Decreasing Variation in Medical Necessity Decision Making

Final Report to the California HealthCare Foundation, Grant Number 98-5021

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I. Executive Summary: Decreasing Variation in *Medical Necessity* Decision Making

THE MEDICAL NECESSITY DECISION MAKING PROCESS SIGNIFICANTLY IMPACTS THE DELIVERY OF HEALTH CARE

Medical Necessity was not a problematic issue when remote third party payers rarely challenged physicians' decisions and reimbursed physicians for whatever procedures they chose to order and perform. Over the past several decades, the term *medical necessity* has served as an innocuous placeholder, enabling insurance plans and physicians to make judgments about coverage that were usually unchallenged.[1] The fact that individual physicians practiced differently and that some practice variation may be inappropriate was revealed by the path breaking work of John Wennberg, MD and colleagues at Dartmouth Medical School.[2] Awareness of these differences, combined with rising costs, drew attention to the way decisions were being made. Until recently, neither consumers nor their physicians were fully aware of the power of the term *medical necessity* to deny care. The idiosyncratic way that coverage decisions are made in health care organizations has led to variation that creates inequity for consumers, greater cause for appeal of denials, and more litigation.

The California HealthCare Foundation[3] funded research at Stanford University's Center for Health Policy[4] to help clarify the coverage decision making process and to identify variation in the way *medical necessity* is defined and used in making coverage decisions in California. This information was intended to help promote greater clarity and consistency in decision making and to reduce conflict and litigation.

The results of the research are included in this Final Report. The report is organized in three parts: 1) Executive Summary; 2) Findings and Discussion; and 3) Appendices and Supporting Materials.

Understanding *medical necessity* is important for everyone. It is important for consumers because ultimately the decisions about coverage and treatment affect their lives, and they need the information to make prudent choices. It is important for providers because they must now share treatment decision authority with managed care medical directors with whom they may disagree. It is important for the courts because they are the referees of

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[1] Bergthold, LA, Medical necessity: do we need it? *Health Affairs*. 1995; 14-4; 180-190; see also Eddy, DM, Benefit Language: Criteria that will improve quality while reducing costs *JAMA*, February 28, 1996; Vol. 275, No. 8, pages 650-657.

[2] Dartmouth Medical School. The Center for the Evaluative Clinical Sciences, *The Dartmouth Atlas of Health Care 1998*, American Hospital Association, 1998.

[3] The California HealthCare Foundation, based in Oakland, California, is a non-profit philanthropic organization whose mission is to expand access to affordable, quality health care for underserved individuals and communities, and to promote fundamental improvements in the health status of the people of California.

[4] The Center for Health Policy is Stanford University's interdisciplinary center, dedicated to education and rigorous investigation to guide health policy and clinical practices.

last resort, although poorly equipped to play that role. It is important for the California legislature, as well as other states and the federal government, because they must mediate the conflict between clinical professionals, managed care decision makers, and the public over the use and definition of this term, and they need to understand how best to do that. It is important for the regulators and accreditors, because they must apply the laws and the standards for high quality professional performance.

STANFORD'S CENTER FOR HEALTH POLICY SET OUT TO ADDRESS THE PROBLEM

In August 1998, the California HealthCare Foundation funded a planning grant to researchers at Stanford University's Center for Health Policy[5] in collaboration with the Integrated Healthcare Association[6] (IHA) to learn more about this issue. The research team developed a workplan with input from a large group of California stakeholders and commenced research in October 1998.

Staff learned that there had been relatively little prior research on how decisions are made in managed care organizations, although some conclusions were clear: there appeared to be considerable variation in the way *medical necessity* was defined but little consensus about what to do about it; medical directors of managed care organizations were key actors in the process; and California stakeholders had supported a recommendation for more consistency and clarity in the way *medical necessity* decisions were made.

The project had three policy goals: 1) to describe for consumers, providers and policymakers how health plans and medical groups (i.e., multi-specialty groups, IPAs, etc.) define and use *medical necessity*; 2) to understand what works and what does not and to make practical recommendations for change; and 3) to reduce the variation and inconsistency in the decision making process.

THE RESEARCH DESIGN INCLUDED BOTH PRIMARY AND SECONDARY DATA COLLECTION

The research consisted of primary data collection through more than 75 interviews with key informants; analysis of plan contract language and related documents; an analysis of California legal cases related to *medical necessity*; and, in collaboration with the Integrated Healthcare Association, a workshop for key stakeholders to discuss research

[5] Project staff included Sara Singer, MBA, Lead Investigator; Linda Bergthold, Ph.D., Project Director; Carol Vorhaus, MBA, Investigator; Alain Enthoven, Ph.D., Principal Investigator; Research staff: Suzanne Olson, Ian Mutchnick, Ying Ying Goh, and Serl Zimmerman, MD, JD; Consultants included Wade Aubry, MD; David Eddy, MD, PhD; Bill Sage, MD, JD; Henry Greely, JD; Judge Mary Morgan (ret.); and Peter Lee, JD.

[6] The Integrated Healthcare Association (IHA) is a California leadership group of health plans, physician groups, and health systems, plus academic, purchaser and consumer representatives, involved in policy development and special projects around integrated health care and managed care.

findings at the conclusion of the research. The team also conducted secondary research with an extensive literature review.

The final sample of interviews represented 34 health plans, medical groups and integrated delivery systems representing over 88% of the commercial managed care enrollment in California and 84% of the managed Medi-Cal enrollment from all parts of the State of California. Staff also interviewed 8 treating physicians; 28 consumer organizations and advocates; 6 attorneys; 6 purchasers; 7 staff of the Department of Corporations; an independent review organization, and 4 representatives from the Veterans' Health Administration.

THE RESEARCH FINDINGS IDENTIFIED SOME CONSISTENCY AS WELL AS SUBSTANTIAL VARIATION IN *MEDICAL NECESSITY* DECISION MAKING

There are some similarities in the way decisions are made:

- Almost all organizations that make *medical necessity* determinations follow similar basic steps of reviewing eligibility and benefit coverage, consistency with organizational coverage policies and guidelines, and effectiveness and appropriateness of treatment;
- All interviewees report that the contractual definition of *medical necessity* is not particularly helpful in decision making. Most definitions include much of the same basic criteria although they are undefined;
- The most common and problematic *medical necessity* issues are decisions about durable medical equipment, elective surgery, and experimental/investigational treatments;
- Eligibility lags and lack of specificity in covered benefits often lead to disputes between treating physicians and managed care clerical personnel ;
- Lack of standard coverage guidelines and clear definitions of *medical necessity* are important reasons decision making is problematic;
- Coverage guidelines may be vague, and individual patient characteristics may warrant departing from them in certain cases. Time spent arguing with someone other than a medical director under these circumstances compounds physician feelings of loss of autonomy and control.
- Most organizations try to involve physicians in the development of guidelines and policies, but all have mixed success;
- Only a physician can make a denial (this is an accreditation standard of the National Committee for Quality Assurance (NCQA) as well as a requirement in the Knox Keene law in California); this fact is little known;
- The number of denials is relatively small (on average, less than 8% of all documented requests are denied);
- All organizations have internal appeals processes and by law all denial letters must inform consumers about their external appeals rights and responsibilities;
- Denial letters are generally poor in the quality of information they impart;

- Most organizations do some type of retrospective review on their decision making and use the information to improve quality and/or review physician performance;
- All organizations have communication problems among medical directors, between medical directors and treating physicians, and between the organizations and the consumers they serve;
- There are relatively few differences between health plans that serve Medi-Cal and those that serve commercial enrollees in their basic decision making process;
- Language required by law to be included in the evidence of coverage, denial letters, and other documents that refers consumers to the Department of Corporations (DOC) to appeal their denial does not make clear that, unless the case is urgent, consumers must engage their plan's internal appeals process for 60 days. As a result, consumers may become angry and frustrated with the DOC.

There are substantial variations in the way decisions are made as well:

- Variations in the taxonomy for decision making inhibit efforts to track and compare approvals, denials, and overturns by managed care organizations;
- Larger organizations tend to design their own coverage policies and guidelines; smaller organizations buy these guidelines off-the-shelf;
- There is no pattern by size or geography in how guidelines and policies can be most effectively distributed; some health plans openly share guidelines, either in hard copy or on diskette, while others do not;
- Partially because of the volume of guidelines available, most physicians and medical directors do not refer to them consistently;
- Some plans may overturn decisions of contracting medical groups, for which they bear no risk, leaving the medical group to pay for the treatment and without recourse.[7]

The main findings from the case discussions revealed that:

- There is variation in the way medical directors interpreted four hypothetical cases: autologous chondrocyte transplantation (ACT) for knee pain; reconstructive surgery for cleft palate; growth hormone treatment for small stature; and high dose chemotherapy for advanced stage ovarian cancer.
- Medical group medical directors were somewhat less likely to say they would have approved treatment than the health plan medical directors interviewed; The case about which the evidence is the clearest (i.e. the patient population for which growth hormone is effective) produced the most consensus, suggesting, in part, that where evidence is not particularly contradictory, medical directors may make more consistent decisions;
- Medical directors report they rely more heavily on health plan or medical group guidelines/policies and less on expert opinion or their own judgment;

[7] In California, plans with HMO products delegate a substantial proportion of the financial risk to various types of medical groups, and with that risk in general comes the authority to make *medical necessity* decisions. Plans by law, however, have the final authority to determine coverage, so a plan may overturn a medical group's decision, often without any financial consequence to the plan. Plans retain the authority to make coverage decisions with respect to the PPO products they manage.

- In the case of ACT, we reviewed three plan coverage guidelines and found only two areas of agreement among over a dozen factors in the policies we studied;
- When the medical directors who shared their coverage guidelines were asked about whether they would approve or deny the ACT treatment in the case, all three had different responses and two responses contradicted their own coverage guidelines;
- The reliance on contractual definitions of *medical necessity* in decision making is conspicuously absent in the discussions;
- Only one medical group consistently allows its treating physicians to make the final *medical necessity* decision.

The quality and quantity of communication among the stakeholders varies:

- Some managed care organizations contact the treating physician before making a denial; others do not;
- Some explain their decisions and the basis for these decisions; most do not except in appeals cases.
- Some groups contact plans about difficult cases before making an initial decision; some plans contact groups before overturning a decision.

While several aspects of the Department of Corporations Request For Assistance process are generally consistent, there are also some variations:

- In the sample of DOC reconstructive surgery cases reviewed for this study, the DOC used the same external consultant for all the cases. The DOC's decision was almost always consistent with the recommendation of the consultant.
- There was very little evidence of communication between the DOC and the plan or consumer, and the communication that existed demonstrated variations in the amount of information provided about the decision and the decision making process.
- The term *medical necessity* was applied in different ways but seldom defined by the DOC, the consultant, and the health plans; the term was understood in different ways by physicians and consumers as well.
- The most common source of evidence used by the external consultant to determine *medical necessity* was his own clinical or personal judgment. Evidence from medical literature was only used in one case by the health plans, DOC, or the consultant.

There is variation in the way the courts interpret *medical necessity.*

- In the universe of California legal cases between 1978 and 1998 that considered the interpretation of *medical necessity* in the context of insurance coverage disputes (27 cases), we found the following:
    - The number of cases is increasing;
    - Plaintiffs tend to do better in state than federal appellate courts;
    - There is no consistent legal view of *medical necessity*;
    - Court decisions most often turn on facts unique to each patient's particular situation;

- The major factor that courts consider is whether or not the definitions of *medical necessity* in plan documents and contracts are consistent with each other.

There is variation in the definition of *medical necessity* and the way it is applied in practice:

- There is considerable confusion about the language used to describe decision making, such as the difference between a *coverage* decision and a *medical necessity* decision, and a coverage policy or guideline and a clinical practice guideline; not even the participants in the process fully understand the degree to which this confusion produces misunderstanding and conflict;
- There are a number of common criteria used to define *medical necessity* in the contracts we analyzed. The most common are: *prevailing community standards, for the diagnosis and treatment of an illness or injury*, and *appropriateness*;
- The most common criteria used in actual practice by medical directors are *cost effectiveness, diagnosis and treatment,* and *prevailing community standards.*
- Only two of the health plans we interviewed use an evidence-based criterion and only two include a cost effectiveness criterion in their contracts; plan size has no effect on this variable;
- The disconnect between being willing to apply the criterion of cost effectiveness in practice but not put it in contract appears to come from a fear of litigation and backlash by the public;
- We developed a model definition of *medical necessity* based on our research and presented it for discussion to a workshop of decision makers in March 1999: the model definition included criteria addressing the **authority** for who should make the final decision; the **purpose and scope** of a covered intervention; the **evidence** on which the decision should be made; and how to determine the **value** (cost effectiveness) of a proposed intervention.

A Decision Maker Workshop[8] came to some consensus on recommendations for ways to improve the decision making process and on a model definition of medical necessity for use in contract.

- In collaboration with IHA, the two and a half day workshop, facilitated by Dr. David Eddy, produced agreement on the impact and feasibility of several dozen recommendations for process improvement derived from the interview research.[9]
- The highest ranked recommendations involved the use and distribution of guidelines; the need for better communication and education; and the need for more information and disclosure about how decisions are made.

[8] See Appendix C for list of workshop participants which included plan and group medical directors, consumers, treating physicians, legal directors, purchasers, and a regulator.

[9] See Appendix A in Final Report for Model Process for Decision Making based on these recommendations and priorities.

- The workshop also produced a surprising degree of consensus on a model definition of *medical necessity* for use in private contract;[10] the workshop participants opposed any definition of *medical necessity* in statute, but agreed that this contractual definition was better than anything currently being used.

THE FINDINGS HAVE IMPLICATIONS FOR FURTHER RESEARCH AND ACTION

- The variability in form and content of coverage guidelines and the way they are applied suggest that a major effort to achieve more comparability and consensus about coverage guidelines could have substantial impact;
- The difficulty in quantifying and describing denial rates suggests that a study should be done to develop a more reliable and consistent methodology to track denials within and among health plans and medical groups;
- The misperceptions about who makes decisions suggest that more public education is needed about the decision makers and their process;
- The variations in definitions and application of *medical necessity* by health plans and regulators suggest that a common definition may be a good start toward greater consistency;
- There is a need to address the issue of how evidence is used in decision making, particularly the hierarchy of evidence on which decisions are based as well as how cost effectiveness analysis can contribute to the decision making process;
- There is enough dissatisfaction with the current variability to support the implementation of the research recommendations about process and language.

Each stakeholder group has a role to play in the follow-up process:

- **Consumers** should demand more disclosure of information about who makes the decisions and on what basis;
- **Providers** should participate more actively in the development of guidelines as well as in the communication of guidelines to patients;
- **Purchasers** can require more disclosure and consistency in the contractual definitions and processes of the health plans with which they contract;
- **Medical directors** of medical groups and health plans have many communication tasks to implement to ensure public confidence in their policies;
- **Regulators** need to improve the consistency of their external review process and the quality of communication with their own consultants, the public and the managed care plans they regulate.

