Broken Back: A Patient's Reflections on the Process of Medical Necessity Determinations

Margaret Gilhooley
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MARGARET GILHOOLEY*

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* Professor of Law, Seton Hall University School of Law; L.L.B. 1966, Columbia University School of Law. This article is dedicated to Drs. Robert J. D'Agostini and Edward Zampella, who made it possible for me to walk again. I also wish to thank my research assistant Erin Burke.
ON New Year’s Day 1994, while I was ice skating, a young girl crossed suddenly in front of me. I fell to the ice in a sitting position and “broke my back.” That accident, unreal at the time, became an encounter with modern medicine, its miracles and its efforts to control cost. Fortunately, I have emerged from my operation and rehabilitation able to walk and function with no significant impairment.

When my insurer determined that my continued hospitalization was “medically inappropriate,” my reactions were initially those of all patients. Later, my experience as a patient led to some reflections both on the needs of patients who are suddenly hospitalized and on the general process of utilization review and medical neces-
My experiences were of a special type: concurrent review for a patient with a sudden trauma or illness. However, that type of injury is one that raises special fears for all patients. Emergency hospitalized patients have special problems in dealing with the suddenness of injury and in obtaining information to dispute medical necessity determinations. These emergency patients especially need timely notice of the limits on services, an identification of discharge alternatives and an adequate explanation of the grounds for denial of services.

These patients also share needs that are common to other patients. In particular, they all need to understand the underlying basis for medical necessity determinations. If the determinations are not based on professional consensus, then the patients' health plans should indicate the support the plan relies upon for this determination and the process used to develop the standards. The health policies and brochures provided to subscribers should provide information on the criteria used for medical necessity determinations and illustrative examples of the type of care considered necessary for common medical conditions and for medical emergencies. This information can facilitate choice by subscribers among plans based upon the level of care provided. The development of managed care increases the need for patients to determine actively that the care they receive is adequate.

This article also examines the remedies available to patients who are denied benefits. The existing remedies have their drawbacks. Tort and contract suits provide recourse when a sufficient


2. For a discussion of the underlying basis of medical necessity determinations, see infra notes 17-38 and accompanying text.

3. For a discussion of the need for clarification of the criteria for medical necessity determinations, see infra notes 39-54 and accompanying text.

4. For a discussion of the remedies available to patients who are denied benefits, see infra notes 61-111 and accompanying text.

5. For a discussion of the limitations of existing tort remedies, see infra notes
injury can be demonstrated, but these remedies are preempted by federal law in employer-sponsored health care programs.\(^6\) Employer-sponsored plans are required to have internal grievance procedures. While judicial review is available for these procedures, it is an unlikely recourse for minor claims.\(^7\) The pressure to control costs in these programs can make the fairness of the process open to question. Further, the remedies have their drawbacks in providing expeditious resolution of disputes involving prospective treatment of conditions posing risks of serious impairment.

This article suggests the use of a procedural audit of the fairness of a health plan's grievance system.\(^8\) Such an audit would provide some independent check on the fairness of the system and better ensure accurate determinations. In addition, this article considers the circumstances in which second opinions should be available as a part of the dispute resolution process concerning medical necessity determinations for hospitalized patients.\(^9\) The remedy is especially needed for determinations when the patient may be seriously impaired by the denial of benefits, when the issues involve the factual condition of the patient or when circumstances present a significant case for exceptions to the plan's criteria. These referrals can provide a means for expeditious resolution of disputes when they are most needed.

II. Medical Necessity Determinations for Hospitalized Patients: Timely Notice and Discharge Alternatives

Patients hospitalized for traumatic injuries or sudden illnesses face special difficulties. These patients and their families are concerned with the medical outcome. They have not made advance preparations to deal with the patient's discharge and do not understand the options. They are less able to deal with a denial of benefits and to prepare an appeal from a denial of benefits because of their weakened condition and their hospitalized status. These limi

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6. For a discussion of ERISA as a remedy, see infra notes 80-98 and accompanying text.
7. For a discussion of how minor claims are an unlikely recourse for an aggrieved patient, see infra notes 99-100 and accompanying text.
8. For a discussion of the need for a procedural audit, see infra notes 116-20 and accompanying text.
9. For a discussion of the need for second opinions in disputes involving risks of serious impairment, see infra notes 121-23 and accompanying text.
tations accentuate the need that all these patients share for timely notice and an adequate explanation of any denial of benefits. That notice makes possible both planning and an opportunity to make a meaningful appeal. This need for adequate notice arises both in respect to traditional indemnity insurance plans and to managed care programs that provide care and pay for it. This article refers to third-party payers (payers) to indicate the applicability of the comments to both insurers and managed care plans.

A. Experience with Medical Necessity Determination

My experience illustrates some of the difficulties encountered by patients when they do not receive sufficient notice about reimbursement determinations. My spinal fracture and compressed disc, or "broken back," necessitated an operation to stabilize the spine. In the operation, rods were inserted to support the spine and allow the burst disc to decompress, fortunately without any impairment of the spinal cord. After the operation, it was necessary to wear a back brace. The brace, made of heavy plastic, was uncomfortable to wear all day and I required assistance to put it on and remove it. Moreover, it was very painful to sit while wearing the brace for more than a few minutes, and the brace pressed against the neck when seated. By the eleventh day after the operation, I began to walk in the brace without feeling faint, but I did so very cautiously, with a cane and with supervision. I was to receive instruction the next day on climbing stairs and on functioning with a brace, before I was discharged from the hospital.

My insurance plan was a fee-for-service plan that had adopted elements of managed care. Thus, for care provided in participating hospitals, there was full reimbursement, but my insurance required pre-admission review. The insurer approved admission and a hospital stay of ten days. Even if I had heard of this time period, I did not appreciate its significance. Late on the eleventh day after my admission, a member of the hospital's utilization review office brought me a copy of a fax from my insurer to my doctor notifying my doctor that my continued stay in the hospital was "medically inappropriate." Furthermore, the doctor's request for an additional stay had been denied. Although benefits would still cover

10. See Jerry Gray, Blue Cross Says It Plans Clinics in New Jersey, N.Y. TIMES, May 19, 1994, at B1, B7 (discussing how further effort to deliver services through health maintenance organizations builds on April 1993 partnership with selected hospitals under which they provided care at lower rates in exchange for high patient volume).
the date of discharge, my benefits were terminated as of the prior
day. I was stunned by the notice that my benefits had already
ended and that they had been labeled “medically inappropriate.”

The utilization review officer suggested that I call my insurer to
make an appeal. When I reached the insurance review officer, how-
ever, I was told that I could not appeal even though the letter said
that the physician or patient could appeal. I protested that I could
not leave the hospital because of my difficulties with the brace and
inability to walk up steps. I was told that the insurer was not saying
that I did not need medical care, but only that I did not need medi-
cal care in an acute care facility. Because I was not receiving intra-
venous fluids, I no longer needed to be in a hospital and could be
in a semi-skilled nursing facility. I protested that I did not want to
be sent to a nursing home but instead wanted to be rehabilitated.
With that, the reviewer informed me that I could go to a rehabili-
ation institute.\footnote{11} Thus, the call ended, my appeal for continued hos-
pital benefits was denied, and I was uncertain and distressed.
There was something about being termed “medically inappropri-
ate” that seemed like a personal failing, some inability to measure
up to accepted standards.\footnote{12} The denial of additional hospital ben-
efits also forced me to re-examine a more basic issue that had been
troubling to me—whether I had the ability to go home in the near
future given my weakness and difficulties with the brace.

I decided I would stop fighting the insurance company’s efforts
to “evict” me from the hospital. Instead, I would initiate a request
to go to a rehabilitation institute on an inpatient basis to receive
additional care for dealing with my difficulties with the brace. My
stay in the rehabilitation institute was key to my recovery. The insti-
tute changed my ill-fitting brace, enabling me to sit in a chair.
Moreover, I had sufficient time and space to learn to walk and to
climb stairs gaining confidence in my ability. The occupational
therapist provided devices to deal with the limitations of not being
able to bend down. In addition, I had by now gathered sufficient
strength to sit up and put on the brace, eliminating my need for

\footnote{11}{The time needed to schedule the operation may have been a factor in
exceeding the insurer’s 10-day norm for the procedure. Time lost before an op-
eration, however, does not reduce the time needed for the patient to recover. While
the insurer did not pay for the additional days beyond the 10 days initially ap-
proved for the operation, the hospital did not bill me for the additional time.}

\footnote{12}{This reaction may not have been strictly logical, because the care, not the
patient, was designated “medically inappropriate.” However, trauma patients in
hospitals are not always logical. In addition, the term reflected some failure to
conform to the norm, either by the patient or the provider, and thus had a judg-
mental element to it.}
special assistance after I went home.\textsuperscript{13}

B. Need for Timely Notice

One lesson from this experience is that patients play an important role in determining the care they receive. The growth of managed care and the efforts to control costs will accentuate the need for patients to play an active role in ensuring that they receive sufficient care. But patients need to have sufficient information to enable them to have meaningful input into the decisions. Fundamentally, patients need adequate notice about the limitations on the benefits provided by the health plan.

