Special Report

# MEDICAL NECESSITY

## IN PRIVATE HEALTH PLANS

### *Implications for Behavioral Health Care*

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Substance Abuse and Mental Health Services Administration
Center for Mental Health Services
www.samhsa.gov

Special Report

# MEDICAL NECESSITY

## IN PRIVATE HEALTH PLANS

*Implications for Behavioral Health Care*

Sara Rosenbaum
Brian Kamoie
D. Richard Mauery
Brian Walitt

**U.S. Department of Health and Human Services**
Substance Abuse and Mental Health Services Administration
Center for Mental Health Services

# Acknowledgments

This report was prepared by the Center for Health Services Research and Policy, Department of Health Policy, The George Washington University School of Public Health and Health Services under contract number 01M008689 for the Substance Abuse and Mental Health Services Administration (SAMHSA), U.S. Department of Health and Human Services (DHHS). Jeffrey Buck, Ph.D., Associate Director for Organization and Financing, Center for Mental Health Services, served as project officer for this report. William L. Wallace, Ph.D., assisted with the preparation of this report.

### Disclaimer

The views, opinions, and content of this publication are those of the authors and do not necessarily reflect the views or policies of SAMHSA or DHHS.

### Public Domain Notice

All material appearing in this report is in the public domain and may be reproduced or copied without permission from SAMHSA. Citation of the source is appreciated. However, this publication may *not* be reproduced or distributed for a fee without the specific, written authorization of the Office of Communications, SAMHSA, DHHS.

### Electronic Access and Copies of Publication

This publication can be accessed electronically at www.samhsa.gov/. For additional free copies of this publication, please call SAMHSA's Mental Health Services Information Center 1-800-789-2647.

### Recommended Citation

Rosenbaum, S., Kamoie, B., Mauery, D. R., Walitt, B. (2003). *Medical Necessity in Private Health Plans: Implications for Behavioral Health Care.* DHHS Pub. No. (SMA) 03-3790. Rockville, MD: Center for Mental Health Services, Substance Abuse and Mental Health Services Administration.

### Originating Office

Office of the Associate Director for Organization and Financing, Center for Mental Health Services, Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services (DHHS), 5600 Fishers Lane, 15-87, Rockville, MD 20857.
DHHS Publication No. (SMA) 03-3790
Printed 2003

# Table of Contents


I. Executive Summary . . . . . 1

II. Introduction . . . . . 3

Research Methods . . . . . 5

Structure and Organization of the Review . . . . . 6

III. Medical Necessity and the Published Literature . . . . . 7

IV. Industry Practices in the Managed Care Industry . . . . . 11

Analysis of the Structure of Medical Necessity Definitions . . . . . 11

Interviews With Managed Care Officials on the Processes of Medical Necessity Determinations . . . . . 13

Managed Care Accreditation Organizations . . . . . 16

Judicial Case Law, Official Investigations, and Legal Actions . . . . . 19

Judicial Case Law . . . . . 19

Investigations and Official Legal Actions . . . . . 21

New York . . . . . 21

Maine . . . . . 22

Connecticut . . . . . 23

V. State Law Regulation of Medical Necessity . . . . . 25

Laws That Regulate the Content of Insurance Contracts . . . . . 25

Independent Review Statutes . . . . . 26

VI. Relevant Federal Laws Pertaining to Medical Necessity Reviews . . . . . 29

ERISA . . . . . 29

Office of Personnel Management Standards: FEHBP . . . . . 31

VII. Synthesis and Implications . . . . . 33

VIII. References . . . . . 37

IX. Endnotes . . . . . 41

# Figures

Figure 1: The Five Dimensions of the Medical Necessity Definition: Industry Practice . . . . . 13

Figure 2: NCQA and JCAHO Utilization Management Standards . . . . . . 17

Figure 3: NCQA and JCAHO External Appeals Standards . . . . . . . . . . . . 18

Figure 4: Common Procedural Problems in Medical Necessity Determination Processes Noted in Investigations, Litigation, and Case Law . . . . . 22

Figure 5: Medical Necessity Utilization Review and Appeals Procedures . . . 31

# Tables

Table 1. Medical Necessity Definitions in Published Literature (See Also Appendix C) . . . . . 45

Table 2. Medical Necessity Definitions: Managed Care Industry . . . . . . . 50

Table 3. Medical Necessity Definitions Identified in Case Law (Sorted by Case Name) . . . . . 51

Table 4. Medical Necessity Definitions Contained in State Statutes and Regulations . . . . . 56

Table 5. State Independent Review Statutes and Regulations . . . . . . . . . . 64

Table 6. Medical Necessity Definitions: State Insurance Laws and IRO Statutes . . . . . 66

Table 7. State Independent Review Statutes With Specific Behavioral Health Provisions . . . . . 70

Table 8. Qualifications of External Reviewer in State IRO Statutes . . . . . 71

Table 9. Independent Reviews: Standard of Review for Medical Necessity Determinations . . . . . 76

# Appendices

Appendix A. Selected Published Literature on Medical Necessity (Sorted by Year) . . . . . 79

Appendix B. NCQA and JCAHO Utilization Management and External Appeals Standards . . . . . 92

Appendix C. Litigation Regarding Medical Necessity Definitions and Procedures (Sorted by Case Name) . . . . . 95

Appendix D. State Investigations and Legal Actions Regarding Medical Necessity Issues . . . . . 105

# I. Executive Summary

This report addresses how the term "medical necessity" is defined in private health insurance coverage decisions. It summarizes a review of the literature, an extensive review of legal cases that challenge insurer decisions, materials prepared by the insurance industry, consultation with experts in the field, a review of investigations conducted by State departments of insurance and attorneys general, and interviews with health care executives regarding the decisionmaking process itself. The report does not explore factors that can affect access to care that might be considered clinically necessary by treating professionals or the effects of medical necessity decisions on therapeutic outcomes.

*Sources of medical necessity definition:* Few regulations address the definition of medical necessity. There is no Federal definition, and only slightly more than one-third of States have any regulatory definition of medical necessity. As a result, the meaning of "medical necessity" is most commonly found in individual insurance contracts that are defined by the insurer and hold primacy in most determinations.

Rather than turning simply on whether a proposed treatment meets professional medical standards, the prevailing definition of medical necessity is broadly framed, multidimensional, and controlled by the insurer, not the treating professional. The process of medical necessity determination is rarely public information. Even where a claimant can show that a clinical recommendation is consistent with professional clinical standards, the insurer may reject a proposed treatment if it is inconsistent with other definitional elements such as relative cost and efficiency.

*The multiple dimensions of the prevailing medical necessity definition:* The evidence suggests that the medical necessity definition spans five dimensions:

1. *Contractual scope*—whether the contract provides *any* coverage for certain procedures and treatments, such as preventive and maintenance treatments that are not necessary to restore a patient to "normal functioning." This dimension preempts any other coverage decision.
2. *Standards of practice*—whether the treatment accords with professional standards of practice.
3. *Patient safety and setting*—whether the treatment will be delivered in the safest and least intrusive manner.
4. *Medical service*—whether the treatment is considered *medical* as opposed to social or nonmedical.
5. *Cost*—whether the treatment is considered cost-effective by the insurer.

*Regulation of the medical necessity definition and coverage determination process:* Some State external review laws provide appeals procedures that permit reviewers to reject the insurer's medical necessity definition and look at the evidence with a fresh eye. However, many State laws parallel insurers' multidimensional definitional approach. It does not appear that either the State or Federal regulatory process has moved away from the industry's prevailing medical necessity standard.

# II. Introduction

Under basic principles that guide the American health care system, decisions regarding which particular treatments, or the amount of treatment, are medically necessary are made by medical professionals in light of their patients' condition and desires, and the state of health care knowledge. Despite all the changes that have taken place in the health system over the past generation, medical professionals remain legally and ethically obligated to make treatment recommendations that reflect sound professional judgment and that are appropriate in light of their individual patients' needs.

At the same time, however, whether a patient ultimately will receive care considered necessary by a treating professional is influenced heavily by the availability of health insurance coverage to finance the recommended treatments (Hadley, 2002). The influence of health insurance on access to and utilization of behavioral health services is well documented and is a consequence of the high cost of treatment that frequently can involve expensive and (in the case of chronic conditions) long-term therapies (Buck, Teich, Umland, & Stein, 1999). For this reason, the coverage decisions made by health insurers and employee health benefit plans are fundamentally linked to the question of whether individuals will have access to health services that their treating professionals consider medically necessary and appropriate.

In the early years of the modern American health insurance era (said to date to the Second World War, when employer-sponsored group health insurance became increasingly common), insurers paid for whatever health services treating physicians recommended (Rosenblatt, Law, & Rosenbaum, 1997; Rosenblatt, Rosenbaum, and Frankford, 2002). As health care costs escalated, first public and then private health insurers introduced utilization review techniques. These techniques were designed to verify coverage and to independently assess the treatment recommendations made by health professionals. These early utilization review decisions, as they were known, were made retrospectively (after the fact). Subsequent analyses of these early cost containment efforts led to the conclusion that retrospective review was ineffective; as a result, insurers increasingly turned to prospective and concurrent review techniques.

Prospective and concurrent reviews soon became an industry standard, particularly with the growth of managed care. In managed care–style insurance, coverage is either entirely or partially conditioned on

a patient's receipt of care from a medical professional who has been accepted into the plan's treating provider network and whose covered treatment recommendations are subject to the standards set by the plan. An insurer or health plan can exercise control in one of two ways. The intermediary might in the first instance issue general treatment guidelines that are supposed to guide physicians in their treating recommendations. Alternatively, the treating professional may submit specific recommendations for treatment to the insurer or health plan on behalf of an individual patient. Both approaches typically are present in any health plan; that is, a treating professional may apply standard guidelines to many patient treatment decisions (Domino et al., 1998; Institute of Medicine, 1990; Manderscheid, Henderson, & Brown, 2001; Varble, 2001), reserving patient-specific requests for treatment to a relatively small number of cases that do not appear to fit the parameters of such standard guidelines (e.g., patients with co-occurring conditions that place them out of standardized norms or particularly complex versions of a recognized health problem).

This analysis, prepared for the Substance Abuse and Mental Health Services Administration of the U.S. Department of Health and Human Services, focuses on medical necessity in health insurance as the concept applies to utilization management decisions by health insurers and employee benefit plans in specific patient cases. This analysis does not consider other factors that can influence access to coverage in the modern insurance system, such as the quality of the general treatment guidelines used by insurers or the contractual limitations on coverage that can exclude certain treatments altogether, no matter how medically necessary (a phenomenon that has received enormous attention in the case of behavioral health as a result of the mental health parity debate). Nor does this analysis consider limitations on access to care that can result from restrictions on the size and availability of a provider network established and used by an insurer or health plan.

Instead, this analysis focuses on those situations in which, in response to the perceived needs of an individual patient, a treating health professional recommends treatment that may require specific approval of coverage by an insurer or health plan. This analysis examines both the standards and procedures that insurers and health plans use explicitly to determine whether recommended services are necessary in specific instances; it does not address the process involved in determining the amount of treatment deemed appropriate.

The structure of this review is based on the assumption that, in determining whether a recommended course of treatment is medically necessary under the terms of the insurance contract, the definition of medical necessity and the process by which the contract is applied to a particular patient are of equal importance. In assessing the process of decisionmaking, this report considers the qualifications and impartiality of the reviewer as well as the extent to which the reviewer considers the specific condition of the individual patient, not merely what treatments are generally recommended in preset treatment guidelines. The procedural aspects of coverage decisionmaking are critical because, as this analysis shows, medical necessity definitions are broad and ambiguous and vest insurers with a great deal of discretion over the treatment of individual patients. How an insurer goes about deciding the necessity

of care is a particularly important question in the case of patients whose conditions are further complicated by the existence of co-occurring health problems or a history of failure under standard treatments.

This review examines a broad range of information, including peer-reviewed literature, judicial decisions construing contract terms, legislation, and documents developed by insurers themselves. Much of the evidence regarding medical necessity presented in this analysis is found in legal documents, including judicial decisions in cases brought by patients whose requests for treatment have been denied, as well as in investigations conducted and actions brought by State attorneys general and insurance departments in response to evidence of systemic problems in obtaining access to insured coverage as a result of ongoing medical necessity denials.

Judicial decisions and official investigations frequently involve complaints regarding access to behavioral health coverage. This is probably not surprising, given the cost of long-term treatment for health conditions related to mental illness and substance abuse disorders as well as evidence of major efforts by insurers over the past decade to achieve significant reductions in behavioral health spending (DHHS, 1999). Because of the lengthy and costly process of pursuing a case against an insurer or health plan, reported judicial decisions are rare. (Indeed, in great part in response to the difficulty of pursuing legal claims against health plans that have denied coverage, Federal and State lawmakers have sought in recent years to establish simpler, less formal, and less costly external appeals procedures to challenge insurer denials) (Dallek & Pollitz, 2000).[1] At the same time, it is in these official sources of evidence that one is able to see most clearly the terms of the contract (which outside a legal setting is a confidential and closely held document) as well as the process by which an insurer or health plan administrator reached a decision. Medical necessity determinations that do not rise to the level of appeal or complaint are beyond the scope of this analysis.

## Research Methods

The following research methods were used to conduct this review:

- Completing a literature review and synthesis of findings regarding the definition and process of delimiting medical necessity in a behavioral health context. Sources included the peer-reviewed medical and health services literature on medical necessity, as well as judicial decisions, Federal and State laws, illustrative contract terms, accreditation standards, materials gathered from the industry, and State-level investigations and legal settlements regarding medical necessity practices.[2]
- Convening a working group of 20 experts for a half-day consultation (May 7, 2002) on issues related to medical necessity in behavioral health care to provide comment and feedback on the draft literature review. Experts included professionals in clinical practice (e.g., psychiatry, psychology), employer purchasers of health care insurance, officials with managed care accreditation organizations, representatives of consumer advocacy organizations, and individuals with expertise in insurance and health plan regulation at the State and Federal levels. Officials from three large managed care organizations who were not able to attend the May 7 meeting were later interviewed by telephone. Officials from two State attorneys general offices

(New York and Connecticut) and a State bureau of insurance (Maine) were interviewed by telephone to provide additional insight for the section on legal settlements and investigations. This report was refined based on the expert consultation, feedback, and assistance provided by these advisors.

### Structure and Organization of the Review

Part 1 summarizes peer-reviewed and professional literature on medical necessity, and considers the views and recommendations of researchers and analysts regarding both the definition of medical necessity and the structure of the review process.

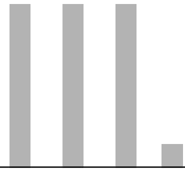
Part 2 describes industry practices as evidenced by individual insurer practices and accreditation standards, as well as judicial opinions and official investigations that have examined contract terms and decision-making procedures.

Part 3 reviews State insurance laws and examines in detail not only the definition of medical necessity adopted by States as part of their insurance regulation laws, but also the procedural elements of their independent review statutes.

Part 4 examines two major sources of law relevant to understanding the medical necessity review process in the private insurance context—the bodies of regulations that govern private employee health benefit plans covered by the Employee Retirement Income Security Act (ERISA) and standards applicable to medical necessity determinations and appeals under the Federal Employee Health Benefits program.

This review concludes with a synthesis of findings and a discussion of their implications for coverage of behavioral health services.

Tables 1–9 and Appendixes A–D can be found at the end of this review.



# Medical Necessity and the Published Literature

Table 1 presents definitions of medical necessity drawn from a search of peer-reviewed journals, trade journals, and industry and organization publications. A full list of these sources appears in Appendix A. Over the past decade, authors have paid considerable attention to the question of medical necessity as prospective utilization review has come to dominate health insurance.

While variation exists in the opinions expressed, the articles summarized in Table 1 display a significant level of consensus on three basic issues. The first is that merely because a recommended treatment falls within the zone of professionally accepted medical practice does not mean it must be covered. Only one source (the National Health Law Program) confines the evidence to the opinion of the treating physician. The second is that a recommended definition of medical necessity should be multidimensional and should consider factors such as cost, convenience, and relative effectiveness compared to other treatments based on various forms of evidence. Third, the authors uniformly recommend broadening the scope of when an intervention can be considered necessary (i.e., not merely to diagnose and treat an illness but also to improve functioning, avert deterioration, and maintain functioning).

Several authors address the issue of the quality, reliability, and relevance of the evidence considered when making a medical necessity determination; in addition, one article examines the question of who bears the burden of proof in a medical necessity determination, an issue that has not been directly addressed in State or Federal law.

From the health services research community, probably the most seminal work is by Singer, Bergthold, Vorhaus, and Enthoven (1999). The definition of medical necessity they crafted was the result of a consensus process among project participants (Singer, Bergthold, Vorhaus, & Enthoven, 1999):

> For contractual purposes, an intervention will be covered if it is an otherwise covered category of service, not specifically excluded, and medically necessary. An intervention is medically necessary if, as recommended by the treating physician and determined by the health plan's medical director or physician designee, it is (all of the following):
> A health intervention for the purpose of treating a medical condition; the most appropriate supply or level of service, considering potential benefits and harms to the patient; known to be effective in improving health outcomes.

> For new interventions, effectiveness is determined by scientific evidence. For existing interventions, effectiveness is determined first by scientific evidence, then by professional standards, then by expert opinion; and cost-effective for this condition compared to alternative interventions, including no intervention. "Cost-effective" does not necessarily mean lowest price. An intervention may be medically indicated yet not be a covered benefit or meet this contractual definition of medical necessity. A health plan may choose to cover interventions that do not meet this contractual definition of medical necessity.

This definition requires a review of the treating clinician's recommendation to ensure that it is "for the purpose of treating a condition" and "the most appropriate" intervention in light of the patient's particular condition, benefits, and risks. The definition also assumes plan review of the provider's treatment recommendations. The authors also contemplate that cost-effectiveness will be a basic element of the decision, but clarify that the question of cost-effectiveness is not one of price alone. In addition, the authors create a hierarchy of evidence, with "scientific" evidence classified as the best evidence. No distinction is made by type of condition.

Of particular significance in the Singer/Bergthold analysis is its emphasis on the primacy of coverage limitations, a major concern of insurers. The authors recognize that once a particular type of treatment is excluded for a specific condition as a contractual matter,[3] no general finding of medical necessity can override the exclusion. This emphasis on the primacy of the contract in controlling the range of treatments and procedures that will be considered at all in a medical necessity determination is reinforced by the Health Insurance Association of America (Schiffbauer, 1999), which has stated:

> When the provider, rather than the health plan or insurer, interprets the *scope of coverage* under the contract, health plan fiduciaries cannot guarantee to the insured that health care dollars are being spent fairly and equitably on medical treatments that are safe, proven, and effective.

The American Medical Association (AMA), representing physicians (including psychiatrists), has created a prototype medical necessity definition as part of its Model Managed Care Contract project:

> Section 1.9 defines medically necessary/medical necessity as health care services or products that a prudent physician would provide to a patient for the purpose of preventing, diagnosing, or treating an illness, injury, disease, or its symptoms in a manner that is a) in accordance with generally accepted standards of medical practice; b) clinically appropriate in terms of type, frequency, extent, site, and duration; and c) not primarily for the convenience of the patient, physician, or other health care provider.[4]

Like the others this definition is multidimensional but it focuses the utilization review on what a prudent physician would conclude based on the evidence rather than what the insurer would determine. While the definition is crafted in such a way as to transfer more medical decisionmaking power back to the provider, the practical impact of this distinction is difficult to assess, since the decision remains reviewable and the review is multidimensional. However, cost considerations as an explicit measure are removed. By using the "prudent physician" rather than the insurer as the standard of measurement where judgment is concerned, the definition

seeks to focus the determination on "generally accepted" medical opinion (and thus the phenomenon of multiple schools of thought) rather than the opinion of utilization review professionals who may or may not be physicians and who view their task as selecting the single best form of treatment. Thus, in an appeal made under the AMA definition, a claimant would be able to introduce a wide range of schools-of-thought evidence from "prudent physicians" to show the variation in treatments that prudent physicians might recognize.

Several authors focus on definitions of medical necessity in the behavioral health arena, although their proposed definitions appear to differ more in terminology than in substance. Paul Chodoff (1998) and William Ford (1998, 2000) have called for replacing the term with "health necessity," "treatment necessity," or "clinical necessity." In Chodoff's view, health necessity criteria would be founded on a biopsychosocial rather than on a medical model. The former model requires a view of health as encompassing quality-of-life factors and not just the absence of disease. The terms "biopsychosocial" and "psychosocial" arose from the need to differentiate between mental and physical health.[5]

The practical effects of this distinction would be on the "scope" element of the definition, that is, the range of possible conditions for which treatment, if necessary, would be approved. Interventions would not be solely for the diagnosis or treatment of an illness, but also for the achievement of broader health goals. Furthermore, Chodoff proposes consideration of services for individuals whose diagnoses may not easily fit into categories defined by the *Diagnostic and Statistical Manual of Mental Disorders* (*DSM-IV*), a reference often cited as a clinical standard in medical necessity definitions for behavioral health (APA, 1994).

Ford's (1998, 2000) behavioral health care definition urges a movement away from covering only acute care to covering longer-term care designed to manage and prevent deterioration of chronic conditions and onset of acute conditions. This definition would include access to psychiatric rehabilitation services when needed for the treatment of chronic mental conditions. (This definition of course would require a dramatic expansion of the terms of coverage under conventional insurance, which, unlike Medicaid, tends to be confined to relatively short-term therapies to help an individual significantly improve or recover in a relatively short period of time.) (Rosenbaum, forthcoming; Rosenbaum & Rousseau, 2001) Like Chodoff, Ford stresses the importance of both the quality of day-to-day functioning as a goal of treatment, and the need to cover treatment designed for alleviation of symptoms in addition to "cure."

Ireys, Wehr, and Cooke (1999) propose a specific definition of medical necessity for persons with developmental disabilities, mental retardation, and other special health care needs. Their article represents a detailed and specific attempt to articulate individualized decisionmaking criteria that can "assist the individual to achieve or maintain sufficient functional capacity to perform age-appropriate or developmentally appropriate daily activities."(p. 19) The authors call for an expanded view of the information sources an insurer should consider beyond "medical evidence" (i.e., information from the patient, the family, collateral providers, and support institutions). They also emphasize the effect of treatment on day-to-day functioning and require that final determinations be made by a physician employed by

the insurer (rather than a claims reviewer with lesser qualifications).

Two articles (Appendix A) deal specifically with evidentiary matters and the use of evidence in decisionmaking. David Eddy (1994) posits that when determining the appropriate use of an intervention, analysis of its potential value should shift from qualitative to quantitative, with use of randomized, controlled clinical trials as a definitive evidence base. Furthermore, in his view, a shift from individual-based decisionmaking to population-based decisionmaking is needed, based largely on the utility of controlled clinical trials that demonstrate treatment efficacy across large numbers of people. He advocates for the development of explicit criteria to sort out high-value practices from those of little or no value and believes that the term "medical necessity" is too vague and open to too much variability in interpretation. By contrast, Rosenbaum, Frankford, Moore, and Borzi (1999) recommend an emphasis on individualized decisions rather than across-the-board conclusions based on the application of generalized guidelines and research results to specific cases. They call for strict scrutiny of the reliability and relevance of scientific evidence, as well as for greater emphasis on the facts of an individual case and expert judgment. They also recommend shifting the burden of proof to the health plan in any review of its decision on medical necessity, arguing that the plan has best access to the evidence, and that fairness in allocating the burden of proof would place the burden on the party with the best access to evidence.

Sabin and Daniels (1994) address the question of the utility of medical necessity definitions for mental health services from the perspective of severity of diagnosis. While no question exists that severe mental illness such as schizophrenia, clinical depression, and bipolar depression are covered by traditional medical necessity definitions, Sabin and Daniels investigate the extent to which such definitions also should cover conditions such as shyness, unhappiness, and lack of personal fulfillment. Using six illustrative case studies, such as "The Shy Bipolar," "The Unhappy Husband," "The Cranky Victim," (pp. 5–7) and others, Sabin and Daniels illustrate the differences of opinion between "hard-line" and "expansive" clinicians (p. 5) in deciding whether psychiatric services are needed. Following an analysis of three models of medical necessity, the authors conclude that the most rational model is one that treats a medically defined diagnosis, such as one delineated in the *DSM-IV*, to decrease the impact of disease or disability. A typical mental health medical necessity definition would be "those mental health services which are essential for the treatment of a Member's mental health disorder as defined by the *DSM-IV* in accordance with generally accepted mental health practice"(p. 12). Sabin and Daniels note that diagnostic categories continue to change but that society "needs a publicly acceptable and administerable system for defining the boundaries of health insurance coverage." To that end, the *DSM-IV* (and subsequent editions) provides a workable definition of those boundaries, to the extent that it is "the result of a highly public process open to scientific scrutiny, field testing, and repetitive criticism over time."[6]

# IV. Industry Practices in the Managed Care Industry

Insurers have continued to customize and streamline their definition of medical necessity over time to expand their control over, and the allocation of, health plan resources. By defining medical necessity and controlling the coverage determination process, insurers can attempt both to stem what they perceive to be the unnecessary expenditure of resources and to improve the quality of health care.[7]

## Analysis of the Structure of Medical Necessity Definitions

Insurers and insuring organizations rarely make their medical necessity definitions and determination procedures public. The definitions and procedures are typically contained in contracts and internal operational documents such as provider manuals and operating guidelines that are considered proprietary and confidential.[8] While many managed care organizations (MCOs) have Web sites, most require registration and passwords from contracted providers to access detailed information about their medical necessity definitions and procedures. Consumers and researchers usually are permitted Web site access only to general health plan information.

Table 2 presents five insurer definitions obtained for this research. An exception to the rule, ValueOptions allows public access to its Web site, which contains the text of its provider manuals. Cigna Behavioral Health Care provides online access to its "Levels of Care Guidelines for Mental Health and Substance Abuse Treatment," which contains a definition of medical necessity.[9] Table 2 also contains definitions from Highmark Blue Cross, an anonymous managed behavioral health plan, and United Behavioral Health. The Highmark definition was obtained from the proceedings of an Agency for Healthcare Research and Quality (AHRQ) User Liaison workshop on coverage decisions by Hill, Hanson, and O'Connell (2000). The third medical necessity definition in Table 2 was obtained from materials provided to one of this review's authors during a December 2001 meeting with behavioral health care providers to discuss medical necessity issues. The company's name is not disclosed for purposes of confidentiality. The United Behavioral Health (UBH) medical necessity definition was contained in a consent agreement that UBH entered into in 2000 with the Maine Bureau of Insurance, published on the Maine Department of Professional & Financial Regulation Web site.[10] The consent agreement itself is discussed in Legal Settlements below.

Despite the limited number of definitions available directly from the industry, those available suggest that insurers and insuring organizations use a definition of medical necessity far more complex than whether the prescribed treatment is consistent with accepted practice in the field. The use of a definition of medical necessity that extends well beyond the threshold question of whether the care is professionally sound can best be understood as an attempt to mitigate the "schools of thought" doctrine. This doctrine, a critical element of professional medical liability law, assumes the existence of multiple and equally professionally acceptable approaches to professional medical practice in any particular case (Rosenblatt, Law, & Rosenbaum, 1997). For this reason, insurers have adopted definitions that vest them with the power to select among various schools of thought for the approach that, in the insurer's view, also best satisfies the other elements of the definition.

The first dimension of the medical necessity definition found in Table 2 (and the one reflected in the overall structure of agreements themselves) can be thought of as *contractual scope*. This dimension is concerned with whether the contract provides any coverage for certain procedures and treatments, such as those that prevent the worsening of a condition or that allow an individual to maintain or promote functioning. It is possible, in other words, for the definition to exclude any procedures that, in the view of the insurer, do not yield recovery or result in what the insurer considers a significant short-term improvement. Table 2 shows that Highmark, the anonymous managed behavioral health organization (MBHO), and UBH limit the concept of medical necessity to services necessary for the diagnosis or treatment of illness. Thus, a treatment necessary to respond to a condition not regarded as an illness (e.g., a developmental disorder in a child) might fall outside the furthest reaches of the contract no matter how necessary the care or effective the treatment. Similarly, if the treatment is designed to avert deterioration rather than treat illness to a point of significant improvement, it might also be considered outside the scope of coverage.[11] ValueOptions, in contrast, will recognize as covered (if medically necessary) services aimed at preventing illness or avoiding deterioration. The Cigna definition, while still including a "reasonable expectation" for improvement, does include "level of functioning" in addition to a patient's condition or illness, an important criterion for persons with mental and physical disabilities whose treatment needs extend beyond the traditional medical model.

The second dimension of the definition reflects whether the treatment is in accord with *professional standards of practice*. This dimension is most directly related to professional opinion and clinical judgment. In the case of ValueOptions and Cigna, the specific frame of reference is national practice standards, although the fact that Highmark does not specifically reference national standards is probably not particularly important, since the professional standard of care has been recognized as a national benchmark for more than 40 years.[12] The UBH definition specifically refers to its own internal guidelines as the standard to measure the appropriateness of the type, frequency, and duration of treatment.[13]

The third dimension can be thought of as *patient safety and setting*. It considers whether the prescribed treatment will be

delivered in a manner that the insurer considers to be safe and effective.

The fourth dimension is whether, in the insurer's view, the treatment is *medical in nature* and not prescribed either as a matter of convenience or as a result of social or environmental considerations. In all of the definitions, convenience is measured in terms of the patient, the family, or the provider, not in terms of the managed care organization.

The fifth dimension of the definition is *cost*. Table 2 suggests that a review of treatment should include consideration of whether there is an equally effective and safe, but less costly, alternative to the recommended treatment. It is unclear whether the UBH reference to "of demonstrated medical value" refers to treatment effectiveness, cost-effectiveness, or both.

The various sources of information that suggest the existence of these definitional dimensions also suggest that the terms tend to remain undefined, allowing an insurer tremendous leeway to define the terms within the context of each determination.

Consistent with the issue of contractual scope, the ValueOptions definition explicitly considers whether care, no matter how necessary, is a service that falls outside the contractual limits of the plan. This consideration can be seen in that portion of the definition that authorizes consideration of whether the recommended course of treatment would result in "non-treatment services addressing environmental factors." It is unclear how this element of the definition would work in practice. An example might be refusal to cover in-home care to a patient unable to obtain transportation to an outpatient provider, while providing the same services in-home to a patient medically unable to travel. Even though the care is technically medically necessary in both cases, ValueOptions could refuse to cover the in-home care to the first on the grounds that such care results from environmental (i.e., lack of transportation) rather than medical need.