[10] See Appendix B in Final Report for Model *Medical Necessity* Definition.

II. The importance of understanding Medical Necessity.

A. The Medical Necessity decision making process significantly impacts the delivery of health care.

Medical Necessity was not a problematic issue when remote third party payers rarely challenged physicians' decisions and reimbursed them for whatever procedures they chose to order and perform. Over the past several decades, the term *medical necessity* served as an innocuous placeholder, enabling insurance plans and physicians to make judgments about coverage that were usually unchallenged.[11] The fact that individual physicians practiced differently and that some practice variation may be inappropriate was revealed by the path breaking work of John Wennberg, MD and colleagues at Dartmouth Medical School. They documented considerable variability in the intensity of hospital use and surgical treatment of common diseases without significant differences in health outcomes. Strikingly wide practice variations prompted serious questions about the basic value of some health care services. How much care is enough? Why does the rate of knee replacement surgery vary from 1.8 to 9.1 per thousand Medicare enrollees depending on where they live?[12] Awareness of these differences, combined with rising costs, drew attention to the way decisions were being made.

Until recently, neither consumers nor their physicians were fully aware of the power of the term *medical necessity* to deny care. *Medical necessity* or related terms continue to be routinely inserted into legislation or regulation as a way to anchor medical decisions and are frequently included in legal contracts and evidence of coverage booklets, without definition or description of the process or criteria upon which determinations on the basis of the term are applied. Conflicting opinions and ambiguous evidence cause a standard of care based on *medical necessity* to break down. The idiosyncratic way that coverage decisions are made in health care organizations has led to variation that creates inequity for consumers, greater cause for appeal of denials, and more litigation.

A few dramatic lawsuits over the coverage of experimental treatments, the rapid growth of public and private managed care plans, and the flurry of external review and patients' bill of rights legislation at the state and federal level have all thrust the issue of coverage decision making into the public light. Key questions include who decides what treatments are necessary, by what criteria, with what input, and with what oversight?

The California Governor's Managed Health Care Improvement Task Force of 1997 received much public testimony from consumers and physicians on this topic. In response, one of the Task Force recommendations was to address the definition and use of *medical necessity* in a way that would promote constructive debate and dialogue

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[11] Bergthold, LA, Medical necessity: do we need it? *Health Affairs*. 1995; 14-4; 180-190; see also Eddy, DM, Benefit Language: Criteria that will improve quality while reducing costs *JAMA*, February 28, 1996; Vol. 275, No. 8 , pages 650-657.

[12] Dartmouth Medical School. The Center for the Evaluative Clinical Sciences, *The Dartmouth Atlas of Health Care 1998*, American Hospital Association, 1998.

among consumers, practitioners, plans, purchasers, and policymakers with a goal of greater clarity and consistency.[13]

In an effort to reduce inappropriate variation and to promote an acceptable balance between the need to control health care costs with consumers' expectations for high quality, accessible care and physicians' desire to provide it to them unencumbered by outside review, Stanford University's Center for Health Policy proposed a policy research project which was funded in the Fall of 1998 by the California HealthCare Foundation.[14] In carrying out this research we assumed a broad scope in learning about the *medical necessity* decision making process. We were most interested in the plans' and providers' decision making processes, the establishment of *medical necessity* criteria by plans and purchasers, and the application of these definitions in the adoption of coverage policies and guidelines for specific conditions and the coverage decisions themselves.

The project consisted of several phases: 1) **Planning -** during the summer of 1998, staff refined the key questions, developed a work plan, and convened a group of stakeholders to provide feedback on the questions asked and the methodology proposed to answer those questions; 2) **Research -**beginning in the fall of 1998, staff began collecting both primary and secondary data. Over 75 interviews were conducted with a variety of key informants. A request for information was submitted to each managed care organization that included a request for samples of their contractual definition of *medical necessity* and other quantitative information about the organization, their enrollees, services, approvals and denials. Other primary and secondary research activities included an analysis of Requests for Assistance received by the California Department of Corporations, an analysis of legal cases based on interpretations of *medical necessity*, a review of other states' experience, a literature review, and the presentation of research findings to two consumer briefings and a workshop of key decision makers in March in partnership with the Integrated Healthcare Association[15]; and 3) **Dissemination** – results from the project were written up, distributed and presented to consumers, policymakers, managed care plans, medical groups and other stakeholders throughout California and the U.S. in a series of meetings during the spring of 1999.

The project was administered by the Center for Health Policy at Stanford University[16]. Funding for this project was provided by the California HealthCare Foundation, with additional support from the Sierra Health Foundation and Stanford Medical School.

[13] Managed Health Care Improvement Task Force, *Improving Managed Health Care in California. Executive Summary*, Vol. One, 1998.

[14] The California HealthCare Foundation, based in Oakland, California, is a non-profit philanthropic organization whose mission is to expand access to affordable, quality health care for underserved individuals and communities, and to promote fundamental improvements in the health status of the people of California.

[15] The Integrated Healthcare Association (IHA) is a California leadership group of health plans, physician groups, and health systems, plus academic, purchaser and consumer representatives, involved in policy development and special projects around integrated health care and managed care.

[16] The Center for Health Policy is Stanford University's interdisciplinary center, dedicated to education and rigorous investigation to guide health policy and clinical practices.

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B. Medical Necessity is important for consumers.

Medical Necessity is a term that holds little meaning for consumers. However, the concept behind the term, while frequently clouded by an asymmetry of information among consumer, treating provider and plan, is very important to consumers because it obscures a decision process about which they know very little. Sixteen individual and group interviews and two consumer briefings revealed that consumers were most concerned about not being able to get information when they needed it. They were also concerned about denials of coverage and the ability to appeal these decisions. They told us that they didn't know who was responsible for the coverage decisions made about their care and felt decision-makers were not taking ownership for their decisions. Additionally, consumers conveyed anecdotal examples where the process did not result in the same decision for similar patient or account for individual patient characteristics and preferences. Many consumers expressed fears that inappropriate incentives, especially financial incentives, influenced coverage decisions. Consumers also expressed great concern about their perception that the doctor was no longer an advocate for the consumer.

The California Governor's Managed Care Task Force in its report issued January 1998 also highlighted many of the problems and recommended solutions identified by consumers in this research.[17] A central recommendation of the Task Force was to create a "blue ribbon" public/private work group of major stakeholders to study and recommend changing the benefit language in health plan contracts. Study of the issues inherent in changing benefit languages was to include the transition from vague, imprecise terms to language intended to maximize quality outcomes, health outcomes, functional outcomes and the scientific underpinnings of treatment decisions while controlling costs.[18]

The findings and recommendations of the Task Force reflect centrist proposals for improving application of the criteria and processes for *medical necessity* decision making within health plans and their contracting medical groups. One of the most contentious votes the Task Force faced was on whether to expand tort liability for HMOs. Members could not agree on whether or not the courts presented a productive or counterproductive way of dealing with medical injuries and accountability for the practice of medicine. This divisive and inconclusive debate convinced the research team that it would be important to study the role and efficacy of the courts in resolving litigated disputes about *medical necessity* decision making.

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[17] Managed Health Care Improvement Task Force, *Improving Managed Health Care in California. Findings and Recommendations*. Volume Two, January 1998. pp. 65, 73-77, 91-96, 99-102, 105-108.
[18] Op-cit., Managed Health Care Improvement Task Force, *Improving Managed Health Care in California. Findings and Recommendations*. Volume Two, January 1998. p. 101.

C. The courts have been inconsistent.

It would seem that a systematic study of prior judicial decisions would easily and quickly answer the question of how the law reviews *medical necessity*. Unfortunately, this is not the case. For one thing, there is no consistent legal view of medical necessity. Rather, there are nearly as many judicial interpretations of the concept as there are judges and cases. In addition, the decisions most often turn on facts unique to each patient's particular situation. Thus, unlike in other areas of the law, little judicial precedent is created. Finally, many *medical necessity* disputes never reach a judgment on the merits because they are dismissed on procedural grounds.

Our analysis of California legal cases also points out how difficult fact-finding has become in the world of modern medicine.[19] Today, coverage disputes often concern highly complex and technologically sophisticated treatments with uncertain success rates. This places a great burden on judges and juries who are asked to decide whether or not the care is *medically necessary*. Is a treatment necessary if it has only one percent chance of helping the patient? What if it is the only treatment available and the patient is sure to die without it? How should we factor the cost into the equation? What about the rights of other plan beneficiaries who are indirectly "footing the bill" for that care? These and other philosophical and ethical questions have no simple answers. Perhaps publicized court cases are valuable simply because they attract our attention and cause us to consider these issues.

D. *Medical necessity* is important to providers.

Inconsistency in the courts has reinforced the importance of understanding the meaning of *medical necessity* in daily treatment decisions and broad coverage policies. The courts do not wish to be the public policy arbiters of this debate and defer to the judgment of treating physicians[20] and medical directors of medical groups and plans. This research reflected a number of issues of importance to physicians also strongly voiced in hearings held by the Task Force in 1997.[21] Treating physicians interviewed in this research expressed serious concerns about professional conflicts between their Hippocratic oath to "follow that method of treatment which, according to my ability and judgment, I consider for the benefit of my patients,"[22] and treatment directives issued by a group or plan medical director trying to conform to a contractual coverage policy. Conversely, medical directors felt ethically bound to interpret *medical necessity* decision making with responsible medical judgment but through the lens of written coverage guidelines and policies. The subtle difference between a treatment or service that is *medically necessary*

[19] Karl Llewellyn, THE CASE LAW SYSTEM IN AMERICA, 79 (Paul Gerwirtz ed. & Michael Ansaldi trans., 1989).
[20] Throughout this report, when we refer to "treating physician" we mean to include physicians and all other health care providers who are authorized to seek approval from groups and plans for the delivery of specific health care services to consumers.
[21] Op.-cit. California Governor's Managed Health Care Improvement Task Force
[22] World Book Encyclopedia, "The Oath of Hippocrates," World Book Inc, Chicago ,1988, vol. 9, p241.

for an individual patient and/or *medically necessary* for coverage by an individual's health benefit contract was a central and recurring theme throughout this project. (See discussion and accommodation reached in Section V. C.)

Front line physicians were also concerned about interpreting and applying the concept of *medical necessity* to treatments because they perceived that their medical judgment was being second guessed and that poor decisions were being made by inexperienced people as agents for plans and groups. This altered path of medical decision making is viewed as a challenge to physician autonomy and engenders great emotion, complicating the working relationships between treating physicians and medical directors of both plans and groups.

E. The California legislature has considered defining *medical necessity*.

The California legislature has recognized problems with the current use and application of the term *medical necessity*. The legislature attempted to define it within the context of independent review legislation introduced in 1998. Although altering the definition would not guarantee an improved decision making process, a clearer statutory definition could promote more consistency in its application. The key issues of debate have focused on which decisions would trigger an independent review, and what criteria an independent review organization might use to determine whether a recommended treatment had been *appropriate* or *medically necessary*. Because the legislature was unsure of the terminology to use, our project staff was asked to participate in a working group meeting on this topic on July 21, 1998 and to submit advance written testimony.

Our testimony included a discussion of the "Decreasing Variation in *Medical Necessity* Decision Making" project – its design, timeframe, proposed outcomes, and the potential problems inherent in defining *medical necessity* through statute. We recommended that the Legislature not define *medical necessity* in statute at that time because there was no consensus on which to base a definition. We felt that without broad support, any choice of language was likely to cause serious unintended consequences. Legislative staff members were faced with a variety of contradictory definitions of *medical necessity* that demonstrated the difficulties in developing a consensus definition.

The California Legislature did not pass any laws that contained a definition of *medical necessity* in 1998. However, with the election of a new Democratic Governor and Democratic majorities in the State Assembly and Senate, prospects for the passage of managed care reform legislation with implications for *medical necessity* decision making are high for the next few years.

F. Federal and state governments address the issue of medical necessity in statute.

In the late 1990s when national polls began to show the public seriously concerned about managed care, Democrats and Republicans began to write "consumer protection" or

"Patients' Rights" bills. The purpose of this legislation was to assure adequate information, disclosure, and review of decisions being made by managed care plans.

The Patients' Bill of Rights Act of 1998 (H.R. 3605(Dingell)/S.1890(Daschle) included a number of requirements to be imposed on the structure and operation of health plans and health insurers related to external appeals, however, no federal legislation was passed in 1998. At the end of 1998, the Department of Labor launched a "Health Benefits Education Campaign," including proposed rules and regulations for internal appeals procedures for plans regulated by the Employee Retirement Income Security Act of 1974 (ERISA). These proposed regulations produced considerable controversy and were still being debated in the spring of 1999 as this project drew to a close.

The 106th Congress has produced a flurry of bills related to patients' rights, including S.6/240 (Daschle/Kennedy), HR 358 (Dingell, "Patients' Bill of Rights Act of 1999"), the Republicans' Senate Leadership Bill, S.300/326 (Jeffords) and various bills introduced in the House, For the first time since the 1993 national health care reform discussion, during which the definition of *medical necessity* was barely a footnote, there has been discussion and concern about the types of decisions that are being made, the basis on which they are being made, and the personnel who are making them. *Medical necessity* has suddenly become the focus of debate. What does it mean? Who decides what it means? The U.S. Senate held a hearing in March 1999 on *medical necessity*[23] to try to determine whether and how it should be defined in the various bills being discussed.

Although the Republican-sponsored bills use the term *medical necessity* without definition, the Democratic Daschle-Kennedy bill defined *medical necessity* in Sec. 151(c) as: "a service or benefit which is consistent with generally accepted principles of professional medical practice." Some witnesses at the Senate hearing explained that this definition was a legal standard and that the courts would interpret it as referring to the highest standards of medical practice, other witnesses argued that the definition was still too vague and implied only an "average" standard. Whatever the outcome of the federal debate in 1999, *medical necessity* has truly come out of obscurity as a term of art in managed care.

Defining *medical necessity* is a problem other states have faced and continue to address. Most states that have statutes referring to *medical necessity* have simply not defined the terms, allowing the medical professionals to interpret it as they chose. In states that have elected to define *medical necessity* in some way, the process has been highly politicized, and the battle between physician associations and managed care plans over language and decision making authority has been fierce. Broad consensus among stakeholders has been difficult to achieve, and there has been no empirical study to test the effectiveness of any of the recently mandated language.

The statutes that attempt to define *medical necessity* vary from state to state. Until the more recent focus on independent review legislation, definitions were mainly to be found

[23] United States Senate, Committee on Health, Education, Labor and Pensions, "Medical Necessity: From Theory to Practice," March 2, 1999. See testimony by Linda A. Bergthold, Ph.D. in Appendix D.

in state Medicaid statutes and insurance statutes regulating utilization review. More recently, states have passed various types of consumer protection legislation, including legislation requiring independent review of disputes and denials of care in managed care, and some of these new statutes have contained definitions of *medical necessity*.

