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## Medicare Coverage Decision-Making and Appeal Procedures: Can Process Meet the Challenge of New Medical Technology?

Eleanor D. Kinney

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# Medicare Coverage Decision-Making and Appeal Procedures: Can Process Meet the Challenge of New Medical Technology?

Eleanor D. Kinney\*

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### *I. Introduction*

Medicare coverage policy for new medical technology has been a very controversial issue in the administration of the Medicare program since its inception. The impact of advances in medical science and medical technology on Medicare program costs has driven this controversy. This Article addresses whether the Medicare coverage decision-making and appeal processes, which are the Medicare program's "first responders" to new medical technology, are adequate to meet the challenges of new medical technologies and their associated costs.

### *II. Background*

This Part describes the Medicare program and its historical development. In particular, it traces inflation in Medicare expenditures and health care costs, and how that inflation was fueled in part by advances in new, expensive medical technology. This Part then describes the Medicare coverage decision-making and appeal processes.

#### *A. The Medicare Program*

Congress enacted Medicare, a federal health insurance program, in 1965<sup>1</sup> and expanded Medicare coverage to the seriously disabled and to people with End Stage Renal Disease (ESRD) in 1972.<sup>2</sup> Nearly all elderly, some severely

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1. Social Security Amendments of 1965, Pub. L. No. 89-97, § 102(a), 79 Stat. 286, 291 (codified as amended at 42 U.S.C. § 1395 (2000)).

2. Social Security Amendments of 1972, Pub. L. No. 92-603, § 301, 86 Stat. 1329, 1471 (codified as amended at 42 U.S.C. § 1395c (2000)).

disabled, and people with ESRD are eligible for Medicare.<sup>3</sup> In 2001, thirty-eight million Americans (13.5% of the population) had health insurance through Medicare.<sup>4</sup>

The Social Security Amendments of 1965 established three distinct programs: the Medicare Hospital Insurance Program (Part A),<sup>5</sup> the Medicare Supplementary Medical Insurance Program (Part B),<sup>6</sup> and the Medicaid Program.<sup>7</sup> Each program has different benefits, is financed and administered independently, and pays for services according to different methodologies. A mandatory Social Security payroll tax on all wage earners funds Part A,<sup>8</sup> while premiums of enrollees and congressional appropriations fund Part B.<sup>9</sup> These funds are invested in designated government trust funds for the exclusive use of the Medicare program.<sup>10</sup>

Medicare benefits include hospital and related benefits for acute illness and injury, as well as physician and other outpatient services.<sup>11</sup> Part A covers hospital care and related home health and skilled nursing home care<sup>12</sup> while Part B covers physician and other outpatient services.<sup>13</sup> Except as otherwise specified, the major criterion for coverage of benefits is that they be "reasonable and necessary for the diagnosis and treatment of illness or injury."<sup>14</sup>

The Balanced Budget Act of 1997 established the Medicare+Choice program (Part C) through which Medicare beneficiaries can enroll in HMOs and other privately administered health plans.<sup>15</sup> Beneficiaries in Medicare+Choice receive both Part A and Part B benefits and, at the option of their health plan, additional benefits such as prescription drugs.<sup>16</sup> Although viewed as a major reform of the Medicare program with the intent of moving

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3. 42 U.S.C. §§ 1395c, i-2, o (2000).

4. U.S. CENSUS BUREAU, HEALTH INSURANCE COVERAGE: 2001 (Sept. 2002), available at <http://www.census.gov/prod/2002pubs/p60-220.pdf>.

5. 42 U.S.C. §§ 1395c-1395i (2000).

6. *Id.* §§ 1395j-1395w-4.

7. Social Security Amendments of 1965, Pub. L. No. 89-97, § 102, 79 Stat. 286, 343 (codified as amended at 42 U.S.C. § 1396 (2000)).

8. 42 U.S.C. § 1395i (2000).

9. *Id.* § 1395t.

10. *Id.* §§ 1395i, 1395t.

11. *Id.* §§ 1395c-1395i, 1395j-1395w-4.

12. *Id.* §§ 1395c-1395i.v

13. *Id.* §§ 1395j-1395w-4.

14. *Id.* § 1395y(a)(1)(A).

15. Balanced Budget Act of 1997, Pub. L. No. 105-33, §§ 4001-03, 111 Stat. 251, 275-31 (codified as amended at 42 U.S.C. § 1395w-21 (2000)).

16. 42 U.S.C. § 1395w-22.

most beneficiaries to managed care plans, the Medicare+Choice program has not attracted participation from as many plans or beneficiaries as anticipated.<sup>17</sup>

For Parts A and B, the Centers for Medicare and Medicaid Services (CMS) contracts with private organizations to administer the Medicare program, including the implementation of Medicare coverage and payment policy.<sup>18</sup> Further, Medicare contracts with health care institutions to serve beneficiaries and often deems private accreditation of health care institutions as compliance with requirements for participating in the Medicare program.<sup>19</sup> For Part C, CMS contracts directly with the health plans and pays them from the trust funds for Parts A and B based on the number of Medicare beneficiaries enrolled.<sup>20</sup>

The advent of the Medicare program was a seminal event in the history of American health care, representing the federal government's direct responsibility for health insurance for the aged and seriously disabled.<sup>21</sup>

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17. See U. S. GEN. ACCOUNTING OFFICE, *MEDICARE MANAGED CARE PLANS: MANY FACTORS CONTRIBUTE TO RECENT WITHDRAWALS; PLAN INTEREST CONTINUES* 2 (1999) (noting that "shortly before the start of the Medicare+Choice program, nearly 100 Medicare managed care plans announced that they would not renew their Medicare contracts or that they would reduce the geographic areas they served"), available at <http://www.gao.gov/archive/1999/he99091.pdf>; see generally Marsha Gold, *Medicare+Choice: An Interim Report Card*, HEALTH AFF. July/Aug. 2001, at 120 (expanding on the idea that "[i]n contrast to the goal of expanded choice, the [Medicare+Choice] program has reduced the range of choice that once existed . . .").

18. 42 U.S.C. §§ 1395h, 1395u (2000) (regarding fiscal intermediaries and carriers); *id.* § 1320c-1320c-12 (regarding quality improvement organizations).

19. *Id.* § 1395bb; see Timothy Stoltzfus Jost, *Medicare and the Joint Commission on Accreditation of Healthcare Organizations: A Healthy Relationship?* 57 LAW & CONTEMP. PROB. 15, 15 (Autumn 1994) (explaining that a health care organization meeting the requirements of the Joint Commission on Accreditation of Healthcare Organizations, a private, non-profit corporation, is deemed to meet the Medicare conditions of participation).

20. 42 U.S.C. § 1395w-21(i)(1) (2000).

21. See KAREN DAVIS & CATHY SCHOEN, *HEALTH AND THE WAR ON POVERTY* 92 (1978) ("Medicare has helped protect the elderly and their children from the financial burden of large medical bills."); JUDITH M. FEDER, *MEDICARE: THE POLITICS OF FEDERAL HOSPITAL INSURANCE* 1 (1977) (reporting that initially Medicare provided health care insurance to the elderly in the hope that the appeal of helping the elderly would overcome physician opposition to any federal health insurance); SYLVIA LAW, *BLUE CROSS—WHAT WENT WRONG?* 31 (2d ed. 1976) (noting that during the early 1960s it became apparent that private medical care programs were inadequate and tracing the increasing congressional awareness of that fact); THEODORE R. MARMOR, *THE POLITICS OF MEDICARE* xxiii (2d ed. 2000) (noting that the Medicare bill included two related insurance programs to finance substantial portions of the hospital and physician expenses incurred by Americans over the age of sixty-five); ROBERT J. MYERS, *MEDICARE* xi (1970) (explaining that the enactment of Medicare provided extensive coverage against the costs of medical care for persons aged sixty-five or over); HERMAN MILES SOMERS & ANNE RAMSAY SOMERS, *MEDICARE AND THE HOSPITALS: ISSUES AND PROSPECTS* 1 (1967) (calling the 1965 enactment of Medicare "revolutionary" and noting its design to meet the needs of the elderly).

Despite great need, health coverage for the elderly attracted formidable opposition.<sup>22</sup> The medical profession approached the concept cautiously out of a fear of government control of medical practices.<sup>23</sup> The hospital industry was somewhat more receptive because the program would assure predictable payment for hospital services in an unprecedented manner.<sup>24</sup> Political conservatives and most Republicans opposed the concept because they fundamentally questioned the role of the federal government in providing health insurance in the first place.<sup>25</sup> Indeed, passage of the Medicare program was possible only because of the 1964 landslide victory of Democratic President Lyndon B. Johnson.<sup>26</sup>

Medicare stands as a quintessential liberal victory in the tradition of Franklin Roosevelt's New Deal.<sup>27</sup> In 1960, Democratic President John F. Kennedy picked up the mantle of health insurance for the elderly.<sup>28</sup> President Johnson, in the aftermath of Kennedy's assassination and with his consummate legislative skills, shepherded the Medicare legislation through a Democratic Congress.<sup>29</sup> Medicare represented another step in the liberal dream of comprehensive social security with the addition of national health insurance. The program was conceived and informed by a liberal ideology of collective action to assure the economic security of working people. The insurance and taxation principles of collective risk-spreading under government supervision and regulation form its foundation.

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22. See Wilbur J. Cohen, *Reflections on the Enactment of Medicare and Medicaid*, 6 HEALTH CARE FIN. REV. 3, 4 (Supp. 1985) (noting that Medicare and Medicaid were highly controversial issues attracting harsh criticism); Marian Gornick et al., *Twenty Years of Medicare and Medicaid: Covered Populations, Use of Benefits, and Program Expenditures*, 6 HEALTH CARE FIN. REV. 13, 14 (Supp. 1985) (asserting that in 1964 about three-fourths of adults under the age of sixty-five had hospital insurance while only about half of adults over sixty-five had hospital insurance).

23. See Cohen, *supra* note 22, at 4 (explaining that the American Medical Association originally opposed early versions of even a limited Medicaid proposal).

24. See SOMERS & SOMERS, *supra* note 21, at 23 (reporting that the hospitals anticipated "substantial advantages" from the Medicare legislation).

25. See MARMOR, *supra* note 21, at 23 (noting that Medicare bills had no chance of congressional enactment during the Eisenhower administration).

26. See Cohen, *supra* note 22, at 5 (identifying Johnson's victory as a catalyst for rallying support for the program).

27. See MARMOR, *supra* note 21, at 56-57 (noting that the most recent precedent to the 1964 social welfare bills was Franklin Roosevelt's New Deal Congresses).

28. See Cohen, *supra* note 22, at 5 (describing Kennedy's steps in support of establishing a Medicare program).

29. See *id.* at 5-7 (outlining President Johnson's participation in the passage of Medicare).

The designers of the Medicare program were aware of the ideological fissures surrounding its design and implementation. Indeed, the opening section of the Social Security Amendments of 1965 states:

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 to exercise any supervision or control over the administration or operation of any such institution, agency, or person.<sup>30</sup>

Further, the designers deliberately maintained the fee-for-service payment methods for all providers, thereby seeding cost inflation, to ensure the participation of reluctant providers. Congress suggested that reimbursement methodologies of private insurance companies should guide the Medicare program in the development of Medicare's reimbursement methodology.<sup>31</sup> The idea was to make Medicare look like Blue Cross Blue Shield service benefit plans, the prevailing model of private health insurance at the time. Wilber Cohen, then Secretary of the Department of Health, Education and Welfare, observed that "[t]he ideological and political issues between 1960 and 1965 were so dominating that they precluded consideration of issues such as reimbursement alternatives and efficiency options."<sup>32</sup>

Nevertheless, the program continues to generate criticism from more conservative elements on the political spectrum. Indeed, it has been the target of conservative ideological attacks, especially in recent years.<sup>33</sup> Also, many proposals for Medicare reform, such as the movement of Medicare beneficiaries into private health plans, fit with more conservative visions of the program like the Bush administration's Medicare reform proposal.<sup>34</sup>

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30. 42 U.S.C. 1395 (2000); *see also id.* § 1396a(a)(23) (expressing similar guarantees for the Medicaid program).

31. S. REP. NO. 89-404 (1965), *reprinted in* 1965 U.S.C.C.A.N. 1943, 1976.

32. Cohen, *supra* note 22, at 5.

33. *See, e.g.*, SUE A. BLEVINS, *MEDICARE'S MIDLIFE CRISIS* 98 (2001) (asserting that "Americans should not be forced into a single-payer government health care system—Medicare—that limits their health care options and prevents them from spending money on the treatments of their choice"); *MEDICARE IN THE TWENTY-FIRST CENTURY: SEEKING FAIR AND EFFICIENT REFORM* (Robert B. Helms ed. 2001) (acknowledging the current political debate surrounding calls for Medicare reform and presenting essays outlining proposals for change); *see generally* DAVID G. SMITH, *ENTITLEMENT POLITICS: MEDICARE AND MEDICAID, 1995–2001* (2002) (describing partisan attempts to shrink the size of government by targeting Medicare and Medicaid).

34. Medicare Reform Act of 2001, S. 1135, 107th Cong. (1st Sess. 2001); *see also* NATIONAL BIPARTISAN COMMISSION ON THE FUTURE OF MEDICARE, *BUILDING A BETTER MEDICARE FOR TODAY AND TOMORROW*, at <http://medicare.commission.gov/medicare/bbmtt31599.html> (Mar. 1999) (proposing changes in the Medicare system).

Immediately upon implementation, the Medicare program generated enormous demand for health care services, and thus created sharp and continuing increases in the cost of health care.<sup>35</sup> Quite simply, the growth in Medicare expenditures far exceeded preprogram estimates.<sup>36</sup> The need to address this growth has dominated Medicare policy-making in all areas ever since.

Two major factors contributed to health care cost inflation. First, the structure and financing of Medicare and private health insurance plans contributed to excessive utilization of health care services.<sup>37</sup> Specifically, beneficiaries were insulated from the financial consequences of their decisions to use health care services and provider payment methods were based on incurred costs and charges which encouraged inefficiencies in care delivery.

Regarding the first factor, the federal government reformed Medicare provider payment methods to facilitate control of Medicare expenditures. In 1983, Congress adopted a prospective payment system for hospitals, paying a price per case based on patient diagnosis.<sup>38</sup> In 1989, Congress enacted a revised payment system for physician services that paid physicians based on the time and resources involved in treating specific conditions rather than on a charge basis.<sup>39</sup> By 2000, almost all providers were being paid a prospectively determined price for services.<sup>40</sup>

Second, increases in costly medical technology contributed to cost inflation.<sup>41</sup> Soon after the inauguration of the Medicare program in 1965, scholars and policymakers identified rapid development of new medical

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35. See Gornick et al., *supra* note 22, at 35–45 (tracing the increase of use in services and the corresponding increase in program expenditures by Medicare beneficiaries from 1967 to 1984).

36. See *Proposed Medicare Reimbursement Formula: Hearings Before the Senate Comm. on Finance*, 89th Cong. ii (1966) (noting that growth in Medicare expenditures exceeded estimates).

37. See Kenneth J. Arrow, *The Economics of Moral Hazard: Further Comment*, 58 AM. ECON. REV. 537, 538 (1968) (noting that "the seeking of more medical care with insurance is a rational action on the part of the individuals if no further constraints are imposed"); see generally THE ROLE OF HEALTH INSURANCE IN THE HEALTH SERVICES SECTOR (Richard N. Rosett ed., 1976) (compiling essays concerning the market for health insurance, the effects of health insurance on the market for health services, and national health insurance).

38. Social Security Amendments of 1983, Pub. L. No. 98-21, § 601(c)(1), 97 Stat. 65, 150 (codified as amended at 42 U.S.C. § 1395ww).

39. Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, § 6102, 103 Stat. 2111, 2169 (codified as amended at 42 U.S.C. § 1395w-4(a) (2000)).

40. Balanced Budget Act of 1997, § 4603 (codified as amended at 42 U.S.C. § 1395fff) (instituting prospective payment for home health agencies); § 4432 (codified as amended at 42 U.S.C. § 1395yy) (instituting prospective payment for skilled nursing facilities).