These dimensions of the medical necessity definition delineate the criteria to be fulfilled for an individual to be eligible for coverage. By choosing a high evidentiary, or tightly limited, standard regarding the evidence that must be present in order to satisfy coverage eligibility, such as the evidence-based medicine standard of requiring two controlled, randomized clinical trials before a medical intervention can be proven effective, insurers could impose limits on many types of care.

Figure 1 summarizes the five dimensions of the medical necessity definition derived from the preceding analysis of industry practice.

## Interviews With Managed Care Officials on the Processes of Medical Necessity Determinations

In mid-June 2002, semistructured telephone interviews were conducted with three officials (two medical directors and a chief executive officer) of two large MBHOs and one nationally based integrated health plan.[14]

### Figure 1: The Five Dimensions of the Medical Necessity Definition: Industry Practice

- The contractual scope of coverage: whether proposed treatment is explicitly included or excluded in the health plan contract
- Whether the proposed treatment is consistent with professional standards of practice
- Patient safety and setting of the treatment
- Whether the treatment is medical in nature or for the convenience of the health professional or patient and family
- Treatment cost

These officials, who, due to scheduling difficulties, were unable to participate in the May 7 meeting of the expert panel, also reviewed the draft of this document. The interview questions focused on the processes used in the managed behavioral health care industry for making initial medical necessity determinations and resolving appeals of claims denials, as well as internal quality management procedures used to incorporate and update treatment guideline information into decisionmaking processes.

One official noted that his MBHO prefers to use the term "clinical appropriateness" rather than "medical necessity." In the official's view, the latter term implies a restrictive orientation relating to the question of whether or not a patient needs care (a clinical decision that can only be made by the provider and the patient). The official emphasized that, in his opinion, the pivotal question is what level of services in which settings are most clinically appropriate for a given patient in light of his or her clinical and social needs. Thus, as the definition suggests, the MCO medical director views his task as analyzing the health professional's recommendations in accordance with those dimensions of the medical necessity definition that focus on how the care will be furnished, by whom, and in what settings, not whether the professional was justified in concluding that some particular approach to treatment was needed. In this vein, the coverage decision concentrates more on the form and manner of treatment than whether any treatment at all will take place.

The interviews confirmed that managed care executives view their jobs not as determining the necessity of care from a professional point of view but as determining whether the professional's treatment judgment is consistent with the terms of coverage in the contract. The organizations view their task as administering and managing a package of contractual benefits to determine what is included in the benefit package purchased by an employer, not to determine what the benefit package should contain. Within that determination is the task of ensuring that the levels of care and treatments provided are appropriate for an enrollee's needs and covered in the benefit package.

When asked why behavioral health medical necessity definitions have been the subject of a higher level of discussion and scrutiny than in general medicine, the interviewees offered several reasons:

- The nature of behavioral health care services compared to general physical medical care is such that there is less "objective" evidence available to guide decisions that reflect a consensus as to what the appropriate treatments should be for a given diagnosis. While progress has been made in developing a clinical evidence base for behavioral health care, it has not yet reached the level of precision as in, for example, cardiology or orthopedics. Behavioral health conditions are defined by "clusters" of symptoms (e.g., as found in the *DSM-IV*), and the technology available to provide confirmations of diagnoses is less precise than in general medical care (e.g., X-ray, magnetic resonanace imaging, blood enzyme levels).
- Heterogeneity of providers and variety of treatment modalities and settings is much greater in behavioral health than in general medical care. Behavioral health care providers include M.D. psychiatrists to Ph.D. psychologists, clinical nurse specialists, psychiatric social workers, addic-

tion disorder treatment providers, and others, all receiving different professional educations and with different preferences for how they approach and work with patients. The range of treatment modalities spans psychoanalysis, problem-focused and insight-oriented psychotherapy (e.g., cognitive, behavioral), psychopharmacology, intensive inpatient care and crisis management, and long-term treatment of severe mental illness. This heterogeneity relates to the "schools of thought" doctrine discussed above.

- Compared to behavioral health, general medical health plans enjoy greater clarity and specificity as to the scope of covered benefits. The more clear and specific the terms of the contract are, the less likely it is that disputes will occur.
- One interviewee cited greater antagonism for managed care in behavioral health provider associations, which has led to their encouraging members to file appeals in situations that they feel are questionable.

The officials from all three organizations stated that requests for authorization of services are handled by clinical intake staff with at least a master's degree, supplemented by ongoing in-house training. The guidelines used to "vet" a request for authorization focus on two criteria: a) level of care criteria (e.g., inpatient, partial hospitalization, outpatient therapy in individual or group settings), and b) treatment guidelines (e.g., crisis intervention, psychotherapy, prescription drugs). One MBHO preauthorizes 10 outpatient visits, requiring the provider to request and justify additional needed visits.

In all three organizations, board-certified or board-eligible staff psychiatrists must review all denied claims. The vast majority of disputed claims arise for inpatient admissions. As one interviewee noted, in behavioral health, unlike general medicine, most inpatient admissions are unplanned and occur because a person (or family member or provider on behalf of that person) seeks emergency crisis admission. Typically the inpatient facility calls for authorization. While the initial admission usually is approved, disputes may arise over length of stay, treatment plans, and care management. The interviewees stated that many of these disputes are later resolved when additional information regarding the patient's clinical needs is provided. If such information had been provided at the outset, the claim would not have been denied. Most claims disputes are resolved through internal appeals processes; only a few go to the external appeals process.

Interviewees cited a variety of sources for the treatment guidelines used in the care management and review processes: among them guidelines developed by provider organizations, such as the American Psychiatric Association and the American Psychological Association; guidelines promulgated by accreditation organizations; and ongoing feedback and advice from contracted providers. One MBHO reported the use of local clinical advisory committees in each location, including subject matter specialists (e.g., addiction disorder providers) who provide feedback and information on treatment advances. Guidelines are updated annually based on actual practice and expert opinion.

Interviewees stated that guidelines are not mandates or absolute protocols; rather, they are considered "guideposts" to be informed by, and adapted to, individual circumstances and psychosocial needs of patients. Ongoing audits, performance measurement of in-house

care managers and contracted providers, and member and provider satisfaction surveys are used to monitor the appropriate use of treatment guidelines in medical necessity decisions and to build in quality improvements at all levels of decisionmaking.

## Managed Care Accreditation Organizations

Accreditation organizations such as the National Committee for Quality Assurance (NCQA) and the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) have not formulated a medical necessity definition. For example, NCQA officials say they want to avoid conflicts with existing laws governing the definition of medical necessity (Pawlson, 2002). Instead, the accreditation bodies focus on the medical necessity review process, including both utilization management and internal appeals. In addition, NCQA and JCAHO specify the existence of an external appeals process as a condition of accreditation.

Figures 2 and 3 and Appendix B excerpt utilization management and external appeals standards promulgated by NCQA and JCAHO (JCAHO, 1997, 2001; NCQA, 2000, 2001). NCQA's procedural standards for MBHOs stress the individualization of the process. The entity must consider evidence from the individual patient's case (as well as the characteristics of the local delivery system) and therefore, presumably cannot rely on national treatment guidelines for specified conditions.[15] NCQA standards also assume involvement of practitioners in the development of criteria, though not necessarily in the evaluation of individual cases.

The JCAHO standards are written from the point of view of providers and provider networks, typically the focus of JCAHO accreditation. Standard CC 1 stipulates provision of health care appropriate to the sociocultural needs of the provider's patient population and consistent with the provider's mission and contractual obligations, as well as being based on an individual patient's needs. Disclosure of the review criteria used in adverse determination decisions, timely notice, and a review of adverse decisions by a physician, dentist, or behavioral clinician prior to notification to the enrollee or prescribing provider are all required by JCAHO.

The JCAHO guidelines for MBHOs are very similar to its general MCO guidelines. However, in some instances the MBHO guidelines are somewhat more explicit. Decisions regarding a member's eligibility for entry into specific treatment programs can be interpreted as a frame of reference for meeting medical necessity criteria.

> CC 2.1: Criteria define the information necessary to determine a member's eligibility for entry to a program or service within the delivery system.
>
> Intent of CC 2.1: The delivery system's central operations require care and service provider organizations to define the information necessary to determine a member's eligibility for entry to a program or service. The care and service provider organization defines the minimum essential information needed to determine a member's eligibility for entry to a setting or program. The criteria are based on the specific program or service that can meet or respond to the member's needs or presenting conditions. To add clarity, entry criteria also include exclusionary statements that indicate the information needed to initiate referral to another, more appropriate care and service provider organization.

JCAHO takes a condition/treatment-specific view for substance abuse services

## Figure 2: NCQA and JCAHO Utilization Management Standards

***NCQA Managed Behavioral Health Utilization Management Standards***

UM 2. To make utilization decisions, the managed healthcare organization uses written criteria based on sound clinical evidence and specifies procedures for applying those criteria in an appropriate manner:

- The criteria for determining medical necessity are clearly documented and include procedures for applying criteria basedon the needs of individual patients and characteristics of the local delivery system.
- The managed healthcare organization involves appropriate, actively practicing practitioners in its development or adoption of criteria and in the development and review of procedures for applying criteria.
- The managed healthcare organization reviews the criteria at specified intervals and updates them, as necessary.
- The managed healthcare organization states in writing how practitioners can obtain the UM [Utilization Management] criteria and makes the criteria available to its practitioners upon request.
- At least annually, the managed care organization evaluates the consistency with which the health care professionals involved in utilization review apply the criteria in decision making.

***JCAHO Utilization Management Standards***

CC 1: Health care services provided directly or by arrangement are appropriate:

- In scope to meet the health care needs of the population served;
- To the health care needs, as influenced by socio-cultural characteristics, of the population served;
- To the network's mission;
- To the network's contractual obligations.

CC 8: When the network or an external entity conducts a utilization review of a licensed independent practitioner's or a network component's care that results in denial of payment, decisions by the licensed independent practitioner or network component regarding ongoing care or discharge are based on the care required by the member's assessed needs.

CC 8.1: When utilization review results in an adverse utilization management decision, the network provides the criteria for the decision and information regarding appeal to the licensed independent practitioner responsible for the member's care.

JCAHO provides examples of implementation. "*These examples are simply ideas for your network to consider.*"

*Example of implementation for CC 8:* The network requests the review criteria used by any external entity that carries out a utilization review on the network's members. The review criteria are made available to those within the network responsible for treatment and discharge decisions. When the external utilization review organization's recommendation conflicts with the member's medical care requirements, justification for the course of action taken is documented. Information from the external entity is collected and incorporated into the network's assessment and improvement activities.

RI 2: The network provides for member involvement in care and treatment decisions.

RI 2.1: The network provides an authorization process for care and treatment that is timely, efficient, and meets member health care needs.

The network's process for authorizing care and treatment includes:

- Providing members with a description of the treatment authorization process.
- Initial decisions made by an appropriately trained health care professional using evidence-based, network approved criteria to authorize admission, care, and transition to another care setting.
- A review of all initial treatment authorization denials by a physician, dentist, or behavioral clinician prior to notifying the member or their representative(s) of an adverse determination.
- Informing members in a timely manner, in writing, when a request to authorize treatment has been denied.
- Informing members of the basis and reason(s) for the adverse determinations.
- Informing members of the review criteria used to make the determination.
- Providing members with information as to whether, and under what circumstances, investigational procedures are available and are covered by the network.

## Figure 3: NCQA and JCAHO External Appeals Standards

***NCQA Managed Behavioral Health External Appeals Standards***

UM 7.5 The managed behavioral healthcare organization has a procedure for providing independent, external review of final determinations, including:

Eligibility criteria stating that the MBHO offers enrollees the right to an independent, third party, binding review whenever:

- The enrollee is appealing an adverse determination that is based on medical necessity, as defined by MBHO.
- The MBHO has completed two levels of internal reviews and its decision is unfavorable to the enrollee, or has elected to bypass one or both levels of internal review or has exceeded its time limit for internal reviews, without good cause and without reaching a decision.
- The enrollee has not withdrawn the appeal request, agreed to another dispute resolution proceeding, or submitted to an external dispute resolution proceeding required by law.
- Notification to enrollees about the independent appeals program and clear and timely explanations of denials and approvals to both enrollees and their physicians.

Use of an independent review organization that meets the following criteria:

- Conducts a thorough review in which it considers anew all previously determined facts, allows the introduction of new information, considers and assesses sound medical advice, and makes a decision or conclusions that are not bound by the decisions or conclusions of the internal appeal.
- Has no material professional, familial, or financial conflicts of interest with the MBHO.
- MBHO non-interference with the proceedings of the external review.
- Enrollee exemption from the cost of external review, including filing fees, and allowance of designating a representative to act on the behalf of the enrollee.
- Implementation of independent review organization decision within specified timeframe. MBHO data tracking of external appeals for use in evaluating its medical necessity decision making process.

***JCAHO External Appeals Standards***

RI 2.2: The network provides a method for resolving disagreements between the network and the member or designated decision maker(s) regarding care or treatment authorization decisions.

The network's process includes:

- Informing members how to seek appeals of adverse determinations.
- Defined timeframes in which the member can anticipate response to an appeal.
- Appeal timeframes that are appropriate to the urgency of the member's health care needs.
- An appeal review panel including health care professionals who are appropriately trained, experienced, and competent with respect to the care and treatment involved, and who were not involved in the initial determination.
- Informing members about further steps available when disagreements cannot be resolved through the treatment authorization and appeal process, such as an internal grievance process, arbitration, legal proceedings, and any other external review processes.

RI 5: The network provides for the receipt and resolution of complaints and grievances from members in a timely manner.

The member has the right to voice complaints without fear of recrimination about the care received and to have complaints reviewed and, whenever possible, resolved. This right and the way it is protected are explained to the member. The network has a means of providing for the following:

- Procedures for registering and managing complaints and grievances, including identifying the party receiving complaints and grievances.
- Aggregating and reporting actions taken on complaints and grievances.
- A timely response to the member, substantively addressing the action taken on the complaint or grievance.
- Including the aggregate complaint and grievance information in performance improvement activities.
- An appeal process for grievance decisions.
- Member protection from any sanctions or penalties resulting solely or primarily from using the complaint or grievance process.

as well. In discussing how an MBHO can provide access to the appropriate level of care to meet an enrollee's needs, it provides the following example:

> The alcohol/drug program of a community mental health center established separate admission criteria for subpopulations. Separate criteria are in place for alcoholism, cocaine dependence, dual diagnosis, and heroin dependence. Members are placed in levels and sites of care in accordance with the primary substance(s) being abused.

In sum, neither NCQA nor JCAHO provide prototypical medical necessity definitions but rather focus on the adequacy of the decision processes used by the organizations they accredit. As is shown in the discussion of case law below, the procedures used to make these decisions are as important as, and at times more important than, the structure and content of the definitions upon which they are based.

## Judicial Case Law, Official Investigations, and Legal Actions

Since the introduction of the concept of medical necessity into insurance contracts, countless challenges have been made to insurer and health plan denials of coverage based on medical necessity criteria. In deciding a medical necessity case, a court must construe the terms of an agreement; consequently these decisions offer a rich source of contractual medical necessity definitions, since the court's opinion almost invariably sets out the relevant contract terms.

### *Judicial Case Law*

Two types of medical necessity cases predominate. The first type of case involves challenges to the actual decision on the merits, with the claimant arguing that the insurer's conclusions about a treatment's medical necessity are not supported by the evidence in the record. The second type of challenge goes to alleged flaws in the decisionmaking process, such as a decisionmaker's failure to follow applicable legal procedural standards in reviewing the case or considering the evidence. In all such cases the claimant (i.e., the provider and/or the patient) carries the burden of proving that the insurer's decision was contrary to the terms of the agreement.

Other cases raise questions of medical necessity in a malpractice context. In such cases, a managed care organization's allegedly negligent treatment (and subsequent coverage) decisions are claimed to be a proximate cause of death or injury. These cases typically appear in the case law at a threshold point (i.e., before there is any review on the merits of the claim) and are decided on ERISA preemption grounds. For this reason, these cases are omitted from this review. Two of the best known managed care liability cases involving behavioral health services are *Moscovitch* v. *Danbury State Hospital* (1998) and *Lazorko* v. *Pennsylvania Hospital* (2000). Both cases involved suicides by individuals covered by ERISA health plans. The patients were ordered to be discharged from treatment following a determination by the MCO that care was not medically necessary. Both cases were permitted to proceed as malpractice actions after a judicial determination that the claims in question fell outside of the scope of ERISA because they raised issues of State law professional liability rather than ERISA coverage claims.

For this review, an online search was conducted for all cases decided since 1992 involving challenges to medical necessity coverage decisions. The search was confined to

the past decade in order to avoid examining contracts whose terms may be significantly outdated. A total of 54 medical necessity cases were identified, 21 of which involve appeals by insurers and health plans seeking reversals of treatment orders issued by lower courts, and 33 of which are cases brought by providers and patients that seek to reverse a claims denial. Insurers are slightly more likely to prevail in these cases with 29 of the 54 cases decided in favor of the insurers while in only 25 of the cases the insurers' denials were reversed. A summary of all of the cases reviewed can be found in Appendix C.

The fact that insurers are somewhat more likely to prevail in medical necessity cases may reflect the merits of their decisions. It may also reflect the difficulties claimants encounter in challenging a medical necessity denial. For example, the plaintiff carries the burden of proof and generally is barred from introducing new medical evidence on appeal, since review is limited to the evidentiary record before the court. Thus, if the insurer or plan failed to consider certain evidence or misconstrued the evidence before it, the plaintiff typically cannot rectify the shortcoming in court. Furthermore, under principles of contract and trust law (the two bodies of law that apply to decisions on coverage in the case of employee health plans) (*Firestone Tire and Rubber* v. *Bruch*, 1989), insurers and health plan administrators are vested with considerable power to decide whether contract beneficiaries are entitled to the benefits they seek. A court's scope of review is therefore limited under judicial principles, and a court will generally scrutinize a record closely if it considers the insurer or plan to have a clear conflict of interest that has colored its views (*Bedrick* v. *Travelers Ins. Co.*, 1996).[16]

Of the 54 identified cases, 28 contain a definition of medical necessity (Table 3). *Jones* v. *Kodak Medical Assistance Plan* (1999), not included in Table 3 but summarized in Appendix C, is the leading case for the proposition that insurers have the power to contractually limit the types of necessary treatments they will cover by building their guidelines directly into the structure of the plan documents. As a result, *Jones*, which concerned treatment of alcoholism, contained no medical necessity definition *per se* but instead a provision construed by the court as limiting treatment to the guidelines used by the managed behavioral health subcontractor.

Other cases shown in Table 3 contain a more traditional definition of medical necessity and reflect the multidimensional approach seen in Table 2. This finding suggests that rather than being isolated events, the multidimensional definitions found in Table 2 are the prevailing industry standard. That is, the insurance industry today uses an approach to defining medical necessity that goes beyond assessing whether treatment meets a professional standard of care and permits the insurer to select among the treatments that ostensibly are all appropriate in favor of one that is the safest, the least costly, and not only for the convenience of the member or provider.

Four of the definitions drawn from the case law contain an explicit reference to the site of care, identifying treatment delivery in outpatient settings as preferable to inpatient care (*Dettmer Clinic* v. *Associated Insurance Companies, Inc.; Kornman* v. *Blue Cross Blue Shield of Louisiana; Milone* v. *Exclusive Health Care, Inc.; Scalamandre* v. *Oxford*

*Health Plans, Inc.*). For example, in the 1995 case *Kornman* v. *Blue Cross Blue Shield of Louisiana*, the insurer's third criterion for medical necessity was as follows: "as to inpatient care, could not have been provided in a Physician's office, in the Outpatient department of a Hospital, or in a lesser facility without affecting the patient's condition or quality of medical care rendered."[17]

Forty-two of the 54 cases reviewed—the single largest subgroup—involved a challenge to a medical necessity determination based on a treatment exclusion clause or an alleged flaw in the insurer's decisionmaking processes. Twenty-two cases focused on exclusions based on the allegedly experimental status of the requested treatment and thus dealt with the proper application of an exclusionary term rather than a medical necessity denial on the merits. Twenty cases involved allegations that the insurer improperly applied the definition in its determination procedures. Plaintiffs most typically alleged that the insurer acted in an arbitrary or capricious manner by unfairly denying claims in some cases while approving them in equivalent cases.

Four of the 54 cases involved mental health and substance abuse services (*Heil* v. *Nationwide Life, Koenig* v. *Metropolitan Life, Burrell* v. *United Health Care Insurance,* and *Jones* v. *Kodak Medical Assistance Plan*). The *Heil* and *Burrell* cases involved denials of inpatient hospitalization for a mental condition, and the *Koenig* and *Jones* cases involved denial of substance abuse treatment services. All four were concerned with alleged flaws in the insurers' determination procedures.

### *Investigations and Official Legal Actions*

In addition to cases decided in courts of law, State attorneys general and bureaus of insurance have responded to complaints filed by providers and patients regarding adverse determinations based on MCOs' medical necessity criteria. In New York, Maine, and Connecticut, official investigations were launched in response to alleged instances of arbitrary and capricious decisionmaking, inconsistent application of criteria, failure to meet disclosure requirements, and conflicts of interest on the part of MCO decisionmakers. In New York and Maine, MCOs entered into settlement agreements with the States; in Connecticut, an MCO's alleged abuses formed the basis for remedial legislation. Figure 4 summarizes the most common problems identified from these investigations of the procedures used by health plans and insurers to make medical necessity determinations, followed by descriptions of each of these States' legal actions.

#### New York

The series of October 2001 settlement agreements reached between the New York State Attorney General's Office and six large MCOs was a significant legal development regarding medical necessity.[18] Following a 2-year investigation into how these MCOs informed their providers and enrollees of adverse determination decisions on the grounds of medical necessity, the Attorney General found that these MCOs were not in compliance with New York State's utilization review law (discussed in more detail in Part V below). The focus of the investigation was on the processes used by the MCOs to make determinations and to inform providers and enrollees, rather than the content of the medical necessity definitions themselves. The

## Figure 4: Common Procedural Problems in Medical Necessity Determination Processes Noted in Investigations, Litigation, and Case Law

- Decision made in arbitrary or capricious manner without consideration of individual patient needs
- Decision made inconsistently (i.e., some patients' claims denied while others in equivalent circumstances approved)
- Claims reviewers unqualified or not appropriately trained
- Application of arbitrary and unreasonable caps on coverage and/or dollar limits
- Insufficient information provided in claims denials:
  - No disclosure of clinical rationale used in making decision
  - No disclosure of qualifying credentials of reviewer
  - No disclosure of evidence or documentation used in decision
  - No description of the procedures, timeframes, and consumer rights for grievance and appeal
- Failure to consult with treating physician
- Failure to consider medical evidence provided by patient
- Failure to provide full and fair review to patient appealing claims denial
- Lack of clarity and specificity in plan documents of excluded services (e.g., definitions of "experimental," "convenience")
- Conflict of interest of MCO decisionmaker that biased impartial judgment

Attorney General's office found, for example, that MCOs were often denying authorization or reimbursement for inpatient mental health and substance abuse treatment and offering nothing more than a generic explanation that the service was "not medically necessary." There was often no disclosure of the underlying reasons or clinical rationale the MCOs used in making their decisions, which is required in New York's utilization review law (see Appendix D for more details).

A representative of the New York Attorney General's Office indicated that although their investigation did not review the underlying substance of claims denied owing to medical necessity, behavioral health patients appeared to be more vulnerable to abusive medical necessity practices than patients with physical conditions. In the representative's view, medical necessity is harder to define and measure in behavioral health. The representative cited New York's utilization review law as an effort to overcome this difficulty by ensuring that all patients receive individualized medical necessity decisions based on specific clinical facts and individualized assessments. Despite this statute, the New York Attorney General's office continues to receive complaints from providers and patients regarding the medical necessity decision process used by MCOs in behavioral and physical health cases.

The Attorney General's Office representative cited the lack of a uniform medical necessity definition in State insurance laws as the most significant problem in medical necessity decisionmaking and investigation of abusive practices. External appeal statutes, utilization review regulations, and other insurance laws use medical necessity definitions and standards that are often conflicting or confusing. No uniform criteria are required. As a result, each health plan uses its own definition, and this variation makes regulation of medical necessity practices difficult.

### Maine

In 2000, both United Behavioral Health and Cigna Behavioral Health, Inc., entered into consent agreements with the Maine Bureau of Insurance.[19] These agreements were reached as a result of complaints filed with the bureau by health plan enrollees concerning denials of coverage based on medical necessity grounds. The bureau determined that the denials were not in conformance with Maine rules regarding utilization review (see Appendix D for more details).

A representative from the Maine Bureau of Insurance indicated the potential for medical necessity abuses is similar in the physical and behavioral health care contexts, but that behavioral health medical necessity determinations in Maine are qualitatively different from those in other jurisdictions. Both the rural character of the State and general shortage of behavioral health care providers have a significant effect on the application of medical necessity criteria. For example, there is only one practicing psychiatrist in Washington County, which has a population of over 30,000 people. Since outpatient settings are scarce, national MCOs that do business in Maine often apply medical necessity and "appropriate setting" criteria to resist coverage of inpatient behavioral health treatment, sometimes all that is available in certain regions of the State.

The paucity of providers also affects grievance procedures. Maine requires MCOs to offer an independent medical review as part of their internal grievance process (it also has an external review statute for further appeals after the internal process has been exhausted). The shortage of providers leads MCOs to find reviewers from other jurisdictions. These reviewers often question the medical necessity or appropriateness of inpatient behavioral health care even though outpatient care is not available or not practical owing to distance. Maine consumers and providers file complaints with the Bureau of Insurance over these issues and the general shortage of behavioral health care providers and services.

Maine's Insurance Code contains a definition of "medically necessary health care," and according to the representative, insurers generally appear to understand the definition and the statute's process requirements (despite the frequent struggle over inpatient behavioral health services). The representative indicated that several high-profile consent agreements with insurers that failed to follow Maine's definition or process requirements have had a deterrent effect on other insurers.

### Connecticut

A recent case that dramatically highlights the potential for misconduct in the area of medical necessity decisionmaking by health plans involves an investigation conducted by the Connecticut Attorney General into the activities of the State's largest insurer, Anthem Blue Cross/Blue Shield, and its subcontractor, Psych Management, Inc. (PMI). In a widely disseminated report issued in February 2002, the Attorney General reported that Anthem Blue Cross/Blue Shield (which enrolls 600,000 State residents), prompted by desires for significant savings and profit maximization, contracted with PMI to administer the behavioral health component of its product line following a notably low project bid. The investigation found that PMI's president had serious financial conflicts of interest and engaged in inappropriate use of aggressive utilization management and denials of medically necessary care solely to

improve PMI's profit margin (Blumenthal, 2002) (see Appendix D for more details).

A representative of the Connecticut Attorney General's Office indicated that their investigation showed that the potential for abuses of medical necessity is greater in the behavioral health context than in physical health cases. In the view of the office, not only is it harder to define what is medically necessary in behavioral health, but the patients involved are more vulnerable and politically weak. In addition, the representative indicated that the behavioral health provider lobby in Connecticut is relatively weak and not effectively organized.

The Connecticut Attorney General's office receives more complaints from providers and consumers regarding behavioral health care than physical health care. The complaints include a failure to pay claims in a timely manner, arbitrary coverage denials (citing medical necessity), and difficulties in finding behavioral health providers due to out-of-date provider lists given to consumers (commonly known as "phantom panels").

Finally, the representative indicated that the arbitrary financial goals, phantom panels, and lack of regulatory oversight of subcontractors are the most pressing problems they found during their investigation. The Connecticut Department of Insurance has taken the position that the State's laws regulating managed care practices do not give the department jurisdiction over subcontractors.

# V. State Law Regulation of Medical Necessity

In their capacity as insurance regulators, States have developed an extensive body of law related to the insurance industry. State laws fall into two basic categories: laws that regulate the actual content of the insurance contract itself (e.g., mandated benefit laws); and laws that regulate other aspects of the business of insurance (e.g., consumer protection laws, antidiscrimination law, corporate law, laws providing for oversight of insurance practice, and administrative and judicial review of insurer determinations). This section examines two types of State insurance laws that address medical necessity: insurance contract statutes and laws that establish independent review procedures for medical necessity determinations.

## Laws That Regulate the Content of Insurance Contracts

In addition to detailing specific classes of benefits and services that must be included in a contract of insurance sold in the State (e.g., pediatric immunizations, in vitro fertilization, inpatient psychiatric care),[20] a number of States have attempted to define medical necessity. This effort to define medical necessity by statute is relatively recent and tracks the growth of (and backlash against) managed care. It probably would be incorrect to view the evolution of medical necessity definitions in State law solely in the context of consumer protection. Indeed, codifying a medical necessity definition in statute actually might favor the industry, since once a statutory definition exists, a court cannot insert its own definition into the contract. Today it is still relatively common to find insurance contracts that authorize an insurer to decide issues of medical necessity without a precise definition of the term.[21] In the face of this silence, a court can fashion its own definition under common law principles of jurisprudence.[22] In so doing, a court might be inclined to use principles of professional liability law to arrive at a definition and adopt a standard that measures the recommended treatment against accepted standards of professional practice, as established through the testimony of experts.[23]

The absence of a medical necessity definition can be as harmful to insurers as it might be to patients. In this situation, it would be in the interest of the industry as well as consumers to adopt a definition, particularly if the definition adopted is multidimensional, giving the insurer discretion to select among competing schools of thought in accordance with criteria other than whether the treatment meets professional standards of practice.