Starting in 1991, all state independent review programs created new processes by which to review denials of care for *medical necessity* only.[24] This focus on *medical necessity* provoked interest in and discussion about what types of disputes should trigger independent review and what standard of care should be used to judge these appeals. Defining *medical necessity* has become even more problematic as legislators have attempted to understand the coverage decision making process and to disentangle purely clinical decisions from disputes over the use of out-of-network providers or contractually excluded benefits.

Those states that have chosen to define *medical necessity* in statute have generally selected definitions that break little new ground. Some states have simply borrowed definitions from each other (e.g. Illinois and Arkansas) or from the types of definitions in most insurance contracts, utilizing terms such as "appropriate supply and level of service", "for the diagnosis or treatment of an illness" and "prevailing community standard of practice." In attempting to address the standard by which decisions should be made, most states have chosen a broad "professional" reference, such as care that is "generally accepted" either in the "(medical) community" or the "same or similar general specialty as manages the condition". The Louisiana statute refers to "nationally accepted current medical criteria" and Georgia refers to "acceptable medical practice in the United States." None of the statutory definitions of *medical necessity* except New York's proposed definition in S-5161-a refers to evidence-based medicine.[25]

G. The regulatory and accrediting agencies have identified a need for more consistency

State regulators and national accreditation agencies have also recognized that *medical necessity* criteria and decision making processes are important aspects of ensuring high quality care. The Department of Corporations (DOC) primarily regulates “Health care service plans” or HMOs in California under the Knox-Keene Health Care Service Plan Act of 1975. The DOC administers the Knox-Keene Act in many ways but principally by conducting or overseeing health care service plan quality and solvency audits. The private sector supplements this state function through private accreditation by the National Committee for Quality Assurance (NCQA). These regulatory and accrediting agencies have both developed requirements that, if applied more consistently, would create more clarity and consistency in *medical necessity* decision making processes and definitions.

[24] Pollitz, K., Dallek, G. Tapay, N., Institute for Health Care Research and Policy, Georgetown University, "External Review of Health Plan Decisions: An Overview of Key Program Features in the States and Medicare", a report prepared for the Kaiser Family Foundation, November 1998, p. 1.

[25] See Bill Text S-5161a and A-7440a introduced in the Senate by Senators Stafford and Volker in the 1999-2000 New York Regular sessions, March 30, 1999.

Mindful that regulation and accreditation should be efficient, streamlined and conducted in cooperation with other public and private bodies that oversee related areas of managed care, we reviewed the research findings and recommendations relative to the existing requirements of the Knox Keene Act (KKA) and NCQA accreditation. Many of the stakeholder recommendations made in this research project already existed in either KKA or NCQA requirements or standards. For example, given the stated recommendations to improve clarity and consistency of process it is interesting to note that both KKA and NCQA specifically address these concerns in the following ways:

> KKA § 1363.5 Requires plan to disclose the process and criteria requirements to be used for decisions to providers and enrollees on request. The criteria must be developed with involvement from practicing providers, using "sound clinical principles and processes," and must be evaluated and updated annually.[26]
>
> NCQA UM 1-1-1.4
>
> - **Description of Scope and Content.** Management structures and processes should be clearly defined, and responsibility assigned to appropriate individuals.
> - **Written Description.** Policies and procedures must be written and task accountability clear.
> - **Senior Physician.** A senior physician has substantial involvement in UM program implementation.
> - **Scope.** Description includes the program scope, processes and information sources used. All UM activities performed should list the **"**criteria used to determine *medical necessity***"** including how the criteria were developed, chosen (most plans use nationally developed criteria) and updated. Description must identify the *medical necessity* determination process including who has the authority to deny coverage; the data and information used to make decisions; procedures for appeal; description of the role of UM within QI; description of any delegated UM arrangements.
>
> NCQA UM 5.1-5.2
>
> **Coverage Based on Medical Necessity.** Plans must obtain relevant clinical information and consult with the treating physician. A written description identifies all information used to make *medical necessity* decisions**.** Document that information has been gathered consistently.[27]

A more detailed analysis of stakeholder recommendations, comparing them to existing requirements of regulation or accreditation appears in Section V.

[26] State of California Department of Corporations, *Knox-Keene Health Care Service Plan Act of 1975 Including Amendments Enacted in 1997*, 1998.
[27] National Committee for Quality Assurance, *Surveyor Guidelines for the Accreditation of Managed Care Organizations*, 1998.

III. Project Workplan and Methodology

A. In developing the workplan for the research project, the Stanford staff held a planning meeting with key stakeholders.[28]

The California HealthCare Foundation awarded a planning grant to the Stanford project team, and work commenced June 25, 1998. This grant funded an extensive planning process that included obtaining feedback from key stakeholders, an expert team of consultant-advisors, and the California legislature relative to the pending proposals.

On August 12, Stanford hosted a Stakeholder meeting to promote the buy-in of those who would benefit from changes to the current system. Project staff invited key stakeholders, foundation staff, and our consultant-advisors to attend. The purpose of the session was to incorporate stakeholder and consultant advice into the developing work plan.

Prior to the meeting, we distributed copies of a draft work plan to 66 individuals, including invited stakeholders, consultant-advisors, other stakeholders, and academics. We asked them to rate the project workplan (prior to incorporation of stakeholder suggestions) on its goals, methodology and usefulness. We received 27 evaluations with an overall average rating of 4.1 (on a scale of 1 to 5, with 5 being "very valuable"). The meeting provided us with an opportunity to clarify our goals, outcomes, project scope, and methodology.

There were many helpful suggestions from the stakeholders:

- Purchasers viewed the project as a way to develop a “next generation” definition of *medical necessity* and greater consistency of decisions;
- Physicians and medical groups believed that defining the terminology and decision making process could enhance clinical input into coverage decisions;
- Health plans expected that clearer processes for coverage decision making within the plan might reduce the number of decisions appealed or sent to independent review organizations;
- Legislators and regulators hoped to use information provided by our research and consensus-building process to develop appropriate language for statute and regulation;
- Consumers hoped that more transparent policies would promote greater participation by consumers in decisions about their care and coverage.

Project staff incorporated input from the meeting and the written evaluations into a revised workplan, timeline and final proposal to the California HealthCare Foundation in September. The full research project was funded to commence work on October 15, 1998.

[28] See Appendix E for list of stakeholders who attended meeting

B. There is little research on how decisions are made in managed care.

In developing our methodology, we relied on the few studies that have been done on this topic. A recent article in *The New England Journal of Medicine* noted "decision making by insurers about medical care is not well understood." [29] The authors cite the work of Claudia Steiner, MD, MPH at the Agency for Health Care Policy and Research and her colleagues Neil Powe, MD, MPH, MBA and Gerard Anderson, Ph.D. of Johns Hopkins University, who conducted a series of studies on technology assessment in managed care plans. These researchers examined the process and information used by medical directors of private health plans to make coverage determinations for new medical technologies and assessed the influence of plan characteristics on the process. Although their research validates the importance of the medical director as medical decision-maker, they also found that decision makers do not always use clinical information, including research evidence or clinical guidelines, in many of their decisions, even though that information may have been available to them. They found that along with clinical considerations, economic and regulatory considerations played an important role in coverage recommendations.[30]

The work of researchers at the University of Michigan, RAND, and UCLA/Veterans Affairs Medical Center produced a study with similar conclusions, on the usefulness of *medical necessity* in decision making within the Oregon Health Plan and by health plans in Oregon and Washington.[31,32,33] These researchers interviewed medical directors in private plans and the Oregon Health Plan (OHP) and found little consistency or consensus on the definitions of *medical necessity*. They concluded that capitation and benefit definitions taken together have a stronger impact on utilization than the use of contractual definitions of *medical necessity*. Their report suggested a similar study be done in other states to determine the generalizability of their findings to other regions and plans, given the unique selection of defined benefits in Oregon. Peter Jacobson, Ph.D., at the University of Michigan shared his interview guide for the Oregon and Washington study with the Stanford project team, and we used similar questions in our interview protocols.

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[29] Rosenbaum, S., Frankford, D., Moore, B., Borzi, P. "Who Should Determine When Health Care is Medically Necessary?" *New England Journal of Medicine*, January 21, 1999, 340:3:229-232.

[30] C.A. Steiner, N.R. Powe, Gerard F. Anderson, "Coverage Decisions for Medical Technology," 1996; C.A. Steiner et al, "The Review Process Used by U.S. Health Care Plans to Evaluate New Medical Technology for Coverage," *J General Intern Med*, 1996, 11: 294-302.

[31] D.M. Eddy, "Clinical Decision Making: From Theory to Practice. Benefit Language that will Improve Quality While Reducing Costs," *JAMA*, 1996: 275:650-657; L.A. Bergthold and W.M.Sage, "Medical necessity, Experimental Treatment and Coverage Determinations: Lessons from National Health Reform, "NIHCM White Paper, October 1994.

[32] P. Jacobson et al, "Defining and Implementing *Medical Necessity* in Washington State and Oregon, *Inquiry*, Summer 1997, 34: 143-154; P. Glassman et al, "Medical necessity and Defined Coverage Benefits in the Oregon Health Plan," *AJPH*, June 1997, 87:6:1053-1058; C.Steiner, et al, "Technology Coverage Decisions by Health Care Plans and Considerations by Medical Directors," *Medical Care*, 1997, 35:5:472-489.

[33] NIHCM, "Model Coverage Language" from a workshop in Boulder Colorado, September 1994, moderated by D.Eddy with assistance from L. Bergthold and W. Sage.

Other research providing guidance for the development of our interview protocols was a study of California health plans conducted by Judge Mary Morgan for the California HealthCare Foundation.[34] Judge Morgan's objectives were to provide background on how health plan's internal dispute resolution processes work, analyze productive dispute resolution processes, and identify "best practices" and standards for effective dispute resolution. Her methodology included an examination of 13 health plans representing 89% of California managed care enrollees, 4 medical groups, 1 physician practice management company and 2 purchasers. She also conducted interviews with state and federal officials and trade groups.

Review of the draft Morgan study, discussions with its author, feedback from our stakeholders and consultants, and an interview with David Richardson, President of the Center for Health Dispute Resolution,[35] the organization that provides independent review to Medicare, revealed that dispute data are not defined or collected in a uniform fashion on a national level either. Disputes move through various levels of the review process in ways unique to individual plans and their contracting medical groups. Some plans' processes are better at resolving disputes to consumer, provider and plan satisfaction than others' processes. The format and reporting cycles of existing dispute data are kept in ways that are responsive to the industry's regulatory requirements as defined by the Department of Corporations' Knox-Keene Act, Medicare, and the National Committee for Quality Assurance. Judge Morgan did not specifically study decisions or processes that reflected a denial of care based on *medical necessity* criteria. However, she found that it was relatively easy to identify cases in which care or service was denied when the request involved experimental or investigative therapy. We incorporated Judge Morgan's denial related findings into our protocols and Request for Information to plans and groups.

Building on this and other research, we began this project knowing a few important things about the general coverage decision making process in managed care organizations:

- there has not been much in-depth study of the processes by which decisions are made;
- there is little consensus on what *medical necessity* means;
- medical directors infrequently rely on contractual definitions of *medical necessity* when making decisions; and
- stakeholders in California believe that more consistency and clarity would improve the quality of decision making and thus the quality of care for consumers.

[34] Morgan, Hon. Mary C. (Ret.), Dispute Resolution in the California Healthcare Industry (1999), research sponsored by the California HealthCare Foundation, Oakland, CA.

[35] May 27, 1999 Telephone interview with Dr. David Richardson, CEO of the Center for Health Dispute Resolution.

C. We identified several important policy goals for the project:

1. **To describe for consumers, providers and policy makers how health plans and medical groups in California define and use medical necessity in decision making;**

2. **To understand what works and what does not, and to make concrete recommendations for improvement in policy and practice;**

3. **To reduce variation in the definition of medical necessity and to encourage consistency and fairness in the decision making process.**

This policy research project was designed to focus on practical applications of our findings. We limited our analyses to information that could be used to encourage a reduction in the variation in the definition of *medical necessity* and the coverage decision making process. We believe that the process of making decisions is more important to understand and clarify than the actual language in the contractual definitions of *medical necessity*; however, clear and specific definitions of terms are an important first step in a more consistent and transparent decision making process. We also believe that variation is not, by itself, negative. Medical decision making will always have variations because medicine is an art as well as a science. Patient preferences, values, and ethical beliefs enter in also. In addition, not all organizations can or should do things the same way; competition should produce new and better ways of accomplishing the same goals. However, when variation in decision making results in consumers receiving coverage for a treatment in one plan but not in another based on idiosyncratic procedural differences, that variation is undesirable.

D. This project was designed to produce a number of specific outcomes to improve the quality of care in California:

- Model contract language and processes for coverage decisions that several plans/purchasers and plans/provider groups would agree to implement or pilot test;
- Clearer understanding of the coverage decision making process for consumers;
- Guidance for physicians as to their appropriate role in health services disputes (e.g., advocacy for individual versus society);
- Assistance to the purchasers of insurance by increasing consistency of interpretation for patients;
- Better media understanding of the complexities of coverage and medical decision making;
- Relief and guidance for the courts assuming that consistency can reduce the number of disputes that arise over this issue; and
- A process and product that could be applied nationally as well as in California by state and national policy makers and advocacy groups.

E. Our research addressed the following central questions:

- How are decisions made in managed care organizations?
- What are the common processes that organizations follow?
- What are the variations in process and language? Why do they exist?
- Will the knowledge of decision making variations help craft improved processes, language and decisions?

F. Our project hypotheses were based on prior work done in this field and on feedback we had received from our stakeholders and consultant-advisors in the planning phase of the project.

- We expected to confirm prior findings that the term *medical necessity* would no longer be considered a useful tool by decision-makers in California and that guidelines, utilization review procedures, and organization structure would have a greater impact on *medical necessity* decisions than contractual terminology;
- There would be differences in the use and availability of resources related to the size of the organization and the beneficiaries served by those organizations;
- There would be differences in denial rates by geographic region and organizational type;
- There would be differences in process and definitions between organizations serving a commercial population and those serving primarily Medi-Cal beneficiaries;
- There would be variation in process and definitions among organizations, not attributable to specific organizational characteristics.
- There would be considerable variation in decisions about our hypothetical cases and these differences would vary on multiple dimensions; and,
- There would be enough dissatisfaction with the current variability to support the need for consensus around model language and process.

G. The research design included both primary and secondary data collection.

We selected both primary and secondary research methods to "map the chaos" of the existing system. Primary research consisted of key informant interviews with plans, physician groups, consumers, attorneys, purchasers, treating physicians, and other stakeholders; an analysis of plan contract language and related documents; data solicited in a Request for Information;[36] development of a structured database for interview and RFI data;[37] an in-depth analysis of publicly reported disputes from the request for

[36] See Appendix F for Request for Information given to Health Plans.
[37] See Appendix G for list of database variables.

assistance files of the California Department of Corporations (DOC)[38]; an analysis of California legal cases pertaining to *medical necessity*; consumer briefings to gather input and feedback on preliminary findings; and a Decision Maker Workshop, where research findings were tested with a sample of key informants and stakeholders.

