APA Resource Document: II. Regulatory Guidelines for Protecting the Interests of Psychiatric Patients in Emerging Health Care Systems

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I. Introduction

In a companion document on professional responsibilities, we have discussed four principles of psychiatric care jeopardized by managed care systems and other new health care arrangements: (1) psychiatrists' fiduciary obligations to patients, (2) patients' participation in health care decisions, (3) access to psychiatric care, and (4) quality psychiatric care. Systems of health care, however, have become increasingly organized and control of significant decisions has become centralized. Therefore, it is no longer reasonable to discuss professional responsibilities without addressing the structure and operation of these systems. It is necessary to ensure that psychiatry can be practiced in a sound and ethical fashion within these systems.

In this document, we attempt to address the problems raised by managed care that require changes in systems. In the first section, we discuss the general problems raised by managed care and the ways in which the principles of practice—described in the companion document—are threatened. In the second section, we examine the managed care enterprise and specific problems in detail. Many of these problems are of immediate concern, and it appears likely that legal regulation is necessary to bring about the kinds of structural changes needed in managed care systems. A set of guidelines for legislation and other regulatory action have been drafted, so that the District Branches may be better informed about legislative initiatives.

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II. Systemic Problems Raised by Managed Care

Managed care entities play an active role in the delivery of health care, in contrast to the passive role played by

third-party payers under traditional indemnity insurance schemes. As a result, health care decisions are no longer made solely within the doctor-patient relationship; there are now important doctor-managed care relationships and patient-managed care relationships that shape the decision-making process. The introduction of these new relationships alone would strain the traditional moorings of the doctor-patient relationship. But the fact that managed care entities strive to lower health care costs places the principles of psychiatric care at significant risk. Two areas are of particular concern. First, the just allocation of medical resources requires patients' participation. Second, health care must be delivered in such a way to ensure that psychiatrists can continue to serve their patients' best interests.

Patients' participation in allocation decisions. Patients must be able to participate in making decisions on two levels. First, allocation decisions are legitimated by the collective decision making of covered individuals (or, in the case of government entitlements, society). Second, individuals must be able to make personal decisions about health care.

Questions about the appropriate distribution of resources and the relative values of various expenditures are ultimately the decisions of all concerned individuals. Decisions such as these, involving judgments about the relative merits of health care expenditures, benefits to be gained from covering and limiting allocations, and structuring health care systems are obviously complex. Patient participation in making these allocation decisions is critical. Absent principled approaches to health care decisions, the allocation of resources within a plan will necessarily be haphazard. Physicians or hospitals adept at gaming the system may receive a disproportionate share of medical resources as will patients who are able to complain articulately or to bring pressure to bear on insurance companies. Health care plans may also game the system by harassing physicians in order to discourage the appropriate use of health care, or through the implementation of undisclosed policies that gut the apparent policy benefits. Efforts such as these are wasteful, and lead to an unfair distribution of health care resources. Powerful and advantaged patients benefit at the expense of disadvantaged patients. Psychiatric patients, particularly the more disabled and chronic patients, are likely to lose out in such a system.

In order to assure adequate participation at this level, the process of decision making must be open to all covered individuals and the formation of policy must be responsive to their directives. Covered individuals must be able to play a responsible role in the generation of the rules governing their health care plans.

On the individual level, patients must be able to make meaningful choices about their personal health care. In order to choose among available health care plan options, patients need to have accurate and relevant information about the merits and limitations of the plans. And, when coverage limitations affect their personal health care, patients need to be aware of this fact. Although health care plans may make decisions about coverage, individ-

uals must ultimately make decisions about health care.

Of course, these two levels of participation are related. In order to provide meaningful input, insured individuals need to understand how their health care plan operates on the individual level. Patients may be motivated to urge systemic changes in their health care plan when they perceive inequities or implementation problems in their personal health care.

Currently, many practices of managed care entities frustrate hopes of achieving the goal of participatory decision making. For the most part, allocation decisions have not been made with the input of covered individuals. Indeed, many managed care entities have concealed from their subscribers the fact that allocation decisions have been made. Many companies promote the illusion of unrestrained access to health care or broader coverage than that which is actually provided. Some companies may deny responsibility for adverse coverage decisions and attempt to blame individual practitioners for limiting care. These practices may leave patients uninformed that care was denied for economic reasons, and therefore they will not be able to voice their preferences and to have meaningful input into how their health care dollars are administered.

