Medicare coverage decision process); Letter from Rick Creech, user of augmentative communication devices to HCFA (June 23, 1987) (commenting on Medicare coverage determination process).

184. *Id.*

185. *See supra* notes 40-45 & accompanying text.

186. *See supra* notes 29-36 and accompanying text.

capped.<sup>187</sup> Beneficiaries also question the current decentralized policymaking process that results in beneficiaries in different parts of the country getting different benefits.<sup>188</sup> The American Association of Retired Persons was especially vocal on this point, stating:

First, since Medicare is a federal program, Medicare beneficiaries should in general have access to the same broad package of benefits. Carriers should not be permitted to deny coverage in all cases for a benefit when it is covered elsewhere, unless such denial is based on nationally accepted criteria of medical appropriateness and necessity.<sup>189</sup>

In addition, beneficiaries object to the lack of both public and regular procedures for making coverage policy of all types. As discussed below, beneficiaries have challenged HCFA coverage policy judicially on grounds that it has not been properly promulgated under the APA.<sup>190</sup> They are also concerned about HCFA's delays in making coverage policy that relate to new technologies. Beneficiaries claim that these delays effectively mean that they are denied the benefit of new technologies for which they cannot pay.<sup>191</sup>

Beneficiaries are particularly concerned about the criteria that HCFA uses in making and applying national coverage policy. They assert that the statutory criteria of "reasonable and necessary" do not contemplate the criterion of saving the Medicare program costs that beneficiaries believe both HCFA and Medicare contractors use in making coverage policy.<sup>192</sup> Beneficiaries would like to have all criteria for making coverage policy explicit in order to determine whether HCFA has complied with criteria, e.g., cost effectiveness, in making the challenged coverage policy.<sup>193</sup>

Beneficiaries are extremely critical of the new restrictions on administrative and judicial review of national coverage policy contained in the Omnibus Budget Reconciliation Act of 1986,<sup>194</sup> which imposed limits on administrative and judicial review of national coverage deter-

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187. See White letter, *supra* note 183.

188. See *supra* note 181.

189. Brickfield Letter, *supra* note 181.

190. Beneficiary complaints include challenges against HCFA coverage policy because it has not been properly promulgated under the APA. See *infra* notes 365, 391-400 and accompanying text.

191. Telephone interview with Sally Hart Wilson, Staff Attorney of the National Senior Citizens Law Center (Aug. 22, 1987) [hereinafter Wilson interview].

192. Letter from R. Charles Harker, Esq., Director of Government Affairs of the American Physical Therapy Association to HCFA (June... 24, 1987) [hereinafter Harker Letter] (commenting on Medicare coverage process); see also Butler, *supra* note 131; Wilson, *supra* note 131.

193. Wilson interview, *supra* note 191.

194. *Id.*; see also Pub. L. No. 99-509, § 9341, 100 Stat. 2037 (1986) (to be codified at 42 U.S.C. § 1395ff).

minations. Beneficiary advocacy groups argue that if a broad definition of "national coverage determination" is applied, these restrictions sharply curtail the ability of beneficiaries to challenge national coverage policy effectively and virtually vitiate their rights to administrative and judicial review.<sup>195</sup>

Perhaps the greatest concern of beneficiaries regarding administrative and judicial review of Medicare coverage policy is that these policies establish inflexible and categorical prescriptions which apply without regard to mitigating circumstances affecting the individual beneficiary's need for a particular item or service.<sup>196</sup> In light of this situation, beneficiaries find that they can modify the application of an individual coverage policy only upon administrative and judicial review, where the ALJ and the court can invalidate the coverage policy in question or at least conclude that it was inappropriately applied.

However, the new limitations on administrative and judicial review inhibit the ability of ALJs, in particular, and federal judges to review the application of national coverage determinations in individual cases.<sup>197</sup> Furthermore, beneficiaries believe that administrative and judicial review is the most appropriate point for individual beneficiaries to challenge Medicare coverage policy, claiming that neither beneficiaries nor their advocacy groups have the requisite medical expertise to participate in an informed fashion in the formulation of coverage policy.<sup>198</sup>

#### b. *Professional Concerns*

The organized medical profession and other health professional groups objected most to the utilization screens, and other coverage policies of Medicare contractors, rather than national coverage determinations regarding medical technologies and procedures.<sup>199</sup> The concern regarding these screens is that their application with automatic denials of claims exceeding preset norms for frequency, duration or intensity of services effectively constitutes a coverage decision by the Medicare con-

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195. See *supra* note 181 and accompanying text.

196. *Id.*; see also Wilson interview, *supra* note 191.

197. See Waxman letter, *supra* note 181; Wilson interview, *supra* note 191.

198. *Id.*

199. Letter from Deborah M. Prout, Director of Public Policy of the American College of Physicians to HCFA (June 29, 1987) [hereinafter Prout letter] (commenting on process for Medicare coverage determinations); Harker letter, *supra* note 192; Letter from W. Randall Rawson, Director of Governmental Relations of the American Chiropractic Association to HCFA (June 29, 1987) [hereinafter Rawson letter] (commenting on Medicare coverage process); White letter, *supra* note 183; Letter from James H. Sammons, M.D., Executive Vice President of the American Medical Association to William L. Roper, M.D., Administrator of HCFA (June 29, 1987) [hereinafter Sammons letter] (commenting on the HCFA's 1987 Notice); see also Buto interview, *supra* note 64.

tractor that does not account for the specific circumstances of the individual patients involved.<sup>200</sup> Also, physicians and other health care professionals object to the fact that they are generally unaware of these screens and their medical rationale, and thus are unable to tailor their services to beneficiaries to comply with screens that comport with good medical practice. Addressing this issue, the American College of Physicians recommended that "dissemination of coverage policy should be widespread so that providers and patients are not in a position of learning about coverage only when a claim is denied."<sup>201</sup> The College pointed out that dissemination of coverage policy and its medical rationale could be an important means of improving quality of medical care for Medicare beneficiaries as occurred with its Medical Necessity Project conducted with Blue Cross and Blue Shield Association.<sup>202</sup> The College further observed that "dissemination of credible medical information is sufficient to cause significant positive changes in practice patterns."<sup>203</sup> Advocacy groups for the handicapped have pointed out that where the Medicare contractor consulted with local professional groups, coverage policy conformed to better practice standards and was better accepted by providers.<sup>204</sup>

Interestingly, physicians and other health care professionals expressed little concern about the process for making national coverage determinations for medical technologies and procedures. The AMA reports considerable satisfaction with the extant process for making national coverage policy affecting new technologies and enjoys access and influence in the policymaking process because of frequent consultation with OHTA in particular and also with HCFA.<sup>205</sup> Nevertheless, in comments on the April 29th Notice, the AMA strongly supported HCFA's plans to make national coverage determinations "in a more public manner with greater reliance on outside expert opinion."<sup>206</sup>

It was interesting that the AMA and the American College of Physicians supported a pluralistic process for making coverage policy affecting new technologies which allowed Medicare contractors the flexibility to make coverage decisions regarding new technologies.<sup>207</sup>

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200. Prout Letter, *supra* note 199.

201. *Id.*

202. *Id.* The College's Medical Necessity Project, conducted with Blue Cross and Blue Shield, is a model for such an approach.

203. *Id.*

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

205. Telephone interview with William T. McGivney, Ph.D., Director of Technology Assessment, American Medical Association (May 21, 1987).

206. The AMA and the American College of Physicians supported a pluralistic process for making coverage policy affecting new technologies which allowed Medicare contractors the flexibility to make coverage decisions regarding new technologies. Sammons Letter, *supra* note 199; Prout letter, *supra* note 199.

207. Sammons letter, *supra* note 199.



Specifically, the AMA urged that the coverage decisionmaking process be essentially a "bottom-up process" that included both collection and circulation of contractor decisions regarding new technologies and also greater public and physician input into coverage policymaking process:

Since coverage issues are generally raised initially at the carrier level, carriers should continue to have authority to make initial coverage decisions. However, when a new service or technology is involved, the carrier also should be responsible to quickly report the determination to the HCFA Regional Office for broad dissemination of this decision. In this manner, other carriers will have greater information when they consider coverage determinations. The results of local decisions should be collected by the Bureau of Eligibility, Reimbursement and Coverage (BERC) which in turn should have authority to convene consensus panels, as well as utilize the HCFA physician's panel to review coverage determinations. Through such a bottom-up process, the Medicare program can be sensitive to innovation and practice variations that do exist around the country, as well as work toward greater uniformity in coverage. By following this federation-type process, beneficiaries will not be denied coverage for necessary and appropriate medical items or services simply based on where they reside—a condition that exists today.<sup>208</sup>

The American College of Physicians, while generally supportive of national criteria and standards for coverage policy, urged that Medicare contractors retain some flexibility in covering new technologies in order to encourage new innovations in medical diagnosis and treatment.<sup>209</sup> Further, the College emphasized that Medicare contractors be authorized to pay for the new technologies on an interim basis. To assure eventual national uniformity, the College suggested that Medicare contractors be required to report coverage decisions regarding new technologies to HCFA for monitoring and suggested the following coverage review process and the rationale for this process:

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208. *Id.* The AMA also urged that there be greater openness in the coverage policymaking process:

An additional element in coverage determinations that will prove beneficial to both providers and beneficiaries is public and practitioner input into coverage determinations. Such input can be accomplished by allowing more lead time and public involvement in determinations of coverage for new technologies and services. By having such determinations made through a public forum, especially with the use of consensus panels, the health care community will likely be more aware of decisions and the facts upon which they are based, both while they are being considered and when made. Through such a process, beneficiaries will gain through better access to new services and technology. Concurrently, HCFA stands to gain also through fewer waiver of liability payments and greater uniformity throughout the carrier areas.

209. Prout letter, *supra* note 199.

In the development of medial technology, between the experimental stage in which a procedure is not reimbursable and the stage of general application by the practicing physician, which is reimbursable, there is a grey zone in which local carrier flexibility may be desirable. This grey zone is that significant and sometimes long period in which a technology is neither experimental nor ready for wide application, but during which—when performed in certain appropriate setting—the technology may clearly benefit patients. If the local carrier has the flexibility to reimburse the procedure under these limited applications, HCFA could accumulate valuable data that would make a later decision on nationwide reimbursement better informed. We believe that HCFA should allow this flexibility and adopt procedures requiring local carriers to notify the central office of these unusual cases. This in turn should trigger a central monitoring process, so that HCFA can begin to put together information from the carrier together with assessment data from other sources and make a decision on national coverage as quickly as is appropriate.<sup>210</sup>

c. *Hospital Concerns*

Hospital providers also commented on the April 29th Notice.<sup>211</sup> Hospitals share the same concerns as other commentators about the lack of a public process for making Medicare coverage policy which prevents them from meaningful participation in the coverage policymaking process.<sup>212</sup> Hospitals also question whether restricting coverage of certain highly-specialized procedures to certain institutions, as in the case of the heart transplant benefit,<sup>213</sup> is legally permissible or fair.<sup>214</sup>

Hospitals, however, seem to be most concerned about the unpublished coverage policies of PROs and fiscal intermediaries that result in retroactive denials of payment for hospital services when applied. The reason for these objections is that they depart from conventional conceptions of quality care, and hospitals are unaware of these policies before they provide the services in question to Medicare benefi-

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210. *Id.*

211. Letter from Jacquelin Harris, R.N., M.A., C.N.A.A., Director of Professional Services Delaware Valley Hospital Council, Inc. to HCFA (May 28, 1987) [hereinafter Harris letter] (commenting on Medicare program procedure for medical services coverage decisions); Letter from Jack Owen, Executive Vice President of the American Hospital Association to William Roper, Administrator of HCFA (June 29, 1987) [hereinafter Owen letter] (commenting on HCFA's procedures for making medical services coverage decisions).

212. Owen letter, *supra* note 211.

213. Health Care Fin. Admin., Medicare Program; Criteria for Medicare Coverage of Heart Transplants, 52 Fed. Reg. 10935 (1987).

214. Owen letter, *supra* note 211.

ciaries.<sup>215</sup> Regarding these unpublished policies, the American Hospital Association stated:

However, in many cases, Medicare is not enforcing prevailing standards of medical care. They are establishing new standards that providers must infer from their payment denials. Medicare's contractors are not informative about the reasons for these coverage denials. Although PROs are required to notify a provider when a denial is issued, providers only receive general information that is not useful for discerning behavior changes expected by HCFA.<sup>216</sup>

Like physician groups, hospitals observe that this confusion over Medicare coverage policy and particularly its lack of publication makes it difficult for hospitals to know what is expected of them for purposes of future action.<sup>217</sup>

Hospitals also assert that the fact that HCFA has not explained the statutory criteria for coverage, namely, "reasonable and necessary," more specifically or identified explicitly other criteria to be used in making coverage decisions results in insufficient guidance to Medicare contractors for making coverage decisions. Consequently, each Medicare contractor makes different coverage decisions for its own claims with "little agreement and uniformity" with other contractors about coverage of Medicare benefits.<sup>218</sup>

#### d. *Health Equipment Manufacturer Concerns*

Health equipment manufacturers are especially vocal critics of existing procedures for making national coverage policy under the Medicare program.<sup>219</sup> They have expressed two basic concerns. The first concern is how HCFA and Medicare contractors make and apply cov-

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215. Owen letter, *supra* note 211; Harris letter, *supra* note 211.

216. Owen letter, *supra* note 211.

217. *Id.*

218. Harris letter, *supra* note 211.

219. HEALTH INDUSTRY MANUFACTURERS ASSOCIATION, RECOMMENDATIONS OF THE HIMA PRODUCT INTRODUCTION COORDINATION TASK FORCE (May 29, 1986) [hereinafter HIMA RECOMMENDATIONS]; Letter from Frank E. Samuel, Jr., President of the Health Industry Manufacturers Association to Barton McCann, M.D., Chief of the Special Coverage Issues Branch of the Office of Coverage Policy of the Bureau of Eligibility, Reimbursement and Coverage of the Health Care Financing Administration (Jun. 29, 1987) [hereinafter Samuel letter] (commenting on Medicare procedures and criteria for coverage decisions); Letter from Craig Jeffries, Governmental Affairs Counsel of the Foster Medical Corporation to Dr. William Roper, M.D., Administrator of HCFA (Jun. 26, 1987) [hereinafter Jeffries letter] (commenting on procedures for medical services coverage decisions); Letter from David A. Miller, President of the Medical Equipment Distributors, Inc. to the Health Care Financing Administration (Jun. 12, 1987) [hereinafter Miller letter] (commenting on Medicare coverage decision procedures). *See generally* Schatz, *Medicare Coverage of Technology*, HEALTH SPAN, July 1987 at 9.

erage policy regarding durable medical equipment and other more conventional medical devices and equipment and also how contractors determine whether use of a medical device was medically necessary and therefore covered in individual cases.<sup>220</sup> The Health Industry Manufacturers Association, the most vocal advocate for the medical equipment industry, has urged that HCFA should "clarify contractor's authority" to make coverage decisions where no national coverage decision applies and require that all contractors use the same criteria in making their coverage decisions as well as publicize the criteria they use in making coverage decisions.<sup>221</sup>

The second concern of manufacturers is that the OHTA technology assessment process used in making national coverage policy regarding new medical technologies and equipment is duplicative of the mandatory FDA approval process for medical devices under the Medical Devices Amendments of 1976.<sup>222</sup> Specifically, manufacturers assert that the OHTA assessments of the "safety and effectiveness" of new medical technologies for Medicare coverage purposes<sup>223</sup> duplicates FDA review for "safety and effectiveness" under the Medical Devices Amendments of 1976.<sup>224</sup> This duplication, which critics argue is contrary to a statutory directive for coordinating technology assessment in HHS,<sup>225</sup> results in unnecessary and extensive delays in making coverage decisions affecting new equipment and technologies. Further, manufacturers assert that a negative decision for a medical device that has obtained prior FDA approval has significant financial consequences for the manufacturer and arguably may inhibit private development of new medical technologies.<sup>226</sup>

OHTA maintains that its assessments do not duplicate FDA assessments but generally cover only Class I and Class II medical devices for which premarket testing under FDA requirements is not required.<sup>227</sup> OHTA, however, reports that it rarely conducts full technology assessment on a Class III device for which FDA required full premarket testing, except in cases where the medical literature has subsequently questioned the safety or efficacy of the technology. OHTA reports further that most OHTA technology assessments in-

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220. Jeffries letter, *supra* note 219.

221. Samuel letter, *supra* note 219; HIMA RECOMMENDATIONS, *supra* note 219.

222. Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified as amended in scattered sections of 21 U.S.C. (1982 & Supp. III 1985)); *see supra* notes 131-39 and accompanying text.

223. *See* Bucci & Reiss, *Technology Assessment of Medical Devices under Medicare: Who Should Examine "Safety and Effectiveness,"* 40 FOOD DRUG COSM. L.J. 445, 448-49 (1985).

224. *Id.*

225. *See* Bucci & Reiss, *supra* note 223, at 448-49.

226. Samuel letter, *supra* note 219.

227. Carter interview, *supra* note 64.

volve Class I or Class II devices for which no premarket testing is required.

Also, HCFA and OHTA maintain that their inquiry into "safety and effectiveness" of a medical device for purposes of determining Medicare coverage is different than FDA's inquiry in that HCFA and OHTA are concerned about the effectiveness of the device in curing or alleviating disease and FDA is concerned with whether the device performs as the manufacturer represents.<sup>228</sup> Further, OHTA and HCFA contend that their technology assessments regarding Class III devices pertain only to those devices about which questions regarding the continued efficacy of the device suggest that additional study is warranted.<sup>229</sup>

Health equipment manufacturers are also concerned about the non-public and irregular nature of the national coverage policymaking process.<sup>230</sup> These features, manufacturers assert, prevent affected manufacturers from knowing that HCFA is considering coverage policy affecting their products and precludes manufacturers and other interested parties from participating in the coverage policymaking process.<sup>231</sup> Manufacturers complain that HCFA and OHTA take too long in making national coverage determinations, thus limiting the availability of new technologies to Medicare beneficiaries and effectively limiting beneficiaries' access to new technologies since the Medicare program will not pay for a new technology until a national coverage determination is made. Manufacturers want an opportunity for public participation in the HCFA Physicians Panel, publication in the *Federal Register* of coverage issues that the HCFA Physicians Panel will consider, and an opportunity to review OHTA findings and recommendations at the same time they are sent to HCFA since this would give manufacturers an opportunity to influence the HCFA decision on coverage.<sup>232</sup> The Health Industry Manufacturers Association has also argued for the right of manufacturers to appeal adverse coverage decisions to ALJs and the courts.<sup>233</sup>

The call by manufacturers for more defined procedures for making national coverage policy represents a sharp reversal from their former position on this issue. Previously, manufacturers objected to the involvement of the federal government in the technology assessment process in any capacity: they vigorously opposed establishment of the National Center for Health Care Technology in 1978 and supported its

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228. McCann interview, *supra* note 54; Carter interview, *supra* note 64.

229. *Id.*

230. *See supra* note 219 and accompanying text.

231. *Id.*

232. Samuel letter, *supra* note 219.

233. HIMA RECOMMENDATIONS, *supra* note 219.

demise in 1982.<sup>234</sup> Their change in position occurred after inauguration of the prospective payment system for hospitals.<sup>235</sup> Under this payment system, coverage of new technology has more financial significance for hospitals because, if hospitals use a non-covered technology in treating a Medicare patient, fiscal intermediaries and PROs may deny payment for the entire hospital stay rather than just the procedure for which the technology was used.<sup>236</sup> Health equipment manufacturers have difficulty selling major medical equipment to physicians and hospitals without the imprimatur of Medicare coverage, and desire a Medicare coverage policymaking process that assures this imprimatur more expeditiously.<sup>237</sup>

### 3. Government-Sponsored Studies

In response to continued concern about Medicare coverage policy and the process by which it is made, Congress and HHS have conducted and are now working on several studies of the Medicare coverage policymaking process, as well as HHS's technology assessment activities as they relate to that process. HHS has conducted two major studies on Medicare coverage policy.<sup>238</sup> The Congressional Office of Technology Assessment (OTA) has also conducted one study.<sup>239</sup> The

234. Perry, *The Brief Life*, *supra* note 153, at 1098-99; Iglehart, *supra* note 132, at 36.

235. See *supra* notes 103-04 and accompanying text.

236. Buto interview, *supra* note 64.

237. The Medicare program still pays hospitals for capital costs according to cost reimbursement principles, thereby ensuring that hospitals will be paid their capital costs of depreciation and interest expense associated with new equipment. 42 U.S.C. § 1395x(v)(1)(A) (1982 & Supp. III 1985); 42 C.F.R. §§ 405.415-.418 (1985). Thus, hospitals are in a financial position to buy new equipment because the Medicare program will pay most of its share of the interest and depreciation costs on covered items and procedures within limits imposed under the Consolidated Omnibus Budget Reconciliation Act of 1985, Pub. L. No. 99-272, 100 Stat. 161 (1986) (to be codified at 42 U.S.C. § 1395ww(g)(2)). HHS has proposed discontinuing cost reimbursement for capital costs by paying these costs as part of the Diagnosis Related Group (DRG) single payment. 52 Fed. Reg. 18,840 (1987) (to be codified at 42 C.F.R. § 405.412) (capital payments under the inpatient hospital prospective payment system).

238. The two completed studies are: LEWIN & ASSOCIATES, *supra* note 33; MACRO SYSTEMS, *supra* note 33. In addition to the completed studies discussed in the text, several studies remain in progress. For instance, the National Advisory Council to the National Center for Health Services Research and Health Care Technology Assessment is finalizing the results of a study of OHTA technology assessment process used in making coverage decisions for federally-funded health care programs. NATIONAL CENTER FOR HEALTH SERVS. RESEARCH AND HEALTH CARE TECHNOLOGY ASSESSMENT, NATIONAL ADVISORY COUNCIL, COMMITTEE ON MEDICARE COVERAGE PROCESS, STUDY PROTOCOL (1987). Based on the results of this study, the Advisory Council will develop recommendations to improve the technology assessment process for all federally funded health care programs. *Id.*

239. See *infra* notes 255-60 & accompanying text.

National Advisory Council for Health Services Research and Health Care Technology Assessment and the Institute of Medicine's Council on Health Care Technology are now in the process of conducting studies as well.<sup>240</sup> Most of these studies have focused chiefly on the problems and methods of technology assessment, and not on the administrative law issues associated with promulgating and publicizing coverage policy or administrative or judicial review of Medicare coverage policy.