The purpose of the secondary research was to understand other research that has been done and thus place the California research in context. It consisted of an annotated literature review.

1. Primary Research

a) Terminology-- Coverage vs. Medical Necessity

Throughout the project we wrestled with the distinction between a *medically necessary* decision and a coverage decision. We struggled to define the terms we were using so that we could all speak the same language. We knew that there was considerable "gray" territory on this issue, because our stakeholders alerted us to the complexities of these definitions. Therefore, we included questions in the interview protocol to try to clarify how each organization viewed the differences in terminology and process.

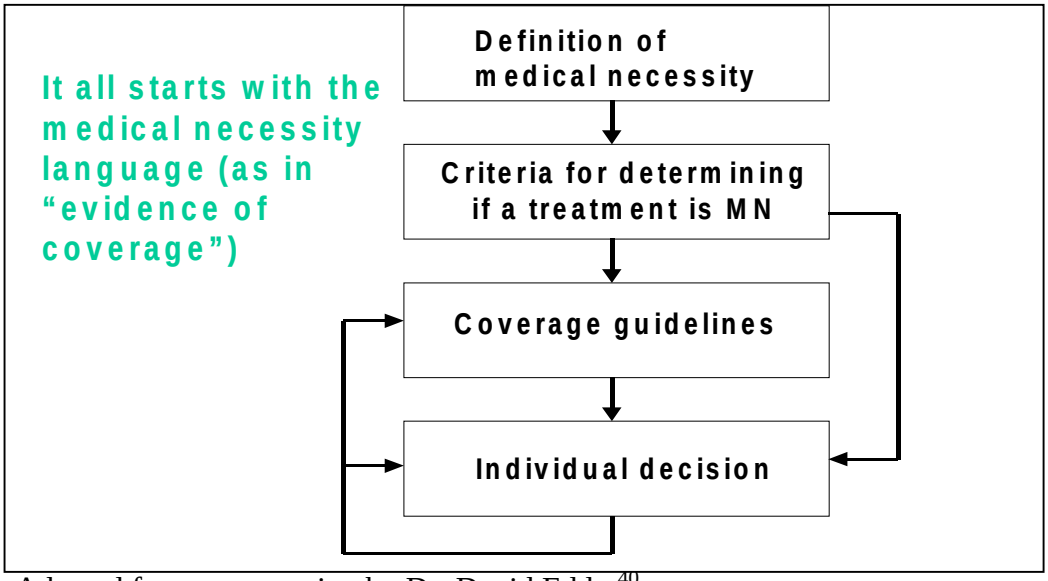
As we interviewed the key informants, several different approaches emerged. Some medical directors felt that a coverage decision described only the process by which plans and employers define the categories of services to be covered in the benefit package (e.g., hospital, physician, lab, home health, etc.) and its description in the Evidence of Coverage. Others viewed the coverage decision as a policy or committee decision at the corporate or plan level about a treatment for a condition in a given population. Still other interviewees separated the *medical necessity* decision from the coverage decision by ascribing the former to the individual case and the latter to groups of cases. The most common distinction was that a coverage decision is a policy decision about whether a plan will pay for an intervention and the indications for which it would be appropriately used for a class of consumers with a given condition (e.g. coverage guideline for autologous chondrocyte transplantation)[39]. A *medical necessity* decision would be the application of that coverage guideline to an individual case by either or perhaps both a plan and medical group depending upon which was the risk bearing entity and whether or not an appeal was involved.

Some distinctions made by our consultant Dr. David Eddy, an advisor to our project, were helpful in clarifying the confusion. He suggested that *medical necessity* is actually a system of "principles" that should pervade the entire "system" of decision making, from the establishment of coverage categories and guidelines to the individual decision about what intervention to cover. To say that *medical necessity* only applies to the individual decision is to deny its importance and role in establishing contractual language, or plan or

[38] This component of our primary research program was aided by a successful Stanford University School of Medicine grant application, which sponsored the research assistant to gather information on how the DOC handles the dispute process.

[39] See examples of two different types of coverage policies in Appendix H.

group coverage policies or guidelines. In an ideal system, the individual decision and the coverage guideline should be consistent with the principles and definitions of *medical necessity* in the contract and Evidence of Coverage.



Adapted from presentation by Dr. David Eddy [40]

b) Key Informant Interviews

There is relatively little publicly available information on the ways in which individual health plans and medical groups come to decisions based on *medical necessity*. Plans generally do not share their internal processes with potential competitors and rarely provide this information to consumers. Therefore, we collected primary data through structured face-to-face interviews with a variety of key informants. We chose a face-to-face interview method wherever feasible, because we felt greater trust could be established in person than by telephone.

We selected our interviewees from a variety of settings and geographic areas throughout California, including non-profit and for-profit HMOs, PPOs, delegated medical groups, independent practice associations, integrated delivery systems with limited Knox Keene licenses, county organized health systems, and local Medi-Cal initiatives within two-plan model counties. Health plans were selected to represent a distribution of sizes, geographic locations, and tax statuses. Our final sample represented plans with over 88% of the commercial managed care enrollment in California and 84% of the managed Medi-Cal population. Medical groups were selected to represent different organizational structure (i.e. management companies, IPAs, groups), size, and geography. Although our plan sample is reasonably sturdy, our medical group sample was too small to permit any generalizations to the larger universe of such diverse groups. However, we were able to

[40] Eddy, DM. From presentation to Medical Necessity Decision Makers Workshop, March 11-13, 1999.

identify some of the most contentious issues confronted by groups and to bring these issues to the Workshop for further discussion.

During applicable interviews, we discussed multiple products with individual organizations (e.g., HMO and PPO products offered by the same health plans) to determine if definitions of *medical necessity* or the process for making the decision differed by product. When scheduling allowed, we spoke with the medical director with the most hands-on responsibility for decision making, followed by the director of quality improvement or utilization management. Legal directors were also interviewed whenever available.

Our samples of consumers, physicians, legal directors and purchasers were selected from lists provided to us by our plan and group interviewees, trade associations, personal referrals, and our stakeholder network. These interviews were not meant to be representative of these stakeholders in general but to provide *context* for the decision making process and to identify the perceptions, misperceptions, and critical issues for each constituency. We expected the interviews to provide a rich source of data on the criteria applied and the concrete processes by which *medical necessity* decisions are made, disputes resolved, and contractual language clarified. We also hoped the interviews would help us identify potential participants for our *Medical Necessity* Decision Maker Workshop.

(1) Structured Interview Protocols/Process

The strengths of an interview process are the level of detail that can be obtained and the ability to follow up on questions where answers may be ambiguous. The weakness of the interview process is its messiness; that is, answers do not always fall neatly into codable categories. Also, multiple interviewers can contaminate the reliability of the responses. To mitigate these weaknesses, we developed a structured interview protocol,[41] as well as a computerized database into which our research analyst inserted the findings from the interviews in a more codable form. We also sent out a Request for Information ahead of each interview asking for more quantitative data on the organization. To reduce reliability problems, we assigned only one interviewer to a category of informants: Medi-Cal plans, treating physicians, purchasers and legal experts. For other categories (medical directors of plans and medical groups and consumer groups), we assigned no more than two interviewers who generally conducted the interviews jointly.

The following are sample categories of questions we included in our interview protocols. We developed several different types of protocols for medical directors of plans (with some minor variation for the public Medi-Cal plans); medical directors of medical groups; consumers; purchasers; legal experts; and treating physicians. We asked all of the interviewees a core set of questions similar to those that follow:

[41] See Appendix I for interview protocol for health plans.

- **Who makes the *medical necessity* decisions within the organization**?
  - Who makes the final decision, at what level, with what input, and from what other levels of the organization?
- **What is the process by which decisions are made?**
  - Describe how *medical necessity* decision making proceeds and how utilization review or other guidelines and protocols are used to support the *medical necessity* decision.
  - How would your process work for each of the following four hypothetical case examples, and would you approve or deny these treatments?[42]
  - What is the process by which plans work with employers to decide what treatments are *medically necessary* and should be covered and what treatments are not *medically necessary* and can be excluded from coverage?
  - How are *medical necessity* determinations communicated to enrollees? With what impact?
- **For what types of problems?**
  - Where are the gray areas? What are the types of treatments and conditions that cause the most common and most problematic types of decisions organizations face?
  - How are **coverage decisions** distinguished from ***medical necessity*** decisions, what is the continuum of differences, and how are these terms defined?
- **What are the criteria on which these decisions are based?**
  - What are the criteria and analyses used to make *medical necessity*, medical appropriateness, and experimental/investigational decisions? What are the most useful criteria in supporting a judgment of *medical necessity* (e.g., evidence, cost effectiveness, benefit, accepted medical practice, etc.)? What criteria are most important and used most frequently? Least important or least used? What other factors affect decisions?
- **Impact of external organizations on plan process/criteria**
  - Interaction between plans, limited licensed plans, and provider groups and the Department of Corporations. Impact on process/definitions?
  - What impact, if any, does legislation (proposed or enacted) have on process/definitions?
  - Have any recent court decisions changed plan processes or definitions?
- **What are recommendations for change in terminology, criteria, or process?**
  - What is right/wrong with the way things work now? How would you make changes?

[42] See Appendix J for case studies. Four case studies were developed by Dr. Wade Aubry, in collaboration with our staff, to test the consistency and reliability of medical directors' decision making processes and criteria. The four cases were selected to represent an important and current policy issue. The first case addressed the change in California AB 1621 to require plans in July 1999 to consider "improved function" and "normal appearance" in making decisions about reconstructive surgery; (i.e. reconstructive surgery for cleft palate.) The second case dealt with a new technology for which evidence of effectiveness was unclear (i.e. autologous chondorcyte transplantation.) The third case described a treatment for short stature for which evidence was relatively clear and well known (i.e. growth hormone.) The fourth case delineated a treatment for ovarian cancer in Phase III trial with long term outcome unknown (i.e. high dose chemotherapy with stem cell support.) The medical director interviewee was asked to decide whether each case was *medically necessary* for coverage and the reasons for either approval or denial.

- How wedded is the plan or group to the existing terminology of *medical necessity* or *appropriateness?* What other terms might be substituted? Have any changes been made in the past few years?
- What do interviewees believe would be the greatest internal and external obstacles to change in the form of a broader consensus on a model definition? Process for applying it? What factors might promote consensus?

(2) Pre-Testing of Interview Protocol

We pre-tested the main interview protocol to determine what information we could realistically expect to obtain within our time frame. This involved drafting the interview instrument and allowing our consultant-advisers and project staff to review it. Then we conducted pre-test interviews with four types of key informants: a medical director, a practicing physician, a legal director, and a consumer advocate. We also pre-tested the usefulness of our proposed case examples.

c) Request for Information and Data Analysis

To reduce the time required for the interview, some data were requested in advance of the interview. This Request For Information (RFI) included questions about the types of cases reviewed, rates of denials, and organizational statistics. In most cases, the RFIs were reviewed by staff before the interviews were conducted.

(1) Denial Rates

Staff used the RFI to determine the number of cases reviewed by the organization each month, and the number denied. In cases where numbers reported on the RFI were unclear, staff clarified the answers in the interview. Analysis was carried out on the raw numbers reported by each organization in the RFI, but the interpretation of the data is very problematic. For example, some organizations view a *medical necessity* denial differently from a utilization review denial. There is no consistent taxonomy of decisions. There are both formal and informal denials and most informal denials are not logged in. There is also no requirement for reporting or tracking disputes so rates can be compared across organizations. Although the numbers of denials reported by our interviewees is generally consistent with other anecdotal information and prior research,[43] we urge great caution in interpreting the denial data.

The RFI asked: "How many cases related to *medical necessity* does your organization review?" Some organizations reported the number of cases specifically about *medical necessity*, others listed *all* types of cases reviewed. In some instances respondents provided a range of numbers. When a range was given, the analyst chose the midpoint to facilitate analysis. If two numbers were reported, the analyst took the average. Average values were obtained by dividing the sum of all responses in a field by the number of responses (not by the total number of respondents). (See Section IV.B,2(d) for findings related to denial rates.)

[43] Remler, D.K. et. al, *Inquiry*, vol. 34, Fall, 1997, pp. 196-204.

(2) Types of Cases

The RFI asked respondents to cite the most commonly reviewed and most problematic cases. These will be discussed in Section IV.D.

(3) Organization Characteristics

RFI data included questions about types of product mix, payer mix, and rates of capitation and reinsurance. Approximately what percent of your members are enrolled in each of the following types of health insurance products? Approximately what percent of your members obtain coverage through the following types of payers? To health plans: for approximately what percent of your members do you capitate the provider organizations with which you contract for the following services? Alternatively, to medical groups: for approximately what percent of your members do you receive capitation payments from the health plans with which you contract for the following services? For what percentage of members does the health plan help cover the care of high cost members? [44]

From the data reported, most of the plan and group enrollment was HMO, and a substantial proportion of the members was privately insured. This is consistent with other sources about payer mixes in California.

As the following tables indicate, 75% of the medical groups we interviewed reported that they took risk for all professional services and 75% for ancillary services, in both cases higher proportions than the risk plans reported delegating on average; groups and plans reported that groups assumed slightly less than 45% of the risk for facilities; and approximately 25% of the medical groups assumed risk for pharmacy services. Health plans reported reinsuring or covering the care of high cost patients in full for 50% of the members, and in part for another 33%.

Member Enrollment by Product Type

Type	***Indemnity***	***PPO***	***POS***	***HMO***
Plan (n=12)	1%	20%	14%	65%
Medical Group (n=9)	8%	6%	13%	76%

Members' Source of Coverage

Type	***Private***	***Medicare***	***Medi-Cal***
Plan (n=11)	60%	5%	38%
Medical Group (n=9)	83%	13%	3%

[44] The reason we asked about proportion of capitation and reinsurance was to determine how much risk was being assumed by each organization and how that risk might impact their decisions. Since we did not interview a statistically significant sample of medical groups in California or match medical groups with the plans with which they contract, we could not analyze the precise impact of risk on any medical group's behavior.

Percentage of Members Covered by Capitation by Type of Service

Type	***Primary Care Only***	***All Professional Services***	***Facilities***	***Ancillary Services***	***Pharmacy***
Plan (n=11)	24%	55%	42%	44%	22%
Medical Group (n=10)	20%	75%	44%	75%	24%

Percentage of Members for Which Health Plans Help Cover the Care of High Cost Patients:

Type	***Not at All***	***In Part***	***In Full***
Medical Group (n=6)	17%	33%	50%
Range	0 to 100%	0 to 100%	0 to 100%

(4) Types of Organizations

Using information from the RFI, our interviewees broke down by organization in the following way:

Plans (19 Total, 11 Returned RFIs)	
Number	**Type**
7	Large Private HMOs
4	Small & Mid-Size Private HMOs
1	Preferred Provider Organization
3	County Organized Health Systems (Medi-Cal)
3	Local Medi-Cal Initiatives
1	Veterans' Administration

Medical Groups (15 Total, 12 Returned RFIs)	
Number	**Type**
8	Medical Groups
3	Independent Practice Associations
3	Management Services Organizations
1	Integrated Delivery System

(5) Size of Organizations and Tax Status

Our interviewees represented organizations of various sizes. Based on number of enrollees, we determined that small plans would be defined as those with fewer than 500,000 enrollees and large plans with over 500,000 enrollees; small medical groups would be those with fewer than 500 physicians and large groups with at least 1000 physicians or more.