The time for providing adequate notice to a patient arises during pre-authorization or concurrent review when the payer establishes a limitation on the amount of care to be provided. Authorization by a payer of a particular hospitalization period functions as a denial of benefits for any further time. If patients, particularly hospitalized patients, are to make any appeal on a timely basis or to request an extension of their stay, they need to know of the limits when the limits are established. To emphasize the significance of the limits, the insurer needs to state the limits expressly and to indicate specifically the deadline for filing requests for extended stays, appeals and requests for exceptions. Moreover, the insurer must provide the information in writing to the patient or the patient's representative.\textsuperscript{14} The payer should also indicate how the patient can request more information about the underlying basis for the determination.

Insurers have a fiduciary responsibility to inform patients of their appeal rights and not to hinder appeals.\textsuperscript{15} The failure to

\textsuperscript{13} The insurer provided reimbursement for the stay in the rehabilitation institute.

\textsuperscript{14} My benefits brochure on pre-admission review states that written confirmation of the authorized hospital stay is to be given by the insurer to the patient, as well as to the provider. Blue Cross and Blue Shield of New Jersey, Your Medallion Health Coverage Program, Addendum, Pre-admission Review (1995) ("An approval or denial will be provided by telephone and a confirmation letter will be sent to the patient, the Physician and the Hospital."). When such an obligation is recognized, there still needs to be adequate safeguards to ensure that there is compliance. For a discussion of remedies as one of the safeguards to ensure compliance, see infra notes 61-111 and accompanying text. For a discussion of the use of procedural audits as a means of providing additional safeguards, see infra notes 116-20 and accompanying text.

Medicare patients are to receive written notice from hospitals and other providers of their right to appeal denials of benefits and the practical steps to initiate such appeals. 42 U.S.C. § 1395cc(a)(1)(M). See copy of disclosure form on file with author.

\textsuperscript{15} See Sarchett v. Blue Cross, 729 P.2d 267 (Cal. 1987) (en banc). For a dis-
vide a timely notice about the limitation of benefits can frustrate the patient's ability to make an appeal or a request for an extension.\textsuperscript{16} As discussed in Part V, there needs to be adequate safeguards to ensure that this obligation is observed.

Of course, there can be a concern that the patient will worry unduly and prematurely about a possible exhaustion of benefits. Accordingly, before an operation, the insurer could provide written notice to the patient's representative. Thereafter, the patient, who will have to deal with the consequences of a denial, would be informed.

C. Disclosure of Discharge Alternatives

Discharge planning is focused on home care. Sending the patient home is generally the most cost-efficient alternative. In a time when health care providers are concerned with reducing costs of health care, home care will undoubtedly remain a primary option. In addition, patients in hospitals generally want to go home. In my case, therapy was initially planned to be at home, so the discharge planning focused on that option. It was only later, during my appeal of the denial of further hospital benefits, that I found there was another option— inpatient rehabilitation care.

In addition to discharge planning by the provider, the payer should give trauma patients some overview information on the range of alternatives available, including inpatient rehabilitation and twenty-four hour assistance. Information should be provided even if these alternatives are not the recommended ones at the time or ones for which the insurer will routinely provide reimbursement. Developments in the patient's strength, progress at therapy


However, the payer, not the provider, is denying the additional benefits and it is the payer that should have the primary responsibility to provide notice and not to hinder the patient's ability to appeal. If the payer wants to have the provider communicate the limits to the patient, the payer should provide written copies of the claims determination to the provider to give to the patient.
and ability to deal with medical equipment, such as a brace, affect which site is appropriate for discharge. The patient is in a special position to reassess and monitor what is needed. Knowing what options exist for future care can also bring into focus what a patient needs to request from one's doctor as an alternative. The patient may know special circumstances which make that care appropriate even if it is not the norm. The payer should also have an obligation to provide the trauma patient with written information about the range of discharge alternatives potentially reimbursable by the health care plan. Information from the payer is particularly important because of the great variability of medical plans.

There may be some reluctance to recognize an obligation to inform patients about alternative discharge options for fear of a "moral hazard": the possibility that patients will request more care and not try hard enough to do what they can do on their own. On the other hand, patients may force themselves to do that which they are physically or psychologically unprepared because they think no alternative exists. Insurance co-payments and a clearer identification of the criteria for the service provide better alternatives to deal with this hazard than nondisclosure.

III. Medical Necessity Criteria

Patients with any medical condition also need a better understanding of how payers determine the level of care that is medically appropriate. How does a payer determine that ten days of hospitalization is sufficient for a spinal fracture? Why ten days, rather than nine, eleven or some other number? Information about the basis on which medical necessity determinations are made should be provided in connection with a denial of specific services. In addition, more information about the general criteria should be provided to subscribers with their basic policy.

A. Process of Medical Necessity Determinations

The traditional means of determining the medical necessity of a medical procedure was the judgment of the patient's individual
Initially, insurers largely deferred to that judgment. Moreover, denial of reimbursement was considered inappropriate if reasonable physicians could differ about the need for it.

The increasing concern with controlling health costs has led to the use of utilization review even in fee-for-service plans. Admission to a hospital is increasingly subject to pre-admission prospective review and continued hospitalization is subject to concurrent review. If the care is not deemed medically necessary or is otherwise determined to be inappropriate, benefits are denied. If prior authorization is not obtained, a penalty is assessed even if the care is needed.

The determination of medical necessity appeals to the norm of professional judgment, but the criteria employed are not necessarily based on a professional consensus and may not even be based on public information. The criteria can be influenced by cost-benefit factors in various ways. In many cases, payers use a protocol for determining the need for hospitalization. This protocol was developed through federal funding of research on inappropriate hospital stays. These protocols are public and studies have indicated their reliability. Nevertheless, other protocols used by payers are proprietary and lack reports on their reliability.

Length of stay standards are usually derived from published data on hospital stays in Western states where stays are typically shorter.

Insurers have also used the criteria developed by private organizations, such as the RAND Corporation, to assess the appropriateness of specific procedures. The RAND protocols were originally developed through federal funding of research on inappropriate hospital stays. These protocols are public and studies have indicated their reliability. Nevertheless, other protocols used by payers are proprietary and lack reports on their reliability.


21. See id. (noting that certain protocols, such as ISD-A (intensity of services, severity of illness, discharges and appropriateness screens) have no reports judging their reliability).

22. See id. at 83 (noting that former RAND Corporation researchers developed "review protocols for procedures . . . [which] involve a series of questions
developed by convening panels of “distinguished physicians” who reviewed the literature, used their own judgment and, after discussion, developed a group consensus rating of appropriateness.\textsuperscript{23}

The guidelines of Millman & Robertson have recently become the “most influential” among scores of health care plans.\textsuperscript{24} The standards are developed not by leading academic researchers, but by consultant doctors and nurses—often from Health Maintenance Organizations (HMOs)—based on a study of medical charts and medical literature.\textsuperscript{25} The guidelines do not have input from medical groups and are often criticized by medical associations.\textsuperscript{26} The validity of the guidelines in improving care while lowering costs is being studied for the first time by an academically-affiliated plan.\textsuperscript{27}

The criteria used by insurers and other third-party payers are also modified by the plans in various ways. Although some may use the criteria to state a specific length of stay approved for hospitalization, others will use the norm as a guide for scheduling continued reviews.\textsuperscript{28} The criteria of utilization management organizations are also in “a continuous process of modification.”\textsuperscript{29} These modifications may be made by the medical director after consultation with physician reviewers and outside consultants and may follow a literature review. Plans also provide for exceptions to their criteria.\textsuperscript{30}

These plans also may utilize medical practice guidelines in developing their reimbursement criteria. The development of medical practice guidelines originated with physician organizations and professional societies generally led their development.\textsuperscript{31} In more
recent years, public and private payers have been interested in using guidelines as a possible means of controlling costs, a development that has been "a major source of anxiety" for professional groups involved in developing guidelines.\textsuperscript{32}

In a review of the use of medical practice guidelines, the Institute of Medicine (Institute) identified the defining characteristic of the medical practice guidelines as assisting patients and practitioners in making decisions.\textsuperscript{33} Developing criteria to evaluate the decisions and reviewing the reimbursement of medical care serve different purposes, although the criteria do and should build on guidelines, and "science-based" guidelines can serve as a tool in reducing unnecessary care.\textsuperscript{34}

To make the expanded use of medical practice guidelines more appropriate, the Institute recommended that future guidelines indicate the strength of the evidence upon which they are based, as well as projections of the health and cost outcomes of different treatments.\textsuperscript{35} Scientific data should have "precedence" as the basis for support for the guidelines, but studies may not be available, and the guidelines should indicate whether they are based on studies, on consensus or some other basis.\textsuperscript{36} Consideration should also be given to establishing an organization to evaluate the guidelines issued by various organizations, because the guide-

\textsuperscript{32} IOM, Guidelines for Clinical Practice, supra note 31, at 112; see id. at 41 (noting that organizations and individuals may refer to practice guidelines in effort to structure organizational procedures, to guide equipment purchases and hiring decisions and prioritizing efforts to improve performance); id. 60-61 (discussing fact that in 1990, American Medical Association, RAND Corporation and Academic Medical Center Consortium signed memorandum of agreement to develop appropriateness criteria and to convert them into practice guidelines for physicians' everyday use).

