1984

Determining Medical Necessity within Medicaid: A Proposal for Statutory Reform

Anita F. Sarro
United States District Court, District of Massachusetts

Follow this and additional works at: https://digitalcommons.unl.edu/nlr

Recommended Citation

This Article is brought to you for free and open access by the Law, College of at DigitalCommons@University of Nebraska - Lincoln. It has been accepted for inclusion in Nebraska Law Review by an authorized administrator of DigitalCommons@University of Nebraska - Lincoln.
Determining Medical Necessity Within Medicaid: A Proposal for Statutory Reform

TABLE OF CONTENTS

I. Introduction .............................................. 836
II. Background: The Medicaid Scheme ..................... 838
III. Federal Limitations on State Discretionary Power .... 840
IV. Medical Necessity: A Fundamental Requirement ...... 842
V. Existing Procedural Mechanisms for Determining the Medical Necessity of Proposed Treatment .............. 844
   A. The Fair Hearing ................................... 844
   B. Review Organizations .............................. 845
   C. Utilization Review Committees .................... 846
   D. The Courts ........................................ 847
VI. A Proposal for Statutory Reform ....................... 849
   A. The Proposal ...................................... 850
   B. Explanation of the Model ........................... 851
      1. Initial Decision by the Recipient and the Donor ............................................ 851
      2. The Concurring Opinion ......................... 851
      3. The Presumption ................................ 852
      4. Local and State Level Determinations—Due Process Fulfilled ................................. 855
      5. Appeal to the Secretary and Judicial Review .. 856
VII. Conclusion ............................................. 857

* Bachelor's degree in Nursing (B.S.), University of Massachusetts, Amherst; Juris Doctor, Western New England College School of Law, Springfield, Massachusetts; Law Clerk to Hon. Frank H. Freedman, United States District Court, District of Massachusetts (Western Section, Springfield, Massachusetts). The author would like to acknowledge the guidance provided by Professors Cathy Jones and Peter Holmes of Western New England College of Law.
I. INTRODUCTION

In 1965, Congress enacted Medicaid in order to help states provide medical care to the poor. Unlike Medicare, which is nationally funded and administered, Medicaid is a program of cooperative federalism; while the federal government funds a substantial portion of the state's medical assistance to designated groups of eligible persons, the administration of the program is left largely to the state agency. Consequently, the precise contours of the program differ from state to state.

The Medicaid program, hastily conceived as an adjunct to the Medicare proposal, has never fulfilled its original promise: to bring the poor "into the mainstream of medicine." Placed into the Social Security system, it has maintained its character as a program of welfare, so the program has never been seen as analogous to private schemes of health insurance. In addition, subsequent amendments have shifted the program away from health care delivery and toward economic efficiency. Cost containment, not the provision of health care, has become the primary concern of program administrators.

States enjoy broad discretion in shaping their Medicaid programs. As the federal government cuts back on its financial support, and as economic pressures build within states themselves,
state programs respond by reducing both the amount and types of services available to eligible recipients. This reduction in services occurs at the same time that American medicine is experiencing an explosion of technology. New methods of diagnosis and treatment are being developed for diabetes, neurological disorders, and handicaps of mobility; all these innovative techniques could prolong life or significantly enhance the quality of life for those who have access to them. If states continue the present trend of reducing benefits for Medicaid recipients, the more advanced methods of diagnosis and treatment will not be incorporated willingly into a state's reimbursement plan. This emphasis on fiscal concerns could freeze a state's approval policies and, in turn, limit Medicaid recipients and their providers to only a few traditional choices for treatment of a particular disorder.

At the heart of the Medicaid program is an intent to provide its recipients with "medically necessary care," yet the legislative scheme lacks both a substantive definition and a procedure designed to arrive at a determination of what is, in fact, medically necessary. Perhaps a substantive definition is neither desirable nor possible. The concept of necessary medical care should be sufficiently flexible to reflect the current state of medical art and, therefore, a substantive legislative definition of the term could artificially confine the scope of permissible benefits. Also, judicial attempts at defining necessary medical care have been inconsistent and largely ignored. Even if a substantive definition is not required, a procedure for determining whether a particular treatment fits the current notion of necessary care is urgently needed. Without a procedure accessible to recipients, necessary care becomes only that which a state is willing to fund.

20. See infra notes 60-79 and accompanying text.
21. See infra notes 104-24 and accompanying text.
22. See infra notes 112-23 and accompanying text.
23. See infra note 57 and text accompanying note 69.
24. See Caper, Massachusetts' New Hospital Payment Law, 308 New Eng. J. Med. 542, 544 (1983). In Harris v. McRae, 448 U.S. 297 (1979), Justice Marshall in dissent contended that the state refusal to reimburse costs of abortions was an "effort to deny to the poor the constitutional right recognized in Roe v.
A determination of the necessity of medical care should reflect careful consideration of two opposing interests: the recipient's interest in securing the desired medical treatment and the state's interest in maintaining the fiscal integrity of the program. Present philosophy and procedural safeguards overwhelmingly emphasize the latter.

Mechanisms exist to challenge a state agency's denial of reimbursement for the cost of a particular medical treatment, but they are either inadequate, inaccessible, or strongly biased in favor of fiscal concerns. This proposal for federal statutory reform attempts to correct these inadequacies.

This Article will first review the Medicaid scheme, and identify the limitations on the discretionary power of the state to restrict coverage, the most important of which is the requirement that a state provide medically necessary care. Existing statutory, regulatory, and judicial mechanisms for determining medical necessity will be presented and critiqued. Finally, a proposed federal statutory procedure will be presented and explained.

II. BACKGROUND: THE MEDICAID SCHEME

Medicaid is a program of federal assistance created to enable each participating state "as far as [is] practicable . . . to furnish medical assistance" to certain groups of needy persons whose income is "insufficient to meet the cost of necessary medical serv-

Wade, even though the cost may be serious and long-lasting health damage." Id. at 338 (Marshall, J., dissenting).