We had originally planned to analyze our data on the basis of the size and tax status of the organizations we interviewed. Size was relatively straightforward as demonstrated above. However, tax status was more complicated, particularly for the so-called "public" Medi-Cal plans. The plans serving the Medi-Cal managed care population were not public in the sense of being governmental entities; they were either for-profit (e.g. Blue Cross) or nonprofit (e.g. the County Organized Health Systems or Local Initiatives), even though the beneficiaries they serve were publicly funded. Therefore, although the tax status of our health plan sample included 11 non-profit plans, 1 public (VA) and 6 for-profit plans, we analyzed the data on the basis of whether or not the plan served a primarily privately insured population or a publicly (i.e. Medi-Cal) insured population. By that definition, our sample gave us 10 "private" plans and 9 "public" plans, including the Veterans' Health Administration. We interviewed two private plans about their exclusively Medi-Cal population, so we considered those interviewees to be "public" plans.

19 Plans	
Number	Number of Enrollees
5	<500,000
6	500,000 to 1 million
4	1 to 2 million (includes VA)
4	2 to 5 million

15 Medical groups	
Number	Number of Physicians
1	<100
3	100 to 200
5	200 to 500
1	1000 to 2000
5	2000 to 5000

d) The Sources and Structure of the Database

In order to organize the interview and RFI data in a way that could be quantified more easily, staff set up a computerized database, using Microsoft Access. The primary sources for the information in the database were the interviews; Requests for Information; Evidence of Coverage documents; denial letters; purchaser contracts; and data from the National Coalition of Independent Practice Associations and Interstudy Competitive Edge, 1998. [45] Where needed, staff sought additional information on the World Wide Web.

[45] Interstudy Competitive Edge, 1998.

e) Analysis of DOC Requests for Assistance [46]

The California Department of Corporations (DOC) is the state government agency responsible under the Knox-Keene Health Care Service Plan Act of 1975 for oversight and regulation of all health maintenance organizations in the state. The DOC conducts a process that allows consumers to dispute health plan coverage and *medical necessity* decisions by filing a Request for Assistance (RFA). There is no definition of medical necessity or specific evaluation criteria for the DOC RFA process outlined in the Knox-Keene Act.

The DOC granted a Stanford project team member access to its confidential RFA files, allowing the team to take a snapshot of 1) the DOC review process and 2) when and how the term "*medical necessity*" was used by the DOC, DOC consultants, health plans, providers and consumers in a limited sample of cases. The DOC also granted face to face and telephone interviews with several staff involved in the RFA process.

The DOC processes about 350 RFAs of all types of complaints each month. Typical RFA files include the following documents: the initial complaint form filled out by the complainant, an RFA control sheet filled out by DOC staff, the review letter from the DOC physician consultant, the DOC closing letter to the consumer, the DOC demand letter to the health plan, and correspondence between the DOC, health plan, physicians and consumers (including documents from the internal appeals process of the health plan or medical group).

The project team member reviewed 22 RFAs which were closed within the period from October 1, 1996 to September 30, 1998 that concerned a medical necessity dispute over a reconstructive surgery procedure. This sample was selected for its manageable size and ease of identification. The DOC does not regularly track the type of therapy or procedure disputed in each RFA. However, the DOC sends nearly all the reconstructive surgery RFAs to the same physician consultant, enabling an automated search for reconstructive surgery cases. Thirty-nine RFAs were sent to the physician consultant and closed during the time period under study. Of these, 10 could not be located by the DOC or were not available, and 7 were not disputes over medical therapies. Rather, they concerned dental procedures, imaging procedures, experimental therapies, procedural payment issues, and referrals that were procedural issues rather than *medical necessity* issues. Because of the consistency in the type of procedure and in the outside consultant, this sample allowed for case to case comparison of the main variable: application of *medical necessity* criteria in the decision making process.

Another reason for using this sample was that reconstructive surgery (of a cleft palate) was one of the hypothetical cases presented to key informant interviewees in the medical necessity project. The types of reconstructive surgery cases in this sample included breast reduction and augmentation, breast reconstruction, breast implant repair, skin tumor removal, sebaceous cyst removal, abdominal panniculectomy, and excess skin removal.

[46] The DOC Requests for Assistance analysis was supported by a grant from Stanford University's School of Medicine.

A standard form was constructed as a data collection tool. Data points collected from information tracked by the DOC included:

- RFA number
- Date the RFA was opened
- Date the RFA was closed
- Complaint type, by DOC category (the reconstructive surgery sample included: "Plan denial of treatment," "Refusal to authorize treatment," "Refusal to pay treatment")
- Health plan name
- DOC decision (health plan was or was not in compliance with the Knox-Keene Act)
- DOC reviewer who closed the case.

Additional data points collected which were not tracked by the DOC, requiring individual analysis of each RFA, included:

- Therapy requested by and denied to the consumer
- Medical group, when available
- Whether the initial denial was by the plan or provider group, when available
- Criteria used by the DOC, DOC physician consultant, health plans, consumers, and physicians to determine *medical necessity*
- When and how the term *medical necessity* was used
- Reasons for the DOC decision, as stated in the closing letter to the consumer and/or the demand letter to the health plan
- Use of the consultant report in the DOC decision
- Any other pertinent information on criteria used for determining *medical necessity*.

See section IV.E for findings related to the DOC Request For Assistance analysis.

f) Analysis of California legal cases

Decisions of state and federal courts in California and the Ninth Circuit that considered the interpretation of *medical necessity* in the context of insurance coverage disputes were analyzed as part of this study. The conclusions are based primarily on an evaluation of 27 published cases decided between 1978 and 1998. The methodology was loosely modeled after that of Hall and colleagues who previously conducted a national study of medical necessity court cases,[47] as well as a critique of the Hall methodology by Sage.[48]

Twelve of the cases were decided in California state courts. Eleven of these were decided at the appellate level while the state's highest Court agreed to hear only one. In four disputes, the defendant was a private insurer (equally divided between Blue Cross

[47] *See* Mark A. Hall et al *Judicial Protection of Managed Care Consumers: An Empirical Study of Insurance Coverage Disputes,* 26 SETON HALL L. REV. 1055 (1996).
[48] William M. Sage, *Judicial Opinions Involving Health Insurance Coverage: Trompe Loeil or Window on the world?* IND L. REV. 49, 68 (1998)

and Blue Shield plans) and in eight it was the Director of the California Department of Health, representing Medi-Cal.

Of the fifteen cases heard in federal courts, twelve involved welfare benefit plans controlled by ERISA. The remaining three were Medicare cases. Ten of the federal cases reached the US Court of Appeals for the Ninth Circuit and five were decided at the District Court Level.[49]

Because of the small sample size and methodological limitations, the California and Ninth Circuit analysis cannot be considered statistically significant. However, the relative dearth of reported cases should not be taken to mean that the denial of medically necessary care is not a significant problem for consumers. For one thing, published decisions are only the tip of the iceberg. "What occurs outside the purview of the courts is probably far more significant to the average patient."[50] For example, the published decisions provide no indication of how often necessary care is denied to consumers who do not choose to pursue litigation. They do not tell us how often consumers and insurers come to an agreement through the plan's internal grievance process, how frequently cases settle out of court, or how often a physician fails to request a "necessary" treatment because of personal financial incentives or certainty that it will be denied.

In addition, research on published decisions fails to tell us the frequency of (or outcome in) unpublished cases. It sheds no light (at least in California) on state cases that were not appealed.

Moreover, a study of judicial opinions is always stale, a snapshot in time that does not reflect events as they are today. First, there is a lag time between when the study is completed and when it is published. Second, and more important, there is generally a long lag time between the events that precipitated the litigation, the decision at the trial court level, and the final appellate opinion. In the Hall Study, the median time to final disposition was 2.5 years, but one quarter took four years or more.[51] These time delays are of special concern when one is trying to evaluate *medical necessity* decision making in the context of a rapidly changing managed care environment. There is a danger that the conclusions one draws may be based on a data set that is irrelevant. In addition, "the law" changes with each decision as new precedents are established. In the Hall data set only six (three percent) of their 203 cases clearly implicated decisions made by HMOs or other managed care plans.[52] In the California study, we identified only two cases (eight percent of the total) in which it was clear that the defendant health plan was an HMO.[53] Both of these cases were decided within the past six years.

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[49] The case names and citations are included in Appendix Z.
[50] William M. Sage, op.cit
[51] Hall Study paper, op.cit
[52] William M. Sage, op.cit.
[53] *Bast v. Prudential* 150 F. 3d 1003 (1998) and *Bellanger v. Health Plan of Nevada* 814 F. Supp. 918 (1993). (In other cases the defendant may be an HMO but this is not clear from the record.)

Another observation that we can confirm is that many judicial outcomes in *medical necessity* cases seem idiosyncratic and fact specific.[54] Therefore, we must be careful not to draw unwarranted generalizations about the substantive issues that influence such decisions.
See Section IV.F for findings related to the analysis of California court cases.

g) Consumer Briefings

Two consumer briefings were designed and held to maximize consumer involvement in our research. Consultants advised staff on the most appropriate ways to present research findings to consumers and to provide consumer input to stakeholders. To reach the greatest number of consumers and to develop appropriate briefing materials and interview questions for the consumer briefings we partnered with the Center for Health Care Rights, a non-profit agency that promotes consumer quality-of-care protections in health maintenance organizations (HMOs) and other managed care plans. Working with the California HealthCare Foundation, the California Wellness Foundation, the Center for Health Care Rights, Consumers Right to Know and funded by the Sierra Health Foundation, we identified a list of consumers and consumer groups representing a variety of disease-focused and general consumer advocacy organizations in both Northern and Southern California. We sent 47 invitations to consumer groups located throughout the state. To provide maximum access for consumers, one briefing was held in Oakland on February 8 at the California HealthCare Foundation (CHCF) and a second was held in Los Angeles at LA Care Health Plan on February 12. Representatives from 17 organizations attended these meetings.

h) Decision Maker Workshop

At the conclusion of the research phase of the project, Stanford's Center for Health Policy and the Integrated Healthcare Association sponsored an in-depth Workshop (March 11-13, 1999 at the Sierra Health Foundation in Sacramento, California) to review the research findings and to determine areas of consensus and disagreement with respect to the decision making process and model contractual language. The workshop participants included treating physicians, health plan and medical group medical directors, legal experts, purchasers, regulators, and consumers directly involved in various aspects of *medical necessity* decision making. All but one of the participants had been interviewed during the research phase. Observers included Stanford project staff, project consultants, and staff from the California HealthCare Foundation and the Sierra Health Foundation. The Workshop was facilitated by Dr. David Eddy.

The Workshop was based on a similar workshop conducted by Drs. Eddy, Bergthold and Sage with Blue Cross medical and legal directors in 1994 and sponsored by the National

[54] Karl Llewellyn, THE CASE LAW SYSTEM IN AMERICA, 79 (Paul Gewirtz ed. & Michael Ansaldi trans., 1989).

Institute for Health Care Management (NIHCM).[55] The NIHCM workshop focused on a definition of *medical necessity* proposed by the workshop leaders and the supporting criteria by which it could be applied. Dr. Eddy then spent several days with participants, during which the meaning and application were dissected and discussed until a general consensus on "model language" emerged. The Blue Cross workshop did not address the coverage decision making process, but focused on contract language, without prior research about how the Blue Cross plans were handling questions of *medical necessity.* Although the NIHCM workshop produced some consensus, it did not include a formal process for evaluating implementation of the model language, and no follow-up plan was adopted.

The California Workshop drew on the experience of the NIHCM workshop but differed in a few ways. The California Workshop was based on research; the participants were drawn from a broader group of stakeholders than just medical directors; the process of decision making was emphasized as equally if not more important than contractual definitions; the participants made commitments to take the workshop recommendations back to their organizations for further study and implementation; and follow-up initiatives were recommended.

The agenda of the two and a half-day California workshop included an introduction to the terminology of *medical necessity,* research findings on the process of decision making in California health plans and medical groups, perspectives of the various stakeholders on the decision making process, and a discussion of a model definition of *medical necessity* based on the research findings (see Section V for additional information on the process and outcomes of the workshop).

2. Secondary Research: Literature Review

Medical necessity is not a new issue. A substantial body of theoretical and anecdotal literature does exist that discusses variations in coverage decision making processes, the challenges associated with defining and applying *medical necessity,* and recommendations and attempts to resolve them. One of our first tasks was to undertake a review of the important literature related to *medical necessity.*[56] Staff collected articles using several sources including MEDLINE searches and recommendations from project consultants and stakeholders.

The primary purpose of the literature review was:

- To assist in the formulation of interview methodology;
- To assist in the design of analytical frameworks for our primary and secondary research;

[55] Workshop on Medical Necessity, Appropriateness, and Experimental and Investigational Treatments, Boulder Colorado, September 8-9, 1994.
[56] See Appendix K for Annotated Bibliography.

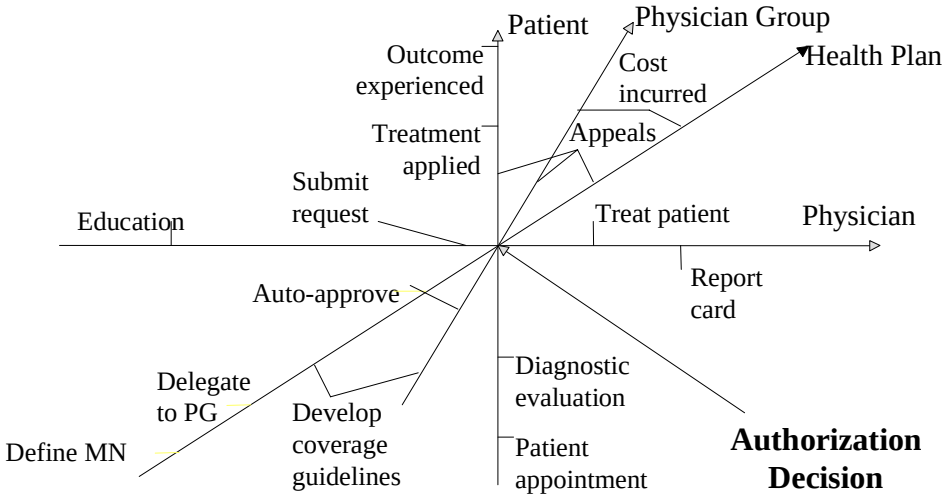
- To assist in the structure and organization of proposed model *medical necessity* contract language and model coverage decision making processes.