\textsuperscript{33} Id. at 2; see also Institute of Medicine, Clinical Practice Guidelines: Directions for a New Program 8 (Marilyn J. Field & Kathleen N. Lohr eds., 1990) [hereinafter IOM, Directions for a New Program] (discussing various meanings given to term "guidelines" and recommending distinct terms).

\textsuperscript{34} Id. at 2-3. The Institute was uncertain whether the expanded use of guidelines would ultimately reduce health costs, noting the limited base of scientific knowledge for developing guidelines and the possibility the guidelines would indicate the need for more care. Id. at 4.

\textsuperscript{35} Id. at 27; see id. at 199 (noting that "weak [quality control] procedures and products" are common with respect to guidelines and review criteria); see also IOM, Directions for a New Program, supra note 33, at 6 (finding that, in general, there are "deficiencies" in the "systematic development, implementation and evaluation of practice guidelines based on rigorous clinical research and soundly generated professional consensus"); id. at 15 ("The field also suffers from imperfect and incomplete scientific knowledge.").

\textsuperscript{36} IOM, Guidelines for Clinical Practice, supra note 31, at 32-33; see also Blustein & Marmor, supra note 23, at 1548-49 (noting that research is expensive to gather, is never exact and is usually outdated before the study is completed).
lines "vary enormously in quality" and their use is becoming more significant. The review criteria used by payers should also be available to practitioners and others affected in an effort to increase their acceptance.

B. Need for Clarification of Criteria for Medical Necessity Determinations

1. Clarification of Basis

Medical necessity determinations, thus, reflect various bases and differ in their underlying support. Some of the criteria for medical necessity determinations reflect consensus standards of the profession about minimally acceptable practices. Some may be supported by scientific studies. Other standards reflect the views of particular experts. Some criteria may be regarded as proprietary and may vary by insurance program. In addition, there is an ambiguity about the meaning of terms such as "medical necessity," "medically inappropriate" and "waste." The terms "medically inappropriate" and "waste" can be used to refer to services that are unacceptable based on the standards recognized by the medical community, by other tests developed by some experts or by the plan itself.

To promote a clearer understanding, the terms "medical necessity" and "medical inappropriateness," when used alone in an insurance plan or claims determination, should refer to the standard of what reasonable professionals would regard as either an acceptable practice or an unacceptable practice. This recognition can be based on medical custom or standards of leading professional organizations that reflect a general professional consensus, supported by scientific studies when available. The standard would

38. Id. at 17; see also IOM, Controlling Costs, supra note 20, at 6 ("The review criteria . . . should be available for outside scrutiny. Physicians, purchasers and patients should know the basis for judgments about the site, timing, and need for care"); IOM, Directions for a New Program, supra note 25, at 13 (arguing that guidelines used for utilization review need to be "public with respect to their content and their development process").
39. See Helvestine, supra note 1, at 172-73 (finding that term "medically necessary" is "difficult to define" and "frequently confused with other terms," which "can result in wrong decisions" and care is needed to delineate basis for denial under definition).
40. See Blustein & Marmor, supra note 23, at 1546-47 (finding that "medical waste" and "inappropriateness" have various meanings and can refer to ineffective treatment, treatment of uncertain effectiveness and ethically debated treatment, such as expensive care for very sick).
41. Id.
thus be one where reasonable physicians would not disagree about the standard and would permit denial of claims only when the service would be inconsistent with accepted practice.

This is not to say, however, that a third-party payer should only be able to deny benefits if it meets the consensus standards of the medical profession. The profession may have had little reason in the past to determine what care is excessive and liability concerns may have created disincentives to do so. More care is not necessarily better care, though no studies indicate which approach is better. Moreover, the traditional standard left much to the judgment of the individual physician and there could be considerable variability in the level of care provided.

The concern with cost containment has created an interest in limiting care. When the plan seeks to limit reimbursement within the realm where reasonable physicians differ, the plan should clearly indicate its standards and the supporting basis. The plan itself should state that claims can be denied as medically unnecessary based not only on criteria that reflect a professional consensus, but also on the plan’s criteria for what is medically unnecessary. The nature of the plan’s criteria, the general sources of support and the process for the formulation of criteria should be identified. Thus, if the criteria regularly relies on expert opinions, the identity and qualifications of the experts should be identified. If the criteria are developed based on the insurer’s experience with similar claims, this source should be identified. If the determination is based on cost factors and cost-benefit determinations, these factors should be clearly stated in the policy and the relevant determination. When the support relies on medical practice guidelines, the statement should indicate how the guidelines are developed and the type of support used for the guidelines.

The plan’s criteria should be supported by a valid medical judgment. The criteria should be based on more than a difference in views and should have more support than that available to an individual practitioner. Such additional support is fairly implied when a denial is based on a determination that a physician’s judgment represents unnecessary medical services, even when the plan states its standards. The patient chooses the particular physician


43. See Franks v. Louisiana Health Servs. & Indem. Co., 382 So. 2d 1064, 1068
and relies on the individual physician's best judgment within the
realm where opinions differ. If the plan is to supersede that judg-
ment, then the plan should have the burden of affirmatively show-
ing that the alternative care is adequate. That support should
consist of something more than the views of another physician
whom the patient has not chosen and who may have no legal obli-
gation to the patient with respect to the quality of the care.44

2. Disclosure of Illustrative Benefits

The health care plans and brochures provided to subscribers
should also provide illustrative examples of the level of care consid-
ered medically necessary for a representative number of medical
conditions. The disclosures should cover not only the most fre-
quent types of procedures, but also the ones for which the stan-
dards are especially prone to vary.45

In addition, examples should be listed of the limits on benefits
provided for the most common medical emergencies involving hos-
pitalization. The disclosure should indicate the length of hospital
stay typically authorized and the availability of post-discharge care,
such as physical therapy, in-patient rehabilitation care or home
health aides. The plan should also explain the basis underlying the
illustrative criteria.

3. Need for Clarification of Benefits and Grounds for Denials

a. Patient Choice Among Plans and Planning

This approach to the interpretation of the insurance provisions
can promote informed patient choice among plans with respect to
this key factor. If the policies clearly identify the basis upon which
medical necessity determinations are made and provide illustra-
tive examples, subscribers can consider this factor in exercising
whatever choice they may have among plans.

These criteria for determination of what is medically necessary
have important consequences for patients and their families. The
length-of-stay criteria can involve the shifting of the responsibility

(1a. Ct. App. 1980) (holding that contract provision allowing denial of benefits in
discretion of insurer's medical director did not permit denial at whim, but re-
quired "honest, sincere efforts" and use of medical experts; criteria was met when
insurer used two physicians to evaluate need).

44. For a discussion of the limited applicability of tort liability to those in-
volved in utilization review, see infra notes 65-70 and accompanying text.

45. See IOM, CONTROLLING COSTS, supra note 20, at 82-84 (surveying varia-
tions in criteria for tonsillectomies and for low back pain, procedures where varia-
tions are predictable).
for providing care during recuperation from an institution to family members. Subscribers who receive better notice of the limits of services can consider what alternative strategies they may need to undertake to deal with the limits, such as making alternative arrangements for home care.

The disclosures, thus, can facilitate planning by patients and help them in choosing among plans. In many cases, though, the choice between plans is limited to those made available by employers, and people with lower incomes may have fewer choices. The disclosures may still be useful in enabling the employees to persuade their employer to seek changes in the plans. In addition, as citizens, subscribers may seek legislation to change restrictions that are not publicly acceptable.

b. Inducement for Cooperation in Development of Criteria

The distinction made in the plan’s policy between those criteria based on professionally-accepted standards and those based on the plan’s own criteria may indirectly encourage more efforts by payers to work with the profession to develop more consensus standards. The disclosure of variations between the plans may spur some efforts at coordination. There may also be some public resistance to standards that are “the insurer’s” rather than those of the profession. Such public resistance could provide more incentive for the development of widely-accepted standards.

c. Patient Reassurance

When a specific claim is denied, the payer should also provide an explanation of the denial that indicates the basis for the criteria used for the denial. The information may provide some reassurance to the patient that the denial has substantial support and is fair. The patient may be less inclined to pursue an appeal if the grounds are satisfactorily explained.

46. *Hospitals Cost Too Much for Long Birth Stays Shifting the Burden*, N.Y. Times, Feb. 28, 1994, at A18 (noting that early dismissal of husband from hospital made it necessary for wife to stay home from work to provide care).