25. One author has identified the competing interests as the state's fiscal interest and the state's interest in the health of its citizens. See Note, State Restrictions on Medicaid Coverage of Medically Necessary Services, 78 COLUM. L. REV. 1491, 1503 (1978).

26. Id. at 1504. The soaring costs of medical treatment have forced Congress to hedge on originally promised goals, in favor of fiscal reality. See infra notes 63-68.

27. See infra notes 80-124 and accompanying text.

28. See infra notes 80-88 and accompanying text.

29. See infra notes 89-100 and accompanying text.

30. See infra notes 101-02 and accompanying text.

31. Participation in the program is voluntary. All states now have some form of Medicaid assistance. For a detailed description of each state's plan, see MEDICARE & MEDICAID GUIDE (CCH) ¶ 15,501-660 (1983).


33. A state plan must cover the categorically needy, including those persons who are eligible for benefits under Aid to Families With Dependent Children (AFDC), 42 U.S.C. § 1396a(a)(10)(A) (1982). A state plan may also provide coverage for the medically needy, including those brought within eligibility guidelines because of incurred medical expenses whose income does not exceed 133.33 percent of the maximum income level for coverage under AFDC. Id. § 1396a(a)(10)(C).
DETERMINING MEDICAL NECESSITY

ices. In return for compliance with statutory requirements and regulations promulgated by the Secretary of Health and Human Services, a participating state can receive reimbursement for up to 80 percent of the cost of providing medical assistance to eligible individuals.

Before a state receives funding under Medicaid, it must submit a plan to the Secretary for approval. This plan must include, among other things, the designation of a state agency responsible for the administration of a program, procedures to insure a fair hearing for recipients whose benefits are denied or terminated, and mechanisms to monitor the quality of care being given by providers and institutions. Any deviations from federal requirements must secure prior approval from the Secretary. The Medicaid program, therefore, provides some uniformity of design and administration.

The program imposes additional uniformity by requiring that state plans must provide certain mandatory services to those deemed categorically needy. Mandatory services include in-patient hospital services, out-patient services, laboratory and X-ray procedures, physician services, certain skilled nursing care, and any other medical or remedial care recognized under state law as specified by the Secretary. Congress has never restricted or eliminated any of these categories, despite the repeal of other stat-

---

35. The Secretary is empowered to promulgate rules and regulations “not inconsistent with this chapter, as may be necessary to the efficient administration of the functions with which [he] is charged.” Id. § 1302.
37. 42 U.S.C. § 1396a(a)(2) (1982). Certain other administrative costs are reimbursed as well. These include the costs of processing claims, maintaining peer review systems, and general administrative costs. Id. § 1396d. A state can maximize this funding by vigorous anti-fraud and abuse programs, by establishing a hospital cost review commission, or by proof that the state's unemployment rate exceeds 150 percent of the national average. Id.
39. Id. § 1396a(a)(9). The agency can be autonomous or be part of an existing state health or welfare agency. Whether the agency responsible for administering the program is a health or welfare agency will affect the philosophy and priorities of the program. See Butler, supra note 8, at 219.
41. Id. § 1396a(a)(9)(A).
42. Id. § 1396a(b).
43. Id. § 1396a(a)(10). States are free to offer optional services, id. § 1396d(a)(6)-(16), to both the categorically needy and medically needy. Id. § 1396a(a)(10)(C).
utory provisions relating to scope of benefits and total annual expenditures. These mandatory categories remain an important benchmark in determining the type of medical care a state plan must provide.

The Medicaid program, therefore, imposes certain basic requirements on a participating state in the form of procedural obligations and the categories of care that a state must provide. Although a state has broad discretion to design its program, this discretion is not absolute. Federal statutes and regulations impose important limitations on the power of a state to limit the scope of its medical assistance to the poor.

III. FEDERAL LIMITATIONS ON STATE DISCRETIONARY POWER

Medicaid legislation and regulations limit a state’s discretion to control the type of medical treatment a recipient can expect to receive. The first of these limitations is the statutory requirement that a state plan must provide payment for certain mandatory services. As noted before, the designated categories have never been restricted or reduced. This indicates that Congress intended that the mandatory nature of the services remain intact. Moreover, Congress anticipated an expansion of essential services in the “catch-all” clause, which authorizes the Secretary of Health and Human Services to designate additional types of services as mandatory.

Second, each service which a state offers, whether mandatory or optional, must be sufficient in amount, scope, and duration to reasonably achieve its purpose. The court in *White v. Beal* applied this requirement to invalidate a state policy of providing the optional service of prescription lenses only if the recipient suffered from certain types of visual impairments. The court reasoned that the purpose of providing prescription lenses was to correct visual impairment, and if the state were to offer lenses as an optional service, it had to reimburse the cost of the lenses for all recipients.

45. See infra note 65.
46. See infra note 64.
47. See supra note 44.
DETERMINING MEDICAL NECESSITY

who suffered such impairment.\textsuperscript{51} The "amount, scope, and duration" requirement can thus impose a substantial limitation on the state's ability to restrict the type of care given even under optional services.\textsuperscript{52}

The third limitation on state administration of Medicaid benefits is contained in federal regulations: a state cannot arbitrarily limit coverage based upon diagnosis, type of illness, or condition.\textsuperscript{53} If a state offers a service, either mandatory or optional, it cannot categorically preclude reimbursement for treatment of a particular disease or medical syndrome. In an interesting case involving a recipient's claim for reimbursement of the cost of sex reassignment surgery, the court held that a state policy of refusing to cover such surgery violated the above regulation.\textsuperscript{54}

As a fourth limitation, states must design their programs to assure that medical "care and services will be provided in a manner consistent . . . with the best interests of the recipient."\textsuperscript{55} This limitation has not been used extensively either to uphold or invalidate state agency action, but is nonetheless important.\textsuperscript{56} Although this requirement does not impose an affirmative duty on the state to provide the best medical treatment available, it at least requires that a state provide some safeguards to ensure that recipients will receive needed medical care.\textsuperscript{57}

Finally, even though a state may make reasonable regulations and policies governing its Medicaid program, these regulatory actions must be consistent with the objectives of the federal program.\textsuperscript{58} The objectives of the program are expressed in the

\textsuperscript{51} Id. at 1155.