Psychiatrists' fiduciary responsibilities to their patients. Even under ideal circumstances that maximize patients' involvement in health care, at critical junctures patients must rely on psychiatrists to act in their best interests.

Traditionally, physicians have exerted considerable control over the health care system. Professional input has helped to protect patients' interests and to produce appropriate investments in needed services. Physicians have acted with autonomy within these systems and have thus been free to act on behalf of their patients and to discuss their health care with them freely.

Some managed care companies have adopted procedures that impair psychiatrists' ability to act as fiduciaries. Managed care entities make allocation decisions without the input of treating psychiatrists. These decisions determine whether and to what extent services will be made available. Managed care entities have also attempted to interfere with psychiatrists' allegiance to their patients. For example, some provider contracts contain "gag" provisions, precluding full discussion of health care matters with patients.

Patients must be able to trust their psychiatrists in managed care systems. Lay people cannot be expected to anticipate future psychiatric problems, to educate themselves about diagnosis and treatment, and then to negotiate with a managed care company on equal footing prior to entering an agreement for health insurance. Patients seek psychiatric attention with the expectation that they can trust psychiatrists to help them.

In this document, we attempt to describe features of health care systems that enable the traditional principles of psychiatric care to be maintained.

III. Regulating Managed Care

As the health care field becomes more complex, the need for regulation in-

creases and the number of regulatory opportunities multiplies. This section addresses areas of potential legislation by topic area. The first section discusses general strategies for regulating managed care. The second section addresses legislative remedies designed to promote patients' participation. The third section addresses ways in which psychiatrists' role as a fiduciary can be preserved in managed care systems.

A. General Regulatory Strategies

1. Certification of managed care

Traditional legal regulation of the insurance industry has not encompassed the new activities of managed care that insurers have undertaken. Very recently, some states have begun to regulate utilization review activities by implementing plans for certifying UR organizations, often on a voluntary basis. Managed care companies are playing an increasingly important role in the provision of medical services and it is imperative that they be regulated to ensure that quality medical care is provided.

Legislative options. State certification requirements may be helpful in regulating every facet of managed care and, therefore, may incorporate elements of regulation discussed in later sections. There are two significant goals of certification, however, which may be particularly amenable to this regulatory approach. Both are related to the structure of managed care companies. First, in order for patients to retain control of health care decision making, they must have access to the decision-making process within UR and managed care structures. All decisions that materially affect health care decisions must be known to patients and patients must have a role in the process. No decisions regarding resource allocation or limits on coverage should be made in closed, corporate meetings. Second, psychiatrists must participate and have a significant role in the determination of policy in order to ensure that quality care is provided. Decisions about credentialing and health care delivery should be made in collaboration with treating psychiatrists. Psychiatrists must have input into all such decisions to ensure that the quality of mental health care is preserved. Currently, managed care companies make these significant decisions without the involvement of patients or their psychiatrists. Mandatory certification or accreditation of managed care companies, with real penalties attached to enforce regulations, may be an effective way of improving managed care procedures.

2. Liability

Legal liability can play a useful role in ensuring adherence to standards of care. To the extent that the threat of liability leads managed care entities to strive to maintain adequate standards, the tort laws serve a useful purpose. Potential liability also serves to press participants in new areas of activity such as managed care, where the standards may be unclear, to develop and articulate clear standards more quickly.

Many psychiatrists believe that managed care practices have forced changes in their standard of care, creating risks for their patients. For example, coverage may be denied to suicidal patients for services that are judged by the treating psychiatrist to reduce the likelihood of self-harm. In

other cases, inpatient coverage may be terminated before an outpatient plan has been secured. Many patients may be unable to pay for needed services out-of-pocket and psychiatrists and hospitals have a limited capacity to provide free care. Therefore, patients may be placed at risk by managed care decisions. Many psychiatrists are fearful that they may be found liable for the actions of managed care entities.