41. *Infra* note 42 and accompanying text.



technology as a factor in Medicare's cost inflation.<sup>42</sup> No doubt Medicare contributed to this escalation in new medical technology by infusing new funding to pay for services to patients which included the new technology. Indeed, in 1972, Congress expanded Medicare coverage to people with End Stage Renal Disease to enable their access to the expensive new technology of renal dialysis.<sup>43</sup> Of note, Congress enacted the Medical Device Amendments of 1976 during this period to address the flood of new medical devices on the market and to assure their "reasonable safety and effectiveness . . . for human use."<sup>44</sup>

In 1978, Congress created the first formal government technology assessment function to analyze medical technology and its impact on federal health care programs with the establishment of the National Center for Health Care Technology within the Public Health Service.<sup>45</sup> This federal technology assessment function, although modified, has continued until the present.<sup>46</sup> During the early 1980s, much interest evolved in the use of technology assessment in determining coverage policy for public and private health insurance programs.<sup>47</sup> Private third party payors, also facing inflationary

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42. See LOUISE B. RUSSELL, *TECHNOLOGY IN HOSPITALS: MEDICAL ADVANCES AND THEIR DIFFUSION* 2 (1979) (describing that new technologies are a possible explanation for growth in costs, but that third-party payors are the real culprit); see generally DEP'T OF HEALTH, EDUCATION & WELFARE, *MEDICAL TECHNOLOGY: THE CULPRIT BEHIND HEALTH CARE COSTS?* (1977).

43. Social Security Amendments of 1972, Pub. L. No. 92-603, § 2991, 86 Stat. 1329, 1463-64 (codified as amended at 42 U.S.C. § 426(e)-(g) (2000)).

44. Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified as amended at 42 U.S.C. § 360c-k (2000)); see Bradley Merrill Thompson & Brian A. Dahl, *The Food and Drug Administration Review Process for Medical Devices*, in *GUIDE TO MEDICARE COVERAGE DECISION-MAKING AND APPEALS* 41 (Eleanor D. Kinney ed., 2002) (noting that devices are reviewed to insure their safety and efficacy).

45. See Eleanor D. Kinney, *National Coverage Policy under the Medicare Program: Problems and Proposals for Change*, 32 ST. LOUIS U.L.J. 869, 898-99 (1988) (describing the creation of the National Center for Health Care Technology); Seymour Perry, *The Brief Life of the National Center for Health Care Technology*, 307 NEW ENG. J. MED. 1095 (1982); see generally Seymour Perry & Michael Eliastam, *The National Center for Health Care Technology*, 245 JAMA 2510 (1981).

46. See Kinney, *supra* note 45, at 899 (explaining modifications in the federal technology assessment function).

47. See John P. Bunker et al., *Evaluation of Medical-Technology Strategies: Effects of Coverage and Reimbursement*, 306 NEW ENG. J. MED. 620, 621 (1982) (describing how inadequate technology assessment resulted in the failure to develop a consistent reimbursement policy); John P. Bunker et al., *Evaluation of Medical Technology Strategies: Proposal for an Institute for Health-Care Evaluation*, 306 NEW ENG. J. MED. 687, 688 (1982) (outlining the general structure for a proposed institute for health care evaluation which would perform technology assessment); Stan N. Finkelstein, *The Process of Evaluating Medical Technologies for Third-party Coverage*, 1 J. HEALTH CARE TECH. 89, 91 (1984) (reporting a study of the

pressures, likewise gave greater attention to coverage policy in order to curtail costs.<sup>48</sup>

The debate over the impact of medical technology continues today. Mark Pauley's article in this Symposium Issue analyzes these developments and their implication for the Medicare program.<sup>49</sup> Medical technology has had a profound impact on the health care system and offers many new and effective treatments.<sup>50</sup> Further, the flow of new technological developments continues to expand with enormous advances imminent.<sup>51</sup>

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process by which coverage technology assessments are carried out by or for two large insurance carriers); Barbara Greenberg & Robert A. Derzon, *Determining Health Insurance Coverage of Technology: Problems and Options*, 19 MED. CARE 967, 967 (1981) (noting that in 1981, Medicare was "reevaluating [its] coverage guidelines and considering curtailing reimbursement for unproven, outmoded or marginal procedures"); John K. Iglehart, *The Cost and Regulation of Medical-Technology: Future Policy Decisions*, 55 MILBANK MEMORIAL FUND Q. 25, 56 (1977) (asserting that federal decision makers have begun to recognize links between the amount of reimbursement and the amount of technology deemed as essential); O.B. Towery & Seymour Perry, *The Scientific Basis For Coverage Decisions By Third-Party Payers*, 245 JAMA 59, 61 (1981) (discussing the progress of the National Center for Health Care Technology in developing "an explicit, well-defined process for the medical and scientific evaluation of medical tests and procedures to determine the appropriateness of their coverage under Medicare").

48. See Mark A. Hall & Gerard F. Anderson, *Health Insurers' Assessment of Medical Necessity*, 140 U. PA. L. REV. 1637, 1691-94 (1992) (calling for the insurance industry to regulate health care costs by modifying general coverage policy to exclude less cost-effective and less established treatments); Sara Rosenbaum et al., *Who Should Determine When Health Care Is Medically Necessary?* 340 NEW. ENG. J. MED. 229, 230 (1999) (noting that "as the cost of health insurance escalated, commercial insurers, Medicare, and Medicaid began to review the medical necessity of physicians' treatment recommendations as the basis for determining which procedures and services would be covered"); Claudia A. Steiner et al., *Technology Coverage Decisions by Health Care Plans and Considerations by Medical Directors*, 35 MED. CARE 472, 484 (1997) (describing that with regard to private insurance plans, "economic considerations, particularly cost-effectiveness, are now important criteria for coverage").

49. Mark V. Pauly, *What if Technology Never Stops Improving? Medicare's Future Under Continuous Cost Increases*, 60 WASH. & LEE L. REV. 1233 (2003).

50. See generally Claude H. Organ, Jr., *The Impact of Technology on Surgery*, 134 ARCHIVES OF SURGERY 1175 (1999) (describing technological advances and their impact on surgery); John M. Eisenberg & Elaine J. Power, *Transforming Insurance Coverage into Quality Health Care: Voltage Drops from Potential to Delivered Quality*, 284 JAMA 2100, 2100 (2000) ("The stream of innovations that reach the US health care system holds enormous potential to improve the quality of care.").

51. See Einer Elhauge, *The Limited Regulatory Potential Of Medical Technology Assessment*, 82 VA. L. REV. 1525, 1526 (1996) (noting that if incentive is provided to encourage the provision of all medical care having positive net health benefits regardless of cost, then innovations which provide only marginal health benefits at a great cost will flourish); Lars Noah, *Medicine's Epistemology: Mapping the Haphazard Diffusion of Knowledge in the Biomedical Community*, 44 ARIZ. L. REV. 373, 404-05 (2002) (asserting that rapid progress and the pace of knowledge production and acquisition in both biomedical research and medicine in general make it difficult for physicians to keep up with all of the changes); see also

But technology also raises several important additional issues—some of which are profoundly philosophical. First, and of interest to the medical community, policy makers, and third party payors, is a new technology really effective in treating illness and injury in ways that justify its costs? Second, does new technology add more to the care process and substitute for older, less effective technologies? Important evidence suggests that when new technologies come on line, they do not necessarily replace older technologies, thereby increasing the overall cost of care.<sup>52</sup> Third, under what circumstances should third party payors cover new technologies, particularly when they are expensive and do not add appreciable value to care in terms of patient outcomes? This last issue has been an especially contentious one with respect to new cancer treatments.<sup>53</sup>

Further, the process by which third party payors make decisions about coverage is important. All third party payors invoke some process, albeit unconsciously.<sup>54</sup> Notably, many private payors have been sued over adverse coverage decisions regarding new medical technologies and have been ordered by courts to pay for the technology in specific cases.<sup>55</sup> Also note that Medicare

Biotechnology Industry Organization, *Biotechnology's Impact on Diseases of the Elderly: A White Paper*, at [www.bio.org/news/white\\_paper.html](http://www.bio.org/news/white_paper.html) (Sept. 2000) (examining biotech medicines on the market and in development and detailing their impact on patients); William B. Schwartz, *In the Pipeline: A Wave of Valuable Medical Technology*, HEALTH AFF., Summer 1994, at 70, 79 (describing a few of the technological advances expected to come about in the next twenty-five to thirty years).

52. See John M. Eisenberg et al., *Substituting Diagnostic Services: New Tests Only Partly Replace Older Ones*, 262 JAMA 1196, 1200 (1989) (presenting test results which show that the adoption of new technology is only sometimes associated with abandonment of the corresponding older services, possibly increasing the cost of medical care).

53. See William P. Peters & Mark C. Rogers, *Variation in Approval by Insurance Companies of Coverage for Autologous Bone Marrow Transplantation For Breast Cancer*, 330 NEW ENG. J. MED. 473, 474–75 (1994) (studying trends in coverage approval or denial by third-party payors for patients participating in clinical studies of new cancer treatments); Henry M. Williams, *Cancer Therapy: Reimbursement of New Therapeutic Technologies*, 65 YALE J. BIOLOGY MED. 83, 94 (1992) (addressing the problems associated with reimbursement for new technologies and proposing a model coverage decision process); see also George Anders, *Researchers Call Insurers 'Arbitrary' in Covering Bone-Marrow Transplants*, WALL ST. J., Feb. 17, 1994, at B12 (summarizing the 1994 study by William P. Peters and Mark C. Rogers).

54. See ELEANOR D. KINNEY, PROTECTING AMERICAN HEALTH CARE CONSUMERS 109–13 (2002) (describing "processes for making policies pertaining to the content and quality of health care").

55. See, e.g., Mark A. Hall et al., *Judicial Protection of Managed Care Consumers: An Empirical Study of Insurance Coverage Disputes*, 26 SETON HALL L. REV. 1055, 1056 (1996) ("Analyz[ing] judicial determinations of health insurance coverage disputes from an empirical perspective, using a method called 'content analysis.'"); Richard Saver, *Reimbursing New Technologies: Why Are the Courts Judging Experimental Medicine?*, 44 STAN. L. REV. 1095, 1098–1104 (1992) (examining case law arising from denials of coverage); see also Gerard F.

coverage decision-making influences decisions for public health insurance programs.<sup>56</sup>

Finally, the controversy over the Medicare coverage decision-making and appeal procedures (or coverage issues of private insurers, for that matter) is not likely to diffuse in the future given trends in the growth in health care expenditures and also the growth in the proportion of the population over 65. Table 1 illustrates these important trends.

**Table 1: National Health Expenditures and Selected Economic Indicators, Years 1980-2010 (Modified CMS Table)<sup>57</sup>**

Item	1980	1990	2000	2010
National Health Expenditures (billions)	\$245.8	\$696.0	\$1,299.5	\$2,639.2
National Health Expenditures as a Percent of Gross Domestic Product	8.8	12.0	13.2	16.8
National Health Expenditures Per Capita	\$1,067	\$2,738	\$4,637	\$8,704
Population Age 65 Years and Older	25.8	31.5	35.1	39.0

*B. The Medicare Coverage Decision-Making and Appeals Processes*

From 1965 to the present, due to the pressure for coverage of new medical procedures, devices, and other technologies, the Medicare coverage decision-making process moved from an informal, primarily local process, in which

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Anderson et al., *Medical Technology Assessment and Practice Guidelines: Their Day in Court*, 83 AM. J. PUB. HEALTH 1635, 1635 (1993) (noting that "[p]ast efforts by public and private insurers to deny claims on the basis of the results of formal technology assessments or practice guidelines have frequently been overturned by the courts"); John H. Ferguson et al., *Court-Ordered Reimbursement for Unproven Medical Technology: Circumventing Technology Assessment*, 269 JAMA 2116, 2118-20 (1993) (providing studies of cases in which the court has ordered reimbursement for emerging medical technologies).

56. See KINNEY, *supra* note 54, at 110 ("[G]overnment agencies rely extensively on standards made by private organizations for public regulatory programs.")

57. CTRS. FOR MEDICARE & MEDICAID SERVS., OFFICE OF THE ACTUARY, NATIONAL HEALTH EXPENDITURES AND SELECTED ECONOMIC INDICATORS, LEVELS AND AVERAGE ANNUAL PERCENT CHANGE: SELECTED CALENDAR YEARS 1980-2011, at <http://www.cms.hhs.gov/statistic/snhe/projections-2001/t1.asp> (last visited May 19, 2003).

Medicare carriers and other Medicare contractors made coverage decisions locally, to a more formal, more centralized process for making national coverage determinations (NCDs). CMS publishes national coverage policy in program manuals.<sup>58</sup> Medicare contractors make and publicize local coverage decisions.

The transformation in this process occurred because of pressure from an increased rate of advances in new medical technology and a call for coverage of these new technologies. For example, with highly visible life-saving technologies such as organ transplantation, nationwide consistency in coverage decisions became more important. For example, in the early 1980s, heart transplants were covered only in California, which caused some concerns about the fairness of the treatment of similarly situated Medicare beneficiaries in different regions.<sup>59</sup>

In the early 1980s, the Health Care Financing Administration (HCFA), the predecessor agency to CMS, developed an internal process for making national coverage decisions.<sup>60</sup> Specifically, HCFA convened an informal committee of physicians who worked for HCFA.<sup>61</sup> The committee was not established by statute or regulation and met privately with no published agenda or opportunity for participation by interested parties or members of the public.<sup>62</sup> The HCFA office in charge of coverage policy conducted reviews of the relevant medical literature and consulted with medical specialty societies and other physicians' organizations. For more complex or controversial coverage issues, the HCFA coverage policy-making office would request a technology assessment from the Public Health Service (PHS).<sup>63</sup>

The informality and the secrecy of the Medicare coverage decision-making process generated much criticism in the 1980s, as coverage decision-making became more frequent and gained the attention of the constituencies of the

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58. HEALTH CARE FIN. ADMIN., CARRIERS MANUAL (1998); HEALTH CARE FIN. ADMIN., COVERAGE ISSUES MANUAL (1998) in MEDICARE AND MEDICAID GUIDE (CCH) ¶ 27,201 (1998); see generally Timothy S. Jost, *Governing Medicare*, 51 ADMIN. L. REV. 39 (1998) (providing a brief outline of the administration of Medicare); Kinney, *supra* note 45, at 879–83 (outlining the procedures for making national coverage policy).

59. See Richard A. Knox, *Heart Transplants: To Pay or Not to Pay*, 209 SCIENCE 570, 575 (1980) (noting that when confronted with a dying patient, resource allocation arguments tend to appear bureaucratic).

60. See Kinney, *supra* note 45, at 879–83 (describing the national coverage decision process).

61. See *id.* at 880 (noting that the HCFA Physicians Panel was formed in 1980).

62. See *id.* (stating that the panel meets "in private and without a published agenda").

63. *Id.* at 881.

Medicare program.<sup>64</sup> For example, the Administrative Conference of the United States, the U.S. General Accounting Office, and also the American Bar Association expressed concerns about the closed character of HCFA's coverage decision-making process and suggested reforms.<sup>65</sup>

A major source of pressure for national coverage decision-making has been the medical device manufacturers who, as of 1976, had to get approval from the Food and Drug Administration (FDA) before marketing new medical devices.<sup>66</sup> The fact that FDA approval did not necessarily result in Medicare coverage and that further review for Medicare coverage purposes was required, and was not always successful, confounded and frustrated medical device manufacturers.<sup>67</sup>

Further, beneficiaries increasingly challenged negative coverage decisions in court, and with some success.<sup>68</sup> In 1987, as part of the settlement in *Jameson*

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64. See Timothy P. Blanchard, "Medical Necessity" Denials as a Medicare Part B Cost-Containment Strategy: Two Wrongs Don't Make It Right or Rational, 34 ST. LOUIS U. L. J. 939, 1002-12 (1990) (criticizing HCFA's refusal to disclose coverage criteria and guidelines); Kinney, *supra* note 45, at 903 (commenting on calls for publication and accountability within the various coverage policymaking processes); Sally Hart Wilson, *Benefit Cutbacks in the Medicare Program Through Administrative Agency Fiat Without Procedural Protections: Litigation Approaches on Behalf of Beneficiaries*, 16 GONZ. L. REV. 533, 536 (1981) (criticizing the lack of administrative hearing rights and judicial review rights of the Medicare program).

65. See ADMIN. CONF. OF U.S., RECOMMENDATION 87-8, NATIONAL COVERAGE DETERMINATIONS UNDER THE MEDICARE PROGRAM, 52 Fed. Reg. 49,144 (Dec. 30, 1987) (expressing concerns about and suggesting reforms for HCFA's coverage decision-making process); ADMIN. CONF. OF U.S., RECOMMENDATION 86-5, NATIONAL MEDICARE APPEALS, 51 Fed. Reg. 46,987 (same); AMERICAN BAR ASSOCIATION, RECOMMENDATIONS ON MEDICARE PROCEDURES BY THE ABA HOUSE OF DELEGATES (Aug. 1988) (same).

66. See *supra* note 44 and accompanying text (noting that Congress enacted the Medical Device Amendments of 1976 to evaluate new medical devices).

67. See Bradley Merrill Thompson & Brian A. Dahl, *The Perspective of Manufacturers*, in GUIDE TO MEDICARE COVERAGE DECISION-MAKING AND APPEALS 127, 127-28 (Eleanor D. Kinney ed., 2002) (noting that many manufacturers support Medicare coverage based on FDA approval).