47. See Hall & Anderson, *supra* note 17, at 1645.

d. Removing Obstacles to Appeals and Disclosing Proprietary Data

An adequate explanation of the basis for a denial is also necessary to enable a patient to pursue his or her rights to an appeal. If the patient is to have a meaningful opportunity to appeal or request an exception, the explanation for the specific determination should reflect whether the denial is based on consensus professional standards or some other basis. Insurers have a fiduciary responsibility not to obstruct appeals.49

To facilitate an appeal, the underlying data supporting the specific determination needs to be available to the patient. A denial of benefits merely because the patient exceeded the insurer's authorized time for hospitalization was found by the United States Court of Appeals for the Fourth Circuit to be inconsistent with the insurer's responsibility to provide specific reasons for the denial in Weaver v. Phoenix Home Life Mutual Insurance Co.50 In Weaver, the insurer maintained that the norms for hospital stays developed by its consultant were proprietary and their value would be lost if disclosed.51 Nonetheless, the court found that the insurer was obliged to make arrangements with its consultant to permit both sufficient disclosure and an effective appeal.52

4. Clarification of the Term Medically Necessary

These changes could, of course, be adopted by legislation. Some clarification of the meaning of medical necessity in the policy can also be justified as needed to provide an appropriate interpretation of the contractual provisions. The contractual exclusion of medically unnecessary claims provides little guidance as to the test that will be used. The term by itself suggests to patients that the treating physician's judgment fails to meet minimally acceptable medical standards, implying that these are the standards that the

49. For a discussion of insurer's fiduciary responsibilities, see supra note 15 and accompanying text, and infra notes 73-75, 89-91 and accompanying text.
50. 990 F.2d 154, 158-59 (4th Cir. 1993). The court denied summary judgment for the insurer and granted summary judgment to the patient who was admitted to the hospital for alcoholism for a pre-approved 12-day stay but who actually stayed 30 days at the recommendation of his physician and independent consultant. Id. Furthermore, the insurer was required to state "specific reasons" for limiting the stay to 12 days. Id. Plans subject to ERISA must provide "specific reasons" for denials of benefits. See 29 U.S.C. § 1104 (1985) (identifying fiduciary responsibilities of ERISA). For a discussion of fiduciary responsibilities under ERISA, see infra notes 81-84 and accompanying text.
51. Weaver, 990 F.2d at 158-59.
52. Id. at 158.
profession recognizes. This interpretation is in accord with the traditional interpretation of the provisions of the contract.\textsuperscript{53} When the policy is intended to permit denial of services based on factors in addition to those that reflect consensus professional standards, the contract should indicate the additional grounds for denial generally used. If the insurer fails to provide this information in its policy or in the explanation for a specific denial, the determination should be viewed as governed only by criteria for which there is a professional consensus.

Some plans may, in addition, provide that the determination of medical necessity is to be made by the plan or rests “in the sole discretion” of the plan’s medical director or a peer review organization.\textsuperscript{54} Such a provision does not eliminate the need for the clarification suggested here. The provision can be read as allowing the plan to make the determination, but not as resolving the test that should be used in making the determination. The director and the peer review organization should be viewed as being required to use consensus professionally recognized standards in their determinations, unless the plan provisions go further and indicate that the criteria for the medical necessity determination permit other bases to be considered.

This clarification of the meaning of medical necessity should not impair utilization review and the efforts at cost containment. Rather, it is made necessary by the increased importance of utilization review. The clarification would not preclude plans from having distinct criteria. It would, though, promote greater accountability by making the basis of the determinations better known to those affected and facilitating patient choice.

\textsuperscript{53} Mount Sinai Hosp. v. Zorek, 271 N.Y.S.2d 1012, 1018 (Civ. Ct. 1966); see Annotation, What Services, Equipment, or Supplies Are “Medically Necessary” for Purposes of Coverage Under Medical Insurance, 75 A.L.R. 4TH 763 (1990); cf. Bucci v. Blue Cross-Blue Shield of Conn., Inc., 764 F. Supp. 728 (D. Conn. 1991) (finding that experimental treatments can be excluded only if medically unnecessary, as determined by whether no reasonable segment of the medical community would accept treatment as within appropriate range of medical treatment in circumstances of case); see Hall & Anderson, supra note 17, at 1650, 1655 (noting that contract cases in past left medical necessity determination to physician’s good faith judgment and insurers continue to lose under contract revisions allowing utilization review).

IV. Procedures and Remedies

From a patient's standpoint, there are drawbacks to the existing procedures and remedies to dispute a denial of claims based on the lack of medical necessity. The typical claims process and the potential forums for relief from incorrect decisions are considered below.

A. Procedures of the Payers

Decisions about the medical necessity of a procedure are typically made initially by a claims reviewer who is not a physician. The final denial of benefits, though, is reviewed by a physician. The claims reviewer is to obtain information sufficient to make a determination and obtain a medical consultation when needed.

The appeals processes are diverse. Under most plans, a review may be made by a physician adviser, the medical director or a committee. Some plans provide that the decision-maker on the appeal may not have been involved in the initial decision. Appeals are to be resolved by written decisions.

While in the hospital, the patient may not have a direct role in this internal appeals process, because part of the appeals may be handled by the treating physician. As a practical matter, leaving the appeal to the doctor is often the best course. The issues are medical questions and the doctor can be the best advocate in addressing issues regarding professional standards. Indeed, the development of cost containment has given doctors a responsibility for "economic advocacy" on behalf of their patients. Doctors also have considerable success on appeals in obtaining authorization for some additional benefits, as reviewers and doctors negotiate care alternatives that they can both accept. The patient should be informed that the appeal is being made and should have the opportunity to participate.

55. IOM, CONTROLLING COSTS, supra note 20, at 85.
57. Morreim, supra note 16 (discussing economic advocacy by physicians for benefit of their patients).
58. IOM, CONTROLLING COSTS, supra note 20, at 77; Hall & Anderson, supra note 17, at 1658 (noting that doctors reach accord in all but 1-2% of cases); cf. Blustein & Marmor, supra note 23, at 1551 (finding that physician appeals reduced denials from 15% to 9% in trial run).
The doctor faces some disincentive in continuing appeals, because the appeals are time-consuming and frustrating for doctors as they work their way through the layers of utilization reviewers. Before care is provided, a physician has an economic incentive to support the allowance of benefits, but after the surgery or other medical procedure has occurred, the economic incentive is lessened. The doctor’s reimbursement from the insurer is fixed at customary rates and will not increase for time spent in pursuing appeals in an individual case. The doctor may also be precluded from charging the patient additional fees if the physician is a participating member of the insurer’s health plan. The payer, thus, affects the compensation of the provider to whom the patient looks for advocacy with respect to the claim. From the patient’s standpoint, the patient may need to take a more direct role in pursing the appeal in this setting.

B. Tort Liability as a Remedy

1. Liability of the Treating Physician

When reimbursement is denied, the treating physician must advise the patient on whether to continue treatment and the physician will have to decide whether to pursue an appeal of the insurer’s determination. If the treating physician acquiesces in the insurer’s denial and does not recommend further treatment, the patient may have a tort claim against the doctor if an injury occurs as a result of premature discharge. The standard for judging the physician’s conduct is based on a professional standard of reasonable care. Medical necessity decisions can fall into a “grey area,” though, on whether additional care is needed. If reasonable physicians differ on the need, the physician may not be in violation of the professional standard and there may be no malpractice liability for not seeking the additional care.

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59. See Gerald W. Grumet, Health Care Rationing Through Inconvenience: The Third Party’s Secret Weapon, 321 NEW ENG. J. MED. 607, 608 (1989); see State MDs Prescribe Own Health Insurance, STAR LEDGER (Newark), Mar. 24, 1994, at 1, 19 (discussing physicians who are starting own plan in response to “hassle factor” involved in medical necessity reviews).

60. See Morreim, supra note 16, at 308 (“The physician ... will increasingly be embroiled in ... appeals procedures, for which the time spent is ordinarily not billable.”).

61. If the physician believes further treatment is needed that will not be reimbursed by the insurer, the physician will face a dilemma if the patient is unable to pay privately for the care.

62. The tort standard should not necessarily be the contract standard for de-
The lack of tort liability, when reasonable opinions differ, can remove some of the incentive to resist the payer's denial of benefits, even though the treating physician reasonably believes the care is necessary. As physicians are influenced by utilization review to provide less care, the professional standard as to the care needed may also change.\textsuperscript{65}

2. \textit{Tort Liability of Reviewers and Insurer}

If the patient is injured as a result of an early discharge from a hospital because of a denial of insurance benefits, the plan could be subject to tort liability, but only in limited circumstances. Tort suits are preempted in the case of employer-sponsored health plans that are qualified plans under the Federal Employment Retirement Income Security Act (ERISA).\textsuperscript{64} Because ERISA generally covers those who receive their insurance through their employer, tort liability is precluded for many utilization review decisions.

In private health plans not covered by ERISA, establishing tort liability of reviewers presents considerable difficulties. The standard for determining negligence of those responsible for the review will reflect the need to abide by the professional standards of medical care.\textsuperscript{65} If reasonable physicians can differ, there will be no liability for a denial, even though the provision of additional care

termining what care is medically necessary under the plan. The lack of tort liability when reasonable physicians differ is appropriate because the patient has chosen the physician and is only entitled to receive the physician's best judgment within the range of reasonable care. However, denying benefits as medically unnecessary when reasonable physicians differ, based on the views of experts, or other authorities, presents a different issue. The patient has not chosen to rely on the opinions of these experts and the patient loses the benefit of the treating physician's individual best judgment. If benefits are to be denied as medically unnecessary when reasonable physicians differ, the plan's criteria should be clearly identified so that the patient can decide whether to rely on these standards. For a discussion of the process of medical necessity determinations, see \textit{supra} notes 17-38 and accompanying text.