Seventeen definitions of medical necessity were found in the course of this review. Table 4 sets forth these definitions, which vary considerably in length and scope. For example, at one end of the spectrum, Massachusetts defines medical necessity as "health care services that are consistent with generally accepted principles of professional medical practice."[24] At the other end, Hawaii offers:

> A health intervention is medically necessary if it is recommended by the treating physician or treating licensed health care provider, is approved by the health plan's medical director or physician designee, and is: (1) For the purpose of treating a medical condition; (2) The most appropriate delivery or level of service, considering potential benefits and harms to the patient; (3) Known to be effective in improving health outcomes; provided that: (A) Effectiveness is determined first by scientific evidence; (B) If no scientific evidence exists, then by professional standards of care; and (C) If no professional standards of care exist or if they exist but are outdated or contradictory, then by expert opinion; and (4) Cost-effective for the medical condition being treated compared to alternative health interventions, including no intervention. For the purposes of this paragraph, cost-effective shall not necessarily mean lowest price.[25]

It is evident that Hawaii's definition approximates those found in modern industry practices, while Massachusetts's definition tracks the unidimensional standard that limits the authority of the industry to choose among equally appropriate types of treatments. Of special note is the fact that Hawaii's definition, enacted in 2000, is virtually identical to the prototype definition proposed in 1999 by Singer et al. (see Part 1 and Table 1).

## Independent Review Statutes

By 2002, 40 States and the District of Columbia had enacted external review laws that allow enrollees to appeal to an independent review organization (IRO) health plan decisions to deny, reduce, or terminate care. Nearly half of these States have drafted regulations pursuant to their IRO statutes.[26] Table 5 lists the statutory and regulatory citations of these laws.

External review laws are a recent development. Only Michigan (1978) and Florida (1985) had external review statutes prior to 1990. By 1998, the number of statutes had grown to 13 (Dallek & Pollitz, 2000), with the remaining 28 statutes enacted within the past 4 years.

IRO statutes and administrative regulations raise, and try to answer, many questions. This section focuses on questions in three critical areas that courts consider to be basic issues of fairness in decisionmaking: (1) whether the States are tailoring statutes specifically to address appeals of denials involving behavioral health care; (2) the key procedural elements of the statutes, including who may serve as an IRO and the qualifications of IRO reviewers (including the possession of expertise relevant to the case under review); and (3) how much deference the IRO must give to the initial decision and whether new evidence may be introduced during the IRO review. In addition, the statutes were reviewed to determine whether they specify who has the burden of proof in the appeal (i.e., whether the insurer must present evidence defending its initial decision or the claimant must present evidence to challenge it). Only one State, Maryland,

addresses the specific burden of proof and places it on the MCO to demonstrate that its initial adverse decision was correct.[27]

In States that regulate the definition of medical necessity under their insurance content statutes, the IRO presumably would be guided by this definition. Among States that do not have a definition of medical necessity in their insurance laws but that have enacted IRO statutes, seven include a definition of medical necessity in the IRO statute itself. Table 6 lists these States and the definition of medical necessity that they have adopted for IRO purposes.

Only two States, Pennsylvania and Vermont, specifically mention behavioral health care in their IRO statutes.[28] Table 7 sets forth the relevant provisions from State law. Pennsylvania's statute identifies licensed psychologists as qualified reviewers; Vermont specifies an independent review system for appeals involving mental health services and substance abuse treatment. While most State IRO statutes use broad language that could include a range of providers to review behavioral health determinations, the Vermont statute is unique in its explicit recognition of behavioral health reviewers.

*The independent reviewer: Who, how chosen, and what qualifications?* Central to the process of obtaining external review are questions about who performs the review, how the reviewer is chosen, and what qualifications the reviewer possesses. Table 8 sets forth information on the review process. All 41 statutes provide some detail about what entities qualify to perform IRO functions. Most States require that the IRO obtain certification or a license from the State insurance or health department, and many States use accreditation by a national accrediting organization as a proxy for State certification.

Thirty-seven of the 41 States require that reviewers used by the IRO have appropriate license, board certification (if applicable), and experience in the medical condition or health care service under review. Of the remaining four States, three do not specify such a requirement, and the last makes utilizing relevant expertise an option "when necessary," but does not define when that is or who makes that determination.

In seven States, the MCO chooses the independent review organization to perform the review (either from an approved insurance/health department list or from any qualified IRO). The insurance or health departments assign the reviewer in the remaining States. A number of States require a rotation of the IRO so no MCO is reviewed by the same organization for every case.

Thirty states disqualify an IRO from serving as a reviewer if the entity has financial or other conflicts of interest with the parties to the case. Nine of the 11 remaining States do not explicitly prohibit conflicts, and one State requires only that the conflict be disclosed.

*Standard of review and permissible evidence:* Table 9 addresses the issue of standard of review, identifying those States in which review is *de novo* (i.e., brand new) and those in which additional evidence of necessity can be submitted. The standard of review specifies how much deference, if any, the IRO should or must give to the prior decision made by the MCO. In a *de novo* review, the IRO is not bound at all by an earlier decision and no deference is required. Six States accord this absolute review power to their IROs. Few States specify any level of review short of *de novo*, and the majority of State IRO statutes and regulations are silent on

what standard of review to apply to prior decisions by the MCO.

Twenty-seven of the States permit the enrollee requesting the review to submit additional evidence for consideration by the IRO. The statutes range from allowing specific additional medical evidence to allowing any evidence the enrollee considers relevant to the appeal. Three States allow the enrollee to request or attend a review hearing.

*Additional process questions:* The statutes and regulations compiled in this review contain additional process questions worth noting. Most States require an enrollee to exhaust an MCO's internal appeals process before filing a request for external review, but there are notable exceptions. Some States require a preliminary review by the department of insurance or IRO to determine whether the request is eligible for review. Many States require the enrollee seeking review to pay a filing fee. Most States require the MCO to pay the cost of each appeal, but other States have assessed a fee for each MCO operating in the State to cover the costs of the entire appeals system. Almost every statute includes detailed timelines for filing requests for appeal and responses, and some States require that the appeal be filed on specific forms. While none of these process questions answer large questions, taken together, they allow an examination of the burdens that enrollees face when attempting to invoke the right to an external review.

Viewed as a whole, State independent review statutes suggest a desire on the part of States to afford insured persons a right to a second opinion in the case of medical necessity determinations. While State insurance law contains minimal regulation of insurers' internal utilization management and internal appeals processes, these statutes suggest that States are willing to establish minimum standards for how insurer decisions are to be reviewed, including absolute review powers, impartial reviewers, and the authority to consider new evidence in reviewing a medical necessity determination. Few IRO statutes contain independent definitions of medical necessity, although the State's content definition presumably would apply where one exists.

The power of the procedural standards to support the overturning of a denial may be somewhat limited, however. For example, if the definition of medical necessity gives the insurer discretion to select from among several professionally acceptable courses of treatment, one would expect an independent reviewer to uphold the insurer's decision unless it was not supported by the evidence (i.e., the insurer's choice among selected treatments was not grounded in sufficient evidence to justify a rejection of other choices).

# VI. Relevant Federal Laws Pertaining to Medical Necessity Reviews

This part considers two sources of law relevant to medical necessity determinations. First, two sets of Federal standards governing employee health plans are examined. The first set of standards is embodied in the regulations promulgated by the Department of Labor in 2000 that set forth the "full and fair review" procedural requirements that all ERISA health benefit plans must meet. The second set is embodied in the standards governing medical necessity reviews that are currently in use by the U.S. Office of Personnel Management.

## ERISA

The ERISA statute regulates health and welfare benefits for more than 140 million workers and their families (Rosenbaum, Frankford, Moore, & Borzi, 1999). ERISA requires every health benefit plan within its scope to provide adequate notice in writing to a participant when a claim is denied, "setting forth the specific reasons for such denial, written in a manner calculated to be understood by the participant."[29] In addition, ERISA affords a health plan member whose claim has been denied a "reasonable opportunity . . . for a full and fair review by the appropriate named fiduciary of the decision denying the claim."

In November 2000, the Department of Labor issued final regulations that revise the full and fair review requirements for appeals of denials of claims for health benefits, including both retrospective and prospective claims. These regulations became effective for group health plans on July 1, 2002. Although ERISA does not define medical necessity or provide a right to external administrative review,[30] these regulations establish extensive standards for internal reviews required in the case of health claims.[31]

The November 2000 regulations require ERISA-covered plans to "establish and maintain reasonable procedures governing the filing of benefit claims, notification of benefit determinations, and appeal of adverse benefit determinations."[32] A plan's claims procedures must safeguard and verify that claims are made in accordance with governing plan documents and that plan provisions are applied consistently for similarly situated claimants.

The full and fair review regulations were intended to make the claims process "faster, fairer and fuller." With respect to the speed of the process, the regulations shortened the permissible time for initial claim decisions and appeals. Instead of 90 days under the prior applicable regulation, the November 2000 rule requires initial decisions in 72 hours for urgent care claims, 15 days for pre-service claims, and 30 days for post-service claims.[33] Health plans are allowed one 15-day extension for pre- and post-service claims. On appeals of denied claims, instead of 60 days under the prior applicable regulation, the new regulation requires decisions on appeals within 72 hours for urgent care claims, 30 days for pre-service claims, and 60 days for post-service claims. There are no extensions of time for health plans in determining appeals.[34]

Under the "fairness" category, the regulation allows claimants more time to file an appeal (180 days instead of 60 under the prior regulation). The decisionmaker cannot be the same person who denied the initial claim or that person's subordinate. The claimant also has the opportunity to submit written comments, documents, records, and other information related to the claim, and the review must take into account all information submitted by the claimant (whether or not the information was considered in the initial benefit determination).[35]

If the appeal involves a decision based on medical judgment, including whether an item or service was medically necessary, the health plan must consult with a "health care professional who has appropriate training in the field of medicine involved in the medical judgment." The health care professional must not have been involved with the initial decision or be a subordinate of the initial decisionmaker. Upon request, the health plan must disclose the identity of the health care expert it consulted. Health plans cannot require more than two levels of internal review of denied claims, and if there are two levels, both levels must be completed within the time frames required of one level.[36]

The "fullness" category relates to improved access to information by persons appealing an adverse determination. As an initial matter, the plan must provide all plan members with a full description of the plan's claims and appeals procedures. Claimants appealing an adverse determination must have access to any information relevant to their claim upon request and free of charge. Relevant information includes any information the health plan relied on in making the initial decision; any information submitted, considered, or generated while making the initial decision; and any statements of policy or guidance concerning the denied treatment or benefit, even if such documents were not relied upon in making the decision.[37] In addition, when a health plan denies a claim based on a protocol or guidelines, the plan must disclose such reliance and inform the claimant that a copy of the protocol is available upon request. Similarly, when the denial is based on medical necessity, the rule requires the plan either to explain the scientific or clinical judgment used in applying the plan's terms or to include a statement that such an explanation will be provided free of charge if requested.[38]

With disclosure of protocols and explanations of the application of medical necessity, the Federal full and fair review regulations exceed the reach of State utilization and independent review statutes and regulations.

## Office of Personnel Management Standards: FEHBP

Another relevant Federal law establishes separate standards for reviewing claims involving the denial of medical necessity for Federal employees. The Federal Employees Health Benefit Plan (FEHBP)[39] provides health insurance coverage to more than nine million Federal employees and their dependents. The U.S. Office of Personnel Management (OPM), which contracts with health plans to serve Federal employees, administers the FEHBP.

Neither the FEHBP statute nor its implementing regulations define "medical necessity" or how health plans are to make such determinations. The FEHBP regulations, however, do offer enrollees a right to appeal to OPM if the health plan denies a claim a second time after reviewing its first denial or if it fails to respond to an enrollee's request for reconsideration of a claim's denial.[40] The enrollee must exercise the right to appeal within 90 days of the health plan's decision, or within 120 days of the request for reconsideration if the health plan failed to respond. In reviewing the claim denied by the health plan, OPM may (1) request that the claimant submit additional information; (2) obtain an advisory opinion from an independent physician; (3) obtain any other information it believes is required to make a decision; or (4) make its determination based solely on the information the claimant submitted with the request for OPM review.[41]

Neither the OPM statute nor its implementing regulations specify the standard OPM is to use in reviewing denied claims. If a claimant wishes to sue, the suit must be filed in Federal court to review OPM's final action on the claim, but the claimant is limited to ERISA remedies. The suit must be brought against OPM, not the health plan or its contractors, and a recovery in such a suit is limited to a court order directing OPM to require the health plan to pay the amount of the benefits in dispute.[42]

Figure 5 presents the key elements of medical necessity review and compares ERISA procedures with those established by OPM.

Although the ERISA full and fair hearing regulations and the FEHBP provide further procedural safeguards to health plan enrollees, both have important limitations. The ERISA regulations do not contain a right to an external appeal, despite providing important additional access to information and better claims procedures not previously available. The FEHBP, limited to Federal employees, provides a right to appeal outside the health plan to the OPM or to Federal court if necessary, but, as with ERISA plans, monetary damages are limited to payment for the cost of the denied benefit itself (i.e., punitive and "pain and suffering" damages are not available).

As a result of the modest reach of Federal law, the definition of medical necessity is still governed by the terms of the contract negotiated between buyers and sellers.

Figure 5: Medical Necessity Utilization Review and Appeals Procedures

| *Issue* | *ERISA* | *FEHBP* |
|---|---|---|
| Standards for initial utilization review process | ✓ | |
| Standards for internal appeals of initial denials | ✓ | |
| Timelines | ✓ | ✓ |
| Qualifications of reviewer | ✓ | |
| *De novo* review | ✓ | |
| Evidentiary standards | ✓ | |
| Access by claimant to health plan evidence | ✓ | |
| Treatment guidelines | ✓ | |
| Definition of medical necessity | | |
| External *de novo* administrative review of health plan decision | | |

# VII. Synthesis and Implications

As recently as 30 years ago, health professionals had virtual autonomy to determine whether health care was medically necessary. Today the evidence suggests that this autonomy had a profound impact on both health care cost and quality. After tentative incursions on decisionmaking through retrospective utilization review, the health insurance industry has moved to prospective review and has developed increasingly tight coverage provisions and definitional terms. Some commentators such as Eddy, Singer, and Bergthold have focused on the importance of scientific evidence in decisionmaking. Others such as Rosenbaum and Frankford have readily acknowledged the need for external review of clinical judgment.

The evidence presented in this literature review suggests that the modern definition of medical necessity is multidimensional and turns only in part on the consideration of whether the treating professional's recommendations fall within professionally accepted standards. Whether in State statutes, insurance contracts, case law, or peer-reviewed literature, the modern medical necessity definition assumes external control of the ultimate decision. Furthermore, relatively widespread consensus has been reached that the definition of medical necessity should have certain specific dimensions.

The first dimension (and the one that is most embedded in the structure of the agreement itself and often the most elusive) is best thought of as *contractual scope*. Does the agreement cover treatments that prevent worsening and maintain or promote functioning, or is the agreement limited to treatments that show recovery or at least significant improvement in the short term?[43] The second dimension is the *professional standard*. Is the treatment in accord with professional standards of care in the relevant area of practice? The third dimension can be thought of as *patient safety and setting*. Is the prescribed treatment gauged to be delivered in the safest and most effective setting? The fourth dimension is that the *treatment be medical and not a convenience matter* or one that emanates from social or environmental factors.

The fifth dimension is *cost*. Here, however, most of the definitions (and the literature as well) are vague on exactly what is meant by cost. Ford (2000) attempts to grapple with what is meant by cost, emphasizing long-term over short-term in order to permit coverage of care and services that, while not capable of producing immediate improvements, show long-term payoff. At this point, of course, one begins to cross over from questions

related to the necessity of covered services to the underlying issue of coverage itself, since coverage may be structured to categorically exclude services of certain duration or services that do not show recovery or significant improvement within a brief period of time.

One of the notable aspects of this review is that there is little to suggest that health insurers, State legislators, accreditation bodies, or the experts consider behavioral disorders to be so unique that the general multidimensional test used to measure medical necessity is not appropriate. A number of commentators call for a broadening of coverage to include services related to the treatment and management of chronic conditions, where the goal is to attain or maintain functioning over the long term. Such goals can be thought of as a form of significant improvement: attaining the ability to function better can be thought of as a significant improvement in the case of individuals with serious and chronic behavioral health disorders. But the improvement in such cases is not on a "recovery" trajectory (in the sense that the insurer may equate "recovery" with "leading to cure") and so may continue to fall outside the scope of coverage. This represents an inconsistency with treatment for many persons with severe mental illness, wherein recovery, as evidenced by improved functioning, is a primary treatment goal.

The evolution of a multidimensional definition of medical necessity reflects the problems inherent in a standard that measures the proposed treatment simply against the prevailing standard of care. As the schools-of-thought doctrine in liability law underscored, the professional standard is built on custom, practice, clinical observation, and consultation and may embody several possible approaches to a single condition. Were an insurer to seize on one school of thought to the exclusion of all others, its determination would be vulnerable on appeal. Even if the plaintiff carries the burden of proof, it is possible to introduce evidence showing the full range of possible and professionally appropriate approaches to a particular problem, thereby undermining the insurer's insistence on one particular approach.

The modern definitions found in the industry's own materials, the case law, State statutes, and the literature all point to an emerging standard of medical necessity that effectively permits an insurer or health plan vested with decisionmaking discretion to select among a series of professionally accepted approaches to care and to choose the approach that best satisfies other considerations, including cost, safety, and convenience factors. This power to choose one specific approach to treatment, as opposed to being obligated to recognize the full range of treatments that fall within the professional standard of care, is the essence of what separates the modern definition from its predecessors.

Furthermore, depending on how the definition is drafted, an insurer or health plan can exclude all evidence from its consideration other than evidence gleaned from certain sources of information such as randomized controlled studies (*Harris* v. *Mutual of Omaha Co.*, 1993).

This shift to a multidimensional test of necessity can be expected to affect any condition where there are multiple professionally recognized approaches to the treatment of any particular condition. Because professional opinion varies to a disproportionate degree in the area of behavioral health, the issue of medical necessity has generated heightened attention in this area. However,

experts in behavioral health who write about medical necessity do appear to advocate a definition that allows a decisionmaker to select among competing approaches in accordance with numerous other factors.

The cost dimension of the modern medical necessity definition also may have an especially strong impact in behavioral health if treatments for such illnesses vary widely in cost. A course of treatment that emphasizes prescribed medications and brief therapy may have radically different costs from one that is long-term and emphasizes psychotherapy over medication. Similarly, a requirement of prior failure as a precondition to the use of more expensive prescription drug therapies may have a greater impact in behavioral health, depending on the cost of emerging medication treatments compared to existing treatments. A corollary consideration is that of consumer choice, which is rarely, if ever, addressed in medical necessity definitions except in the context of exclusions for "convenience."

The concept of convenience is a difficult one. For example, could a "fail first" policy be designed to limit "convenience" treatments for patients and thus be a basis for denying access to emerging and professionally accepted treatments? There has been a rapid increase in the development of a new generation of psychopharmaceuticals used to treat unipolar and bipolar depression, anxiety, schizophrenia, and alcohol and opiate addictions. These drugs have usually been found in clinical development testing to have greater effectiveness and fewer negative side effects than previous drugs, thus increasing the likelihood that patients who use them will be able to adhere to the treatment regimen. Since these drugs are new to the market and not yet widely prescribed, they are typically relatively expensive. A "fail first" test used as part of the convenience or cost dimension of the medical necessity review would result in a denial of access to certain advanced medications. The impact of this decision might extend beyond the immediate denial of certain forms of recognized treatment. Because the modern medical necessity definition turns in part on what is the accepted treatment, the fact that insurers and health plans reject use of the treatment on a widespread basis may lengthen the delay before the treatment becomes "accepted."

The evidence also shows a consensus in the law and literature for an independent review of an insurer's medical necessity decision. More than 40 States have enacted legislation that, to varying degrees, establishes an independent review process and the ability to introduce additional relevant and reliable evidence. While the burden of proof is not specifically addressed in these laws, these statutes lean toward creating an independent second opinion process, in which the original determination is given no benefit of weight or presumption. Federal regulations revising the full and fair review process in the case of ERISA plans also emphasize (to the extent possible given the internal nature of these reviews) independence, fresh evidence, and claimant access to the plan's evidence and information. On June 20, 2002, the U.S. Supreme Court ruled that Illinois's independent review statute is not preempted by ERISA. The majority opinion (five justices) stated that: "[A]n HMO is both: it provides health care, and it does so as an insurer.... [R]egulating insurance tied to what is medically necessary is probably inseparable from enforcing the quintessentially state-law standards of reasonable medical care." (*Rush Prudential HMO, Inc.,*

*Petitioner,* v. *Debra C. Moran et al.,* 2002) The practical effect of the decision is to leave intact the status quo regarding States' abilities to enact independent review statutes, thus preserving consumers' right to pursue State-level appeals of claims denials, which occur in behavioral health care cases more often than in general medical care.

Regardless of how the process is structured, however, the importance of the modern medical necessity definition is the power it affords an insurer or health plan to select from among professionally accepted treatments the one treatment that it will elect to cover. Depending on the quality of the evidence pointing to one treatment as preferable to all others, this power may represent an advance in the effort to standardize the approach to the treatment of certain conditions. But to the extent that the evidence is weak, unreliable, or irrelevant, or that little focus is given to a particular patient's condition (or conditions) in the course of evaluating possible treatments, the power to select on the basis of factors other than the professional standard of care may result in the rejection of possible treatment approaches that are beneficial in the long run.

Finally, even the broadest definition of medical necessity that tolerates multiple schools of thought and that calls for extensive consultation with the treating physician in arriving at the right treatment cannot overcome contractual terms that limit or exclude long-term maintenance treatments designed to avert deterioration or maintain functioning in the case of persons with chronic behavioral health conditions. This is a wholly separate issue, and one that is of increasing importance for behavioral health care services.

# VIII. References

American Psychiatric Association. (1994). *Diagnostic and Statistical Manual of Mental Disorders* (4th ed.). Washington, DC: Author.

*Bedrick* v. *Travelers Ins. Co.*, 93 F.3d 149 (4th Cir. 1996).

Blumenthal, R. (2002). Report of the Attorney General's Investigation Concerning Psych Management, Inc. and Anthem Blue Cross and Blue Shield of Connecticut. Available at http://www.cslib.org/attygenl/mainlinks/tabindex6.htm. Accessed April 3, 2002.

Buck, J. A., Teich, J. L., Umland, B., & Stein, M. (1999). Behavioral health benefits in employer-sponsored health plans, 1997. *Health Affairs, 18*(2), 67–78.

Chodoff, P. (1998). Medical necessity and psychotherapy. *Psychiatric Services, 49*(11),1481-1483.

Dallek, G. & Pollitz, K. (2000). *External review of health plan decisions: An update*. Prepared for the Kaiser Family Foundation (Washington, DC).

*Dettmer Clinic* v. *Associated Insurance Companies, Inc.* U.S. Dist. LEXIS 20896 (1993).

Domino, M. E., Salkever, D. S., Zarin, D. A., & Pincus, H. A. (1998). The impact of managed care on psychiatry. *Administration & Policy in Mental Health*, *26*(2),149–157.

Eddy, D. (1994). From theory to practice: Rationing resources while improving quality: How to get more for less. *JAMA, 272*, 817–824.

*Firestone Tire and Rubber* v. *Bruch*, 489 U.S. 101 (1989).

Ford, W. (1998). Medical necessity: Its impact in managed mental health care. *Psychiatric Services 49*(2), 183-184.

Ford, W. (2000). Medical necessity and psychiatric managed care. *Psychiatric Clinics of North America, 23*(2), 309-317.

Hadley, J. (2002). *Sicker and poorer: The consequences of being uninsured: A review of the research on the relationship between health insurance, health, work, income and education*. Prepared for the Kaiser Commission on Medicaid and the Uninsured. Available at http://www.kff.org/content/2002/20020510/4004.pdf. Accessed May 29, 2002.

*Harris* v. *Mutual of Omaha Co.*, 992 F.2d 706 (7th Cir. 1993).

Hill, H., Hanson, A., & O'Connell, B. (2000). Using evidence: Coverage decisions. *Proceedings from Agency for Healthcare Research and Quality (AHRQ) User Liaison Program Workshop for State and Local Healthcare Policymakers*. Available at http://www.ahrq.gov/news/ulp/evidence/ulpevdnc5.htm. Accessed December 15, 2001.

Institute of Medicine. (1990). *Clinical practice guidelines: Directions for a new program*. Washington, DC: National Academy Press.

Ireys, H., Wehr, E., & Cooke, R.E. (1999). Defining medical necessity: Strategies for promoting access to quality care for persons with developmental disabilities, mental retardation, and other special health care needs. Washington, DC: National Center for Education in Maternal and Child Health Report.

JCAHO. (2001). *2001–2002 Comprehensive accreditation manual for health care networks*. Oakbrook Terrace, IL: Author.

JCAHO. (1997). *Comprehensive accreditation manual for managed behavioral health care*. Oakbrook Terrace, IL: Author.

*Jones* v. *Kodak Medical Assistance Plan.,* 169 F. 3d 1287 (10th Cir. 1999).

Kaplan, A. (1999). Medical necessity: What is it? *Psychiatric Times*, 16:12 Available at http://www.psychiatrictimes.com/p991238.html.

*Kornman* v. *Blue Cross Blue Shield of Louisiana* 662 So. 2nd 498 (1995).

*Lazorko* v. *Pennsylvania Hospital.,* 237 F. 3d 242 (3d Cir. 2000).

Manderscheid, R. W., Henderson, M. J., & Brown, D. Y. (2001). Status of national efforts to improve accountability for quality. In B. Dickey & L.I. Sederer (Eds.). *Improving mental health care: Commitment to quality.* (pp. 163-178). Washington, DC: American Psychiatric Publishing, Inc.

*Milone* v. *Exclusive Health Care, Inc.,* 224 F.3rd 615 (8th Cir. 2001).

*Moscovitch* v. *Danbury State Hospital.,* 25 F. Supp. 2d 74 (D. Ct. 1998).

NCQA. (2001). *Standards for the accreditation of MCOs (Effective July 1, 2001).* Washington, DC: Author.

NCQA. (2000). *Standards and surveyor guidelines for the accreditation of MBHOs.* Washington, DC: Author.

Pawlson, G., (April 3, 2002). NCQA, personal communication.

Rosenbaum, S. (2002). Medicaid. *NEJM. 346*(8), 635–640.

Rosenbaum, S., & Rousseau, D. (2001). Medicaid at thirty-five. *St. Louis University Law Jour*. *45,* 1–53.

Rosenbaum, S., Frankford, D., Moore, B., & Borzi, P. (1999). Who should determine when health care is medically necessary? *NEJM, 340*, 229–232.

Rosenblatt, R., Law, S., & Rosenbaum, S. (1997). *Law and the American health care system.* New York: Foundation Press.

Rosenblatt, R., Rosenbaum, S., & Frankford, D. (2002). *Law and the American health care system*. 2001–02 Supplement. New York: Foundation Press.

*Rush Prudential HMO, Inc., Petitioner,* v. *Debra C. Moran et al.,* U.S. Supreme Court. No. 00-1021. 2002 U.S. LEXIS 4644. Available at http://www.supremecourtus.gov/opinions/01slipopinion.html. Accessed June 21, 2002.

Sabin, J., & Daniels, N. (1994). Determining "medical necessity" for mental health practice. *Hastings Center Report*, *24*(6), 5–13.

*Scalamandre* v. *Oxford Health Plans, Inc.* 823 F. Supp. 1050 (E.D. NY, 1993).

Schiffbauer, W. G. (1999). *Medical necessity and health plan contracts*. Washington, DC: Health Insurance Association of America.

Singer, S. J., Bergthold, L. A., Vorhaus, C., & Enthoven, A. (1999). *Decreasing variation in medical necessity decision-making*. Palo Alto, CA: Stanford University.

U.S. Department of Health and Human Services (DHHS). (1999). *Mental health: A report of the surgeon general*. Rockville, MD: Substance Abuse and Mental Health Services Administration.

Varble, D. (2001). Comments on practice guidelines. In N. A. Cummings & W. O'Donohue (Eds.), *Integrated behavioral healthcare: Positioning mental health practice with medical/surgical practice*. (pp. 251–255). San Diego, CA: Academic Press.

# IX. Endnotes

[1] Legislation to establish simplified review procedures for all health benefit plans maintained by private employers is currently pending in the 107th Congress. Since 1997 the Medicare program has offered an informal administrative review system, and courts have consistently held that external impartial review of health plan treatment decisions is a legal right of Medicaid managed care enrollees (Rosenblatt, Law, & Rosenbaum, 1997).

[2] Review of the medical and health services literature was conducted via searches on MEDLINE, HealthSTAR, and PsycINFO. Legal cases and decisions were retrieved using LEXIS-NEXIS. Additional research included retrieval of information from State attorneys general Web sites. A unified database was created using EndNote 5 to facilitate organization and analysis of medical necessity definitions across all sources of information.

[3] It is worth noting that the Senate mental health parity legislation would appear to allow contractual treatments to vary by diagnosis, even as it constrains insurer discretion to formulate mental illness-specific coverage limitations for broad classes of benefits. Thus, an insurer presumably could specify covered contractual treatments in the case of mental illness while using a broader and more flexible individualized "medical necessity" decisionmaking approach in the case of physical illness.

[4] Available at http://www.ama-assn.org/ama1/pub/upload/mm/368/supplement1.pdf. Accessed December 19, 2001.

[5] The plausibility of this distinction has been most recently called into question in *Fitts* v. *Fannie Mae,* No. 98-00617, 2002 U.S. Dist. LEXIS 3071 (D. D.C. Feb. 26, 2002).

[6] According to the American Psychiatric Association, "the *DSM-IV (Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition*), published in 1994 was the last major revision of the *DSM*. It was the culmination of a six-year effort that involved over 1,000 individuals and numerous professional organizations. Much of the effort involved conducting a comprehensive review of the literature to establish a firm empirical basis for making modifications. Numerous changes were made to the classification (i.e., disorders were added, deleted, and reorganized), to the diagnostic criteria sets, and to the descriptive text based on a careful consideration of the available research about the various mental disorders." The APA has recently begun considering "relational disorders" as a new diagnostic code in the future *DSM-V* (expected for publication in 2010). See http://www.psych.org/clin_res/dsm/dsmintro81301.cfm.

[7] The fact that the industry views the utilization review process as linked to both health care quality and cost is best evidenced in industry accreditation standards, which identify an appropriate utilization management program as an essential feature of health care quality and thus, of accreditation. See, e.g., JCAHO (1997, 2001) and NCQA (2000, 2001).