68. See, e.g., *Heckler v. Ringer*, 466 U.S. 602, 627 (1984) (requiring that administrative remedies be exhausted before judicial review of the Secretary's decisions in the context of coverage denial for a surgical procedure); *Linoz v. Heckler*, 800 F.2d 871, 878 (9th Cir. 1986) (deeming a coverage determination to be a substantive rule and reversing a grant of summary judgment for the Secretary of the Department of Health and Human Services); *Vorster v. Bowen*, 709 F. Supp. 934, 947 (C.D. Cal. 1989) (deciding that review determination notices must contain language indicating that a frequency of service was exceeded and requesting additional confirmation from the beneficiary to show medical necessity); *Griffith v. Bowen*, 678 F. Supp. 942, 947 (D. Mass. 1988) (refusing to dismiss a class action brought against the Secretary of Health and Human Services for coverage denials on the grounds of subject matter jurisdiction or mootness); *Jameson v. Bowen*, No. CV-F-8-547, 1987 WL 108970, at \*1 (E.D. Cal. Feb. 20, 1987) (reaching a settlement agreement under which HCFA was required to publish coverage decision procedures); *Leduc v. Harris*, 488 F. Supp. 588, 591 (D. Mass. 1980)

*v. Bowen*,<sup>69</sup> which contested the application of a national coverage policy, HCFA promulgated a notice explaining its procedures for making coverage decisions.<sup>70</sup> In this notice, HCFA stated its intention to promulgate a rule for making national coverage determinations.

In 1986, when it established administrative and judicial review for Part B claims, Congress expressly exempted HCFA national coverage determinations from judicial challenges on grounds that they were not promulgated as legislative rules under § 553 of the Administrative Procedure Act (APA).<sup>71</sup> Congress's rationale for this special treatment of national coverage decisions was that HCFA had an established process for the solicitation of medical input from private medical organizations and the Public Health Service.<sup>72</sup> Since then, federal courts have uniformly upheld this amendment and the authority of HCFA to make coverage decisions without using APA rulemaking procedures.<sup>73</sup>

Following the *Jameson* decision, HCFA was unsuccessful in developing a formal procedure for making national coverage determinations. In 1989, HCFA published a notice of proposed rulemaking, which was never promulgated as a final rule, to make a more public, accountable process for making national and local coverage policy for the Medicare program.<sup>74</sup> The proposed rule, adopted in response to *Jameson*, proved controversial chiefly

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(determining that a denial of reimbursement for an electric wheelchair operated as a violation of due process while a denial of reimbursement for an electronically operated bed was not); *see also* Kinney, *supra* note 45, at 918–23 (outlining judicial challenges to Medicare coverage policy).

69. *Jameson v. Bowen*, No. CV-F-8-547, 1987 WL 108970 (E.D. Cal. Feb. 20, 1987).

70. *See* Medicare Program; Procedures for Medical Services Coverage Decisions; Request for Comments, 52 Fed. Reg. 15,560, 15,561–63 (Apr. 29, 1987) (presenting HCFA's notice explaining its procedures for making coverage decisions).

71. 42 U.S.C. § 1395hh(b)(2)(C) & (b)(4) (2000); *see also* 5 U.S.C. § 553 (1994) (providing definition of legislative rules).

72. H.R. REP. NO. 99-102, at 350–51 (1986).

73. *See, e.g., St. Francis Health Care Ctr. v. Shalala*, 205 F.3d 937, 947 (6th Cir. 2000) (determining that the HCFA was not required to comply with the APA's notice and comment procedures in denying St. Francis's requests for an "upward adjustment" to its costs limits because the denial was an interpretive rule); *Warder v. Shalala*, 149 F.3d 73, 75 (1st Cir. 1998) (holding that a specific administrative ruling by the HCFA classifying a piece of equipment as "'durable medical equipment' rather than 'braces' . . . [was] an interpretive rule and was not invalidated by HCFA's failure to have adopted notice and comment procedures").

74. *See* Medicare Program; Criteria and Procedures for Making Medical Services Coverage Decisions that Relate to Health Care Technology, 54 Fed. Reg. 4302 (proposed Jan. 30, 1989) (presenting HCFA's notice of proposed rulemaking to design a more public decision-making process).

because of its articulation of cost effectiveness as a criteria for making coverage decisions.<sup>75</sup>

Following publication of the 1989 proposed rule, HCFA made the process more regular and established an internal review process with its Technical Advisory Committee (TAC), which is comprised of carrier medical directors, including a medical director of a managed care organization and representatives of other interested federal agencies.<sup>76</sup> This committee met out of public view and its recommendations were not binding on HCFA.<sup>77</sup>

Through the 1990s, HCFA continued to struggle with designing a coverage decision-making process that responded to the concerns of beneficiaries, device manufacturers, and other critics while maintaining tight control over decision-making. In 1998, the U.S. General Accounting Office (GAO) reported that the TAC violated the Federal Advisory Committee Act.<sup>78</sup> Following this report, HCFA appointed a Medicare Coverage Advisory Committee (MCAC). The MCAC, comprised of outside experts, conducted public meetings on coverage issues and permitted manufacturers and other interested parties to present their views.<sup>79</sup>

In the late 1990s, the Republican-dominated House Ways and Means Committee put great pressure on HCFA to reform its coverage decision-making and appeals processes. The Health Subcommittee held multiple hearings on the coverage decision-making and appeals processes.<sup>80</sup> Much of this activity was

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75. See Darrel J. Grinstead, *Evolution of the Medicare Coverage Policy-Making Process*, in *GUIDE TO MEDICARE COVERAGE DECISION-MAKING AND APPEALS* 1, 9–13 (Eleanor D. Kinney ed., 2002) (discussing the 1989 proposed rule, which included a controversial cost-effectiveness requirement).

76. *Issues Relating to Medicare's Coverage Policy, Hearing Before the Health Subcommittee of the House Committee on Ways and Means*, 105th Cong. 12 (1997) (statement of Hon. Bruce C. Vladeck, Administrator, Health Care Financing Administration); see Grinstead, *supra* note 75, at 14 (discussing TAC's membership and role in the coverage decision-making process).

77. See Grinstead, *supra* note 75, at 14 (discussing TAC's membership and role in the coverage decision-making process).

78. U.S. GEN. ACCOUNTING OFFICE, *ADVISORY COMMITTEE ACT: VIOLATION BY THE HEALTH CARE FINANCING ADMINISTRATION* 1–2 (1998); see *Federal Advisory Committee Act*, 5 U.S.C. app. 2 (2000) (regulating those groups that advise agencies of the executive branch).

79. Medicare Program; Establishment of the Medicare Coverage Advisory Committee and Request for Nominations for Members, 63 Fed. Reg. 68,780 (proposed Dec. 14, 1998).

80. See *Patient Appeals in Health Care: Hearing Before the Subcommittee on Health House Committee on Ways and Means*, 105th Cong. 4–76 (1998) (providing testimony of several witnesses on due process in patient appeals); *The Medicare Coverage Decisions and Beneficiary Appeals: Hearings Before the Subcommittee on Health House Committee on Ways and Means*, 106th Cong. 21–128 (1999) [hereinafter *Medicare Coverage Decisions*] (providing testimony from six witnesses discussing the procedural problems HCFA faces and the



encouraged by the health equipment manufacturing industry.<sup>81</sup> In April 1999, in response to pressure from the subcommittee, HCFA published a notice (the April 1999 Notice) that outlined the administrative process for making national coverage policy.<sup>82</sup> In 2000, Congress changed the national coverage decision-making process to provide more accessibility to interested parties, namely medical device manufacturers, and imposed deadlines and other formal hearing requirements on HCFA to make it more accountable for its decisions.<sup>83</sup> This legislation was quite responsive to the health equipment manufacturing industry's concerns with the Medicare coverage decision-making and appeals processes.

### 1. The April 1999 Notice

In April 1999, CMS initiated a four-step plan to create a coverage decision-making process that was "open, accountable, clear and dependable."<sup>84</sup> First, CMS created a new decision-making process. Second, CMS continued the MCAC, comprised of "leading private sector experts on health care coverage" and dedicated to review relevant scientific evidence and advise CMS on whether Medicare should cover a particular service or item. Third, CMS published a Notice of Intent that would lead to a proposed rule on the criteria for making coverage decisions. The final step was a final rule on criteria with sector-specific guidance.<sup>85</sup>

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procedures HCFA created in the April 1999 notice).

81. See Press Release, Health Industry Manufacturers Association, Medical Device Industry Applauds Representative Thomas' Efforts on Medicare Appeals, at [www.advamed.org/publicdocs/williamthomasrelease62499.htm](http://www.advamed.org/publicdocs/williamthomasrelease62499.htm) (June 24, 1999) (supporting a House bill titled "Medicare Appeals Act of 1999").

82. Medicare Program; Procedures for Making National Coverage Decisions, 64 Fed. Reg. 22,619 (April 27, 1999), *revised*, Medicare Program; Revised Process for Making Medicare National Coverage Decisions, 68 Fed. Reg. 55,634 (Sept. 26, 2003); see *infra* Part II.B.1 (outlining April 1999 notice).

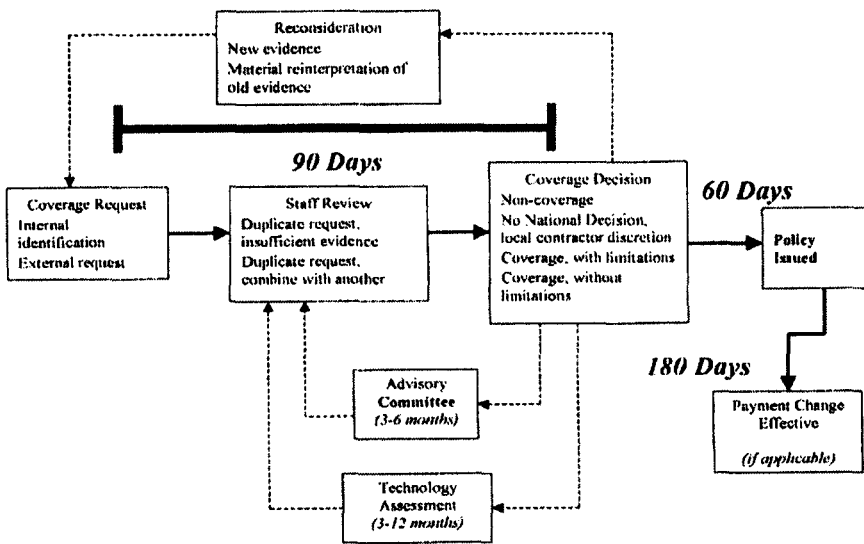
83. See 42 U.S.C. § 1395y(a) (2000) (requiring notice and comment on national coverage determinations, on-the-record advisory committees, review of applicable scientific data, and a clear statement of the reasons behind determinations).

84. CTRS. FOR MEDICARE & MEDICAID SERVS., FACT SHEET: MEDICARE'S PROCESS FOR MAKING COVERAGE DECISIONS, at <http://cms.hms.gov/media/press/release.asp?Counter=381> (May 1, 2000).

85. In its September 2003 notice, CMS announced that it would not pursue this rulemaking due to the fact that "there are substantial competing interests about the coverage criteria." Medicare Program; Revised Process for Making Medicare National Coverage Decisions, 68 Fed. Reg. 55,634, 55,634-35 (Sept. 26, 2003).

These new procedures made major changes to the Medicare coverage decision-making process<sup>86</sup> and form the basis of the current coverage decision-making process. Figure 1 is a diagram of the coverage decision-making process established in the April 1999 Notice.

**Figure 1: Medicare National Coverage Decision-Making Process (April 1999 Notice)<sup>87</sup>**



The major changes established in the April 1999 Notice specify procedures for making coverage policy decisions and guaranteeing input from beneficiaries and other interested parties through open meetings of the

86. See Procedures for Making National Coverage Decisions, 64 Fed. Reg. 22,619, 22,620 (proposed April 27, 1999) (stating that the goal of the new rule is to make the decision-making process "more open, responsive, and understandable to the public"); Grant Bagley, *Current Procedures and Standards for Making Medicare Coverage Decisions*, in GUIDE TO MEDICARE COVERAGE DECISION-MAKING AND APPEALS, 17, 18-20 (Eleanor D. Kinney ed., 2002) (discussing the impact of the April 1999 notice).

87. Notice, Procedures for Making National Coverage Decisions, 64 Fed. Reg. 22,619 (Apr. 27, 1999).

MCAC.<sup>88</sup> The April 1999 Notice specifically authorizes any person to request a national coverage decision.<sup>89</sup> The majority of requests come from medical device manufacturers, with physicians or their organizations a distant second.<sup>90</sup> CMS can, and often does, initiate a request for a national coverage decision.<sup>91</sup> In addition, the April 1999 Notice establishes a ninety-day time frame, starting at the "acceptance" of the request for making a final coverage decision.<sup>92</sup> Several events, such as the receipt of significant new information, can toll the ninety days. Device manufacturers oppose these exceptions because CMS often invokes them and eviscerates the deadline.<sup>93</sup> Pursuant to the April 1999 Notice, CMS can refer a coverage request to the MCAC which can add an additional three to six months to the decision-making process.<sup>94</sup> When a particularly controversial case presents a serious scientific question about the effectiveness of a new technology, CMS can request a technology assessment through the Agency for Healthcare Research and Quality.<sup>95</sup> A technology assessment can add three to twelve months to the process.<sup>96</sup>

The April 1999 Notice added a new process for reconsideration of negative coverage decisions in the event of new evidence or material reinterpretation of old evidence.<sup>97</sup> This process enables interested parties to reopen coverage decisions if they have more evidence.

Pursuant to the April 1999 Notice, CMS publishes requests for coverage policy on the CMS web page and also maintains a docket of deliberations on requests for coverage on the internet.<sup>98</sup> This step has done much to address a

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88. *The Medicare Coverage Process and Beneficiary Processes: Hearings Before the Subcomm. on Health of the House Comm. on Ways and Means*, 106th Cong. 22 (1999) (statement of Michael Hash, Deputy Administrator, Health Care Financing Administration).

89. *Id.*

90. See Bagley, *supra* note 86, at 22 (stating that coverage decision requests usually come from manufacturers).

91. *Id.*

92. *Id.* at 20.

93. Thompson & Dahl, *supra* note 67, at 130 (describing the national decision-making process as inefficient and sometimes longer than the product life cycle for many devices).

94. Notice, Establishment of the Medicare Coverage Advisory Committee and Request for Nominations for Members, 63 Fed. Reg. 68,780 (Dec. 14, 1998).

95. Procedures for Making National Coverage Decisions, 64 Fed. Reg. 22,619, 22,623-24 (proposed Apr. 27, 1999); see Agency for Healthcare Research and Quality, at <http://www.ahrq.gov/clinic/techix.htm> (last visited Sept. 2, 2003) (stating that the agency conducts technology assessments for CMS and listing completed technology assessments).

96. 64 Fed. Reg. at 22,624.

97. *Id.*

98. *Id.* at 22,622; see CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE COVERAGE HOME PAGE, at <http://cms.hhs.gov/coverage/default2.asp> (last visited Sept. 2, 2003) (providing

prior criticism of the process—namely that CMS made decisions in secret and interested parties did not have an opportunity to provide input. The publication requirement does much to enhance the transparency of the national coverage decision-making process.

Finally, the process enunciated in the April 1999 Notice establishes a high evidentiary burden for demonstrating that Medicare should cover a new medical technology. This evidentiary burden has been most controversial among device manufacturers and also physicians.<sup>99</sup> They claim that CMS expects empirical analysis, which is expensive and difficult to obtain, to demonstrate the effectiveness of the new technology.<sup>100</sup>

## 2. Section 522 of BIPA

The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA)<sup>101</sup> established statutory requirements for the national and local coverage decision-making processes. While CMS had already adopted many of the BIPA reforms in the April 1999 Notice, CMS now has a statutory mandate to operate an open process rather than an option to do so.<sup>102</sup> Specifically, in making a national coverage determination, the Secretary must "ensure that the public is afforded notice and opportunity to comment" and that determinations are made "on the record."<sup>103</sup> Further, in making the determination, the Secretary must consider "applicable information (including clinical experience and medical, technical, and scientific evidence)" and "provide a clear statement of the basis for the determination (including responses to comments received from the public)" as well as "the assumptions underlying that basis."<sup>104</sup> The Secretary must make the data that he or she used in making the decision available to the public.<sup>105</sup>

Most importantly, BIPA empowered beneficiaries to challenge both national and local coverage decisions independent of explicit coverage denials

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access to, among other things, NCDs, technology assessments, and Federal Register notices).