\textsuperscript{65} Helvestine, \textit{supra} note 1, at 177-78 (finding that to some extent, criteria is "self-validating" as criteria that comes into widespread use becomes the community standard); IOM, \textit{CONTROLLING COSTS}, \textit{supra} note 20, at 95 (noting that use of utilization review reduced hospital stays for procedures even for patients not covered by program).

\textsuperscript{64} 29 U.S.C. § 1144(a) (1988); see Johnson v. District 2 Marine Eng'rs Beneficial Ass'n, 857 F.2d 514 (9th Cir. 1988) (holding that state law fraud and intentional infliction of emotional distress claims are pre-empted under ERISA). In Corcoran v. United Healthcare, Inc., 965 F.2d 1321 (5th Cir.), \textit{cert. denied}, 113 S. Ct. 812 (1992), the United States Court of Appeals for the Fifth Circuit criticized the preclusion of damages when errors led to injury and urged Congressional reform. \textit{Corcoran}, 965 F.2d at 1338.

\textsuperscript{65} See Helvestine, \textit{supra} note 1, at 177.
would also have been a reasonable judgment.66

Even if breach of duty of care by the reviewers can be established, establishing causation remains a major difficulty for patients in bringing tort suits against insurers. When the doctor fails to appeal a case, the reviewers may not be liable, even if the reviewers were negligent in denying benefits, on the grounds that the reviewers did not cause the injury.67 Instead the doctor, in discharging the patient, may be seen as the cause of the injury. This narrow view of causation has been criticized as inconsistent with more modern theories of causation and with a more realistic assessment of the effects of a denial of benefits.68 Consequently, at least one recent case has held that a reviewer can be liable in tort if the denial of benefits was a substantial factor in causing injury to a patient.69

One lesson that reviewers may have learned from these developments is that to protect themselves from any risk of liability, the reviewers should have the “concurrence” of the treating physician with the review decision.70 If the doctor agrees and does not appeal, the discharge may be seen as the doctor’s decision, not the insurer’s responsibility under the more limited view of causation. As a result, the concern for tort liability on the part of reviewers

66. Id. at 178 (suggesting that in close cases, it is advisable for reviewers to research literature or data that provides basis for disagreeing with physician who persists in believing additional care is needed).

67. In Wickline v. California, 239 Cal. Rptr. 810 (Ct. App. 1986), the insurer’s denial of benefits was not considered the cause of injury because the doctor discharged the patient without an appeal. Wickline, 239 Cal. Rptr. at 819. However, the case is ambiguous because further hospitalization may not have avoided the injury and other physicians concurred in discharge as acceptable practice. Id. at 817-19.


69. Wilson v. Blue Cross of S. Cal., 271 Cal. Rptr. 876 (Ct. App. 1990). When a patient who was discharged by his doctor after his insurance benefits terminated committed suicide as a result of the early discharge, the insurer, as well as the physician, could be regarded as a “substantial factor” that caused the injury, notwithstanding that the discharge was made by the physician, and that the physician did not pursue informal reconsideration opportunities. Id. at 883. The court relied on the Restatement (Second) of Torts § 431 (1977) for the substantial factor test. Id.

may play some role in encouraging negotiation and compromises with the treating physician.

3. Additional Factors Limiting Usefulness of Tort Suits

In practice, few lawsuits are actually brought on the tort theory against reviewers. From the patient's standpoint, particularly an in-patient facing concurrent review, a tort suit has its limits, because it is retrospective and requires a showing of injury. When the patient is in the hospital, the patient is concerned with receiving the care that is needed. Furthermore, the denial of benefits can cause a risk of loss that, fortunately for the patient if not the lawsuit, is not realized. Premature discharge can also cause hardship that may not produce a tangible injury that can justify a tort suit. Thus, tort suits provide only a limited check on benefit denials. It may benefit patients most by encouraging compromises between the utilization reviewers and the physician about the level of care.

C. The Insurers Obligations Based on Contract: The Insurer as Fiduciary

1. Private Insurance Not Covered by ERISA: Contract Actions and Fiduciary Obligations

The insurer has an obligation to the patient under contract. In early years, claimants had some success as the courts were deferential to the doctor's determination of medical necessity.71 With increasing concern about health care costs in the 1970s, insurers wrote express provisions into contracts concerning cost containment and the denial of benefits for medically unnecessary procedures. The insurers have had only limited success in contract suits when litigated.72

71. Mount Sinai Hosp. v. Zorek, 271 N.Y.S.2d 1012, 1015 (Civ. Ct. 1966) (holding that standard for judging necessity of treatment prescribed is care considered necessary by treating physician so long as reasonable physician could agree); see Hall & Anderson, supra note 17, at 1644-45.

72. See Hall & Anderson, supra note 17, at 1644-55 (discussing cases through the late 80s and their relative rarity); Annotation, supra note 53, at 763; see, e.g., Taylor v. Prudential Ins. Co. of Am., 775 F.2d 1457 (11th Cir. 1985); Ex parte Blue Cross-Blue Shield, 401 So. 2d 783 (Ala. 1981) (holding that medical necessity is jury issue when treating physician testified services unnecessary but had admitted patient to hospital); Ponder v. Blue Cross, 193 Cal. Rptr. 632, 643 (Ct. App. 1983) (holding that exclusion was invalid because exclusion of coverage not sufficiently clear); Abernathy v. Prudential Ins. Co., 264 S.E.2d 836, 837-38 (S.C. 1980) (holding that treatment is medically necessary if it is medically appropriate, but does not have to be medically essential). A contract provision allowing denial of benefits in the discretion of the insurer's medical director did not permit denial at whim, but required "honest, sincere efforts" and the use of medical experts; the criteria was
Insurers are also considered fiduciaries under insurance law and can be liable for bad faith in paying claims. Because this theory is a tort theory, punitive damages may be recoverable, making litigation a more realistic alternative. The insurers are obliged to give the subscriber's interest "at least as much" consideration as it gives its own interest. Bad faith may be shown if the insurer has a pattern of denying routine claims, uses a process that fails to consider relevant information or makes it difficult for claimants to pursue their rights. An example of bad faith is not informing claimants of appeal rights or by failing to provide adequate information.

This theory potentially provides some relief with respect to the problems of a failure to provide sufficient notice of benefits or the grounds for denial, when these failures may frustrate the ability to seek benefits or appeal. The theory might also be of some applicability if the insurer's appeal procedures could themselves be shown to be unfair. While the theory may provide some relief, the scope of the principle remains largely untested.

2. Difficulties with Contract Suits as a Form of Relief

Contract suits provide a means of retrospective relief, with the decision being made independently by a judge or jury; however, there are difficulties with contract suits as an effective form of relief for mistaken decisions. In employer-sponsored health plans, the common-law contract suit is not available and is instead replaced by the grievance and review procedures provided by ERISA.

When a contract action is available, the amount of damages that may be recovered for mere economic loss may not be sufficient

73. Blum, supra note 68, at 211.
74. Silberg v. California Life Ins. Co., 521 P.2d 1103, 1108-09 (Cal. 1980) (finding that implied covenant of good faith and fair dealing in every insurance contract required insurer to give interests of insured equal consideration to its own interests).
75. Sarchett v. Blue Shield, 729 P.2d 267, 276 (Cal. 1987) (en banc) (holding good faith requires insurer to inform insured of his remedial rights); Davis v. Blue Cross, 600 P.2d 1060, 1063 (Cal. 1979) (en banc) (holding insurer's failure to inform insured of arbitration rights constituted breach of duty of good faith); Blum, supra note 68, at 211; Joanne B. Stern, Bad Faith Suits: Are They Applicable to Health Maintenance Organizations?, 85 W. VA. L. REV. 911 (1983) (arguing for application of bad faith suits to HMOs as method for policing their conduct); Linda Tiano, The Legal Implications of HMO Cost Containment Measures, 14 SETON HALL LEGIS. J. 79, 90 (1990) (discussing generally bad faith claims against insurers).
76. See Blum, supra note 68, at 193; Stern, supra note 75, at 913-15.
to make litigation worthwhile for smaller claims. If the patient leaves the hospital because of the denial of benefits, it may also be difficult to establish that the patient has damages when the patient suffers no further physical injury, and does not incur costs to replace the services lost. Continued hospitalization, though, may have reduced a risk of injury that will not seem as valuable an interest if the risk does not materialize.

A recovery in a lawsuit afterwards does not help an inpatient obtain care at the time it is needed, unless the patient initially pays for the care. Many patients may not be able to afford to pay privately. Even patients with some resources may be cautious about paying for care, not knowing what further expenses may arise from their illness. In this time of concern with cost containment, the designation of care as "medically unnecessary" can influence patients and providers to forego care unless the determination can be changed.