It is important that actual responsibility and legal liability be coupled. Unfortunately, insurance companies have asserted that existing federal law has provided an exemption against liability that, in our view, is detrimental to patient care and good clinical practice. The Employee Retirement Income Security Act (ERISA) was enacted by the U.S. Congress as a way of providing uniformity of law to large insurance plans.[1] One provision of ERISA preempts all state laws regarding the liability of these plans (states still can regulate the business of insurance). In place of state law actions, ERISA provides that suits must be brought in federal court. Recovery is limited by ERISA to payment of withheld benefits; claims cannot be brought for harms suffered or for punitive damages. Thus, if an insurer negligently denies coverage for care and the ERISA preemption applies, the patient may sue and recover only the lost health care costs. The patient cannot recover for any damages that may have resulted as a consequence of the negligent denial, as under state tort law actions.

As a result of the assertion of the ERISA preemption, insurers may not have appropriate incentives to ensure that standards of review are met. Many providers feel that insurance reviewers sometimes make decisions based on insufficient information and make determinations without adequate time for consideration. Clinicians may feel that the insurer, insulated from liability, can deny coverage with impunity, since the worst outcome is that they will be required to pay the same amount later. Patients are left in the position of making decisions about the probability of obtaining payment, perhaps after protracted litigation or face paying out of pocket for their care. This decision making under uncertainty is not appropriate at the time of acute distress and need for treatment.

Legislative options. Recent federal court decisions limiting the ERISA preemption clause (*see* Dukes v. U.S. Healthcare, 57 F.3d 350 (1995)), if they stand, open the way to malpractice liability for insurors. However, the status of preemption remains open and it may be years before the courts clarify contradictory rulings. The best solution to the problems posed by ERISA preemption would be for Congress to repeal or modify this provision of the law. The APA has been lobbying for removal of the problematic preemption clause.

Because the federal law preempts all state law, it is not possible to modify ERISA through state legislation. However, it may be possible to restore some balance to liability at the state level. One possibility is for states to require insurance companies to indemnify doctors for malpractice losses that can be attributed in whole or part to arise from negligent managed care actions. It is also likely that

greater regulation of the operation of managed care entities, such as that outlined above, will reduce the likelihood of problematic actions. Nonetheless, tort liability probably will be necessary to provide the managed care industry with the appropriate incentives to act responsibly.

B. Patients' Participation in the Operation of Managed Care

1. Patient participation in decision making

Managed care companies should involve subscribers in decision making.

Legislative options. The AMA's proposed Patient Protection Act is a useful model for legislative efforts.[2] Subscribers must be kept informed about the methods of decision making and the criteria being used to select physicians, to approve treatments for coverage, and to determine medical necessity. Subscribers should have the opportunity to make their preferences known and to influence the determinations of the managed care company. Access to criteria for physician credentialing, facility and treatment selection, and review of treatment should be guaranteed for all subscribers to a plan. As with informed consent, patients must be the ultimate decision makers regarding health care decisions. One AMA document puts it this way: "The decision-making process should include some mechanism for taking into account the preferences and values of the people whom the rationing decisions will most directly affect."[3]

C. Patients' Participation in Health Care Decision Making

1. Access to accurate information about managed care

Individuals often opt for a health care plan based on advertised claims about coverage and access. In some cases, these claims hide high rates of denial of coverage or other significant impediments to care that are imposed once the individual has enrolled.

Enrollment in an insurance plan is analogous to the selection of a physician, particularly in those plans that offer a closed panel of physicians. It is extremely important that patients have the opportunity to find their best fit with insurance plans, just as it has been important in the past for them to find the best fit with treating physicians. Informed patient choice of health care plans is an essential component of a just and efficient health care system.

Legislative options. Reform would be desirable which has the following aims:

a. Truth-in-advertising. Prior to enrollment, patients should have access to data regarding denial of coverage, the frequency of complaints about the insurer, and the number and nature of past provision of mental health care visits.

b. Enrollment periods. Individuals are often given limited and infrequent opportunity to switch plans. Legislation should require that patients be given the opportunity to change at more frequent intervals. Patients must always be able to switch if they have a reasonable reason to do so, such as frequent denial of claims.

c. Full disclosure. In order to preserve the principle of patient involvement, it is necessary that covered individuals receive full and accurate information about their coverage, the appeals process, and other relevant information when they enroll. Currently, many covered individuals are unaware of the provisions of their policy until problems develop. Patients should be informed, prior to enrollment, about the nature of any incentives or disincentives provided

by the insurer to providers that may affect clinical decision making about their care.