\textsuperscript{52} But see Ledet v. Fischer, 548 F. Supp. 775, 786 (M.D. La. 1982) (The amount, scope, and duration requirement was held applicable only when the service at issue was mandatory, not optional.). For a discussion of judicial interpretations of 42 C.F.R. § 440.230(b), see Butler, State Limits on the Amount, Scope and Duration of Services Under Medicaid, 10 CLEARINGHOUSE REV. 456, 457-56 (1977).

\textsuperscript{53} 42 C.F.R. § 440.230(c) (1983).

\textsuperscript{54} Pinneke v. Preisser, 623 F.2d 546 (8th Cir. 1980). But see Curtis v. Taylor, 625 F.2d 645, 653 (5th Cir. 1980) (state policy of limiting benefits for physicians' services to three visits per month did not violate federal requirement).


\textsuperscript{56} At least one court has used this limitation. See Coe v. Hooker, 406 F. Supp. 1072, 1081 (D.N.H. 1976) (holding that a state regulation restricting Medicaid reimbursements for medically "unnecessary" abortions "ignores the statutory mandate of Section 1396a(a)(19) that medical services are to be offered in 'the best interests of the recipients' ").

\textsuperscript{57} One commentator has offered the explanation that states must provide "care which is responsive to the problem for which it is offered." Butler, The Right to Medicaid Payments for Abortion, 28 HASTINGS L.J. 931, 955 (1977).

\textsuperscript{58} 42 U.S.C. § 1396a(a)(17) (1982). This stipulation applies even if a state requests a waiver of a program requirement. 42 C.F.R. § 431.55 (1983).
preamble of the statute: to enable each state, "as far as is practicable... to furnish medical assistance... [to those] whose income and resources are insufficient to meet the cost of necessary medical services."

Medication legislation, therefore, imposes a duty on states to provide medically necessary care.

IV. MEDICAL NECESSITY: A FUNDAMENTAL REQUIREMENT

The purpose of the Medicaid program is to provide medical assistance to persons unable to afford necessary medical care. Although Congress does not explain what it means by "medically necessary" care in the statute's preamble, the statute itself expressly obliges states to implement procedures to control the use of "unnecessary" services. Requiring a state to provide medically necessary treatment remains an important safeguard against the unlimited use of a state's discretionary power.

In 1972, Congress repealed a statutory provision that had prevented reductions in total annual state expenditures under Medicaid, so that states could reduce the scope of optional services they offered. In that same session, Congress—in response to the unanticipated economic drain on the states—repealed the statutory requirement that states move toward providing comprehensive care. Some commentators have contended that these actions indicate a congressional intent to grant nearly absolute control over the Medicaid program to the states. This interpretation, however, is inconsistent with the legislative history accompanying the repeal of these sections. The authorization to reduce expenditures applied only to optional Medicaid services, and in no way affected the delivery of basic mandatory services. Also, the

59. 42 U.S.C. § 1396 (1982). The effect of this preamble of determinations of medical necessity is beyond the scope of this Article.

60. 42 U.S.C. § 1396 (1982). As one commentator explained, "[t]he program was in response to widespread problems of poor quality and low availability of medical services for the indigent." Note, supra note 25, at 1491 n.2.

61. See Note, supra note 25, at 1495.


63. See infra notes 64-67 and accompanying text.


66. See, e.g., Note, supra note 25, at 1494-95 (these congressional actions "expanded state discretion to limit Medicaid coverage; this commentator concluded that states were not required to fund all medically necessary services).

relaxation of the goal to provide comprehensive care was to be merely a temporary stay, as the goal would be reinstated once the state program had achieved fiscal stability. There was no intention to abandon all federal control; rather, the revisions were supposed to foster more uniformity of treatment among recipients of the program. Therefore, Congress never intended to turn absolute control over to the states, and the goal of providing medically necessary care remains an important part of the program.

Medical necessity has been called a “red herring,” a term with no substance, yet, courts have considered the words worthy of interpretation. In Beal v. Doe, the Supreme Court upheld a Pennsylvania regulation denying Medicaid payment for non-therapeutic abortions. The Court concluded that Medicaid legislation required only that regulations be reasonable and consistent with the objectives of the Act. Because the state’s interest in encouraging childbirth was reasonable, an abortion, not necessary for the preservation of maternal life or health, was unnecessary. The Beal majority admitted, however, that a more difficult question would have arisen had the state tried to eliminate coverage for medically necessary abortions.

Several years before the holding in Beal, the Court had struck down certain procedural requirements of a Georgia abortion statute as unduly burdening the constitutional right to an abortion as defined in Roe v. Wade. In Doe v. Bolton, the Court defined medical necessity as the medical needs of the patient “in light of all the factors—physical, emotional, psychological, familial, and . . . age—relevant to the well-being of the patient.” It is unclear whether the Beal court adhered to this definition, yet the “Bolton definition” continues to be viewed as an important Supreme Court interpretation of the term medically necessary care.

Medical necessity remains an important counter-balance to a

---

68. Id.
69. See Butler, supra note 57, at 954.
71. An abortion was deemed medically necessary if the continuance of the pregnancy threatened the life or health of the mother or resulted from rape or incest, or if there was medical evidence that an infant would be born physically or mentally impaired. Id. at 441 n.3.
72. Id. at 444 (relying on 42 U.S.C. § 1396a(a) (17) (1982)).
73. Id. at 446.
74. Id. at 444.
75. 410 U.S. 113 (1973).
77. Id. at 171.
78. For a summary of the arguments over whether Beal adopted the Bolton definition, see Note, supra note 25, at 1496-97.
79. See Butler, note 57, at 957.
state's broad discretionary powers. The issue is, therefore, how best to determine whether a particular medical treatment is necessary. Existing federal and judicial mechanisms do not adequately address this issue.