In the most recent study, commissioned by the HHS Office of the Secretary and prepared by Lewin and Associates, Inc., *A Forward Plan for Medicare Coverage and Technology Assessment*,<sup>241</sup> HHS sought to identify and assess options regarding both the appropriate goals and current needs for technology assessment and coverage decisionmaking in HHS and to explore ways to improve the coverage policymaking process without increasing costs.<sup>242</sup> This report identified the problems in the Medicare coverage policymaking process and proposed specific reforms. While the Lewin Report focused on the more technical, non-legal aspects of technology assessment and Medicare coverage policymaking process, it did include a legal analysis of the Medicare policymaking process by Hogan & Hartson.<sup>243</sup> However, this legal analysis did not address issues posed by provisions in the Omnibus Budget Reconciliation Act of 1986.

The Lewin Report identified the following problems with the Medicare coverage policymaking process: widespread uncertainty both in and out of government about the procedures and criteria for making national coverage policy, with no systematic means for public input and no systematic process for identifying technologies to be assessed or for addressing outmoded, unnecessary or overused technologies.<sup>244</sup> Indeed, the Lewin Report emphasized that the Medicare program now pays extensively for ineffective technologies and suggested that a tighter coverage policymaking process could preclude this situation.<sup>245</sup> The report also criticized OHTA for not taking advantage of new methodologies for technology assessment and, given public perceptions of duplication of assessments for medical devices in various federal agencies, maintained that OHTA and HCFA should do more to explain their technology assessment activities and coordinate them more closely with other government agencies.<sup>246</sup> The report also found that Medicare national coverage policy was neither uniformly understood by affected parties

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240. See *infra* notes 261-63 & accompanying text.

241. LEWIN & ASSOCIATES, *supra* note 33.

242. *Id.* at 3.2-9, 5.

243. See Hogan & Hartson Memorandum, *supra* note 17.

244. LEWIN & ASSOCIATES, *supra* note 33, at 3.2-9, 5.

245. *Id.* at 3.18.

246. *Id.* at 5.

nor uniformly implemented by Medicare contractors.<sup>247</sup>

The Lewin report also criticized the lack of more specific criteria for explaining the general statutory criterion of "reasonable and necessary" and questioned whether the criterion of cost effectiveness and limitations on coverage of items or procedures to particular providers were authorized.<sup>248</sup> The Hogan & Hartson legal memorandum maintained that HHS should promulgate a rule outlining the procedures, as well as the criteria, for making national coverage policy and concluded that, if HCFA did so, individual national coverage policies could be considered and promulgated as interpretative rules.<sup>249</sup> In addition, Hogan & Hartson concluded that HCFA could use cost effectiveness as a criterion in making national coverage policy without a statutory amendment, particularly if it promulgated a rule under ¶ 553 of the APA stating that cost effectiveness would be used as a criterion for making coverage policy.<sup>250</sup> Hogan & Hartson also commented on the April 29th Notice, raising many of these and other points and calling generally for a more open coverage policymaking process.<sup>251</sup>

In 1984, HHS commissioned another study of the entire Medicare coverage policymaking process, *Technology Assessment and Coverage Decisionmaking in the Department of Health and Human Services*.<sup>252</sup> This study also identified similar problems with the Medicare coverage policymaking process as the Lewin report, but probed more deeply into the activities of Medicare contractors. The study found that the coverage policymaking process, because primarily reactive, often did not address technologies that might be relevant in terms of cost or quality of care of services to Medicare beneficiaries.<sup>253</sup> This study's findings and recommendations pertained more specifically to the technical deficiencies in making coverage policy, rather than to the procedures for making and disseminating coverage policies. However, the study did indicate a lack of regularity in the procedures for making and disseminating national coverage policy.<sup>254</sup>

The Congressional Office of Technology Assessment conducted a study of the Medicare coverage process in 1982 which also identified problems and recommended reforms in the Medicare coverage policymaking process.<sup>255</sup> This report, *Medical Technology and Costs of the*

247. *Id.* at 6.

248. *Id.*

249. Hogan & Hartson Memorandum, *supra* note 17, at 46.

250. *Id.* at 27.

251. Letter from Robert F. Leibenluft, Earl M. Collier, Jr., Helen R. Trilling & Ann Morgan Vickery to HCFA (Jul. 24, 1987) (comments on Medicare Coverage Process).

252. MACRO SYSTEMS, *supra* note 33.

253. *Id.* at ii, IV-2.

254. *Id.* at iii, IV-2, 3.

255. OFFICE OF HEALTH TECHNOLOGY ASSESSMENT, *MEDICAL TECHNOLOGY*



*Medicare Program*, focused on the impact of technology on Medicare program costs. In addition to recommending changes in payment methods for hospitals and physicians,<sup>256</sup> the report recommended changes in Medicare coverage policy for specific technologies.<sup>257</sup> The report noted that Medicare coverage policies were made primarily in deference to Medicare's statutory principles of not interfering with the practice of medicine and assuring beneficiaries a free choice of providers.<sup>258</sup> The report recommended that the Medicare program depart from this deferential posture in coverage policymaking, in light of its powerful position in the health care system, to promote efficient behavior on the part of providers, and use technology assessment criteria and methodologies that identify cost saving, as well as safe and effective technologies, for Medicare coverage purposes.<sup>259</sup> While an appended report identified some of the irregularities and inconsistencies in the process by which Medicare contractors made coverage policy,<sup>260</sup> the report did not analyze specific process with the procedures for promulgating or publicizing Medicare coverage policy.

There are several important studies in progress. The National Advisory Council to the National Center for Health Services Research and Health Care Technology Assessment is currently conducting a study, to be completed in December 1987, of the current OHTA technology assessment process used in making coverage decisions for federally-funded health care programs.<sup>261</sup> This study is focusing chiefly on the technology assessment process conducted by OHTA. Based on this study, the Advisory Council will develop recommendations to improve the Medicare coverage policymaking process that involves technology assessment for medical technologies and procedures.<sup>262</sup> The Institute of Medicine is also currently conducting a general study of technology assessment including how best to coordinate public and private technol-

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AND COSTS OF THE MEDICARE PROGRAM (1982) [hereinafter COSTS OF THE MEDICARE PROGRAM]

256. *Id.* at 4, 156.

257. *Id.* at 4, 151.

258. *Id.* at 11; *see also* 42 U.S.C. § 1395a (1982 § Supp. III 1985).

259. COSTS OF THE MEDICARE PROGRAM, *supra* note 255, at 86-69 (1982). Specifically, the report urged consideration of cost-benefit analysis and cost-effectiveness analysis analyzed in other OHTA studies, in conjunction with methodologies that assessed the quality of care afforded by a new technology. *Id.* *See* OFFICE OF HEALTH TECHNOLOGY ASSESSMENT, STRATEGIES FOR MEDICAL TECHNOLOGY ASSESSMENT (1982); OFFICE OF HEALTH TECHNOLOGY ASSESSMENT, THE IMPLICATIONS OF COST-EFFECTIVENESS ANALYSIS OF MEDICAL TECHNOLOGY (1980).

260. Delmo, Hammons, Kuder, Rogers & Lynch, *supra* note 33, at 191-205.

261. *Nat'l Center for Health Services Research and Health Care Technology Assessment, National Advisory Council, Committee on Medicare Coverage Process, Study Protocol (1987)*.

262. *Id.*

ogy assessment activities.<sup>263</sup>

### B. *Judicial Challenges to Medicare Coverage Policy*

Beneficiaries and providers, to a lesser extent, have also challenged Medicare coverage policies in court since the inception of the Medicare program. Many of these challenges reflect the concerns about Medicare coverage policy already discussed. However, these challenges have been relatively few, given the statutory barriers that precluded judicial review of Medicare coverage disputes. Until 1986, the Medicare statute only permitted administrative and judicial review of claims under Part A.<sup>264</sup> Other forms of action for judicial review of Part B claims were unavailable because section 205(h) of the Social Security Act barred federal question jurisdiction except when judicial review was otherwise authorized under the Act.<sup>265</sup>

In 1986, two significant events opened up the process for judicial challenge of Medicare coverage policy. First, the United States Supreme Court ruled in *Bowen v. Michigan Academy of Family Physicians*<sup>266</sup> that the statutory bar to federal question jurisdiction did not bar challenges to HHS policies, but rather barred challenges to the amount of Medicare claims.<sup>267</sup> Thus, for the first time since 1965, all Medicare coverage policies are subject to judicial challenge and review. The second event was Congress's authorization of administrative and judicial review of Part B claims, albeit only on a limited basis, in the Omnibus Budget Reconciliation Act of 1986.<sup>268</sup> As already explained, Congress also imposed significant limits on the administrative and judicial review of "national coverage determinations" in that legislation.

Thus, since 1965, judicial challenge to Medicare coverage policy has been limited. Most challenges, particularly in the early years of the Medicare program, involved services for which Part A beneficiaries would sustain substantial financial liability for adverse coverage decisions, for example, denials of skilled nursing or inpatient hospital care.<sup>269</sup> These challenges, it should be noted, also followed the Medi-

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263. See *supra* note 172 & accompanying text.

264. See *supra* notes 109-14 and accompanying text.

265. 42 U.S.C. § 405(h) (1982 & Supp. III 1985). See *Weinberger v. Salfi*, 422 U.S. 749 (1975); see also Goldstein, *The Procedural Impact of Weinberger v. Salfi Revisited*, 31 DEPAUL L. REV. 721 (1982); Comment, *Federal Question Jurisdiction over Medicare Provider Appeals after Weinberger v. Salfi: Toward a Principled Construction of the Statutory Bar*, 65 VA. L. REV. 1383 (1979).

266. 476 U.S. 667 (1986). Suit in this case was brought by Part B providers.

267. *Id.*

268. Pub. L. No. 99-509 § 9341(a)(2)(D), 100 Stat. 2037, 2038 (1986) (to be codified as amended at § 1869, 42 U.S.C. § 1395ff).

269. For cases involving disputes over coverage of services in a skilled nursing facility, see *Mayburg v. Secretary of Health & Human Services*, 740 F.2d 100 (1st Cir. 1984); *Tompkins v. Sec'y of Health & Human Services*, [1986 Transfer Binder]

care program's frank policy change to define skilled nursing services more restrictively and custodial care more expansively in order to control the escalating costs of the skilled nursing benefit.<sup>270</sup>

In recent years, judicial challenges have increasingly involved coverage of specific items or procedures. The first category of cases has challenged coverage policy, including national coverage determinations, regarding new technologies or experimental procedures.<sup>271</sup> For example, in *Heckler v. Ringer*,<sup>272</sup> beneficiaries challenged the application of HCFA's national coverage determination<sup>273</sup> and subsequent HCFA ruling<sup>274</sup> denying coverage for bilateral carotid artery resections used to relieve respiratory distress. The Supreme Court ruled that, pursuant to § 205(h) of the Social Security Act, the federal district court had no jurisdiction to hear these claims since three of the beneficiaries had not exhausted their administrative remedies. The Court ruled further that one plaintiff had no standing to bring suit since he had not yet received

Medicare & Medicaid Guide (CCH) ¶ 35,334 (E.D.N.Y. Mar. 11, 1986); *Mazzella v. Heckler*, [1985-86 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 34,863 (D. Conn. Aug. 18, 1985); *Kuebler v. Secretary of the United States Dep't of Health & Human Services*, 579 F. Supp. 1436 (E.D. N.Y. 1984); *Gerstman v. Sec'y of Health, Educ. & Welfare*, 432 F. Supp. 636 (W.D. N.Y. 1977); *Klofta v. Mathews*, 418 F. Supp. 1139 (E.D. Wis. 1976); *Rine v. Weinberger*, 401 F. Supp. 1134 (N.D. W.Va. 1975); *Chodle v. Sec'y of Dep't of Health Educ. & Welfare*, 368 F. Supp. 389 (N.D. Ill. 1973); *Pippin v. Richardson*, 349 F. Supp. 1365 (M.D. Fla. 1972); *Reading v. Richardson*, 339 F. Supp. 295 (E.D. Mo. 1972); *Ridgely v. Sec'y of the Dep't of Health, Educ. & Welfare*, 345 F. Supp. 983 (D. Md. 1972), *aff'd*, 475 F.2d 1222 (4th Cir. 1973); *Johnson v. Richardson* 336 F. Supp. 390 (E.D. Pa. 1971); *Sowell v. Richardson*, 319 F. Supp. 689 (D. S.C. 1970).

For cases involving disputes over coverage of inpatient hospital services including rehabilitation hospital services, see *Lereum v. Heckler*, 774 F.2d 210 (7th Cir. 1985); *Hultzman v. Weinberger*, 495 F.2d 1276 (3rd Cir. 1974); *Tivan v. Weinberger*, [1979 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 30,001 (D. Mass. Aug. 23, 1979); *Hartman v. Weinberger* [1977 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 27,773 (M.D. PA Jan. 23, 1976); *Westgard v. Weinberger*, 391 F. Supp. 1011 (D. N.D. 1975); *Giove v. Weinberger*, 380 F. Supp. 364 (D. Md. 1974); *Whitman v. Weinberger*, 382 F. Supp. 256 (E.D. Va. 1974); *Schoultz v. Weinberger*, 375 F. Supp. 929 (E.D. Wis. 1974); *Samuels v. Weinberger*, 379 F. Supp. 120 (S.D. Ohio 1973).

270. See *Butler*, *supra* note 131; *Wilson*, *supra* note 131.

271. See, e.g., *Heckler v. Ringer*, 466 U.S. 602 (1984); *Jameson v. Heckler*, [1984-85 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 34,534 (E.D. Cal. Feb. 15, 1985); *Mayfield v. Secretary*, [1976-77 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 27,948 (N.D. Ill. July 1, 1976); *cf. Starnes v. Schweiker*, 748 F.2d 217 (4th Cir. 1984), *cert. denied sub nom.*, *Starnes v. Heckler*, 471 U.S. 1017 (1985) (challenge to reimbursement cap under Part B for computerized tomography scans barred on jurisdictional grounds).

272. 466 U.S. 602 (1984).

273. *Id.* at 614-15.

274. Exclusion from Medicare Coverage of Bilateral Carotid Body Resection to Relieve Pulmonary Distress, 45 Fed. Reg. 71,426 (1980).

the treatment or submitted a claim.<sup>275</sup>

In the most recent suit, *Jameson v. Bowen*,<sup>276</sup> involving an experimental procedure under Part B, the United States District Court for the Eastern District of California denied HHS's motion to dismiss and ruled that *Heckler v. Ringer* and *United States v. Erika, Inc.*<sup>277</sup> did not bar federal question jurisdiction and judicial review of the national coverage policy involved in this case. Subsequently, HHS entered into a settlement in which HHS agreed to publish a description of its procedures for making national coverage decisions.<sup>278</sup>

275. 466 U.S. at 619-22.

276. [1984-85 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 34,534 (E.D. Cal. Feb. 15, 1985); [1988-87 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 36,073 (E.D. Cal. Feb. 20, 1987) (settlement agreement and release of claims).

277. 456 U.S. 201 (1982).

278. *Jameson v. Bowen*, [1986-87 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 36,073 (E.D. Cal. Feb. 20, 1987). The settlement order provided:

This Settlement Agreement and Release of Claims is made and entered into by and between Bernard F. Jameson ("Plaintiff") and Otis R. Bowen ("Defendant").

WHEREAS, there is a bona fide dispute between the parties, and they desire to resolve this dispute without the time and expense of further litigation;

NOW, THEREFORE, in consideration of the foregoing and the mutual covenants contained herein, it is hereby stipulated and agreed, by and between the undersigned, that all of the claims asserted in this case by plaintiff are settled on the following terms:

3. Defendant agrees that the Health Care Financing Administration ("HCFA") will prepare a description of the process that it uses to make Medicare coverage decisions, including decisions as to whether new procedures are not covered because they have not yet have been found to be reasonable and necessary and/or safe and effective. HCFA will publish the description in the *Federal Register* for public comment, and the procedure will allow for public input into the coverage decisionmaking process where appropriate. HCFA will publish the description in the *Federal Register* on or before *May 1, 1987*.

4. Defendant intends to publish a description of the process and criteria it uses to make Medicare coverage decisions, including decisions as to whether new procedures are not covered because they have not yet been found to be reasonable and necessary and/or safe and effective. HCFA intends to publish this description in the *Federal Register* for public input into the coverage decisionmaking process where appropriate. Because this publication will require coordination with approval by other executive agencies, defendant cannot represent that the publication will ultimately occur, or that if the publication occurs, it will occur by a specific date ultimately occur, or that if the publication occurs, it will occur by a specific date.

6. The parties agree that this Settlement Agreement does not constitute in any manner a finding or admission of any violation of applicable law, rule, or regulation by defendant.

The second category of cases includes challenges to coverage of more conventional medical care items such as ambulance services or special types of durable medical equipment.<sup>279</sup> In *Forbes v. Bowen*,<sup>280</sup> for example, a federal district court allowed coverage of physical therapy services provided as part of home health care,<sup>281</sup> on the grounds that HCFA failed to show by substantial evidence that the therapy was not reasonable and necessary.<sup>282</sup> A recently filed case, *Griffith v. Bowen*,<sup>283</sup> challenges the entire "Screening List for Durable Medical Equipment" that HCFA publishes as part of the MEDICARE COVERAGE ISSUES MANUAL,<sup>284</sup> maintaining that the screening list was not promulgated as a rule under the informal rulemaking requirements set forth in section 553 of the APA.<sup>285</sup> One of the primary concerns of plaintiffs in this lawsuit is that the decision of whether an item of deductible medical equipment is covered is made categorically for all patients, and not with reference to the specific needs of individual beneficiaries. As explained above, the handicapped and other beneficiary groups are extremely concerned about national coverage policy pertaining to the "Screening List for Durable Medical Equipment," and other manual provisions regarding similar items.<sup>286</sup>

A third category of coverage cases involves challenges to utilization screens that Medicare contractors have established and use to make Medicare coverage decisions in individual cases.<sup>287</sup> In *Fox v. Bowen*,<sup>288</sup> the United States District Court for the District of Connecticut considered an intermediary-created policy denying coverage of

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*Id.*

279. See *Linoz v. Heckler*, 800 F.2d 871 (9th Cir. 1986) (claimants deserved notice of denial of coverage for ambulance services); *Hatcher v. Harris*, [1985-86 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 34,989 (8th Cir. Sept. 4, 1985) (dismissed on jurisdictional grounds); *Leduc v. Harris*, 488 F. Supp. 588 (D. Mass. 1980) (claim for electronic hospital bed granted).

280. No. CIV-2-86-339 (Jun. 10, 1987).

281. See *supra* note 25 and accompanying text.

282. See *supra* note 280.

283. No. 86-2556-Y (D. Mass. Feb. 1, 1988) (LEXIS, Genfed library, Dist file).

284. See *supra* note 38 and accompanying text.

285. See *infra* notes 328-29 and accompanying text.

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

287. See *Dirksen v. U.S. Dep't of Health & Human Services*, 803 F.2d 1456 (9th Cir. 1986) (request to review denied); *Fox v. Bowen*, [1986 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 35,374 (D. Conn. Apr. 23, 1986) (court has jurisdiction and ruled for plaintiff on challenge to intermediaries improper practices of evaluating claims for physical therapy benefits); see also *Vorster v. Heckler*, No. 84-9700 (C.D. Cal. filed Dec. 20, 1984) (claim to use facts of individual case as opposed to utilization screens); *Duggan v. Bowen*, No. 87-0383 (D.D.C. filed Feb. 17, 1987) (individual patient needs, opinion of the attending physician, and local medical practices are not taken into consideration).

288. [1986 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 35,374 (D. Conn. Apr. 23, 1986).

physical therapy services for (1) non-weightbearing limbs; (2) amputees not being fitted for a prosthesis; and (3) termination of benefits when a patient could walk fifty feet.<sup>289</sup> The court ruled that these intermediary screens were contrary to the Medicare regulations outlining physical therapy services.<sup>290</sup> Thus, the court rejected a scheme whereby an intermediary denies "benefits on the basis of informal presumptions, or 'rules of thumb,' that are applied across the board without regard to the medical condition or therapeutic requirements of the individual patient."<sup>291</sup>

More recently, in *Duggan v. Bowen*,<sup>292</sup> several Medicare beneficiaries, thirteen congressmen, the National Association for Home Care, and several home health agencies filed suit in the United States District Court for the District of Columbia, challenging HHS's "attempted dismantling of the Medicare home health care benefit,"<sup>293</sup> through delegation of the coverage decisionmaking process to Medicare contractors "without adequate supervision or regulatory mandate."<sup>294</sup> The complaint in this action further states:

As a result, Medicare patients and providers of home health care services are faced with irrational and unexplained coverage determinations which fail to take into account and consideration individual patient needs, the attending physician's opinion, and community medical practice. The challenged actions are violating plaintiffs' rights under the Medicare statute, the Administrative Procedure Act, and the United States Constitution. Judicial relief is necessary to prevent further administrative erosion of the home care benefit that Congress has consistently determined is so crucial to the elderly and infirm of this nation.<sup>295</sup>

Most of these cases involve challenges to the coverage policy in question, on grounds either that it constituted a legislative rule not promulgated under notice and comment rulemaking procedures of section 553 of the APA,<sup>296</sup> or that it was not properly publicized under section 552 of the APA.<sup>297</sup> Beneficiary advocacy groups have also maintained that many coverage policies, whether made by Medicare contractors or HCFA, constitute legislative rules that impose new obli-

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289. *Id.*

290. 42 C.F.R. § 409.30-.36 (1987).

291. [1986 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 35,374, at 10,938.

292. No. 87-0383 (D.D.C. filed Feb. 17, 1987).

293. *Id.* at 6.

294. Complaint at 6, *Duggan v. Bowen*, No. 87-0383 (D.D.C. filed Feb. 17, 1987).

295. *Id.* at 6.

296. 5 U.S.C. § 553 (1982 & Supp. III 1985).