99. Rachel F. Ochs-Ross & Thomas A. Connaughton, *The Perspective of Providers, in GUIDE TO MEDICARE COVERAGE DECISION-MAKING AND APPEALS*, 105, 105–07 (Eleanor D. Kinney ed., 2002).

100. *See id.* at 111–13 (discussing criticisms of CMS's coverage criteria).

101. 42 U.S.C. § 1395y(a) (2000).

102. *See id.* (establishing requirements for openness in national coverage determinations).

103. *Id.*

104. *Id.*

105. *Id.*

in the context of claims.<sup>106</sup> Specifically, an aggrieved party—a Medicare beneficiary in need of an item or service—can invoke this appeals process.<sup>107</sup> An aggrieved party can initiate an appeal of an implemented national coverage determination to the Departmental Appeals Board (DAB) for the U.S. Department of Health and Human Services (HHS).<sup>108</sup> DAB has *de novo* review and can consult with scientific and clinical experts, permit discovery, and take evidence to evaluate the reasonableness of the determination.<sup>109</sup> A DAB decision constitutes the final HHS action for which judicial review is available.<sup>110</sup> An aggrieved party similarly can appeal a local coverage determination made by Medicare contractors to an administrative law judge (ALJ) who adjudicates other Medicare appeals.<sup>111</sup> The reviewing ALJ has the same latitude of review for local coverage determinations as the DAB has for national coverage decisions.<sup>112</sup> The ALJ decision on a local coverage determination is then reviewable by the DAB.<sup>113</sup> A DAB decision on the local coverage determination constitutes the final HHS action for which judicial review is available.<sup>114</sup> Under current law, an ALJ does not have authority to adjudicate a national coverage determination.<sup>115</sup>

### 3. *The August 2002 Proposed Rule*

CMS did not implement the BIPA reforms immediately. In 2001, CMS issued a ruling explaining that it would delay implementation of the BIPA reforms and established procedures for handling any beneficiary challenges to national or local coverage decisions.<sup>116</sup> CMS claimed that Congress did not appropriate the requisite resources to implement the mandate, stating: "[A]bsent new funding sources, CMS is unable to implement many of these far-

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106. See 42 U.S.C. § 1395ff(b)(1)(A) (2000) (stating that any individual is entitled to reconsideration of a coverage determination).

107. *Id.*

108. *Id.* § 1395ff(f)(1)(A)(iii).

109. *Id.*

110. *Id.* § 1395ff(f)(1)(A)(v).

111. *Id.* § 1395ff(f)(2)(A)(i).

112. See *id.* (permitting the ALJ to consult with experts, conduct discovery, and evaluate the reasonableness of the determination).

113. *Id.* § 1395ff(f)(2)(A)(ii).

114. *Id.* § 1395ff(f)(2)(A)(iv).

115. See 42 U.S.C. § 1395ff(f) (2000) (granting DAB the sole authority to review NCDs).

116. Centers for Medicare and Medicaid Services, Ruling 01-01, <http://cms.hhs.gov/rulings/01-01.asp> (Sept. 28, 2001).

reaching changes."<sup>117</sup> CMS has been particularly reluctant to implement the provisions that allow beneficiaries to initiate processes for making national and local coverage decisions when they are directly affected by a coverage decision. Indeed, CMS only published the proposed rule in August 2002 after multiple advocacy groups representing the disabled threatened to bring a class action suit to compel promulgation of a rule to implement these procedures.<sup>118</sup>

In August 2002, CMS issued a proposed rule implementing some of the BIPA mandated reforms.<sup>119</sup> The proposed rule defined which Medicare beneficiaries qualified as "aggrieved parties" and specified the process for challenging national coverage determinations and local coverage decisions outside the current appeals process for Medicare claim denials.<sup>120</sup> Specifically, the proposed rule requires that in order to invoke the process, aggrieved parties must obtain certifications from treating physicians and other evidence of need for an item or service.<sup>121</sup> These requirements and others have generated considerable opposition from the health equipment manufacturers who charge that these requirements eviscerate the BIPA process.<sup>122</sup>

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117. Notice of CMS Ruling, The National and Local Coverage Determination Review Process for an Individual with Standing as Defined in Section 522 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protections Act of 2000, 66 Fed. Reg. 54,253 (Oct. 26, 2001).

118. See Press Release, American Association of People With Disabilities, AAPD Plaintiff in Lawsuit Filed Today Against the U.S. Department of Health and Human Services (HHS), at <http://www.aapd.com/docs/aapdplaintiffagainsthhs.html> (Aug. 6, 2002) (announcing that AAPD, the American Council of the Blind, the Gray Panthers, and three individual Medicare beneficiaries had filed a lawsuit against HHS); see also Markian Hawryluk, *Medicare Denials Can Be Appealed: CMS Acts Following Lawsuit: The Right to Appeal Is Seen as Essential to Ensuring that Medicare Allows Physicians to Provide the Best Treatments, and Get Reimbursed*, AM. MED. NEWS, <http://www.amaassn.org/sci-pubs/amnews/pick02/gv110902.htm> (Sept. 2, 2002) (discussing reactions to CMS's national coverage decision-making process).

119. Medicare Program; Review of National Coverage Determinations and Local Coverage Determinations, 67 Fed. Reg. 54,534 (proposed Aug. 22, 2002).

120. *Id.* at 54,538, 54,540–46.

121. *Id.* at 54,540.

122. Memorandum from the Advanced Medical Technology Association to Thomas A. Scully, Administrator, Centers for Medicare and Medicaid Services, HHS (Oct. 21, 2002) (on file with the author); Letter from Carl B. Feldbaum, President, Biotechnology Industry Organization to Thomas A. Scully, Administrator, Centers for Medicare and Medicaid Services, HHS, Comments on CMS-3063-P (Medicare Program; Review of National Coverage Determinations and Local Coverage Determinations) (Oct. 18, 2002) (on file with the author); Letter from Rachel S. Kramer, RHIA, American College of Radiology (and for the American Society of Neuroradiology; American Society for Therapeutic Radiology and Oncology; and the Society of Nuclear Medicine) to Thomas A. Scully, Administrator, Centers for Medicare and Medicaid Services, HHS, Comments on Review of National Coverage Determinations and Local Coverage Determinations; Proposed Rule (CMS-3063-P) (Oct. 22, 2002) (on file with the author).

#### 4. *The September 2003 Notice*

In September 2003, CMS issued a notice revising the procedures for making Medicare coverage decisions stated in its April 1999 Notice.<sup>123</sup> Essentially, the coverage process remains the same except for the following improvements. The September 2003 Notice reorganizes the instructions on the reconsideration process and distinguishes this process from an initial request to make an NCD.<sup>124</sup> Also, the notice more clearly identifies the elements of a complete, formal request for an NCD including the requirement that the request include all evidence currently available and the evidence must be adequate for CMS to determine that the item or service is reasonable and necessary.<sup>125</sup> The major change in the September 2003 Notice is the establishment of two main tracks for the initial NCD request.<sup>126</sup> One track is a "highly time-structured track" only available to aggrieved parties who have the right to immediate appeal of a coverage determination under § 522 of BIPA.<sup>127</sup> The other track is open to anyone, including aggrieved parties, beneficiaries, and manufacturers, and offers a "more collaborative and less time-stringent" process.<sup>128</sup>

#### C. *The Medicare Part B Beneficiary Appeals Process*

From the perspective of Medicare coverage decisions, the most important appeals process is the Part B beneficiary appeals process.<sup>129</sup> The Social Security Amendments of 1965 expressly provided that beneficiaries under Parts A and B could obtain administrative and judicial review of any determination regarding eligibility for benefits as well as the amount of benefits under the appeals provisions in § 205 of the Social Security Act.<sup>130</sup> For Part B, the legislation also required that carriers establish fair hearing procedures for beneficiaries' disputes over payments and claims.<sup>131</sup>

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123. Medicare Program; Revised Process for Making Medicare National Coverage Decisions, 68 Fed. Reg. 55,634 (Sept. 26, 2003).

124. *Id.*

125. *Id.*

126. *Id.* at 55,638.

127. *Id.*; see *supra* notes 111–14 and accompanying text (discussing appeals process under § 522 of BIPA).

128. Medicare Program; Revised Process for Making Medicare National Coverage Decisions, 68 Fed. Reg. 55,634 (Sept. 26, 2003).

129. Eleanor D. Kinney, *Medicare Beneficiary Appeal Processes* in GUIDE TO MEDICARE COVERAGE DECISION-MAKING AND APPEALS 65, 66 (Eleanor D. Kinney ed., 2002). Much of the material in this Section is based on this chapter.

130. 42 U.S.C. §§ 402(b)(g), 1395ff(d), (f) (2000).

131. See *id.* § 1395u(b)(3)(C) (requiring a fair hearing when the amount in controversy is greater than \$100 and less than \$500).

Further, only beneficiaries had the right to appeal a Part B claim; the providers and supplier could appeal the beneficiary's claim if they had accepted assignment of the claim.<sup>132</sup> Beneficiaries could not challenge the Medicare program in court outside this appeals process due to the explicit bar in the Social Security Act to federal question jurisdiction for independent challenges.<sup>133</sup>

In 1972, due to the high volume of small Part B appeals, Congress eliminated administrative and judicial review for Part B claims.<sup>134</sup> Part B appeals were limited to the fair hearing procedures before carriers. By the mid-1980s, however, there was much concern about the fairness of the Part B appeals process and in particular, the lack of access to further administrative and judicial review for Part B claims.<sup>135</sup>

In the Omnibus Budget Reconciliation Act of 1986 (OBRA 86), Congress established administrative review for claims over \$500 and judicial review for claims over \$1,000.<sup>136</sup> HCFA retained carrier hearings for all Part B claims prior to administrative review even though OBRA 86 required fair hearings only for claims under \$500.<sup>137</sup> OBRA 86 also imposed significant limitations on administrative and judicial review of national coverage determinations.<sup>138</sup> Specifically, these limits precluded judicial review of Medicare's national coverage determinations as well as procedural challenges of national coverage determinations for failure to comply with APA and other statutory rulemaking procedures.<sup>139</sup> Also, OBRA 86 required a court to remand a challenged national coverage determination back to HCFA for

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132. *See id.* § 1395u(b)(3) (granting the right to a fair hearing only to enrolled individuals); Grinstead, *supra* note 75, at 6 (explaining the Medicare appeals process).

133. 42 U.S.C. § 405(h) (2000).

134. Social Security Amendments of 1972, Pub. L. No. 92-603, § 2990, 86 Stat. 1329, 1464-65 (1972) (codified as amended at 42 U.S.C. § 1395ff(b) (2000)).

135. *See Medicare Appeals Provisions: Hearings Before the Health Subcomm of the Senate Fin. Comm.*, 99th Cong. 270 (1985) (statement of P. John Seward, M.D., Vice Chairman, Council on Legislation, American Medical Association) (supporting proposal to provide recourse for beneficiaries and physicians after denial of benefits at carrier hearing).

136. Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 9341(a), 100 Stat. 1874, 2037 (1986) (codified as amended at 42 U.S.C. § 1395(b) (2000)).

137. Hearings by Administrative Law Judges of Certain Medicare Claims, 53 Fed. Reg. 20,023, 20,024 (proposed June 1, 1988); *see Isaacs v. Bowen*, 865 F.2d 468, 477 (2d Cir. 1989) (upholding HCFA's authority to retain this step).

138. *See Isaacs*, 865 F.2d at 471 (citing additional amount in controversy requirements on fair hearings and ALJ and judicial review).

139. *See supra* note 71 and accompanying text (stating that Congress expressly exempted challenges of national coverage determinations for failure to comply with § 553 of the APA).



amplification before invalidating it on any grounds.<sup>140</sup> Courts have generally upheld these requirements.<sup>141</sup>

Currently, the Part B beneficiary appeals process proceeds as follows. First, if the amount in controversy is between \$100 and \$500, there is a fair hearing before the carrier.<sup>142</sup> After the carrier's final disposition, a beneficiary can appeal an adverse determination if the amount in controversy is \$100 or more to an ALJ within the Social Security Administration.<sup>143</sup> Judicial review is available for disputes of \$1,000 or more after a prior internal appeal to the DAB.<sup>144</sup>

Despite the addition of administrative and judicial review, the Part B appeals process continued to be problematic.<sup>145</sup> The GAO criticized the process as unduly lengthy.<sup>146</sup> In the 1980s, the Administrative Conference of the United States and the American Bar Association recommended changes to the OBRA 86 limitations and other reforms.<sup>147</sup>

Judicial challenges to the Part B appeals procedures persisted as well.<sup>148</sup> In the 1980s, several Supreme Court decisions addressed Part B

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140. Omnibus Reconciliation Act of 1986, Pub. L. No. 99-509, § 9341(a), 100 Stat. 1874, 2038 (1986) (codified as amended at 42 U.S.C. § 1395(b)).

141. See, e.g., *Nat'l Kidney Patients Ass'n v. Sullivan*, 958 F.2d 1127, 1133 (D.C. Cir. 1992) (stating that judicial "review simply awaits *initial* administrative determination [of Part B claims] in a concrete setting"); *Abby v. Sullivan*, 978 F.2d 37, 44 (2d Cir. 1992) (stating that courts ordinarily give an agency the opportunity to review applications of its rules); *Roen v. Sullivan*, 764 F.Supp. 555, 560 (D. Minn. 1991) (concluding that the court did not have subject matter jurisdiction because plaintiff failed to exhaust administrative remedies).

142. 42 U.S.C. § 1395u(b)(3)(C) (2000).

143. *Id.* § 1395ff(b)(1)(E)(i).

144. *Id.*

145. See generally *Adjudicatory Procedures of the Dep't of Health & Human Servs. Before the Subcomm. on Admin. Law and Gov't Relations of the House Judiciary Comm.*, 101st Cong. (1989) (containing testimony on timeliness and quality of hearings).

146. U.S. GEN. ACCOUNTING OFFICE, STATISTICS ON THE PART B ADMINISTRATIVE LAW JUDGE HEARINGS PROCESS (1989).

147. See *supra* note 64 and accompanying text (discussing concerns with HCFA's closed coverage decision-making process).

148. See, e.g., *Warder v. Shalala*, 149 F.3d 73, 83 (1st Cir. 1998) (holding agency's interpretive rule was not binding on courts but deserving of deference); *Friedrich v. Sec'y Health & Human Services*, 894 F.2d 829, 834 (6th Cir. 1990) (holding that § 9341(b) of OBRA allows a court to hold a national coverage determination issued before 1987 unlawful for inadequate notice and comment); *Smith v. Thompson*, 210 F. Supp. 2d 994, 1000 (N.D. Ill. 2002) (upholding Illinois ALJ's refusal to regard non-Illinois Medicare policies as precedent); *Estate of Aitken v. Shalala*, 986 F. Supp. 57, 62 (D. Mass. 1997) (remanding national coverage determinations back to HCFA because "there does not appear to be a relationship between the agency's findings and the applicable criteria of judgment"); *Matthews v. Shalala*, 1997 U.S. Dist. LEXIS 3111, at \*6 (S.D.N.Y., Mar. 18, 1997) (stating that a court will uphold national

beneficiary appeal procedures. In its 1982 decision, *Schweiker v. McClure*,<sup>149</sup> the Supreme Court concluded that carrier Part B hearing procedures were sufficient from a due process perspective and further administrative or judicial review was not constitutionally required.<sup>150</sup> In its 1984 decision, *Heckler v. Ringer*,<sup>151</sup> the Supreme Court ruled that a beneficiary could not challenge a national coverage decision in court without exhausting administrative remedies due to the jurisdictional bar to independent judicial challenges in the Social Security Act.<sup>152</sup> Of note, in a 2000 decision,<sup>153</sup> the Supreme Court conclusively limited an earlier decision that had effectively permitted judicial challenges to Medicare policies outside the statutory appeals process and reasserted the statutory bar to federal question jurisdiction in the Social Security Act.<sup>154</sup>

By the late 1990s, the Republican Congress responded to concerns of health industry manufacturers and expressed interest in reforming the Part B appeals process. The Health Subcommittee of the House Committee on Ways and Means held hearings on the beneficiary appeals process and initiated reforms.<sup>155</sup> Ultimately, reforms to beneficiary appeals processes for Parts A and B were included in BIPA.<sup>156</sup>

BIPA has consolidated the beneficiary appeals processes for Parts A and B and mandated major reforms in the process.<sup>157</sup> Figure 2 is a comparison of the old Part B appeals process and the BIPA beneficiary appeals processes.