V. EXISTING PROCEDURAL MECHANISMS FOR DETERMINING THE MEDICAL NECESSITY OF PROPOSED TREATMENT

When a recipient wishes to have medical expense reimbursed and a particular treatment is not covered by a state plan, either through oversight or because of an explicit policy of exclusion, the recipient may want to compel the state to cover the expense of the desired treatment. The law, both statutory and judicial, provides only a few avenues for a recipient to pursue. All of these avenues suffer problems of inaccessibility, inadequacy, or bias.

A. The Fair Hearing

A state plan must provide an opportunity for a fair hearing before the agency "to any individual whose claim for medical assistance under the plan is denied."\(^8\) The initial evidentiary hearing must meet all the due process requirements of *Goldberg v. Kelly,*\(^8\) including notice, opportunity to present evidence and cross-examine witnesses, and the right to representation by counsel or another party.\(^8\) If the decision is adverse to the recipient, there is a right to appeal to the state agency,\(^8\) and ultimately to the courts.\(^8\)

The fair hearing would seem to provide an appropriate avenue for a recipient who wishes to challenge a denial for reimbursement. Such a hearing, however, may not be available to recipients under such circumstances. The requirement for a fair hearing is triggered only if an agency action is adverse to a recipient.\(^8\) Regulations define an adverse action as "a termination, suspension, or reduction of Medicaid eligibility or covered services."\(^8\) An initial refusal to reimburse the cost of a particular medical procedure not previously covered by a state plan may not fall within the ambit of this definition.

Even if the fair hearing were available to a recipient challenging

\(^83\). *Id.* § 431.232(b)-(c).
\(^84\). See *infra* note 129.
\(^86\). *Id.* § 431.201.
a denial of reimbursement, this procedure would still be inadequate for the purpose of determining whether the requested care was "medically necessary." In a fair hearing, the recipient bears the burden of proving the necessity of the requested medical treatment. This burden is contrary to the implication embodied in the federal statutes and regulations, and puts an unfair burden on the recipient.

B. Review Organizations

In 1972, Congress amended the Social Security Act to require states to institute a system of peer review of medical providers and institutions. Congress created the Professional Standard Review Organization (PSRO) to promote the efficient and economical delivery of health care, and to ensure reimbursement of services "only when, and to the extent, medically necessary, as determined in the exercise of reasonable limits of professional discretion." The local PSRO could control medical necessity by assisting the local agency in developing regulations and guidelines governing reimbursement, or by approving (or denying) individual requests for costly or elective treatment. PSRO legislation also provided an appeals process, which begins with the statewide peer system review council, and then goes to the Secretary of the Department of Health and Human Services, and finally ends in the courts with ultimate judicial review of the Secretary's findings. This scheme seemed to place a determination of medical necessity squarely within the power of the PSRO. However, the PSRO system has recently been replaced by the Utilization and Quality Control Peer Review Organization (Organization).

The Organization system has redefined the function and focus of review in an attempt to remedy the perceived inability of the

87. See infra notes 139-146 and accompanying text.
88. See infra note 139 and accompanying text.
91. Id. § 1320c-4(a)(1)(A).
92. Id. § 1320c-4(a)(2) (A), (B).
93. Id. § 405(g). See infra note 129.
94. Id. § 1320c-8.
95. The regulatory language led one commentator to conclude that "the statute unambiguously places the responsibility for making such a determination [of medical necessity] on Professional Standard Review Organizations (PSRO's)." Note, Determination of Medical Necessity: Medicaid Funding for Sex Reassignment Surgery, 31 CASE W. RES. 179, 185 (1980).
PSRO to control costs. An Organization now functions primarily to review professional activities and to develop professional norms of care, diagnosis, and treatment based on typical patterns of practice in the area. A recipient who is dissatisfied with a determination is entitled to the same review process as was previously available, but the new posture of Organizations indicates strongly that when medical necessity and cost containment concerns collide, the latter will prevail. The Utilization and Quality Control Peer Review Organization is, to state in simple terms, unduly biased towards cost considerations when considering the medical necessity of requested treatment.

C. Utilization Review Committees

A participating state is required to have some mechanism for reviewing the adequacy and appropriateness of the care provided to Medicaid patients. This reviewing function may be provided either by an Organization, as described above, or by a separate entity. These utilization review committees provide an institutionally focused safeguard against the unnecessary use of services and, in turn, ensure the cost effectiveness of a state program. Their sole function is to judge the economic efficiency of an institution. They are, therefore, inaccessible to an individual who wishes to challenge an agency's refusal to reimburse the cost of medical services.

97. See Lang, supra note 13, at 720.
99. Id. § 1320c-3(a) (b).
100. Id. § 1320c-4. See also notes 93-94 and accompanying text.
102. See supra notes 25-26 and accompanying text. See also GAO Report, No. HRD-83-74, MEDICARE & MEDICAID GUIDE (CCH) § 33,407 (1983).
103. An individual is not only barred from approaching a utilization review board for a determination of the medical necessity of proposed treatment, but is also prevented from constitutionally challenging a decision of the board. In Blum v. Yaretsky, 457 U.S. 991, 993 (1982), the Supreme Court held that a class of Medicaid patients in a nursing facility could not challenge the procedural inadequacy resulting from facility-initiated discharges and transfers. Justice Rehnquist, for the majority, found that the class of patients had failed to establish the requisite “state action” in the decisions to transfer or discharge patients, since those decisions were made through the facility's utilization review board. The Court concluded that the state was not responsible for those decisions, in spite of the fact that the review board operated under state regulations which, in turn, were promulgated under the Medicaid statute. Id. The Court also shrugged off the fact that the state responded to the review board decisions to transfer and discharge patients by adjusting the patients' Medicaid benefits. In rejecting the patients' fourteenth amendment claims of due process, the Court blanketed the utilization review board in an immunity to constitutional challenge.
D. The Courts

Occasionally, courts have determined whether a particular procedure or item of care should be reimbursed under a state Medicaid plan. Many of these cases attack the validity of specific regulations that preclude most payments for optional services, such as drug treatment, prescription eyeglasses, or abortions.