2. Choice of psychiatrists

Many schemes to limit health care costs include closed physician panels. Patients are denied the opportunity to make one of the most fundamental choices regarding health care: the selection of a treating clinician. Patients in some areas of the country have faced the prospect of severing longstanding ties to treating physicians who have been excluded from managed care-approved panels. Recently, a new practice, "deselection," has resulted in many previously approved providers being excluded from closed panels because they utilize more resources than other physicians.

The selection of providers should be made on the basis of competence and quality of care. Providers should not be excluded based on economic profiling. Criteria for the selection and elimination of psychiatrists should be made available to all interested psychiatrists and potential enrollees of the plans.

Legislative options. At a minimum, states should enact legislation requiring that patients be informed, before opting for a health care plan, that their choice of psychiatrists will be limited. It also may be possible to implement statutory protection of established doctor-patient relationships. This is particularly important for many chronic psychiatric patients who may have difficulty forming attachments or trusting new health care providers.

Many psychiatrists have favored "any willing provider" laws that would require managed care companies to include any qualified physician in their plans. Managed care companies have resisted these laws, claiming that they would interfere with reasonable efforts to control costs. If "any willing provider" laws are not politically feasible in a given jurisdiction, other protections may be considered. For example, managed care certification requirements may specify that credentialing is to be left in the hands of a medical board representing the treating physicians. Such a provision would provide some assurance that quality of care concerns will not be displaced by economic ones. Legislative efforts may also be directed toward requiring that the criteria for selection and elimination be made public. In addition, legislation could require that psychiatrists and patients receive some period of notice prior to any changes and be given the opportunity to appeal. Managed care companies may be required to grant exceptions and to allow treatment relationships to remain intact when it can be demonstrated that patients will be harmed. Finally, legislation may mandate that patients be allowed to switch health care plans whenever they are seeking to maintain their relationships with psychiatrists.

3. Access to psychiatrists

Patients' access to specialized psychiatric services under managed care has been a growing concern. Often, patients are unaware that referral to a psychiatrist is being withheld pursuant to managed care companies' guidelines.

Legislative options. The principle of patient involvement in health care dictates that patients should have information about the rules for referral available to them prior to enrollment in the plan.

Legislative efforts could be directed toward ensuring that patients with serious, specified psychiatric disorders be treated by psychiatrists. States should require that other patients, with less serious psychiatric disorders, be informed that their condition could be treated by a psychiatrist, and about the managed care criteria for referral to a psychiatrist.

Often, the psychiatric care covered by insurance plans is limited. Legislation could require that patients with psychiatric problems be informed that evaluation and treatment could be provided by a psychiatrist, even if the managed care company does not cover these costs. Legislation could mandate that patients be told of insurance limits prior to enrollment and at some time during the course of evaluation and treatment. And, when further services are needed, legislation may require that patients be informed that psychiatric services, although not covered, are indicated for their condition.

4. Information about denial of coverage

Patients may not be aware why coverage has been denied or, in some cases, that a denial of coverage has occurred.

Legislative options. When insurers deny coverage for patients' care, legislation could require that patients be informed, perhaps in writing, of the reasons for the denial, the right to appeal, and the provisions for pursuing appeals. Required notifications should be written to be understandable by a lay person. Legislatures could require that these notifications be made to the treating psychiatrist as well, and that they specify the reasons for the denial.

Patients could also be protected against retrospective denials of coverage. For example, legislatures could enact statutes providing that any care given in good faith, under the assumption that payment has been approved, should not be subject to retrospective denial unless fraud has been perpetrated. Patients' reasonable expectations of coverage would be protected by such legislation; patients' access to health care would be provided a measure of protection.

Legislation could require that managed care reviewers consider the medical facts and patients' situations at the time of review. Legislatures could specify that insurance coverage cannot be denied based on reviewers' retrospective appraisal of past care or the efficiency of care to date. This would ensure that patients would not be placed at risk by economic decisions of reviewers.

5. Timely response to pre-approval and appeals

The managed care company has an obligation to make timely decisions regarding appeals and pre-approval. Patients in distress cannot be expected to make decisions about their health care while uncertain about insurance coverage. Where the company expects treating psychiatrists, rather than reviewers, to spend time collecting and presenting data, this should be disclosed in contracts. Timely decisions are necessary to the provision of competent care and to allow patient involvement in decision making.

Legislative options. Statutes could be enacted to provide for timely decision making.

D. The Role of Psychiatrists in the Operation of Managed Care

1. The structure of managed care

As corporate entities, managed care companies are under no obligation to observe or maintain the traditional principles of psychiatric practice. Therefore, it is important to find ways to infuse the principles of the psychiatric profession into managed care.