D. ERISA Plans and Remedies

Federal law preempts recovery under common law for contract as well as tort actions for any dispute that "relates to" an employer-funded health plan governed by ERISA. Many health plans provided as an employment benefit fall within this preemption from common-law remedies. The plans may be self-funded or administered by health insurers on behalf of the employer. The beneficiaries are limited to the remedies provided under the federal statute. The beneficiaries can use the grievance procedures, that the plan must establish and the beneficiaries can seek judicial review to correct arbitrary decisions.

1. Remedies Provided: Internal Grievance Procedures

The plans are recognized, by law, to have fiduciary responsibilities to their beneficiaries and are required to provide an internal

78. See Tiano, supra note 75, at 91. To the extent the denial of benefits causes physical injury, the liability turns on the same issues as in a tort suit. Id.
79. See 5 CORBIN ON CONTRACTS § 1002 (1964) (noting damages may be measured by savings in cost caused by breach).
grievance procedure to patients. The aim is to permit the plans to operate not only "without the formality or limitations of adversarial proceedings, but also to protect a plan participant from arbitrary or unprincipled decision-making." The law requires that plan administrators give patients "specific reasons" for denials of benefits and a "reasonable opportunity . . . [for] a full and fair review" of the denial. The implementing regulations require the disclosure of any additional material or information necessary for a claimant to perfect an appeal.

An oral hearing need not be provided to claimants. The appeal can also be decided by the plan administrators who made the initial determination. The "core requirement" is that the claimant know the evidence, have the opportunity to address its accuracy and reliability, and have the decision-maker consider the evidence before deciding the appeal. The plan must also provide reasons for the initial denial that are specific, rather than conclusory, in order to permit a meaningful appeal.

2. Remedies Provided: Judicial Review

If the patient's claim is denied in the grievance procedure, the patient can seek judicial review in state or federal courts for a breach of the obligation to pay under the plan's contract. No dam-

82. Grossmuller v. International Union, 715 F.2d 853, 857 (3d Cir. 1983) (discussing intent of ERISA claims to be settled through internal resolution procedures).
84. 29 C.F.R. § 2560.503-1(f) (requiring specifically that notice of denial of benefits include reference to plan provisions on which denial is based, any information that, if submitted, might perfect claim, and steps which must be taken to pursue appeal).
85. In Brown v. Retirement Comm. of Briggs & Stratton Retirement Plan, 797 F.2d 521 (7th Cir.), cert. denied, 479 U.S. 1094 (1987), the United States Court of Appeals for the Seventh Circuit held that a written record was sufficient for a fiduciary to make a claim denial decision. Brown, 797 F.2d at 534. However, the Seventh Circuit's analysis was based on the "arbitrary and capricious" standard of review. Id. at 525. In Firestone Tire & Rubber Co. v. Bruch, 489 U.S. 101 (1989), the Supreme Court held that claims of breach of fiduciary duty should be reviewed de novo, rather than the "arbitrary and capricious" standard. Firestone, 489 U.S. at 115.
86. Brown, 797 F.2d at 534.
87. Id. at 534 (citing Grossmuller v. International Union, 715 F.2d 853, 858 n.5) (3d Cir. 1983) (describing core requirements of plan administrator's review).
ages are available beyond those for breach of contract. The courts make a de novo determination in the interpretation of contract terms, but they will apply a deferential arbitrary and capricious standard of review with respect to matters vested by the contract to the discretion of the plan administrators.

The underlying premise of the law is that plan administrators are fiduciaries, with responsibilities both to the general group of employees in conserving funds and to the particular claimant. The duty to the particular patient requires good faith in handling the patient's claims and in dealing with the grievance. Furthermore, the Supreme Court has recognized that Congress intended to have the federal courts develop "a federal common law" under ERISA to implement the plan's obligations.

3. ERISA Remedies as a Means of Relief

The ERISA remedies provide some recourse for claimants, although the adequacy of the relief has also been questioned.

a. Requirement for Specific Reasons

ERISA requires that "specific reasons" be given for denials, making conclusory explanations inappropriate. Patients and phy-

89. See, e.g., Massachusetts Mut. Life Ins. Co. v. Russell, 473 U.S. 134 (1985) (denying relief based on preemption basis); Lafoy v. HMO Colo., 988 F.2d 97, 99-101 (10th Cir. 1993) (denying extra-contractual relief, including compensatory damages based on ERISA provision). Damages have been awarded, though, when the failure to provide information by the plan led employees not to take advantage of the opportunity to obtain coverage. See Bixler v. Central Pa. Teamster Health & Welfare Fund, 12 F.3d 1292, 1302-03 (3d Cir. 1993) (holding employer may have breached fiduciary duty by failing to inform beneficiary of available benefits after employer withdrew from plan); Warren v. Society Nat'l Bank, 905 F.2d 975, 981-82 (6th Cir. 1990), cert. denied, 500 U.S. 952 (1991) (holding participant in retirement plan was entitled to monetary damages because trustee breached fiduciary duty).


sicians who receive conclusory denials should insist on a specification of the grounds for the decision in accordance with the statutory requirements.

b. Attorney's Fees and Access to Court

Under ERISA, courts can award reasonable attorney's fees. The availability of fees makes it more feasible to bring some challenges. The award of fees is discretionary, though, and the lack of mandatory awards can be a disincentive.

A number of cases have challenged the denial of benefits for autologous bone marrow and other transplants. These cases have presented an urgency for resolution because the patients had terminal conditions. While the insurers have won a few of these cases, they generally have not fared well. Even when the arbitrary and capricious standard applied, the determinations have been overturned for failure to consider adequately the patient's situation or the degree of acceptance of the procedures in the medical community.

Indeed, according to one report, the insurers now generally settle this type of experimental surgery case for considerable sums once a lawsuit is brought. Thus, the way to prevail in a medical necessity dispute is said to be to "hire a lawyer."

95. See O'Neil, supra note 92, at 769-70 (asserting that lack of mandatory award of attorney's fees makes it difficult for ERISA claimants to obtain legal representation); see also Ann C. Bertio, Note, The Need for a Mandatory Award of Attorney's Fees for Prevailing Plaintiffs in ERISA Benefits Cases, 41 Cath. U. L. REV. 871, 872-73 & n.17, 884-86 (1992) (contending that plaintiff's attorneys have no incentive to accept ERISA claims when award of attorney's fees is not mandatory).
97. See, e.g., Rollo, 1990 WL 312647, at *7 (applying deferential standard but overturning insurer's denial for failure to acknowledge studies that were conducted that involved particular procedure issue); see also Molino, supra note 96, at 334 (discussing designation of board of medical specialists to determine experimental treatment as well as drafting changes); Hall & Anderson, supra note 17, at 1654-57 (discussing court's unwillingness to enforce contract terms over possible loss of life).
98. See Gina Kolata, Patients' Lawyers Lead Insurers to Pay for Unproven Treatments, N.Y. TIMES, Mar. 28, 1994, at A1 (commenting on growing disputes between
E. Limitations of ERISA Remedies

1. Smaller Claims

The cost of bringing cases, though, can be high. In cases challenging denials of benefits for experimental surgery, the cost of attorneys has been approximately $10,000. The experimental surgery cases involve large medical costs, typically approximately $100,000, making the costs of litigation feasible. In more routine cases, bringing a lawsuit to obtain relief is not as practical. The patient can also have the same difficulty in establishing damages that occur with other contract cases.

2. Independence of Reviewers

Whether the reviewers who make medical necessity determinations are sufficiently independent presents an important issue that has arisen in different contexts. The lack of independence may be questioned because the decisions on appeal are made by those involved in the earlier review. The participation of an initial reviewer in the final decision is not impermissible.

The lack of independence can also arise if the medical director or other decision-makers have a financial stake in denying benefits. There has been a report of a director who was eligible for a bonus when the company made a profit. The existence of a personal financial stake in the outcome would be disqualifying in other proceedings.

patients’ lawyers and insurance companies); see also William P. Peters & Marc C. Rogers, Variation in Approval by Insurance Companies of Coverage for Autologous Bone Marrow Transplantation for Breast Cancer, 330 New Eng. J. Med. 473, 476 (“The fact that denials of coverage were frequently reversed when an attorney became involved may offer patients some consolation, but as a policy this approach is to be strongly discouraged.”).


100. For a discussion of the difficulty in establishing damages, see supra notes 78-79 and accompanying text.

101. See Sweatman v. Commercial Union Ins. Co., 39 F.3d 594, 598-99 (5th Cir. 1994) (stating that it is “both legally and factually inaccurate” to argue that review must involve party other than person who initially denied claim).

102. 20/20, (ABC television broadcast, Apr. 15, 1994) (reporting $89 million jury verdict and subsequent settlement). This 20/20 broadcast also reported that a medical director was denied benefits when an expensive transplant operation was performed. Id. Also, an executive in a for-profit corporation became eligible for bonus when the company made a profit. Id.