In Beal v. Doe, the United States Supreme Court upheld a state exclusion from coverage of non-therapeutic abortions. While the Court explained that the decision between the patient and doctor is not conclusive of reimbursability, the Court stated that the determination must be given some weight. Although the state exclusion was upheld, the Beal majority said that serious statutory questions would have been raised had the state plan excluded necessary medical treatment. Unfortunately, the Court did not give any indication as to how a court could distinguish necessary from unnecessary medical care.

Lower courts, however, have attempted to define medically nec-

---

104. Jurisdiction in a federal court has usually been based upon 28 U.S.C. § 1343 (1982). Such jurisdiction apparently requires that the plaintiff allege a substantial constitutional claim, so that the statutory claim can be heard by the exercise of pendent jurisdiction. The statutory claim does not require the convening of a three-judge panel, but may be disposed of by a single justice. Hagans v. Lavine, 415 U.S. 528, 536 (1974). Absent a substantial constitutional claim, the district court may lack jurisdiction under § 1343 to hear only the statutory claim. Chapman v. Houston Welfare Rights Organization, 441 U.S. 600, 618-23 (1979). However, cases have been heard under 28 U.S.C. § 1331 (1982) that claim only the violation of the federal statutory mandate. See, e.g., Rush v. Parham, 625 F.2d 1150 (5th Cir. 1981); Pinneke v. Preisser, 623 F.2d 546 (8th Cir. 1980). These cases involved a review of regulations that could be invalidated only if arbitrary, capricious, or an abuse of discretion. It is doubtful that a direct challenge to compel payment by a state agency, absent a specific regulation excluding such payment, could be sustained as an exercise of federal question jurisdiction. State courts, of course, are always available to the recipient.

105. Vogel v. Blum, MEDICARE & MEDICAID (CCH) ¶ 32,203 (S.D. N.Y. 1982) (State Medicaid Agency's standard of excluding nonessential and ineffective drugs from reimbursement was upheld from the charge that it violated recipients' civil rights.).


109. Id. at 445 n.9.

110. Id. at 444. Since the adoption of the "Hyde amendment" making federal funding unavailable for most elective abortions, the Supreme Court has held that a state plan may properly exclude even necessary abortions. Harris v. McRae, 448 U.S. 297, 326 (1980), reh'g denied, 448 U.S. 917 (1980).

111. The issue of restricting the funding of medically necessary services did not
necessary treatment. Two cases of special interest both addressed the same issue: whether a state policy of denying reimbursement for the surgical treatment of gender dysphoria is contrary to the intent of the Medicaid program and, therefore, invalid. The cases reached different conclusions and, in the process, characterized the determination of medical necessity differently.

In Pinneke v. Preisser, a recipient challenged a state's policy of denying reimbursement for the cost of sex reassignment surgery. The court held that the policy arbitrarily denied coverage solely on the basis of diagnosis, type of illness, or treatment, and thus violated the regulatory ban on such limitations. The policy, the court said, established an irrebuttable presumption that the surgery was not medically necessary, and reflected a complete disregard for the patient's condition, the physician's judgment, and the standards of practice in the medical community. The court held that the determination of what is medically necessary rests with the recipient and physician, not with clerical personnel and government officials.

The test used by the Pinneke court is a simple one to apply: medically necessary treatment is that which the recipient and the physician request. This test, however, ignores the discretion given to the states to reasonably limit the scope of the Medicaid program and sets no limit on the demands recipients may make of a state program. Most importantly, the court made its own finding that surgery was the only appropriate treatment for the recipient's disorder, despite evidence that psychotherapy could also ameliorate the condition.

In Rush v. Parham, the court rejected the argument that Georgia's refusal to reimburse the cost of sex reassignment surgery was a violation of the requirement that Medicaid cover the cost of medically necessary treatment. The court concluded that the refusal was not inconsistent with federal legislation as a matter of law, and thus denied the plaintiff's motion for summary judg-

arise in Beal, as the regulation at issue only restricted funding for allegedly unnecessary abortions. Id. at 441 n.3. See also Note, supra note 25, at 1496.
112. 623 F.2d 546 (8th Cir. 1980).
113. Id. at 549. The court concluded that the treatment logically fell within the scope of mandatory services, particularly in-patient and physician services. Id. at 550.
116. Id. at 550.
119. 625 F.2d 1150 (5th Cir. 1981).
DETERMINING MEDICAL NECESSITY

The court reasoned that while a physician's opinion is important, it is not controlling on the question of whether the treatment is a medical necessity. The *Rush* decision thus recognized that the state has a role to play in determining whether requested care is necessary. Upon remand, the lower court concluded that the state's policy of refusing reimbursement for such surgery was not a violation of the federal statute; the court reasoned that surgery was not necessary for the treatment of this disorder, in light of the available psychotherapeutic alternative. The *Pinneke* and *Rush* cases demonstrate that judicial determinations of medical necessity are bound to be inconsistent. Courts have differing views of the purpose of the Medicaid program, as well as the role the state agency should play in determining coverage. In addition, the recipient—as plaintiff in a lawsuit—bears the burden of proving that the requested treatment is medically necessary. This is contrary to the burden implied in legislative and regulatory language. The judicial process is also costly and time-consuming. Therefore, the courts are not the preferred arbiter in the determination of medical necessity.

VI. A PROPOSAL FOR STATUTORY REFORM

The Medicaid program needs a uniform procedure for resolving disputes between a recipient and a state agency regarding the medical necessity of requested treatment. Such a procedure should fulfill several goals. It should be accessible to the recipient and not unduly burdensome to the state agency, either procedurally or economically. It should afford the recipient adequate procedural due process and should balance the recipient's interest in obtaining medical care against the state's interest in reasonably limiting the medical care it must reimburse. The following proposal is an attempt to incorporate these goals into a statutory provision.