297. 5 U.S.C. § 552 (1982 & Supp. III 1985).

gations or limit previous rights, and therefore should be promulgated under the informal rulemaking procedures of section 553 of the APA.<sup>298</sup> In *Duggan*, plaintiffs also claim that HCFA's failure to define coverage policy for home health benefits in regulations or even program instructions, and its failure to guide Medicare contractors in the coverage decisionmaking process, result in a "pattern of home care decision-making" that violates the fifth amendment as well as the APA.<sup>299</sup>

### C. *Major Problems with the Medicare Coverage Policymaking Process*

Several common themes appear throughout the critiques of the Medicare coverage policymaking process and the litigation challenging Medicare coverage policy. From an administrative and constitutional law perspective, the problems with the Medicare coverage policymaking process fall into two categories: (1) problems related to the promulgation and publication of Medicare coverage policy; and (2) problems related to administrative and judicial review of Medicare coverage policy.

#### 1. Common Themes

The most persistent criticism about the Medicare coverage policymaking process for all types of coverage policy is that the procedures and criteria for making coverage policy are not public or publicized. Further, the procedures provide little opportunity for interested parties to participate in the policymaking process or to comment on individual coverage policies. Regarding the process for making national coverage determinations for medical technologies and procedures, critics are concerned about the informality of the structure and composition of the HCFA Physicians Panel, and the irregular and private way in which the panel conducts its business. Further, there is concern that HCFA, as well as Medicare contractors, use covert criteria such as cost effectiveness for making coverage policy that are not publicized or even suggested by the statutory language regarding coverage.

Providers in particular maintain that the nonpublic coverage policymaking process denies HCFA and its contractors a potentially useful partner in the development of coverage policy and even utilization screens. If provider representatives were to participate in the process of developing national coverage policy and utilization screens used by Medicare contractors, these providers would be more supportive of the

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298. See Wilson, *Administrative Procedure Act Provides Basis for Challenges to Medicare Manuals*, 17 CLEARINGHOUSE REV. 1211 (1984).

299. Complaint at 188, *Duggan v. Bowen*, No. 87-0383 (D.D.C. filed Feb. 17, 1987).

policies, and would ultimately conform their practices accordingly.<sup>300</sup> Further, it is virtually impossible to expect providers to conform their practices to coverage policies of which they are completely unaware.

In general, commentators have criticized the decentralized nature of the coverage policymaking process, which encourages Medicare contractors to make coverage policy absent an applicable national coverage policy. Most comments to HCFA's 1987 Notice addressed the role of Medicare contractors in making Medicare coverage policy, and decried the fact that the decentralized policymaking process resulted in different treatment of similarly situated Medicare beneficiaries. Medicare beneficiaries, providers and other affected parties clearly want consistency in coverage policy, and do not seem concerned that such consistency might threaten HCFA's concept of a decentralized policymaking process to accommodate variations in local health resources and medical practices.<sup>301</sup> These concerns are especially pertinent given important recent evidence that regional variations in medical practices are often not justified by conventional standards of medical practice.<sup>302</sup>

Another quite different concern is the nature of most Medicare coverage policies. Specifically, national coverage policies of all types and coverage policies of Medicare contractors, including utilization screens, are stated in absolute and detailed terms, leaving little room for discretion in their application. Thus, these policies are applied to Medicare beneficiaries without regard to the medical needs of the individual beneficiary and without inquiring whether the use of an alternate approach may be cost-effective for the Medicare program in the long run.<sup>303</sup>

In addition, critics contend that the limitations in the Omnibus Budget Reconciliation Act of 1986 regarding national coverage determinations<sup>304</sup> insulate HCFA from accountability for making fair and accurate coverage policy at all levels. Under both the current process

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300. See *supra* notes 199 & 211 and accompanying text.

301. Spitzer-Resneck letter, *supra* note 181 (regulations should include a list of appropriate criteria that all intermediaries and carriers should apply); Binion letter, *supra* note 183 (rapid growth of medical technology calls for a more centralized process); Harris letter, *supra* note 211; Prout letter, *supra* note 199 (HCFA should adopt changes to centralize the decision on whether to cover a new procedure or terminate coverage of inappropriate procedures); Harker letter, *supra* note 192 (intermediaries' and carriers' definitions of "reasonable and necessary" lead to patchwork coverage, and the values of case-by-case determination have not materialized); Brickfield letter, *supra* note 181 (the scope of carrier discretion should be confined to situations in which there is little national medical consensus on the best treatment.)

302. See, e.g., Caper, *Variations in Medical Practice: Implications for Health Policy*, 3 HEALTH AFF. 110 (1984); Wennberg, *Dealing with Medical Practice Variations: A Proposal for Action*, 3 HEALTH AFF. 6 (1984).

303. *Id.*

304. See *supra* notes 112-14.



for making national coverage determinations for medical technologies and procedures, and the extant procedures for administrative and judicial review of Medicare coverage determinations, there are no opportunities at any point—either at the time of promulgation or administrative or judicial review—for beneficiaries and other affected parties to challenge specific coverage policies.

Further, HCFA's statement in its 1987 Notice that national coverage determinations include all coverage policies published in all HCFA manuals raises the question of whether the limitations on administrative and judicial review of national coverage determinations in the Omnibus Budget Reconciliation Act apply to other types of national coverage policies in addition to national coverage determinations regarding medical technologies. The Act itself uses the term "national coverage determination."<sup>305</sup> The legislative history suggests that Congress intended the term to apply only to coverage determinations regarding new medical technologies. The implications of an expansive reading of the statutory language are serious for beneficiaries, since this reading would virtually insulate HCFA from accountability for the definition of Medicare benefits.

## 2. HCFA's Perspective

In analyzing the problems with the Medicare coverage policymaking process and the administrative and judicial review of Medicare coverage policy, it is essential to appreciate HCFA's perspective. HCFA makes a large number of coverage policies annually about various types of services, new types of durable medical equipment and other items, as well as new or questionable procedures and technologies. In addition, the agency operates under a strong mandate to control costs in the Medicare program,<sup>306</sup> yet is constrained in terms of manpower and other resources. Consequently, HCFA needs a policymaking process for all national coverage policy that is fast, inexpensive, and requires minimal manpower.

According to HCFA, the informal rulemaking procedures set out in section 553 of the APA are simply too time-consuming and burdensome for all Medicare coverage policy. In addition, the agency questions whether informal rulemaking would generate the comments from outside groups that would make use of the process worthwhile.<sup>307</sup> HCFA has an enormous agenda of legislative rules to promulgate annually<sup>308</sup> and, like other agencies, requires six months to a year to pro-

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305. See *supra* note 118.

306. Off. Mgmt. & Budget, Budget of the United States Government, FY 1988, 2-10—2-11 (1987).

307. Buto interview, *supra* note 64.

308. Health Care Fin. Admin., FY 1988 Regulations Agenda (1987).

mulgate these rules.<sup>309</sup> It would be virtually impossible for HCFA to promulgate all program instructions that affect coverage of Medicare benefits in the same manner as legislative rules. Moreover, HCFA might be inhibited from providing guidance to beneficiaries and providers on important coverage issues if required to do so through notice-and-comment rulemaking.

Regarding national coverage determinations for medical technologies and procedures, HCFA maintains that opening up the policymaking process to permit public participation in the deliberations of HCFA Physicians Panel or in BERC decisionmaking process would subject HCFA to undue pressure from Congress, health equipment manufacturers and other quarters to cover questionable technologies. It would seem, however, that political pressure is always present and must be dealt with regardless of whether a process is open or closed. In the long run, an open process that also assures medically defensible coverage policy will enable HCFA to withstand unwarranted political pressure more effectively. HCFA defends its need for the restrictions in the Omnibus Budget Reconciliation Act of 1986 on administrative and judicial review of national coverage determinations as necessary to preserve the scientific integrity of the national coverage determinations that are based on highly technical information and judgments.<sup>310</sup>

### 3. Promulgation and Publication

#### a. *Procedures and Criteria*

There are two issues with respect to the promulgation and publication of Medicare coverage policy: (1) whether and how to promulgate the procedures and criteria by which HCFA makes national coverage policy, including national coverage determinations for medical technologies and procedures; and (2) how to promulgate individual coverage policies. As previously noted, HCFA published a notice in the *Federal Register* in 1987 describing the process for making national coverage determinations for medical technologies and procedures and it plans to promulgate a legislative rule establishing the procedures and criteria for making such determinations.<sup>311</sup> It is unclear whether HCFA's proposed rule would also include other types of coverage policy.

The fundamental question is the nature of the policymaking process that should be adopted for making Medicare coverage policy. For instance, when, if ever, should notice-and-comment rulemaking procedures under section 553 of the APA be invoked?<sup>312</sup> Further, what must

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309. See text accompanying *infra* note 425.

310. See *supra* note 175 and accompanying text.

311. Procedures for Medical Services Coverage Decisions; Request for Comments, 52 Fed. Reg. 15,560 (1987).

312. See *infra* notes 360-403 and accompanying text.

HCFA do, if anything, to comply with the requirements for publication of policies in the Freedom of Information Act?<sup>313</sup> Finally, even if these APA provisions do not apply, what are the appropriate procedures for making Medicare coverage policy in a comprehensible, fair and public fashion?

b. *Individual Coverage Policies*

There are numerous problems with the current procedures for promulgating and publicizing individual national Medicare coverage policies. One critical problem with the promulgation and publication of Medicare coverage policy, suggested particularly in the litigation over Medicare coverage policy, is that not all coverage policy is published in the MEDICARE COVERAGE ISSUES MANUAL. It is also contained in other Medicare program manuals such as the MEDICARE CARRIERS MANUAL<sup>314</sup> or bulletins published by HCFA regional offices. Further, not all coverage policy is specifically designated as coverage policy per se. The dispersed character of the designation and publication of Medicare program policies affecting coverage makes it extremely difficult for beneficiaries and their providers to obtain information on what health care services are actually available under the Medicare program.

The publication and promulgation of coverage policies of Medicare contractors are also problematic. Although problems with individual coverage policy<sup>315</sup> do not fall within the scope of this study, these disputes are noteworthy because of the strong concern of beneficiary and providers regarding this type of coverage policy. This is particularly troubling since Medicare contractors generate most of the coverage policy directly affecting beneficiaries, and these policies are never published to beneficiaries or providers.

4. Administrative and Judicial Review

a. *Administrative review*

There are several significant problems with the administrative review process for national coverage policy. One problem of great concern to health equipment manufacturers in particular, is that HHS has no mechanism to trigger administrative reconsideration of a national coverage policy. The accountability of the Medicare administration is consequently compromised since policy becomes effective upon decisions of individuals in lower levels of the bureaucracy. A second problem of particular concern to health equipment manufacturers is that

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313. See *infra* notes 415-18 and accompanying text.

314. HEALTH CARE FIN. ADMIN., MEDICARE CARRIERS MANUAL (1987).

315. Individual coverage policy was the subject of a 1986 recommendation of the Administrative Conference of the United States. See *supra* note 9.

current procedures provide no opportunity for parties other than beneficiaries, and providers in some instances, to appeal a national coverage policy to an ALJ.

The most serious problem regarding administrative review is that the Omnibus Budget Reconciliation Act of 1986 provides that ALJs may not adjudicate national coverage determinations in administrative appeals.<sup>316</sup> This provision represents a substantial curtailment of the authority of ALJs in adjudicating disputes over national coverage determinations, particularly because of the categorical nature of most coverage policy. This limitation may actually eviscerate an effective administrative review process.

#### b. *Judicial review*

One problematic provision in the Omnibus Budget Reconciliation Act requires a court to remand a case back to HHS when the court determines that the record is incomplete or otherwise lacks adequate information to support the validity of a national coverage determination, and to determine only whether a service is a covered benefit upon review of a supplemental record.<sup>317</sup> This provision, because of the resulting time delays before final adjudication on the merits, puts another substantial barrier before parties challenging national coverage policy. While arguably justified because national coverage determinations are based on medical evidence and expertise, this is nevertheless troubling because of the barriers to beneficiaries, providers and other affected groups to influence the promulgation of a national coverage determination and to challenge a national coverage determination in administrative review.

The limitation in the Act on challenges of national coverage determinations for failure to meet publication and promulgation requirements contained in chapter V of the APA is also problematic. Many courts have invalidated Medicare coverage policies for failing to comply with either section 552 or section 553.<sup>318</sup> Thus, the effect of this statutory preclusion is to prevent beneficiaries and providers from enforcing the rights to which they are entitled under the APA, and to insulate HHS from accountability for observing these laws in the Medicare coverage policymaking process.

### IV. PROMULGATION AND PUBLICATION

This section analyzes the requirements for promulgation and publication of the procedures and criteria for making national coverage

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316. See *supra* notes 118-20 and accompanying text.

317. See *supra* notes 118 & 125-26 and accompanying text.

318. See *infra* notes 365-66, 392-400, 416-18 and accompanying text.

policy of all types. This analysis addresses the extent to which section 553 of the APA requires HCFA to observe notice-and-comment requirements in establishing policymaking procedures and criteria for national coverage policy or in promulgating individual coverage policies. The analysis also addresses the requirements mandated by the Freedom of Information Act and the due process clause of the fifth amendment regarding the promulgation and publication of policymaking procedures and criteria as well as individual coverage policies. Finally, this section suggests approaches to promulgation and publication of the procedures and criteria for making all types of national coverage policy that allow for meaningful participation in the policymaking process by affected parties. These approaches also assure effective publication of Medicare coverage policies, especially to Medicare beneficiaries.

A. *Promulgation Requirements under the APA and Social Security Act*

To determine the requirements for promulgation and publication of Medicare coverage policymaking procedures and criteria as well as for individual coverage policies, it is necessary to ascertain how they are defined in the Medicare statute and how they would be characterized under the APA.<sup>319</sup> The Medicare statute does not specifically address the procedures for making coverage policy or the character of individual coverage policies except to impose the limits on administrative and judicial review of national coverage determinations discussed above.<sup>320</sup> The Social Security Act grants HHS authority to promulgate rules to implement the Medicare program by authorizing the Secretary of HHS to "prescribe such regulations as may be necessary to carry out the administration" of the Medicare program.<sup>321</sup> In this statutory provision, Congress accorded HHS sufficient authority to promulgate legislative and interpretative rules and policy statements regarding the Medicare program.<sup>322</sup>

The Social Security Act does identify certain procedures to be followed in promulgating regulations under the Medicare program. Specifically, in the Omnibus Budget Reconciliation Act of 1986 Congress requires that HHS provide a comment period of at least sixty days prior to promulgation of most regulations under the Medicare pro-

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319. 5 U.S.C. § 553 (1982 & Supp. III 1985).

320. See *supra* notes 112-14 and accompanying text.

321. 42 U.S.C. § 1395hh(1) (1982 & Supp. III 1985).

322. See ADMIN. CONFERENCE OF U.S., A GUIDE TO FEDERAL AGENCY RULEMAKING 35 (1983) [hereinafter GUIDE TO FEDERAL AGENCY RULEMAKING] (citing *Batterton v. Marshall*, 648 F.2d 694, 705 (D.C. Cir. 1980)); see also K. DAVIS, ADMINISTRATIVE LAW TREATISE 7.8, at 36-43 (2d ed. 1979) (overview of distinction between legislative and interpretive rules).

gram.<sup>323</sup> Regulations excluded from these requirements are those in which a statute expressly permits issuance with a shorter period for public comment, those required by statute to be issued in interim final form within 150 days of a statutory enactment, or those for which the "good cause" exception of section 553(b)(3)(B) applies.<sup>324</sup> The fact that the limitations on administrative and judicial review of national coverage determinations are contained in the same provision of the Omnibus Budget Reconciliation Act of 1986 establishing these promulgation requirements for Medicare regulations indicates that Congress does not consider national coverage determinations to be legislative rules subject to the notice-and-comment rulemaking procedures of section 553 of the APA.<sup>325</sup>

If the enabling statute is silent, the APA governs the requirements for promulgating and publicizing agency rules and policies. Two APA sections govern agency policymaking. Section 553 outlines the requirements for when a policy or directive should be promulgated as a legislative rule and the procedures that should be followed for making legislative rules.<sup>326</sup> Section 552 outlines the requirements for when and how agencies should publicize their policies, procedures and rules.<sup>327</sup>

### 1. Section 553 Rulemaking Requirements

The procedures for rulemaking under the APA are contained in section 553. For all agency rules except those specifically exempted, section 553 basically requires notice procedures, and provides an opportunity for the public to participate in the rulemaking process "through submission of written data, views, or arguments with or without opportunity for oral presentation."<sup>328</sup>

According to section 553(a)(2), rules involving a "matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts" are exempt from section 553 notice-and-comment rulemaking procedures.<sup>329</sup> Scholars, beneficiaries of government programs, and other observers have not viewed the section

323. 42 U.S.C. § 1395hh(b).

324. 42 U.S.C. § 1395hh(b).

325. See H.R. Rep. No. 1012, 99th Cong., 2d Sess. 350-51 (1986). Congress explicitly states notice-and-comment procedures under the APA are not needed as the process itself offers the same benefits.

326. 5 U.S.C. § 553 (1982 & Supp. III 1985); see K. DAVIS, *supra* note 322, at § 6.10-6.14 (rulemaking procedures are governed by § 553). See generally B. SCHWARTZ, *ADMINISTRATIVE LAW* § 4.6-4.10 (2d ed. 1984); *GUIDE TO FEDERAL AGENCY RULEMAKING*, *supra* note 322, at 16-71 (summary of procedures applying to different types of rules).

327. 5 U.S.C. § 552 (1982 & Supp. III 1985).

328. 5 U.S.C. § 553(c) (1982 & Supp. III 1985).

329. 5 U.S.C. § 553(a)(2) (1982 & Supp. III 1985).

553(a)(2) exemptions favorably.<sup>330</sup> In 1969, the Administrative Conference of the United States recommended that Congress eliminate this exemption and that, in the meantime, agencies be required to use section 553 notice-and-comment rulemaking procedures<sup>331</sup>

Medicare benefits are considered government benefits. Thus, under section 553(a)(2), rules regarding these benefits are exempt from the section 553 notice-and-comment process. In 1971, HEW published a notice in the *Federal Register* stating that it would nevertheless comply with the notice-and-comment rulemaking procedures where otherwise required by section 553.<sup>332</sup> In 1982, HHS published a notice in the *Federal Register* indicating its intention to reject this policy but HHS never formerly rescinded its 1971 policy.<sup>333</sup> In 1986, as noted above, Congress codified this requirement with respect to specified Medicare program regulations.<sup>334</sup>

Section 553 delineates four different categories of rules. For three of these categories—interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice—compliance with section 553 notice-and-comment rulemaking procedures is not required.<sup>335</sup> The fourth category comprises “legislative” rules or “substantive” rules as referred to in section 553(d).<sup>336</sup> These rules are subject to section 553 notice-and-comment rulemaking procedures.<sup>337</sup>

The question of what distinguishes a “legislative” rule from the other rules, for which notice-and-comment is not required, is confounding. This question has troubled agencies, courts, and scholars since the enactment of the APA in 1946.<sup>338</sup> The architects of the APA

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330. See GUIDE TO FEDERAL AGENCY RULEMAKING, *supra* note 322, at 26.

331. Admin. Conference of U.S., Recommendation No. 69-8, Elimination of Certain Exemptions from the APA Rulemaking Requirements, 1 C.F.R. 305.69-8 (1987). See Bonfield, *Public Participation in Federal Rulemaking Relating to Public Property, Loans, Grants, Benefits or Contracts*, 118 U. PA. L. REV. 540 (1970) (the elimination of § (a)(2) exemptions would leave ample flexibility for agencies under other exemptions in § 553); GUIDE TO FEDERAL RULEMAKING, *supra* note 322, at 27-28.

332. Public Participation in Rulemaking, 36 Fed. Reg. 2532 (1971).

333. Administrative Practices and Procedures, 47 Fed. Reg. 26,860 (1982) (HHS stated it would not be held to the notice requirements where the detriment of the delay caused by the notice procedure outweighs the benefit of giving notice); see also *Guide to Federal Rulemaking*, *supra* note 322, at 27 n.44.

334. See *supra* note 323-25 and accompanying text.

335. 5 U.S.C. § 553(b)(3)(A) (1982 & Supp. III 1985).

336. 5 U.S.C. § 553(d) (1982 & Supp. 1985).

337. *Id.*

338. See Asimow, *Nonlegislative Rulemaking and Regulatory Reform*, 1985 DUKE L.J. 381 [hereinafter Asimow, *Nonlegislative Rulemaking*] (A legislative rule completes a legislative design by exercising previously delegated power; an interpretive rule provides guidance to the public and to agency staff and decisionmakers); Asimow, *Public Participation in the Adoption of Interpretive Rules and Policy Statements*, 75 MICH. L. REV. 520 (1977) [hereinafter Asimow, *Public Participation*] (interpretive

offered little explanation of the distinguishing characteristics of these rules in the legislative history.<sup>339</sup> Indeed, the Senate Judiciary Committee declined to define a substantive rule further in the APA, stating that the meaning of the term "substantive" had been "well defined in court decisions and upon principle."<sup>340</sup>

The legislative history of the APA is not otherwise particularly helpful in specifically delineating the character of interpretive rules and policy statements vis-a-vis legislative rules.<sup>341</sup> However, the history does explain Congress' rationale for the different treatment of interpretive

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rules clarifying the meaning of language in statutes or other rules without creating legally binding rights or obligations, and legislative rules prescribe rights or obligations binding on both the agency and the public); Bonfield, *Some Tentative Thoughts on Public Participation in the Making of Interpretative Rules and General Statements of Policy Under the A.P.A.*, 23 ADMIN. L. REV. 101 (1971) (interpretive rules are rules or statements issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers); Davis, *Administrative Rules—Interpretative, Legislative and Retroactive*, 57 YALE L.J. 919, 928 (1948) (legislative rules create new laws while interpretive rules interpret existing ones); Koch, *Public Procedures for the Promulgation of Interpretative Rules and General Statements of Policy*, 64 GEO. L.J. 1047 (1976) (exemptions should be replaced with notions of fairness); Mayton, *A Concept of a Rule and the "Substantive Impact" Test in Rulemaking*, 33 EMORY L. J. 889 (1984) (if the agency in effect instills a cause of conduct in the private sector, it is making a legislative ruling); Warren, *The Notice Requirement in Administrative Rulemaking: An Analysis of Legislative and Interpretive Rules*, 29 ADMIN. L. REV. 367 (1977) (interpretive rules should be subject to notice requirements) [hereinafter *Notice Requirement*]; Note, *An Analysis of the General Statement of Policy Exception to Notice and Comment Procedures*, 73 GEO. L.J. 1007 (1985) [hereinafter Note, *An Analysis of the General Statement of Policy Exception*]; Note, *The Interpretive Rule Exemption: A Definitional Approach to its Application*, 15 IND. L. REV. 875 (1982) [hereinafter Note, *The Interpretive Rule Exception*] (definitional approach, focusing on the agency's authority for issuing the rule and impact in the party's interests); Note, *Administrative Law—The Legislative-Interpretive Distinction: Semantical Feinting with an Exception to Rulemaking Procedures*, 54 N.C. L. REV. 421 (1976) [hereinafter Note, *The Interpretive Rule Exception*]; Comment, *A Functional Approach to the Applicability of Section 553 of the Administrative Procedure Act to Agency Statements of Policy*, 43 U. CHI. L. REV. 430 (1976) (policy statement may reflect the belief that its policy is not yet ripe enough to be formalized in a rule) [hereinafter Comment, *A Functional Approach*].