103. See Withrow v. Larkin, 421 U.S. 35, 47 (1975) (stating that in judicial and administrative proceedings, decision maker’s “pecuniary interest in the outcome” would create “probability of actual bias” that would be “too high to be constitutionally tolerable”).
Difficult questions about the independence of the process also arise from the organization's stake in cutting costs. The cost reductions can benefit the plan's economic health. The increased competition involved in managed care accentuates these concerns. The viability of the plan, or its selection as the plan administrator, may be at stake if the plan cannot hold down costs as well as its competitors. The director of the program can be identified with the success of cost-cutting efforts as to be perceived to be reluctant to grant appeals that raise fiscal concerns.\(^\text{104}\)

On the other hand, the cost-cutting efforts also benefit the members of the plan by potentially reducing their health care costs. The denial of benefits can be seen as serving the interests of the beneficiaries generally, rather than as self-serving cost-cutting by the plan. The difficulty is that the denial of benefits can serve both interests. The savings can benefit the other subscribers, as well as having an organizational benefit. The insurer's organizational interest should be recognized as a potential conflict and one that warrants some added safeguards to provide assurance that the plan decision-makers have carefully considered the decision on its merits.\(^\text{105}\)

The case law under ERISA does not preclude a decision on appeal by those with some conflict of interest. The existence of a conflict, though, is a factor that is considered under the arbitrary and capricious test when discretion is vested in the insurer.\(^\text{106}\) An insurer has been found to have an "inherent conflict" when an employer offers benefits to employees through health insurance for a fixed sum, with any payments for benefits reducing the insurer's own funds.\(^\text{107}\)

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\(^\text{104}\) For examples of Directors being affected by fiscal considerations, see Helvestine, supra note 1, at 174. In Health Maintenance Organizations, where the plan provides the care as well as the reimbursement, the conflicts with economic interest can be accentuated. See Stern, supra note 75, at 920-24.

\(^\text{105}\) The significance of the insurer's financial self-interest was recognized in determining the due process protection needed for Medicare programs where an insurer administered the program, but the government funded it. Schweiker v. McClure, 456 U.S. 188, 196-97 (1982) (holding that insurer is not shown to be biased absent showing of financial interest by company that was not established when funds for the program were "federal and not [the insurer's] own funds").


\(^\text{107}\) See Sweatman, 39 F.3d at 599 (recognizing insurer's conflict of interest as both plan insurer and claims administrator); Brown v. Blue Cross & Blue Shield,
To deal with the potential for conflict, the lower courts have developed different approaches. Some may use a sliding scale approach that decreases deference in proportion to the seriousness of the conflict with the application of the standard shaped by the circumstances. Other courts use a two-tier approach and defer until serious unfairness is shown; the courts then shift the burden to the insurer to show that the decision furthers the interests of the beneficiaries generally. Under this approach the claimant may have the burden to demonstrate through “material probative evidence” that self-interest caused a breach beyond the mere fact of an apparent conflict. A need for “caution” has also been recognized when giving insurers the degree of deference accorded administrative agencies, because the insurers are not as publicly accountable as the agencies and the insurers are more subject to economic pressures.

Judicial review, then, can provide some protection against the economic pressure that a payer may face, because review will take account of the potential conflict in applying the arbitrary and capricious test for review when discretion is granted. This safeguard, though, is not completely sufficient. The beneficiary denied benefits must be able to afford to bring a lawsuit to benefit from any weight given to the conflict during review. Furthermore, the impact that the potential conflict will have on review is not clear and is shaped by the particular factual setting. The claimant may have to demonstrate in some specific way how the potential conflict affected the particular dispute. With such an indeterminate stan-

898 F.2d 1556, 1561-63 (11th Cir. 1990), cert. denied, 498 U.S. 1040 (1991) (stating that benefits determinations made by insurance company administering its own policy poses an “inherent conflict”).

108. See, e.g., Doe v. Group Hospitalization, 3 F.3d 80, 87 (4th Cir. 1993) (reviewing to determine whether denial is “consistent with exercise of discretion by a fiduciary acting free” of conflict). But see, Sweatman, 39 F.3d at 599 (holding that inherent conflict of interest does not affect standard of review).

109. See, e.g., Atwood v. Newmont Gold Co., 45 F.3d 1317, 1323 (9th Cir. 1994) (indicating that “the plan bears the burden of producing evidence to show that the conflict of interest did not affect the decision to deny benefits” when beneficiary produces evidence that insurer violated fiduciary obligation); Brown, 898 F.2d at 1566-67 (ruling that, under principles of federal common law, burden shifts to insurer to prove that its decision was not “tainted by self-interest”).

110. Atwood, 45 F.3d at 1323 (emphasizing need for heightened scrutiny of administrator’s discretion once claimant meets burden through “material probative evidence”).

111. Brown, 898 F.2d at 1556, 1564 n.7 (11th Cir. 1990) (recognizing that deference given to administrative agencies should not be applied broadly to insurer’s decision making because insurers are subject to economic pressures and shielded from outside political pressures).
standard, it may be difficult to establish the added significance to be given to the conflict on review.

The recent explosive growth of managed competition exacerbates the concern with the independence and fairness of grievance procedures. Cutting back on medically unnecessary costs is a key way to control costs. As firms compete to control the costs, economic factors could affect their discretionary decisions—such as the availability of exceptions—in ways that are difficult to identify. There is also likely to be the perception that the plans have a financial interest in denying benefits which affect their objectivity. The impact of that conflict may be difficult to demonstrate, yet it has a potential to erode confidence in the fairness of the process. With for-profit plans, this perception will be accentuated. The increasingly competitive nature of health care plans, thus, creates the need for additional safeguards beyond the uncertain prospect of judicial review to correct conflicts.

V. ADDITIONAL SAFEGUARDS

One means of providing additional safeguards would be to legislate health care reforms that would provide an external administrative review of medical necessity disputes. The Clinton Health Care Plan would have established state-run review offices to resolve disputes brought by patients about denials of benefits by health care plans. The state decisions would have been subject to limited federal administrative and court review.

The Clinton Health Care Plan faltered, in part, because of the objections to the additional level of bureaucracy that would be created. Developing fair administrative procedures for mass benefit programs presents challenging issues. There also are various models for administrative review. This article does not consider whether an administrative forum is appropriate and the form it

113. id. § 5205 (subjecting decision to review by Federal Health Plan Review Board and permitting appeal of Board’s decision to United States Court of Appeals).
should take. At present, there is no prospect for legislation that would mandate separate administrative forums for review. Reforms that work within a framework of private insurance would be more likely to win acceptance. Discussed below are two measures that can provide additional safeguards to ensure a fair procedure for privately-provided health insurance. These procedures relate to a procedural audit and the availability of second opinions for disputes involving the risk of serious impairment.

A. Procedural Audit

1. Aim of the Audit

Health plan payers should sponsor a system of independent audits that selectively sample the adequacy of the claims' determinations and dispute resolution by the plan. A summary of the results of the audit should appear in the plan's brochure provided to subscribers. Under this approach, an auditing staff would review a random sample of the medical necessity decisions made by the plan. The decisions would be evaluated by appropriate criteria covering the accuracy, timeliness and fairness of the decision-making process. The review would examine how well the plan observed the accepted process for making decisions, such as providing timely notice and adequate statements of the basis of the decision. The auditors would also consider complaints filed by patients. An overall evaluation of the plan's performance would be made, along with any recommendations for improvements or clarification of the plan's criteria. A summary of the audit report would be made available to subscribers in order to provide a better means of making choices among plans.

This type of procedural audit is appropriate within a scheme of private health insurance precisely because it facilitates choice by the consumers on an informed basis. The plans could also be expected to improve performance to avoid a negative evaluation. Of course, it would be necessary to ensure that the audits themselves were fair and accurate in their evaluation. Poor audits would damage the plans and mislead the subscribers. The identity, therefore, of the sponsoring organization is key.

2. Establishment of Audit Panels

There could be different types of sponsors for an auditing program. An audit by governmental regulators would provide an added assurance of independence. The framework suggested here, though, reflects an effort at self-regulation by payers to establish audits that can claim to be independent. Under this approach there would be a panel to supervise the audit program. The panel would be made up of representatives of health insurance payers, medical providers, patient representatives and those with an expertise in procedural systems, such as retired judges. The panels, established on a statewide basis, would develop the criteria used in the audits, such as an acceptable level of errors or the norm for timeliness. In addition, the panel would arrange for hiring the auditors to do the actual audits. The audit staff would be made up of individuals with relevant expertise. Lastly, the panel would issue the audit report after considering the comments of the payer affected.

The appointment of the panel would reflect its self-regulatory nature. Health care payers would have to initiate the efforts to form the panels. To safeguard the independence of the endeavor, at least half of the panel should consist of those not connected with payers. Medical organizations should be asked to designate medical representatives. To make self-regulation work properly, it also is important to have representation by those with interests that are adversely affected by claims denials. Accordingly, a special effort should be made to secure adequate representation of patients' interests. Organizations that have a special interest in treating particular illnesses, such as cancer or arthritis, would be a good source for representatives that are attuned to the patients' concerns.