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coverage determinations unless it finds the determination unsupported by adequate information in the record, in which case the court will remand for further proceedings); *Cedars-Sinai Med. Ctr. v. Shalala*, 939 F. Supp. 1459, 1465 (C.D. Cal. 1996) (holding agency rule invalid for failure to comply with notice and comment requirements); *Bosko v. Shalala*, 995 F. Supp. 580, 583 (W.D. Pa. 1996) (upholding a national coverage determination that relied on comprehensive analysis).

149. *Schweiker v. McClure*, 456 U.S. 188 (1982).

150. *Id.* at 200.

151. *Heckler v. Ringer*, 466 U.S. 602, 619 (1984).

152. *See* 42 U.S.C. § 405(h) (2000) (stating that findings of fact or law made by the Commissioner of Social Security will not be reviewed).

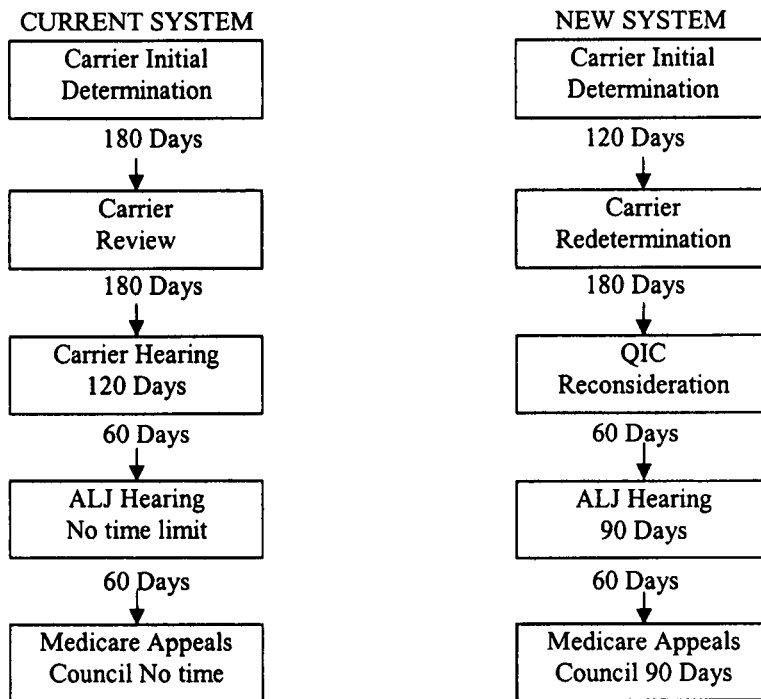
153. *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 25 (2000).

154. 42 U.S.C. § 405(h); *see* *Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667, 678 (1986) (concluding "that those matters which Congress did *not* leave to be determined in a 'fair hearing' conducted by the carrier—including challenges to the validity of the Secretary's instructions and regulations—are not impliedly insulated from judicial review by 42 U.S.C. § 1395ff").

155. *See, e.g., Patient Appeals in Health Care: Hearings before the Health Subcomm. of the House Comm. on Ways and Means*, 105th Cong. 3–78 (1998) (examining the different appeals procedures applied by Medicare and private insurers).

156. *See* U.S.C. § 1935f(b)(1)(A) (2000) (allowing beneficiaries to appeal initial coverage determinations).

157. *Id.*

**Figure 2: Current and New Medicare Beneficiary Appeals Systems<sup>158</sup>**

\*Time in boxes represents time allowed to complete appeal.

\*\*Time between boxes represents time allowed to file for appeal.

BIPA mandated the following reforms: (1) revised time limits for filing appeals, (2) reduced decision-making time frames throughout all levels of the Medicare administrative appeals system; and (3) establishment of "qualified independent contractors" (QICs) to conduct reconsiderations of contractors' initial determinations or redeterminations. The BIPA reforms only apply to the appeal procedures under Parts A and B, leaving the Part C appeals procedures for Medicare+Choice beneficiaries intact.<sup>159</sup>

158. DEP'T OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GEN., MEDICARE ADMINISTRATIVE APPEALS: THE POTENTIAL IMPACT OF BIPA, No. OEI-04-01-00290, at 10 (2002).

159. The Balanced Budget Act of 1997 established grievance and appeal procedures for Medicare+Choice plans., Balanced Budget Act of 1997, Pub. L. No. 105-33 § 4001, 111 Stat. 251, 275-327 (1997) (codified at 42 U.S.C. § 1395w-21); see generally Jennifer E. Gladieux, *Medicare+Choice Appeal Procedures: Reconciling Due Process Rights and Cost Containment*, 25 AM. J. L. & MED. 61 (1999).

Perhaps the most significant reform, which CMS has not implemented,<sup>160</sup> is the creation of independent medical review for the reconsideration of initial determinations of coverage in individual cases.<sup>161</sup> Specifically, BIPA requires that CMS contract with at least twelve QICs nationwide to conduct reconsiderations of Medicare coverage determinations at the request of beneficiaries or CMS.<sup>162</sup> QICs must be organizations independent of any existing Medicare contractors that make initial determinations<sup>163</sup> and be comprised of panels of physicians or other health care professionals.<sup>164</sup> The professional panels must have the ability to consider clinical experience and medical, technical, and scientific evidence associated with reconsidered coverage determinations.<sup>165</sup> Attending physicians cannot be involved in the reconsideration.<sup>166</sup> The written reconsideration decision must include a detailed explanation of the decision, a discussion of pertinent facts and regulations and, where the issue is reasonable and necessary services, an explanation of the scientific rationale.<sup>167</sup> A beneficiary can appeal the QIC decision to an ALJ with further review by the DAB.<sup>168</sup>

Under BIPA, both administrative and judicial review for claims over a specified amount are available. A beneficiary is entitled to an ALJ hearing if the amount in controversy is at least \$100.<sup>169</sup> Further, ALJs must make decisions no later than ninety days after the hearing request, although the party seeking the hearing may waive the time period.<sup>170</sup> If the deadline is not met, the beneficiary may seek review by the DAB.<sup>171</sup> The QIC becomes a party in the ALJ hearing and prepares such information as is required for the appeal, including, as necessary, an explanation of the issues and the relevant policies.<sup>172</sup> The QIC also participates in the hearings as required by HCFA.<sup>173</sup> The DAB

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160. See *infra* note 181 and accompanying text (noting CMS has not yet implemented QIC review).

161. 42 U.S.C. § 1935ff(b) (2000).

162. *Id.* § 1935ff(c)(3).

163. *Id.* § 1935ff(c)(2).

164. *Id.* § 1935ff(c)(3)(B)(i).

165. *Id.*

166. *Id.* § 1935ff(c)(3)(D)(i)(I).

167. *Id.* § 1935ff(c)(3)(E).

168. See *id.* § 1935ff(d) (providing ALJ review of the QIC decision and de novo DAB review of the ALJ decision).

169. *Id.* § 1935ff(b)(1)(E)(i).

170. *Id.* § 1935ff(d)(1).

171. *Id.* § 1935ff(d)(3)(A).

172. *Id.* § 1935ff(c)(3)(J).

173. *Id.*

reviews the case de novo and must make a decision within ninety days of the request.<sup>174</sup> If the deadline is not met, the beneficiary may seek judicial review<sup>175</sup> if the amount in controversy is at least \$1000.<sup>176</sup> BIPA retains the same limitations on judicial review of national coverage determinations established in OBRA 86.<sup>177</sup>

BIPA contains crucial new provisions for provider representation of beneficiaries. Of import, suppliers and providers can represent beneficiaries in appeals and also appeal beneficiary claims for which the suppliers or providers have accepted assignment.<sup>178</sup> Any provider or supplier representing a beneficiary must waive any right to payment from the beneficiary with respect to the services or items being appealed.<sup>179</sup> Further, BIPA now imposes specific mandates on CMS to inform beneficiaries, providers, and suppliers of their appeal rights.<sup>180</sup>

CMS has not yet implemented QIC review, stating it does not have the resources to launch the requisite contracting process to bring QICs on line.<sup>181</sup> Furthermore, the Office of the Inspector General (OIG) has criticized implementation of QICs as very costly at a time of constrained resources.<sup>182</sup> Nevertheless, in November 2002, CMS promulgated a proposed rule to implement some of the changes of BIPA in the appeals process.<sup>183</sup> The proposed rule establishes "a uniform process for handling all Part A and Part B appeals; revised time limits for filing appeals; reduced decision-making time

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174. *Id.* § 1935ff(d)(2).

175. *Id.* § 1935ff(d)(3)(8).

176. *Id.* § 1935ff(b)(1)(E)(i).

177. *See id.* § 1935ff(b)(1)(E)(i) (limiting the amount in controversy); *supra* note 138 (noting limitations on judicial and administrative review of national coverage determinations).

178. *See* 42 U.S.C. § 1935ff(b)(1)(C) (2000) (permitting a beneficiary to assign his right to appeal to a provider or supplier).

179. *Id.* § 1935ff(b)(1)(B)(ii).

180. *See id.* § 1935ff(e)(2) (requiring the Secretary to employ sufficient means, including a toll-free telephone number, to inform beneficiaries of their appeal rights).

181. Notice of CMS Ruling, The National and Local Coverage Determination Review Process for an Individual with Standing as Defined in Section 522 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protections Act of 2000, 66 Fed. Reg. 54,253 (Oct. 26, 2001).

182. *See* DEP'T OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GEN., MEDICARE ADMINISTRATIVE APPEALS: THE POTENTIAL IMPACT OF BIPA, No. OEI-04-01-00290, 1, 14 (2002) (stating that the creation of QICs will have a significant cost and that Medicare is already "backlogged, overwhelmed, and untimely"), available at <http://oig.hhs.gov/oei/oecisearch.html>.

183. Changes to the Medicare Claims Appeal Procedures, 67 Fed. Reg. 69,312 (Nov. 15, 2002) (to be codified at 7 C.F.R. pt. 300).

frames . . . [and] the introduction of new entities known as qualified independent contractors (QICs) . . . ."<sup>184</sup>

Finally, in the last three years, CMS has promoted legislative changes in the beneficiary appeals process that would establish an ALJ corps within CMS to adjudicate beneficiary appeals and institute other reforms.<sup>185</sup> The most recent incarnation of the proposed legislation includes increased funding for training and support of Medicare ALJs, a process for expedited judicial review of claims in which there is no factual dispute, and a requirement for the full and early presentation of evidence at the first external level of appeal with prohibitions against subsequent submission of information, except for good cause.<sup>186</sup> The rationale for many of these reforms, from CMS's perspective, is presented in a 1999 OIG report on Medicare appeals.<sup>187</sup> This report recommended separating true beneficiary appeals from appeals involving providers or suppliers, establishing an ALJ corps within CMS that is more knowledgeable about the Medicare program policies and requirements, requiring ALJs to follow the same standards as Medicare contractors, and establishing a case precedent system for DAB rulings.<sup>188</sup>

One major motive for these reforms is the increase in the number of beneficiary appeals in recent years. Between 1996 and 1998, Part B appeals increased 99%.<sup>189</sup> ALJs reversed appeals of denials of durable medical equipment in 78% of cases, leaving the OIG to comment: "Reversal rates of this magnitude could encourage appellants."<sup>190</sup> This comment begs the question whether a review of coverage policy regarding DME might also be in order as these reversal rates may represent a situation where beneficiaries are not getting coverage of DME items that they clearly need in the view of the ALJ.

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184. *Id.* at 69,312.

185. *See* Medicare Regulatory and Contracting Reform Act of 2003, H.R. 810, 108th Cong. § 401 (2003) (mandating development of a transition plan to transfer oversight of ALJs conducting Medicare hearings from the Social Security Administration to the Department of Health and Human Services); Medicare Regulatory and Contracting Reform Act of 2001, H.R. 2768, 107th Cong. § 8(g) (2001) (same).

186. H.R. 810 §§ 401-03.

187. DEP'T OF HEALTH AND HUMAN SERVS., OFFICE OF THE INSPECTOR GEN., MEDICARE ADMINISTRATIVE APPEALS: ALJ HEARING PROCESS, NO. OEI-04-97-00160, at 1-2 (Sept. 1999) (listing findings of the Office of the Inspector General's evaluation of ALJ appeals for Medicare Parts A and B), available at <http://oig.hhs.gov/oei/reports/oei04-97-00160.pdf>.

188. *Id.* at 2.

189. *Id.* at 8.

190. *Id.* at 8.

### III. Does Process Meet the Challenge?

This section explores the foundational issues that animate the debate over the Medicare decision-making and appeals processes. At this point, the debate seems to be unresolvable. More process never seems to satisfy certain Medicare constituencies, and CMS's effort to control the outcome of the processes is relentlessly persistent.

As a framework for analysis of this debate, it is useful to proceed from the Supreme Court's decision in *Mathews v. Eldridge*,<sup>191</sup> with its three pronged test to assess the constitutionality of government procedures under the procedural Due Process Clause of the Fifth and Fourteenth Amendments to the U.S. Constitution. While this test actually applies to adjudicative and not policy-making procedures, it does represent one consensus on fair process from a legal perspective. The *Mathews* analysis also serves as a useful vehicle for sorting out the critical issues with respect to fairness of any process for adjudicating disputes and, in particular, addresses the critical issues in the debate over the Medicare coverage decision-making and appeals processes.

Specifically, the *Mathews* test calls for consideration of the following three factors:

First, the private interest that will be affected by the official action; Second, the risk of an erroneous deprivation of such interest through the procedures used, and probable value, if any, of additional or substitute procedural safeguards; and finally, the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedures would entail.<sup>192</sup>

The first and third factors call for an assessment of the interests of the private parties and the government and the weighing of these interests.<sup>193</sup> The second factor calls for an assessment of the process in terms of its ability to produce accurate decisions, or at least to avoid erroneous deprivations of protected interests.<sup>194</sup> This test is not without its critics for being a rather bloodless cost-benefit analysis for determining the content of constitutional rights.<sup>195</sup>

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191. *Mathews v. Eldridge*, 424 U.S. 319 (1976).

192. *Id.* at 335.

193. *See id.* at 334 ("[R]esolution of the issue whether the administrative procedures provided . . . are constitutionally sufficient requires analysis of the governmental and private interests that are affected.").

194. *See id.* at 343–47 (discussing the evaluation of existing procedures).

195. *See, e.g.,* Cynthia R. Farina, *Conceiving Due Process*, 3 YALE J. L. & FEMINISM 189, 234–35 (1991) (characterizing the *Mathews* formula as a method of social welfare accounting whereby individual claims are weighed against the government's costs of providing additional process); Jerry L. Mashaw, *The Supreme Court's Due Process Calculus for Administrative*

### A. *The Interests of the Affected Constituencies*

The first prong of the *Mathews v. Eldridge* test is analysis of the private interest at stake.<sup>196</sup> Analysis of this prong reveals a crucial dimension of the debate: the parties with the greatest interests and stakes in the debate, health care manufacturers, do not, under current law, have much, if any, constitutional protection of their interests. Further, Medicare beneficiaries with the greatest constitutional protection of their interest in Medicare benefits are least able to articulate and promote those interests in the Medicare coverage decision-making and appeals processes.<sup>197</sup> Physicians and other providers, who are in the best position to advocate for beneficiaries, have only minimal and derivative interests in Medicare benefits protected under federal law.<sup>198</sup>

#### 1. *Beneficiaries*

Medicare beneficiaries—those for whose benefit the program exists—have the most important interest in the Medicare program.<sup>199</sup> Courts have long recognized that Medicare beneficiaries have a protected interest in receiving their Medicare benefits.<sup>200</sup> Nevertheless, the degree to which beneficiaries have

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*Adjudication in Mathews v. Eldridge: Three Factors in Search of a Theory of Value*, 44 U. CHI. L. REV. 28, 48 (1976) ("The *Eldridge* court conceives of the values of procedure too narrowly: it views the sole purpose of procedural protections as enhancing accuracy, and thus limits its calculus to the benefits or costs that flow from correct or incorrect decisions."); Richard B. Saphire, *Specifying Due Process Values: Toward a More Responsive Approach to Procedural Protection*, 127 U. PA. L. REV. 111, 154–55 (1978) (arguing that the *Mathews* test is unsuitable because it fails to protect the dignitary value of beneficiaries inasmuch as it sets that value off against the cost of providing more process).

196. *Mathews*, 424 U.S. at 335.

197. See Vicki Gottlich, *The Perspective of Medicare Beneficiaries*, in GUIDE TO MEDICARE COVERAGE DECISION-MAKING AND APPEALS 87, 89 (Eleanor D. Kinney ed., 2002) ("[E]ven if beneficiaries have timely knowledge of a proceeding that would affect them, they generally lack the resources to participate effectively in the process.").