120. *Id.* at 1156.
121. *Id.*
122. *Id.* The "experimental" exclusion is not specifically mentioned in either the statute or the regulations promulgated under Medicaid; yet, the court accepted this as a valid exclusion without discussion. Perhaps the court analogized decisions of medical necessity to the determinations of "reasonable and necessary" care which the Secretary of Health and Human Services makes under Medicaid. *See infra* notes 149-150 and accompanying text.
124. *See infra* notes 139-141 and accompanying text.
A. The Proposal

If the recipient and the attending physician agree that a procedure is necessary for the medical diagnosis or treatment of the individual, and the state regulations do not allow reimbursement for this procedure, the recipient can take the following steps:

1. The attending physician must document, with supporting clinical evidence, the necessity of treatment.
2. The recipient must be seen by a second physician not originally involved with the individual's medical care, but who is familiar with the proposed method of treatment.\textsuperscript{125} If the consulting physician agrees that the procedure is medically necessary, a presumption arises in favor of the recipient.
3. The local agency can deny a request for reimbursement only upon a clear showing on the agency record that the requested treatment is medically unnecessary. This determination must be made in consultation with medical advisors. Lack of medical necessity may be demonstrated by a clear showing that the requested procedure is experimental, unsafe, or not accepted by the medical community or by any other standard adopted by the Secretary of Health and Human Services, as applicable in 42 U.S.C. § 1395Y.\textsuperscript{126} Decisions must be made within thirty days of filing the request, and the recipient must receive prompt notice of the refusal as well as a full explanation of the reason for refusal. The recipient must also be allowed access to the file and agency record upon request.
4. If the decision of the local agency is adverse to the individual, the recipient may then request a \textit{de novo} review by the state hearing officer, and will be permitted to submit any additional clinical evidence to support the claim. The finding and conclusions of the hearing officer must be made in consultation with medical advisors, and the decision justified on medical grounds, by the same standards and under the same burden of proof as are binding on the local agency. Determinations must be made within thirty days of filing the request. The recipient must receive prompt notice of the decision and a full explanation of the reasons for a denial.
5. If the decision of the hearing officer is adverse to the recipi-

\textsuperscript{125} The consultation, itself, would be a reimbursable event.
\textsuperscript{126} The statute states, in relevant part, "no payment may be made . . . for any expenses incurred for items or services . . . which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury . . . ." 42 U.S.C. § 1395y(a)(1) (1982).
ent, a review by the Secretary of Health and Human Services may be requested, as described in 42 U.S.C. § 1320c-4.127

6. Judicial review, as described in § 205(g) of the Social Security Act128 will be available if the decision of the Secretary is adverse to the recipient.129

B. Explanation of the Model

1. Initial Decision by the Recipient and the Donor

The initial decision on medical necessity is made by the recipient in consultation with the attending physician. There is some statutory support for this. Freedom of choice is still guaranteed by the program,130 and the Medicaid statute provides that care must be provided in the best interests of the recipient.131

The medical judgment of the physician, while not conclusive, is a factor of considerable importance.132 The issue to be resolved is the medical necessity of a procedure. It follows that the medical judgment of the attending physician must be given considerable weight.

2. The Concurring Opinion

Administrative use of a second medical opinion is not a revolutionary idea. The Massachusetts Medicaid plan, for example, re-

127. See supra notes 93-94 and accompanying text.
129. In 42 U.S.C. § 405(g), the Social Security Act provides for judicial review of all "claim[s] arising under" the Act, 42 U.S.C. § 405(h), to the exclusion of the exercise of federal question jurisdiction pursuant to 28 U.S.C. § 1331. Although a question remains as to the scope of the "arising under" language of § 405(h), see Annot., 42 A.L.R. Fed. 484 (1979), a recent Supreme Court opinion provides a partial answer. In Heckler v. Ringer, 52 U.S.L.W. 4547 (May 14, 1984), the Court assumed without deciding that § 405(h) did not foreclose mandamus jurisdiction in all claims arising under the Medicare Act. However, Justice Rehnquist, writing for the majority, concluded that where § 405(g) clearly provides an adequate remedy to a Medicare claimant to challenge all aspects of a decision of the Secretary, then it also provides the exclusive avenue for judicial relief; thus, a party aggrieved of a decision of the Secretary must exhaust all administrative remedies before seeking judicial relief. Id. at 4551. In so deciding, the Court reaffirmed the broad interpretation of the "arising under" language of § 405(g) first articulated in Weinberger v. Salfi, 422 U.S. 749, 760-61 (1975) (constitutional challenge to the denial of benefits by operation of the duration-of-relationship eligibility statute was claim arising under Title II of the Social Security Act and, therefore, within the meaning of § 405(h)). See also Matthews v. Eldridge, 424 U.S. 319, 327 (1976) (no federal question jurisdiction where claim challenges denial of welfare benefits on the basis of administrative procedures).
131. Id. § 1396a(a) (19).
quires a recipient who requests reimbursement for certain surgical procedures\textsuperscript{133} to obtain a second independent medical opinion on whether the procedure\textsuperscript{134} is deferrable.\textsuperscript{135}

While the Massachusetts program does not require that the consulting physician agree with the initial medical evaluation,\textsuperscript{136} this proposal presumes that the consultation process will only be used when the medical procedure is relatively new and unfamiliar; therefore, this proposal requires agreement between the consultant and the consulting physician. Requiring agreement among physicians introduces an element of community standards into the decisionmaking process,\textsuperscript{137} without making the procedure unduly burdensome to the recipient or to the state administrators.

3. The Presumption

The presumption which arises after consultation in favor of the recipient is an important part of this proposal. All other procedures\textsuperscript{138} have improperly placed the burden of proof on the individual requesting reimbursement. The purpose of the Medicaid program has been—and continues to be—the provision of necessary care to those eligible for coverage.\textsuperscript{139} Since the essential purpose of the legislation is to provide medical care, it places an


\textsuperscript{135} Under the Massachusetts program, surgery is not deferrable when postponing the procedure for six months or more is likely to jeopardize the patient's life or essential function or cause severe pain. Id. § 452.300.