IV. The research findings identified some common steps as well as substantial variation in the *medical necessity* decision making process.

A. There is variation in the way different stakeholders view the problems.

In our stakeholder interviews, we came to understand that different stakeholders view the decision making process from different perspectives. Their view of the problems with this process and their recommendations to improve the process also often vary. One of our workshop medical directors drew the perspectives in the following way:

Different participants have different perspectives on the process



Adapted from Decision Maker Workshop Participant[57]

This diagram suggests and our interviews established the following:

- Patients care about access to information and services when they are in need of treatment;
- Treating physicians interact with multiple medical groups and health plans to obtain appropriate approvals for delivering care to their patients;

[57] Jeffrey Mason, M.D., Decision Maker Workshop, March 11 – 13, 1999.

- Medical directors focus on developing and implementing policies and procedures needed to manage the care for the defined population of treating physicians and patients for whom they are responsible;
- Legal directors' concerns center on developing a contractual definition for coverage policies that clearly defines the terms of the benefit contract;
- Purchasers' attention is directed at creating clearly worded benefit contracts, providing value to their employees for dollars spent on health care, and educating employees about services they are eligible to receive.

B. Research data revealed some common basic steps in the decision making process.

The interviews with plans and medical groups revealed that, although there is substantial variation in the way decisions are made, almost all organizations follow at least some of the following basic steps in the *medical necessity* decision making process. We first report the commonalties, followed by a description of the variations.

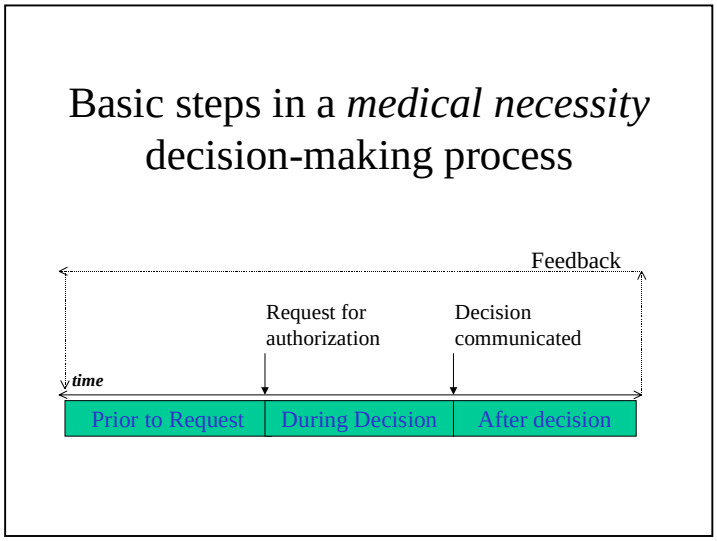
California's decision making process is somewhat unique because of the role that delegated medical groups have in that process. Medical groups (e.g. independent practice associations, multi-specialty and single specialty medical groups, management services organizations) that accept financial risk, follow approximately the same process in authorizing treatments that health plans do that hold the risk. Therefore, the basic steps described below can apply to either a health plan or a medical group.[58,59] The main difference is the role the plan plays when a medical group denies authorization and a treating physician or consumer appeals. The basic process depicted in the chart below is also followed to a large degree by the managed Medi-Cal plans.

There are many decisions made by physicians or other providers that do not require any oversight or pre-authorization. However, for requests that require action by someone other than the treating physician, there are some common steps. We divided these steps into three time-defined phases:

- Basic Steps that occur <u>prior</u> to a request for authorization by a physician to the medical group or plan;
- Steps that occur <u>during</u> the time after the physician makes the request and that request is resolved, either by approval or denial of the service;
- Steps that occur <u>after</u> a decision is rendered and communicated to the physician and consumer.

[58] Throughout our description of findings, we will refer to a decision making process that is applicable both to delegated medical groups and health plans for services for which they retain risk and for their PPO products.

[59] In California, the initial, individual coverage or *medical necessity* decisions more often than not are made by the medical director of the medical group with which their primary care physician is affiliated and with whom their health plan contracts. Consumers are generally unaware of the important decision making role of these medical groups and the conflict between their groups and their plan.



1. Basic steps prior to a request for authorization

a) The definition of terms in the contract.

In order for an organization to develop the capacity to manage care, many policies and procedures need to be developed. One of the first steps is the establishment of contracts between the purchaser (generally the employer) and the plan (and then contracts between the plan and various medical groups that are delegated the authority to approve or deny care). It is this contract that specifies what categories of benefits will be covered or excluded (hospitalization, physician services, lab and x-ray, diagnostic evaluation, home health care, etc. are usually covered in a basic plan; dental,[60] vision, experimental or investigational treatments, infertility treatments, etc. are usually specifically excluded). The contract is explained in a document called the "Evidence of Coverage" that specifies the details of the benefit package, including definitions of terms such as *medical necessity*. Consumers view their relationship with their treating physicians as their primary connection to their health care. Treating physicians feel bound to their patients by the Hippocratic Oath. However, the primary contractual relationship usually exists between the purchaser, on behalf of the employee, and the health plan.

b) The specification of coverage guidelines and practice guidelines.

When plans sell a benefit package to a purchaser, the categories of services are spelled out fairly specifically. What is less visible are the coverage policies or guidelines that plans and large medical groups develop to specify what types of treatment are optimal for groups of consumers with a given condition and how the plan or group will 'cover' or 'pay for' the treatment of these conditions.

[60] Dental associations are particularly concerned about the use of *medical necessity* as it applies to dental care. See Appendix M for letter from the California Association of Dental Plans and their statement and definition of how *medical necessity* differs from *dental necessity*.

There is great confusion and debate about the use of the term "guideline." Plans generally use the words 'coverage policy' or 'coverage guideline' [61] to describe what they will pay for and how decisions should be made about specific conditions for groups of consumers with similar characteristics.

A coverage guideline may be based on evidence-based practice guidelines as promulgated by national or professional medical societies, clinical or scientific evidence from a variety of sources, the plan's own experience, or a combination of the above. Coverage policies or guidelines are usually developed by a committee at the corporate level, with input from medical directors and network physicians, and undergo national review. Large plans may have up to 400 different coverage policies or guidelines and an additional 300 to 400 technology assessments on specific devices or drugs, not including the hundreds, indeed thousands, of practice or clinical guidelines purchased for use in assessing appropriateness of treatment.

We have found it useful to distinguish coverage guidelines from practice or clinical guidelines in the following way. **Practice guidelines** provide a detailed treatment "map" for average patients under optimal conditions. These maps or screens might include information on how the intensity of service is related to the severity of the condition; what to do on each day of hospitalization for drugs, diet, and treatment; how to manage a chronic condition, etc. **Coverage policies or guidelines** describe the steps and indications that a practitioner must follow for a procedure to be approved for coverage by the medical director of the plan. There may be indications of severity or intensity described in a coverage guideline; however, practice guidelines usually do not address payment. The information in coverage policies or guidelines is developed or adapted from other sources by each plan and may include evidence of effectiveness of the treatment, size and location of an injury, age, weight, symptoms, medical conditions that might disqualify an individual for the procedure, response prior to therapy, other therapies that must accompany the requested therapy, and plan policies or procedures that are related to the approval or denial process for a specific treatment or intervention.

NCQA accreditation requires the use of guidelines but does not define them:

> Clinical Practice Guidelines. Plans are accountable for adopting and disseminating practice guidelines for the provision of acute and chronic care services for members. Clinical practice guidelines evaluated under this standard do not include "either UM criteria or guidelines that primarily address medical necessity decision making." [62]

[61] See Appendix H for examples of different coverage guidelines.
[62] NCQA, *Surveyor Guidelines for the Accreditation of Managed Care Organizations*, July 1, 1998-June 30, 1999.

Most of the plans we interviewed told us they relied on a number of different policies or guidelines, and, since they did not always define their terms, we can not be certain whether they meant coverage or practice guidelines in the following analysis. We asked whether or not the organization had crafted its own guidelines, used guidelines crafted by another organization, either public (Health Care Financing Administration (HCFA), Agency for Health Care Policy and Research (AHCPR)) or private (ECRI, InterQual); or purchased guidelines but modified them before applying them to their organization.[63] (See Section IV.C.1.a. for a discussion.) In our research, the most commonly relied upon organizations for proprietary guidelines included:

- **InterQual,**[64] providing Level of Care criteria (used to determine appropriateness of admission, continued care and discharge); Pre-Authorization Criteria (to help the physician or reviewer confirm that all necessary signs, symptoms and findings are documented to support the physician's Request For Authorization; and Primary and Specialty Care Management Criteria (to help organizations determine the appropriateness of referrals);
- **ECRI,** a nonprofit technology assessment organization focusing on the effectiveness of various devices and treatments;
- **Milliman & Robertson**,[65] a private, for-profit organization, providing information and benchmarks for treating common conditions for individuals without complications, based on best observed practices not statistical research;
- **IntraCorp,** drawing on guidelines developed by a variety of other organizations and providing customers with online access to this information;
- specialty guidelines from organizations such as **Cadenza** for treating heart disease.

c) Disseminate guidelines to physicians or consumers.

The most common way to distribute guidelines is in paper form in a binder. Periodic updates are then sent as loose leaf papers, which the medical group is responsible for inserting into the binder, replacing out of date guidelines. It was not uncommon to see a medical director's office with shelves full of such distributions. If a medical group were contracting with 10 or more different plans, that group might need at least some knowledge of hundreds of different policies and guidelines to be in compliance. Our interviewees told us that medical directors of medical groups infrequently consult the coverage guidelines and technology assessments of the plans with which they contract, or consult them only in the most complex cases or when an appeal is likely.

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[63] In addition to these proprietary sources, the Agency for Health Care Policy and Research (AHCPR), in collaboration with the American Medical Association and the American Association of Health Plans, has launched the National Guideline Clearinghouse on the internet (www.guideline.gov) to provide plans and groups with the ability to compare guidelines in a more systematic way. The Agency has received hundreds of guidelines and currently has comparisons for about a dozen different conditions or diagnoses. Several commercial websites also offer guidelines on-line e.g. WebMD.

[64] See Appendix N for example of InterQual guideline.

[65] See Appendix O for example of Milliman & Robertson clinical guideline.

d) Conduct physician education

The next basic step in setting up a process is to educate physicians in the organization. Most education is conducted at the delegated medical group level, although some plans do conduct training and education sessions for treating physicians, about new or controversial coverage policies. The most common educational interventions include orientations for new physicians, where the group provides them with a policy and procedure manual. Beyond the initial orientation, there were few common ways plans or groups approached physician education about medical policy.

e) Determine which decisions to delegate to the medical group

In general, plans delegate initial decision authority to contracting physician groups for decisions involving treatments. The most common decisions retained at the plan level are those to approve or deny treatment for transplants, experimental/investigational treatments, or some tertiary and quaternary care. Most other decisions are delegated to the medical groups, as our request for information confirmed. The risk for pharmacy decisions is mainly at the plan level, and some medical groups that hold pharmacy risk are seeking to shift that risk back to the plans, because its cost is so difficult to manage.

f) Determine which requests to pre-authorize and which providers or treatments to exempt from review

Most groups (and plans that retain risk) have a list of procedures that are either seldom denied or have low volume or cost. These procedures may be placed on a list that does not require pre-authorization. Similarly though less frequently, groups may identify a list of providers individually or by specialty whom they "gold card" by allowing them to deliver care without pre-authorization. These providers tend to have a history of seldom having authorizations denied. (The reverse is also true; providers who are reviewed on every request because of their prior denial rates.) One plan director explained that the neurologists in his community almost never request an unnecessary MRI; therefore, these neurologists are not required to seek pre-authorization for this procedure. In multi-specialty groups, referrals to specialists within the group usually do not require pre-authorization, enabling primary care physicians to make an instant referral for a patient.

g) Submission of Request for Authorization

Once a physician or other provider determines that a specific treatment or intervention is considered "necessary" for an individual, if that treatment is not pre-authorized, the physician must submit a request for authorization to the medical group or health plan for approval or denial. These requests are occasionally submitted online, but the most common mechanism still is the paper form faxed to the medical director.

Physicians told us they might also submit a request for authorization because they don’t want to be the one to deny the patient or they were unsuccessful in dissuading the patient of the necessity of a treatment.

2. Basic steps during the decision

a) Technical review of eligibility

Once the authorization has been submitted, the first level of review is a technical one. Most plans employ clerical personnel to check the eligibility of the member (i.e. that the individual is in fact a member of that plan or group) and to determine whether or not the entire category of service is a covered benefit (e.g. vision care is not a covered benefit.) Most times this process is straightforward. The clerk may have authorization to deny coverage or recommend a denial. However, for significant minorities of cases, decision criteria are vague, uncertainty is present and differences of opinion arise. Eligibility data entry may lag actual enrollment. In addition, covered benefits are not always clear or specific (i.e. what is cosmetic). If the physician interacts with the clerical personnel, there may be conflict, particularly if the clerical person declares that a benefit is not covered, but the physician disagrees. This disagreement is a great source of frustration for physicians. Disputed cases are usually referred to a nurse or medical director for resolution. The time period for processing these requests at this level is reported to be within 24 hours.

b) Guideline application

If the consumer is eligible and the service appears to be covered, the request for authorization is referred on to a clinician, generally a nurse, to review the request against guidelines (see discussion above). The nurse can approve the request but cannot deny authorization, per NCQA accreditation and Knox-Keene requirements. All plans and medical groups that we interviewed had policies in place requiring a physician to make any denial of *medically necessary* services. In practice, nurses often do the background research for the decision process, referring the decision to the medical director for final signature and review. The application of guidelines to requests for authorization is another source of conflict among treating physicians, medical groups, and plans. There are many gray areas in the application of these guidelines, and physicians may feel special patient characteristics warrant exception from a guideline. If nurses do not refer the problematic cases to a medical director immediately, there is potential for ongoing conflict. Time spent arguing with someone other than a medical director under these circumstances compounds physicians' feelings of loss of autonomy and control. The time period for applying guidelines is reportedly within 24 hours from receipt of the request unless additional information is necessary.

Among respondents surveyed 60 - 90% of all requests for authorization within private plans were approved through the first two levels of review. The remainder of the cases was referred to the medical director for a final decision.

c) Information gathering and research

Once a decision reaches the medical director, a number of steps may be taken. The medical director may apply his or her own experience and expertise to make the decision or may refer the case to a medical policy committee; to external physicians or organizations; or to other personnel in the organization who can assist in the gathering of evidence or giving of expert opinion. There is no common process at this level. The way a medical director makes a final decision varies by plan, medical group, and type. Medical directors may be required to consult committees, national databases, other physicians, and outside sources to make a final determination. It is clear that the contractual definition of what constitutes a *medically necessary* service is not the primary driving force in the decision. (See discussion of the application of the contractual definition in Section IV.D.)

d) The medical director makes a decision to approve or deny the request.