[8] Full and fair hearing review regulations issued in 2000 by the U. S. Department of Labor

require ERISA health benefit plans to disclose any relevant information to claimants appealing a benefit denial through the plan's internal review system. See 65 Fed. Reg. 70246 (Nov. 21, 2000); 29 C.F.R. Part 2560 (2001). When a health plan denies a claim based on a protocol or guidelines, the plan must disclose such reliance and inform the claimant that a copy of the protocol or guideline is available upon request. Similarly, when the denial is based on medical necessity, the rule requires the plan either to explain the scientific or clinical judgment used in applying the plan's terms to the claimant's medical circumstances or to include a statement that such an explanation will be provided free of charge if requested. These regulations are effective for claims filed under an ERISA health plan on or after July 1, 2002. The regulations effectively reverse a series of judicial decisions holding that under ERISA, health plans' fiduciary obligations do not require disclosure of treatment guidelines. See *Jones* v. *Kodak,* 169 F.3d 1287 (10th Cir. 1999); *Doe* v. *Travelers Ins. Co.,* 187 F.3d 53 (1st Cir. 1999).

[9] Available at https://apps.cignabehavioral.com/web/basicsite/provider/pdf/CBHguide.pdf. Accessed September 22, 2002.

[10] In RE: United Behavioral Health, Consent Agreement with Maine Bureau of Insurance, Docket No. 00-3005. Available at http://www.state.me.us/pfr/ins/ins003005.htm. Accessed April 16, 2002.

[11] It is typical for insurers to limit the concept of treatment to interventions that are calculated to yield either a full recovery or a significant improvement. See *McGraw* v. *Prudential Ins. Co.,* 137 F.3d 1253 (10th Cir. 1998) and *Bedrick* v. *Travelers Ins. Co.,* 93 F.3d 149 (4th Cir. 1996). Where the patient cannot improve or show significant recovery, an insurer may deny the coverage as unnecessary. Courts that have considered this limitation have tended to uphold it where it is explicit in the contract and have rejected it when it is not an express limitation on coverage. See *McGraw* v. *Prudential Ins. Co.,* 137 F.3d 1253 (10th Cir. 1998) and *Bedrick* v. *Travelers Ins. Co.,* 93 F.3d 149 (4th Cir. 1996) (rejecting limitation when not explicit in contract's medical necessity definition).

[12] In *Shilkret* v. *Annapolis Emergency Hospital,* 349 A.2d 245, 249-50 (Md. 1975), Maryland's highest court set forth what is still viewed as the seminal articulation of the modern standard of care for measuring professional liability:

"...that degree of care and skill which is expected to a reasonably competent practitioner in the same class to which he belongs, acting in the same or similar circumstances. Under this standard, advances in the profession, availability of facilities, specialization or general practice, proximity of specialists and special facilities, together with all other relevant considerations, are to be taken into account."

See also *Law and the American Health Care System,* op. cit., at 846.

[13] Since the UBH guidelines were not available to the authors, it is not known to what extent they refer to professional or national standards of care.

[14] For purposes of confidentiality, we do not identify the managed care organizations or the officials by name.

[15] Of course, if the contract limits coverage for specified conditions to certain treatments, this limitation in coverage would take precedence.

[16] It would probably seem that any insurer has an inherent conflict of interest because it is at risk for the cost of its decision. In fact, courts do not perceive the dual role of insurers as risk bearers and decision makers as a fatal flaw, although many will more closely review a record as a result.

[17] Advocates note the qualitative advances inherent in emphasizing outpatient over inpatient care wherever appropriate. Chris Koyanagi, Bazelon Center for Mental Health Law. Personal communication. April 5, 2002. (By the same token of course, on the outpatient side, providers of long-term psychotherapy and psychoanalysis have seen restrictions put on the scope and duration of their treatments, with a particular emphasis on short-term behavioral and cognitive therapy as preferred.)

[18] Aetna/U.S. HealthCare Inc./Prudential Health Plan of Hartford, CT; Excellus Health Plans of Rochester; Group Health Inc. of Manhattan; HIP Health Plan of Greater New York, Inc.; Oxford Health Plans of Trumbull, CT; and Vytra Health Plans of Long Island, Inc. *See:* "Landmark Agreements Give Consumers New Protections in HMO Disputes." NY Attorney General's Office Press Release. October 16, 2001. Available at http://www.oag.state.ny.us. Accessed October 29, 2001.

[19] In RE: United Behavioral Health, Consent Agreement with Maine Bureau of Insurance, op. cit. In RE: Cigna Behavioral Health, Inc., Consent Agreement with Maine Bureau of Insurance, Docket No. 00-3003. Available at http://www.state.me.us/pfr/ins/ins003003.htm. Accessed April 17, 2002.

[20] In *Metropolitan Life Insurance* v. *Massachusetts,* 471 U.S. 724 (1985), the Supreme Court affirmed the power of states to set minimum content standards in the case of insured ERISA plans. The case involved a Massachusetts state law mandating inpatient hospitalization coverage up to certain levels in the case of mental illness.

[21] A recent decision illustrating the still common practice of insurers to leave critical terms undefined is *Bynum* v. *Cigna Healthcare of North Carolina, Inc.,* 287 F.3d 305 (4th Cir., 2002) in which an insurer denied reconstructive facial surgery for a severely deformed infant on the grounds that the construction was excluded as "cosmetic" without ever defining the term.

[22] See *Dallis* v. *Aetna Life Ins. Co.,* 574 F.Supp. 547 (N.D. Ga. 1983), *aff'd,* 768 F.2d 1303 (11th Cir. 1985) (finding "no consensus among the courts" as to the definition of "necessary" care).

[23] The prospective nature of utilization review means that managed care affects not only coverage but access to the care itself. Courts therefore might consider professional liability law as a relevant source of law from which to derive an insurance standard of medical necessity. In recent years, courts have repeatedly noted the "two hats" of managed care, affecting both coverage and health care quality through their conduct. See *Pegram* v. *Herdrich,* 530 U.S. 211 (2000).

[24] Mass. Ann. Laws ch. 176O (1) (2001).

[25] HRS § 432E-1.4 (2000).

[26] We limited our review of state regulations to those available in the LEXIS-NEXIS legal databases.

[27] Md. Ins. Code Ann. § 15-10A-03(e) (2001).

[28] 28 Pa. Code § 9.504 (2001) and VT. Stat. tit. 8, § 4089f (2001).

[29] 29 U.S.C. § 1133 (2001).

[30] Individuals may seek judicial review of a claim's denial. In such a case the review is on the record rather than *de novo*. Under the standard of review set forth by the United States Supreme Court in *Firestone Tire and Rubber* v. *Bruch,* 489 U.S. 101 (1989), the plan administrator's decision is upheld unless the claimant can demonstrate that it is arbitrary and capricious or an abuse of discretion. Courts may conduct a more rigorous review when a claimant is able to demonstrate a conflict of interest; however, although the fact that the internal review was conducted by the insurer or the health plan

administrator raises the potential for conflict, the interest is not sufficient to compel a more rigorous review in every case. See *Firestone Tire and Rubber* v. *Bruch*, 489 U.S. 101 (1989); *Bedrick* v. *Travelers Ins. Co.*, 93 F.3d 149 (4th Cir. 1996).

[31] Pending patients' bill of rights legislation before Congress would establish independent review as a basic element of ERISA for all covered plans and health insurance arrangements. See H.R. and S. 1052, 107th Cong., 1st sess.

[32] 29 C.F.R. § 2560.503-1(b) (2001).

[33] *See* 29 C.F.R. §§ 2560.503-1(f), (i) (2001).

[34] *See* 29 C.F.R. §§ 2560.503-1 (i) (2001).

[35] 29 C.F.R. §§ 2560.503-1(h) (2001).

[36] *See id.*

[37] *See id.*

[38] *See id.*

[39] 5 U.S.C. § 8901 (2001).

[40] 5 C.F.R. § 890.105 (2001).

[41] *Id.*

[42] 5 C.F.R. § 890.107(c) (2001).

[43] Several cases have focused specifically on the use of "significant improvement" and "recovery" by insurers to narrow the scope of the treatments that can be considered medically necessary. See *McGraw* v. *Prudential Ins. Co.*, 137 F.3d 1253 (10th Cir. 1998) and *Bedrick* v. *Travelers Ins. Co.*, 93 F.3d 149 (4th Cir. 1996). Where the concept is not contractual but is a "gloss on the contract" imposed by utilization management review, courts have tended to overturn the insurer's decision. But where the contract documents actually specify recovery or short term improvements, courts will honor the limitation.

## Table 1. Medical Necessity Definitions in Published Literature (See Also Appendix C)

| ***Year*** | ***Author*** | ***Title, Source*** | ***Summary/Abstract*** | ***Medical Necessity Definition***[1] |
|---|---|---|---|---|
| 1994 | Sabin, James E. and Norman Daniels | "Determining 'Medical Necessity' in Mental Health Practice" *Hastings Center Report* 24(6):5–13 | The authors posed the question, "Should mental health insurance cover only disorders found in *DSM-IV*, or should it be extended to treatment for ordinary shyness, unhappiness, and other responses to life's hard knocks?" Through the use of six illustrative case studies, the authors examined the reasoning behind the determinations of medical necessity. The article includes a discussion of a recurrent conflict between "hard-line" and "expansive" views of medical necessity, noting that it frequently reflects unrecognized moral disagreement about the targets of clinical intervention and the ultimate goals of psychiatric treatment. The authors present three models for defining medical necessity and argue a defensible rationale for the "normal" model, which comprises a target of a medically defined deviation intended to decrease the impact of disease or disability. Three tests of medical necessity are offered: (1) Does it make distinctions the public and clinicians regard as fair? (2) Can it be administered in the real world? (3) Does it lead to results that society can afford? The authors conclude that the DSM-IV standard provides workable boundaries for medical necessity definitions. | Those mental health services that are essential for the treatment of a Member's mental health disorder as defined by the *DSM-IV* in accordance with generally accepted mental health practice. |

[1]Definitions have been taken verbatim from the relevant document; quotation marks have been omitted.

*Table 1. Continued*

| Year | Author | Title, Source | Summary/Abstract | Medical Necessity Definition[1] |
|---|---|---|---|---|
| 1998 | Chodoff, Paul | "Medical Necessity and Psychotherapy" *Psychiatric Services* 49(11):1481–1483 | Managed care and, specifically, the need to conform to medical necessity requirements have had a dramatic effect on the medical and psychiatric practice, especially on psychotherapy. The author describes the progression of the concept of medical necessity from a simple accounting of services reimbursable by insurance companies to an ambiguous term without definitional consensus. He describes its relationship to the medical model and discusses the incongruity between medical necessity and certain aspects of psychotherapy. He proposes a broader concept—health necessity—based on an evaluation of the advantages, disadvantages, and costs of medical and psychiatric services. | "Health Necessity" would rely on medical criteria when they are relevant but would also acknowledge that the health of the citizenry can be perceived in broader terms. A theoretical foundation for this concept may be found in the biopsychosocial model. Health necessity would be based on three broad fundamentals: uniform qualifications for practitioners, acceptable professional identities, and competence; criteria for the kinds of services that would be provided and covered; and a fair mechanism for resolution of disputes about questions of service coverage. The criteria for services would include biotechnical medical criteria when appropriate, as would be the case in most ordinary medical practice, but they would be acknowledged to be only a subset of the health necessity criteria. For mental health needs, a broad range of services could also be considered, including appropriate psychotherapy for individuals who may not fit comfortably with DSM-IV diagnostic categories but who suffer a significant degree of distress and interpersonal impairment. |
| 1998 | Ford, William | "Medical Necessity: Its Impact in Managed Mental Health Care" *Psychiatric Services* 49(2):183–184 | Discusses the impact of managed care medical necessity definitions on psychiatric care. Points to some possible reasons why MBHOs focus on cutting short-term costs rather than managing long-term costs, including short contract terms and labor-intensive reviews. | "Treatment necessity" or "clinical necessity" would require that, to qualify for payment, a service must be: for the treatment of mental illness and substance use disorders, or symptoms of these disorders, and impairments in day-to-day functioning related to them; for the purpose of preventing the need for a more intensive level of mental health and substance abuse care; for the purpose of preventing relapse of persons with mental illness and substance abuse disorders; efficient, in the sense that a less expensive treatment works as well as a more expensive treatment; and not for the patient's or provider's convenience. |

*Table 1. Continued*

| Year | Author | Title, Source | Summary/Abstract | Medical Necessity Definition[1] |
|---|---|---|---|---|
| 1999 | Singer, Sara J., Linda A. Bergthold, Carol Vorhaus, Alain Enthoven, et al. | "Decreasing Variation in Medical Necessity Decision Making" *Stanford University*, August, 1999 | This is an in-depth report looking into the question of medical necessity. It deals with the variation and inconsistencies of definitions that the various stakeholders have. It notes a paucity of research regarding health plan decision-making and whether medical necessity definitions play a real role in decision-making. It documents a number of conferences and original research, eventually concluding with a consensus for a model decision-making process and medical necessity definitions. It concludes by reviewing the various stakeholders, their concerns, and what actions they could take to decrease medical necessity variability. | For contractual purposes, an intervention will be covered if it is an otherwise covered category of service, not specifically excluded, and medically necessary. An intervention is medically necessary if, as recommended by the treating physician and determined by the health plan's medical director or physician designee, it is (all of the following): a health intervention for the purpose of treating a medical condition; the most appropriate supply or level of service, considering potential benefits and harms to the patient; and known to be effective in improving health outcomes. For new interventions, effectiveness is determined by scientific evidence. For existing interventions, effectiveness is determined first by scientific evidence, then by professional standards, then by expert opinion; and the cost-effectiveness for this intervention is compared to alternative interventions, including no intervention. "Cost-effective" does not necessarily mean lowest price. An intervention may be medically indicated yet not be a covered benefit or meet this contractual definition of medical necessity. A health plan may choose to cover interventions that do not meet this contractual definition of medical necessity. |
| 1999 | Ireys, Henry T., Elizabeth Wehr, and Robert E. Cooke | "Defining Medical Necessity: Strategies for Promoting Access to Quality Care for Persons with Developmental Disabilities, Mental Retardation, and Other Special Health Care Needs" *National Center for Education in Maternal and Child Health*, Georgetown University | Discusses medical necessity determinations in regards to persons with developmental disabilities. The report has a flow chart showing the dynamics of medical necessity decisions within current service systems. It also provides its own specifications for determining medical necessity. | A covered service or item is medically necessary if it will do, or is reasonably expected to do, one or more of the following: arrive at a correct medical diagnosis; prevent the onset of an illness, condition, injury, or disability (in the individual or in covered relatives, as appropriate); reduce, correct, or ameliorate the physical, mental, developmental, or behavioral effects of an illness, condition, injury, or disability; and assist the individual to achieve or maintain sufficient functional capacity to perform age-appropriate or developmentally appropriate daily activities. The MCO or insurer must determine medical necessity on the basis of health information provided by the following persons: the individual (as appropriate to his or her age and communicative abilities), the individual's family, the primary care physician, and consultants with appropriate specialty training, as well as other providers, programs, multidisciplinary teams, educational institutions, or agencies that have evaluated the individual. The determination of medical necessity must be made on an individual basis and must consider the functional capacity of the person and those capacities that are appropriate for persons of the same age or developmental level and available research findings, health care practice guidelines, and standards issued by professionally recognized organizations or governmental agencies. Final determinations will be made by a physician in concert with the following persons: the individual's primary care physician; a consultant with experience appropriate to the individual's age, disability or chronic condition; and the individual and/or family. Medically necessary services must be delivered in a setting that is appropriate to the specific health needs of the individual. |

[1]Definitions have been taken verbatim from the relevant document; quotation marks have been omitted.

*Table 1. Continued*

| **Year** | **Author** | **Title, Source** | **Summary/Abstract** | **Medical Necessity Definition[1]** |
|---|---|---|---|---|
| 1999 | National Health Law Program | "Medical Necessity Definition, Model Medicaid Managed Care Contract Provisions" | | Medically necessary care is the care which, in the opinion of the treating physician, is reasonably needed: to prevent the onset or worsening of an illness, condition, or disability; to establish a diagnosis; to provide palliative, curative, or restorative treatment for physical and/or mental health conditions; and to assist the individual to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the individual and those functional capacities that are appropriate for individuals of the same age. |
| 1999 | Corlin, Richard | "Statement of the AMA to the Committee on Health, Education, Labor and Pensions, U.S. Senate" | | "Medical necessity" means: "Health care services or products that a prudent physician would provide to a patient for the purpose of preventing, diagnosing or treating an illness, injury, disease or its symptoms in a manner that is: (1) in accordance with generally accepted standards of medical practice; (2) clinically appropriate in terms of type, frequency, extent, site, and duration; and (3) not primarily for the convenience of the patient, physician, or other health care provider." |
| 2000 | Ford, William | "Medical Necessity and Psychiatric Managed Care" *The Psychiatric Clinics of North America* 23(2):309–317 | The concept of medical necessity is one tool used by third-party payers to contain their financial risk in a seemingly nonarbitrary manner. The definitions tend to reflect corporation philosophies that would need to change to achieve real parity. | Comprehensive reform to increase commercial psychiatric insurance coverage must include changing the definition of medical necessity by reorienting insurers from an acute care model to a model that provides both care for acute episodes and longer-term care designed to manage chronic conditions. Such longer-term management includes delivering services designed to avoid future acute episodes. Commercial insurance ought to understand that a legitimate function of psychiatric services is to maintain behavioral health in addition to returning someone to health after an acute episode. Ford proposed the concept of "treatment necessity" or "clinical necessity" to encompass this broader view of the goals of psychiatric services. Treatment necessity requires a service to be: for the treatment of mental illness and substance abuse disorders, or symptoms of these disorders, and impairments in day-to-day functioning related to them; for the purpose of preventing the need for a more intensive level of psychiatric care; for the purpose of preventing relapse of persons with psychiatric disorders; consistent with generally accepted clinical practice for psychiatric disorders; and not solely for the patient's or provider's convenience. |

*Table 1. Continued*

| Year | Author | Title, Source | Summary/Abstract | Medical Necessity Definition[1] |
|---|---|---|---|---|
| 2000 | Fleishman, Martin | "What is Psychiatric 'Medical Necessity'?" *Psychiatric Services* 51(6):711–712, 719 | Reviews AMA's definition of medical necessity and points out problems with its application to psychiatry. Recommends its own definition for psychiatry after a discussion of HIPAA law and possible implications for fraud in psychiatry. | AMA council on medical service defined medically necessary treatment as: health care products or services that a prudent physician would provide to a patient for the purpose of diagnosing or treating an illness, injury, disease, or its symptoms in a manner that is: (1) in accordance with generally accepted standards of medical practice; (2) clinically appropriate in type, frequency, level, site, and duration; and (3) not primarily for the convenience of the patient, physician, or other health care provider. |
| 2001 | Force, C. T. | "A Strong and Consistent Definition of Medical Necessity Forms the Core of Meaningful Patient Protections" *Consortium for Citizens with Disabilities* | | The CCD believes that a federal definition of medical necessity should require plans to cover services that are: calculated to prevent, diagnose, correct, or ameliorate a physical or mental condition that threatens life, causes pain or suffering, or results in illness, disability, or infirmity; calculated to maintain or preclude deterioration of health or functional ability; individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness, disability, or injury under treatment; not in excess of the individual's needs; necessary and consistent with generally accepted professional medical standards as determined by the Secretary of Health and Human Services or the state Department of Health; and reflective of the level of service that can be safely provided and for which no equally effective treatment is available. |
| 2000 | American Medical Association | AMA Model Provider Contract | | Section 1.9 defines medically necessary/medical necessity as health care services or products that a prudent physician would provide to a patient for the purpose of preventing, diagnosing, or treating an illness, injury, disease, or its symptoms in a manner that is (1) in accordance with generally accepted standards of medical practice; (2) clinically appropriate in terms of type, frequency, extent, site, and duration; and (3) not primarily for the convenience of the patient, physician, or other health care provider. |

[1]Definitions have been taken verbatim from the relevant document; quotation marks have been omitted.

## Table 2. Medical Necessity Definitions: Managed Care Industry

| ***Year*** | ***Source*** | ***Medical Necessity Definition***[1] |
|---|---|---|
| 2000 | Highmark Blue Cross Blue Shield (from AHRQ report on coverage decisions) | Coverage process—contractual definition of medical necessity, which includes the following criteria for establishing the medical necessity of a service: appropriate for symptoms, diagnosis, and treatment of a condition, illness, or injury; provided for diagnosis, direct care, or treatment; in accordance with the standards of good medical practice; not primarily for the convenience of the member or member's provider; the most appropriate supply or level of service that can be safely provided to the member. To determine what services meet this definition, Highmark has an information-gathering process that includes systematic reviews of published literature, a consulting program with practicing physicians, review of coverage decisions by Highmark managers, review by an independent Medical Affairs Committee. |
| 2001 | ValueOptions Providers Manual (available online) | Medically necessary treatment is that which is: intended to prevent, diagnose, correct, cure, alleviate, or preclude deterioration of a diagnosable condition (*ICD-9* or *DSM-IV*) that threatens life, causes pain or suffering, or results in illness or infirmity; expected to improve an individual's condition or level of functioning; individualized, specific, and consistent with symptoms and diagnosis, and not in excess of patient's needs; essential and consistent with nationally accepted standard evidence generally recognized by mental health or substance abuse care professions or publications; reflective of a level of service that is safe, where no equally effective, more conservative, and less costly treatment is available; not primarily intended for the convenience of the recipient, caretaker, or provider; no more intensive or restrictive than necessary to balance safety, effectiveness, and efficiency; and not a substitute for non-treatment services addressing environmental factors. |
| 2000 | Anonymous Managed Behavioral Health Plan Provider Packet | "Medical Necessity" is used here to mean care which that is determined to be effective, appropriate and necessary to treat a given patient's disorder. For all levels and types of care, the definition is as follows: (1) the patient must have been diagnosed with a psychiatric illness by a licensed mental health professional; (2) symptoms of this illness must accord with those described in the *DSM-IV*; (3) the diagnosis must have been arrived at prior to admission in a face-to-face encounter between the professional and patient. [Note: The company defines separate admission and continuing care criteria by type of service, e.g., inpatient and outpatient psychiatric treatment, substance dependence treatment, residential treatment, methadone maintenance, electroconvulsive therapy, psychological testing, etc.] |
| 2000 | United Behavioral Health<br>Source: UBH Consent Agreement with Maine Bureau of Insurance | Medical Necessity—health care services and supplies that are determined by the Plan to be medically appropriate, and (1) necessary to meet the basic health needs of the covered person; (2) rendered in the type of setting appropriate for the delivery of the health service; (3) consistent in type, frequency, and duration of treatment with United Behavioral Health guidelines; (4) consistent with the diagnosis of the condition; (5) required for reasons other than the comfort or convenience of the covered person or his or her physician; and (6) of demonstrated medical value. [Available at: http://www.state.me.us/pfr/ins/ins003005.htm] |
| 1999 | Cigna Behavioral Health Care Source: Cigna's "Level of Care Guidelines for Mental Health and Substance Abuse Treatment" | In considering the appropriateness of any level of care, the four basic elements of Medical Necessity should be present: (1) a diagnosis as defined by standard diagnostic nomenclatures (*DSM-IV* or its equivalent in *ICD-9-CM*) and an individualized treatment plan appropriate for the participant's illness or condition; (2) a reasonable expectation that the participant's illness, condition, or level of functioning will improve through treatment; (3) the treatment is safe and effective according to nationally accepted standard clinical evidence generally recognized by mental health or substance abuse professionals; and (4) it is the most appropriate and cost-effective level of care that can safely be provided for the participant's immediate condition.<br>[Available at: https://apps.cignabehavioral.com/web/basicsite/provider/pdf/LevelofCareGuidelines_2003.pdf] |

## Table 3. Medical Necessity Definitions Identified in Case Law (Sorted by Case Name)

| ***Year*** | ***Case*** | ***Medical Necessity Definition***[1] |
|---|---|---|
| 1996 | Bancroft v. Tecumseh Products Company | Covered charges include only those incurred for services or items specifically recommended by a licensed physician as necessary for the diagnosis, care, or treatment of a physical or mental condition, and falling within the Plan guidelines. For a service to be determined as necessary for medical care, it must be widely accepted by medical professionals in the United States as effective, appropriate, and essential under recognized health care standards. |
| 1996 | Bedrick v. Travelers Insurance | The Travelers determines, in its discretion, if a service or supply is medically necessary for the diagnosis and treatment of an accidental injury or sickness. This determination is based on and consistent with standards approved by Travelers medical personnel. These standards are developed, in part, with consideration to whether the service or supply meets the following: *It is appropriate and required for the diagnosis or treatment of the accidental injury or sickness. *It is safe and effective according to accepted clinical evidence reported by generally recognized medical professionals and publications. *There is not a less intensive or more appropriate diagnostic or treatment alternative that could have been used in lieu of the service or supply given. A determination that a service or supply is not medically necessary may apply to the entire service or supply or to any part of the service or supply. |
| 1994 | Blue Cross and Blue Shield of Virginia v. Katharine Keller | A medically necessary service is one required to identify or treat an illness, injury, or pregnancy-related condition which a Provider has diagnosed or reasonably suspects. To be medically necessary, the service must: be consistent with the diagnosis of your condition; be in accordance with the standards of good medical practice; not be for the convenience of the patient, the patient's family, or the Provider; and be performed in the least costly setting required by your medical condition. |
| 1993 | Dettmer Clinic v. Associated Insurance Companies, Inc. | The group contract defines "medically necessary" or "medical necessity" as those: services or supplies, provided by a Provider, Facility, or Provider Individual, which are required for treatment of illness, injury, diseased condition, or impairment and are: (a) consistent with the Insured's diagnosis or symptoms; (b) appropriate treatment according to generally accepted standards of medical practice; (c) not provided only as a convenience to the Insured or Provider (d) not Investigational or unproven; and (e) not excessive in scope, duration, or intensity to provide safe, adequate, and appropriate treatment to the Insured. Any service or supply provided at a Provider Facility will not be considered medically necessary if the Insured's symptoms or condition indicate that it would be safe to provide the service or supply in a less comprehensive setting. The fact that any particular Provider Individual may prescribe, order, recommend, or approve a service, supply, or level of care does not, of itself, make such treatment medically necessary or make the charge a Covered Charge under this Contract. |
| 1996 | Esdale v. American Community Mutual Insurance Company | Medically necessary means recommended by a licensed physician and commonly recognized in the licensed physician's profession as proper care or treatment. Medically Necessary does not mean a procedure that is deemed experimental or investigational in nature by any appropriate technological assessment body established by any state or federal government. |
| 1993 | Evans v. Blue Cross Blue Shield of South Carolina | Medically Necessary: benefits are payable for services or supplies that are medically necessary. The simple fact that a physician has performed or prescribed something does not mean that it is medically necessary. Some services or supplies that you get may not be covered under your insurance health policy. Expenses for the following will not be paid:<br>*Surgery just to make you look better (usually called cosmetic surgery)<br>*Experimental surgery or services, such as acupuncture or sex change<br>*Services or supplies that are not medically necessary, including luxury or convenience items and travel expenses (except those provided for human organ transplants). |

[1]Definitions are verbatim from case law; quotation marks have been omitted.