339. See K. DAVIS, *supra* note 322; Asimow, *Public Participation*, *supra* note 338, at 532-33; Bonfield, *supra* note 338, at 108, 113-114; Note, *An Analysis of the General Statement of Policy Exception to Notice and Comment Procedures*, *supra* note 338, at 1012-15 (Congress did not provide a mechanism to ascertain whether a particular agency pronouncement required notice and comment).

340. SENATE COMM. ON THE JUDICIARY, 79th Cong., 1st Sess., *Legislative History of the Administrative Procedure Act 19* (Comm. Print 1945), *reprinted in* S. Doc. No. 248, 79th Cong., 2d Sess., *Administrative Procedure Act: Legislative History* (1946) [hereinafter S. Doc. No. 248]; see Warren, *Notice Requirement*, *supra* note 338, at 371.

341. FINAL REPORT OF THE ATTORNEY GENERAL'S COMMITTEE AN ADMINISTRATIVE PROCEDURE, S. Doc. No. 8, 77th Cong., 1st Sess. 26-27 (1941) [hereinafter FINAL REPORT]



rules and policy statements—namely to encourage making such rules for guidance of regulated parties. Congress also perceived that interpretive rules and policy statements were subject to more scrutiny upon judicial review.<sup>342</sup>

The distinction between “legislative” rules, for which section 553 rulemaking procedures are required, and exempt “interpretive rules” and “policy statements” has proved difficult for courts to articulate.<sup>343</sup> Agency policies designated as “interpretive” rules, or other exempt rules, often effectively require a regulated party to modify behavior, as would a statute or legislative rule. Legislative rules, on the other hand, also explain and clarify statutes in addition to setting policy for the agency.<sup>344</sup> Thus, courts have developed two tests to distinguish between

342. S. Doc. No. 248, *supra* note 312, at 19; *see also* FINAL REPORT, *supra* note 341, at 100; U.S. DEP'T OF JUSTICE, ATTORNEY GENERAL'S MANUAL ON THE ADMINISTRATIVE PROCEDURE ACT 30 n.3 (1947).

343. *See, e.g.*, *Cabais v. Egger*, 690 F.2d 234 (D.C. Cir. 1982) (substantial impact does not make an action subject to notice and comment if it is otherwise expressly exempt under the APA); *Batterton v. Marshall*, 648 F.2d 694 (D.C. Cir. 1980) (legislative rules implement congressional intent and effective statutory purposes and have the force of law); *Noel v. Chapman*, 508 F.2d 1023 (2d Cir. 1975), *cert. denied*, 423 U.S. 824 (1975) (immigration policy which only allowed aliens married to U.S. citizens to postpone their departure date to obtain a visa exempt under the APA); *Eastern Ky. Welfare Rights Org. v. Simon*, 506 F.2d 1278 (D.C. Cir. 1974), *rev'd on other grounds*, 426 U.S. 26 (1976) (Internal Revenue Service ruling allowing private non-profit hospitals to qualify as “charitable” institutions without requiring them to provide free or reduced rates deemed an interpretive ruling); *Lewis-Mota v. Secretary of Labor*, 469 F.2d 478 (2d Cir. 1972) (policy forcing aliens to show a specific job offer to obtain visa as opposed to pre-certifying certain jobs found to be a legislative ruling); *Texaco, Inc. v. Federal Power Comm'n*, 412 F.2d 740 (3d Cir. 1969) (rule establishing compound interest on refunds under the Natural Gas Act found to be a legislative action); *Pharmaceutical Mfrs. Ass'n v. Finch*, 307 F. Supp. 858 (D. Del. 1970) (regulation that would cause 2,000 drug products to be removed from the market found to have a substantial impact making a legislative ruling); *see Asimow, Public Participation*, *supra* note 338, at 520, 560-73 (courts have found that regulations should be authoritative whether they are labelled legislative or interpretative); *Bonfield*, *supra* note 338, at 108-15 (courts have tendency to give interpretative rules the force of law); *Warren*, *supra* note 338, at 370-73 (legislative rules limited only by the doctrine *ultra vires*, which means it cannot be arbitrary and it must meet the requirements of procedural due process; an interpretative rule is subject to the full plenary review of the court); Note, *The Interpretive Rule Exemption*, *supra* note 338, at 875-77 (the courts have fashioned vague, confusing, and often conflicting criteria for distinguishing interpretative from legislative rules); Note, *An Analysis of the General Statement of Policy Exception*, *supra* note 338, at 1007-08 (the general statement of policy exception has proved troublesome to the courts due to the absence of congressional clarification).

344. *See Asimow, Public Participation*, *supra* note 338, at 530 (it is often difficult to distinguish interpretative rules from legislative rules except by recourse to the agency's label); *Asimow, Nonlegislative Rulemaking*, *supra* note 338, at 384 (legislative and interpretative rules both interpret the meaning of a statute, and both prescribe how an agency will exercise discretionary power; thus, it is difficult to place certain rulings in pigeonholes); Note, *An Analysis of the General Statement of Policy Excep-*

the legislative and interpretive rules or policy statement rules—a legal effect test which looks to whether the ruling alters the legal rights of members of the public, and the substantial impact test, which assesses the public's need to participate by notice-and-comment.<sup>345</sup>

The first and more widely-accepted test is the so-called “legal effect” test. This test looks at how the agency designated its rule initially, and whether the rule “makes ‘new law,’ as opposed to merely interpreting ‘existing law.’”<sup>346</sup> A rule has a “legal effect” if it “fills a statutory gap by imposing a standard of conduct, creating an exemption from a standard of conduct, erecting a new regulatory structure, or otherwise implementing congressional policy by completing an incomplete statutory design.”<sup>347</sup> Another important factor determining whether a rule is legislative under the legal effect test is whether the rule is so inconsistent with the statute or prior ruling that it cannot reasonably be interpreting the statute or prior ruling, but rather is creating new law.<sup>348</sup>

*tion, supra* note 338, at 1009-11 (general statements of policy and substantive rules are not separate and distinct entities, but rather can be seen as an existing continuum; *see also* Comment, *A Functional Approach, supra* note 338, at 432-33. (there is a large area in the middle where it is not clear if the notice-and-comment procedures of § 553 apply).

345. *See* Asimow, *Nonlegislative Rulemaking, supra* note 338 at 393-402 (legal effect, the traditional test, frequently looks to the intention of the agency; substantial impact instead focuses on the number of people affected by the rule); Asimow, *Public Participation, supra* note 338, at 531 (the courts have adopted one of two inconsistent lines of analysis); Note, *An Analysis of the General Statement of Policy Exception, supra* note 338, at 1011 (the courts have developed two models to address the policies favoring public participation while remaining sensitive to the agencies' need to use general statements of policy); Mayton, *Rulemaking, supra* note 338, at 904 (substantial impact is more straightforward, but legal effect is more statutorily sound).

346. Asimow, *Nonlegislative Rulemaking, supra* note 338, at 394; *see also* Mayton, *Rulemaking, supra* note 338, at 904-06 (legislative rules are authoritative interpretations of the statute; interpretative rules and statements of policy are not); *see e.g.*, *Gibson Wine Co. v. Snyder*, 194 F.2d 329 (D.C. Cir. 1952) (legislative rules create law, whereas interpretative rules state what the regulation means). *But see* *Lewis Mota v. Secretary*, 469 F.2d 478 (2nd Cir. 1972) (rulings found to be legislative based on substantial impact on the public).

347. Asimow, *Nonlegislative Rulemaking, supra* note 338, at 394; *see e.g.*, *American Postal Workers Union v. United States Postal Serv.* 707 F.2d 548, 559 (D.C. Cir. 1983), *cert. denied*, 104 S. Ct. 1594 (1984) (the rule does not fill in legislative gaps, but instead merely interprets language already prescribed in detail by Congress); *Cabais v. Egger*, 690 F.2d 234, 239 (D.C. Cir. 1982) (statute broad as Congress intended to permit wide latitude, thus a ruling establishing new detailed mathematical formulae was legislative); *Batterton v. Marshall*, 648 F.2d 694, 705-06 (D.C. Cir. 1980) (ruling that supplied critical variable in statutory formulae deemed a legislative ruling).

348. *See, e.g.*, *Morton v. Ruiz*, 415 U.S. 199 (1974) (secretary's interpretation of statute as to require Indians to live on reservation to receive general assistance found to be legislative ruling, in spite of Secretary's calling it interpretative); *Eastern Ky. Welfare Rights Org. v. Simon*, 506 F.2d at 1290, 1278 (the ruling conforms to prior regulations and thus it is interpretive); *see also* Asimow, *Public Participation, supra* note

Nevertheless, the legal effect test is unsatisfactory because it does not provide a means of distinguishing interpretive rules and policy statements that require changes in conduct of regulated parties and changes in legislative rules.<sup>349</sup> Nor does the test answer the question of whether an interpretive rule establishing new classifications in a statute, as is often the case with Medicare coverage policy, has effectively modified statutory requirements like a legislative rule.<sup>350</sup> Finally, there is some concern that agencies may designate a truly legislative rule as interpretive in order to avoid public participation, to achieve faster promulgation, to permit retroactivity, or to discourage pre-enforcement judicial review.<sup>351</sup>

Dissatisfied with the legal effect test, some courts have adopted the substantive impact test. Under this test, rules that change "existing rights and obligations" are considered legislative rules subject to APA section 553 notice-and-comment rulemaking procedures.<sup>352</sup> These courts conclude that rules are legislative rules under this test if they have a substantial practical impact on a significant body of persons.<sup>353</sup>

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338, at 556-57 (it is difficult to decide if ruling modifies or amends a prior rule when said ruling classifies, distinguishes, or emphasizes the prior rule).

349. Note, *An Analysis of the General Statement of Policy Exception*, *supra* note 338, at 1010 (Section 553 does not differentiate between different degrees of effect to help courts determine when notice is required); Asimow, *Public Participation*, *supra* note 338, at 556-57 (the effect on consumers and competitors may be substantial while the effect on the regulated parties may be illusory).

350. *Id.*; see *infra* notes 396-401 and accompanying text.

351. Asimow, *Public Participation*, *supra* note 338, at 556-57 (a label may have been chosen specifically to avoid public participation, permit retroactivity, and discourage pre-enforcement judicial review).

352. See *Texaco, Inc. v. Federal Power Comm'n*, 412 F.2d 740 (3d Cir. 1969) (Texaco and other oil companies harmed in future because waiver procedure changed, thus notice was required); *National Motor Freight Traffic Ass'n v. United States*, 268 F. Supp. 90 (D.D.C. 1967), *aff'd*, 393 U.S. 18 (1968) (new provision had palpable effects on carriers and shippers, and as such should be published even though no substantive rules are created); *accord* *Pickus v. United States Bd. of Parole*, 507 F.2d 1107 (D.C. Cir. 1974) (rules of agency organization exemption does not include action which goes beyond formality and substantially affects the rights of those over whom the agency exercises authority); *Pharmaceutical Mfrs. Ass'n v. Finch*, 307 F. Supp. 858 (D. Del. 1970) (when proposed regulation has substantial impact on regulated industry, or an important class of the members or the products of that industry, notice and comment should be provided); see also *St. Francis Memorial Hosp. v. Weinberger*, 413 F. Supp. 323 (N.D. Cal. 1976) (involving a Medicare manual payment provision in which the court applied the substantial impact test).

353. See, e.g., *Lewis-Mota v. Secretary of Labor*, 469 F.2d 478 (2d Cir. 1972) (substantial impact on aliens and employers made regulation subject to notice requirements); *Texaco, Inc. v. Federal Power Comm'n*, 412 F.2d at 473 (the law is not minor as it affects numerous natural gas companies and involves large sums of money); *Pharmaceutical Mfrs. Ass'n v. Finch*, 307 F. Supp. at 864 (the ruling is legislative as it has a substantial impact on prescribing physicians, patients, over 2000 drugs, and the drug industry in general); see also Asimow, *Public Participation*, *supra* note 338, at 555-56

This test addresses the fact that interpretive rules often require modifications in conduct, similar to new laws, and that agencies may try to characterize rules as interpretive in order to take advantage of a simpler promulgation process.

The substantive impact test, however, has also failed to provide a mechanism for conclusively distinguishing between legislative rules and interpretive rules or policy statements at the time of promulgation. This is necessary to avoid successful characteristic judicial challenge of an agency regulation by dissatisfied parties, and thus there is uncertainty about the efficacy of a regulation until judicial review.<sup>354</sup> Further, the test is based on vague factors which can be easily manipulated by the parties,<sup>355</sup> and is not "judicially manageable."<sup>356</sup> Finally, as many scholars have observed, the test is fundamentally inconsistent with the exemptions for nonlegislative rules in the APA.<sup>357</sup>

Neither the legal effect test nor the substantive impact test has provided a completely effective mechanism for determining, at the time of promulgation, whether a court will subsequently find a given rule legislative, and therefore subject to promulgation according to the notice-and-comment rulemaking procedures of section 553. In more recent decisions, the United States Court of Appeals for the District of Columbia resolved the issue of whether notice-and-comment rulemaking should have been used by analyzing whether the agency intended the policy to be mandatory and whether there was a significant impact on regulated parties.<sup>358</sup> Nevertheless, it is the intractable problem of

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(critiquing *Eastern Kentucky Welfare Rights Org.*, 506 F.2d 1278 (D.C. Cir. 1974), *rev'd on other grounds*, 426 U.S. 26 (1976), and maintaining that the legal effects test was not effective as the substantial impact test, which would have required notice to adversely affected poor people).

354. Asimow, *Public Participation*, *supra* note 338, at 556-60 (where a rule interprets a previous ruling, there is no principled way to tell if the prior rule has been interpreted or changed); Asimow, *Nonlegislative Rule Making*, *supra* note 338, at 397-401 (notice and comment required if rule has a substantial impact on a significant body of regulated persons).

355. Asimow, *Public Participation*, *supra* note 338, at 556-58.

356. Asimow, *Nonlegislative Rulemaking*, *supra* note 338, at 400 (it is impossible to quantify the variables a court must address to determine if an affect is substantial).

357. *Id.* at 399 (the exemption under the APA seems to contemplate the legal effect test, not the substantial impact test).

358. See, e.g., *National Latino Media Coalition v. FCC*, 816 F.2d 785 (D.C. Cir. 1987) (viewers and listening public who challenged FCC ruling that provided for a lottery if the comparative proceedings for a license ended in a tie, lost as such ruling was deemed interpretative); *Thomas v. State of N.Y.*, 802 F.2d 1443 (D.C. Cir. 1986), *cert. denied*, 107 S. Ct 3196 (1987) (overturned ruling granting relief to states, national environmental groups, and property owners by finding as interpretative a ruling by the EPA which put a duty on administrators to identify states responsible for an acid spill and implement state clean-up); *cf.* *Brock v. Cathedral Bluffs Shale Oil Co.*, 796 F.2d 533 (D.C. Cir. 1986) (a regulation with some binding impact not legislative if

distinguishing between different types of rules that has led commentators to propose new methods for accomplishing a public promulgation process.<sup>359</sup> These new methods allow for effective notice to and input from affected parties for interpretive rules and policy without unduly burdening agencies.

## 2. Procedures and Criteria for Making Medicare Coverage Policy

Regarding the APA requirements for Medicare national coverage policy, the relevant issue is whether the procedures and criteria for making policy constitute a legislative rule subject to the notice-and-comment rulemaking requirements of APA section 553.<sup>360</sup> Generally, agency procedures for making policies which do not constitute legislative rules fall within the exemption for rules of agency organization, procedure, or practice.<sup>361</sup> Nevertheless, the Freedom of Information Act requires that "the nature and requirements of all formal and informal procedures" must be published in the *Federal Register*.<sup>362</sup>

HCFA has assumed that its procedures and criteria for making national coverage policy need not be promulgated as a legislative rule.<sup>363</sup> HCFA has not been specific regarding what particular exemption applies to its procedures and criteria for making national coverage policy, although it would seem that one of the most appropriate would be an agency procedure exempt under § 553(b)(3)(A).<sup>364</sup>

One important case has addressed whether Medicare program procedures fall within the exemption from notice-and-comment rulemaking for agency procedures in section 553(b)(3)(A). In *National Associ-*

the administrator remains free to exercise his discretion).

The Court in *National Latino Media Coalition v. FCC* stated the distinction between legislative and interpretative rules:

[A legislative rule] is a rule that is intended to have and does have the force of law. A valid legislative rule is binding upon all persons, and on the courts, to the same extent as a congressional statute. . . . An "interpretative" rule, by contrast, does not contain new substance of its own but merely expresses the agency's understanding of a congressional statute.

Whether an agency has acted by legislative rule or interpretative rule turns not on "the nature of the questions they address but the authority and intent with which they are issued and the resulting effect on the power of a court to depart from the decision embodied in the rule."

816 F.2d at 787-88 (citing *Joseph v. United States Civil Serv. Comm'n*, 543 F.2d 1140, 1153 n.24).

359. See *supra* note 338.

360. See *supra* note 312 and accompanying text.

361. 5 U.S.C. § 553(b)(3)(A) (1982 & Supp. III 1985).

362. 5 U.S.C. § 552(a)(1)(B) (1982 & Supp. III 1985).

363. See *infra* notes 404-08 and accompanying text.

364. 5 U.S.C. § 553(b)(3)(A) (1982 & Supp. III 1985).

*ation of Home Health Agencies v. Schweiker*,<sup>365</sup> the United States Court of Appeals for the District of Columbia Circuit ruled that a manual instruction published by HCFA that established certain operating procedures was a legislative rule and did not constitute an exempt agency procedural rule under section 553(b)(3)(A) of the APA. The rule established fiscal intermediaries for home health agencies, and discontinued the right of home health agencies to deal directly with HCFA for payment purposes. The court concluded that the instruction was not exempt because it "does substantially affect the rights and interests of freestanding HHAs [home health agencies]" and this exemption does not apply "where the agency action trenches on substantive rights and interests."<sup>366</sup> Medicare coverage policy also trenches on substantial rights and interests because it actually defines the entitlement interest of Medicare beneficiaries participating in the program.

The treatment of criteria is more complex with Medicare coverage policy because HCFA uses criteria that is not specifically stated in the Medicare statute.<sup>367</sup> One important question regarding national coverage determinations for medical technologies and procedures is whether HCFA's acknowledged criteria of "non-experimental" and "widely accepted in the practice" constitute such a departure from the "reasonable and necessary" criteria set out in the Medicare statute that these criteria should be promulgated as a legislative rule.<sup>368</sup>

Another important question is whether the statutory provision in the Public Health Service Act,<sup>369</sup> mandating OHTA to consider safety, efficacy, cost effectiveness and appropriate uses of technology in technology assessments, accords HCFA the authority to base national coverage determinations for medical technologies and procedures on these same criteria.<sup>370</sup> Further, if these criteria are appropriate for making decisions about coverage of new technologies under the Medicare program, is it also appropriate to use them in making coverage policy regarding durable medical equipment and other types of health care

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365. 690 F.2d 932 (D.C. Cir. 1982), *cert. denied*, 459 U.S. 1205 (1983); *see also* *W.C. v. Bowen*, 807 F.2d 1502 (9th Cir. 1987), *petition for reh'g denied and modified*, 819 F.2d 237 (9th Cir. 1987) (court held that motions to review ALJ decisions in Social Security disability are legislative rules subject to APA notice-and-comment rulemaking requirements).

366. 690 F.2d 932, 949 (D.C. Cir. 1982) (quoting in part *Batterton v. Marshall*, 648 F.2d, 694, 708 (D.C. Cir. 1980)).

367. *See supra* notes 21-25 and accompanying text.

368. *See supra* notes 23-24 and accompanying text. Hogan and Hartson's legal analysis of the national coverage policymaking process for the HHS concluded that the "reasonable and necessary" language in § 1862(a)(1)(A) of the Social Security Act encompassed these criteria. Hogan & Hartson, *supra* note 17, at 41-49.

369. 42 U.S.C. § 242n (1982 & Supp. III 1985).

370. 42 U.S.C. § 242c(e)(2) (1982 & Supp. III 1985).

services?<sup>371</sup>

Of greater concern, however, is whether the criterion of cost effectiveness, which has been advocated for use by some observers,<sup>372</sup> must be established in a legislative rule. In their legal memorandum, Hogan and Hartson suggested that the provision in the Social Security Act requiring the Medicare program to deny payment for costs "found to be unnecessary in the efficient delivery of needed health services"<sup>373</sup> provides statutory authority for HCFA to use the criterion of cost effectiveness.<sup>374</sup>

Further, HCFA's policy of limiting coverage of some procedures to those performed in facilities meeting certain established criteria may constitute a substantial departure from the statutory coverage criteria requiring promulgation as a legislative rule.<sup>375</sup> HCFA has adopted this policy for heart transplants only,<sup>376</sup> although some observers have advocated that this approach should apply to other types of procedures and services as well.<sup>377</sup> Nevertheless, this type of coverage policy is a sharp departure from HCFA's past practice and from its avowed policy that the Medicare program should not interfere with the practice of medicine within autonomous institutions.<sup>378</sup> One practical problem with this policy, for instance, is its susceptibility to invalidation under equal protection principles if HCFA treats comparable institutions differently.<sup>379</sup>

HCFA has decided to promulgate a rule under section 553 describing the procedures and criteria for making national coverage determinations.<sup>380</sup> Regardless of whether this step is necessary under the APA, it comports with the recommendations of several studies conducted under the auspices of HHS.<sup>381</sup> Moreover, Hogan and Hartson recommended that HCFA promulgate all criteria for national coverage policy as a legislative rule.<sup>382</sup> They concluded that if HCFA did in fact

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371. See *supra* notes 39-46 and accompanying text.