\textsuperscript{136} The Code states:

It is not necessary that the consultation(s) rendered through the Program confirm the non-deferrability of the surgery in order for providers of medical and hospital services to be reimbursed. It is only necessary that the recipient go through the Program's process to obtain the medical judgments concerning the surgery's deferrability. The decision as to whether to undergo the surgery in question is the recipient's and his/her physician's.

Id. § 452.301.

\textsuperscript{137} In Beal v. Doe, 432 U.S. 438, 448 (1977), the Court left open the issue of whether a state abortion statute (requiring a second, concurring opinion that the procedure was medically necessary), would infringe on the physician's exercise of independent medical judgment, in a way not contemplated by Medicaid legislation.

\textsuperscript{138} See supra notes 80-122 and accompanying text.

\textsuperscript{139} 42 U.S.C. § 1396 (1982).
undue burden on a recipient to prove, first, eligibility for coverage and, then, eligibility for reimbursement for the type of care he or she wishes to receive. In these two requirements, the recipient's burden of proof should be restricted to producing two physicians who deem the care necessary.

As a general principle, presumptions are created in light of fairness and probability. A Medicaid recipient cannot be expected to have access to any medical evidence beyond that which the two physicians put forth. If the local or state agency is trying to determine the relative safety or medical acceptability of the proposed procedure, the recipient can hardly be expected to have the expertise to defend the treatment choice, or the resources to produce additional medical evidence. In a determination of the relative merits of a medical procedure, the party best able to rebut the presumption is the state, which has ready access to medical advisors.

The presumption of medical necessity would have the effect of shifting the burden of persuasion to the state agency. A statutory presumption must create a rational connection between the basic fact and the presumed fact. So long as a rational connection exists, the presumption is constitutional, even though it imposes the burden of persuasion upon the party against whom it is being directed. In the proposed presumption, the basic fact (the professional judgment of two independent physicians) is rationally related to the presumed fact (the medical necessity of the treatment). The presumption, therefore, meets the test of constitutionality.

The state can overcome the presumption by a showing of lack of necessity. This showing must flow from something other than cost considerations. Regulations currently allow reasonable limits for

---

140. 10 J. Moore & H. Bendix, Moore's Federal Practice ¶ 301.02 (2d ed. 1976).
141. Id.
142. Fed. R. Evid. 301 adopts the view that a non-statutory presumption in a court case shifts only the burden of going forward onto the opposing party.
143. Mobile J. & K.C.R.R. Co. v. Turnipseed, 219 U.S. 35, 43 (1910) ("That a legislative presumption of one fact from evidence of another may not constitute a denial of due process of law or a denial of equal protection of the law, it is only essential that there shall be some rational connection between the fact proved and the ultimate fact presumed . . . ."). In Usery v. Turner Elkhorn Mining Co., 428 U.S. 1 (1976), the Court addressed a statutory presumption that a mine owner incurred civil liability for a worker's black lung disease if the individual had been employed in the mine for ten or more years. The Court held the presumption constitutional under the Turnipseed analysis. Id. at 28.
144. See, e.g., Dick v. New York Life Ins. Co., 359 U.S. 437, 446 (1959) (State law presumed that insured's death was accidental, and thus placed the burden on the insurer to prove that death resulted from suicide.).
reimbursement based upon medical necessity or cost, implying that the two are separate and distinct. While cost considerations cannot be ignored completely in any agency determination, they should not form the basis of the decision when the issue is the medical necessity of treatment. If the medical necessity of treatment is established, cost factors could then influence such details as the length of hospital stay or the type of institutional and provider care required.

The lack of necessity, therefore, must be justified on medical grounds, in consultation with medical specialists. States are now required to establish medical advisory boards to assist in the administration of their programs; and any state that has an organizational review system already deals with a consulting group composed primarily of health care professionals. Medical advisors are, therefore, already an accepted part of the plan. Involving medical experts in the determination of medical necessity takes the decision out of the exclusive control of "clerical personnel or government officials."

If the justification for refusal must be medically based, what are appropriate grounds? The Secretary of Health and Human Services decides similar issues under the Medicare standard that coverage should be excluded if care is not "reasonable and necessary." Under this standard, the Secretary has refused coverage if a procedure is experimental, unsafe, or not accepted by the medical community based on statistical and scientific evidence. These criteria are medically based and focused on the benefit or harm which can accrue to the recipient.

Medicaid decisions have been based on Medicare rules in the past. Both programs provide medical assistance and both are administered by the Secretary of Health and Human Services.


146. 42 U.S.C. § 1396a(a)(9)(A) (1982). At present, medical committees are merely advisory; failure of a state agency to consult a committee is not considered to be a violation of the federal statute. Mississippi Hosp. Ass'n, Inc. v. Heckler, 701 F.2d 511, 523 (5th Cir. 1983). The proposal set forth in this Article, however, would make consultation with the medical committee mandatory.

147. See supra notes 96-100 and accompanying text.


149. 42 U.S.C. § 1395y(a)(1)(A) (1982). For an examination of the standards used in evaluating reimbursement for several treatments, see Medicare Coverage Issues, MEDICARE & MEDICAID GUIDE (CCH) ¶ 27,201 (1976).

150. See Rush v. Parham, 625 F.2d 1150, 1156 (5th Cir. 1980); Lang, supra note 13, at 722.
DETERMINING MEDICAL NECESSITY

The statutory and regulatory language to be interpreted is also similar. It is therefore consistent that Medicaid decisions on medical necessity apply the same criteria used in Medicare decisions under the test of reasonable and necessary care.

The adoption of the parallel criteria would also have practical benefits. Under this proposal, the Secretary would ultimately hear claims on appeal from the states. If the same criteria were used, the expertise of the Department would be applied consistently to all claims. Also, Medicare determinations are a matter of record and, therefore, are publicly available. States could use past Medicare decisions as guidance for their own determinations to bring local determinations into conformity with the Secretary’s opinions. Thus, the number of appeals to the Secretary would be kept low. The criteria a state would apply when justifying a refusal to reimburse a medical procedure, therefore, would be the same as those used by the Secretary when interpreting similar statutory language.