*Table 3. Continued*

| Year | Case | Medical Necessity Definition[1] |
|---|---|---|
| 1992 | Farley v. Benefit Trust Life Insurance Company | The insurance contract defines “medically necessary” treatment as “drugs, therapies, or other treatments that are required and appropriate care for the sickness or the injury; and that are given in accordance with generally accepted principles of medical practice in the U.S. at the time furnished; and that are approved for reimbursement by the Health Care Financing Administration; and that are not experimental, educational, or investigational; and that are not furnished in connection with medical or other research.” |
| 1994 | Fenio v. Mutual of Omaha Insurance Company | “Medically Necessary” service or supply means one which: (a) is appropriate and consistent with the diagnosis in accord with accepted standards of community practice; (b) is not considered experimental or investigative; (c) could not have been omitted without adversely affecting the insured person’s condition or quality of medical care. |
| 1993 | Florence Nightingale Nursing Service, Inc. v. Blue Cross Blue Shield of Alabama | Medically Necessary means the use of a Hospital or the furnishing of other services or supplies which are necessary to treat a Member’s illness or injury. To be medically necessary, the services and supplies furnished must (as determined by the Claims Administrator): be appropriate and necessary for the symptoms, diagnosis, or treatment of the Member’s condition, disease, ailment, or injury; be provided for the diagnosis or direct care of the Member’s medical condition; be in accordance with standards of good medical practice accepted by the organized medical community; and not be solely for the convenience of the Member, his family, his Physician or another provider of services; not be experimental or investigative; and be performed in the least costly setting the Member’s medical condition requires. |
| 1995 | Grethe v. Trustmark Insurance Company | The term “Medically Necessary” as used above means: drugs, therapies, or other treatments that are required and appropriate for care of the sickness or the injury; and that are given in accordance with generally accepted principles of medical practice in the U.S. at the time furnished; and that are reimbursed by Medicare; and are not deemed to be experimental, educational, or investigational in nature by any appropriate technological assessment body established by any state or federal government; and that are not furnished in connection with medical or other research. |
| 1996 | Harrison v. Aetna Life Insurance Company | “Necessary” means a service or supply which is necessary for the: diagnosis; or care; or treatment; of the physical or mental condition involved. It must be widely accepted professionally in the United States as: effective; and appropriate; and essential; based upon recognized standards of the health care specialty involved. |
| 2001 | Hundley v. Wenzel | Medically necessary means that a service or supply is necessary and appropriate for the diagnosis and treatment of an illness or injury based on generally accepted current medical practice. A service or supply will not be considered medically necessary if any of the following apply: (1) It is provided only as a convenience to the covered person or provider; (2) It is not appropriate treatment for the covered person’s diagnosis or symptoms; (3) It exceeds (in scope, duration, or intensity) the level of care that is needed to provide safe, adequate, and appropriate diagnosis or treatment; (4) It is part of an experimental treatment. The fact that any particular doctor may prescribe, order, recommend, or approve a service or supply does not, of itself, make the service or supply medically necessary. |
| 2000 | Juliano v. HMO of New Jersey, Inc., dba U.S. HealthCare | The Contract defines “Medically Necessary or Medical Necessity” as appropriate and necessary services as defined by HMO which are rendered to a Member for a condition requiring, according to generally accepted principles of good medical practice, the diagnosis or direct care and treatment of an illness or injury and which are not provided only as a convenience. |

*Table 3. Continued*

| Year | Case | Medical Necessity Definition[1] |
|---|---|---|
| 1998 | Killian vs. HealthSource Provident Administrators, Inc. | Medically Necessary and/or Medical Necessity—Services or supplies provided by a: (1) Hospital, (2) Physician, or (3) other qualified provider...are medically necessary if they are: (1) required for the diagnosis and/or treatment of the particular condition, disease, injury or illness; (2) consistent with the symptom or diagnosis and treatment of the condition, disease, injury, or illness; (3) commonly and usually noted throughout the medical field as proper to treat the diagnosed condition, disease, injury, or illness; and (4) the most fitting supply or level of service which can be safely given. |
| 1995 | Kornman v. Blue Cross Blue Shield of Louisiana | 1985 policy defines “medically necessary” as health services which: are appropriate and consistent with the diagnosis and which, in accordance with accepted medical standards in the State of Louisiana, could not have been omitted without adversely and severely affecting the patient’s condition; are not primarily custodial care; are appropriate and can be safely used under the circumstances. Inpatient hospital services should be used only when a lesser equipped facility (e.g., outpatient hospital services, physician’s office, etc) could adversely and severely affect the patient’s condition. 1987 policy: “Medically Necessary” means a service or treatment which, in the judgment of the plan: (1) Is appropriate and consistent with the diagnosis and which, in accordance with accepted medical standards in the State of Louisiana, could not have been omitted without adversely affecting the patient’s condition or the quality of medical care rendered; (2) Is not primarily custodial care; and (3) as to institutional care, could not have been provided in a physician’s office, in the outpatient department of a hospital, or in a lesser facility without affecting the patient’s condition or quality of medical care rendered. |
| 1998 | McGraw v. Prudential Insurance | To be considered “needed”, a service or supply must be determined by Prudential to meet all of these tests: (a) It is ordered by a Doctor; (b) It is recognized throughout the Doctor’s profession as safe and effective, is required for the diagnosis or treatment of the particular sickness or injury, and is employed appropriately in a manner and setting consistent with generally accepted United States medical standards; (c) It is neither educational nor experimental or investigational in nature. The case also mentions: “As we read the record, Prudential has modified its definition of “medical necessary” with the additional requirement the treatment provide a measurable and substantial increase in functional ability for a condition having potential for significant improvement.” |
| 2001 | Milone v. Exclusive Health Care, Inc. | The Plan defines medical necessity as follows: A medically necessary service or supply means one which is ordered or authorized by the Primary Care Physician, and which the Primary Care Physician, our medical staff or our Medical Director and/or a qualified party or entity selected by us determines is: (a) provided for the diagnosis or direct treatment of an injury or sickness; (b) appropriate and consistent with the symptoms and findings or diagnosis and treatment of the member’s injury or sickness; (c) provided in accord with generally accepted medical practice on a national basis; and (d) the most appropriate supply or level of service which can be provided on a cost-effective basis (including, but not limited to, inpatient vs. outpatient care, electric vs. manual wheelchair, surgical vs. medical or other types of care). The fact that the member’s physician prescribes services or supplies does not automatically mean such services or supplies are medically necessary and covered by the Contract. |
| 1999 | Milone v. Exclusive Healthcare, Inc. | A medically necessary service or supply means one which is ordered or authorized by the Primary Care Physician, and with the Primary Care Physician, our medical staff or our Medical Director and/or a qualified party or entity selected by us determines is: (1) provided for the diagnosis or direct treatment of an injury or sickness; (2) appropriate and consistent with the symptoms and findings or diagnosis and treatment of the member’s injury or sickness; (3) provided in accord with generally accepted medical practice on a national basis; and (4) the most appropriate supply or level of service which can be provided on a cost-effective basis (including, but not limited to, inpatient vs. outpatient care, electric vs. manual wheelchair, surgical vs. medical or other types of care). The fact that the member’s physician prescribes services or supplies does not automatically mean such services or supplies are medically necessary and covered by the Contract. |

[1] Definitions have been taken verbatim from the relevant document; quotation marks have been omitted.

*Table 3. Continued*

| Year | Case | Medical Necessity Definition[1] |
|---|---|---|
| 1997 | Nichols v. Trustmark Insurance Company | Benefits will be paid only for "medically necessary" care and treatment of sickness and injury. As used above, 'medically necessary' means: drugs, therapies, or other treatments that are required and appropriate for care of the sickness or the injury; and that are given in accordance with generally accepted principles of medical practice in the U.S. at the time furnished; and that are approved for reimbursement by the Health Care Financing Administration; and that are not experimental, educational, or investigational; and that are not furnished in connection with medical or other research. |
| 1994 | Northwest Laundry and Dry Cleaners Health and Welfare Trust Fund v. Burzynski | To be "medically necessary" under the Plan, a treatment must meet two requirements, measured under Oregon law. First, the treatment must be "appropriate and consistent with the diagnosis (in accord with accepted standards of community practice)." Second, "medically necessary" treatments "could not be omitted without adversely affecting the covered person's condition or the quality of medical care." |
| 2002 | Rush Prudential HMO, Inc., Petitioner v. Debra C. Moran et al. | A service is covered as "medically necessary" if Rush finds:<br>(a) [The service] is furnished or authorized by a Participating Doctor for the diagnosis or the treatment of a Sickness or Injury or for the maintenance of a person's good health.<br>(b) The prevailing opinion within the appropriate specialty of the United States medical profession is that [the service] is safe and effective for its intended use, and that its omission would adversely affect the person's medical condition.<br>(c) It is furnished by a provider with appropriate training, experience, staff and facilities to furnish that particular service or supply. |
| 1993 | Scalamandre v. Oxford Health Plans, Inc. | Medically necessary services and/or supplies are defined as: the use of services or supplies as provided by a hospital, skilled nursing facility, physician, or other provider required to identify or treat a Member's illness or injury and which, as determined by the Medical Director, are: (1) Consistent with the symptoms or diagnosis and treatment of the Covered Person's condition, disease, ailment or injury; (2) Appropriate with regard to standards of good medical practice; (3) Not solely for the convenience of the Covered Person, his or her physician, hospital, or other health care provider; and (4) The most appropriate supply or level of service which can be safely provided to the Covered Person. When specifically applied to an inpatient, it further means that the Covered Person's medical symptoms or condition requires that the diagnosis or treatment cannot be safely provided to the Covered Person as an outpatient. |
| 2001 | Smith v. Newport News Shipbuilding Health Plan | The Plan defines 'necessary' as follows: A service or supply is necessary if it is for the diagnosis, care, or treatment of a physical or mental condition and widely accepted professionally in the U.S. as effective, appropriate, and essential, based upon recognized standards of the health care specialty involved. |
| 1997 | Sophie v. Lincoln National Life Insurance Company | Medically necessary is defined as: The extent of services required to diagnose or treat a Bodily Injury or Sickness which is known to be safe and effective by most Qualified Practitioners who are licensed to diagnose or treat that Bodily Injury or Sickness. Such services must be performed in the least costly setting required by the patient's condition, and must not be provided primarily for the convenience of the patient of the Qualified Practitioner. |

*Table 3. Continued*

| ***Year*** | ***Case*** | ***Medical Necessity Definition[1]*** |
|---|---|---|
| 1997 | Squillace v. Wyoming State Employee and Officials Group Insurance Board of Administration | "Medically Necessary" means any services and supplies provided for the diagnosis and treatment of a specific illness, injury, or condition. Such services and supplies must be: ordered by a doctor; required for the treatment or management of a medical symptom or condition; the most efficient and economical service which can safely be provided to such person; and provided in accordance with approved and generally accepted medical or surgical practice. We may require proof in writing satisfactorily to us that any type of treatment, service, or suppy received is medically necessary. Medical necessity will be determined solely by us. The fact that a doctor may prescribe, order, recommend, or approve a service does not, in itself, make such service or supply medically necessary. |
| 1996 | Sven v. Principal Mutual Life Insurance Company | "Medically Necessary Care" is defined as: any confinement, treatment, or service that is prescribed by a physician and determined by the Company [Principal] to be: (a) necessary and appropriate; and (b) non-experimental and non-investigational and not in conflict with accepted medical standards. |
| 1994 | Whitehead v. Federal Express Corporation | Eligible expenses for treatment of an illness or injury must be medically necessary under all plan options. Medical necessity is determined by the claims paying administrator. Care that is medically necessary may include, but is not limited to, care that is: *commonly and customarily recognized as standards of good practice; *appropriate and consistent with the diagnosis or treatment of an illness or injury; *appropriate supply or level of service that can be safely provided. |
| 1998 | Winnega v. North Central Health Protection Plan | Medically necessary services or supplies are defined as: (a) Required for diagnosis or treatment of the illness or symptoms; (b) provided for the diagnosis or direct care and treatment of the illness; (c) Within the standards of normal medical practice; (d) Not primarily for the convenience of the Participant or any provider; and (e) a supply or level of services required to provide safe and adequate care. |

[1]Definitions have been taken verbatim from the relevant document; quotation marks have been omitted.

## Table 4. Medical Necessity Definitions Contained in State Statutes and Regulations

| ***State*** | ***Statute/Regulation*** | ***Medical Necessity Definition[1]*** |
|---|---|---|
| Alabama | None | None |
| Alaska | None | None |
| Arizona | None | None |
| Arkansas | Ark. Code § 23-99-507 (2001) | (b) The term "medical necessity" as applied to benefits for mental illness and developmental disorders means: (1) Reasonable and necessary for the diagnosis or treatment of a mental illness, or to improve or to maintain or to prevent deterioration of functioning resulting from the illness or developmental disorder; (2) Furnished in the most appropriate and least restrictive setting in which services can be safely provided; (3) The most appropriate level or supply of service which can safely be provided; and (4) Could not have been omitted without adversely affecting the individual's mental or physical health, or both, or the quality of care rendered. |
| California | Cal. Wel. & Inst. Code § 14059.5 (2001) | "Medically necessary" or "medical necessity": A service is "medically necessary" or a "medical necessity" when it is reasonable and necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain. |
| Colorado | None | None |
| Connecticut | None | None |
| Delaware | 16 Del. Code § 9119 (2000) (IRO Statute) | For the purpose of this act, "medical necessity" means the providing of covered health services or products that a prudent physician would provide to a patient for the purpose of diagnosing or treating an illness, injury, or disease or its symptoms, in a manner that is: (1) In accordance with the generally accepted standards of medical practice; (2) Consistent with the symptoms or treatment of the condition; and (3) Not solely for anyone's convenience. |
| District of Columbia | None | None |
| Florida | Fla. Stat. § 627.732 (2001) | "Medically necessary" refers to a medical service or supply that a prudent physician would provide for the purpose of preventing, diagnosing, or treating an illness, injury, disease, or symptom in a manner that is: (a) In accordance with generally accepted standards of medical practice; (b) Clinically appropriate in terms of type, frequency, extent, site, and duration; and (c) Not primarily for the convenience of the patient, physician, or other health care provider. |
| Georgia | O.C.G.A. § 33-20A-31 (2000) (IRO Statute) | (5) "Medical necessity," "medically necessary care," or "medically necessary and appropriate" means care based upon generally accepted medical practices in light of conditions at the time of treatment which is: (A) Appropriate and consistent with the diagnosis and the omission of which could adversely affect or fail to improve the eligible enrollee's condition; (B) Compatible with the standards of acceptable medical practice in the United States; (C) Provided in a safe and appropriate setting given the nature of the diagnosis and the severity of the symptoms; (D) Not provided solely for the convenience of the eligible enrollee or the convenience of the health care provider or hospital; and (E) Not primarily custodial care, unless custodial care is a covered benefit under the eligible enrollee's evidence of coverage. |

*Table 4. Continued*

| ***State*** | ***Statute/Regulation*** | ***Medical Necessity Definition***[1] |
|---|---|---|
| Hawaii | HRS § 432E-1.4 (2000) (IRO Statute) | Medical necessity (b) A health intervention is medically necessary if it is recommended by the treating physician or treating licensed health care provider, is approved by the health plan's medical director or physician designee, and is: (1) For the purpose of treating a medical condition; (2) The most appropriate delivery or level of service, considering potential benefits and harms to the patient; (3) Known to be effective in improving health outcomes; provided that: (A) Effectiveness is determined first by scientific evidence; (B) If no scientific evidence exists, then by professional standards of care; and (C) If no professional standards of care exist or if they exist but are outdated or contradictory, then by expert opinion; and (4) Cost-effective for the medical condition being treated compared to alternative health interventions, including no intervention. For the purposes of this paragraph, cost-effective shall not necessarily mean lowest price. |
| Idaho | None | None |
| Illinois | 215 ILCS 105/2 (2001) | "Medically necessary" means that a service, drug, or supply is necessary and appropriate for the diagnosis or treatment of an illness or injury in accord with generally accepted standards of medical practice at the time the service, drug, or supply is provided. When specifically applied to a confinement it further means that the diagnosis or treatment of the covered person's medical symptoms or condition cannot be safely provided to that person as an outpatient. A service, drug, or supply shall not be medically necessary if it: (i) is investigational, experimental, or for research purposes; or (ii) is provided solely for the convenience of the patient, the patient's family, physician, hospital, or any other provider; or (iii) exceeds in scope, duration, or intensity that level of care that is needed to provide safe, adequate, and appropriate diagnosis or treatment; or (iv) could have been omitted without adversely affecting the covered person's condition or the quality of medical care; or (v) involves the use of a medical device, drug, or substance not formally approved by the United States Food and Drug Administration. |
| Indiana | None | None |
| Iowa | Iowa Code 514J.5 | Medical necessity is defined as the insurer's plan defines it. |
| Kansas | None | None |
| Kentucky | None | None |
| Louisiana | None | None |
| Maine | 24-A M.R.S. § 4301-A (11) (2000) | Medical Necessity. "Medical necessity" means health care services or products that a prudent physician or other health care practitioner would provide to an enrollee for the purpose of preventing, diagnosing, or treating an illness, injury, disease, or the symptoms of an illness, injury, or disease in a manner that is: (A) In accordance with generally accepted standards of medical practice; (B) Clinically appropriate in terms of type, frequency, extent, site, and duration; and (C) Not primarily for the convenience of the enrollee or physician or other health care practitioner. |
| Maryland | COMAR § 10.09.62.01 (2001) (Medicaid Managed Care Regulations) | "Medical necessity" means what is medically necessary and appropriate. |

[1] Definitions have been taken verbatim from the relevant document; quotation marks have been omitted.

*Table 4. Continued*

| ***State*** | ***Statute/Regulation*** | ***Medical Necessity Definition[1]*** |
|---|---|---|
| Massachusetts | Mass. Ann. Laws ch. 176O (1) (2001) (IRO Statute) | "Medical necessity" or "medically necessary." health care services that are consistent with generally accepted principles of professional medical practice. |
| Michigan | None | None |
| Minnesota | Minn. Stat. § 62Q.53 (2000) (IRO Statute) | "Medically necessary care" means health care services appropriate, in terms of type, frequency, level, setting, and duration, to the enrollee's diagnosis or condition, and diagnostic testing and preventive services. Medically necessary care must be consistent with generally accepted practice parameters as determined by health care providers in the same or similar general specialty as typically manages the condition, procedure, or treatment at issue and must: (1) help restore or maintain the enrollee's health; or (2) prevent deterioration of the enrollee's condition. |
| Mississippi | None | None |
| Missouri | None | None |
| Montana | None | None |
| Nebraska | None | None |
| Nevada | None | None |
| New Hampshire | None | None |
| New Jersey | None | None |
| New Mexico | None | None |
| New York | Proposed Legislation<br>A.5048a (2001) (In Assembly Committee on Rules as of January 9, 2002) | *PROPOSED DEFINITION:* "medically necessary" means, with respect to a health care service, that it has been reasonably determined, and could be shown, by the enrollee's health care professional in consultation with the patient, or could be reasonably determined and shown by a health care professional in consultation with the patient, to be consistent with the enrollee's condition, circumstances and best interests in relation to type, frequency, site and duration, and with professional health care practice, unless it is reasonably shown by means of substantial medical and scientific literature, and considering the enrollee's condition, circumstances and best interests, that either (a) that the health care service would be unsafe or ineffective, or (b) that the health care plan's preferred health care service or no service would lead to an equally good outcome. "Medical necessity" is the quality of being medically necessary. All definitions in section forty-nine hundred of this chapter shall apply to this subdivision. |

*Table 4. Continued*

| ***State*** | ***Statute/Regulation*** | ***Medical Necessity Definition[1]*** |
|---|---|---|
| North Carolina | G.S. § 58-3-200(b) | Medical Necessity—An insurer that limits its health benefit plan coverage to medically necessary services and supplies shall define "medically necessary services or supplies" in its health benefit plan as those covered services or supplies that are: (1) Provided for the diagnosis, treatment, cure, or relief of a condition, illness, injury, or disease; and, except as allowed under G.S.58-3-255, not for experimental, investigational, or cosmetic purposes. (2) Necessary for and appropriate to the diagnosis, treatment, cure, or relief of a health condition, illness, injury, disease, or its symptoms. (3) Within generally accepted standards of medical care in the community. (4) Not solely for the convenience of the insured, the insured's family, or the provider. For medically necessary services, nothing in this subsection precludes an insurer from comparing the cost-effectiveness of alternative services or supplies when determining which of the services or supplies will be covered. |
| North Dakota | None | None |
| Ohio | None | None |
| Oklahoma | O.A.C. § 317:30-5-46 (2000) (Statute regarding inpatient psychiatric facilities) | (B) Medical necessity criteria for acute psychiatric admissions. Acute psychiatric admissions for children 13 or older must meet the terms and conditions contained in (i), (ii), (iii) and two of the (iv)(I) to (v)(III) of this subparagraph. Children 12 or younger must meet the terms or conditions contained in (i), (ii), (iii) and one of (iv)(I) to (iv)(IV), and one of (v)(I) to (v)(III) of this subparagraph.<br>(i) Any DSM-IV-R Axis 1 primary diagnosis with the exception of V-codes, adjustment disorders, and substance related disorders, accompanied by a detailed description of the symptoms supporting the diagnosis. In lieu of a qualifying Axis I diagnosis, children 18-21 years of age may have an Axis II diagnosis of any personality disorder.<br>(ii) Conditions are directly attributable to a mental disorder as the primary need for professional attention (this does not include placement issues, criminal behavior, status offenses). Adjustment or substance related disorder may be a secondary Axis I diagnosis.<br>(iii) It has been determined by the Gatekeeper that the current disabling symptoms could not have been managed or have not been manageable in a lesser intensive treatment program.<br>(iv) Within the past 48 hours the behaviors present an imminent life threatening emergency such as evidenced by:<br>(I) Specifically described suicide attempts, suicide intent, or serious threat by the patient.<br>(II) Specifically described patterns of escalating incidents of self-mutilating behaviors.<br>(III) Specifically described episodes of unprovoked significant physical aggression and patterns of escalating physical aggression in intensity and duration.<br>(IV) Specifically described episodes of incapacitating depression or psychosis that result in an inability to function or care for basic needs.<br>(v) Requires secure 24-hour nursing/medical supervision as evidenced by:<br>(I) Stabilization of acute psychiatric symptoms.<br>(II) Needs extensive treatment under physician direction.<br>(III) Physiological evidence or expectation of withdrawal symptoms which require 24-hour medical supervision.<br>(C) Medical necessity criteria for continued stay—acute psychiatric admission. Continued stay—acute psychiatric admissions must meet all of the conditions set forth in (i) to (iv) of this subparagraph. |

[1] Definitions have been taken verbatim from the relevant document; quotation marks have been omitted.

*Table 4. Continued*

| ***State*** | ***Statute/Regulation*** | ***Medical Necessity Definition***[1] |
|---|---|---|
| Oklahoma | O.A.C. § 317:30-5-46 (2000) (Statute regarding inpatient psychiatric facilities) | (i) Any *DSM-IV-R* axis 1 primary diagnosis with the exception of V-Codes, adjustment disorders, and substance abuse related disorders, accompanied by a detailed description of the symptoms supporting the diagnosis. In lieu of a qualifying Axis I diagnosis, children 18–20 years of age may have an Axis II diagnosis or any personality disorder. Adjustment or substance related disorders may be a secondary Axis I diagnosis.<br><br>(ii) Patient continues to manifest a severity of illness that requires an acute level of care as defined in the admission criteria and which could not be provided in a less restrictive setting.<br><br>(I) Documentation of regression is measured in behavioral terms.<br><br>(II) If condition is unchanged, evidence of re-evaluation of treatment objectives and therapeutic interventions.<br><br>(iii) Conditions are directly attributable to a mental disorder as the primary need for professional attention (this does not include placement issues, criminal behavior, status offenses).<br><br>(iv) Documented efforts of working with child's family, legal guardians and/or custodians and other human service agencies toward a tentative discharge date.<br><br>(D) Medical necessity criteria for admission—inpatient chemical dependency detoxification. Inpatient chemical dependency detoxification admissions must meet the terms and conditions contained in (i), (ii), (iii), and one of (iv)(I)-(v)(IV).<br><br>(i) Any psychoactive substance dependency disorder described in *DSM-IV-R* with detailed symptoms supporting the diagnosis and need for medical detoxification, except for cannabis, nicotine, or caffeine dependencies.<br><br>(ii) Conditions are directly attributable to a substance dependency disorder as the primary need for professional attention (this does not include placement issues, criminal behavior, status offenses).<br><br>(iii) It has been determined by the gatekeeper that the current disabling symptoms could not be managed or have not been manageable in a lesser intensive treatment program.<br><br>(iv) Requires secure 24-hour nursing/medical supervision as evidenced by:<br><br>(I) Need for active and aggressive pharmacological interventions.<br><br>(II) Need for stabilization of acute psychiatric symptoms.<br><br>(III) Need extensive treatment under physician direction.<br><br>(IV) Physiological evidence or expectation of withdrawal symptoms which require 24-hour medical supervision.<br><br>(E) Medical necessity criteria for continued stay—inpatient chemical dependency program. No continued stay in inpatient chemical dependency program is allowed. Initial certification for admission is limited to up to five days; exceptions may be made up to seven to eight days based on a case-by-case review.<br><br>(F) Medical necessity criteria for admission—residential treatment (psychiatric and chemical dependency). Residential Treatment Center admissions must meet the terms and conditions in (i) to (iv) and one of (v)(I)-(v)(IV), and one of (vi)(I)-(vi)(III) of this subparagraph. |

*Table 4. Continued*

| **State** | **Statute/Regulation** | **Medical Necessity Definition[1]** |
| --- | --- | --- |
| Oklahoma | O.A.C. § 317:30-5-46 (2000) (Statute regarding inpatient psychiatric facilities) | (i) Any *DSM-IV-R* Axis 1 primary diagnosis with the exception of V-codes, adjustment disorders, and substance related disorders, accompanied by detailed symptoms supporting the diagnosis. In lieu of a qualifying Axis I diagnosis, children 18–20 years of age may have an Axis II diagnosis or any personality disorder. Adjustment or substance related disorders may be a secondary Axis I diagnosis.<br>(ii) Conditions are directly attributed to a mental disorder as the primary reason for professional attention (this does not include placement issues, criminal behavior, status offenses).<br>(iii) Patient has either received treatment in an acute care setting or it has been determined by the gatekeeper that the current disabling symptoms could not or have not been manageable in a less intensive treatment program.<br>(iv) Child must be medically stable.<br>(v) Patient demonstrates escalating pattern of self injurious or assaultive behaviors as evidenced by:<br>(I) Suicidal ideation and/or threat.<br>(II) History of or current self-injurious behavior.<br>(III) Serious threats or evidence of physical aggression.<br>(IV) Current incapacitating psychosis or depression.<br>(vi) Requires 24-hour observation and treatment as evidenced by:<br>(I) Intensive behavioral management.<br>(II) Intensive treatment with the family/guardian and child in a structured milieu.<br>(III) Intensive treatment in preparation for re-entry into community.<br>(G) Medical necessity criteria for continued stay—residential treatment center. Continued stay residential treatment center admissions must meet the terms and conditions contained in (i); (ii); and either (iii) or (iv); and (v); and (vi) of this subparagraph.<br>(i) Any *DSM-IV-R* Axis 1 primary diagnosis with the exception of V codes, adjustment disorders, and substance abuse related disorders, accompanied by detailed symptoms supporting the diagnosis. In lieu of a qualifying Axis I diagnosis, children 18–20 years of age may have an Axis II diagnosis of any personality disorder.<br>(ii) Conditions are directly attributed to a mental disorder as the primary reason for continued stay (this does not include placement issues, criminal behavior, status offenses).<br>(iii) Patient is making measurable progress toward the treatment objectives specified in the treatment plan.<br>(I) Progress is measured in behavioral terms and reflected in the patient's treatment and discharge plans.<br>(II) Patient has made gains toward social responsibility and independence.<br>(III) There is active, ongoing psychiatric treatment and documented progress toward the treatment objective and discharge.<br>(IV) There are documented efforts and evidence of active involvement with the family, guardian, child welfare worker, extended family, etc. |

[1] Definitions have been taken verbatim from the relevant document; quotation marks have been omitted.

*Table 4. Continued*

| ***State*** | ***Statute/Regulation*** | ***Medical Necessity Definition***[1] |
|---|---|---|
| Oklahoma | O.A.C. § 317:30-5-46 (2000) (Statute regarding inpatient psychiatric facilities) | (iv) Child's condition has remained unchanged or worsened.<br>(I) Documentation of regression is measured in behavioral terms.<br>(II) If condition is unchanged, there is evidence of re-evaluation of the treatment objectives and therapeutic interventions.<br>(v) There is documented continuing need for 24-hour observation and treatment as evidenced by:<br>(I) Intensive behavioral management.<br>(II) Intensive treatment with the family/guardian and child in a structured milieu.<br>(III) Intensive treatment in preparation for re-entry into community.<br>(vi) Documented efforts of working with child's family, legal guardian and/or custodian and other human service agencies toward a tentative discharge date.<br>(A) Pre-authorization and extension procedures. Pre-admission authorization for inpatient psychiatric services must be requested from the OHCA designated agent. The OHCA or designated agent will evaluate and render a decision within 24 hours of receiving the request. A Certificate of Need will be issued by the OHCA or its designated agent, if the recipient meets medical necessity criteria.<br>(B) Extension requests (psychiatric) must be made through the OHCA designated agent. All requests shall be made prior to the expiration of the approved extension following the guidelines in the Gatekeeping Manual. Extension requests for the continued stay of a child who has been in an acute psychiatric program for a period of thirty (30) days will require a face to face evaluation by the gatekeeper. Requests for the continued stay of a child who has been in an acute psychiatric program for a period of sixty (60) days will require a review of all treatment documentation completed by the OHCA designated agent.<br>(C) If a denial decision is made, a reconsideration request may be made directly to the OHCA designated agent within ten (10) working days of notification of the denial. The agent will return a decision within ten (10) working days from the time of receiving the reconsideration request. If the denial decision is upheld, the denial can be appealed to the Oklahoma Health Care Authority within 20 working days of notification of the denial by the OHCA designated agent. |
| Oregon | None | None |
| Pennsylvania | None | None |
| Rhode Island | None | None |
| South Carolina | None | None |

*Table 4. Continued*

| State | Statute/Regulation | Medical Necessity Definition[1] |
| --- | --- | --- |
| South Dakota | S.D. Codified Laws 28-13-27.1 (2001) | Medically necessary hospital services are services provided in a hospital which meet the following criteria: (1) Are consistent with the person's symptoms, diagnosis, condition, or injury; (2) Are recognized as the prevailing standard and are consistent with generally accepted professional medical standards of the provider's peer group; (3) Are provided in response to a life-threatening condition; to treat pain, injury, illness, or infection; to treat a condition which would result in physical or mental disability; or to achieve a level of physical or mental function consistent with prevailing standards for the diagnosis or condition; (4) Are not furnished primarily for the convenience of the person or the provider; and (5) There is no other equally effective course of treatment available or suitable for the person needing the services which is more conservative or substantially less costly. A court shall rely on the attending physician's determination as to medical necessity of hospital services unless evidence exists to the contrary. |
| Tennessee | None | None |
| Texas | None | None |
| Utah | None | None |
| Vermont | None | None |
| Virginia | Va. Code Ann. § 38.2-5800 (2001) (IRO Statute) | "Medical necessity" or "medically necessary" means appropriate and necessary health care services which are rendered for any condition which, according to generally accepted principles of good medical practice, requires the diagnosis or direct care and treatment of an illness, injury, or pregnancy-related condition, and are not provided only as a convenience. |
| Washington | Rev. Code Wash. § 71.34.020 (2001) (mental health services for minors) | Medical necessity for inpatient care means a requested service which is reasonably calculated to: (a) Diagnose, correct, cure or alleviate a mental disorder; or (b) prevent the worsening of mental conditions that endanger life or cause suffering and pain, or result in illness or infirmity or threaten to cause or aggravate a handicap, or cause physical deformity or malfunction, and there is no adequate less restrictive alternative available. |
| West Virginia | None | None |
| Wisconsin | None | None |
| Wyoming | None | None |

[1] Definitions have been taken verbatim from the relevant document; quotation marks have been omitted.