Any participation by the payers in the audited program may be questioned as inconsistent with the aim of having an independent procedural audit. To induce the payers to establish an audit program, though, the payers can be expected to want to have a role that will enable them to prevent what they would perceive as mistaken standards or poor judgment. Moreover, to make a self-regulatory program work, the various adversely-affected interests need to participate. In addition, because there are no established

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117. See Douglas C. Michael, Federal Agency Use of Audited Self-Regulation as a Regulatory Technique, 47 ADMIN. L. REV. 171, 226 (1995) (stating that experience with health care financing suggests “that it is difficult for a self-regulatory program to succeed if opposing groups are not given meaningful input in the process”).

118. Id. (emphasizing need for opposing groups' participation in self-regulatory system).
standards for judging these procedural systems, these standards need to be formulated. The payers have an important insight to contribute about the appropriate criteria.

The participation of payer-industry representatives, though, is a complicating factor, especially when the panel is reviewing the audit for a particular payer. Any representative from that particular company inevitably is faced with a conflict of interest. Representatives of other companies may have a competitive advantage to gain from an adverse report on another company. Thus, the payer representatives should probably not vote on the decision whether to issue an audit report for a particular company. If they are allowed to participate when their own company is not directly involved, there may need to be an opportunity for arbitration to resolve contentions by the affected payer that the audit is unwarranted and has been affected by competitive concerns.

3. Incentive to Establish Audit Program

The incentive for payers to establish such a program would be to safeguard patient confidence in the fairness of the procedural relief provided by the payers. Confidence is important in its own right and is a matter that the payers, as fiduciaries, should want to ensure. Moreover, if numbers of patients believe that the grievance procedures of the payer are "stacked" and provide no relief, there may be pressure for Congress or state legislatures to provide additional recourse and forms of review of payer decisions. Finally, the existence of an audit may make courts more willing to accept the decisions of the payers as non-arbitrary and as providing a "full and fair review" under ERISA.

If such programs are not established voluntarily, then a legislative requirement for such audits should be considered. The regulatory standards governing HMOs could conceivably be amended to require some type of procedural audit. In any legislatively established program, the program should ensure clear standards, public access to its records and authority for a regulatory agency to review the audit program. In a self-regulatory program voluntarily es-

119. See 42 U.S.C. § 300e(c)(5) (1988) (requiring grievance procedures for HMOs but not establishing specific standards); Stayn, supra note 115, at 1702 (indicating that individuals who plan to enroll in federally-qualified HMO have no way of learning of particular HMO's noncompliance and that existing federal system "provides minimal substantive and procedural protection for non-Medicare member of HMOs").

120. See Recommendation 94-1 of the Administrative Conference of the United States, The Use of Self-Regulation as a Regulatory Technique, 3 C.F.R. Recommend. 94-1 (1995); cf. Michael, supra note 117, at 189-95 (discussing how proce-
Established along the lines recommended here, the program should endeavor to meet the criteria for an effective and fair program that have been recommended for programs under government auspices.

B. Second Opinions in Disputes Involving Risks of Serious Impairment

Health plans should also have a policy of providing second opinions as a means of resolving disputes involving cases where patients may suffer serious impairment if denied services. Health plans should offer patients with these serious conditions the opportunity for a second opinion at least when the issue turns on a factual dispute or when the patient has raised substantial grounds for believing an exception to the usual criteria are warranted.

1. Advantages of Second Opinions

For patients, the use of second opinions to resolve disputes about medical necessity determinations has clear advantages. First, the accuracy of the decision can be promoted by a direct contact between the patient and the physician. Second, when a patient is hospitalized and a dispute arises about prospective treatment, the opportunity for a second opinion can be reassuring for the patient, no matter what the outcome. In addition, a consultation in the hospital also permits a more timely resolution.\textsuperscript{121} The length of time for grievance procedures to operate is currently a “major weakness” when issues arise concerning hospitalized patients.\textsuperscript{122} Finally, second opinions also offer the opportunity to have involvement by those not previously involved in the decision.

Some insurers now provide or require the use of second opinions to advise on the need for certain operations.\textsuperscript{123} Because second opinions are relevant in the insurer’s judgment in discouraging unnecessary surgery, the opinions should also be considered to be relevant as a fair procedure in resolving other disputes about when further care is unnecessary.

\textsuperscript{121} See Stayn, supra note 115, at 1712-13 (discussing advantage for patients and providers of second opinion procedure established by Illinois statute).

\textsuperscript{122} See Helvestine, supra note 1, at 193 (discussing need for expedited judicial relief to solve lengthy grievance procedure problems).

\textsuperscript{123} See Blue Cross and Blue Shield of New Jersey, Your Medallion Health Care Coverage (1995). Under this type of program, the patient can consult any physician who has agreed to participate in the program, with the cost borne by the insurer.
2. **Concerns About Second Opinions: Selection of Physicians**

Payers, though, can be expected to be reluctant to provide for second opinions for several reasons. They may be concerned about the selection of the physician providing the opinion and the criteria to be used. In addition, the cost of the opinions will be an important factor. The physicians providing the opinions would be subject to tort liability for malpractice, which may make it more difficult to obtain their participation.

The physicians providing the second opinions should be those who are participating providers of the payer's health care plan. The physician should be a practicing physician in the relevant specialty. While the physician might be selected solely by the payer, the results would be more acceptable and fair if made with the concurrence of the patient and patient's physician. The opinions would still be governed by the plan's criteria for medical necessity. If there is any challenge to the legal validity of the criteria, that challenge should be made by pursuing other applicable remedies. The physician providing the second opinion, as well as the treating physician, should be protected against retaliation for reaching a determination adverse to the payer.\(^\text{124}\)

3. **Limitations of Second Opinions**

The cost of second opinions is an important concern and the availability of this remedy should be limited to areas where the use of second opinions is most warranted on a policy basis.

a. **Factual Disputes and Risks of Serious Impairment**

If the need for further care turns on a dispute about the patient's physical condition and the condition involves a risk of serious impairment, resolution by a second opinion or referral is appropriate.\(^\text{125}\) The risk of serious health consequences if care is not provided warrants the provision of more safeguards.

The physician providing the second opinion should ordinarily observe the patient. If the physician determines that the matter can be reliably determined by consultation of the medical records, 

\(^{124}\) For a discussion of a program that provides protection to physicians, see Stayn, *supra* note 115, at 1713.

\(^{125}\) The Health Security Act Amendments considered in the last Congress provided for expedited administrative review of any disputes involving "serious impairment" of bodily functions or other "serious" harm. See H.R. 7509, 103d Cong., 2d Sess. § 9302(c)(2) (as amended Aug. 10, 1994); S. 7509, 103d Cong., 2d Sess. § 5501(c) (1995).
some contact with the patient should be made by phone. A medical contact with the hospitalized patient can probe further into the patient's condition at the actual time at issue to determine if there are special factors or additional tests needed. When a medical necessity dispute turns on such a factual dispute, there may be no other alternative means of resolving the matter reliably. Indeed, a second opinion may be necessary to ensure a "full and fair review" under ERISA. When these factual disputes arise, the payer should bear the cost of the second opinion.

b. Significant Exceptional Circumstances Involving Serious Impairments

Situations can arise when exceptions may be warranted to the general criteria governing reimbursement. If a patient raises significant grounds to show there are special factors to justify an exception, with respect to a condition involving a risk of serious impairment, referral for a second opinion is useful in evaluating the issue. The opinion can provide some counterweight to the tendency to treat the matter by the usual rules without focusing on special factors. Physicians, through their practice, gain the experience to judge when there are compelling circumstances in which fairness warrants a different approach. There is a risk that some patients will readily claim exceptions. To encourage more realistic claims, the patient should have to share the cost for the second opinion.

The second opinions need not necessarily be given conclusive weight, but if the insurer did not accept the result, the insurer would need to provide strong support for reaching a different result.

VI. CONCLUSION

The effort to control medical care costs carries the risk that health insurers or managed care providers will inappropriately determine that medical care is unnecessary. These determinations of medical inappropriateness can be especially difficult ones for hospitalized patients suffering from traumatic injuries or sudden ill-

127. See Helvestine, supra note 1, at 178 ("If criteria are used, there should be procedures available to allow the reviewer to deviate from them in individual cases of medical necessity.").
128. If the patient is indigent, the need for a co-payment should be waived.
nesses. These patients need timely notice of any planned denial of benefits, an identification of discharge alternatives and an adequate explanation of benefits. This additional information can help the patient to become his or her own advocate in seeking the appropriate type of care. The physician's role in determining care is increasingly managed and incentives are being created to reduce costs and the services prescribed. The patient will need to take a more active role in evaluating whether his or her needs are being sufficiently considered. Greater clarity about the general criteria for medical necessity determinations would further the public's understanding in choosing among plans. Health care policies should provide examples of the type of care they provide for a number of important conditions.

Lastly, the competitive nature of managed care raises at least a perception that disputes about medical necessity of treatment may be affected by the payer's competitive interest in restraining costs. Judicial review can provide some check to ensure that the decisions are made on the merits, but review is not a practical recourse in many cases. Measures need to be developed that will enhance the fairness of the process. Procedural audits and opportunities for second opinions in special cases are steps that could further that aim. Making sure the disputes are fairly decided is important to the health of us all.