4. Local and State Level Determinations—Due Process Fulfilled

The interest at stake in this proposal is an important one. No need is so compelling as the need for medical care; so it would seem at first glance that this procedure would require a full evidentiary hearing as prescribed in Goldberg v. Kelly. Yet, due process is a flexible concept and “calls for such procedural protections as the particular situation demands.” In Matthews v. Eldridge, the Supreme Court rejected the notion that due process required a full evidentiary hearing prior to the termination of Social Security disability benefits. Since the majority of the claimant’s proof was in the form of medical data and clinical evidence, the Court held that a paper hearing would suffice.

Resolution of the constitutional sufficiency of an administrative procedure requires an analysis of the government and private interests at stake. In Matthews, the Court considered three distinct factors: (1) the private interest that would be affected by the

---

152. MEDICARE & MEDICAID GUIDE (CCH) ¶ 27,201 (1976).
153. 397 U.S. 254 (1970). The Goldberg Court required that before termination of welfare benefits, the claimant should be afforded adequate notice detailing the reasons for the termination and an effective opportunity to defend by confronting adverse witnesses and by presenting his or her own arguments and evidence orally before the decisionmaker. Counsel may be present if the claimant desires but need not be furnished.
156. Id. at 334.
official action; (2) the risk of an erroneous deprivation of that interest by the procedures prescribed and the probable value, if any, of additional procedural safeguards; and (3) the governmental interest, including the fiscal and administrative burdens that the additional procedures would entail.\textsuperscript{157}

In determining medical necessity, the private interest in securing the requested care is high. The recipient is presumably convinced that the desired care is essential to his or her physical well-being. The type of proof upon which the determination will rest and the presumption in the recipient's favor, however, minimize the risk of erroneous deprivation. A full evidentiary hearing would not afford the recipient a significant advantage, since objective medical data is usually unbiased and best presented in written form. Also, the proposed statutory presumption requires that the agency come forward with rebutting evidence, so the recipient has little to gain by being given the opportunity to confront witnesses and refute testimony.

On the other hand, both the recipient and the state have much to lose if a full trial-type hearing were required. Evidentiary hearings cost both time\textsuperscript{158} and money. The recipient's interest is of a nature such that expeditious decisions are desirable, and the governmental interest in preserving agency time and money is well-documented.\textsuperscript{159} As neither party would be served by an evidentiary hearing, the proposal meets the constitutional standard of the \textit{Matthews} Court.

The proposed procedure gives the recipient notice of denial and the opportunity to present initial evidence in the form of physicians' reports or any additional evidence. The recipient also must be given the reasons for denial of the request and access to the full agency record. These requirements provide adequate procedural safeguards against the denial of due process.\textsuperscript{160}

5. \textit{Appeal to the Secretary and Judicial Review}

The power of the Secretary to impose procedural requirements\textsuperscript{161} and substantive limitations\textsuperscript{162} on state Medicaid plans is well established. The present system of Organization\textsuperscript{163} review and its predecessor, the PSRO,\textsuperscript{164} both prescribe an appeal to the

\begin{itemize}
\item\textsuperscript{157} Id. at 334-35.
\item\textsuperscript{158} Id. at 341-42.
\item\textsuperscript{159} See supra notes 24-25 and accompanying text.
\item\textsuperscript{160} Mathews v. Eldrige, 424 U.S. 319, 346 (1976).
\item\textsuperscript{161} See supra note 38 and accompanying text.
\item\textsuperscript{162} See supra note 44 and accompanying text.
\item\textsuperscript{163} See supra notes 95-100 and accompanying text.
\item\textsuperscript{164} See supra notes 89-95 and accompanying text.
\end{itemize}
Secretary and limited judicial review.\textsuperscript{165} Thus, the notion of the Secretary as final arbiter is not new to the Medicaid program.

But can the national administrator of the Medicaid program be expected to make any better decision about medical necessity than the individual state agencies? If present Medicare decisions\textsuperscript{166} are any indication, the Secretary has the access to medical expertise and the capacity to make sound, reasonable medical judgments. If this trend were to change dramatically, the political process would force the Department to be accountable for its change of philosophy and—if Medicaid recipients were uniformly affected nationwide—pressure could be brought to bear on the Department more easily than it could be on fifty separate states.

The uniformity that the proposal imposes on the states is both appropriate under the legislative scheme and advantageous to the recipient. Judicial review as provided in this proposal would not consist of a \textit{de novo} determination. Section 205(g) of the Social Security Act provides that “the findings of the Secretary as to any fact, if supported by substantial evidence, shall be conclusive.”\textsuperscript{167} Under this standard, courts may not substitute their own judgment for that of the Secretary; rather, courts must only review the record for such relevant evidence as a reasonable mind might accept as adequate to support the Secretary’s conclusion.\textsuperscript{168} Limiting the scope of judicial review would minimize the occasion for substantially inconsistent judicial definitions of medical necessity,\textsuperscript{169} and would also make the role of the judiciary in the Medicaid program consistent with its role in other programs within the Social Security Act.\textsuperscript{170}

\section*{VII. CONCLUSION}

The Medicaid program grants broad discretion to a state to tailor its program, but this discretion is limited primarily by the requirement that a state program provide its recipients with “medically necessary” care. Although medical necessity defies substantive description, it is possible to prescribe a procedure that a state must use when a recipient and an agency disagree on the necessity of requested care. The proposal for federal statutory re-
form sets forth a procedure that is relatively uncomplicated and accessible to the recipient, and that does not unduly burden program administrators. As medical technology continues to develop newer, better, and perhaps even cheaper methods of diagnosis and treatment than are currently available, determinations of medical necessity will require case-by-case consideration. The foregoing proposal presents one method for making those determinations.