372. See LEWIN & ASSOCIATES, *supra* note 33, at 4. This HHS-commissioned study strongly recommended that HCFA should use cost-effectiveness as a criterion for making national coverage policy regarding new technologies.

373. 42 U.S.C. § 1395x(v)(1)(A) (1982 & Supp. III 1985).

374. See Hogan & Hartson, *supra* note 17, at 21-22.

375. *Id.* at 30-34.

376. Medicare Program, Criteria for Medicare Coverage of Heart Transplants, 52 Fed. Reg. 10,935 (1987).

377. See LEWIN & ASSOCIATES, *supra* note 33, at 3.23-3.33.

378. 42 U.S.C. § 1395 (1982); see *supra* note 87 and accompanying text.

379. See Hogan & Hartson, *supra* note 17, at 31-32.

380. Jameson v. Bowen, [1986-87 Transfer Binder] Medicare and Medicaid Guide (CCH) ¶ 36,073 (E.D. Cal. Feb. 20, 1987) (settlement agreement and release of claims); see *supra* note 276 and accompanying text.

381. See LEWIN & ASSOCIATES, *supra* note 33, at 3.12; MACRO SYSTEMS, *supra* note 33, at IV-5; *supra* notes 241-54 and accompanying text.

382. Hogan & Hartson, *supra* note 17, at 44.

promulgate all criteria for national coverage policy according to section 553 rulemaking procedures, then individual coverage policies should be deemed interpretive rather than legislative rules.<sup>383</sup> The big question remaining is whether this legislative rule will describe the procedures for making other types of national coverage policy in addition to national coverage determinations for medical technologies and procedures. HCFA's 1987 Notice refers to coverage of "items" as well as "procedures." However, it is unclear what HCFA means by the term "item" and, specifically, whether it meant to include durable medical equipment or any other items used in the treatment of Medicare beneficiaries.

### 3. Individual Coverage Policies and National Coverage Determinations

The critical issue raised by specific coverage policies is whether they constitute legislative rules that must be promulgated under section 553's notice-and-comment rulemaking procedures. If specific coverage policies are legislative rules, then section 553(b) establishes the procedures, although not the criteria, for their promulgation, and there is no need for HHS to establish other promulgation procedures. If specific coverage policies fall within one of section 553's exemptions, then there is a question regarding what promulgation procedures would be desirable to allow adequate input from affected parties in the coverage policymaking process. Finally, there is a question concerning what form of publication must be observed, namely, whether the rule must be published, either in the *Federal Register* or by some other means. HCFA has consistently taken the position that Medicare coverage policies are not legislative rules subject to notice-and-comment rulemaking procedures,<sup>384</sup> rather, they are interpretive rules that merely amplify and explain the basic coverage provision of the Social Security Act.<sup>385</sup> HCFA further maintains that it need not publish all national coverage policies in the *Federal Register*,<sup>386</sup> although in practice it often publishes na-

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383. *Id.* at 50-51.

384. Dep't Health & Human Services, Notice, Administrative Practices and Procedures, 47 Fed. Reg. 26,860 (1982); Dep't Health, Educ. & Welfare, Public Participation in Rulemaking, 36 Fed. Reg. 2532 (1971); *see, e.g.*, *Linoz v. Heckler*, 800 F.2d 871, 875-76 (9th Cir. 1986); *Hatcher v. Heckler*, [1985-86 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 34,989 (8th Cir. Sept. 4, 1985); *John Muir Memorial Hosp., Inc. v. Schweiker*, 664 F.2d 1339 (9th Cir. 1981); *Kron v. Schweiker*, [1982 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 32,136 (E.D. La. Aug. 23, 1982), *modified*, [1983 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 33,105 (E.D. La. Sept. 12, 1983); *Leduc v. Harris*, 488 F. Supp. 588, 591 (D. Mass. 1980).

385. *See supra* note 384.

386. *See Kron v. Schweiker*, [1982 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 32,136, 10,462 (E.D. La. Aug. 23, 1982), *modified*, [1983 Transfer



tional coverage determinations for medical technologies in the *Federal Register* or as HCFA rulings.<sup>387</sup> Congress clearly indicated that national coverage determinations regarding new technologies need not be promulgated as legislative rules because HHS has other effective means to provide notice and opportunity for comment on these determinations.<sup>388</sup>

The question of whether national coverage determinations for medical technologies and procedures and other types of national coverage policies should be promulgated according to the notice-and-comment rulemaking procedures has been litigated.<sup>389</sup> In the few judicial decisions adjudicating the issue, the courts have split. Most decisions uphold the coverage policies on the grounds that they are interpreting statutory provisions.<sup>390</sup> A few courts, in cases involving Medicare hospital payment policies, have ruled that HCFA did not have to comply with notice-and-comment rulemaking in cases involving payment policies for hospitals because the regulations pertained to government benefits and were thus exempt pursuant to section 553(a)(2) of the

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Binder] Medicare & Medicaid Guide (CCH) ¶ 33,105 (E.D. La. Sept. 12, 1983).

387. See *supra* notes 38-39 and accompanying text.

388. See *supra* notes 123-24 and accompanying text.

389. See *infra* notes 390-400 and accompanying text.

390. See, e.g., *John Muir Memorial Hosp., Inc. v. Schweiker* [1981-82 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 31,613 (9th Cir. Nov. 12, 1981); *St. Joseph Hosp. v. Heckler*, 570 F. Supp. 434, 445 (N.D. Ind. 1983); *Leduc v. Harris*, 488 F. Supp. 588, 591 (D. Mass. 1980).

In similar challenges to Medicare payment policies, courts have upheld the applicable manual provisions. See, e.g., *St. Mary's Hosp. of Troy v. Blue Cross & Blue Shield Ass'n*, 788 F.2d 888, 891 (2d Cir. 1986); *Baylor Univ. Medical Center v. Heckler*, 758 F.2d 1052, 1058 (5th Cir. 1985); *Homan & Crimen, Inc. v. Harris*, 626 F.2d 1201, 1210 (5th Cir. 1980), *cert. denied*, 450 U.S. 975 (1981); *Fairfax Nursing Center, Inc. v. Califano*, 590 F.2d 1297 (4th Cir. 1979); *American Med. Ass'n v. Heckler*, 606 F. Supp. 1422, 1439-40 (S.D. Ind. 1985); *Spartanburg Gen. Hosp. v. Heckler*, 607 F. Supp. 635, 643 (D.S.C. 1985); *Bio-Medical Applications v. Heckler*, 593 F. Supp. 1233, 1237 (D.D.C. 1984), *aff'd*, 776 F.2d 365 (D.C. Cir. 1985); *Alexander v. Schweiker*, 516 F. Supp. 182, 188 (D. Conn. 1981); *Humana of Ky., Inc. v. Harris*, [1981-82 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 31,610 (W.D. Ky. Feb. 13, 1981); *Research Med. Center v. Schweiker*, [1981-82 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 31,593 (W.D. Mo. Oct. 8, 1981); *Portland Adventist Med. Center v. Harris* [1981-82 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 31,484 (D. Ore. Feb. 5, 1980); *American Med. Int'l, Inc. v. Secretary*, 466 F. Supp. 605 (D.D.C. 1979), *aff'd*, 677 F.2d 118 (D.C. Cir. 1981); *Harris Hosp. v. Group Hosp. Serv. Inc.* [1979 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 29,910 (N.D. Tex. June 7, 1979); *Hillhaven, Inc. v. Califano*, [1977-78 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 28,733 (D.D.C. Jan. 11, 1978); *Heritage Manor of Chattanooga, Inc. v. Califano* [1977-78 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 28,731 (E.D. Tenn. Nov. 28, 1977); *Sierra Vista Hosp., Inc. v. Weinberger* [1975 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 27,440 (D.C. Cal. May 30, 1975); *Saint Francis Memorial Hosp. v. United States*, 648 F.2d 1305, 1308 (Ct. Cl. May 6, 1981).

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However, the Ninth Circuit did invalidate a national coverage policy for failure to comply with section 553 notice-and-comment rulemaking procedures<sup>392</sup> and, since the Supreme Court's decision in *Bowen v. Michigan Academy of Family Physicians*,<sup>393</sup> which expanded the opportunity for judicial challenges of Medicare coverage policy, there have been several such challenges to other national coverage policies in the federal courts.<sup>394</sup> Many of these cases have challenged the utilization screens and other coverage policy of Medicare contractors on grounds that such policies are effectively legislative rules that should be promulgated under section 553 notice-and-comment rulemaking procedures.<sup>395</sup>

*Linoz v. Heckler*<sup>396</sup> is the only case to date ruling on the merits of whether a national coverage policy must be promulgated pursuant to section 553 notice-and-comment rulemaking procedures. In *Linoz*, HCFA denied coverage of ambulance services for a beneficiary who needed a specialty health service provided by one particular hospital only. The basis for the denial was a *Medicare Carriers Manual* provi-

391. See *Baylor Univ. Med. Center v. Heckler*, 758 F.2d 1052 (5th Cir. 1985); *Good Samaritan Hosp. v. Mathews*, 609 F.2d 949, 953 (9th Cir. 1979); *Humana of S.C., Inc.* 590 F.2d 1070, 1082-84 (D.C. Cir. 1978); *Research Med. Center v. Schweiker* [1981-82 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 31,593 (W.D. Mo. Oct. 8, 1981); *Alexander v. Schweiker*[sic], 516 F. Supp. 182, 183 (D. Conn. 1981); *St. Francis Memorial Hosp. v. United States*, 648 F.2d 1305, 1308 (Ct. Cl. May 6, 1981).

392. *Linoz v. Heckler*, 800 F.2d 871 (9th Cir. 1986); see *supra* note 279 and accompanying text.

393. 476 U.S. 667 (1986).

394. See *Linoz v. Heckler*, 800 F.2d 871 (9th Cir. 1986) (Medicare claimants whose claims for air and ground ambulance transfers were denied, sued for judicial declarations of invalidity in regard to the Medicare carriers manual); *Jameson v. Heckler*, [1984-85 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 34,534 (E.D. Cal. Feb. 15, 1985) (district courts have jurisdiction over claims involving the constitutionality of the procedures that govern the payment of Medicare Part B claims).

There have also been successful challenges to manual provisions regarding payment policies. See, e.g., *Starnes v. Harris*, [1980 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 30,412 (D.S.C. Mar. 6, 1980) (limits on reimbursement for CT head scan have a substantial impact, and therefore must be promulgated under the APA); *Christian Hosp. of St. Louis v. Califano*, [1978 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 28,968 (E.D. Mo. Feb. 28, 1978) (when Commissioner of Social Security prohibited the recognition of gain or loss under section 132E of the PROVIDER REIMBURSEMENT MANUAL, the court concluded this departed from the original section 132 and deprived substantial rights); *Schupack v. Mathews*, [1976-77 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 27,987 (D.D.C. Sept. 17, 1976); see also *National Ass'n of Home Agencies v. Schweiker*, 690 F.2d 932 (D.C. Cir. 1982), *cert. denied*, 459 U.S. 1205 (1983).

395. See *Vorster v. Bowen*, No. 84-9700 (C.O. Cal. filed Dec. 22, 1986); *Griffith v. Bowen*, No. 1728E086 (D. Mass. filed Feb. 13, 1986).

396. 800 F.2d 871 (9th Cir. 1986).

sion that "a physician in a specific specialty does not make that hospital the nearest hospital with appropriate facilities" and the ambulance services in question had not taken the plaintiff to the nearest hospital as defined by the manual.<sup>397</sup> This manual provision was based on a regulation requiring that patients in need of ambulance services be transported to "the nearest institution with appropriate facilities."<sup>398</sup> The Ninth Circuit concluded that the manual provision should have been promulgated as a legislative rule because this rule "withdrew coverage previously provided and thus 'effect[ed] a change in existing law or policy.'"<sup>399</sup> The court reasoned that the policy is, in a literal or formal sense, "interpretive," since it in effect interprets or construes the statutory criteria of "reasonable and necessary" by identifying what would or would not constitute covered Medicare benefits. Nevertheless, the court maintained that because the policy limits benefits by denying coverage for a service that the beneficiary reasonably expected to be reasonable and necessary for the treatment of his disease, the policy is in substance a legislative rule.<sup>400</sup>

Whether Medicare coverage policies are legislative or interpretative rules is an intractable question. Coverage policies define specific items or procedures that are covered under the statutory criteria of "reasonable and necessary."<sup>401</sup> They are interpretative in that they often identify specific examples of items or procedures that the statute criteria of "reasonable and necessary" would or would not encompass as covered Medicare benefits. But because they limit benefits by denying coverage for items and procedures that one might reasonably expect would be reasonable and necessary for the treatment of disease or injury, it can be persuasively argued that they are legislative rules. Any unexpected restriction on benefits has a substantial impact on beneficiaries, and the requisite legal effect in that the Medicare program will not pay for the item or service that the policy says is not covered.

Similarly, *Herron v. Heckler*<sup>402</sup> involved a challenge to an agency manual provision that limited the type of property considered in making eligibility determinations under a Social Security welfare program. A federal district court ruled that these provisions were legislative because they "create[d] precise, objective limitations where none existed before."<sup>403</sup> National coverage policies are analogous to the *Herron* type

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397. HEALTH CARE FIN. ADMIN., MEDICARE PART B CARRIERS MANUAL ¶ 2120.3F (1987).

398. 42 C.F.R. § 405.232(i) (1986).

399. 800 F.2d at 877 (citing *Powderly v. Schweiker*, 704 F.2d 1092, 1098 (9th Cir. 1983)).

400. See *supra* note 16 and accompanying text.

401. See *supra* note 16 and accompanying text.

402. 576 F. Supp. 218 (N.D. Cal. 1983).

403. *Id.* at 231. The claims manual contained language not found in the gov-

of policy. In general, the coverage policies create precise and objective limitations regarding items and services that are used to treat illness or injury that one would not necessarily expect from the general statutory criteria of "reasonable and necessary."

## B. Publication Requirements Under the APA

### 1. Section 552 Publication Requirements

If a rule is not a legislative rule for which section 553 notice-and-comment rulemaking procedures are required, the next issue concerns whether the Freedom of Information Act requires publication, and if so, what type of publication is adequate. The Freedom of Information Act requires publication of agency policies that affect the public.<sup>404</sup> Subsection 552(a)(1)(D) of the Act requires that "substantive rules of general applicability adopted as authorized by law, and statements of general policy or interpretations of general applicability" must be published in the *Federal Register* for "guidance of the public."<sup>405</sup> Similarly, the "requirements of all formal and informal procedures" must also be published in the *Federal Register*.<sup>406</sup> If an agency fails to comply with this publication requirement, the APA provides that "a person in any manner . . . may not be adversely affected" by the unpublished rule or policy unless that person had "actual and timely notice" of the terms thereof.<sup>407</sup> Subsection 552(a)(2) requires that agencies make available for public inspection and copying "those statements of policy and interpretations which . . . are not published in the *Federal Register*" as well as "administrative staff manuals and instructions to staff that affect a member of the public."<sup>408</sup>

Since the enactment of section 552, considerable controversy has developed. This controversy has centered on: (1) when an agency policy statement or interpretive rule is of "general applicability" and should be published in the *Federal Register*; and (2) when making the interpretation or policy statement available for public inspection and copying is sufficient.<sup>409</sup> Several courts have addressed this issue and

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erning statutes or regulations.

404. 5 U.S.C. § 552 (1982 & Supp. III 1985).

405. 5 U.S.C. § 552(a)(1)(D) (1982 & Supp. III 1985).

406. *Id.* at § 522 (a)(1)(B).

407. *Id.* at § 552 (a)(1).

408. 5 U.S.C. § 552(a)(2) (1982 & Supp. III 1985).

409. See COMMITTEE ON GOVERNMENT, OPERATIONS, REPORT TO THE CHAIRMAN, SUBCOMMITTEE ON GOVERNMENT INFORMATION, JUSTICE AND AGRICULTURE, FREEDOM OF INFORMATION ACT: NONCOMPLIANCE WITH AFFIRMATIVE DISCLOSURE REQUIREMENTS (1986) (arguing the significant impact test is inconsistent with the language of the statute and with the intent of Congress); K. DAVIS, *supra* note 322, at § 5.11; Note, *The Freedom of Information Act: A Seven Year Assessment*, 74 COLUM. L. REV. 895 (1974) (examining the significant problems encountered in interpreting the

have attempted to delineate what the term "general applicability" means.<sup>410</sup> In *Lewis v. Weinberger*,<sup>411</sup> the United States District Court for New Mexico crafted the significant impact test to determine when an interpretive rule or policy statement has the requisite general applicability to be published in the *Federal Register*.<sup>412</sup> Other courts have subsequently expanded the test.<sup>413</sup> Nevertheless, courts have had great difficulty developing a workable definition of the word "general" in the requirement for publication, leading one commentator to observe:

The best answer . . . is that probably no judge, no administrator, no practitioner, and no commentator knows the answer. Even though the question of what must be published is so highly practical, the meaning of the FOSA remains about as vague after more than a decade as it was when it was enacted.<sup>414</sup>

## 2. Publication of Medicare Coverage Policy

Medicare beneficiaries and providers have also challenged Medicare coverage policies under section 552.<sup>415</sup> In at least one case, *Kron v. Schweiker*,<sup>416</sup> the United States District Court for the Eastern District

FOIA against the policy backdrop); Comment, *Publication Under the Freedom of Information Act of Statements of General Policy and Interpretations of General Applicability*, 47 U. CHI. L. REV. 351, 352-53 (1980) [hereinafter Comment, *Publication*]; see also Comment, *A Model for Determining the Publication Requirements of Section 552(a)(1) of the Administrative Procedure Act*, 13 U. MICH. J.L. REF. 515, 529-36 (1980) (focusing on the "interpretations of general applicability and "statements of general policy" requirements of the A.P.A.).

Further, there is evidence that agency compliance with the publication requirements of the Freedom of Information Act across the federal government has not been exemplary.

410. See, e.g., *Anderson v. Butz*, 550 F.2d 459, 462-63 (9th Cir. 1977); *Appalachian Power Co. v. Train*, 566 F.2d 451, 455 (4th Cir. 1977); *Lewis v. Weinberger*, 415 F. Supp. 652, 659 (D.N.M. 1976); *Tax Analysts and Advocates v. Internal Revenue Serv.*, 362 F. Supp. 1298, 1303-04 (D.D.C. 1973), *modified on other grounds*, 505 F.2d 350 (D.C. Cir. 1974); Comment, *Publication*, *supra* note 409, at 352-54; K. DAVIS, *supra* note 322, at § 5.11.

411. 415 F. Supp. 652 (D. N.M. 1976).

412. See K. DAVIS, *supra* note 322, at 341, 343-44.

413. See *Saint Francis Memorial Hosp. v. Weinberger*, 413 F. Supp. 323, 329 (N.D. Cal. 1976); see also Comment, *Publication*, *supra* note 409, at 354.

414. K. DAVIS, *supra* note 322, at 341.

415. See *Kron v. Schweiker*, [1983 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 33,105 (E.D. La. Sept. 12, 1983) (injunction granted); *Hooper v. Harris*, [1985 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 34,619 (D. Conn. May 1, 1985) (motion for a specific order granted below); *Cheshire Hosp. v. New Hampshire-Vermont Hospitalization Serv., Inc.* [1981-82 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 31,685 (D.N.H. Dec. 30, 1981) (involving § 552 challenges to Medicare reimbursement manual provisions).

416. [1982 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 32,136 (E.D. La. Aug. 23, 1982), *permanent injunction granted*, [1983 Transfer Binder]

of Louisiana ruled that a beneficiary was not bound by a manual provision defining a skilled nursing facility for coverage purposes because it had not been published in the *Federal Register*. Similarly, in *Harris v. Hooper*,<sup>417</sup> the United States District Court for the District of Connecticut ruled that a bulletin published by a regional office limiting coverage for services in rehabilitation hospitals was not binding because of HCFA's failure to meet section 552 publication requirements.<sup>418</sup>

The question of what type of publication satisfies the requirements for national coverage policy under section 552 is relatively straightforward. The procedures and criteria for making national coverage policy fall within the charge of section 552(a)(1)(B) that the "requirements of all formal and informal procedures" be published in the *Federal Register*.<sup>419</sup> On the other hand, individual national coverage policies of all types arguably come within the purview of section 552(a)(1)(D), which requires that "substantive rules of general applicability adopted as authorized by law, and statements of general policy or interpretations of general applicability" be published in the *Federal Register*.<sup>420</sup>

### C. *Suggested Approaches to Effective Promulgation and Publication*

The debate over whether the character of Medicare coverage policies mandates promulgation as a rule under section 553 or publication in the *Federal Register* under section 552 misses the point in many ways. It is questionable whether notice-and-comment rulemaking procedures provide aged and disabled beneficiaries, as well as the providers that serve these beneficiaries, an effective means of influencing medical and other questions associated with the formulation of national coverage policy. Further, there is question whether publication of policies in the *Federal Register* accomplishes the objective of informing all Medicare beneficiaries, particularly the sick and disabled who are most in need, about coverage of the health care services they need. The real challenge concerns how to establish a promulgation process which allows appropriate input from beneficiaries, providers and other affected parties, and which ensures that beneficiaries and providers are adequately informed about coverage policy. Whether the APA promulgation and publication procedures are really designed to accomplish these objectives in the case of Medicare coverage policy is an open question.

The issue with respect to beneficiaries is complex. Beneficiaries are

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Medicare & Medicaid Guide (CCH) ¶ 33,105 (E.D. La. Sept. 12, 1983).

417. [1984 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 33,527 (D. Conn. Sept. 20, 1983).

418. [1984 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 33,527 (D. Conn. Sept. 20, 1983), *motion for more specific order granted*, [1985 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 34,619 (D. Conn. May 1, 1985).