Legislative options. Recently, the AMA proposed model legislation that would require managed care companies to establish a medical staff structure like the ones in hospitals.[2, 3] As with hospitals, the managed care organizations under this plan would be split into a governing board and a medical board. The medical board would be drawn from participating physicians and would be responsible for reviewing restrictions on services, physicians' credentials, and issues related to quality of care. The governing board would be ultimately responsible for the activities of the organization, but the medical board and participating physicians would have input into issues related to medical practice.

2. Credentialing

Managed care companies should select psychiatrists on the basis of the quality of care that they practice, not on exclusively on economic grounds. Moreover, a requirement that selections be based on competence would protect psychiatrists who might otherwise be excluded because they oppose managed care directives detrimental to patients' interests.

Legislative options. States could require that psychiatrist selection criteria be made public. Protections could be provided to psychiatrists who use the appeals process or who take unpopular positions in the decision-making process of the managed care company to ensure that they are not denied credentials for these actions. It is particularly important that psychiatrists be able to continue to advocate for quality care. Credentialing decisions must be made on the basis of quality of care.

3. "Gag" provisions

Some managed care companies have placed "gag" clauses in their contracts with treating psychiatrists. These clauses vary in content, ranging from prohibitions against informing patients about uncovered care to general provisions that the psychiatrist not undermine patients' confidence in the company. To the extent that these clauses interfere with patients' right to be informed, they are contrary to the principle of patient participation in health care decision making. Psychiatrists should not sign contracts that include "gag" provisions. Courts may rule that these clauses are unenforceable because they are contrary to the public's interest. However, legislation may be useful to prevent the possibility that psychiatrists will inadvertantly agree to be "gagged" and to avoid unnecessary litigation.

Legislative options. Legislative protection of psychiatrists' communications are necessary. Contractual agreements between managed care entities and individual psychiatrists cannot be allowed to undermine psychiatrists' traditional allegiance to patients. Legislation outlawing gag provisions could be enacted by state legislatures. Psychiatrists' obligations to their patients should not be sub-

ject to contractual obligations to third parties.[5] Psychiatrist must be able to freely communicate with their patients.

4. Incentives and the treating psychiatrist

Incentive provisions are frequently used by managed care companies to encourage cost-effective treatment. Capitation payment or other fixed fee schemes, such as DRGs, compel physicians to consider the cost consequences of health care decisions. Managed care companies often use other devices, such as hold-back provisions, or shared-risk pools, to provide financial incentives to providers. Many commentators have noted that this places psychiatrists in a position where a conflict of interest may occur. Psychiatrists will need to balance their own economic well-being against the interests of their patients if the economic incentives are too great.

Legislative options. Recently the AMA provided a set of guidelines regarding managed care incentives.[3] The AMA report concluded that financial incentives, if they are too great, can pose a risk to the doctor-patient relationship.

Legislation to cap the percentage of payment based on incentive may be an effective way to reduce the likelihood of conflicts in this area. Legislation requiring that all incentive provisions regardless of size, be disclosed to patients at the time of enrollment should be considered.

5. The role of psychiatrists in the review process

Psychiatrist reviewers in the employ of managed care companies are critically important to the process. Yet, the ethical norms governing their activity have not been articulated and it remains uncertain how the role of reviewer should be viewed. Nevertheless, psychiatrists play a crucial role in the review process since no other group is in the position to understand psychiatric conditions and treatments. Screening guidelines or other criteria cannot be mechanically applied to individual clinical situations; medical judgment is critical.

It must be recognized that the role of reviewers has changed over time. Initially, the review process was designed to weed out truly unnecessary claims. As health care systems have been pushed to constrain costs, reviewers have become *de facto* allocation decision makers in many managed care systems. There are two possible ways to view the allocation function of psychiatrist reviewers. Either psychiatrist reviewers are acting in a forensic role and are excepted from the ordinary principles of practice; alternatively, reviewers are bound by the rules applying to the general practice of psychiatry.

Under a forensic model, the reviewers' role is to try to make accurate determinations about patients' insurance coverage. Reviewing psychiatrists must be able to determine accurately whether a particular case meets specified criteria for coverage. There are several flaws in managed care review schemes which are apparent when they are compared to forensic roles. First, many managed care entities have not established procedures designed to facilitate accurate and legitimate decision making. In many instances, clear criteria for coverage have not been established. Often, reviewers are not provided with adequate information or time to assess claims.