## Table 5. State Independent Review Statutes and Regulations

| ***Jurisdiction*** | ***IRO Statute (√ if yes)*** | ***IRO Regulations (√ if yes)*** | ***Citations*** |
|---|---|---|---|
| Alabama | | | |
| Alaska | √ | | Alaska Stat. § 21.07.050 (2001) |
| Arizona | √ | | Arizona Rev. Stat. § 20-2537 (2001) |
| Arkansas | | | |
| California | √ | √ | Cal. Ins. Code § 10169 (2001) Proposed Regulation at Cal. Reg. Law Bulletin 2001-39 CRLB 500 (Sept. 28, 2001) |
| Colorado | √ | √ | Colo. Rev. Stat. § 10-16-113.5 Colo. Ins. Reg. 4-2-21 (2000) |
| Connecticut | √ | √ | Conn. Gen. Stat. § 38a-478n (2001)<br>Conn. Agencies Regs. §§ 38a-478n-1 to 5 (2001) |
| Delaware | √ | | Del Code tit. 16 § 9119 (2001) |
| District of Columbia | √ | | D.C. Code § 44-301.07 (2001) |
| Florida | √ | | Fl. Stat. §§ 408.7056 (2001) |
| Georgia | √ | | Ga. Code § 33-20A-32 (2001) |
| Hawaii | √ | | Hi. Rev. Stat. § 432E-6 (2001) |
| Idaho | | | |
| Illinois | √ | | 215 Ill. Comp. Stat. 125, § 4-10 (2001) |
| Indiana | √ | | Ind. Code § 27-13-10.1-1 (2001) |
| Iowa | √ | | Iowa Code §§ 514J.1 to .14 (2001) |
| Kansas | √ | | Kan. Stat. §§ 40-22a13-16 (2000) |
| Kentucky | √ | | Ky. Stat. § 304.17A-623 (2001) |
| Louisiana | √ | | La. Rev. Stat. § 22:3081 (2001) |
| Maine | √ | | Me. Rev. Stat. tit. 24-A § 4323 (2001) |
| Maryland | √ | √ | Md. Ins. Code § 15-10A-03 (2001) |
| Massachusetts | √ | √ | Mass. Gen. Laws ch. 1760, § 14 (2001) 105 C.M.R. 128.00 (2001) |
| Michigan | √ | | Mich. Comp. Laws §§ 550.1901-1929 (2001) |
| Minnesota | √ | | Minn. Stat. § 62Q.73 (2000) |
| Mississippi | | | |
| Missouri | √ | √ | Mo. Rev. Stat. § 376.1385 (2000) 20 C.S.R. 100-5.020 (2001) |
| Montana | √ | √ | Mont. Code § 33-37-102 (2001)<br>Mont. Admin. R. § 37.108.315 (2001) |

*Table 5. Continued*

| ***Jurisdiction*** | ***IRO Statute (√ if yes)*** | ***IRO Regulations (√ if yes)*** | ***Citations*** |
|---|---|---|---|
| Nebraska | | | |
| Nevada | | | |
| New Hampshire | √ | | N.H. Rev. Stat. 420-J:5 (2000) |
| New Jersey | √ | √ | N.J. Stat. §§ 26:2S-11 to 26:2S-12 (2001)<br>N.J. Adm. Code § 8:38A-3.6 |
| New Mexico | √ | √ | N.M. Stat. Ann. § 59-A-57-1 (2001)<br>N.M. Adm. Code tit. 13, § 10.17.24 (2001) |
| New York | √ | √ | N.Y. Ins. Law § 4910 (2001) 11 N.Y.C.R.R. § 410.1 (2001) |
| North Carolina | √ | | 2001 N.C. Sess. Laws 446 (S.B. 199) (2001) |
| North Dakota | | | |
| Ohio | √ | | Ohio Rev. Code § 1751.84 (2001) |
| Oklahoma | √ | | Okla. Stat. tit. 63, § 2528.3 (2001) |
| Oregon | √ | | Or. Legis. ch. 266 (effective date July 1, 2002) |
| Pennsylvania | √ | √ | 40 Pa. Stat. § 991.2162 (2001) 28 Pa. Code § 9.501 (2001) |
| Rhode Island | √ | √ | R.I. Gen. Laws § 23-17.12-10 (2001) R23-17.12-I-UR (2001) |
| South Carolina | √ | | S.C. Code §§ 38-71-1910-2060 |
| South Dakota | | | |
| Tennessee | √ | | Tenn. Code § 56-32-227 (2001) |
| Texas | √ | √ | Tex. Ins. Code art. 21.58A 28 Tex. Adm. Code 12.5 (2001) |
| Utah | √ | √ | Utah Code § 31A-22-629 (2001) Proposed Regulation at 2001-23 Utah Bull. 126 (Dec. 1, 2001) |
| Vermont | √ | √ | For Physical Health Services:<br>VT. Stat. tit. 8, § 4089f (2001)<br>Regulation H-99-1 (2001)<br>For Mental Health Services:<br>VT. Stat. Tit. 8, § 4089a (2001)<br>Regulation 95-2 (2001) |
| Virginia | √ | √ | Va. Code §§ 38.2-5900 – 5905 (2001) 14 VAC 5-215-10 (2001) |
| Washington | √ | √ | Wash. Rev. Code § 48.43.535 (2001) WAC § 246-305-050 (2001) |
| West Virginia | √ | | W.Va. Code § 33-25C-6 (effective July 1, 2002) |
| Wisconsin | | | |
| Wyoming | | | |

## Table 6. Medical Necessity Definitions: State Insurance Laws and IRO Statutes

| ***State*** | ***Medical Necessity Definition in Insurance Content Statutes (Y/N)*** | ***IRO Statute (Y/N)*** | ***Medical Necessity Definition in IRO Statute*** | ***IRO Statute Definition*** |
|---|---|---|---|---|
| Alabama | N | N | | |
| Alaska | N | Y | N | |
| Arizona | N | Y | N | |
| Arkansas | Y | N | | |
| California | Y | Y | N | |
| Colorado | N | Y | N | |
| Connecticut | N | Y | N | |
| Delaware | N | Y | Y | For the purpose of this act, “medical necessity” means the providing of covered health services or products that a prudent physician would provide to a patient for the purpose of diagnosing or treating an illness, injury, or disease or its symptoms, in a manner that is: (1) In accordance with the generally accepted standards of medical practice; (2) Consistent with the symptoms or treatment of the condition; and (3) Not solely for anyone’s convenience. 16 Del. Code § 9119 (2000) |
| District of Columbia | N | Y | N | |
| Florida | Y | Y | N | |
| Georgia | N | Y | Y | (5) “Medical necessity,” “medically necessary care,” or “medically necessary and appropriate” means care based upon generally accepted medical practices in light of conditions at the time of treatment which is: (A) Appropriate and consistent with the diagnosis and the omission of which could adversely affect or fail to improve the eligible enrollee’s condition; (B) Compatible with the standards of acceptable medical practice in the United States; (C) Provided in a safe and appropriate setting given the nature of the diagnosis and the severity of the symptoms; (D) Not provided solely for the convenience of the eligible enrollee or the convenience of the health care provider or hospital; and (E) Not primarily custodial care, unless custodial care is a covered benefit under the eligible enrollee’s evidence of coverage. O.C.G.A. § 33-20A-31 (2000) |

*Table 6. Continued*

| State | Medical Necessity Definition in Insurance Content Statutes (Y/N) | IRO Statute (Y/N) | Medical Necessity Definition in IRO Statute | IRO Statute Definition |
|---|---|---|---|---|
| Hawaii | N | Y | Y | Medical necessity (b) A health intervention is medically necessary if it is recommended by the treating physician or treating licensed health care provider, is approved by the health plan's medical director or physician designee, and is: (1) For the purpose of treating a medical condition; (2) The most appropriate delivery or level of service, considering potential benefits and harms to the patient; (3) Known to be effective in improving health outcomes; provided that: (A) Effectiveness is determined first by scientific evidence; (B) If no scientific evidence exists, then by professional standards of care; and (C) If no professional standards of care exist or if they exist but are outdated or contradictory, then by expert opinion; and (4) Cost-effective for the medical condition being treated compared to alternative health interventions, including no intervention. For the purposes of this paragraph, cost-effective shall not necessarily mean lowest price. HRS § 432E-1.4 (2000) |
| Idaho | N | N | | |
| Illinois | Y | Y | N | |
| Indiana | Y | Y | N | |
| Iowa | N | Y | Y | Medical necessity is defined as the insurer's plan defines it. Iowa Code 514J.5 |
| Kansas | N | Y | N | |
| Kentucky | N | Y | N | |
| Louisiana | N | Y | N | |
| Maine | N | Y | Y | "Medically necessary health care" means health care services or products provided to an enrollee for the purpose of preventing, diagnosing or treating an illness, injury or disease or the symptoms of an illness, injury or disease in a manner that is (A) consistent with generally accepted standards of medical practice; (B) clinically appropriate in terms of type, frequency, extent, site and duration; (C) demonstrated through scientific evidence to be effective in improving health outcomes; (D) representative of "best practices" in the medical profession; and (E) not primarily for the convenience of the enrollee or physician or other health care practitioner. 24-A MRSA § 4301-A(10-A). |
| Maryland | Y | Y | N | |
| Massachusetts | N | Y | Y | "Medical necessity" or "medically necessary," health care services that are consistent with generally accepted principles of professional medical practice. Mass. Ann. Laws ch. 176O (1) (2001) |
| Michigan | N | Y | N | |

*Table 6. Continued*

| ***State*** | ***Medical Necessity Definition in Insurance Content Statutes (Y/N)*** | ***IRO Statute (Y/N)*** | ***Medical Necessity Definition in IRO Statute*** | ***IRO Statute Definition*** |
|---|---|---|---|---|
| Minnesota | Y | Y | N | |
| Mississippi | N | N | | |
| Missouri | N | Y | N | |
| Montana | N | Y | N | |
| Nebraska | N | N | | |
| Nevada | N | N | | |
| New Hampshire | N | Y | N | |
| New Jersey | N | Y | N | |
| New Mexico | N | Y | N | |
| New York | N | Y | N | |
| North Carolina | Y | Y | N | |
| North Dakota | N | N | | |
| Ohio | N | Y | N | |
| Oklahoma | N | Y | N | |
| Oregon | N | Y | N | |
| Pennsylvania | N | Y | N | |
| Rhode Island | N | Y | N | |
| South Carolina | N | Y | N | |
| South Dakota | N | N | | |
| Tennessee | N | Y | N | |
| Texas | N | Y | N | |
| Utah | N | Y | N | |
| Vermont | N | Y | N | |

*Table 6. Continued*

| State | Medical Necessity Definition in Insurance Content Statutes (Y/N) | IRO Statute (Y/N) | Medical Necessity Definition in IRO Statute | IRO Statute Definition |
|---|---|---|---|---|
| Virginia | N | Y | Y | "Medical necessity" or "medically necessary" means appropriate and necessary health care services which are rendered for any condition which, according to generally accepted principles of good medical practice, requires the diagnosis or direct care and treatment of an illness, injury, or pregnancy-related condition, and are not provided only as a convenience. Va. Code Ann. § 38.2-5800 (2001) |
| Washington | N | Y | N | |
| West Virginia | N | Y | N | |
| Wisconsin | N | N | | |
| Wyoming | N | N | | |

## Table 7. State Independent Review Statutes With Specific Behavioral Health Provisions

| ***Jurisdiction*** | ***Content of Behavioral Health Provision*** |
|---|---|
| Pennsylvania | Specifies that licensed psychologists may be reviewers for IROs, with Insurance Department approval. Licensed psychologists may not review denials regarding inpatient care or prescription drugs. 28 Pa. Code § 9.504 (2001). |
| Vermont | Establishes a separate independent review system for mental health services, including substance abuse treatment. 8 Vt. Stat. § 4089a (2001). Provides for a seven-member Independent Panel of Mental Health Care Providers appointed by Insurance Commissioner to review mental health service decisions. The Panel must include at least one psychiatrist, psychologist, mental health social worker, psychiatric nurse, mental health counselor, and drug and alcohol counselor. |

Table 8. Qualifications of External Reviewer in State IRO Statutes

| ***Jurisdiction*** | ***Reviewer*** | ***Entity that Selects Reviewer*** | ***Requirement that Reviewer Have Relevant Expertise or Particular Case? (√ if yes)*** | ***Conflict of Interest Prohibition (√ if yes)*** |
|---|---|---|---|---|
| Alaska | Certified appeal agency using panels of "two clinical peers." Agency must be certified by a private standard-setting organization approved by Department of Health or a health insurer operating in state. | MCO | | √ |
| Arizona | IRO using physicians and other health professionals licensed in Arizona or another state (if board-certified or eligible). | Department of Health | √ | √ |
| California | IRO certified by Insurance Commissioner and using health care providers licensed in California and board-certified. | Department of Insurance | √ | √ |
| Colorado | IRO certified by Insurance Commissioner and using physicians or other health care professionals. | Department of Insurance | √ | √ |
| Connecticut | IRO may include medical peer review organizations, independent utilization review companies, or nationally recognized health experts or institutions approved by the Insurance Commissioner. | Department of Insurance | √ | √ |
| Delaware | IRO certified by Secretary of Health or accredited by an independent national accrediting organization and includes licensed and board-certified physicians or other appropriate health care providers. | Department of Health | √ | √ |
| District of Columbia | IRO consisting of at least two physicians licensed in D.C., Maryland, or Virginia (exceptions when necessary due to the condition under review) who have meaningful experience in prior utilization review. | Department of Insurance | √ (noted "when necessary") | √ |
| Florida | IRO panel consisting of individuals from the Agency for Health Care Administration, the Department of Insurance, a consumer, a physician appointed by the Governor, physicians with relevant expertise to case at issue (rotating pool), and a medical director from an MCO (not a party) and a primary care physician. | Agency for Health Care Administration | √ | |
| Georgia | IRO with licensed and board-certified health care providers certified by the Department of Health Planning Division. | Department of Health Planning Division | √ | √ |
| Hawaii | Three-member panel appointed by the Insurance Commissioner and composed of a representative from the managed care plan not involved in the complaint, a provider licensed in Hawaii not involved in the complaint, and the Commissioner or Commissioner's designee. The Commissioner may also retain an IRO to assist in the review. | Commissioner of Insurance | | √ |

*Table 8. Continued*

| ***Jurisdiction*** | ***Reviewer*** | ***Entity that Selects Reviewer*** | ***Requirement that Reviewer Have Relevant Expertise or Particular Case? (√ if yes)*** | ***Conflict of Interest Prohibition (√ if yes)*** |
|---|---|---|---|---|
| Illinois | A physician who holds the same class of license as the patient's primary care physician and who is appointed by the patient, the primary care physician, and the MCO. | MCO | | |
| Indiana | IRO certified by the Department of Insurance assigns a medical review professional who is licensed and board certified in applicable specialty for the appeal and who has knowledge about the proposed service at issue. | MCO (but must go through the entire list of certified IROs before selecting the same one again) | √ | √ |
| Iowa | IROs certified by the Insurance Commissioner may include (but are not limited to) medical peer review organizations and nationally recognized health experts or institution. Individual reviewer must hold applicable health care license and be board-certified. | MCO selects from list of certified IROs | √ | √ |
| Kansas | IRO under contract with Commissioner of Insurance. IRO must have experience in administering Kansas health programs or be a nationally accredited external review organization that uses Kansas health care providers to conduct the review (unless no Kansas providers are qualified and credentialed in the specialty at issue in the case) | Commissioner of Insurance | √ | √ |
| Kentucky[1] | IROs must use a reviewer(s) with the appropriate license, board certification, and clinical experience applicable to the medical condition under review. | Department of Insurance | √ | √ |
| Louisiana | IRO must be licensed by the Insurance Commissioner and have qualified and impartial clinical peer reviewers who hold appropriate licenses and board certification in the specialty at issue and have clinical expertise in the relevant medical condition. | MCO | √ | √ |
| Maine | IRO must have qualified and impartial reviewers who hold applicable licenses and board certification with respect to the adverse health care treatment under review. | Insurance Bureau | √ | √ |
| Maryland | The Commissioner may make a determination on a patient's appeal or designate an IRO to do so. An IRO must have qualified and impartial reviewers who hold applicable licenses and board certification with respect to the adverse health care treatment under review. | Commissioner of Insurance | √ | √ |
| Massachusetts | Department of Public Health's Office of Patient Protection contracts with "unrelated and objective" review agencies and refers appeals to them on a random basis. Reviewers are to be actively practicing health care professionals in the same or similar specialty who typically treat the medical condition, perform the procedure or provide the treatment under review. | Department of Public Health, Office of Patient Protection | √ | √ |

[1] A patient cannot obtain an external review if the subject of the patient's adverse determination has previously gone through the external review process and the independent review entity found in favor of the insurer and no new clinical evidence is available. Ken. Rev. Stat. ß 304.17A-623(6).

*Table 8. Continued*

| ***Jurisdiction*** | ***Reviewer*** | ***Entity that Selects Reviewer*** | ***Requirement that Reviewer Have Relevant Expertise or Particular Case? (√ if yes)*** | ***Conflict of Interest Prohibition (√ if yes)*** |
|---|---|---|---|---|
| Michigan | IROs approved by Commissioner of Insurance. IROs must use reviewers licensed and board-certified in the applicable specialty and who have had an active clinical practice in the last year in which the reviewer "devoted a majority of his or her time in . . . the specialty most relevant to the subject of the review." | Commissioner of Insurance | √ | √ |
| Minnesota | IRO under contract to Commissioner of Health and using qualified reviewers. | Commissioners of Health, Administration | √ | √ |
| Missouri[2] | IRO under contract to the Department of Insurance. | Director of Insurance | | |
| Montana | Party seeking review and the MCO may agree upon a peer to conduct the review (a peer is defined as "a health care provider actively practicing in this state who has substantially the same education and training...who provides substantially the same service...who has the same license or certification...as the provider whose practice...[is] being considered, reviewed, evaluated or judged."<br>If the parties cannot agree on a peer, then the Insurance Department designates an IRO. | Insurance Department | √ | √ |
| New Hampshire | Commissioner of Insurance certifies IROs. Reviewers must hold appropriate licenses and board certification in the specialty at issue and have clinical expertise in the relevant medical condition. | Commissioner of Insurance | √ | √ |
| New Jersey | IROs conduct an initial review through a registered professional nurse or physician licensed in New Jersey, and, when necessary, refer all cases to a consultant physician in the specialty or area of practice that generally would manage the type of treatment that is the subject of the appeal. | Commissioner of Health | Provides "when necessary" but does not require (and does not define "when necessary" but implies this determination is in the discretion of the IRO). | |
| New Mexico | The Superintendent of Insurance designates a hearing officer (an attorney licensed in New Mexico) and two medical co-hearing officers (at least one of whom practices in a specialty that would typically manage the case that is the subject of the review). | Superintendent of Insurance | √ | Requires disclosure of potential conflicts to Superintendent but does not prohibit conflicts |

[2] Missouri has three levels of review for adverse medical determinations. The first level is internal to the health plan, and the second level is external but arranged by the health plan (involving other enrollees, representatives of the plan not involved in the case, and clinicians not involved in the case). The third level is independent review and is the level addressed in this analysis. See Rev. Stat. Mo. ß 376.1385 (2000).

*Table 8. Continued*

| ***Jurisdiction*** | ***Reviewer*** | ***Entity that Selects Reviewer*** | ***Requirement that Reviewer Have Relevant Expertise or Particular Case? (√ if yes)*** | ***Conflict of Interest Prohibition (√ if yes)*** |
|---|---|---|---|---|
| New York | The Superintendent of Insurance and the Commissioner of Health certify IROs and randomly assign appeals to them. IRO reviewers must have the appropriate license, board certification, and clinical experience applicable to the medical condition under review. | Superintendent of Insurance and Commissioner of Health | √ | √ |
| North Carolina | Insurance Commissioner assigns IRO on a rotating basis from list of approved organizations. IRO reviewers must have the appropriate license, board certification, and clinical experience applicable to the medical condition under review. | Insurance Commissioner | √ | √ |
| Ohio | Insurance Superintendent accredits IROs and maintains a list of approved organizations. Upon a request for external appeal, Superintendent provides two IROs chosen at random from the list, and the MCO chooses one of them. One reviewer conducts the review (unless the MCO or IRO determines that more than one is necessary), and the reviewer(s) must have the appropriate license, board certification, and clinical experience applicable to the medical condition under review. | Insurance Superintendent (MCO chooses among two IROs selected at random) | √ | √ |
| Oklahoma | MCO selects IRO from a list of organizations certified by the Department of Health. Reviewers have the appropriate license, board certification, and clinical experience applicable to the medical condition under review. | MCO chooses from Department of Health-certified organizations. | √ | √ |
| Oregon | When legislation becomes effective (July 1, 2002), Director of Business and Consumer Affairs Department will contract with IROs qualified under regulations to be developed prior to July 1, 2002. | Director of Business and Consumer Affairs Department | To Be Determined | To Be Determined |
| Pennsylvania[3] | Insurance Commissioner assigns IRO on a rotating basis from list of approved organizations. IRO reviewers must have the appropriate license, board certification, and clinical experience applicable to the medical condition under review. Reviewers may include licensed psychologists (although they cannot review denials of inpatient care or prescription drugs).<br>If Insurance Commissioner fails to assign an IRO within 2 business days of the request for review, the MCO may assign an IRO from list of organizations approved by Insurance Department. | Insurance Commissioner (or MCO if Insurance Commissioner fails to assign IRO within 2 business days of request for external review) | √ | √ |
| Rhode Island | Insurance Department certifies IROs. Reviewer must be a physician, dentist, or other health care professional of the specialty relevant to the care or service under review. | Designated by Insurance Director | √ | √ |

[3] Pennsylvania allows an MCO and provider to agree to an alternate dispute resolution system in a written contract if the Insurance Department approves of the alternate system. 40 Pa. Stat. ß 991.2162.

*Table 8. Continued*

| ***Jurisdiction*** | ***Reviewer*** | ***Entity that Selects Reviewer*** | ***Requirement that Reviewer Have Relevant Expertise or Particular Case? (√ if yes)*** | ***Conflict of Interest Prohibition (√ if yes)*** |
|---|---|---|---|---|
| South Carolina | Insurance Department maintains list of approved IROs and designates IRO upon request for external review. IRO reviewers must have the appropriate license, board certification, and clinical experience (within the past three years) applicable to the medical condition under review. | Insurance Department | √ | √ |
| Tennessee | MCO designates IRO, which must be impartial and use reviewers that have the appropriate license and board certification applicable to the medical condition under review. | MCO | √ | √ |
| Texas | Department of Insurance assigns IROs randomly from an approved list. Reviewers must be in active practice and have the appropriate license and board certification applicable to the medical condition under review. | Department of Insurance | √ | √ |
| Utah | MCO designates IRO, which must be impartial. | MCO | | |
| Vermont | Commissioner of Department of Banking, Insurance, Securities, and Health Care Administration (BISHCA) designates IROs. Reviewers must be in active practice and have the appropriate license and board certification applicable to the medical condition under review.<br>An Independent Panel of Mental Health Care Providers reviews decisions involving mental health services, including drug and alcohol treatment. | Commissioner of BISHCA | √ | √ |
| Virginia | IROs contract with the Bureau of Insurance. Reviewers must have the appropriate license and board certification applicable to the medical condition under review. | Bureau of Insurance | √ | √ |
| Washington | Department of Health certifies IROs and maintains registry for assignment. Reviewers must have five years of clinical experience and have the appropriate license and board certification applicable to the medical condition. Under review. | Department of Health | √ | √ |
| West Virginia[4] | The Department of Insurance certifies IROs, which must use at least one physician or other health care provider knowledgeable about the health care service under review. | Department of Insurance | √ | √ |

[4] West Virginia allows MCOs an exemption from the IRO statute if the MCO has an external review plan approved by the Department of Insurance. W. Va. Code ß 33-25C-6.

## Table 9. Independent Reviews: Standard of Review for Medical Necessity Determinations

| ***Jurisdiction*** | ***De Novo*** | ***Other*** | ***If Standard is De Novo or Not Specified, Can Insured Submit Additional Evidence? (√ if yes)*** |
|---|---|---|---|
| Alaska | √ | | |
| Arizona | | | √ |
| California | | | √ |
| Colorado | √ | | √ |
| Connecticut | | | √ |
| Delaware | | | √ |
| District of Columbia | | | √ (Insured can also request a hearing before IRO.) |
| Florida | | | |
| Georgia | | | √ |
| Hawaii | | | |
| Illinois | | | |
| Indiana | | | √ |
| Iowa | √ | | √ |
| Kansas | | | √ |
| Kentucky | | | √ |
| Louisiana | | | |
| Maine | | | √ (Patient may attend the external review, ask questions of the insurance company representative, and use outside assistance such as counsel [at the patient's expense].) |
| Maryland[1] | | | √ |
| Massachusetts | | | |
| Michigan | √ | | √ |
| Minnesota | | | √ |
| Missouri | | | √ |
| Montana | | | |
| New Hampshire | √ | | √ |

[1] Maryland's IRO statute places the burden of proof on the MCO to demonstrate that its initial adverse decision was correct. Md. Ins. Code Ann. ß 15-10A-03(e) (2001).

*Table 9. Continued*

| ***Jurisdiction*** | ***De Novo*** | ***Other*** | ***If Standard is De Novo or Not Specified, Can Insured Submit Additional Evidence? (√ if yes)*** |
|---|---|---|---|
| New Jersey | | | |
| New Mexico | | | √ (Hearing officer and co-medical hearing officers conduct hearing with witnesses and presentation of evidence.) |
| New York | | | √ |
| North Carolina | | | √ |
| Ohio | | | √ |
| Oklahoma | | | √ |
| Oregon | | | To Be Determined |
| Pennsylvania | | | √ |
| Rhode Island | | | |
| South Carolina | √ | | √ |
| Tennessee | | | |
| Texas | | | √ |
| Utah | | | |
| Vermont | | | √ |
| Virginia | | | |
| Washington | | | √ |
| West Virginia | | | |

# Appendix A. Selected Published Literature on Medical Necessity (Sorted by Year)

| Year | Author | Title | Source | Summary/Abstract |
|---|---|---|---|---|
| 1992 | Eddy, David | Clinical Decision Making: From Theory to Practice. Applying Cost Effectiveness Analysis, the Inside Story | JAMA 268(18): 2575–2582 | An account of how analysis of cost-effectiveness was used to change practice guidelines on high and low osmolar radiographic contrast agents at Kaiser. Difficulties with analysis and buy-in are discussed. The general logistics of the analysis itself are described, as are the lines of thought behind each step of the analysis. |
| 1992 | Hall, Mark, and Gerard Anderson | Models of Rationing: Health Insurers' Assessment of Medical Necessity | University of Pennsylvania Law Review 140 U Pa.L.Rev. 1637 | EXCERPTS: … Tishna, I was told, had virtually no chance of surviving the relapsed Wilms' tumor [of the kidney] from which she is suffering and Blue Cross/Blue Shield had denied coverage for autologous bone marrow transplant ("ABMT") with accompanying high dose chemotherapy, a treatment which could well prolong and quite possibly save her life and which, concededly, provided her only realistic hope of either. … In about a dozen similar cases, however, judges have ruled that the use of ABMT is still experimental and denied coverage. … From a legal perspective, however, these rulings are merely the latest in a long series of ordinary contract disputes over the interpretation of terms such as "medical necessity" or "experimental," which determine the coverage of health insurance policies. … In addition to this humanitarian objective, the courts have been concerned about the perceived unfairness of a retroactive denial of coverage after a patient has relied on his physician's advice and incurred a bill for treatment later found by the insurer to be inappropriate. … An assessment that a technology is "experimental" at one time must be modified if additional research or clinical findings validate (or repudiate) its effectiveness.… |
| 1993 | Anderson, G. F., and M. A. Hall | Medical Technology Assessment and Practice Guidelines: Their Day in Court | American Journal of Public Health 83:1635–1639 | There is the expectation that outcomes research and the promulgation of medical practice guidelines will be able to identify and hopefully reduce the amount of unnecessary or inappropriate medical care through a variety of methods, including utilization review. However, the courts for multifarious reasons have frequently overturned past efforts by public and private insurers to deny claims on the basis of formal technology assessments or practice guidelines. This paper examines the court's reluctance to accept a variety of technology assessment methods in coverage policy decisions. The paper reviews the options that have been proposed to restrict judicial involvement in the formulation of coverage policy and then proposes a new option that employs a more precise taxonomy of medical practice assessment. |

*Appendix A. Continued*

| **Year** | **Author** | **Title** | **Source** | **Summary/Abstract** |
|---|---|---|---|---|
| 1994 | Sabin, James E., and Norman Daniels | Determining "Medical Necessity" in Mental Health Practice | Hastings Center Report 24(6):5–13 | The authors posed the question, "Should mental health insurance cover only disorders found in *DSM-IV*, or should it be extended to treatment for ordinary shyness, unhappiness, and other responses to life's hard knocks?" Through the use of six illustrative case studies, the authors examined the reasoning behind the determinations of medical necessity. The article includes a discussion of a recurrent conflict between "hard-line" and "expansive" views of medical necessity, noting that it frequently reflects unrecognized moral disagreement about the targets of clinical intervention and the ultimate goals of psychiatric treatment. The authors present three models for defining medical necessity and argue a defensible rationale for the "normal" model, which comprises a target of a medically defined deviation intended to decrease the impact of disease or disability. Three tests of medical necessity are offered: (1) Does it make distinctions the public and clinicians regard as fair? (2) Can it be administered in the real world? (3) Does it lead to results that society can afford? In the authors' view, a typical medical necessity definition in the "normal" model would be "those mental health services which are essential for the treatment of a Member's mental health disorder as defined by the *DSM-IV* in accordance with generally accepted mental health practice." The authors conclude that the *DSM-IV* standard provides workable boundaries for medical necessity definitions to the extent that they are the result of a highly public process open to scientific scrutiny, field testing, and repetitive criticism over time. |

*Appendix A. Continued*

| Year | Author | Title | Source | Summary/Abstract |
|---|---|---|---|---|
| 1994 | Eddy, David M. | From Theory to Practice: Rationing Resources While Improving Quality: How to Get More for Less | JAMA 272(10) | EXCERPT: "[...] when determining the appropriate use of an intervention, we will need to change our way of thinking from qualitative reasoning to quantitative reasoning. To a great extent, the predicament we face today is the result of qualitative reasoning that assumes that if a practice might have any benefit it should be done—the "criterion of potential benefit." Because this type of reasoning does not try to determine the amount of value a practice provides—separating those with high value from those with small value—it has left us with the large inefficiencies that we see in our practices today. To take advantage of these inefficiencies, we will have to develop better skills for quantitative reasoning. It is no coincidence that every example in this article was studded with numbers; it is not possible to determine how much benefit will be gained or how much cost will be saved by a transfer without estimating the benefits or the costs.<br><br>"[...] we will need to change from focusing on individuals to focusing on populations—from "individual-based" decision making to "population-based" decision making. In particular, practitioners need to develop an allegiance to the entire membership of the health plan. This will be difficult for those who see themselves as serving as their patients' advocate in a struggle with administrators and insurers. That perception is incorrect. When physicians hoard resources for their own patients, they are not taking from administrators or insurers; they are taking from other patients. If each practitioner is concerned only about his or her individual patient, without concern for the impact of his or her decisions on other patients, the result will not be lower costs and higher quality, but higher costs and lower quality.<br><br>"If health plans and individual practitioners are to succeed in making transfers that increase quality while reducing costs, they will need both guidance and protection. Guidance will be needed to ensure that decisions are consistent and have the desired effects. Protection will be needed to defend both plans and practitioners when they make and implement controversial decisions. The best way to address both those needs is to develop explicit criteria that will sort out high-value practices from those that have little or no value and will support transfers from one to the other. Currently, the closest we get to such criteria are through vague and variable terms such as "medically necessary" and "medically appropriate." But these are far too vague and variably interpreted. If we are to control costs while preserving quality, the first need is to develop better criteria for benefit language." |