419. 5 U.S.C. § 552(a)(1)(B) (1982 & Supp. III 1985).

420. *Id.* at § 552(a)(1)(D).

the most important group of concern because they are the only parties that have a constitutionally protected interest in Medicare benefits.<sup>421</sup> Most Medicare coverage policy primarily involves medical questions beyond the expertise of Medicare beneficiaries.<sup>422</sup> Thus, it is doubtful how much influence individual Medicare beneficiaries possess in the formulation of Medicare coverage policy even if they have notice and an opportunity to comment. Beneficiary advocacy groups, at best, can only assure that appropriate medical input is provided in the policymaking process.

Publication is a similarly complex issue. Clearly, most beneficiaries are not devotees of the *Federal Register*, so even the most rigorous publication requirements under section 552 would not guarantee that individual beneficiaries will acquire the relevant information about coverage to govern their decisions in obtaining health care services.<sup>423</sup> Furthermore, even if beneficiaries are informed about Medicare coverage policies, they do not exercise final control of the benefits that are actually provided to them. Rather physicians and other providers make such decisions.<sup>424</sup> Likewise, most physicians are not devoted readers of the *Federal Register*.

Clearly, any publication requirements imposed upon the policymaking process must assure the desired results without impeding the formulation of coverage policy in an efficient, inexpensive and timely fashion. Under section 553, notice-and-comment rulemaking procedures are both time and resource consuming processes. Agencies often take several months to promulgate legislative rules under this process.<sup>425</sup> Many commentators oppose the adoption of notice-and-comment rulemaking procedures for interpretive and other exempt rules because such requirements would effectively inhibit agencies from clarifying statutory language or publicly stating agency policy on future statutory interpretations.<sup>426</sup> Requiring HCFA to promulgate all national coverage policy pursuant to section 553 notice-and-comment rulemaking procedures could conceivably inhibit HCFA's ability to make national coverage policy, thereby leaving coverage policymaking strictly to Medicare contractors. This result would be contrary to the expressed desires of many parties who commented on HCFA's 1987

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421. See *O'Bannon v. Town Court Nursing Center*, 447 U.S. 773, 789-90 (1980); *Gray Panthers v. Schweiker*, 652 F.2d 146, 166-67 (D.C. Cir. 1980).

422. See *supra* notes 26-39 and accompanying text.

423. Communicating information about benefits, coverage and other matters regarding the Medicare program to beneficiaries is a difficult problem about which HCFA, Congress and the courts have exhibited concern. See Kinney, *supra* note 9, at 133.

424. Wilson interview, *supra* note 191.

425. Asimow, *Public Participation*, *supra* note 338, at 530.

426. See *supra* note 338.

Notice.<sup>427</sup>

Nevertheless, the Medicare coverage policymaking process should still comport with the general promulgation and publication requirements of the APA, and result in policies that can withstand subsequent attack and invalidation upon judicial review for failure to comply with the APA. Although Congress sought to insulate national coverage determinations in the Omnibus Budget Reconciliation Act of 1986,<sup>428</sup> it does seem that more artful ways exist for ensuring judicial approval of the Medicare coverage policymaking process than bluntly cutting off the right to challenge the process because it fails to comply with extant legal requirements.

Similar concerns have surfaced in other areas of administrative law regarding policy promulgation processes that are fair to affected parties but can withstand challenges under sections 552 and 553 of the APA. What has emerged in administrative law scholarship, often through the leadership of the Administrative Conference of the United States, are examinations of new approaches to policymaking. These approaches ensure proper promulgation and publication procedures under the APA, but also facilitate meaningful input into the formulation of policy by affected parties as well as genuinely effective publication of that policy to affected parties. Some of these approaches attempt to obtain the cooperation of the affected parties in formulating and accepting policy thereby avoiding subsequent judicial challenge.

### 1. Post-adoption Publication

In 1976, the Administrative Conference of the United States concluded that it is difficult to distinguish between legislative rules and interpretive rules or policy statements.<sup>429</sup> The Conference concluded that the legal effect and the substantial impact tests are not successful in accomplishing this distinction.<sup>430</sup> The Conference adopted a recommendation that agencies publish all interpretive rules of general applicability before promulgation or if unfeasible, publish such rules and policy statements post-adoption to permit public comment notwithstanding the requirements of the APA.<sup>431</sup> Clearly, HCFA is well advised to publish national coverage policies in the *Federal Register* following promulgation in order to obtain comments regarding the practical implications of the policy, and the medical validity of its decisions.

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427. See *supra* note 301 and accompanying text.

428. See *supra* notes 118, 121-24 and accompanying text.

429. Interpretive Rules of General Applicability and Statement of General Policy, 1 C.F.R. § 305.76-5 (1987).

430. *Id.*; see Asimow, *Public Participation*, *supra* note 338, at 573.

431. *Id.*



Post-adoption publication, however, does not address the entire problem of the Medicare policymaking process, particularly the problem of apprising beneficiaries of national coverage policies that affect their medical care. More creative approaches are needed, such as active involvement of all interested parties at the national and local levels in a public and accessible fashion. A publication that identifies all Medicare coverage policy and that is genuinely accessible to Medicare beneficiaries and providers is also necessary.

## 2. Negotiated Rulemaking

One approach to rulemaking that could serve as a model for the Medicare coverage policymaking process is negotiated rulemaking. The concept of negotiated rulemaking involves convening the major interests affected by a proposed regulation, before the agency issues a proposed rule, and endeavoring to ongoing interested parties in a negotiation that develops a consensus on an acceptable rule that accommodates all legitimate concerns.<sup>432</sup> Negotiated rulemaking has been used successfully in a number of contexts,<sup>433</sup> and has the advantage of allowing affected parties to participate in the formulation of the rule. The parties do not merely submit comments on a proposed rule. They actually negotiate the contents of the draft rule with the agency in a dialogue directed by a mediator.<sup>434</sup> The Administrative Conference<sup>435</sup> and other commentators<sup>436</sup> perceive negotiated rulemaking as a positive alternative to the protracted litigation that often follows informal rulemaking under section 553 of the APA.<sup>437</sup>

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432. Breger, *Thoughts on Accountability and the Administrative Process*, 39 ADMIN. L. REV. 399, 413 (1987); see Harter, *Negotiating Regulations: A Cure for Malaise*, 71 GEO. L.J. 1, 28-31, 52-53 (1982); Perritt, *Negotiated Rulemaking Before Federal Agencies: Evaluation of Recommendations by the Administrative Conference of the United States*, 74 GEO. L. J. 1625, 1637-38 (1986); Popper, *An Administrative Law Perspective on Consensual Decisionmaking*, 35 ADMIN. L. REV. 255, 258 (1983); Susskind & McMahon, *The Theory and Practice of Negotiated Rulemaking*, 3 YALE J. ON REG. 133, 136-37 (1985); Note, *Rethinking Regulation: Negotiation as an Alternative to Traditional Rulemaking*, 94 HARV. L. REV. 1871, 1876-78 (1981); see also Reich, *Regulation by Confrontation or Negotiation?*, 59 HARV. BUSINESS REV. 82 (May-June 1981); Schuck, *Litigation, Bargaining, and Regulation*, 3 REG. 26, 31 (July-Aug. 1979).

433. See Harter, *Regulatory Negotiation: The Experience So Far*, RESOLVE 1 (Winter 1984); Perritt, *supra* note 432.

434. See Harter, *supra* note 432, at 52; Popper, *supra* note 432, at 280-81; Susskind & McMahon, *supra* note 432; Perritt, *supra* note 432, at 1644-45.

435. Procedures for Negotiating Proposed Regulations, 1 C.F.R. § 305.82-4 (1987); Procedures for Negotiating Proposed Regulations, 1 C.F.R. § 305.85-5 (1987); see Harter, *supra* note 432, at 259; Perritt, *supra* note 432, at 1634.

436. See, e.g., Susskind & McMahon, *supra* note 432, at 134; Popper, *supra* note 432, at 259; Schuck, *supra* note 432, at 34.

437. See *supra* note 432.

Negotiated rulemaking was designed chiefly as a tool for legislative rulemaking, but the concept has much to offer HCFA policymaking process for all types of national coverage policy.<sup>438</sup> The interested parties, which include beneficiaries, providers, and HCFA representatives, could convene for a structured discussion prior to promulgation of major national coverage policies. HCFA should be an active participant in such a discussion. HCFA alone is fiscally responsible for the Medicare program and thus has the objective, not shared by beneficiaries, providers or other affected groups, of containing program costs. Also, unlike the conventional regulatory agencies and regulated industries, HCFA is the major payer for health care services<sup>439</sup> and an active participant in the health care industry. However, negotiated regulation theorists condition that there must be a reasonable expectation that the agency will implement the negotiated rule to ensure continued participation of the parties in the negotiation process.<sup>440</sup>

The negotiated rulemaking process is desirable for several reasons. First, this approach would ensure that Medicare coverage policies reflect up-to-date medical practices, and that provider groups not only acquiesce in, but even concur with, the coverage policy. In addition, participating in negotiations would serve as an impetus for provider groups to educate their members about Medicare coverage policy and its rationale. Providers would be encouraged to conform their treatment of Medicare beneficiaries accordingly, thereby diminishing beneficiaries' unanticipated exposure to financial liability for uncovered services.

Further, the negotiation process might force beneficiaries and providers to confront the cost problems posed by excessive utilization of services. Providers would be encouraged to identify ways to practice more efficiently and beneficiaries would be encouraged to use services in a more cost-effective manner. The negotiation process would also be consistent with the objectives of ensuring public participation in agency policymaking to ensure more agency accountability for policy and exercise of agency discretion in implementing broad statutory mandates.<sup>441</sup> Last but not least, negotiated rulemaking would improve relations between the HCFA, beneficiaries and providers, thereby reducing the in-

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438. See Stewart, *Reformation of American Administrative Law*, 88 HARV. L. REV. 1667 (1975) (recommending a comparable negotiation for agency policies that are not promulgated as legislative rules); see also Crampton, *The Why, Where and How of Broadened Public Participation in the Administrative Process*, 60 GEO. L. J. 525 (1972); Sinaiko, *Due Process Rights of Participation in Administrative Rulemaking*, 63 CAL. L. REV. 886 (1975); Comment, *Public Participation in Federal Administrative Proceedings*, 120 U. PA. L. REV. 702 (1972).

439. The Medicare program pays 17% of all health care expenditures. Waldo, Levit and Lazenby, *supra* note 2, at 8.

440. See *supra* note 338.

441. See Stewart, *supra* note 438, at 1575.

vidence of protracted litigation over HCFA coverage policy.

### 3. Other Suggested Reforms

Notwithstanding whether HCFA borrows from the negotiated rulemaking concept to reform the Medicare coverage policymaking process, there are other important reforms that could be implemented to improve the process. Without HCFA's incurring additional costs, the policymaking process could be more regular, public and expeditious. Further, the criteria for making all Medicare coverage policy, including policy made by Medicare contractors, must be identified and publicized. HCFA has recognized the need for these reforms in its plans to promulgate a rule under the notice-and-comment rulemaking procedures of section 553.<sup>442</sup>

For policies involving questions about new or questionable technologies that are referred to OHTA for a full assessment, the notice-and-comment procedures are quite extensive. As a practical matter, these requirements probably meet section 553 notice-and-comment rulemaking requirements except in one major respect. OHTA does not publish its proposed coverage recommendations in the *Federal Register* before HCFA acts on recommendations and makes a final national coverage determination. HCFA and OHTA should reconsider this practice as it precludes the opportunity for affected parties to comment on the recommendation before policy is made. The other major criticisms of OHTA's technology assessment process concern technical issues of the agency's methodologies, and whether OHTA's assessments are duplicative of other federally-sponsored assessments.

For national coverage determinations for medical technologies and procedures referred to the HCFA Physicians Panel only, an opportunity for parties to express their views to the panel in a regular and public process is needed. HCFA could release a notice of a public meeting of the panel with a brief agenda in the *Federal Register*. Because HCFA does not always know what items will be discussed by the HCFA Physicians Panel until shortly before a meeting, interested parties could have the obligation of obtaining the specific agenda items from HCFA as the meeting date approaches.

For policies not involving complex medical decisions, as is the case with most policies concerning durable medical equipment used by the disabled and handicapped, and national coverage policy outlining specific coverage in limiting home health, skilled nursing home and many other broad categories of medical service, there is a need for identification of the decisionmakers within HCFA as well as a means for public input into the formulation of this type of coverage policy. It should be

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442. 52 Fed. Reg. 15,560, 15,562 (1987) (delineating the procedure and criteria for making national coverage determinations).

emphasized that this type of coverage policy affects far more people than the twenty to thirty policies per year concerning new or questionable technologies, and thus the procedures for making and publicizing these decisions are of critical importance. Because the policymaking process regarding this type of coverage policy is diffuse and not structured like the process for new technologies, such as OHTA or HCFA Physician Panel referrals, it is difficult to conceptualize an efficient process for obtaining public input before promulgation of these policies.

To address this particular problem as well as to identify concerns and problems with all types of national coverage policies as soon as possible, publication of all national coverage policies in the *Federal Register* after promulgation pursuant to Recommendation 76-5 of the Administrative Conference would be useful.<sup>443</sup> The post-adoption publication would also function as an administrative reconsideration process.<sup>444</sup>

Finally, it is critical that HCFA develop a publication system for national coverage policy of all types that is genuinely accessible to Medicare beneficiaries. HCFA should endeavor to enumerate all national policies affecting coverage of Medicare benefits in one index, and create or utilize a form that is accessible to Medicare beneficiaries.<sup>445</sup> Currently, HCFA organizes its policies and instructions on all matters in manuals compiled solely for Medicare contractors and providers. At present, no comparable manual or index for beneficiaries exists that would enable beneficiaries to find applicable coverage policy in other manuals. Thus to determine coverage of services in a given case, beneficiaries and providers must made through the maze of HCFA to find the applicable coverage policy—a formidable task indeed.

## V. ADMINISTRATIVE AND JUDICIAL REVIEW

This section examines the current procedures for administrative and judicial review of national coverage policies and their application to individual beneficiaries. The analysis focuses primarily on the critical issues raised by the limits on the administrative and judicial review of national coverage determinations that Congress imposed in the Omni-

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443. See *supra* notes 429-30 and accompanying text.

444. Many parties have pressed for this type of reform, particularly the health equipment manufacturers.

445. Letter from Professor Maxwell J. Mehlman, Case Western Reserve University School of Law to Jeffrey Lubbers, Research Director, Administrative Conference of the United States (Oct. 22, 1987). One commentator has suggested that a solution to this publication problem might be as simple as contracting with a commercial enterprise such as Commerce Clearinghouse to publish Medicare program policies. In addition, HCFA could create a central process by which all policies affecting Medicare beneficiaries would be identified.

bus Budget Reconciliation Act of 1986.<sup>446</sup> Further, the analysis will review specific issues regarding administrative and judicial review of national coverage policy raised in the comments to the HCFA's 1987 Notice and the Medicare appeals study of the Administrative Conference of the United States.

The central issue in this examination is what do current principles of administrative and constitutional law require regarding opportunities for affected parties to challenge Medicare coverage policy through administrative and judicial review. In particular, the relevant issue can be narrowed to an inquiry of whether the restrictions on administrative and judicial review of national coverage policy in the Omnibus Budget Reconciliation Act comport with requirements of procedural due process. This analysis will not consider the general question of whether current administrative and judicial review procedures by which beneficiaries and other affected parties can challenge coverage policy for failure to meet procedural due process requirements. The Supreme Court and several lower courts have upheld the constitutionality of the administrative and judicial review structure of Medicare coverage and payment disputes, even before the Omnibus Budget Reconciliation Act of 1986 extended administrative and judicial review to Part B claims.<sup>447</sup> Furthermore, in 1986, the Administrative Conference examined the Medicare appeals system for coverage and payment disputes, and made comprehensive recommendations.<sup>448</sup>

#### A. *Administrative Review*

There are two major areas of concern regarding administrative review of national coverage policy: (1) restrictions on the authority of ALJs to review Medicare coverage policy in beneficiary appeals; and (2) lack of opportunity for interested parties other than beneficiaries to challenge Medicare coverage policy. The first issue is of critical concern to beneficiaries seeking to challenge specific applications of national coverage policies. The second issue is of greatest interest to

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446. See *supra* note 118.

447. See, e.g., *United States v. Erika, Inc.*, 456 U.S. 201 (1982); *Schweiker v. McClure*, 456 U.S. 188 (1982); *Gray Panthers v. Schweiker*, 652 F.2d 146 (D.C. Cir. 1980), *on remand*, [1982 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 32,144 (D.D.C. Sept. 10, 1982), *rev'd*, 716 F.2d 23 (D.C. Cir. 1983), *on remand sub nom.*, *Gray Panthers v. Heckler*, [1985-86 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 34,981 (D.D.C. Nov. 4, 1985), *on remand*, (parties' stipulation regarding Part B claims under \$100 approved) [1985-86 Transfer Binder] Medicare & Medicaid Guide ¶ 35,140 (D.D.C. Feb. 14, 1986) (ruling that oral hearings are not required for Part A claims under \$100). In the *Gray Panthers* litigation, the United States Court of Appeals for the District of Columbia Circuit required additional procedural protections for beneficiaries in cases of disputed claims of less than \$100 under Part A and Part B of the Medicare program.

448. See *supra* notes 9-10 and accompanying text.

groups representing beneficiaries, providers, and health equipment manufacturers who seek to modify or reverse a national coverage policy at the time of promulgation. Indeed, the greatest pressure for an administrative reconsideration and appeal process at the time of the national coverage policy's promulgation comes from health equipment manufacturers.

In *Goldberg v. Kelly*<sup>449</sup> the Supreme Court established that the procedural due process clauses of the fifth and fourteenth amendments ensure that beneficiaries of a government benefit program whose benefits are adversely affected by an administrative agency's action have a right to adequate notice of the agency action and to a hearing challenging the merits of the agency action. This decision precipitated what has been called a "due process explosion" in which courts have recognized a right to notice and hearing regarding a wide variety of agency actions affecting beneficiaries of federal and state social welfare programs.<sup>450</sup>

Since 1970, the Supreme Court, lower courts and scholars have wrestled with the enormous financial and other implications of a judicial model of evidentiary hearings that the Supreme Court appeared to embrace in *Goldberg v. Kelly*.<sup>451</sup> Soon after the *Goldberg* decision, it became evident to many observers, including the Supreme Court,<sup>452</sup> that requiring evidentiary hearings for all beneficiary disputes with government benefit programs was both extremely costly for increasingly constrained social program budgets and often ineffective in achieving the desired fairness for these beneficiaries.<sup>453</sup>

In *Mathews v. Eldridge*,<sup>454</sup> the Supreme Court departed from the *Goldberg* approach and crafted the current formula for assessing procedural due process in social welfare cases. The Court required the claim to be assessed in terms of three factors: (1) the private interests at stake; (2) the fairness and reliability of existing procedures, including the risk of erroneous deprivation and the benefit of additional safeguards; and (3) the public (government) interest at stake, including the financial and social costs of additional safeguards.<sup>455</sup> Although this analytical approach has effectively organized the inquiry about whether government notice and hearing procedures in a given instance comport with procedural due process requirements, it has not necessarily im-

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449. 397 U.S. 254 (1970).

450. See Mashaw, *The Management Side of Due Process: Some Theoretical and Litigation Notes on the Assurance of Accuracy, Fairness, and Timeliness in the Adjudication of Social Welfare Claims*, 59 CORNELL L. REV. 772 (1974); Van Alstyne, *Cracks in "The New Property": Adjudicative Due Process in the Administrative State*, 62 CORNELL L. REV. 445 (1977).

451. 424 U.S. 319 (1976).

452. *Id.*

453. See Mashaw, *supra* note 450.

454. 424 U.S. 319 (1976).

455. *Id.*

posed consistency in judicial decisions on the requirements of procedural due process in social welfare cases.<sup>456</sup> It has also been criticized as promoting utility and accuracy of decisionmaking at the expense of other values that procedural due process ought to promote as well.<sup>457</sup>

An astute scholar of procedural due process, Professor Jerry Mashaw, observed that the adjudicative model for hearings for social welfare programs unexpectedly transformed social welfare programs from "avowedly paternalistic, discretionary, and individualized" programs into "semiadversary, impersonal, property-rights regimes"<sup>458</sup> and forced agencies to find ways to make defensible decisions regarding benefits through more specific rules applied across the board.<sup>459</sup> Agencies were also forced to limit the discretion of agency decisionmakers in making decisions that reflected the specific needs of individual beneficiaries.<sup>460</sup> This seems to have occurred in the case of HCFA and national coverage policy since the inception of the Medicare program in 1965. Also, several prominent scholars are concerned that the procedural due process concept remain expansive enough to provide beneficiaries with a sense that they had been treated with dignity and fairness in contesting agency actions, and that notice and particularly hearing procedures did not just meet more narrow objectives of ensuring accuracy of decisions and administrative efficiency.<sup>461</sup>

#### 1. Restrictions on ALJ Review of National Coverage Determinations

The critical question is whether the prohibition of the Omnibus Budget Reconciliation Act of 1986, which prohibits ALJs from review-

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456. Another court using the same analytical approach but coming from different political and philosophical perspectives, reached a very different conclusion regarding what due process requires in a social welfare case. In *Gray Panthers v. Schweiker*, 652 F.2d 146 (D.C. Cir. 1980), involving Medicare beneficiary appeals of claims under \$100, the United States Court of Appeals for the District of Columbia held that the interest of Medicare beneficiaries with such claims was sufficient to require a simple oral hearing on grounds that HCFA's procedures did not contain the requisite safeguards to protect the core requirements of due process and the costs imposed on the Medicare program to make reforms. Providing limited oral hearings were therefore justified.

457. See Mashaw, *The Supreme Court's Due Process Calculus for Administrative Adjudication in Mathews v. Eldridge: Three Factors in Search of a Theory of Value*, 44 U. CHI. L. REV. 28 (1976).

458. MASHAW, *DUE PROCESS IN THE ADMINISTRATIVE STATE*, 34 (1985).

459. *Id.* at 31-41.