In every interview we conducted, the response was consistent. Only a physician makes a decision to deny treatment in California plans and medical groups. No variation in this part of the decision making process was reported, although nurses assist in the decision making process by doing research and proposing recommendations to the final physician decision-maker.

As noted below, in data reported from our Request for Information, 80% to 99% of all initial requests within medical groups are reported to be approved.

Number of Cases and Denial Rates

Type	***Average # Cases Reviewed/Month***	Range	***Average Approval Rate***	Range
Plans (n=12)	3,791	175 to 15,000	91%	72 to 100%
Medical Groups (n=10)	11,526	50 to 50,000	94%	80 to 99%
Both	7,149	–	92%	–

One finding from this research is that most documented requests for authorization of treatment are approved, not denied. Since the definition of what constitutes a *medical necessity* request or denial is not clear and the denominator of requests thus varies within groups and plans, this range must be considered approximate.[66] Also, a medical director might verbally deny the requested service but recommend an alternate level of care, type of treatment or provider. This "diversion" would not generally be considered a denial.

In our interviews, we also discovered that there is another aspect of the denial of coverage in the form of an “overturn” of the decisions made by delegated medical groups. Even though delegated groups have the financial risk and the authority to make

[66] The size of our sample of medical groups did not allow us to make generalizations about denial rates with any precision.

medical necessity decisions and denials, plans retain the authority to make the final determination of coverage and can overturn the group's decision.

By the time that a request for authorization reaches a medical director, in general approximately 48 hours has elapsed. The time required to resolve these more complex cases varies considerably, although NCQA requires a specified timeframe for resolution of most cases that accredited plans are bound to follow.

3. Basic steps after the decision

a) The decision to approve or deny is communicated to the physician and the consumer.

There are a few common processes in the way the decision to approve or deny is communicated within plans or medical groups. One pattern is for the treating physician and the consumer to be notified of the denial by letter at the same time.[67] Often the physician will be notified first by telephone and encouraged to call the patient. The variations in communication will be discussed in the Section 3 (c).

b) If a physician or consumer disagrees with the decision, an internal appeals process may commence.

Although it was not the purpose of this research to document the percentage of those appeals, others have suggested that most denials are not appealed.[68] Of the few that are appealed, the process for reviewing the denial was reported to be problematic by our interviewees. In general, the consumer or the physician will appeal the denial of service to the group's medical director first. The medical director reviews the decision and may uphold or reverse that decision. If the decision is upheld, the physician or consumer may then appeal that decision to the plan. The plan has ultimate authority for these decisions under Knox-Keene and may overturn the group's decision for any number of reasons, including legitimate disagreement with the decision's clinical basis, for marketing reasons or pressure from the consumer. The plan, however, has mixed financial incentives in this process, because for delegated services, the plan holds no financial risk for the overturn decisions.

Most delegated decisions relate to physician or ancillary services, so the total amount of the overturn may be relatively small. Medical groups we interviewed reported that, in general, they receive capitation payments for about a quarter of pharmacy services, half of facility services and 75% of professional services. Health Plans also reported that they

[67] Examples of denial letters are in Appendix P.
[68] Op. Cit., M. Morgan.

might share with medical groups in the cost of high cost patients (some of whom may present cases that have been overturned) in full for 50% of the members and in part for 33% of the members.

The "overturn" issue is a common and serious source of conflict between plans and groups. It is clear that some medical groups have rates of overturns that are problematic both to them and to plans, because our medical groups reported that 30 to 80% of their denials were overturned by the plans with which they contracted. The actual overturn rate varies by group and by plan, and our research was unable to determine specific factors that might account for this variation.

c) Independent review process

(1) The California Department of Corporations (DOC) conducts a limited independent document review process that allows consumers to dispute health plan coverage, *medical necessity,* and other decisions by filing a Request for Assistance (RFA).

If a consumer has been denied coverage by his or her medical group or health plan and has appealed that decision using the health plan's internal appeals process for at least 60 days or has an urgent case, he or she has the right to request an independent review by the Department of Corporations. Plans are required by law to notify the consumer (using scripted language) of their right to appeal to the DOC. This language is found in the Evidence of Coverage, denial letters, and other documents, although the sixty-day waiting period for all but urgent cases is not made clear. As a result, many consumers become angry and confused by the DOC process.[69]

The individual initiates a request for assistance by filing a form. The case is assigned to a DOC staff attorney who reviews the request, notifies the health plan, collects relevant documentation from the consumer and health plan regarding the case, and if necessary sends the RFA to a physician consultant for review. Upon receipt of the consultant's review, the DOC staff attorney decides whether or not the health plan is in compliance with pertinent Knox-Keene Act requirements. If the DOC finds the plan in compliance, the DOC sends a closing letter to the consumer, with a copy to the health plan. If the DOC concludes the plan has violated pertinent requirements, the DOC will send a demand letter to the plan. In these cases, the DOC sends a closing letter to the consumer stating either that the plan has agreed to reverse its decision or that it has not, in which case the DOC refers the case to its enforcement division. The DOC may take enforcement action against a plan and issue fines.[70] (See Section E for a detailed description of the variations in the DOC process.)

[69] Effective July 1, 1999, the California legislature passed a law (Knox-Keene Act Section 1368.02) which modifies the required language by clarifying the general 60-day waiting period requirement.

[70] As of July 15, 1999, primary responsibility for the request for assistance process within the DOC moved to its enforcement division, though the consumer services division continues to receive the complaints.

(2) The Friedman-Knowles Act established an independent review process for experimental treatments.

In 1996, the California legislature passed AB 1663, the Friedman-Knowles Act, which requires external or independent review for experimental treatments in terminal cases. The Knox Keene law states in Section § 1370.4(a) (which AB 1663 created), that every plan must provide an external, independent review process for coverage decisions regarding experimental or investigational therapies if (1) the enrollee is terminal and likely to die within two years; (2) the enrollee's physician certifies that standard therapies have not been effective or are not medically appropriate, or therapies not covered by the plan are not more beneficial; and (3) the enrollee's network physician certifies in writing that the recommended therapy is likely to be more beneficial than any available standard therapy or an out of network physician demonstrates that two documents of medical and scientific evidence demonstrate that the treatment will be more beneficial than the covered treatment. The independent review entity must be a panel of at least three experts in the patient's medical condition who are knowledgeable about the recommended therapy. This legislation has promoted a consistent standard for terminal patients that is being followed by the California plans.

(3) Voluntary independent review.

During the course of this research, the California Association of Health Plans announced that their plan membership would voluntarily submit all *medical necessity* and coverage decision disputes to independent review, and at least one health plan is currently doing so for these cases. Process details and evaluation criteria may vary by plan.

d) Retrospective review and remedies

After a decision has been rendered, plans and groups conduct retrospective review, although the extent and use of these tools varies. Tools such as inter-rater reliability tests are conducted on medical director decision making to determine how much variability might exist among different decision-makers for the same case. Other tools include the profiling of physicians or groups of physicians, or the review of denial patterns.

C. There are substantial variations in the way decisions are made in managed care organizations.

We expected to find variation in the way managed care organizations made decisions, and we did. We had assumed that there would be variation that interviewees and staff characterized as innovative or best practice, some judged to be less desirable, and a range of actions between these points. We have selected three types of process variations to highlight, although there were many other types of variations that did not fit these

categories.[71] They represented "problems" with the process noted by multiple stakeholders as significant.

1) **Variations in the development and distribution of guidelines and the impact on decision making;**
2) **Variations in the logic and process of authorizations; and,**
3) **Variations in the quality and quantity of communication among health plans, medical groups, physicians, and consumers.**

1. Development, distribution, and decision making using coverage policies or guidelines vary.

a) Plans and medical groups use a variety of coverage policies or guidelines to make decisions about approval or denial of services.

Plans or groups may use either "off the shelf" guidelines or develop or adapt their own. We did not determine that one or the other was used more by practicing physicians, so are unable to suggest which is preferable. However, a proliferation of multiple guidelines for the same condition is undesirable if it results in reduced use as was suggested by many interviewees.

We had hypothesized that larger private plans would have more resources than small plans or plans serving Medi-Cal beneficiaries. Large plans, therefore, may be more likely to craft their own guidelines than to purchase them from the outside. In fact 78% of private plans that responded to the question said they created their own guidelines in comparison to only 17% of the Local Initiative or County Organized Health System managed Medi-Cal plans. Of the private plans that contracted to provide managed care services to Medi-Cal beneficiaries, 67% created their own guidelines, lending some credibility to the claim by private plans that they do not vary their processes by product or payor type.

Larger plans were more likely to create their own guidelines than smaller plans. Respondents from organizations of any size told us they were unlikely to modify outside guidelines for their own use, tending to either adopt guidelines "as is" or to create entirely new ones. Of the medical groups we interviewed, Independent Practice Associations (IPAs) were more likely to use outside guidelines than non-IPAs, although there was no relationship between the size of the group and their use of guidelines, and the small number of total responses makes this finding "suggestive" not conclusive.

[71] See Appendix Q , "Summary Process Variations" for a description of the many organizational variations we identified through the interview process.

b) Form and extent of physician participation in guideline development also varied, despite the NCQA accrediting standards requiring that participation. [72]

We found that some plans or groups said they included treating physicians routinely on guideline development committees, rotating new physicians on to committees systematically, while others included treating physicians more haphazardly. Physicians reported that they valued being involved, but admitted that the amount of time required for active involvement was a significant barrier to participation. One medical director commented that he had tried every way he could to educate and involve his physicians in the development of coverage guidelines, but had no confidence that any method worked very well. This suggests that such efforts to encourage participation in guideline development must be weighed against their cost and effectiveness in getting physicians to use them. In general, the larger the group or plan, the more difficult it is to achieve substantial representation of treating physicians.

c) The distribution of guidelines to providers and consumers also varied across organizations.

Some plans openly shared guidelines either in hard copy or by diskette. A few health plans reported projects underway for online access to guidelines. Most plans supported the idea of making guidelines available on request to consumers, but a few noted that the guidelines were technical and proprietary. Some plans distributed guidelines only to medical directors. Although most medical groups shared guidelines with their physicians upon request, one medical group reported that they never shared guidelines with physicians because, "they just lose them and it's too expensive to reproduce them for everyone." Statements such as this suggest that, with the bewildering array of competing guidelines, current efforts to disseminate guidelines may be going to waste. Another group didn't want the physicians to know what they would approve because the physicians might request it more often.

d) Communication about the guidelines ranged from extensive in-service training to education on a case by case basis.

Plans and groups reported using a variety of techniques to encourage their physicians to use guidelines: monthly newsletters and internal bulletins; in-service training required for new physicians; regular educational forums such as monthly meetings; education for physician leaders to enable them to work with their peers more effectively; policy and procedure manuals distributed to physicians and/or to their administrative staff; sending guidelines to physicians at the time of the denials so that physicians could link the

[72] NCQA Quality Management and Improvement standard on the practitioner role states, "There should be evidence that practitioners participate actively in the Quality Improvement (QI) program. Primary care practitioners' and specialists' participation should include: guideline development, peer review, and related clinical activities." The NCQA Practitioner Review of Guidelines' standard states, "Plans should involve practitioners in the adoption of guidelines. There should be evidence that practitioners who are from specialties that would use the guideline had an opportunity to advise their development."

decision to the guideline more concretely, or to the supporting evidence or other quality improvement activities. None of our interviewees suggested that they had a methodology that worked particularly well, however. The degree of effort organizations expended to be more effective also varied.

e) The decisions based on guidelines varied because the guidelines themselves and the evidence on which they were based differed significantly.

The Autologous Chondrocyte Transplantation case for knee pain,[73] exemplifies this variation in decision making based on the application of guidelines. Case responses varied across medical groups and health plans, unrelated to size, geography or populations served.

Three plans with different approval/denial responses on this case supplied us with their coverage guidelines/ policies for ACT. A comparison of these guidelines[74] showed that there were only two areas of agreement among the policies: patients must have clinically significant symptoms due to cartilage injury, and patients with osteoarthritis should be excluded. These coverage policies differed in a number of other ways: two policies required a "full thickness defect" (i.e. all the way through the cartilage); one did not specify. Two policies required a stable knee; one did not specify. Other differences included use of evidence citations; age; weight; response to prior therapy; and surgeon characteristics.

Interestingly, the verbal responses of two of the medical directors about whether they would approve or deny this intervention contradicted their own coverage guidelines. Plan A would have approved the case, in keeping with the plan's coverage guideline. Plan B would have referred the case for consultation, even though the guideline was specific enough to make a decision. Plan C would have approved the intervention, even though the information provided in the case was insufficient to apply the guideline. This suggests that medical directors may not be fully aware of or don't use their own coverage policies/ guidelines.

e) The plan and physician group medical directors responded differently to the ACT case. More plans would have approved treatment. [75]

Although the decision about ACT would most likely have been delegated to the medical group level, we asked medical directors of both groups and plans how they would respond, hypothetically, to this case. Of the 11 health plans that chose to respond to the ACT case example, 6 would have approved it (one only at a tertiary care Center of Excellence, however); 4 were undecided and suggested they would check plan guidelines, other experts, or would try to divert the case to more conservative treatment first; and only 1 plan medical director indicated he would have denied the treatment. Of

[73] Refer to case descriptions in Appendix I.
[74] See Appendix R for ACT Coverage Guideline Comparison.
[75] See Appendix S for Medical Necessity Case Response Results

the 7 medical group medical directors who responded to this case, 1 would have approved the case if more conservative treatment were first tried; 2 would have denied the treatment; and 4 were undecided and would have asked for expert opinion or plan guidelines. Only one of the respondents indicated substantial familiarity with the intervention and his own organizational guidelines related to this treatment.

f) The case studies showed that decisions for the same consumers would differ and that they were not necessarily based on guidelines.

We also asked medical directors of both plans and medical groups to comment on three other cases, in addition to the ACT case. [76]

The responses to the **reconstructive surgery case** for a young boy with a cleft palate reflected the uncertainty of the policy environment around this issue as well as each organization's approach to this type of treatment[77] and the difficult psychological aspects to the decision. There were few differences between health plans and medical groups in this case. Of the 9 plan medical directors who commented, 4 would have approved the surgery; 3 would have denied it prior to the July 1 legislative implementation date but were not sure what they would do post-July 1; and 2 said they didn't know what they would do about this case. Of the 12 medical group medical directors who commented on the case, 6 would approve the treatment (citing it was clearly reconstructive, or they were obliged by law, or it wasn't strictly *medically necessary* but would benefit the patient); 5 would have denied the surgery (citing it was cosmetic, they would require a photo to see how disfiguring the scar was, or they would need more information); only 1 director said he was undecided. Though not all cleft palate cases, it is interesting to note that the DOC, in consideration of reconstructive surgery cases it reviewed through its Request for Assistance process, upheld the health plan's decision in 13 out of 22 cases.