198. See 42 U.S.C. § 1395ff(f)(5) (2000) (granting standing for appeals of national coverage decisions and local coverage decisions only to beneficiaries); see also Eleanor D. Kinney, *Medicare Beneficiary Appeals Processes*, in GUIDE TO MEDICARE COVERAGE DECISION-MAKING AND APPEALS 65, 69 (Eleanor D. Kinney ed., 2002) (explaining that providers do not have standing to appeal coverage decisions and can only appeal the decisions if a beneficiary assigns the claim to them).

199. See Gottlich, *supra* note 197, at 87 (stating that advocacy groups have brought litigation on behalf of Medicare beneficiaries to challenge the processes used to determine coverage decisions and appeals).

200. See *Goldberg v. Kelly*, 397 U.S. 254, 264 (1970) (determining that due process requires that recipients of public assistance benefits are entitled to an evidentiary hearing prior to termination of benefits); see also *O'Bannon v. Town Ct. Nursing Ctr.*, 447 U.S. 773, 786–87



an interest in coverage decisions, even in individual cases, is open to question after the Supreme Court's decision in *American Manufacturers Mutual Insurance Co. v. Sullivan*.<sup>201</sup> In *Sullivan*, the Supreme Court ruled that a private insurer's decision to withhold payment for disputed medical treatment in a state-mandated workers' compensation program was not state action under the procedural due process doctrine and that claimants had no property interest in payment for medical treatment before the insurer's determination that the service was reasonable and necessary.<sup>202</sup> *Sullivan* begs the question of whether the beneficiaries' entitlement exists only after the decision on coverage has been made. If so, a beneficiary arguably would not be entitled to a review of a decision on coverage in any event.

The medical nature of the beneficiary's interest diminishes its effective articulation and protection in the coverage decision-making process as well as in the appeals process. Specifically, beneficiaries generally do not have the requisite medical expertise to assess their need for specific procedures, devices or other technologies or articulate those needs in the coverage decision-making and appeal process.<sup>203</sup> They must necessarily rely on the medical profession for expertise to define and articulate their needs for health care services. Even beneficiary advocacy organizations need medical expertise to represent beneficiaries adequately in coverage decision-making proceedings. Indeed, Medicare beneficiary advocates have been largely absent in national and local coverage decision-making proceedings. But they have been very active and effective in helping individual beneficiaries in their appeals of coverage decisions.<sup>204</sup>

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(1980) (explaining that due process requires notice and an opportunity to be heard before the government can withdraw the direct benefits of Medicare or Medicaid from a recipient); *Gray Panthers v. Schweiker*, 652 F.2d 146, 172 (D.C. Cir. 1980) (finding that elderly persons permanently denied statutory insurance benefits financed by the federal government have a protected interest entitling them to notice of the evidence used to determine denial of their benefits and an opportunity to present evidence on their own behalf).

201. *Am. Mfrs. Mut. Ins. Co. v. Sullivan*, 526 U.S. 40 (1999).

202. *See id.* at 43–44; *see also* *Grijalva v. Shalala*, 526 U.S. 1096, 1096 (1996) (invoking the decision in *Sullivan* in remanding the decision of the Court of Appeals for the Ninth Circuit). The Ninth Circuit had ruled that extant Medicare HMO grievance and appeal procedures failed to secure minimum due process for Medicare beneficiaries on several grounds and that HMO service denials constituted federal action for purposes of the procedural due process clause. *Grijalva v. Shalala*, 152 F.3d 1115, 1120 (9th Cir. 1998).

203. *See* *Gottlich*, *supra* note 197, at 89 (explaining that beneficiary involvement in coverage decision-making is rare because beneficiaries usually are not aware that they need a certain treatment at the time the rulemaking decision is being considered). Even if the beneficiaries know they need the treatment, they cannot effectively participate in the process because they lack the proper resources. *Id.*

204. *See id.* at 87 (stating that public interest organizations work on behalf of beneficiaries

Another important characteristic of Medicare beneficiaries is their relative economic and social vulnerability as a group. However, the Medicare beneficiaries as a group are not monolithic. Important differences in this group could have a substantial effect on the debate over Medicare coverage decision-making in the future. The most important difference is the evolving divide in incomes of Medicare beneficiaries. Today, nearly 65% of Medicare beneficiaries have incomes at or under \$25,000, while 16% have incomes of \$40,001 or more.<sup>205</sup> Projections on the demographics of Medicare beneficiaries in the future suggest that many will be very affluent.<sup>206</sup> One study reported that by 2015, elderly persons with an annual income less than \$20,000 will drop to 38%, while 30% will have incomes over \$40,000, and that by 2030, 30% of the elderly will earn less than \$20,000, while those with incomes greater than \$40,000 will reach 36%.<sup>207</sup> Further, the numbers of elderly with total assets exceeding \$150,000 will more than triple—moving from 13.2 million in 2000 to 44.5 million in 2030.<sup>208</sup> The study predicts that "many elders in the future will be able to pay for both necessary services such as long-term care and discretionary, uncovered services."<sup>209</sup> The study also warns that "[w]ithout major changes in the way we pay for healthcare, however, multiple-tier medicine will become more and more pronounced."<sup>210</sup>

Income inequity among the elderly could adversely affect the advocacy of the interests of Medicare beneficiaries. If affluent beneficiaries are able to purchase health care services or private coverage independent of the Medicare program, they will have less incentive to advocate for Medicare coverage of new medical procedures, devices and other new technologies. Empirically-based social theory on the effects of inequality in societal income suggests that when the social leadership gets so rich that it need not rely on public programs for basic needs, it loses interest in the public sector, thereby denying the public sector of leadership and advocacy.<sup>211</sup> In the case of the Medicare program, lack

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to challenge Medicare coverage and appeals procedures).

205. OFFICE OF RESEARCH, DEV. & INFO., CTRS. FOR MEDICARE & MEDICAID SERVS., *Program Information on Medicare, Medicaid, SCHIP, and Other Programs of the Centers for Medicare and Medicaid Services* § 3.B.1, at 7 (June 2002).

206. See James R. Knickman et al., *Wealth Patterns Among Elderly Americans: Implications for Health Care Affordability*, HEALTH AFF., May/June 2003, 168, 169 exhibit 1 (showing the distribution and projected distribution of income for all elderly persons for the years 2000, 2015 and 2030).

207. *Id.*

208. *Id.* at 172.

209. *Id.* at 171.

210. *Id.* at 172.

211. See Robert D. Putnam, *Bowling Alone: America's Declining Social Capital*, J.

of such leadership could lead to Medicare's transition to a needs-based welfare program like the Medicaid program, with more limited coverage of new medical procedures, devices, and technology. Providers and manufacturers with access to a large class of affluent patients with the ability to pay for or obtain private coverage of new medical technologies could have diminished interest in pressing for coverage of new technologies in the Medicare program. Such an eventuality could result in compromised access to many new technologies for low and middle income elderly who rely only on the Medicare program for their health coverage.

## 2. Providers

Physicians and other providers of health care services under Part B have a derivative interest in the Medicare program.<sup>212</sup> Historically, the courts have ruled that neither physicians nor other institutional providers have a protected entitlement in Medicare payments protected under the procedural due process clause.<sup>213</sup> But recently, in *Fischer v. United States*,<sup>214</sup> the Supreme Court acknowledged that providers do have a recognized interest in Medicare benefits beyond compensation for services.<sup>215</sup> The Court has not specified how this observation translates into additional rights of providers to represent patients and advocate for coverage of new procedures, devices, or technology.

Experience with Part B of the Medicare program has demonstrated that physicians, in their roles as certifiers of needed Medicare benefits for beneficiaries<sup>216</sup> and as patient advocates under ethical codes of the medical

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DEMOCRACY 65, 65–78 (Jan. 1995) (arguing that social capital has declined in recent decades and suggesting further studies to explore the effects of weak civil societies). See generally THE POLITICAL ECONOMY OF INEQUALITY (Frank Ackerman et al. eds., 2000) (analyzing the causes and consequences of inequality in the United States and around the world).

212. See *supra* note 6 and accompanying text (identifying Part B).

213. See *St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 876 (7th Cir. 1983) (finding that due process does not require that non-proprietary hospitals receive a return on equity capital); *Geriatrics, Inc. v. Harris*, 640 F.2d 262, 265 (10th Cir. 1981) (determining that a nursing home which received Medicaid funds was not entitled to a hearing before termination of those funds).

214. *Fischer v. United States*, 529 U.S. 667 (2000).

215. See *id.* at 673 (stating that healthcare providers receive Medicare funds not only as compensation for services rendered, but also to fund programs that enable the provider to continue offering quality services).

216. See 42 U.S.C. § 1395g(a) (2000) (stating that providers cannot be paid for services rendered until they have "furnished such information as the Secretary may request in order to determine the amounts due such provider").

profession,<sup>217</sup> have an important role in the Medicare coverage decision-making and appeals processes. Indeed, given that physicians are the sole repository of information and that they must make a judgment about whether a procedure is reasonable and necessary in the diagnosis or treatment of disease or injury, the role of physicians in these processes is essential. As discussed above, the coverage decision-making process invites and indeed heavily relies on the input of the medical profession and its associations and specialty societies in making national and local coverage decisions, particularly if a formal assessment of the new technology is required.<sup>218</sup>

With respect to the appeals of coverage decisions for cases of individual beneficiaries, which might result in diminished or no Medicare payment for a physician under Part B, physicians have only derivative appeal rights.<sup>219</sup> They may only appeal beneficiary claims for which they have accepted assignment of the beneficiary's right of reimbursement.<sup>220</sup> Yet it is often important for a beneficiary's physician to participate in an appeal to address the medical issues which are beyond lay expertise.

Many factors limit the interests of physicians in mounting or participating in a beneficiary's appeal of a coverage denial. First, the physician's payment for the care of Medicare beneficiaries is based on the resources that the physician used to treat an episode of illness and generally not on a specific procedure.<sup>221</sup> Therefore, only when a physician wants to perform a specific procedure that is the subject of a national or local coverage decision, or is so new that it does not fit within existing codes and comes to the attention of the carrier, does coverage of a procedure become an important economic concern to physicians.

The regulations governing beneficiary appeal procedures make it difficult for physicians to participate in beneficiary appeals. Physicians cannot initiate appeals of coverage decisions, but can only participate in beneficiary-initiated

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217. See William M. Sage, *Physicians as Advocates*, 35 Hous. L. Rev. 1529, 1542–43 (1999) ("In this newer version [of medical ethics], the medical profession continues to assert a general right to oversee clinical care, but also frames itself as an advocate for patients . . .").

218. See *supra* notes 59–60, 72, 86 and accompanying text (providing examples of physicians and others in medical profession giving input to decision-making process).

219. See *supra* note 198 and accompanying text (stating that while physicians are in the best position to advocate for beneficiaries, they only have derivative interests in Medicare benefits).

220. See *id.* (explaining that providers can only appeal the decision if a beneficiary assigns the claim to them).

221. See *supra* note 39 and accompanying text (noting that the payment system is based on time and resources spent on treating conditions).

appeals.<sup>222</sup> In addition, the Medicare statute does not permit physicians to consolidate appeals which involve different beneficiaries, but the same procedure.<sup>223</sup> In the cases involving DME, in which the physician is generally not the supplier and does not receive payment, the physician's role is basically advisory. Finally, given the realities of compressed medical practice, few physicians have the time or resources to participate or otherwise assist beneficiaries in Part B appeals.<sup>224</sup>

### 3. Durable Medical Equipment (DME) Suppliers

DME is sold or rented directly to Medicare beneficiaries by so-called "DME Suppliers." Suppliers have no recognized entitlement interest in Medicare coverage for their products or in Medicare payment.<sup>225</sup> Further, like physicians, the supplier's appeal rights are derivative from those of beneficiaries.<sup>226</sup>

Yet, the interest of DME suppliers in the Medicare coverage decision-making and appeals process is great.<sup>227</sup> Of note, Medicare expenditures for DME in 2000 were \$18.5 billion<sup>228</sup>—1.4% of all health care expenditures.<sup>229</sup>

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222. *Supra* note 198 and accompanying text.

223. See 42 U.S.C. § 1395ff(b)(1)(B)(ii) (2000) (stating that a person who provides services to an individual may only participate in the appeal of a coverage denial if he waives his right to payment for the service or item involved in the appeal).

224. See Ochs-Ross & Connaughton, *supra* note 99, at 121 (explaining that physicians are unlikely to participate in Medicare appeals because the administrative burden of treating Medicare patients already takes up large portions of their time).

225. See, e.g., *TAP Pharm. v. DHHS*, 163 F.3d 199, 208 (4th Cir. 1998) (holding that a drug manufacturer does not fall within the zone of interests protected under Medicare Part B and thus does not have standing for a claim challenging a Medicare decision reducing reimbursement for the drug); see also Grinstead, *supra* note 75, at 6 (explaining that after *TAP Pharmaceuticals*, a manufacturer "may not be able to formally challenge a decision by the Medicare program not to pay for that item").

226. See 42 U.S.C. § 1395ff(b)(1)(B)(ii) (2002) (stating that a person who provides services to an individual may only participate in the appeal of a coverage denial if he waives his right to a payment for the service of item involved in the appeal).

227. See Ochs-Ross & Connaughton, *supra* note 99, at 105 ("DME suppliers, who are paid on a retrospective basis for specific items of DME, are especially concerned about Medicare coverage decisions and are active in assisting individual Medicare beneficiaries in appeals of coverage denials.").

228. CTRS. FOR MEDICARE & MEDICAID SERS., TABLE 13: DURABLE MEDICAL EQUIPMENT EXPENDITURES AGGREGATE AND PER CAPITA AMOUNTS, PERCENT DISTRIBUTION AND AVERAGE ANNUAL PERCENT CHANGE BY SOURCE OF FUNDS: SELECTED CALENDAR YEARS 1980–2011, at <http://cms.hhs.gov/statistics/nhe/projections-2001/t13.asp> (last visited Aug. 20, 2003) (on file with the Washington and Lee Law Review).

The products of DME suppliers are often the subject of local and national coverage decisions as well as coverage denials for the claims of individual beneficiaries.<sup>230</sup> Also, because suppliers are still paid on a retrospective basis for each item of DME used by a beneficiary, a coverage denial of a beneficiary's claim for DME results in a direct denial of payment for supplier.<sup>231</sup>

#### 4. Health Industry Manufacturers

Health industry manufacturers develop and make the new medical technology that is the subject of most local and national coverage decisions and coverage denials precipitating individual appeals. In terms of constitutional and statutory law, manufacturers have no legal recognition in the Medicare program. Yet of all constituencies, health industry manufacturers have exhibited the greatest interest in the Medicare coverage decision-making and appeals processes.<sup>232</sup> They have been the greatest advocates for reforms in the processes and were the major force in pressing for the BIPA reforms described above.<sup>233</sup>

The interest of manufacturers is a business interest. Quite simply, positive decisions and Medicare coverage at all levels—national, local and individual—are crucial for manufacturers if their products are to reach their full potential markets. With Medicaid a close second, Medicare is the largest single payor for health care services in the United States.<sup>234</sup> Of the nation's health dollar, 17% comes from the Medicare program.<sup>235</sup> Further, Medicare beneficiaries,

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229. See CTRS. FOR MEDICARE & MEDICAID SERVS., TABLE 1: NATIONAL HEALTH EXPENDITURES AND SELECTED ECONOMIC INDICATORS, LEVELS AND AVERAGE ANNUAL PERCENT CHANGE: SELECTED CALENDAR YEARS 1980–2011, at <http://cms.hhs.gov/statistics/nhe/projections-2001/tlp> (last visited Sept. 1, 2003) (listing the National health expenditures in 2000 as \$1,299.5 billion) (on file with the Washington and Lee Law Review).

230. See Bagley, *supra* note 86, at 22 (stating that requests for new coverage decisions usually come from device manufacturers).

231. See *supra* note 227 and accompanying text (noting that DME suppliers are concerned about Medicare coverage decisions because they are paid on a retrospective basis for each item of DME used by a beneficiary).

232. See Ochs-Ross & Connaughton, *supra* note 99, at 105 (stating that DME suppliers and physicians have the greatest interest in Medicare coverage and appeals decisions).

233. See Thompson & Dahl, *supra* note 67, at 128–29 (discussing manufacturers' concerns about the coverage process).

234. CTRS. FOR MEDICARE & MEDICAID SERVS., THE NATION'S HEALTH DOLLAR: 2001, at <http://cms.hhs.gov/statistics/nhe/historical/chart.asp> (last visited Aug. 20, 2003) (on file with the Washington and Lee Law Review).

235. *Id.*

who are elderly, severely disabled, or both, are the heavy users of new procedures, devices and other medical technologies. In addition, Medicare has the most formal coverage decision-making process. For these reasons, the Medicare program therefore exercises great influence over other federally sponsored health insurance programs, such as, Medicaid and health plans for the military, their dependants and other federal employees, as well as privately-sponsored health insurance plans.<sup>236</sup> Without Medicare coverage, the marketing of a health industry manufacturer's product is dead in the water with the specter of losses and inability to recoup development costs.