460. *Id.*

461. See generally Mashaw, *Administrative Due Process: The Quest for a Dignitary Theory*, 61 B.U.L. REV. 885 (1981) (arguing that a dignitary theory of administrative due process is attractive); Tribe, *Structural Due Process*, 10 HARV. C.R.-C.L. L. REV. 269 (1975) (a concern with structure is already implicit in some constitutional doctrines).

ing national coverage determinations, compromises both beneficiary and provider rights to procedural due process in challenges to coverage and payment decisions based on national coverage determinations.<sup>462</sup> The chief complaint about this restriction is that it limits, if not eliminates, the opportunity for beneficiaries to achieve effective administrative review of coverage policies in their individual cases. HCFA maintains that this prohibition is necessary because ALJs do not have the requisite medical expertise to assess the validity of these policies, which are based on medical judgments.<sup>463</sup>

The nature of national coverage policies of all types contributes to this situation in a unique fashion. As discussed above, national coverage policies are usually stated as flat prohibitions against coverage of an item or procedure and do not generally provide for exceptions in the application of the policy. Thus, the posture of the beneficiary in challenging the application of a coverage policy in a particular case is generally not the factual question of whether the policy is appropriately applied in the given case, but whether the policy itself is appropriate from a medical perspective or valid as a matter of law. Consistent with Professor Mashaw's observation, national coverage policy is characteristic of specific rules applied across the board with the aim of creating uniform and defensible decisions.<sup>464</sup>

In *Leduc v. Harris*,<sup>465</sup> the court addressed the constitutionality of similar restrictions reflected in HCFA regulations with respect to Part B hearings before Medicare carriers.<sup>466</sup> *Leduc* involved a national policy regarding coverage of a particular type of wheelchair that HCFA claimed was not covered as durable medical equipment because it is not used primarily by ill or injured people.<sup>467</sup> The United States District Court for Massachusetts denied HHS' motion to dismiss for lack of federal question jurisdiction. The court concluded that the hearing procedures violated procedural due process because they denied the

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462. This prohibition is actually a codification of a similar prescription for Part B hearing officers of carriers in 42 C.F.R. 405.860 (1986).

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

464. See *supra* notes 458-61 and accompanying text.

465. 488 F. Supp. 588 (D. Mass. 1980).

466. See *supra* note 462 and accompanying text; see also *Linoz v. Heckler*, 800 F.2d 871 (9th Cir. 1986) (the court did not reach the issue of federal jurisdiction); *Hatcher v. Heckler*, [1985-86 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 34,989 (8th Cir. Sept. 4, 1985). In *Hatcher*, the Eighth Circuit refused to hear a similar challenge that HCFA policy binding hearing officers to HCFA coverage policies violated beneficiaries' due process rights. The basis for this refusal was that the court did not have federal question jurisdiction because of the statutory bar in § 205(h) of the Social Security Act.

467. 488 F. Supp. at 590 (noting the HCFA's reliance on HEALTH CARE FIN. ADMIN., MEDICARE CARRIERS MANUAL ¶ 2100.1 (1987), which defines covered durable medical equipment).



hearing officer the opportunity to consider the validity of the challenged coverage policy.<sup>468</sup> The court stated:

The hearing officer rejected [plaintiff's] claim on the basis that she was bound by the Health Care Financing Administration's "policy" to refuse reimbursement for "Amigo" electric wheelchairs. The hearing officer also specifically found that the plaintiff . . . required an electric wheelchair and that the "Amigo" is "more efficient, practical, and economical than the standard electrical power model wheelchair." She further held that under Sec. 12013.7 of the Medicare Guidelines she was bound by the "policy" of the Health Care Financing Administration. . . .

When one of the crucial issues in the granting of benefits was thus foreclosed by unilateral action of the Health Care Financing Administration, there was no fair hearing. In the circumstances of this case this is a violation of due process.<sup>469</sup>

The statutory restriction imposed by the Omnibus Budget Reconciliation Act of 1986 on ALJ consideration of national coverage policy is qualitatively different from restrictions imposed on Medicare contractors through regulations or program instructions. In the latter situation, the issue becomes a question of congressional authority to legislate rather than agency authority to regulate. Nevertheless, the same constitutional considerations apply with respect to the congressional enactment. May a beneficiary still receive a fair hearing in an adjudication of his right to a benefit if Congress has restricted the ability of the hearing officer to adjudicate the agency's policy or statutory interpretation delineating the benefit? Although only one case has found a procedural due process violation with respect to limitations on the decision-making authority of administrative hearing officers, the case is an indicator of how other courts, now confronted with challenges to national coverage determinations for the first time since the inception of Medicare, might perceive this limitation with respect to policies that have not been promulgated according to a public process.

Although the prohibition is legal, it is questionable whether the prohibition reflects good policy. Because most national coverage policy is highly specific and provides no exceptions for its application, it would seem desirable to have an appeals process that allowed for the full administrative consideration of the coverage policy in a timely fashion and before judicial review. This would also facilitate expeditious disposition of challenge over national coverage determinations without resort to court. Under the present arrangement, a final decision on the merits of a national coverage determination cannot be obtained until judicial review and then only after the court has remanded the issue of the

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468. 488 F. Supp. at 590.

469. *Id.* at 590-91.

policy's validity to HHS for amplification of the record. A beneficiary seeking an adjudication has no choice but to proceed to court.

The scholarship on the goals of procedural due process<sup>470</sup> has much to inform the analysis of administrative review issues regarding Medicare national coverage policy. The important theme of this scholarship is that an administrative hearing process should allow beneficiaries to come away from the proceeding feeling that their concerns have been ventilated and justice has been served, regardless of the decision on the merits. It would seem that these values would be compromised in administrative review of Medicare coverage policies because of the limitations imposed by the Omnibus Budget Reconciliation Act of 1986. Specifically, by limiting the opportunities for beneficiaries to challenge the validity of a coverage policy on the merits at the administrative hearing level, in proceedings in which the ALJ has no authority to consider the central issue, it is less likely that the beneficiaries will conclude they received a full and fair hearing. Rather, the beneficiary may conclude, given the ALJ's diminished authority, that they have participated in a wasted exercise in which the deck is stacked against them.

## 2. Administrative Reconsideration of National Coverage Policy

As noted above, some critics of the Medicare coverage policymaking process, namely health equipment manufacturers, are especially concerned that there is no opportunity for invoking reconsideration or appeal of national coverage determinations and other types of national coverage policy for other parties affected by national coverage policy. Yet HCFA has opposed providing an opportunity for mandatory administrative reconsideration or administrative review before an ALJ for any dissatisfied party, except beneficiaries who already possess this right by statute,<sup>471</sup> because of concerns that HCFA would be subjected to strong political pressure to reconsider its coverage policies.<sup>472</sup> In light of this agency opposition, the question is whether, under the requirements of procedural due process, HHS must provide an opportunity for administrative reconsideration and even administrative appeal to ALJs of national coverage policy to beneficiaries, providers, medical equipment manufacturers or other affected parties.

The APA does not require that an agency provide an opportunity for dissatisfied parties, even those directly affected, to seek administrative reconsideration of rules or policy statements. Section 553(e) of the APA, however, requires that each agency give an interested person the right to petition for the issuance, amendment, or repeal of any rule

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470. See *supra* notes 118, 125-26 and accompanying text.

471. See 42 U.S.C. §1395ff (1982 & Supp. III 1985).

472. See *supra* notes 306-07 and accompanying text.

including interpretive rules and policy statements.<sup>473</sup> Moreover, in *O'Bannon v. Town Court Nursing Center*, the Supreme Court ruled that only beneficiaries, rather than providers, have a constitutionally protected interest in federal health insurance programs.<sup>474</sup> Furthermore, reconsideration is generally afforded only to parties in adjudicative proceedings before agencies. In the context of adjudication, the Supreme Court has concluded that a private litigant with a constitutionally protected interest at stake does not have a right, as a matter of procedural due process, to obtain reconsideration of an order.<sup>475</sup>

Thus, the question becomes one of whether it would be desirable as a matter of policy to require HHS to institute a mandatory reconsideration process for national coverage policies. If national coverage policies are only interpretive rules or policy statements for which notice-and-comment rulemaking under section 553 is not required, and if the procedures adopted for promulgating national coverage policies offer little opportunity for public input in the promulgation process, the case for a mandatory reconsideration process is strong. Such a process may provide HCFA with an opportunity to test the propriety of its decisions on coverage policy. On the other hand a more public promulgation process or negotiated rulemaking process would mitigate the need for a mandatory reconsideration process.

Post-adoption publication of interpretive rules of general applicability pursuant to Recommendation 76-5 of the Administrative Conference of the United States could serve as an effective alternative to a mandatory reconsideration process for national coverage determinations and other types of national coverage policies. Post-adoption publication could provide the agenda for HCFA's reconsideration by identifying policies over which there is considerable controversy as reflected in post-adoption comments. This approach would provide an efficient means for interested parties to make known to HCFA their views about controversial coverage policies. Thus, HCFA would not be subject to excessive political pressure, and there would be little need to establish another formal agency procedure with all the attendant trappings of staff and resources.

The concerns of health equipment manufacturers that current procedures provide no opportunity for parties other than beneficiaries and providers to appeal national coverage determinations to an ALJ are

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473. 5 U.S.C. § 553(e) (1982).

474. 447 U.S. 773, 777-78 (1982); *see, e.g.*, *Saint Francis Hosp. Center v. Heckler*, 714 F.2d 872, 875-76 (7th Cir. 1983), *cert. denied*, 465 U.S. 1022 (1984); *Geriatrics, Inc. v. Harris*, 640 F.2d 262, 265 (10th Cir.), *cert. denied*, 454 U.S. 832 (1981).

475. *See, e.g.*, *United States v. Pierce Auto Freight Lines, Inc.*, 327 U.S. 515, 535 (1945); *Interstate Commerce Comm'n. v. Jersey City*, 322 U.S. 503, 514-15 (1944); *Northeast Broadcasting, Inc. v. FCC*, 400 F.2d 749, 758 (D.C. Cir. 1968).

troubling. Clearly, this limitation prevents health equipment manufacturers from challenging adverse national coverage determinations affecting their products and resulting in severe economic hardship to their businesses.<sup>476</sup> The severe economic hardship levied upon health equipment manufacturers is a serious problem that could be devastating to a small manufacturer. Nevertheless, it does not seem appropriate to establish a process that allows health equipment manufacturers, rather than program beneficiaries who have the support of their providers, to drive administrative review of national coverage determinations affecting medical equipment and new technologies. The requirements of procedural due process would not recognize an obligation of this nature.<sup>477</sup> Furthermore, such national coverage determinations would generally involve technical judgments outside the expertise of the ALJs that currently hear Medicare appeals.

### B. *Judicial Review*

Since the 1960s, when agencies began to use legislative rulemaking extensively,<sup>478</sup> judicial review of agency regulations and particularly agency procedures generating regulations has been controversial.<sup>479</sup> In brief, courts and Congress, on the basis of procedural due process and other grounds, had imposed more required procedures on agencies for their informal rulemaking proceedings in addition to those imposed under the APA.<sup>480</sup> However, in *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council*,<sup>481</sup> the Supreme Court conclusively curtailed the authority of courts to impose additional requirements for rulemaking proceedings over and above the requirements Congress imposed in the APA or the agency's enabling act. The result of this decision was to leave to Congress the primary role of delineating

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476. HIMA Recommendations, *supra* note 219; Samuel letter, *supra* note 219.

477. See *O'Bannon v. Town Court Nursing Center*, 447 U.S. 773 (1980). In this decision, the Court clarified that the only entitlement interest protected in federal health insurance programs is the right of the beneficiaries to specified benefits. *Id.* at 784-87.

478. Gellhorn & Robinson, *Rulemaking "Due Process": An Inconclusive Dialogue*, 48 U. CHI. L. REV. 201, 202-03 (1981).

479. See GUIDE TO FEDERAL AGENCY RULEMAKING, *supra* note 322, at 1-8; K. DAVIS, *supra* note 322, at § 6.35-37; *cf.* Hamilton, *Procedures for the Adoption of Rules of General Applicability: The Need for Procedural Innovation in Administrative Rulemaking*, 60 CALIF. L. REV. 1276 (1972) (noting most statutes enacted blend the formal and informal rulemaking requirements, and suggesting a re-examination of the APA is appropriate).

480. See, e.g., Gellhorn & Robinson, *supra* note 478, at 203; Morrison, *The Administrative Procedure Act: A Living and Responsive Law*, 72 VA. L. REV. 253, 254-68 (1986); GUIDE TO FEDERAL AGENCY RULEMAKING, *supra* note 322, at 1-8.

481. 435 U.S. 519 (1978).

the procedures by which agencies make regulations and policy.<sup>482</sup> Another result of this decision was to limit the protective oversight of procedural due process in agency rulemaking proceedings in a fashion described aptly by two renowned scholars:

Thus the judicial examination and imposition of procedural requirements may have peaked, but it has raised questions about the basic character of agency rulemaking and of rulemaking "due process" that have yet to be answered. Although due process has always been a concern lurking in the background of rulemaking authority and rulemaking procedure, attention has not been sharply focused on the issue. This previous lack of concern may be explained by the existence of other safeguards. Agency rules are not self-enforcing, pre-enforcement judicial review is available, and the necessity of enforcing agency rules through adjudication provides those affected by rulemaking both with notice and with an opportunity to be heard by an impartial tribunal prior to the imposition of any sanction.<sup>483</sup>

The two major restrictions on the judicial review of Medicare coverage policy that Congress imposed in the Omnibus Budget Reconciliation Act of 1986,<sup>484</sup> in light of other characteristics of the current procedures for making and publicizing Medicare coverage policy as well as restrictions on administrative reconsideration and appeal of Medicare coverage policy, do raise questions of whether beneficiaries are accorded procedural due process in the current provisions for judicial review of Medicare coverage policy. The two restrictions on judicial review in question are mandatory remand of judicially-challenged national coverage determinations to HCFA and the restriction of judicial authority to invalidate national coverage determinations for failure to comply with chapter V of the APA regarding publication in the *Federal Register* or providing an opportunity for public comment.

### 1. Mandatory Remand of National Coverage Determinations

The Omnibus Budget Reconciliation Act of 1986 requires courts that consider invalidating a national coverage determination to remand the question of its validity to HHS for further amplification of the record. This requirement is essentially a statutory invocation of the doc-

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482. See, e.g., Davis, *Administrative Common Law and the Vermont Yankee Opinion*, 1980 UTAH L. REV. 3; Scalia, *Vermont Yankee: The APA, the D.C. Circuit, and the Supreme Court*, 1978 SUP. CT. REV. 345; Verkuil, *Judicial Review of Informal Rulemaking: Waiting for Vermont Yankee II*, 55 TUL. L. REV. 418 (1981); cf. Howarth, *Informal Agency Rulemaking and the Courts: A Theory for Procedural Review*, 61 WASH. U.L.Q. 891 (1984) (stating that in the years following the *Vermont Yankee* decision many reviewing courts have simply ignored the spirit and letter of the decision).

483. Gellhorn & Robinson, *supra* note 478, at 204 (citations omitted).

484. See *supra* notes 118-26 and accompanying text.

trine of primary jurisdiction and raises two important issues. First, is this an appropriate invocation of the doctrine of primary jurisdiction, particularly in view of the fact that initial consideration of the validity of the national coverage determination on the merits will be delayed? Second, do these mandatory remand procedures compromise the rights of beneficiaries to procedural due process in challenges to coverage and payment decisions based on national coverage determinations? The overriding factor in resolving these issues is the fact that neither the current promulgation process nor procedures for administrative review accord beneficiaries or other parties any meaningful opportunity to challenge a national coverage determination generally or the application of a national coverage determination in a specific case.

Under the doctrine of primary jurisdiction, courts may postpone assuming jurisdiction over a case in which an agency has concurrent jurisdiction "whenever enforcement of the claim requires the resolution of issues which . . . have been placed within the special competence of an administrative body."<sup>485</sup> Primary jurisdiction is generally invoked when the issue involved concerns a technical question for which the "expert and specialized" knowledge of the agency would be helpful for resolution.<sup>486</sup> The more important reason for invoking the doctrine and one of great interest to Congress in requiring remand of national coverage determinations to HCFA, is to promote the "uniform and expert administration of the regulatory scheme."<sup>487</sup> Congress has successfully required invocation of the doctrine of primary jurisdiction by statute in a few situations, including cases involving national coverage determinations.<sup>488</sup>

Clearly, disputes over national coverage policy, with its medical character and importance to the proper functioning of the Medicare program, are appropriate candidates for invoking the doctrine of primary jurisdiction. However, there is still question about whether such invocation is appropriate, in light of the virtual dearth of opportunities for beneficiaries and other affected parties to challenge Medicare coverage policy, and given the fact that invocation of the doctrine of primary jurisdiction invariably delays the ultimate disposition of the case. To tell a beneficiary, who has pursued a challenge all the way to federal court, that he must wait still longer for a decision on the merits, until after HCFA has had an opportunity to justify its coverage policy in the record, frankly seems unfair.

Justice Douglas' observation in *Ricci v. Chicago Mercantile Ex-*

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485. *United States v. Western Pac. R.R.*, 352 U.S. 59, 64 (1956); see K. DAVIS, *supra* note 322, at § 22.1; B. SCHWARTZ, *supra* note 326, at 8.26.

486. *United States v. Western Pac. R.R.*, 352 U.S. 59, 64 (1956).

487. *Id.* at 65.

488. See K. DAVIS, *supra* note 322, at § 22:1.

*change*<sup>489</sup> about the operation of the primary jurisdiction doctrine is particularly apt in the case of Medicare beneficiaries. He stated that, when this doctrine is invoked, the “road” that the litigant is “required to travel to obtain justice is . . . long and expensive and available only to those with long purses . . . .”<sup>490</sup> Medicare beneficiaries have “short purses” generally. They are less economically and physically well off compared to other Americans. Aged beneficiaries, for example, had an average annual income in 1982 of \$11,000.<sup>491</sup> Furthermore, Medicare beneficiaries—who are aged and disabled by definition—frankly do not have much time to wait for the vindication of their rights in most cases.

Second is the problem that the Medicare statute does not accord the party challenging the national coverage determination an opportunity to participate in HCFA’s deliberations when the validity of the national coverage determination is remanded to HCFA for amplification of the record. The Supreme Court, on one occasion,<sup>492</sup> ruled that it is inappropriate to apply the doctrine of primary jurisdiction where the claimant will not have an opportunity to participate as a party in the administrative proceeding considering the remanded issue.<sup>493</sup>

In sum, the medical character of national coverage determinations may seem to justify the remand procedure established in the Omnibus Budget Reconciliation Act of 1986. However, the fact that invoking the remand procedure will further delay a full consideration of the merits of challenges to national coverage determinations raises questions as to whether beneficiaries have been denied procedural due process, given the lack of meaningful opportunities during the promulgation and administrative review processes to challenge national coverage determinations or their application in individual cases. If such opportunities were made available, then the mandatory remand upon judicial review would be far more defensible.

## 2. Preclusion of APA Chapter 5 Challenges to National Coverage Policy

The Omnibus Budget Reconciliation Act of 1986 withdrew from the federal courts the power to declare unlawful or to set aside a na-

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489. 409 U.S. 289, 309 (1973) (Douglas, J., dissenting) (referring to Medicare beneficiaries).

490. *Id.* at 309.

491. Waldo & Lazenby, *Demographic Characteristics and Health Care Use and Expenditures by the Aged in the United States: 1977-1984*, HEALTH CARE FIN. REV. 1, 3-5 & 4 (Table 6) (Fall 1984); see also DEP’T OF HEALTH & HUMAN SERVICES, HEALTH STATUS OF AGED BENEFICIARIES (1983) (discussing generally the status and profile of the aged medicare beneficiary).

492. *Nader v. Allegheny Airlines, Inc.*, 426 U.S. 290 (1976).

493. *Id.* But see *Ricci v. Chicago Mercantile Exch.*, 409 U.S. 289 (1973) (the application of primary jurisdiction was one basis for the dissents in the case).

tional coverage determination because it failed to comply with the requirements of chapter V of the APA regarding publication in the *Federal Register* or the opportunity for public comment. This extraordinary limitation precludes the federal courts from considering whether one agency has complied with basic requirements of the APA in the promulgation and publication of its policies and rules in a specified area. The effect of this provision is to insulate the Medicare coverage policymaking process from attacks for failing to comply with fundamental statutory policies regarding the promulgation and publication of rules and policies that Congress established in the APA. In view of HCFA's definition of national coverage determinations in its 1987 Notice, this provision could be interpreted as including all national coverage policy rather than just national coverage determinations pertaining to medical technologies or procedures.

As explained above, Congress justified this prohibition on grounds that current procedures for making national coverage determinations and the need to preserve the scientific integrity of national coverage determinations made compliance with certain APA publication requirements unnecessary.<sup>494</sup> This rationale does not take into account national coverage policy pertaining to durable medical equipment and other types of policy that are not referred to OHTA or even the HCFA Physicians Panel. It is apparent that Congress has a misconception about the subject matter of Medicare national coverage determinations and the different ways in which national coverage policy is made.

Despite a relatively reserved attitude toward preclusion of judicial review,<sup>495</sup> the Supreme Court has recognized that Congress may preclude judicial review of specified agency action in several contexts.<sup>496</sup> Furthermore, Article III of the United States Constitution grants Congress considerable latitude in defining the jurisdiction of federal courts, especially in cases involving nonconstitutional questions.<sup>497</sup> The Court

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

495. See, e.g., *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986); *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967); *Stark v. Wickard*, 321 U.S. 288 (1944).

496. See K. DAVIS, *supra* note 322, at § 28.11-13; B. SCHWARTZ, *supra* note 326, § 8.5; see also *supra* notes 407-08 and accompanying text. Certainly, preclusion of review has been the case with the Medicare program. See, e.g., *United States v. Erika, Inc.*, 456 U.S. 201 (1982); cf. *Schweiker v. McClure*, 456 U.S. 188 (1982) (holding that due process requires additional protection to reduce the risk of erroneous deprivation of benefits).