There is a second critical flaw: there is no independent factfinder (e.g., a judge, jury, or tribunal) to adjudicate disputes. Managed care reviewers formulate an opinion and then, in effect, sit as judge and jury.

Elsewhere, we have discussed a model for psychiatrists to make allocation decisions consistent with the ethics of the profession.[6] When it is unclear whether care is covered, treating psychiatrists should have access to an allocation board, comprised of their peers. Treating psychiatrists would serve on this board on a rotating basis, ensuring that decision making remains sensitive to the interests of patients. Moreover, the allocation board would make its decisions in awareness of competing demands for available resources. Documentation of decisions would be made to facilitate fair and consistent determinations. Current managed care review schemes depart in significant ways from this model. Reviewers are not required to be drawn from the pool of treating psychiatrists and owe their primary loyalty to the managed care entity. Thus, it is possible that reviewers will not be subject to feedback from treating psychiatrists regarding the practicality and usefulness of their reviews. Indeed, some reviewers may not actually be engaged in the practice of psychiatry and may be out of touch with reasonable guidelines for practice. Moreover, it has been alleged that some managed care entities retain only those reviewers who meet a quota of denials; thus, performance assessments are based on economic rather than clinical grounds. Finally, managed care reviewers may operate without knowledge of the determinations made by other reviewers or the availability of resources in the plan. Thus, decisions may be made inconsistently and without sufficient concern for the needs of patients.

Legislative options. Although the ethical foundation of clinical review remains obscure, there are several ways in which states may improve current practices. States may require that all cases in which coverage is disputed should be reviewed by a physician with comparable training to that of the treating psychiatrist. In order to improve the accuracy of review, managed care companies could be required to establish procedures for the accumulation of clinical data for reviewers' determinations. States could specify that reviewers devote sufficient time reviews to make an accurate determination and that adequate documentation of decisions be made to enable later audit. States may consider a requirement that reviewers be drawn from the list of practicing clinicians. States may also limit the proportion of time and income a psychiatrist could derive from review activity. Legislation could require managed care companies to convey to the treating psychiatrist immediately an explanation of the reasons for denial of coverage, including specific reasons. States may also consider a requirement that the reviewer convey that the denied review concerns insurance coverage only. The treating psychiatrist may feel that the treatment under review should be offered to the patient nonetheless. This latter requirement would protect patients' right to determine the course of their own care. States may require that an independent tribunal be available to adjudicate disagreements between re-

viewers and treating psychiatrists. Alternatively, states may require that an allocation board model be developed, drawing on treating psychiatrists who participate in the health care plan to make the allocation decisions.

6. Criteria for denial of coverage

The APA believes that it is imperative that psychiatrists and their patients maintain control over the standards of practice in the profession. These standards should continue to reflect psychiatrists' long-standing commitment to quality care. "Medically necessary" should not become code words for the cheapest, lowest-common-denominator services. At least one court has agreed that insurers are obligated to cover services that meet the medical community's standard of care.[4] In order to ensure that patients exercise control over managed care, coverage criteria must be made available.

Managed care companies have been secretive about coverage criteria. Thus, it is not always clear that criteria have been established or, if they have, if they meet prevailing standards of care.

Legislative options. Legislation could require insurance companies to establish review criteria that reflect practice guidelines established by independent professional organizations. Coverage criteria must be made available to covered individuals and to participating psychiatrists.

7. Appeals

The appeal processes created by managed care often are the focus of patients' and psychiatrists' complaints. Typically, these complaints are that the appeal process is inaccessible or not timely.

Legislative options. States may consider requirements that managed care companies be required to establish an appeal process which can be invoked shortly after any denial of coverage. The appeal process should be required to consider any deficiencies that may have occurred in the original psychiatrist's review, including the possibility of an inaccurate or incomplete data base and the erroneous application of established criteria. Finally, legislation may require that the appeal process allow for reversal of the original decision when there is evidence that the treatment will significantly benefit the patient. Written criteria, even when fairly and accurately applied, cannot be expected to address the circumstances of all individual patients. What is fair in the aggregate may be grossly unfair to individuals. Individualized assessments are essential to assure that patients receive needed care.

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