Moreover, the interests of the health industry manufacturers are not insignificant to the U.S. economy. The manufacture and sale of medical equipment is a major American industry and has continued to grow in the current economic downturn.<sup>237</sup> In 2000, the medical equipment industry exported more than \$15.4 billion in medical equipment.<sup>238</sup> A national interest in maintaining a strong medical device industry may be an appropriate factor to consider in the Medicare program's coverage decision-making about new medical technologies.

### *B. The Risk of Erroneous Deprivation of Rights and Probable Value of Substitute Procedures in the Medicare Coverage Decision-Making and Appeal Processes*

The second prong of the *Mathews v. Eldridge* analysis addresses the characteristics of the process at issue.<sup>239</sup> In that regard, the first of two issues of interest is the risk of erroneous deprivation of the protected private interest. This issue is really concerned about the ability of a process to produce an accurate determination of the issue at hand and also whether alternative or additional procedures might do a better job. This Part will analyze the coverage

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236. See Ochs-Ross & Connaughton, *supra* note 99, at 105 ("Medicare coverage decisions influence the coverage provided by private carriers as they often follow Medicare's lead when deciding whether to provide coverage for new therapies.").

237. See, e.g., Milt Freudenheim, *The Healthier Side Of Health Care*, N.Y. TIMES, Oct. 23, 2002, at C1 (explaining that sales and profits for both firms that manufacture and firms that sell pacemakers increased more than fifteen percent in 2002); David Leonhardt, *Health Care As Main Engine: Is That So Bad?*, N.Y. TIMES, Nov. 11, 2001, § 3, at 1 (stating that the healthcare industry, including the manufacture of medical equipment, has expanded during the recession).

238. DEP'T OF COMMERCE OFFICE OF MICROELECTRONICS, MED. EQUIP. AND INSTRUMENTATION, INDUS. AND TRADE STATISTICS, at <http://www.ita.doc.gov/td/mdequip/totalexports.htm> (last visited Aug. 20, 2003) (on file with the Washington and Lee Law Review).

239. *Mathews v. Eldridge*, 424 U.S. 319, 335 (1976).

decision-making process and then the Part B beneficiary appeals process in terms of this standard.

### 1. *The Medicare Coverage Decision-Making Process*

The Medicare coverage decision-making process is a legislative policy-making process. As such, interested and affected individuals do not have a constitutional right grounded in the procedural Due Process Clause to have an opportunity to be heard in this process.<sup>240</sup> That is as it should be, as the process is the determination of "legislative facts" and the making of policy. Legislative facts are those facts such as scientific research findings which are necessary to determine policy.<sup>241</sup> Nevertheless, it is useful to compare the Medicare coverage decision-making process to the constitutional standard for good process in *Mathews v. Eldridge*.

#### a. *The Risk of Erroneous Deprivation*

Regarding the risk of erroneous deprivation, the current Medicare coverage decision-making process for NCDs does contain mandated procedures to assure that decision-makers have good information upon which to base their decisions.<sup>242</sup> Specifically, public notice is given of the initiation of the process to make an NCD which is designed to give interested constituencies notice and an opportunity to participate.<sup>243</sup> The process invokes scientific review for evaluation of the coverage issue through a coverage advisory panel of outside experts.<sup>244</sup> Independent peer review of medical issues is a time-honored and

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240. See *Bi-Metallic Inv. Co. v. State Bd. of Equalization of Colo.*, 239 U.S. 441, 445 (1915) (finding that there is no constitutional right to be heard when a rule affects more than a few people and noting that the rights of a large group are protected by their power to elect the officials that make the rule), followed in *United States v. Fla. E. Coast Ry. Co.*, 410 U.S. 224 (1973); see also *Ass'n of Nat'l Advertisers v. FTC*, 627 F.2d 1151, 1165-66 (D.C. Cir. 1979) ("When a proceeding is classified as rulemaking, due process ordinarily does not demand procedures more rigorous than those provided by Congress.").

241. Kenneth Culp Davis, *An Approach to Problems of Evidence in the Administrative Process*, 55 HARV. L. REV. 364, 402 (1942) (describing legislative facts as those facts which help an agency determine questions of law or policy).

242. See Bagley, *supra* note 86, at 19-20 (describing mandated procedures in the coverage decision-making process).

243. See *id.* at 25 (explaining that once someone makes a coverage request, CMS makes the record open to the public).

244. See *id.* at 31-33 (describing the structure and role of the MCAC, which makes coverage recommendations to CMS).



widely accepted approach, used pervasively throughout the federal government, to address controversial scientific issues.<sup>245</sup>

As a further check, disappointed parties can invoke a procedure for reconsideration.<sup>246</sup> Reconsideration is widely used in adjudicative proceedings, essentially to enable parties to correct errors or otherwise clear up problems in the decision-making process. It is not always invoked in policy-making proceedings, and its presence in the Medicare coverage decision-making process is exemplary.

In recent years, the process by which Medicare carriers and other Medicare contractors make local coverage decisions has become much more formal and transparent. Local coverage decision-making is in keeping with a foundational value of the Medicare program—the recognition that program administration should be decentralized.<sup>247</sup> The theory of this approach, especially with respect to coverage decision-making, is that decentralized decision-making allows for needed flexibility in a rapidly developing health sector.<sup>248</sup> Decision-making that is too centralized leads to ossification of coverage policy and might well inhibit desirable innovation. Nevertheless, the process for making local coverage decisions also must be fair and transparent. The April 1999 Notice recognizes these needs and addresses them accordingly.

Whether the resulting decisions in this process are truly "accurate," however, is open to question. The major reason for this concern is that often there is a range of opinions on coverage of a medical technology depending on views of scientific evidence, costs and other factors. Ultimately, a coverage decision is a political decision that balances many factors. There really is no "accurate" decision regarding a disputed coverage issue. Thus, at least insofar as reviewing courts are concerned, the question becomes one of whether the decision is reasonable rather than accurate.<sup>249</sup>

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245. See *id.* at 31 (stating that HCFA examined how other government agencies structured and used advisory committees in its creation of the MCAC).

246. See *id.* at 35 (discussing HCFA's policy to reconsider a national coverage decision if it receives a request and explanation from a disgruntled party).

247. See Ochs-Ross & Connaughton, *supra* note 99, at 109–10 ("Local carriers make between eighty percent and ninety percent of all coverage decisions."); see also Judith Lorette et al., *The Perspective of the Centers for Medicare and Medicaid Services*, in *GUIDE TO MEDICARE COVERAGE DECISION-MAKING AND APPEALS* 149, 158 (Eleanor D. Kinney ed., 2002) (stating that most coverage decisions are made locally).

248. See Lorette et al., *supra* note 247, at 158 (explaining that flexibility created by local decision-making may encourage new technologies to spread faster).

249. See *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 834 (1984) (determining that when Congress has given implicit legislative powers to an agency, the "court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency"); see also SECTION OF ADMIN. LAW &

Indeed, the development of criteria for making coverage decisions has been a very intractable issue for the Medicare program since coverage surfaced as a serious policy issue in the 1980s. CMS (then HCFA) first tried to state criteria for coverage decision-making in its 1989 proposed rule.<sup>250</sup> In that proposed rule, HCFA proposed that HCFA and Medicare contractors should consider the cost-effectiveness of a service in addition to the safety and effectiveness, experimental, or investigational component, and the appropriateness when making national coverage decisions.<sup>251</sup> With respect to cost-effectiveness, HCFA stated: "[C]onsiderations of costs are relevant in deciding whether to expand or continue coverage of technologies, particularly in the context of the current explosion of high-cost medical technologies."<sup>252</sup>

This criterion generated considerable debate within the health care industry. Some physicians and health services researchers welcomed the cost-effectiveness criterion as an effort to address escalating costs while assuring the availability of quality health care services to Medicare beneficiaries.<sup>253</sup> It is noteworthy that during the 1980s, HCFA had embarked on a formal and extensive health services research program to evaluate many widely used medical and surgical procedures in randomized clinical trials.<sup>254</sup> The focus of these trials and other research was analysis of the outcomes of procedures including cost effectiveness.<sup>255</sup>

In 2000, CMS published a notice to adopt criteria for Medicare coverage decision-making.<sup>256</sup> In this proposed rule, CMS stated that it anticipated CMS and local contractors would apply two criteria when making NCDs or LCDs,

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REGULATORY PRACTICE OF THE AM. BAR ASS'N, *A Blackletter Statement of Federal Administrative Law*, 54 ADMIN. L. REV. 17, 37–39 (2002) (explaining the *Chevron* doctrine).

250. Medicare Program; Criteria and Procedures for Making Medical Service Coverage Decisions that Relate to Healthcare Technology, 54 Fed. Reg. 4302 (Jan. 30, 1989) (to be codified at 42 C.F.R. pts. 400 & 405).

251. *Id.* at 4308.

252. *Id.* at 4308–09.

253. See, e.g., Alexander Leaf, *Sounding Board: Cost Effectiveness as a Criterion for Medicare Coverage*, 321 NEW ENG. J. MED. 898, 898 (1989) (suggesting that the cost effectiveness criterion could be beneficial in determining whether to fund new procedures).

254. See William L. Roper et al., *Effectiveness in Health Care: An Initiative to Evaluate and Improve Medical Practice*, 319 NEW ENG. J. MED. 1197, 1198 (1988) (stating that the HCFA is funding research to examine the effectiveness of numerous medical procedures).

255. See *id.* (noting the focus of the trials); see also William L. Roper & Glenn M. Hackbarth, *HCFA's Agenda for Promoting High-Quality Care*, HEALTH AFF., Spring 1988, at 91, 92 ("Most experts agree that Medicare's quality assurance efforts—indeed, all quality assurance programs—should focus more on the outcome of care and less on the process.").

256. Medicare Program; Criteria for Making Coverage Decisions, 65 Fed. Reg. 31,124 (May 16, 2000) (to be codified at 42 C.F.R. pt. 403).

respectively: (1) the item or service must demonstrate medical benefit; and (2) the item or service must demonstrate added value to the Medicare population.<sup>257</sup> CMS also proposed sequential steps for analyzing these criteria.<sup>258</sup> First, CMS or its contractors would determine whether there is "sufficient evidence that demonstrates that the item or service is medically beneficial for a defined population."<sup>259</sup> If they determined that the item or service would be beneficial, CMS and its contractors would then determine whether there is a "medically beneficial alternative item or service(s) that is the same clinical modality and is currently covered by Medicare."<sup>260</sup> If Medicare did not already cover an alternative, CMS and its contractors determine whether the item or service is substantially more or substantially less beneficial than the Medicare-covered alternative.<sup>261</sup>

Many Medicare constituencies have expressed concern about these criteria. The health industry manufacturers have been especially concerned and vocal about the criteria CMS employs in making coverage policy.<sup>262</sup> The manufacturers have three fundamental arguments. First, they are required to get premarket approval of many medical devices and new technologies under the FDA review process for determining whether their new products are "safe and effective."<sup>263</sup> The manufacturers believe that this FDA approval process should be sufficient for the purposes of determining Medicare coverage, and that the Medicare coverage decision-making processes are redundant.<sup>264</sup> Second, the CMS criteria of cost-effectiveness and added value are not contemplated by the statutory coverage provisions that items and services be "reasonable and necessary," but rather the criterion is an unwarranted and unduly restrictive interpretation of the statutory coverage criteria.<sup>265</sup> Third,

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257. *Id.* at 31,127.

258. *Id.*

259. *Id.*

260. *Id.*

261. *Id.*

262. Ochs-Ross & Connaughton, *supra* note 99, at 105.

263. See Thompson & Dahl, *supra* note 44, at 50–54 (outlining the premarket approval process for new devices).

264. See Thompson & Dahl, *supra* note 67, at 142 ("Many manufacturers support the use of FDA approval as sufficient for coverage and propose that CMS cover FDA-approved treatment options . . ."); see also Christopher D. Zalesky, *Considering Changes to CMS's National Coverage Decision Process: Applying Lessons Learned from FDA as a Regulator of Access to Healthcare Technology*, 57 FOOD DRUG L.J. 73, 75 (2002) (recommending "the establishment of a CMS/FDA interagency process for reaching national coverage decisions, whereby CMS would delegate the bulk of the scientific review required for a national coverage decision to FDA to render a presumptively-final national coverage or non-coverage decision").

265. See Thompson & Dahl, *supra* note 67, at 141 (discussing the manufacturers' concerns

health industry manufacturers assert that the evidentiary bar is too high in the Medicare coverage decision-making process, and that the process often requires results of randomized clinical trials which are too costly and time-consuming for most manufacturers in the product development process.<sup>266</sup>

While a stated goal of CMS in reforming the coverage decision-making process is the development of criteria for coverage decision-making, CMS has yet to promulgate its final rule on criteria. The criteria are just as controversial today as they were when CMS (then HCFA) embarked on this effort in 1989. This impasse is really due to the lack of consensus among CMS, the Medicare constituencies, and American society at large about what the criteria should be.

The debate over these criteria goes to the heart of the debate over coverage of new technology. Should beneficiaries have access to all technology that is arguably beneficial? Such a criterion would espouse Dr. Avedis Donabedian's "absolutist" definition of quality of care—that high quality care requires all care that is beneficial to a patient.<sup>267</sup> On the other hand, should CMS be more proactive in coverage policy and consider such issues as the fiscal impact of the coverage of new technology on the costs of the Medicare program? Such criteria would espouse Dr. Donabedian's "social" definition of quality of care.<sup>268</sup> Or should the criteria strike a middle ground and cover new technology that the physician and the patient mutually agree provides benefits at minimal risk? Such an approach would embrace Dr. Donabedian's preferred definition of health care quality—the "individualist" definition.<sup>269</sup> Ideally, the Medicare program should strive toward criteria that promote this third definition of health care quality. However, if costs continue to climb, the stewards of the Medicare program may have to adopt coverage criteria that espouse a more "social" definition of health care quality and consider the societal impact of the high cost of a new technology. According to the Medicare Trustees, by 2035, Medicare expenditures will comprise 5.3% of GDP, and by 2077, Medicare

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that the cost-effectiveness and added value criterion impose limitations on the practice of medicine).

266. See *id.* at 142–43 (listing the hierarchy of clinical evidence which CMS uses to determine whether the evidence is sufficient).

267. See AVEDIS DONABEDIAN, THE DEFINITION OF QUALITY AND APPROACHES TO ITS ASSESSMENT 13 (1980) (defining the "absolutist" definition of quality of care); see also Avedis Donabedian, *Quality, Cost, and Clinical Decisions*, 468 ANNALS AM. ACAD. POL. & SOC. SCI. 196, 199–204 (1983) (same).

268. See Donabedian, *Quality, Cost and Clinical Decisions*, *supra* note 267, at 202 (defining the "social definition of quality" as balancing "the expected net benefits of care against the social as well as the individual costs of care").

269. See DONABEDIAN, THE DEFINITION OF QUALITY, *supra* note 267, at 13–14 (explaining the "individualist" definition of quality of care).

expenditures will comprise 9.3% of GDP, compared to only 2.6% in 2002.<sup>270</sup> A social definition of coverage in the Medicare program ultimately may be necessary to preserve the program.

*b. The Probable Value of Additional or Substitute Procedures*

The second prong of the *Mathews v. Eldridge* analysis also calls for the determination of the probable value of additional or substitute procedures in making accurate decisions.<sup>271</sup> The analysis of this criterion exposes an important truth in the Medicare coverage decision-making process. Specifically, the truth is that the health industry manufacturers' press for more formal and public decision-making procedures and the resistance to these measures by HCFA and CMS has actually been a battle for control of the Medicare coverage decision-making process.

Initially, the manufacturers pressed to bring the process out into the open by making the deliberations of the HCFA physicians committee public and accessible.<sup>272</sup> In following years, HCFA—only after much pressure—passed reforms designed to make the process more regular, transparent and participatory.<sup>273</sup> Still not satisfied, in 1999, representatives of the health industry manufacturers initiated a rulemaking procedure pursuant to § 553(e) of the Administrative Procedure Act.<sup>274</sup> In the petition for rulemaking, attorneys for the Indiana Medical Device Manufacturers Council petitioned HCFA for a rule to establish a transparent coverage decision-making process.<sup>275</sup> The manufacturers also attracted the interest of the Republican Chair of the Health

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270. 2003 ANNUAL REPORT OF THE BOARD OF TRUSTEES OF THE FEDERAL HOSPITAL INSURANCE AND FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUNDS, § 1.B, at <http://cms.hhs.gov/publications/trusteesreport/2003/secib.asp> (last visited Sept. 8, 2003) (on file with the Washington and Lee Law Review).