497. See *Ex parte McCardle*, 74 U.S. (7 Wall.) 506 (1868); *Weinberger v. Salfi*, 422 U.S. 749 (1974); see, e.g., Eisenberg, *Congressional Authority to Restrict Lower Federal Court Jurisdiction*, 83 YALE L.J. 498 (1974); Gunther, *Congressional Power to Curtail Federal Court Jurisdiction: An Opinionated Guide to the Ongoing Debate*, 36 STAN. L. REV. 895 (1984); Hart, *The Power of Congress to Limit the Jurisdiction of Federal Courts: An Exercise in Dialectic*, 66 HARV. L. REV. 1362 (1953); Redish & Woods, *Congressional Power to Control the Jurisdiction of the Lower Federal Courts:*



has recognized that such statutory withdrawals of jurisdiction to review certain matters are permissible.<sup>498</sup> Furthermore, at least one scholar, who examined the issue for the Administrative Conference of the United States in 1983, concluded that Congress could restrict judicial review of agency rules.<sup>499</sup>

Nevertheless, restrictions on jurisdiction and judicial are not highly regarded by the courts.<sup>500</sup> The statutory preclusion regarding APA challenges to national coverage determinations, however, is quite unique and one wonders at the motive for its conception. It appears that Congress was cognizant of the spate of judicial challenges to Medicare coverage policy on the basis of the APA, since *Bowen v. Michigan Academy of Family Physicians*<sup>501</sup> removed the jurisdictional bar to challenges to Medicare program policies in 1986 as well as the strategy of beneficiary advocates to use the APA to challenge Medicare coverage determinations.<sup>502</sup> Congress clearly sought to limit the litigation over national coverage policies. This was a laudable objective, given increased concern that litigation unduly dictates the shape of federal regulatory policy.<sup>503</sup> However, the legislative history suggests that Congress was primarily concerned about requiring notice-and-comment rulemaking for policies concerning new technologies<sup>504</sup> and not publica-

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*A Critical Review and a New Synthesis*, 124 U. PA. L. REV. 45 (1975); Sager, *Foreword: Constitutional Limitations on Congress' Authority to Regulate the Jurisdiction of the Federal Courts*, 95 HARV. L. REV. 17 (1981); Tribe, *Jurisdictional Gerrymandering: Zoning Disfavored Rights Out of the Federal Court*, 16 HARV. C.R. & C.L.L. REV. 129 (1981); Tushnet & Jaff, *Why the Debate Over Congress' Power to Restrict the Jurisdiction of the Federal Courts is Unending*, 72 GEO. L.J. 1311 (1984).

498. For example, the Supreme Court has sustained a statute providing that no court will have jurisdiction to review a decision of the Administrator of the Veterans Administration on any question of law or fact arising under any law administered by the Veterans Administration. See *Johnson v. Robison*, 415 U.S. 361 (1974) (upholding 38 U.S.C. § 211(a) (1982)); *Gott v. Walters*, 756 F.2d 902 (D.C. Cir. 1985); see also K. DAVIS, *supra* note 322, at § 28.14 (stating the statutory policy is inconsistent because approximately five percent of the total civil case load of federal courts is comprised of non-veteran disability claims despite the fact that veterans claims are not reviewable); cf. B. SCHWARTZ, *supra* note 326, at 8.7 (the legislative intent to preclude review is so clear that it has been given full effect).

499. Verkuil, *Congressional Limitations on Judicial Review of Rules*, 57 TUL. L. REV. 733 (1983).

500. See, e.g., *Ungar v. Smith*, 667 F.2d 188 (D.C. Cir. 1981); *DiSilvestro v. United States*, 405 F.2d 150 (2d Cir. 1968); *de Magno v. United States*, 636 F.2d 714 (D.C. Cir. 1960); K. DAVIS, *supra* note 322, at § 28.13-14.

501. 476 U.S. 667 (1986).

502. See WILSON, *supra* note 298, at 1211.

503. See Stewart, *The Discontents of Legalism: Interest Group Relations in Administrative Regulation*, 1985 U. WIS. L. REV. 655 (1985) (suggesting that limitations on existing rights of private parties to challenge regulatory policy judicially should be limited in order to address this problem).

504. See *supra* note 124 & accompanying text.

tion of types of national coverage policies including those relating to coverage of durable medical equipment and other types of national coverage policy that are not subject to medical review through OHTA or even the HCFA Physicians Panel.<sup>505</sup> The result of this preclusion is to insulate challenges of entitled beneficiaries, providers and other affected parties to agency action that might be in violation of the APA.

Although this prohibition is probably legal due to the acknowledged power of Congress to preclude judicial review of agency action by statute, and to restrict jurisdiction of the federal courts under Article III of the Constitution, the prohibition is highly undesirable from a policy perspective. Two policy issues are at stake: (1) it is ill-advised to cut off all opportunities for challenging the promulgation and publication of national coverage determinations under the APA particularly in view of the controversy over the present procedures for promulgation and publication of national coverage policy; and (2) more importantly, this particular preclusion strikes at the heart of the policies that Congress sought to establish for the promulgation and publication of agency policies, rules and regulations in the APA. In sum, it is incongruous, as well as undesirable, that Congress should insulate a major policymaking process of the second largest federal entitlement program from the requirements of the APA, particularly at a time when there is so much controversy about the Medicare coverage policymaking process and whether beneficiaries are getting their benefits under the program.

## VI. RECOMMENDATIONS

Offered below are proposed recommendations for changes in the national coverage policymaking process and the administrative and judicial review of individual national coverage determinations. The recommendations are addressed primarily to HHS and, in some instances, to Congress. The recommendations are offered with the recognition that HHS and HCFA face serious problems in controlling Medicare program costs and ensuring the efficient administration of the Medicare program. The recommendations are also conceived as appropriate to protect the recognized entitlement interest of Medicare beneficiaries in Medicare benefits, and to afford beneficiaries the means by which they can protect these interests.

### A. *Promulgation and Publication*

The recommendations for reforms of the Medicare policymaking process are addressed strictly to administrative law issues. Some criticisms of the Medicare coverage policymaking process, namely, the

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505. See *supra* notes 40-46 & accompanying text.

methodologies used in the technology assessment process of OHTA, are not addressed in these recommendations. The overall concept encompassed in these recommendations regarding promulgation and publication is that HCFA's policymaking process should encourage participation of beneficiaries, providers and other interested groups in the promulgation of Medicare coverage policy and that publication assures that beneficiaries as well as the providers that decide what services will actually be provided beneficiaries are aware of Medicare coverage policies and their rationale.

1. Procedures and Criteria for Making National Coverage Policy

a. *Promulgation*

HCFA should promulgate the procedures and all criteria used in making all types of national coverage policy as a legislative rule under the notice-and-comment rulemaking procedures of section 553 of the APA. In this rulemaking proceeding, HCFA should specifically solicit the input of beneficiaries, providers, health equipment manufacturers and other affected parties. As indicated above, HCFA plans to proceed with this recommendation.

b. *Elements of procedures for making national coverage policy*

HCFA should specify its procedures for making national coverage policy in the legislative rule. The process should include the following features:

- (1) specification of the process by which HCFA selects coverage questions that will be considered in this process;
- (2) identification and description of what type of coverage issues will be left to Medicare contractors and the HCFA regional offices to decide;
- (3) identification of who within HCFA makes national coverage policy, particularly if the underlying coverage question is not referred to the HCFA Physicians Panel or OHTA;
- (4) opportunities for public input for all national coverage policies, including policies affecting durable medical equipment, home health benefits and other types of national coverage policies that are not referred to the HCFA Physicians Panel or OHTA;
- (5) a fixed deadline from the point at which a coverage issue is referred to HCFA by which HCFA must make a decision on a coverage issue; and
- (6) a description and index of all locations in which coverage policy will be published including HCFA manuals, letters to Medicare contractors, bulletins or other statements of HCFA regional offices and the **MEDICARE COVERAGE ISSUES MANUAL**.

c. *Specification of criteria*

In the legislative rule that HCFA promulgates regarding the national coverage policymaking process, HCFA should specify criteria it uses in making national coverage policy. Also, if HCFA intends to adopt cost effectiveness as a criterion for making national coverage policy,<sup>506</sup> this criterion should be included in the legislative rule. Finally, HCFA should establish in the legislative rule all of the criteria that regional offices and Medicare contractors use in making other types of coverage policy and individual coverage decisions.

d. *Publication*

If HCFA promulgates the procedures and criteria for making national coverage policy as a legislative rule under section 553 of the APA, then publication of these procedures and criteria will be accomplished through a proposed and final rule publication in the *Federal Register*. Nevertheless, HCFA would be required, by the Freedom of Information Act, to publish its final procedures in the *Federal Register*. HCFA should also endeavor to ensure that the organizations representing beneficiaries, providers, health equipment manufacturers and other interested parties are informed of the rule which establishes the procedures and criteria for national coverage policy.

2. Individual National Coverage Policies

a. *Promulgation*

Assuming that HCFA promulgates the procedures and criteria for making national coverage policy as a legislative rule, then individual coverage policies could appropriately be promulgated as interpretive rules. It is important that HCFA devise a policymaking procedure that accords beneficiaries, providers and other interested parties an opportunity to contribute to the formulation of specific national coverage policies. Input from groups with medical expertise is especially important because of the medical nature of the decisions involved in making most national coverage policy.

HCFA should develop a policymaking process that offers an opportunity for a structured discussion with beneficiary, provider, industry and HCFA representatives about proposed policies in a manner similar to the negotiated rulemaking approach used by other agencies. Such a structured discussion would provide an excellent opportunity to obtain the requisite medical and technical input needed to develop fair and sound policies. Such a discussion would educate beneficiary groups about the rationale for HCFA's position on coverage issues and the

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506. This approach has been encouraged by many observers.

resulting coverage policies. The structured discussion would also enable HCFA to obtain a better understanding of beneficiary concerns, thereby mitigating subsequent judicial challenges of national coverage policies.

b. *Publication*

HCFA should follow Recommendation 76-5 of the Administrative Conference of the United States on publication of interpretive rules of general applicability by publicizing all national coverage policies in the *Federal Register* upon promulgation. Following this procedure provides an informal reconsideration process of controversial national coverage policy without subjecting HCFA to undue political pressure or the administrative inconvenience of a mandatory reconsideration process.

Regarding other types of Medicare coverage policy of Medicare contractors and HCFA regional offices, Recommendation 86-5 of the Administrative Conference of the United States on Medicare Appeals expressly recommends that HCFA and Medicare contractors publish and make available all coverage policy, including "insurance industry rules or other screening devices" used in making coverage decisions regarding the amount, duration and scope of benefits accorded beneficiaries in specific cases.

HCFA and Medicare contractors must actively ensure that the aged and infirm beneficiaries of the Medicare program, and the providers who serve them, are informed of coverage policy. HCFA and Medicare contractors should work closely with national organizations representing beneficiaries, including legal services advocates for the elderly and disabled, to apprise these organizations of Medicare coverage policy and its rationale. HCFA and Medicare contractors should provide these groups with sufficient information to inform their constituents of Medicare coverage policy.

HCFA should provide an accessible and comprehensible means by which Medicare beneficiaries and their providers can inquire about coverage of specific items or services. Most importantly, HCFA should identify and index all policies in manuals and other documents defining coverage of Medicare benefits in a form that is not only accessible, but comprehensible to beneficiaries.

B. *Administrative and Judicial Review*

1. *Administrative Review*

The restrictions imposed on the authority of administrative law judges to adjudicate national coverage determinations in the Omnibus Budget Reconciliation Act of 1986 are inappropriate and vitiate effective administrative review of national coverage determinations. Congress should repeal these restrictions.

## 2. Judicial Review

### a. *Mandatory remand to HCFA of challenged coverage determinations*

The concept of mandatory remand of challenged coverage determinations is an appropriate approach to maintaining the scientific integrity of medically-based coverage policy. This also is clearly consistent with the administrative law doctrine of primary jurisdiction. However, in the context of the current coverage policymaking process, which accords little opportunity for public participation of beneficiaries, providers and other interested groups in the formulation of coverage policy, and the limitations on the authority of ALJs to adjudicate the validity of national coverage determinations, mandatory remand upon judicial review is undesirable. The reason is that it postpones the opportunity for beneficiaries to get a decision on the validity of the coverage policy applied to curtail the benefits to which they may well be entitled. Beneficiaries who are forced to wait so long for a decision on the merits on a coverage policy applied with respect to their medical treatment would likely become discouraged about a process weighted so heavily in favor of HCFA. This process poses too many obstacles to beneficiaries' efforts to get a final decision on the merits. Congress should repeal this mandatory remand requirement.

### b. *Preclusion of APA Chapter 5 Challenges*

The provision in the Omnibus Reconciliation Act of 1986, proscribing courts from invalidating national coverage determinations for failure to comply with certain requirements of the APA is ill-conceived. First, it appears to be based on Congress' misconception that national coverage policies pertain only to medical technologies that OHTA has assessed. Second, and more importantly, it exempts an important policymaking process in a major federal entitlement program from thorough judicial scrutiny, and withdraws the protections of the APA from a vulnerable class of beneficiaries chiefly to insulate HCFA from litigation as well as accountability. There are other ways, including a public and expeditious promulgation and publication process and meaningful administrative review, to decrease judicial challenges to national coverage determinations. Congress should repeal this provision and assure the beneficiaries of the Medicare program the full protection envisioned by the drafters of the APA.

## C. *Conclusion*

Medicare coverage policy is extraordinarily important to the aged and disabled beneficiaries of the Medicare program because it defines the type, amount, duration and scope of the health services that will be available to them for the treatment of their illness or injury. While it is

important for HCFA to administer the Medicare program efficiently and inexpensively and to control Medicare expenditures, HCFA should not lose sight of the importance to Medicare beneficiaries of coverage policy and its implementation. Therefore, HCFA must craft a promulgation and publication process for all Medicare coverage policy, including national coverage policy, as well as procedures for administrative and judicial review, that genuinely protect and, indeed, promote the entitlement interest of Medicare beneficiaries in the Medicare program over the achievement of other goals.

## VII. APPENDIX

The following represents the complete text of the recommendations on national coverage determinations compiled by the Administrative Conference of the United States.

### Recommendation 87-8

#### National Coverage Determinations Under the Medicare Program

1 C.F.R. § 305.87-8

Adopted December 17, 1987

In 1986, the Administrative Conference undertook a broad overview of the administrative procedures employed by the federal government (primarily the Health Care Financing Administration within the Department of Health and Human Services) in administering and deciding appeals under the Medicare program. Recommendation 86-5, *Medicare Appeals*, 1 C.F.R. § 305.86-5, urged the Health Care Financing Administration (HCFA) to improve its system for publishing, updating, and making accessible the standards, guidelines and procedures used in making coverage and payment determinations in the Medicare program. The recommendation also suggested some improvements in the administrative appeals system and listed some fruitful areas for further research.

This recommendation builds on Recommendation 86-5 by focusing on a major aspect of the Medicare program: the making of policy concerning what aspects of medical care are covered by, and therefore reimbursable by, the Medicare program. Implementation determinations must be made every day on a case-by-case basis by Medicare contractors (peer review organizations, carriers and fiscal intermediaries such as Blue Cross). In most of these cases the coverage question involves a determination of whether an item or service was medically necessary for the individual or was furnished in the appropriate setting. Typically, the Medicare contractor has considerable discretion in ruling on individual claims although that discretion is bounded by policy pronouncements made in various ways by HCFA. If an individual claim for reimbursement is denied by the Medicare contractor, the claimant (whether a beneficiary or provider of care) may appeal the denial of

claims over \$500 to an administrative law judge and then further appeal to a federal district court for claims over \$1,000. Recent legislative restrictions, however, have further limited claimants' opportunities to challenge coverage determinations in court or before an ALJ, and it is difficult for equipment manufacturers to participate in or challenge national coverage determinations even though their financial stakes can be significant.

HCFA makes coverage policy in a number of ways.<sup>507</sup> In some cases, Medicare contractors refer questions about new medical procedures or technologies to the HCFA regional or national office which makes an informal judgment for application in that case. In other cases, HCFA makes "national coverage determinations" which apply in all future similar cases. Since the beginning of the program, HCFA (and its predecessor agency) have made about 200 such national determinations on medical procedures and technologies, and the number made each year is growing. However, in its recent *Federal Register* notice, HCFA stated that a "national coverage determination" included any coverage policy published in any HCFA manual. Such rulings are published either in the *Federal Register* or the *MEDICARE COVERAGE ISSUES MANUAL*, although many other coverage policies are published in other manuals that are less widely available, and are not designated as national coverage determinations.

Although the making of these national coverage determinations constitutes rulemaking, HCFA does not use a notice-and-comment procedure in most cases. HCFA's Bureau of Eligibility, Reimbursement and Coverage normally simply makes rulings on coverage determinations referred from contractors unless it determines that a medical question is presented. In such cases the question is referred to the in-house HCFA Physicians Panel which meets in private to decide on these referrals. The Physicians Panel may recommend a further referral to the Public Health Service's Office of Health Technology Assessment (OHTA). Most referrals to OHTA are in the form of informal inquiries, without public notice, after which OHTA simply conducts in-house investigations and reports back to HCFA. Requests for full OHTA assessments, on the other hand, usually result in a *Federal Register* notice and widespread consultation with affected groups. In either event, OHTA makes a recommendation to HCFA which then makes and publishes the determination. Only then are the OHTA findings disclosed.

Except in these "formal OHTA assessments," beneficiaries, providers and manufacturers have no opportunity to participate in this poli-

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507. HCFA's procedures for making national coverage policy had not been published until April 29, 1987 when under court order. The agency issued a notice in the *Federal Register* describing its process (though not its criteria) and sought comments.



cymaking process. Nor are the criteria used by HCFA and the Medicare contractors in making this policy identified or published. Moreover, once the policy is announced, opportunities to challenge it have been severely circumscribed by the 1986 Omnibus Budget Reconciliation Act. (Pub. L. 99-509, § 9341; 42 U.S.C.A. § 1395ff(b)(3) (1987)). The Act provides that administrative law judges may not review national coverage determinations in administrative appeals. It also limits judicial review by providing that national coverage determinations may not be held unlawful on the grounds of violation of the APA or lack of opportunity for public comment, and further provides that reviewing courts cannot overturn a denial based on coverage determinations without first remanding to HHS for supplementation of the record.

In Recommendation 86-5, the Conference recommended that HHS "introduce more openness and regularity" into these important determinations through "(1) [d]evelopment of published decisional criteria; (2) providing for notice and inviting comments in such cases, both in HCFA's decisionmaking process and in the process by which [OHTA] supplies recommendations to HCFA; and (3) providing for internal administrative review or reconsideration of such decisions." The Conference commends the recent HCFA notice and request for comments on its procedures as a good first step, but urges that further steps be taken to open up the decisional criteria and procedure to public participation and also urges Congress to consider modifying the statutory limitations on the review of the reasonableness and the procedural fairness of such national coverage determinations.

#### RECOMMENDATION

##### *1. Publication of Procedures and Criteria Through Rulemaking*

The Health Care Financing Administration (HCFA) should continue its recent steps toward describing and seeking comments upon the procedures it uses for making national coverage determinations in the Medicare program. HCFA should follow its recent informational notice with a notice-and-comment rulemaking proceeding setting forth the procedures as well as all decisional criteria for making national coverage determinations.

##### *2. Elements of the National Coverage Determination Process*

HCFA's proposed and final rule on national coverage determinations procedures and criteria should:

(a) specify the procedure by which HCFA selects coverage questions that will be considered in this process;

(b) identify and describe what categories of coverage issues will be left to the decision of Medicare contractors and HCFA regional offices; and address the extent to which, and the manner in which, significant coverage determinations made by contractors and regional offices can

be identified and disseminated more widely;

(c) provide for the opportunity for public comment prior to promulgation (or if that is infeasible, an opportunity for comment after adoption)<sup>508</sup> of *all* national coverage policies whether or not the determination is referred to the HCFA Physicians Panel or to the Office of Health Technology Assessment;

(d) establish internal management controls to facilitate the timely processing of requests from Medicare contractors and petitions filed by beneficiaries, providers and other affected persons for initiation of a national coverage determination;<sup>509</sup>

(e) develop techniques to encourage the HCFA Physicians Panel, the Office of Health Technology Assessment, and the Public Health Service to respond expeditiously to referrals; and

(f) identify all publications in which coverage policy will be published, and the method by which those publications will be made reasonably accessible to beneficiaries and other affected groups.

### 3. *Use of Negotiated Rulemaking*

In addition to providing for a national coverage decisionmaking process that accords beneficiaries, providers, equipment manufacturers and other interested parties an opportunity to have input into the formulation of specific national coverage determinations, HCFA should in appropriate cases also consider use of elements of a negotiated rulemaking procedure.<sup>510</sup>

### 4. *Modification of Recent Legislative Restrictions on Administrative and Judicial Review*

Congress should reconsider and, at minimum, clarify its intent<sup>511</sup> with regard to the recent restrictions it placed upon administrative and judicial review of national coverage determinations. In so doing, Congress should:

(a) consider whether to clarify the restriction against administrative law judge review of national coverage determinations [42 U.S.C.A. § 1395ff(b)(3)(A)] by (i) making clear that administrative law judges may review the application of such determinations to claimants and (ii) specifying that this limitation only applies to those national coverage determinations that are properly published and indexed, and that have

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508. The agency should then re-evaluate the policy after receiving comments. See ACUS Recommendation 76-5, *Interpretive Rules of General Applicability and Statements of General Policy*, 1 C.F.R. § 305.76-5.

509. See ACUS Recommendation 86-6, *Petitions for Rulemaking*, ¶ 2(d), 1 C.F.R. § 305.86-6(2)(d).

510. See ACUS Recommendations 82-4 and 85-5, *Procedures for Negotiating Proposed Regulations*, 1 C.F.R. §§ 305.82-4, 85-5.

511. In particular, Congress should, for the purposes of these restrictions, clarify its definition of "national coverage determination" and explain whether or not policies other than those concerning medical procedures and technologies and published in the *Federal Register* or *MEDICARE COVERAGE ISSUES MANUAL* are included.

been issued after an adequate opportunity for public comment;

(b) consider repealing 42 U.S.C.A. § 1395ff(b)(3)(B), which restricts judicial review of procedures used in promulgating national coverage determinations;

(c) eliminate the provision [42 U.S.C.A. § 1395ff(b)(3)(C)] that limits reviewing courts' ability to review the validity of a national coverage determination applied in a particular case without first remanding the case to the agency for supplementation of the record.