*Appendix A. Continued*

| Year | Author | Title | Source | Summary/Abstract |
|---|---|---|---|---|
| 1995 | Bergthold, Linda A. | Medical Necessity: Do We Need It? | Health Affairs 14(4): 180–190 | The term medical necessity has been mainly a placeholder in insurance plans for over thirty years. More recently, the national health care reform debate and litigation over denials of costly experimental treatments have broken the term out into open discussion about what a necessary service is and who should decide if it is covered. This paper summarizes the history of the term and its evolution from an insurance concept controlled by practicing physicians to a rationing tool used by insurance administrators. How did national reform efforts address this terminology, and how should we define medical necessity in a changing delivery system? |
| 1996 | Eddy, David | Clinical Decision Making: From Theory to Practice. Benefit Language: Criteria That Will Improve Quality While Reducing Costs | JAMA | The idea that benefit language is one of the most important determinants of the quality and cost of care is at the core of this paper. Sample language is supplied describing health intervention, medical condition, health outcomes, sufficient evidence, and cost effectiveness. It is noted that the criteria are interconnected and points to some of the shortcomings of the proposed language. |
| 1997 | Gross, Joshua M. | Promoting Group Psychotherapy in Managed Care: Basic Economic Principles for the Clinical Practitioner | International Journal of Group Psychotherapy 47(4):499–507 | Knowledge of the basic economic factors underlying managed mental health care directly impacts the clinical practitioners' ability to make constructive changes in the system. To aid understanding this article introduces the managed care marketplace model, the interactive relationship between medical necessity and patient co-payment, and demand management economics. The author encourages practitioners to develop strategies to overcome specific economic obstacles that prevent the promotion of group psychotherapy. |
| 1997 | Hester, Thomas W. | Algorithms and the Medication Treatment of People with Serious Mental Illness | MASMHPD Research Institute Report | The goals of this paper are to provide the reader with an understanding and rationale for the appropriate use of treatment algorithms for people with serious mental illness. It suggests effective strategies for using treatment algorithms to improve the quality of treatment and to increase the accountability of medication treatment. The paper also addresses potential dangers in developing practice guidelines and provides advice for avoiding these pitfalls. Issues related to legal matters and managed care contracting are discussed briefly. |

*Appendix A. Continued*

| Year | Author | Title | Source | Summary/Abstract |
|---|---|---|---|---|
| 1997 | Jacobson, Peter D., Steven Asch, Peter A. Glassman, Karyn E. Model, and John B. Hernandez | Defining and Implementing Medical Necessity in Washington State and Oregon | Inquiry 34:143–154 | This paper reports on a qualitative study of how health care providers in the states of Washington and Oregon define and implement medical necessity. Based on a series of semi-structured interviews, we found that few insurers or health care plans in our sample attempted to resolve the ambiguities inherent in defining medical necessity. More importantly, our results suggest that physicians in managed care plans were not using general definitions of medical necessity to make clinical decisions, but instead relied on utilization management techniques to guide the use of medical resources. We conclude that medical necessity as an organizing principle for clinical practice decision-making is likely to continue to erode in a managed care environment. |
| 1997 | Moran, Donald W. | Federal Regulation of Managed Care: An Impulse in Search of a Theory? | Health Affairs 16(6):7–21 | Although there is growing demand for regulation of the managed care industry, regulatory proponents have yet to articulate a clear theory of regulation. Most observers acknowledge consumer information problems that regulation could address, but there is no consensus regarding regulation of the broader public concern about restrictive medical-necessity determinations by health plans. Concerns about these issues—which fall within the gray areas of divergent clinical opinion—may be difficult or impossible to address by explicit regulation. If policymakers forbear on regulation of medical necessity determinations, private market innovation may ultimately remedy this problem. |
| 1998 | Anderson, G. F., and M. A. Hall | When Courts Review Medical Appropriateness | Medical Care 36(8):1295–1302 | OBJECTIVES: The authors examined how the courts have responded to public and private insurers' use of medical appropriateness criteria to establish coverage and payment policies.<br><br>METHODS: A structured review of all federal and state court health insurance cases decided between 1960 and June 1994 that involved a dispute involving medical appropriateness was performed. A total of 3,215 published court decisions were analyzed, of which 203 met the criteria of relevance and 124 explicitly mentioned medical appropriateness criteria. The main outcome variable was whether the court ordered the insurer to provide coverage.<br><br>RESULTS: In 185 cases, a definitive decision was rendered, and the insurer was required to pay in 57% of the decisions. Whether the insurer relied on an assessment or not, whether the assessment process was formal or informal, and who conducted the assessment did not appear to influence courts' decisions, nor did the specificity of the coverage exclusion. Significant predictors of courts ordering coverage were court jurisdiction, contract language assigning discretion to the insurer, severity of patient's condition, and whether the treatment appeared to work for the particular patient.<br><br>CONCLUSIONS: For practice guidelines to be accepted by the courts, it is more important to focus on how insurance contracts are written than on how medical assessments are performed. |

*Appendix A. Continued*

| Year | Author | Title | Source | Summary/Abstract |
|---|---|---|---|---|
| 1998 | Chodoff, Paul | Medical Necessity and Psychotherapy | Psychiatric Services 49(11):1481–1483 | Managed care and, specifically, the need to conform to medical necessity requirements have had a dramatic effect on the medical and psychiatric practice, especially on psychotherapy. The author describes the progression of the concept of medical necessity from a simple accounting of services reimbursable by insurance companies to an ambiguous term without definitional consensus. He describes its relationship to the medical model and discusses the incongruity between medical necessity and certain aspects of psychotherapy. He proposes a broader concept—health necessity—based on an evaluation of the advantages, disadvantages, and costs of medical and psychiatric services. |
| 1998 | Ford, William | Medical Necessity: Its Impact in Managed Mental Health Care | Psychiatric Services 49(2):183–184 | Discusses the impact of managed care medical necessity definitions on psychiatric care. Points to some possible reasons why BHMOs focus on cutting short-term costs rather than managing long-term costs, including short contract terms and labor-intensive reviews. |
| 1998 | Miller, Monica | Research: The Debate Over Medical Necessity in Case Law and Government/ Industry Forums | Foundation for the Advancement of Innovative Medicine Report | The report reviews the terms 'medical necessity' and 'medically necessary care' as they are discussed in New York case law. They contend that the judicial, contractual, and statutory developments in New York created a standard of care that was lower than the negligence standard. |
| 1998 | Mohl, Paul C. | Medical Necessity: A Moving Target | Psychiatric Services 49(11):1391 | Letter from the editor discussing physician culpability in engendering HMOs and medical necessity definitions. |
| 1998 | The National Health Law Program | Medical Necessity Definition Model Medicaid Managed Care Contract Provisions | The National Health Law Program Report | Provides NHeLP's model medical necessity language. |
| 1998 | Olson, Kristi | The Threat of Evidence-Based Definitions of Medical Necessity | The National Health Law Program Report | Discusses possible consequences of using an evidence-based standard for determining medical necessity. It points to the fact that many commonly used practices will fail to meet evidence-based criteria. It also is concerned that minority groups, children, and women, who are historically limited in access to care and trials, will suffer disproportionately under evidence-based criteria. |

*Appendix A. Continued*

| Year | Author | Title | Source | Summary/Abstract |
|---|---|---|---|---|
| 1998 | Rosenbaum, Sara, et al. | Negotiating the New Health Care System: A Nationwide Study of Medicaid Managed Care Contracts | Center for Health Services Research and Policy | Contains compiled list and analysis of medical necessity definitions contained in state Medicaid managed care contracts. |
| 1999 | Bergthold, Linda A. | Testimony to the US Senate Committee on Health, Education, Labor, and Pensions: Medical Necessity: From Theory to Practice | US Senate Committee on Health, Education, Labor, and Pensions Report | Policy paper discussing the problems inherent in defining the term "medical necessity." She points out that the process by which decisions are made is far more important to understand and improve than the terminology used to describe those decisions, that there is substantial variation in the way medical necessity is defined and used in private contract, and that there is considerable discrepancy between contractual definitions and the way those definitions are applied in practice. Her final recommendation is that the Senate not define the terms in statute. Rather they should appoint a broader group of stakeholders to take on the task. |
| 1999 | Berman, Steve | Measuring and Improving the Quality of Care of Health Plans | The Joint Commission Journal on Quality Improvement 25(8): 434–442 | BACKGROUND: More than 200 health care policymakers and researchers, clinicians, quality professionals, and other representatives of managed care organizations, government, and academia attended the fifth annual Building Bridges conference, "The Health Care Puzzle: Using Research to Bridge the Gap Between Perception and Reality," in Chicago, April 11–13, 1999. Sponsored by the American Association of Health Plans and the Agency for Health Care Policy and Research—and now, the Centers for Disease Control and Prevention—these annual conferences are intended to promote research in measuring the quality and effectiveness of the services health plans provide. Selected plenary sessions from the conference are represented in this report. KEYNOTE ADDRESS: "Three worthy objectives" for managed care—harmonize practice guidelines, develop evidence-based co-pays or price structure for drugs, and demystify medical necessity—were discussed. PLENARY: A POPULATION HEALTH PERSPECTIVE: Population-based care is designed to identify effective clinical and service interventions and ensure their efficient delivery, identify ineffective interventions and minimize their use, and monitor outcomes and change practice if outcomes are sub-optimal. Yet certain questions need to be asked about how to put this strategy in place, especially, "Why should any individual or potential patient be willing to be treated in a population-based delivery system?" THE FINANCIAL AND SCIENTIFIC EVIDENCE BEHIND PREVENTION: The concepts of scientific evidence and financial evidence for prevention were reviewed and applied in scenarios of the effectiveness and cost-effectiveness of selected preventive care services. Education efforts are needed to promote the use of effective interventions and encourage questioning of interventions with unproven or less important effectiveness and poor cost-effectiveness. |

*Appendix A. Continued*

| Year | Author | Title | Source | Summary/Abstract |
|---|---|---|---|---|
| 1999 | Corlin, Richard | Statement of the AMA to the Committee on Health, Education, Labor and Pensions, United States Senate | American Medical Association | Formal AMA statement before the Senate addressing the issue of medical necessity. Emphasizes that the definition of medical necessity will become the standard applied to all review decisions. Health plan definitions may place barriers between patients and specialty care. They also leave most of the medical decision-making discretion with health plans as opposed to the patient's physician. Recounts 1998 AMA consensus definition of medical necessity, using a prudent physician standard. It also mentions the health plan practice of retroactive denials for rendered care, which the AMA believes should also be addressed. |
| 1999 | Hallam, K. | Lawmakers Define Medical Necessity | Modern Healthcare (3) | Discusses federal medical necessity legislation in brief. |
| 1999 | Ireys, Henry T., Elizabeth Wehr, and Robert E. Cooke | Defining Medical Necessity: Strategies for Promoting Access to Quality Care for Persons with Developmental Disabilities, Mental Retardation, and Other Special Health Care Needs | National Center for Education in Maternal and Child Health Report | Discusses medical necessity determinations in regards to persons with developmental disabilities. The report has a flow chart showing the dynamics of medical necessity decisions within current service systems. It also provides its own specifications for determining medical necessity. |
| 1999 | Macielak, Paul, and Monica Miller | The Atomic Bomb Scare Over Defining Medical Necessity | Health Lobby Letters | Two letters regarding New York State's medical necessity statute. The first opposes the statute because of concerns that it leaves all medical decision-making in the hands of the physicians and eliminates the plan's abilities to conduct utilization reviews. The second letter is a rebuttal that attempts to debunk the first point-by-point. |

*Appendix A. Continued*

| ***Year*** | ***Author*** | ***Title*** | ***Source*** | ***Summary/Abstract*** |
|---|---|---|---|---|
| 1999 | Rosenbaum, S., D. Frankford, B. Moore, and P. Borzi | Who Should Determine When Health Care Is Medically Necessary? | The New England Journal of Medicine 340(3):229–232 | In the authors' view, an insurer should be able to set aside the recommendations of a treating physician only in restricted circumstances. Decisions about coverage should continue to be weighed against clinically accepted standards of medical practice. An insurer's decision should be lawful only if the insurer can prove that the decision rests on valid and reliable evidence that is relevant to a patient's individual circumstances. The authors advocate neither a return to total autonomy for treating physicians in determining insurance coverage nor a system in which insurers decide on coverage according to criteria that are totally independent of professional standards of clinical practice. Rather, they propose maintaining the middle position represented by current law. This middle position requires insurers to act reasonably and weighs the reasonableness of their conduct against professional standards of practice as reflected by valid and reliable evidence. |
| 1999 | Rovner, Julie | Medical Necessity Takes Center Stage | Business and Health (26) | Discusses the general background of the current medical necessity debate in brief. |
| 1999 | Singer, Sara J., Linda A. Bergthold, Carol Vorhaus, Alain Enthoven, et al. | Decreasing Variation in Medical Necessity Decision Making | Stanford University Report | This is an in-depth report looking into the question of medical necessity. It deals with the variation and inconsistencies of definitions that the various stakeholders have. It notes a paucity of research regarding health plan decision-making and whether medical necessity definitions play a real role in decision-making. It documents a number of conferences and original research, eventually concluding with a consensus for a model decision-making process and medical necessity definitions. It concludes by reviewing the various stakeholders, their concerns, and what actions they could take to decrease medical necessity variability. |
| 2000 | Allen, Kathryn | Employers' Mental Health Benefits Remain Limited Despite New Federal Standards | United States General Accounting Office Report | This report examines the implementation and effects to date of the federal parity law, and focuses on: (1) employers' compliance and the changes made to their health benefit plans, (2) what is known about the costs of complying with the law, and (3) the oversight roles of HHS and DOL in enforcing the law. In brief, they found that most employers comply with the law; however, they have become more restrictive in the number of hospital days or outpatient visits covered for mental health when compared with traditional medical benefits. Few employers reported that the law has resulted in higher costs. Finally, the recent laws have expanded DOL's role in regulating health benefits. |

*Appendix A. Continued*

| Year | Author | Title | Source | Summary/Abstract |
|---|---|---|---|---|
| 2000 | Health Insurance Association of America | "Medical Necessity" and Health Plan Contracts | Health Insurance Association of America Report | This policy piece scripted on behalf of the HIAA highlights the problems of allowing medical necessity to be defined by physicians rather than insurers. Essentially, it argues that legislation changing the status quo would: (1) undermine utilization management and increase costs, (2) encourage fraud and abuse, (3) undermine quality and perhaps even expose patients to danger, and (4) undermine contract law. In the end they conclude that placing determination powers back squarely in the hands of providers will simply undo all the progress made in health care since its departure from widespread fee-for-service arrangements. |
| 2000 | Apgar, Kristen Reasoner | Large Employer Experiences and Best Practices in Design, Administration, and Evaluation of Mental Health and Substance Abuse Benefits: A Look at Parity in Employer-Sponsored Health Benefit Programs | Office of Personnel Management Report | Prepared for OPM, this report described how large corporations were structuring their insurance plans in order to deal with new mental health parity legislation. It discusses a 'big picture' approach, reportedly focusing on keeping employees healthy and well in order to avoid later problems with absenteeism, disability, and lost productivity. Eight employers were studied: American Airlines, AT&T, Delta Airlines, Eastman Kodak, IBM, General Motors, the Massachusetts Group Insurance Commission, and PepsiCo. They highlight what they believe to be essential mechanisms to providing parity in care as well as identify problematic areas. The author discusses the use of managed behavioral care carve-outs. The document ends by making recommendations regarding how OPM should structure future insurance programs. |
| 2000 | Fleishman, Martin | What is Psychiatric "Medical Necessity"? | Psychiatric Services 51(6): 711–712, 719 | This article reviews AMA's definition of medical necessity and points out problems of its application to psychiatry. It also recommends its own definition for psychiatry after a discussion of HIPAA law and possible implications for fraud in psychiatry. |
| 2000 | Ford, William | Medical Necessity and Psychiatric Managed Care | Psychiatric Clinics of North America 23(2):309–317 | The concept of medical necessity is a provision of commercial insurance contracts and federal government Medicaid requirements that limits the payment to only those services that are essential for treating a person's sickness, injury, or condition. The concept of medical necessity is one tool used by third-party payers to contain their financial risk in a seemingly non-arbitrary manner. Also, the definitions of medical necessity used by commercial insurers or by the federal government reflect their product's or program's philosophies. Expanding commercial insurance or Medicaid psychiatric coverage would require changing those philosophies. As long as society is faced with a greater demand for health-related service than resources to meet them, such systems of rationing will be used. Even with full parity for psychiatric benefits, mechanisms will be used by payers to limit or control demand, thereby controlling financial risk. The short-term challenge for psychiatric advocates is to secure the most acceptable definitions of medical necessity from third-party payers. The long-term challenge for MH/SA advocates and for all health care advocates, is to develop a system that pays for the greatest number of quality services for the greatest number of people in need, in an affordable manner, regardless of diagnosis. |

*Appendix A. Continued*

| Year | Author | Title | Source | Summary/Abstract |
| --- | --- | --- | --- | --- |
| 2000 | AMA Private Sector Advocacy Group | Medical Necessity | AMA Private Advocacy Group Report | This document contains the AMA model definition of medical necessity and discusses the need for providing a definition that reflects a clinical determination rather than a business determination. |
| 2000 | Hill, Hugh, Annette Hanson, and Brent O'Connell | Coverage Decisions | AHRQ User Liaison Program Report | This report summarizes a session that evaluated the processes for making coverage decisions in private, State, and Federal venues. Highmark Blue Cross Blue Shield describes their decision-making process, built around a contractual definition of 'medical necessity,' which it provides. The Massachusetts Medicaid model is based on statutory definitions of medical necessity and evidence-based assessments of new interventions. HCFA is also described, drawing its authoritative powers from section 1862 of the Social Security Act. Services or technologies that fulfill the criteria of the definition are divided into 55 statutorily defined benefit categories. |
| 2000 | Landau, Morris | The Difficulties in Defining Medical Necessity | Health Law and Policy Institute Report | This short briefing on the nature of the current difficulties in defining medical necessity concludes that a comprehensive approach that differs from third party rationing should be used in forming a decision. |
| 2000 | Sabin, James, and Norman Daniels | Public-Sector Managed Behavioral Health Care: V. Redefining "Medical Necessity"—The Iowa Experience | Psychiatric Services 51(4):445–459 | This article discusses psychiatric problems with medical necessity definitions and expresses a need for 'psychosocial necessity' expansion. It reviews Iowa's experience with managed behavioral health care and prognosticates that psychiatrists will be forced to opt out of the outpatient treatment of the severely mental ill due to current BHMO policies. |
| 2000 | Satcher, David | Mental Health: A Report of the Surgeon General | United States Public Health Service Report | This comprehensive report gives detailed background into many facets of mental health care. Chapter 6, "Organizing and Financing Mental Health Services," gives an in-depth analysis of the economic structure and costs of modern mental health care with comparisons to traditional medical health care. The document also examines the issue of mental health parity, looking at legislative trends and costs. Throughout the document, however, there is no discussion of mental health medical necessity. |
| 2000 | American Psych Systems | American Psych Systems Provider Packet | American Psych Systems Provider Packet | This packet of materials sent to psychiatric providers contains newsletters about recent changes, a complete copy of the updated Utilization Management criteria, and a copy of policies and procedures regarding coordination of care and provider appeals. Medical necessity is defined in loose terms for each condition; however, a separate set of admission criteria also must be met prior to admitting a patient for a psychiatric condition or continuing care for a protracted period of time. |

*Appendix A. Continued*

| **Year** | **Author** | **Title** | **Source** | **Summary/Abstract** |
|---|---|---|---|---|
| 2001 | National Committee for Quality Assurance | Standards and Surveyor Guidelines for the Accreditation of MBHOs | National Committee for Quality Assurance MBHO Handbook | These are the published guidelines used by NCQA to accredit MBHOs. Definitions of medical necessity are not suggested by NCQA; the MBHOs' definitions simply must be accessible and include procedures for applying criteria based on the needs of individual patients and characteristics of the local delivery system. NCQA does define medical necessity denial and underscores the need for MBHOs to use clinical practice guidelines. |
| 2001 | Cleary, Patrick | Benefit Mandates | National Association of Manufacturers Letter | Letter to Senator Gregg on behalf of National Association of Manufactures. The letter speaks out against S 543, the Mental Health Equitable Treatment Act of 2001. They argue that the new bill would greatly expand the parity laws of 1996 and would have many drawbacks. Costs would increase, while other benefits would be reduced to meet the bill's requirements. They argue that there are no discernable limits to the scope of potential coverage. They also voice concern over the bill's preemption provisions that would preserve State legislation and extend it to ERISA plans. |
| 2001 | Eddy, David | How Evidence-Based Balance Sheets Can Help Make Decisions | Kaiser Permanente Report | The author discusses the use of balance sheets and evidence-based medicine for clinical decision-making. He points to their ability to summarize in one place all the critical information needed to make decisions as a great strength. |
| 2001 | Fleishman, Martin | Medication Management, Medical Necessity and Residential Care | Psychiatric Times XVIII:3 | This article considers the difficulties of applying medical necessity definitions, including the AMA-APA definition, to the unique needs of the field of psychiatry. The term ' for convenience' is found to be a potential obstacle to providing psychiatric care. The paper also laments the lack of a specified role for external contributions from families, social workers, and non-professional caretakers. The article voices concern over the HIPAA alterations that make penalization of providers for medical fraud. It points to steeper fines, unclear definitions of medical necessity as its standard, and the fact that no specific intent to defraud is necessary. |
| 2001 | CCD Task Force | A Strong and Consistent Definition of Medical Necessity Forms the Core of Meaningful Patient Protections | Consortium for Citizens with Disabilities Report | Offers a proposed CCD medical necessity definition and discusses the implications such definitions can have on the disabled. It discusses the need to fabricate protections to ensure that patients with disabilities get the care they need. They point to a need to address functional ability in any final necessity definition. |

*Appendix A. Continued*

| Year | Author | Title | Source | Summary/Abstract |
|---|---|---|---|---|
| 2001 | Joint Commission on Accreditation of HealthCare Organizations | 2001-2002 Comprehensive Accreditation Manual for HealthCare Networks | Joint Commission on Accreditation of HealthCare Organizations MCO Handbook | This manual lays out the various rights of the beneficiaries, response mechanisms, and ethical outlook that JCAHO evaluates in determining if an organization receives accreditation. The guidelines do not offer any standards for medical necessity definitions, but rather clearly define standards regarding the medical decision-making process and information dissemination. |
| 2001 | Havighurst, Clark | Evidence: Its Meanings in Health Care and in Law. Summary of the 10 April 2000 IOM and AHRQ Workshop | Journal of Health Politics, Policy, and Law 26:2 | The author reviews Jacobson's presentation entitled "Cost-Effectiveness Analysis in the Courts: Recent Trends and Future Prospects." Of note, he discusses making contracts more explicit with regard to the use of CEA in coverage decisions. Havighurst mentions the possibilities of systematic misrepresentation of benefits by insurers using this technique. |
| 2001 | Regier, Darrel | Statement of APA Executive Director to US Senate Health, Education, Labor, and Pensions Committee on 'Parity for Mental Health Treatment' | American Psychiatry Association Report | This APA report to the Senate on the need for mental health parity legislation reinforces current understandings of the scientific basis underlying the causal mechanisms of mental disorders and provides evidence that parity insurance coverage is affordable, addresses a specific market failure, and can support cost-effective treatment to reduce disability. |
| 2001 | Singer, Sara J., and Linda A. Bergthold | Prospects for Improved Decision Making About Medical Necessity | Health Affairs 20(1):200–206 | Previous research has shown considerable variability in the process and criteria used for decision making in both public and private plans regarding medical necessity. This paper seeks to document differences in decision-making criteria and to explain the relationship between contractual definitions and the way decisions are made in practice. The investigators used descriptions of 'best practices' and 'unacceptable variations' from health plan interviews to provide insight into how medical necessity decisions are made. They also produced a model contractual definition and decision-making process based on best-practice models. |
| 2001 | Sturm, Roland | The Costs of Covering Mental Health and Substance Abuse Care at the Same Level as Medical Care in Private Insurance Plans | RAND Health Report | Research paper delving into the issue of the cost for health insurers to implement mental health parity. Their results suggest that parity in employer-sponsored health plans is not very costly under comprehensive managed care. Also data do not support excluding substance abuse from parity efforts due to prohibitive cost, because decoupling mental health and substance abuse care in terms of benefits cannot save any meaningful amount. These results may not apply to unmanaged indemnity plans, and they may only hold for large employers but not for individuals or for small groups buying insurance. |

# Appendix B. NCQA and JCAHO Utilization Management and External Appeals Standards

## National Committee for Quality Assurance (NCQA)

| ***NCQA Managed Behavioral Health Utilization Management Standards*** | ***NCQA Managed Behavioral Health External Appeals Standards*** |
|---|---|
| UM 2. To make utilization decisions, the managed healthcare organization uses written criteria based on sound clinical evidence and specifies procedures for applying those criteria in an appropriate manner:<br>• The criteria for determining medical necessity are clearly documented and include procedures for applying criteria based on the needs of individual patients and characteristics of the local delivery system.<br>• The managed healthcare organization involves appropriate, actively practicing practitioners in its development or adoption of criteria and in the development and review of procedures for applying criteria.<br>• The managed healthcare organization reviews the criteria at specified intervals and updates them as necessary.<br>• The managed healthcare organization states in writing how practitioners can obtain the UM (utilization management) criteria and makes the criteria available to its practitioners upon request.<br>• At least annually, the managed care organization evaluates the consistency with which the health care professionals involved in utilization review apply the criteria in decision-making. | UM 7.5 The managed behavioral healthcare organization has a procedure for providing independent, external review of final determinations, including:<br>Eligibility criteria stating that the MBHO offers enrollees the right to an independent, third party, binding review whenever:<br>• The enrollee is appealing an adverse determination that is based on medical necessity, as defined by MBHO.<br>• The MBHO has completed two levels of internal reviews, and its decision is unfavorable to the enrollee, or has elected to bypass one or both levels of internal review or has exceeded its time limit for internal reviews without good cause and without reaching a decision.<br>• The enrollee has not withdrawn the appeal request, agreed to another dispute resolution proceeding, or submitted to an external dispute resolution proceeding required by law.<br>Notification to enrollees about the independent appeals program and clear and timely explanations of denials and approvals to both enrollees and their physicians.<br>Use of an independent review organization that meets the following criteria:<br>• Conducts a thorough review in which it considers anew all previously determined facts, allows the introduction of new information, considers and assesses sound medical advice, and makes a decision or conclusion that is not bound by the decisions or conclusions of the internal appeal.<br>• Has no material professional, familial, or financial conflict of interest with the MBHO.<br>MBHO non-interference with the proceedings of the external review.<br>Enrollee exemption from the cost of external review, including filing fees, and allowance of designating a representative to act on the behalf of the enrollee.<br>Implementation of independent review organization decision within specified timeframe.<br>MBHO data tracking of external appeals for use in evaluating its medical necessity decision-making process. |

*Appendix B. Continued*

| ***JCAHO Utilization Management Standards*** | ***JCAHO External Appeals Standards*** |
|---|---|
| CC 1: Health care services provided directly or by arrangement are appropriate:<br>• In scope to meet the health care needs of the population served.<br>• To the health care needs, as influenced by socio-cultural characteristics, of the population served.<br>• To the network's mission.<br>• To the network's contractual obligations.<br>CC 8: When the network or an external entity conducts a utilization review of a licensed independent practitioner's or a network component's care that results in denial of payment, decisions by the licensed independent practitioner or network component regarding ongoing care or discharge are based on the care required by the member's assessed needs.<br>CC 8.1: When utilization review results in an adverse utilization management decision, the network provides the criteria for the decision and information regarding appeal to the licensed independent practitioner responsible for the member's care.<br>JCAHO provides examples of implementation. ***"These examples are simply ideas for your network to consider."***<br>***Example of implementation for CC 8:*** The network requests the review criteria used by any external entity that carries out a utilization review on the network's members. The review criteria are made available to those within the network responsible for treatment and discharge decisions. When the external utilization review organization's recommendation conflicts with the member's medical care requirements, justification for the course of action taken is documented. Information from the external entity is collected and incorporated into the network's assessment and improvement activities.<br>RI 2: The network provides for member involvement in care and treatment decisions.<br>RI 2.1: The network provides an authorization process for care and treatment that is timely, efficient, and meets member health care needs.<br>The network's process for authorizing care and treatment includes:<br>• Providing members with a description of the treatment authorization process.<br>• Having initial decisions made by an appropriately trained health care professional using evidence-based, network-approved criteria to authorize admission, care, and transition to another care setting.<br>• Having a physician, dentist, or behavioral clinician review all initial treatment authorization denials prior to notifying the member or their representative(s) of an adverse determination. | RI 2.2: The network provides a method for resolving disagreements between the network and the member or designated decision maker(s) regarding care or treatment authorization decisions.<br>The network's process includes:<br>• Informing members how to seek appeals of adverse determinations.<br>• Defined timeframes in which the member can anticipate response to an appeal.<br>• Appeal timeframes that are appropriate to the urgency of the member's health care needs.<br>• An appeal review panel including health care professionals who are appropriately trained, experienced, and competent with respect to the care and treatment involved, and who were not involved in the initial determination.<br>• Informing members about further steps available when disagreements cannot be resolved through the treatment authorization and appeal process, such as an internal grievance process, arbitration, legal proceedings, and any other external review processes.<br>RI 5: The network provides for the receipt and resolution of complaints and grievances from members in a timely manner.<br>The member has the right to voice complaints without fear of recrimination about the care received and to have complaints reviewed and, whenever possible, resolved. This right and the way it is protected are explained to the member. The network has a means of providing for the following:<br>• Procedures for registering and managing complaints and grievances, including identifying the party receiving complaints and grievances.<br>• Aggregating and reporting actions taken on complaints and grievances.<br>• A timely response to the member, substantively addressing the action taken on the complaint or grievance.<br>• Including the aggregate complaint and grievance information in performance improvement activities.<br>• An appeal process for grievance decisions.<br>• Member protection from any sanctions or penalties resulting solely or primarily from using the complaint or grievance process. |