271. See *supra* notes 192, 194 and accompanying text (identifying and discussing the second prong of *Mathews v. Eldridge*).

272. See *supra* notes 80–81 and accompanying text (noting that the health equipment manufacturing industry encouraged the Subcommittee on Health to hold hearings on the coverage decision-making process).

273. See *supra* note 83 and accompanying text (stating that Congress responded to pressure from the medical device manufacturers and enacted legislation making HCFA more accountable to parties interested in its decisions).

274. See 5 U.S.C. § 553(e) (2000) ("Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.").

275. Citizens Petition from Bradley Merrill Thompson, Baker & Daniels, to Nancy-Ann Min DeParle, Administrator, Health Care Financing Administration (Mar. 4, 1998) (on file with author).

Subcommittee of the House Ways and Means Committee in the Medicare coverage decision-making and appeals process, which eventually resulted in the enactment of § 551 and § 552 of BIPA, described above.<sup>276</sup>

CMS's reluctance to implement BIPA reforms, especially those permitting affected beneficiaries from initiating reviews of national and local coverage decisions is probably due in part to concern about losing control of the coverage decision-making processes.<sup>277</sup> Like none other, this reform would wrest much control of the coverage decision-making agenda from CMS. This process not only gives beneficiaries, and the manufacturers who support them financially, control over initiation of the proceeding, but also locates decision-making in the context of a beneficiary's desperate struggle for healing and not in a more dispassionate process where contrary scientific evidence would inevitably be more persuasive. It is not surprising (although not politically astute) that CMS specifically chose not to pursue such individual requests for coverage decisions.<sup>278</sup>

CMS only promulgated a proposed rule after beneficiaries and several beneficiary advocacy groups filed suit to prevent requests for individual coverage decisions regarding new medical procedures from being shelved in CMS.<sup>279</sup> This incident begs the question of whether beneficiary-initiated coverage decision-making proceedings do add probable value to the process of Medicare coverage decisions. The answer to this issue is political and depends on how one believes power over the process should be allocated among CMS and its constituencies.

## 2. *The Medicare Beneficiary Appeals Process*

The Medicare beneficiary appeals process is protected as an adjudicative process under the constitutional guarantee of procedural due process in the Fifth Amendment. As such, beneficiaries who are adversely affected by government action in a public entitlement program are entitled to notice and an

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276. See *supra* Part II.B.2 (outlining BIPA's reforms of coverage decision-making processes).

277. See *supra* note 117 and accompanying text (describing CMS's refusal to implement the provisions allowing beneficiaries to initiate processes for coverage decisions).

278. See *supra* note 116 and accompanying text (noting a 2001 CMS ruling announcing that CMS would delay implementation of the reforms and established procedures for handling beneficiary challenges to coverage decisions).

279. See *supra* note 118 and accompanying text (finding that the threat of a class action by advocacy groups representing the disabled finally led CMS to publish the proposed rule in August 2002).

opportunity to be heard. As an adjudicative process, it concerns so-called "adjudicative facts," involving circumstances and events at issue in the dispute.<sup>280</sup> The *Mathews v. Eldridge* due process analysis pertains to this type of proceeding.

*a. The Risk of Erroneous Deprivation*

Since 1986, with the addition of administrative review before an ALJ and judicial review,<sup>281</sup> the beneficiary Part B appeals process has contained all the procedures of other government benefit programs. Specifically, like the Social Security income support programs,<sup>282</sup> and more recently veterans' benefit programs,<sup>283</sup> the Medicare Part B appeals process offers both administrative and judicial review.<sup>284</sup> In addition, beneficiaries have always had a right to a "fair hearing" before the Medicare carrier.<sup>285</sup> In *Schweiker v. McClure*,<sup>286</sup> the Supreme Court ruled that this "fair hearings" process alone—even without further administrative and judicial review—passed constitutional muster under the *Mathews v. Eldridge* test.<sup>287</sup>

Yet the beneficiary appeals process under Part B has been exceptionally controversial since the inception of the Medicare program. One reason for the controversy has been the high rate of decisions in favor of beneficiaries by ALJs. Specifically, in the last five years, claimants prevailed in fifty-three percent of appeals.<sup>288</sup>

There are several reasons for this controversy. The primary reason is that the appeals process is handling two fundamentally different types of disputants with fundamentally different concerns at issue: (1) individual beneficiaries

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280. See Davis, *supra* note 241, at 402 (defining administrative facts as information concerning the actions of the parties, the circumstances, and the background conditions).

281. See *supra* note 71 and accompanying text (noting that Congress established administrative and judicial review for Part B claims).

282. 42 U.S.C. § 405 (2000).

283. 38 U.S.C. § 7101 (2000).

284. See *supra* note 130 and accompanying text (finding that the Social Security Amendments of 1965 provided administrative and judicial review of eligibility determinations for beneficiaries under Parts A and B).

285. See *supra* note 131 and accompanying text (citing the Social Security Amendments of 1965 as requiring carriers to provide fair hearing procedures for beneficiaries).

286. *Schweiker v. McClure*, 456 U.S. 188 (1981).

287. See *id.* at 200 (finding that additional procedures were not needed to reduce the risk of erroneous deprivation of benefits).

288. Robert Pear, *Bush Pushes Plan to Curb Medicare Appeals*, N.Y. TIMES, Mar. 16, 2003, at A1.

who are challenging the denial of an item or service that they need; and (2) health equipment manufacturers and DME suppliers that have a financial interest in Medicare coverage as the key to the market for their products. The interests of these two categories of disputants are described above.<sup>289</sup> Quite simply, the current "one-size-fits-all" appeals process may not be conducive to the accurate or the satisfactory disposition of the concerns of these types of disputants.

The current process of a fair hearing before the carrier with administrative review before an ALJ with strong authority to develop the record is probably ideal for assuring that accurate determinations are made in the appeal of coverage denials of individual beneficiaries. The procedures are informal and not adversarial—hallmarks of sound process designed to adjudicate relatively small claims of unsophisticated individuals.<sup>290</sup>

The current process probably does not assure accurate determinations with respect to claims of interest by health equipment manufacturers, DME suppliers, or providers. These constituencies, although representing individual beneficiaries, are generally interested in challenging unfavorable local or national coverage decisions to obtain the requisite Medicare coverage needed to market their products. In this instance, the nature of the adjudicative decision is fundamentally different than that in the case of an independent beneficiary. The issue is really one of policy, similar to the coverage decision-making process involving "legislative facts."<sup>291</sup> It is not really a decision about whether the coverage denial, given the particular circumstances of the individual beneficiary in the case, was based on existing law and policy. In this case, as with the coverage decisions made in the Medicare coverage decision-making process described above, there is really no "accurate" decision but rather a "political" decision that is reasonable.

#### *b. The Probable Value of Additional or Substitute Procedures*

In conceiving reforms and thereby evaluating the probable value of additional or substitute procedures, it is wise to appreciate that different procedural elements might be appropriate for each of the two types of

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289. See *supra* Parts III.A.1, III.A.3–4 (discussing the interests of beneficiaries, DME suppliers, and health industry manufacturers).

290. See Henry Friendly, *Some Kind of Hearing*, 123 U. PA. L. REV. 1267, 1278 (1975) ("As we go down the [list of types of government actions that call for a hearing] from the more severe actions to the less, the needle would point to fewer and fewer requirements on the list of required safeguards.").

291. See *supra* note 241 and accompanying text (defining legislative facts).



disputants. Often the interests of the two types of disputants are not always compatible. For example, while health industry manufacturers assert that the carrier "fair hearings" are unnecessary and burdensome,<sup>292</sup> beneficiary advocates have argued that the fair hearings are good for beneficiaries because they facilitate quick resolution of appeals without the expense of an ALJ hearing.<sup>293</sup>

Other areas where procedural elements to the appeals process might be reconceived is with respect to the involvement of CMS in the hearing. For beneficiary appeals that are supported by manufacturers, suppliers, or providers, it is advisable to permit CMS to participate in the hearing, to elucidate the paramount policy issues that are really at stake in hearings with this class of disputants. The question of independent medical review is interesting. BIPA mandated the designation of eleven independent expert review organizations, the QICs to perform reconsideration of carrier decisions on issues of medical necessity.<sup>294</sup> Under current process theory, independent medical review should contribute to greater accuracy in adjudicating coverage denials in beneficiary appeals. This independent review is consistent with recent reform proposals for the protection of patients in managed care plans.<sup>295</sup> Furthermore, social science research has demonstrated that litigants are more comfortable with the decisions in adjudications proceedings when physicians who are independent of each party make decisions on medical issues.<sup>296</sup> CMS is just starting to implement independent review process,<sup>297</sup> and has asked Congress to reduce the number of required QICs to not less than four.<sup>298</sup>

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292. *Medicare Coverage Decisions*, *supra* note 80 (Testimony of Walter M. Rosenbrough, Jr., Member, Board of Directors, Health Industry Manufacturers Association).

293. *Medicare Coverage Decisions*, *supra* note 80 (Testimony of Vicki Gottlich, National Senior Citizens Law Center).

294. *See supra* notes 163–68 and accompanying text (describing the role of qualified independent contractors in reviewing Medicare coverage determinations).

295. *See* KINNEY, *supra* note 54, at 12–13 (noting that most work by consumer advocates has focused on, among other things, external medical review).

296. *See* Norman G. Poythress et al., *Procedural Justice Judgments of Alternative Procedures for Resolving Medical Malpractice Claims*, 23 J. APPLIED SOC. PSYCHOL. 1639, 1655 (1993) (indicating that court-appointed expert model is perceived to be fairer than adversarial model).

297. *See supra* note 183 and accompanying text (noting that in November 2002 CMS promulgated a proposed rule to implement some of the BIPA reforms).

298. *Hearings of the Subcomm. on Health of the House Ways & Means Comm. on Medicare, Regulatory, and Contracting Reform*, 108th Cong. (2003) (statement of Thomas A. Scully, Administrator, Centers for Medicare & Medicaid Services) (suggesting that by reducing the number of quality improvement contractors from twelve to four, CMS could perform the

In considering all reform proposals, it is important to preserve access to the appeals process for individual Medicare beneficiaries who are not supported by health equipment manufacturers, suppliers or providers in their appeals. Thus, appeal procedures need to be informal, straightforward, inexpensive, and accessible. Evidentiary burdens should not be great. Also, process elements such as mediation—which has been used effectively to resolve coverage disputes in managed care plans<sup>299</sup>—should be considered for resolving these types of beneficiary appeals.

In March 2003 in a front-page article, the *New York Times* criticized CMS proposals as compromising fairness in the beneficiary appeals process.<sup>300</sup> In reality, however, this article critiques those procedures that CMS contemplated as reforming undesirable aspects of the appeals process with respect to appeals in which beneficiaries are supported by manufacturers, providers, or suppliers. To avoid such criticism and address the legitimate concerns regarding appeals of independent beneficiaries, different procedures for each type of disputant might be appropriate.

In sum, the CMS proposals for reforms of the appeals process as well as BIPA's mandate to impose independent medical review of national and local coverage decisions and beneficiary appeals indicate a battle for control of the beneficiaries' appeals process and the outcomes of this process. CMS wants to bring the process into its power and also to lower the visibility of the disposition of appeals through more private dispute resolution methods such as mediation. Beneficiaries and particularly the health industry manufacturers and suppliers prefer the current process, with more independence of critical decision-makers such as ALJs. This battle for control ultimately indicates a fundamental debate about the coverage and scope of Medicare benefits. Yet this debate ultimately invokes policy issues. Its resolution essentially involves political decisions about how much the federal government should spend on the Medicare program in view of competing priorities for public funding.

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same functions more economically and efficiently).

299. See Nancy Neveloff Dubler, *Mediating Disputes in Managed Care: Resolving Conflicts over Covered Services*, 5 J. HEALTH CARE L. & POL'Y 479, 500 (2002) (concluding that mediation provides a "simple and appealing process for settling conflicts in managed care situations that are based on disagreements about benefits coverage").

300. See Pear, *supra* note 288 (characterizing the proposed reforms as "legislation and rules that would limit the judges' independence and could replace them in many cases").

### C. The Government's Interest

The final prong of the *Mathews v. Eldridge* analysis is the government's interest, including its fiscal interests. The opinion explains that, while "financial cost alone is not a controlling weight in determining whether due process requires a particular procedural safeguard," the government's interest does permit a determination that "at some point the benefit of an additional safeguard to the individual affected by the administrative action and to society in terms of increased assurance that the action is just, may be outweighed by the cost."<sup>301</sup> In one sense the interest of CMS is obvious and has been a major factor in driving the reality of the Medicare coverage decision-making and appeals processes. In another sense, the interest of the federal government is more complex and may be at odds with the first interest.

The first interest, of course, is the need to control escalating Medicare expenditures. Medicare expenditures have been rising, and continue to rise, at an alarming rate. Further, as discussed above, the most recent Medicare Trustees report shows dramatic increases in the growth of Medicare expenditures in the twenty-first century.<sup>302</sup> Obviously, with such trends the stewards of the Medicare program have been ever vigilant in efforts to control Medicare program expenditures and their growth. Appreciating that new medical technology is an important contribution to growing Medicare expenditures, stewards of the Medicare program have sought to ensure appropriate access and use of new medical technology in the Medicare program through tight management of the Medicare coverage decision-making and appeals processes.

However, a more permissive coverage decision-making and appeals process that calibrates the interpretation of Medicare coverage policy generally in favor of expansion of Medicare coverage may be desirable public policy. Several reasons support the reconsideration of the interests of the federal government in this regard. First, health industry manufacturing is an important industry for the United States, commanding its own office in the Department of Commerce to promote the export of health equipment manufactured in the United States.<sup>303</sup> This industry, with

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301. *Mathews v. Eldridge*, 424 U.S. 319, 348 (1976).

302. See *supra* note 270 and accompanying text (predicting that Medicare expenditures will comprise 5.3% of GDP by 2035, 9.3% by 2077).

303. See *supra* notes 237–38 and accompanying text (citing the Department of Commerce Office of Microelectronics, Medical Equipment and Instrumentation's statistics of significant medical equipment exports and noting the industry's growth during an economic downturn).

its skilled and well-paid workforce, is important for the economic security of the United States.

It may well be that it is good public policy for Medicare coverage decision-making to be more receptive to the research and development agenda of health industry manufacturers. For example, for especially promising technologies it may be desirable to grant provisional coverage during a randomized clinical trial of the technology to mitigate some of the research and development costs incurred in developing the requisite data for a comparative efficacy with existing technologies and cost effectiveness needed for making a final coverage decision. It is noteworthy that the Medicare program has already taken this step with respect to coverage of clinical trials for certain experimental drugs.<sup>304</sup> Such coverage could do much to establish the scientific basis of the most promising new technologies and establish their comparative clinical efficacy and cost-effectiveness. However, such a step would be a sharp departure from the current CMS policy of not financing research and development of health industry manufacturers.

#### *IV. Conclusion*

The projections of national health expenditures and the proportion of the elderly in the national population portend continued controversy for the Medicare coverage decision-making and appeals processes. These trends will continue to put great pressure on these processes. Medicare coverage decision-making and appeals processes are the venues in which the battle over program costs, and ultimately the future design and content of the Medicare program, will play out.

The operation of Medicare coverage decision-making and appeals processes will greatly influence the future of the Medicare program. Specifically, if the coverage decision-making process—at both the national and local level—continues to work in a scientifically sound fashion and with an expanded appreciation and accommodation of the situation of health industry manufacturers in bringing beneficial new products to market, the Medicare program will retain its leadership in the complex but crucial role of sorting out what expensive new medical technology is really beneficial. If the Medicare program becomes too restrictive in coverage decision-making and in adjudicating appeals, then the program may block access to beneficial

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304. See *CTRS. FOR MEDICARE & MEDICAID SERVS., COVERAGE ISSUES MANUAL, CLINICAL TRIALS*, at <http://www.cms.gov/manuals/06cim/ci30.asp> (last visited Sept. 9, 2003) (detailing the Medicare coverage of routine costs of qualifying clinical trials).

technologies and the interest of key constituencies for the Medicare program as a universal social insurance program—the medical profession and more affluent Medicare beneficiaries—will wane as they seek access to noncovered technologies outside the context of the Medicare program. Consequently, their important advocacy for Medicare coverage of new technologies will weaken. Also, the program might well move towards becoming a needs-based program for the poor and lower-middle class, with the more affluent beneficiaries getting access to new technologies through private insurance coverage or their own resources.

Nevertheless, the implementation and operation of the Medicare coverage decision-making and appeals processes should not contribute inadvertently to a more limited Medicare program. Rather, the evolution of the future Medicare program to the extent played out in coverage decision-making and appeals processes should be made democratically in existing and hopefully transparent political processes.

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