*Appendix B. Continued*

| ***JCAHO Utilization Management Standards*** | ***JCAHO External Appeals Standards*** |
|---|---|
| • Informing members in a timely manner, in writing, when a request to authorize treatment has been denied.<br>• Informing members of the basis and reason(s) for the adverse determinations.<br>• Informing members of the review criteria used to make the determination.<br>• Providing members with information as to whether, and under what circumstances, investigational procedures are available and are covered by the network. | |

## Appendix C. Litigation Regarding Medical Necessity Definitions and Procedures (Sorted by Case Name)

| ***Year*** | ***Case*** | ***Court*** | ***Claim*** | ***Disputed Subject*** | ***Disposition*** | ***Insurer's Decision*** |
|---|---|---|---|---|---|---|
| 1996 | Bancroft and Bancroft v. Tecumseh Products | US District Court for the Eastern District of Michigan, Southern Division | Sought reimbursement for breast reduction surgery; denied on medical necessity grounds. | Court found that Plan administrator improperly denied benefits in an arbitrary and capricious manner. | Judgment entered for the plaintiff. | Reversed. |
| 1999 | Bauer v. Country Life Insurance | US District Court for Northern District of Illinois | Sought preliminary and permanent injunction for high dose chemotherapy with allogenic bone marrow transplant after medical necessity denial. | Procedure found to be experimental and thus excluded from the policy. There was no evidence that the Plan administrator acted in an arbitrary or capricious manner. | Judgment entered for the Plan. | Affirmed. |
| 1996 | Bedrick v. Travelers Insurance | US Court of Appeals, 4th Circuit | Appeal of summary judgment in favor of Plan regarding the denial of physical, occupational, and speech therapy benefits. | On appeal, the court found the patient did not receive a "full and fair" review. | Reversed judgment in regards to physical and occupational therapy and remanded with instructions to grant summary judgment for the plaintiff. Affirmed all other aspects of judgment, including denial of speech benefits specifically excluded under the contract. | Reversed in part, affirmed in part. |
| 1994 | Blue Cross Blue Shield of Virginia v. Keller | Supreme Court of Virginia | Appeal of summary judgment awarded to Plan regarding denial of benefits on medical necessity grounds. | Court of Appeals found that there was no evidence presented to show that the Plan abused its discretion. | Affirmed lower court's summary judgment. | Affirmed. |
| 2001 | Burrell v. United Health Care Insurance | US District Court for the Eastern District of Pennsylvania | Made bad faith claim regarding denial of coverage of inpatient stay for post-traumatic stress disorder. Plan argued that refusal was based on both medical necessity grounds as well as ineligible treatment facility. | Court found that there was no clear evidence that the Plan acted in an arbitrary or capricious manner. | Partial summary judgment entered for Plan. | Affirmed. |

*Appendix C. Continued*

| Year | Case | Court | Claim | Disputed Subject | Disposition | Insurer's Decision |
|---|---|---|---|---|---|---|
| 1996 | Bushman v. State Mutual Life | US District Court for the Northern District of Illinois, Eastern Division | Sought injunction in regards to medical necessity denial of high-dose chemotherapy and bone marrow transplant. | Court found that the policy language clearly stated that the plaintiff's illness was excluded from coverage and that the plaintiff failed to show that the Plan acted in an arbitrary and capricious manner. | Summary judgment entered for the Plan. | Affirmed. |
| 1993 | Camelot Care v. Planters Lifesavers | US District Court for the Northern District of Illinois, Eastern Division | Sought reimbursement for care delivered. Plan defined provider as "primarily" a "custodial care" facility and not a "hospital," and thereby expressly excluded it from reimbursement under the Plan's contract. | Court found that the summary Plan description defined neither custodial nor domiciliary care that was excluded from coverage. It found the provider to be a hospital for the Plan's purposes. | Judgment entered in favor of plaintiff. | Reversed. |
| 2000 | Chemacki v. Meijer, Inc. | US District Court, Western District of Michigan, Southern Division | Sought reimbursement for immunotherapy and allergy antigen injections after medical necessity denial. | Claim fell outside 1-year window following denial notification. Plan administrator also was found not to have acted in an arbitrary and capricious manner. | Judgment entered for the Plan. | Affirmed. |
| 1996 | Couri v. Guardian Life | US District Court for the Northern District of Illinois, Eastern Division | Sought dental benefits denied on medical necessity grounds. Plan sought summary judgment. | Court found that genuine issues of material fact existed regarding whether the insurer's actions constituted arbitrary and capricious conduct. | Summary judgment was denied. | Reversed. |
| 1998 | Crocco v. Xerox and American Psych Management, Inc. | US Court of Appeals, 2nd Circuit | Appeal of judgment in favor of plaintiff regarding the Plan's "full and fair" review guaranteed under ERISA when making benefit determinations. | On appeal, the court upheld the previous ruling that the Plan's administrator acted in an arbitrary and capricious manner and remanded the case for a full and fair review. It also found that Xerox was not the administrator in this case, dismissing Xerox from the suit. | Affirmed in part, reversed in part. | Reversed. |

*Appendix C. Continued*

| **Year** | **Case** | **Court** | **Claim** | **Disputed Subject** | **Disposition** | **Insurer's Decision** |
|---|---|---|---|---|---|---|
| 1998 | D'Angelo v. Blue Cross Blue Shield of Central New York | Supreme Court of New York, Appellate Division, 3rd Department | Appeal of judgment in favor of plaintiff regarding benefits denied on medical necessity grounds. Plan argued that verdict was not supported by legally sufficient evidence. | On appeal, the court found that the evidence was legally sufficient. | Affirmed. | Reversed. |
| 2000 | Delmarva Health Plan v. Aceto | Court of Chancery of Delaware, New Castle | Plan sought declaration that it had no duty to provide coverage for a lung transplant. | Court found that the policy did not expressly exclude the procedure and that a policyholder could reasonably expect that services necessary to life would be provided. | Summary judgment entered for Aceto. | Reversed. |
| 1993 | Dettmer Clinic v. Associated Insurance | US District Court for the Northern District of Indiana, South Bend Division | Chiropractor sought reimbursement for rendered services denied on medical necessity grounds. | Court upheld the insurer's right to determine medical necessity. | Summary judgment awarded to Plan. | Affirmed. |
| 1992 | Deville Nursing Service v. Metropolitan Life | US District Court for the Western District of Louisiana, Lake Charles Division | Sought reimbursement for custodial care services denied on medical necessity grounds. | Court found that Plan's contractual language clearly states that custodial care is not a covered service. Plan's decision was not arbitrary or capricious. | Summary judgment entered for Plan. | Affirmed. |
| 1997 | Dowden v. Blue Cross Blue Shield of Texas | US Court of Appeals, 5th Circuit | Appeal of summary judgment in favor of Plan regarding the denial of expenses incurred in treatment of silicone breast implant complications. | On appeal, the court affirmed the lower court's ruling, finding nothing arbitrary or capricious in the decision-making process. | Affirmed. | Affirmed. |
| 1996 | Esdale v. American Community Mutual Insurance | US District Court for the Northern District of Illinois, Eastern Division | Sought benefits for high-dose chemotherapy with peripheral stem cell rescue denied on medical necessity grounds as experimental. Plan sought summary judgment. | Court found that evidence presented revealed that the experimental status of the treatment was unclear in the literature. | Summary judgment was denied. | Reversed. |

*Appendix C. Continued*

| Year | Case | Court | Claim | Disputed Subject | Disposition | Insurer's Decision |
|---|---|---|---|---|---|---|
| 1993 | Evans v. Blue Cross Blue Shield of South Carolina | US District Court for the District of South Carolina | Sought reimbursement for radial keratotomy denied on medical necessity grounds. | Court found that the procedure did not meet the requirements of medical necessity set forth by the contract. | Judgment and attorney's fees awarded to Plan. | Affirmed. |
| 1992 | Farley v. Benefit Trust Life Insurance | US Court of Appeals, 8th Circuit | Appeal of judgment in favor of Plan regarding the denial of high-dose chemotherapy and allogenic bone marrow transplant on medical necessity grounds. | On appeal, the court found that the burden of proof was on the plaintiff to show that the procedure was not experimental. | Affirmed. | Affirmed. |
| 1994 | Fenio v. Mutual of Omaha | US District Court for the Southern District of Florida | Sought preliminary injunction for high-dose chemotherapy and allogenic bone marrow transplant denied on medical necessity grounds. | Court found on review of evidence that patient demonstrated a substantial likelihood of success on the merits. | Preliminary injunction ordered for plaintiff. | Reversed. |
| 1993 | Florence Nightingale Nursing Service v. Blue Cross Blue Shield of Alabama | US District Court for the Northern District of Alabama, Southern Division | Sought reimbursement for services provided. Plan argued that services charges were unreasonable and that nursing care after IV removal was not medically necessary. | Court found that the Plan administrator had a conflict of interest that tainted his judgment. Nursing charges were found to be reasonable. | Payment awarded to plaintiff. | Reversed. |
| 1993 | Fuja v. Benefit Trust Life | US Court of Appeals, 7th Circuit | Appeal of judgment in favor of plaintiff regarding the denial of "experimental" cancer therapy on medical necessity grounds. | On appeal, the court reversed the lower court's interpretation of experimental, finding that the treatment in this case was clearly experimental. | Reversed. | Affirmed. |
| 1995 | Grethe v. Trustmark Insurance | US District Court for the Northern District of Illinois, Eastern Division | Sought preliminary injunction and benefits for high-dose chemotherapy and allogenic bone marrow transplant denied on medical necessity grounds. | The court, after de novo review, found that the plaintiff had not met her burden of establishing that the proposed treatment met all the criteria for medical necessity as defined by the policy. | Preliminary injunction was denied. | Affirmed. |

*Appendix C. Continued*

| Year | Case | Court | Claim | Disputed Subject | Disposition | Insurer's Decision |
|---|---|---|---|---|---|---|
| 1996 | Harrison v. Aetna Life | US District Court for the Middle District of Florida, Orlando Division | Sought reimbursement for jaw surgery denied on medical necessity grounds. | Court found that the insurer actually extended coverage not only through its coverage provisions but also through some of its limitations. The surgery was found to be medically necessary and not done for cosmetic purposes. | Damages rewarded to plaintiff. | Reversed. |
| 1993 | Heasley and Heasley v. Belden and Blake Corporation | US Court of Appeals, 3rd Circuit | Appeal of judgment in favor of plaintiff regarding the denial of liver/pancreas transplant benefits on medical necessity grounds. | On appeal, the court found that the lower court's analysis was suspect, as it was unable to be determined whether the procedure was experimental. | Judgment vacated and remanded. | Affirmed. |
| 1993 | Heil v. Nationwide Life | US Court of Appeals, 6th Circuit | Appeal of summary judgment awarded to Plan regarding the medical necessity denial of plaintiff's inpatient psychiatric treatment. | Court of Appeals found the lower court erred by not reviewing the entire Plan and making its own determination regarding the appropriate standard of review rather than relying on the stipulation made by the parties. Secondly, it erred when it determined that, as a matter of law, the treatment was not medically necessary. | Vacated the judgment and remanded for further proceedings. | Reversed. |
| 2001 | Hundley v. Wenzel and Conseco Medical Insurance | Missouri Court of Appeals, Western District | Appeal of judgment in favor of Plan regarding denial of chiropractic care on medical necessity grounds. | On appeal, the court reversed the trial court's findings. It found that the medical director made his decision in an arbitrary and capricious manner. | Reversed and remanded. | Reversed. |
| 1999 | Jones v. Kodak Medical Assistance Plan | US Court of Appeals, 10th Circuit | Appeal of judgment in favor of Plan regarding denial of inpatient substance abuse treatment and allegation that insurer acted arbitrarily and capriciously in its denial determination. | The case contained no medical necessity definition per se but instead included a provision construed by the court as limiting treatment to the guidelines used by the managed behavioral health subcontractor. | Judgment entered for the defendant. | Affirmed. |

*Appendix C. Continued*

| **Year** | **Case** | **Court** | **Claim** | **Disputed Subject** | **Disposition** | **Insurer's Decision** |
|---|---|---|---|---|---|---|
| 1999 | Hunter v. Wal-Mart Stores | US District Court for the Eastern District of Arkansas, Western Division | Sought reimbursement for hysterectomy twice denied by Plan on medical necessity grounds. | Plan administrator found to have abused his discretion because the involved physicians determined that the operation was not the next therapeutic step, rather than determining that the operation was not medically necessary. | Judgment entered for plaintiff. | Reversed. |
| 2000 | Juliano v. HMO of New Jersey | US Court of Appeals, 2nd Circuit | Appeal of judgment for reimbursement for home nursing care denied on medical necessity grounds. Plan argued that its discretion allows for it to offer care at skilled nursing facilities and that private care was not medically necessary. | Initial court found that the rates of home nursing were actually less than that of the skilled nursing facility. On appeal, the court found that additional proceedings were needed to assess damages. | Vacated and remanded. | Reversed. |
| 1998 | Killian and Killian v. HealthSource | US Court of Appeals, 6th Circuit | Appeal of judgment citing arbitrary and capricious behavior by Plan in regards to denial of breast cancer treatment on medical necessity grounds. | On appeal, court found the Plan to be arbitrary and capricious in considering additional evidence after deadlines, but not so in making its determination. | Case was affirmed in part, reversed in part, and remanded for further proceedings. | Affirmed. |
| 1993 | Koenig v. Metropolitan Life | US District Court for the Northern District of Illinois, Eastern Division | Sought reimbursement for substance abuse care denied by Plan. Plan argued that plaintiff did not exhaust internal remedies. | The court found that the evidence showed that continued internal appeal attempts would have proven futile and useless. | Plan's motion to dismiss the case was denied. | Reversed. |
| 1992 | Lehman v. Mutual of Omaha | US District Court for the District of Arizona | Sought reimbursement for high-dose chemotherapy and allogenic bone marrow transplant denied on medical necessity grounds. | Court found after de novo review that the evidence presented suggested that the procedure was experimental and, therefore, not covered under the Plan's contract. | Judgment entered for the Plan. | Affirmed. |
| 1999 | Lewis v. Trustmark Insurance | US Court of Appeals, 4th Circuit | Appeal of summary judgment in favor of Plan regarding denial of benefits for high-dose chemotherapy and allogenic bone marrow transplant on medical necessity grounds. | On appeal, the court was unable to conclude that the Plan was unreasonable in their interpretation of the policy. | Affirmed. | Affirmed. |

*Appendix C. Continued*

| Year | Case | Court | Claim | Disputed Subject | Disposition | Insurer's Decision |
|---|---|---|---|---|---|---|
| 1992 | Mann v. Prudential Insurance | US District Court for the Southern District of Florida | Sought benefits for uterine monitoring services denied on medical necessity grounds as specifically excluded. | Court found that the plaintiff failed to provide evidence that the Plan's decision was arbitrary or capricious. | Summary judgment entered for Plan. | Affirmed. |
| 1996 | Maune v. International Brotherhood of Electrical Workers | US Court of Appeals, 8th Circuit | Appeal of summary judgment in favor of Plan regarding the denial of benefits for breast implant removal. | On appeal, the court upheld the finding that the procedure was not medically necessary. The court found the case not trivial, reversing the legal fee rulings. | Affirmed in part, reversed in part. | Affirmed. |
| 1992 | McGee v. Equicor-Equitable HCA | US Court of Appeals, 10th Circuit | Appeal of judgment in favor of Plan regarding denial of rehabilitative care on medical necessity grounds. | On appeal, the court affirmed that the patient's transfer severed relations with Plan physicians and prevented the Plan from making necessary predeterminations of improvement as required by contract. | Affirmed. | Affirmed. |
| 1998 | McGraw v. Prudential Insurance | US Court of Appeals, 10th Circuit | Appeal of summary judgment in favor of Plan regarding the denial of physical therapy benefits on medical necessity grounds. | On appeal, the court affirmed that ERISA governed action and reversed conclusion that denial of benefits was not arbitrary and capricious. | Case was affirmed in part, reversed in part, and remanded for further proceedings. | Reversed. |
| 1999 | Meditrust v. Sterling Chemicals | US Court of Appeals, 5th Circuit | Appeal of summary judgment in favor of Plan regarding denial of rehabilitative care on medical necessity grounds. | Court of Appeals found that the lower court had applied the correct discretionary standard and that the Plan did not act in an arbitrary and capricious manner. | Affirmed summary judgment in favor of Plan. | Affirmed. |
| 1995 | Miller v. United Welfare Fund | US Court of Appeals, 2nd Circuit | Appeal of judgment in favor of plaintiff regarding the denial private nursing benefits on medical necessity grounds. | On appeal, the court upheld that the Plan acted arbitrarily and capriciously. It also found that the lower court erred by considering evidence outside of the administrative record. | Case was remanded to trial court with instructions. | Reversed. |

*Appendix C. Continued*

| Year | Case | Court | Claim | Disputed Subject | Disposition | Insurer's Decision |
|---|---|---|---|---|---|---|
| 2001 | Milone v. Exclusive Healthcare | US Court of Appeals, 8th Circuit | Sought pre-certification for breast reduction surgery after medical necessity denial. Plan later appealed, arguing that its contract had a direct exclusion for the surgery in her case. | Plan's denial was found to be internally inconsistent and ambiguous. Other women had been previously approved. On appeal, the court disagreed with the Plan's interpretation of the contractual language. | Judgment entered for the plaintiff. Lower court decision upheld on appeal. | Reversed. |
| 1999 | Neurocare and Whitmore v. Principal Life | US District Court for Northern District of California | Sought reimbursement for rehabilitation services delivered after medical necessity denial. | Plan found to rely on excerpts of only one of the treating physicians in exclusion of the others, thus abusing its discretion. | Judgment entered for the plaintiffs. | Reversed. |
| 1997 | Nichols v. Trustmark Insurance | US District Court for the Northern District of Ohio, Eastern Division | Sought benefits for high-dose chemotherapy and allogenic bone marrow transplant denied by Plan on medical necessity grounds. Plan sought summary judgment. | Court found that genuine issues of material fact exist as to whether the treatment is experimental and to whether the Plan had 'reasonable justification' for its decision to deny benefits. | Plan's motion for summary judgment was denied. | Reversed. |
| 1995 | Personnel Pool of Ocean County v. Trustees Fund | US District Court for the District of New Jersey | Sought reimbursement for nursing benefits denied on medical necessity grounds. | Court found that the decision was reasonable and not arbitrary and capricious. | Judgment with prejudice entered for Plan. | Affirmed. |
| 2000 | Risenhoover v. Bayer | US District Court, Southern District of New York | Sought preliminary injunction to prevent Plan from discontinuing IV treatments for Lyme disease after medical necessity denial. | Denial found not to be arbitrary or capricious. | Judgment entered for the Plan. | Affirmed. |
| 1993 | Scalamandre v. Oxford Health Plans | US District Court for the Eastern District of New York | Sought reimbursement for high-dose chemotherapy and allogenic bone marrow transplant received outside of Plan's chosen hospitals and denied on medical necessity grounds. | Court found that the contract language and actions of the Plan made it impossible to comply with pre-certification requirements. | Full benefits awarded to plaintiff. | Reversed. |
| 1997 | Semmler v. Metropolitan Life | US District Court for the Southern District of New York | Sought benefits for patient-controlled anesthesia denied by Plan. Plan claimed that the service was covered in the physician's package fee and reimbursement would be equivalent to double billing. | Court found no abuse of discretion using an arbitrary and capricious standard. | On appeal, the plaintiff's motion to vacate the judgment was denied. | Affirmed. |

*Appendix C. Continued*

| Year | Case | Court | Claim | Disputed Subject | Disposition | Insurer's Decision |
|---|---|---|---|---|---|---|
| 1994 | Sheppard and Enoch Pratt Hospital v. Travelers Insurance | US Court of Appeals, 4th Circuit | Appeal of judgment awarded to Plan regarding denial of partial benefits of 16-month long hospital stay on medical necessity grounds. | Court of Appeals affirmed that the Plan administrator's denial of coverage was not an abuse of discretion. The Plan's failure to provide specific reasons as to why the hospitalization was not medically necessary for the full 16 months was not necessary. | Affirmed lower court's judgment. | Affirmed. |
| 2001 | Smith v. Newport News | US District Court, Eastern District of Virginia | Sought injunction in regards to medical necessity denial of coverage for high-dose chemotherapy. | Questioned whether Plan administrator abused his discretion in making the decision. | Preliminary injunction granted. | Reversed. |
| 1993 | Snell v. Travelers Insurance | US District Court for the Eastern District of Pennsylvania | Sought reimbursement for high-dose chemotherapy and allogenic bone marrow transplant denied on medical necessity grounds. | Court found that the Plan was only beholden to a deferential standard and the Plan's decision was not arbitrary and capricious. | Summary judgment awarded to the Plan. | Affirmed. |
| 1997 | Sophie and Sophie v. Lincoln National Life | US District Court for Northern District of Illinois, Eastern Division | Sought benefits for artificial insemination denied on medical necessity grounds. | Court found that artificial insemination was not a covered benefit and further held that the plaintiffs could not show that, in the absence of treatment, state of health would deteriorate. | Summary judgment entered for Plan. | Affirmed. |
| 1996 | Sven v. Principal Mutual Life | US District Court for the Northern District of Illinois, Eastern Division | Sought reimbursement for allergy treatments denied on medical necessity grounds. Plan sought summary judgment. | Court found that de novo standard was most appropriate. | Summary judgment was denied. | Reversed. |
| 1994 | Trustees of Northwest Laundry v. Burzynski | US Court of Appeals, 5th Circuit | Appeal of judgment in favor of Plan regarding the denial of reimbursement for provider's services. | On appeal, the court affirmed the lower court's ruling that the provider defrauded the Plan by submitting claims for unorthodox cancer treatments. | Affirmed. | Affirmed. |
| 2000 | Trustmark Life v. University of Chicago Hospitals | US Court of Appeals, 7th Circuit | Appeal of judgment for Plan to recover money spent on breast cancer treatment later found to be medically unnecessary. | On appeal, the court found that the provider hospital was entitled to keep the money under the theory of estoppel. | Reversed. | Reversed. |

*Appendix C. Continued*

| Year | Case | Court | Claim | Disputed Subject | Disposition | Insurer's Decision |
|---|---|---|---|---|---|---|
| 1999 | Wellness Aerobic Clinic v. United HealthCare | US District Court for Eastern District of Louisiana | Sought reimbursement for rehabilitation services delivered after medical necessity denial. | Denial of benefits found to be legally correct and not an abuse of discretion. | Summary judgment for Plan | Affirmed. |
| 1994 | Whitehead v. Federal Express | US District Court for the Western District of Tennessee, Western Division | Sought preliminary injunction for high dose chemotherapy with peripheral stem cell rescue denied on medical necessity grounds. | Court found it did not have the authority to usurp the power of Plan to interpret contract terms. It did not find that the Plan acted in an arbitrary and capricious manner. | Preliminary injunction denied. | Affirmed. |

## Appendix D. State Investigations and Legal Actions Regarding Medical Necessity Issues

| State | Description |
|---|---|
| **New York** | A significant legal development regarding medical necessity was the series of October 2001 settlement agreements reached between the New York State Attorney General's Office and six large MCOs.[1] Following a two-year investigation into how these MCOs informed their providers and enrollees of adverse determination decisions on the grounds of medical necessity, Attorney General Eliot Spitzer found that these MCOs were not in compliance with New York State's utilization review law (discussed in more detail in Part 3 below). The focus of the investigation was on the processes used by the MCOs in making their determinations and informing providers and enrollees of them, rather than the content of the medical necessity definitions themselves. Spitzer's office found, for example, that MCOs were often denying authorization or reimbursement for inpatient mental health and substance abuse treatment and offering nothing more than a generic explanation that the service was "not medically necessary." There was often no disclosure of the underlying reasons or clinical rationale used by the MCOs in making their decisions, which is required in New York's utilization review law. An example of such an inadequate disclosure, as contained in Exhibit A of the settlement agreements, was:<br><br>***Denial of continuation of stay at psychiatric inpatient facility:*** *Patient was cooperative throughout stay with no overt psychiatric symptom according to the attending Doctor. Medication was discontinued during the stay. This referral does not meet either severity of illness, or intensity of service and is therefore denied.*[2]<br><br>The settlement agreements defined "reasons and clinical rationale" as follows, stipulating consideration of individualized medical assessments and disclosure of sufficient information in adverse determination notices:<br><br>*"Reasons and Clinical Rationale" means the individualized medical basis for an Adverse Determination. A statement of Reasons and Clinical Rationale must demonstrate that the UR [Utilization Review] Agent made an individualized medical assessment of the Enrollee by referring to the specific medical data relating to the Enrollee, which the Clinical Peer Reviewer took into consideration when making the Adverse Determination. Merely stating that the service at issue is not medically necessary is not sufficient, nor is a statement that the proposed service does not meet the UR Agent's criteria. A statement of Reasons and Clinical Rationale must be sufficiently specific to enable the Enrollee and/or the Enrollee's health care provider to make an informed decision about whether or not to appeal the Adverse Determination and to determine the issue or issues to address in the appeal.*[3]<br><br>Rather than take the cases to trial, the Attorney General's Office and the MCOs agreed to settle out of court. Under the terms of the settlement agreements, the MCOs (while admitting no wrongdoing) agreed to reform their notification practices to bring them into compliance with state law and to each pay $1 million towards the cost of the investigation. The Attorney General's office will continue to monitor their practices until January 2004, with a possible one-year extension of the monitoring for MCOs still found to be noncompliant.[4]<br><br>[1] Aetna/U.S. HealthCare Inc./Prudential Health Plan of Hartford, CT; Excellus Health Plans of Rochester; Group Health Inc. of Manhattan; HIP Health Plan of Greater New York, Inc.; Oxford Health Plans of Trumbull, CT; and Vytra Health Plans of Long Island, Inc. *See:* "Landmark Agreements Give Consumers New Protections in HMO Disputes." NY Attorney General's Office Press Release. October 16, 2001. Available at http://www.oag.state.ny.us. Accessed October 29, 2001.<br>[2] Attorney General of the State of New York, Health Care Bureau. "In the matter of Group Health Incorporated: Assurance of Discontinuance Pursuant to Executive Law Section 63, Subdivision 15 (Exhibit A)." August 27, 2001.<br>[3] Id., p. 4.<br>[4] NY Attorney General's Office Press Release. October 16, 2001. op. cit. |

*Appendix D. Continued*

| | |
|---|---|
| **Maine** | In 2000, both United Behavioral Health and Cigna Behavioral Health, Inc., entered into consent agreements with the Maine Bureau of Insurance.[5] Health plan enrollees had filed complaints with the Bureau concerning denials of coverage based on medical necessity grounds. A subsequent determination by the Bureau that the denials were not in conformance with Maine rules regarding utilization review led to the agreements.<br><br>In the UBH case, two separate enrollees were denied coverage for mental treatment of two or more family members by the same therapist. At the time, UBH had a written guideline that it was generally necessary for family members to receive concurrent treatment by separate therapists. The Bureau found that the denial notices did not adequately conform to the state agency rules[6] in that they did not contain the qualifying credentials of the reviewer; did not include a statement of the reviewer's understanding of the consumer's reasons for appeal; did not clearly state the decision and clinical rationale in sufficient detail to allow the consumers to respond further; did not include a reference to the evidence or documentation used for the adverse determination; did not include a description of the procedures, time frames, and consumers' rights for second level grievance review; and did not include a notice of the right of the consumers to contact the Bureau of Insurance. UBH was fined $10,000, and further adjudicatory proceedings were dropped.<br><br>In the Cigna case, an enrollee was denied benefits for the last three days of her minor child's five-day inpatient stay at a hospital on the grounds that the child ostensibly could have been transferred to a psychiatric facility after the first 48 hours. On the fifth day, the child, who was suicidal, was transferred to a non-Cigna-contracted facility on the first day that facility had a vacant bed. There were no other contracted or non-contracted facilities in Cigna's network within 60 minutes travel distance from the enrollee's home (required by Maine law). Following a series of reviews and appeals, Cigna reversed its original denial nearly a year later. The Bureau of Insurance found that:<br><br>*By reversing its denial of benefits, CBH acknowledged the need for holding Consumer's child on an inpatient basis until her move to Acadia. Participation by CBH in the unsuccessful effort on July 24th for an immediate transfer shows it then knew or should have known that: 1) until the transfer could be effected, it was medically necessary for the child to continue receiving inpatient care at EMMC; and 2) CBH's guideline for transfer to a psychiatric facility within 48 hours of admission to an acute care hospital could not be met where, as here, through no fault of Consumer there was no psychiatric facility reasonably available to accept her daughter prior to July 27th.*<br><br>The Bureau also found that the content of Cigna's denial letters was not in conformance with Maine law, for many of the same reasons as the UBH case. Cigna was fined $5,000, and further adjudicatory proceedings were dropped.<br><br>In distinguishing these two cases, it is notable that in the UBH case, its "separate therapists" guideline was not called into question on the grounds of reasonableness or appropriateness. Rather, the company was cited for deficiencies in the processes it used to notify the enrollees of the benefit denials. In the Cigna case, however, the Bureau found the application of the "48-hour rule" for transfer in medical necessity decisions to be substantively inappropriate in light of the inadequacy of the provider network, which did not meet state standards. |

[5] In RE: United Behavioral Health, Consent Agreement with Maine Bureau of Insurance, op. cit. In RE: Cigna Behavioral Health, Inc., Consent Agreement with Maine Bureau of Insurance, Docket No. 00-3003. Available at http://www.state.me.us/pfr/ins/ins003003.htm. Accessed April 17, 2002.

[6] Bureau of Insurance Rule Chapter 850(8) and (9).

Center for Mental
Health Services

DHHS Publication Number (SMA 03-3790)

Printed 2003

Substance Abuse and Mental
Health Services Administration