There was the most consensus among medical directors on the **growth hormone case**; slightly more medical group medical directors than plan medical directors would have denied the case. Of the 9 plan medical directors who commented on the case, 5 said they would have denied the case and 1 more thought he would probably have denied the case, although he would require more documentation. Only 1 medical director would have approved; and 2 others wanted to check guidelines or California Children's Services requirements. Of the 9 medical group medical directors, 7 would have denied, 1 didn't know, and 1 would have approved, deferring to the treating physician's decision. We have discerned from our discussions with respondents that the relative consistency in responses to this case reflects the considerable evidentiary literature on the effectiveness

[76] It should be noted that while the coverage guidelines are developed mainly at the plan level, it is the medical director of the delegated medical group who would make the first level denial or approval of these cases. We asked both plan and group medical directors to comment, however, knowing that the plans would make the decisions for their PPO products and would be asked to make a decision should there be an appeal.

[77] By July 1999, AB 1621 requires plans to consider "improved function" and "normal appearance " in their decisions about cosmetic vs. reconstructive surgery.

of growth hormone,[78] the relative comfort that most medical directors have about approving or denying this treatment based on patient characteristics such as those presented in the case, and medical directors' familiarity with the evidence.

The **high dose chemotherapy for ovarian cancer case** elicited some variation in approval or denial decisions by the medical directors. Of the 9 plan medical directors who responded to this case, 3 would have approved it within the context of a clinical trial; 2 would have denied the treatment; and 3 did not know but would refer to external review or check the guideline. Of the 9 medical directors of medical groups who responded, only 1 would have approved it at a Center of Excellence; 2 others would have denied for lack of effectiveness evidence; and 6 were undecided.

g) While the variation in response rates and the brevity of the cases do not merit drawing conclusive opinions, it is interesting to note the following:

- As predicted, decisions to approve or deny the four cases varied considerably among respondents.
- In general, medical group medical directors were somewhat less likely to approve treatments than plan medical directors;
- The reliance on the contractual definition of *medical necessity* was conspicuously absent in the discussions; this is consistent with the medical director's reporting to use that they refer very infrequently to written definitions;
- The treatment about which evidence (i.e., the patient population for which growth hormone is effective) was clearest produced the most consensus, suggesting that where evidence is not particularly contradictory, medical directors may make more consistent decisions;
- Only one medical group consistently allowed their treating physicians to make the final *medical necessity* decision.

2. Authorization logic and processes vary.

The second type of variation we found refers to the different ways in which plans or groups determine what requests to pre-authorize or pre-approve for coverage and which providers to exempt from pre-authorization requirements. The pre-authorization process is one that has provoked a great deal of conflict between physicians and the plans or groups that manage the decisions.[79] In order to reduce the conflict and the cost of utilization management, speed up the authorization process, and reward appropriately utilizing providers, groups and plans have set up a number of different procedures for eliminating some of the barriers to practice, but the extent and form of these procedures vary from organization to organization.

[78] Hintz, RL, et. al., Effect of Growth Hormone Treatment on Adult Height of Children with Idiopathic Short Stature, *The New England Journal of Medicine*, Volume 340, number 7, February 18, 1999: pp. 502-505.

[79] California Governor's Managed Health Care Improvement Task Force, op cit.

a) Plans or groups may require that only a defined list of procedures require pre-authorization before they can be prescribed for the consumer.

In general, organizations pre-authorized treatments that were low in cost, volume or controversy such that an authorization requirement wasn't worth the cost of additional intervention. Some pre-authorization decisions are based on past experience of the medical director with the particular panel of treating physicians. For example, some interviewees told us there was evidence that some gastroenterologists were not ordering the appropriate diagnostic tests before administering a procedure, and therefore the procedure was put on the pre-authorization list. If primary care physicians were ordering an unusually large number of MRIs, a request by a primary care physician for an MRI might be required. If certain procedures consistently had higher volume than would have been predicted for the group population, the procedure might require pre-authorization.

b) Plans or groups may identify or "gold card" providers to be exempt from authorization requirements.

For some medical groups and health plans, if a physician's profiled performance merits fast tracking or exemption from pre-authorization because that physician seldom over-utilizes or experiences denials for requests, then the physician may be "gold carded" for either some or all procedures, allowing treatment without pre-approval. In smaller groups and communities, interviewees felt it was easier to identify exempt providers because the medical director knew the physicians personally. Larger plans or groups used profiling information or decentralized their decision making to smaller units around the state or assigned medical directors to specific medical groups so they could become more familiar with that group's performance, both collectively and individually.

Occasionally, if there is under-utilization of requests in an IPA, a medical director may do a 100% review of those cases for a period of time to determine if members are receiving sufficient access to services.

In multi-specialty groups, there may be no authorizations required for referrals within the group, speeding up the process by which a primary care physician can authorize and send the member to a specialist for treatment.

c) Pre-authorization may or may not be tied to periodic evaluation of physician utilization.

Not all plans review all or even any of the group denials. Most groups use information from the denial process to design education and training sessions for physicians and to review their performance as it relates to the coverage decision making process. Physicians whose requests are frequently denied may receive individual feedback from the group's medical director. This information may be used to improve quality and in the review of physician performance. However, not all groups use the information for improvement purposes.

3. The quality and quantity of communication varies.

While most plans intend to communicate well with providers and consumers, and both legislation and NCQA accreditation mandate certain types of communication, overall communication was relatively poor among all parties. From the perspective of those who are "communicated to" – generally the physicians and consumers, but also the plans and groups at certain points in the process – in many instances not enough or the right kind of information is disclosed or requested, and the information that is disclosed is neither clear nor particularly helpful.

Our interviews identified many different communication problems between plans and medical groups; between medical groups and their providers; and between both plans and medical groups and consumers. The research identified several areas where some organizations sometimes were exemplary in their efforts to communicate effectively while in other organizations at other times communication needed to be improved. Following are some of the more significant variations in communication practices.

a) Before the request for authorization is made, physicians and consumers are confused about what to do and when to do it.

Our interviews revealed that many physicians view the authorization process as a barrier to treatment. When there is a problem with a request, the interaction with the group or plan can be time-consuming; there is so much paperwork there is "rationing by inconvenience"; written communication is not always effective because bulk mailings look like "junk;" and treating physicians may not understand who within the managed care infrastructure is making what decisions at what point.

Conversely, physicians may be unresponsive to the communication efforts of plans and medical groups as evidenced by not returning their calls or not indicating clearly what they want and need from the process.

Consumers we interviewed said they do not understand how *medical necessity* decisions are made or what they should do to be more effective consumers of health insurance. Other research has confirmed these same problems.[80] Consumers receive information at the time of open enrollment that is focused on overall plan performance. Generally this information does not address what will happen if they need to see a physician and if that physician decides to request a treatment that is not pre-authorized. Similarly, evidence of coverage documentation varies widely in the quality and quantity of information about

[80] See entire issue of *Medical Care Research and Review*, Vol. 56: Supplement 1, "The Power of Choice in the Health Care marketplace and Its Consequences", Guest Editors: Amy Bernstein and Anne Gauthier, 1999, Sage Publications; also Hibbard, J. and J.J. Jewett. 1996. What Type of Quality Information Do Consumers Want in a Health Care Report Card? *Medical Care Research and Review* 53 (1):28-47; Blankenau, R. 1993. Confused Consumers: When Given Options, What Health Plans Do Consumers Choose -- and Why? *Hospitals & Health Networks*, March 5, 54; McLaughlin, C. Health Care Consumers: Choices and Constraints. 1999. *Medical Care Research and Review*. 56:1, 24-59.

the coverage decision process. Some exemplary information does exist. However, respondents told us most consumers don't read this information because they don't need it at the time of receipt. Consumers suggested that information about both the authorization and appeals processes would be useful at the point in the process at which an authorization is required. Instruction consumers receive from their physicians or nurses at this time varies by both physician and consumer accounts, but in general needs improvement.

b) Once a request for treatment authorization has been submitted, communication frequency varies.

A physician decides that her patient needs a treatment. The physician may or may not know if that treatment requires authorization. Clerical personnel in the physician office are asked to fill out the form that is submitted to the medical director of the group for approval. The consumer may not even be aware that the physician has submitted a request, or how long it might take for approval. In multi-specialty groups, a referral to a specialist may require no paperwork; but in other types of medical groups, paper or electronic forms are required for lab tests, for referrals, and for any treatments that are not pre-approved. The fact that the decision will probably be made within 24 to 48 hours is not known to either the physician or the consumer.

The medical group or plan may contact the physician if the request is questionable, seeking additional information and giving the physician an opportunity to make a case for authorization. Or they may not. The medical group may contact the plan in complicated cases to confirm plan policies and reduce the likelihood of being overturned. Or they may not. The process of making the decision to approve or deny can be so opaque that neither the physician nor the consumer is aware that their request has been reviewed; it just happens. If the treatment is likely to be denied, however, a number of things may occur. Some organizations call the treating physician before a denial is issued to give them an opportunity to provide additional information or to give the physician an opportunity to phone the patient; many do not.

When the medical director denies a treatment, the consumer receives a letter from the group or plan that may say only that the requested treatment has been denied because it was not *medically necessary*. The one sentence or one paragraph denial is then followed by several boilerplate paragraphs required by the DOC about the right to appeal. The letter itself rarely explains who made the decision, the reason for the decision, on what evidence the decision was made, what guidelines were applied, or anything else about the process of making that decision. Occasionally the consumer will hear about the denial before the physician. While some organizations make some effort to communicate effectively, almost all the variations on this process were perceived by consumers as well as some medical directors to be negative ones.

c) After the decision has been communicated, there are opportunities to appeal the decision.

As we have reported, most consumers do not realize that it is their medical group making the denial, not the plan. Therefore, one of the most confusing parts of the denial process for consumers is figuring out whom to contact to discuss the decision.

In the internal appeals process, procedures vary somewhat about who will be involved. Some plans invite consumers to present their cases; others do not. The amount of information communicated to consumers and physicians about the availability of second opinions and about the internal appeals process is "grim and slim". That is, the letters and communications are generally brief and not positive.[81] Yet this is another point in the process at which patients are acutely interested in their rights and alternatives and the explanation of decisions rendered.

When a decision made originally by a delegated medical group is appealed to the health plan, some plans discuss the case with the group medical director and the treating physician. Others may overturn the decision with little or no contact. Organizations do not always allow the consumer to discuss the decision with the decision-maker.

D. There is variation in the definition of *medical necessity* and the way it is applied in practice.

Prior research and our own hypotheses suggested that the definitions of *medical necessity* in contract were not likely to be helpful in decision making. The medical directors quickly confirmed our expectations about current practice: "we should drop it altogether;" "it's a moving target"; "it's a state of mind." Prior court cases had demonstrated that the content of definitions was not as important as the fact that the definition existed at all (see section F). However, as one of the first steps in the *medical necessity* decision making process, we had hypothesized that adopting a definition that reflects and helps to determine actual practice could be useful. Our research revealed the types of cases medical directors view as most difficult or problematic to handle. Durable medical equipment is clearly a common problem and a difficult one to resolve.

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Most Common and Most Problematic Cases (15 Responses; multiple responses)[82]

Common	Problematic
Durable medical equipment (6)	Experimental / Investigational(5)

[81] See Appendix P for examples of denial letters at the initial and appeals levels. These letters offer examples of both the better and the worst of the communication of denials. (There is no "best" yet.)

[82] The Request for Information asked respondents to cite the most commonly reviewed and problematic cases they encountered. The numbers in parentheses indicate how many organizations mentioned the case.

Elective surgery (5)	Durable medical equipment (3)
Radiology/MRI (4)	Elective surgery (3)
Experimental / Investigational (3)	Hysterectomies (2)
Hysterectomies (3)	ER (2)
Dental (3)	–
ER (3)	–

The reasons given for problematic cases were consistent across the interviews. The numbers in parenthesis indicate how many organizations mentioned any single reason. The most frequently mentioned reason was consistent with our project goal of increasing consistency. Eight of 11 responses reported that a lack of standard guidelines and/or definitions of medical necessity made cases problematic for them.

What Makes a Problematic Case? (11 Responses)

Lack of standard guidelines and/or definitions of medical necessity (8)
Discerning dental from medical benefits (2)
Difficulty assessing the value of a treatment (1)

To define the relationship between *Medical Necessity* contract language and its application in practice, we reviewed a number of contractual definitions and asked medical directors in the interviews if they used the criteria in their decision making and with what frequency. The treatment criteria we selected for query included those most frequently included in standard contracts, as well as some less frequent and controversial criteria (see Appendix I - Interview Protocol). The criteria were:

- *prevailing community standard of practice;*
- *for the diagnosis and treatment of a medical condition;*
- *most appropriate level or supply of service;*
- *most cost effective treatment available for the medical needs of the recipient;*
- *effective and appropriate use of plan or group resources;*
- *not experimental or investigational;*
- *prevent significant illness, disability or pain;* and
- other.

Medical directors of private plans were generally though not universally unaware of the criteria in their own contractual definitions. When asked if they considered the criteria listed above when they made a decision, there was some consistency between what medical directors said they used and what was actually written in their contracts. Medi-Cal plan directors tended to know that the Medi-Cal statute specified criteria that included *prevention of illness, disability and severe pain.* They used those criteria but also additional criteria in their practical decision making. For example, Medi-Cal regulations expand the criteria that can be considered: Title 22, section 51003 states "authority shall be granted only for the lowest cost item or service covered by the program that meets the patient's medical needs."

When private plan medical directors made decisions they most commonly mentioned *cost effectiveness,* followed by *diagnosis and treatment, appropriateness* and *community standards* criteria. While *cost effectiveness* was frequently mentioned in the interviews, it rarely appeared in written contract, revealing that *cost effectiveness* is a concept used often in practice but not described explicitly in contractual language. The most common criteria in written contract were the following: *community standards, diagnosis and treatment*, and *appropriateness.*

We also presented the following mini-case about cost effectiveness, because we knew this was a controversial issue. If five superb randomized control trials had demonstrated that treatment A had a cure rate of 50% and treatment B had a cure rate of 50.1%, and alternative B was $10,000 more, would they consider alternative B to be medically necessary? We also asked the reasons for their decision.

Medical directors responded to the mini-case on cost effectiveness in a variety of ways. Most acknowledged that they would prefer to deny the more expensive, but equivalently effective treatment on the basis of its cost, but almost as many said they would actually approve the more expensive treatment for fear of litigation or backlash if it were to be discovered that they had considered cost. Several of those who would actually have denied the more expensive alternative said they would not use cost as an explanation, but simply would say that they had denied it because it was no more effective than the other treatment.

As for the medical group medical directors, they had little knowledge of the plans' definitions of *medical necessity* to which they were bound or of their own definitions, if they existed. Most medical groups did not have their own definition of *medical necessity.* Most said they had never seen the plan's contractual definition. In practical application, however, a frequently mentioned criterion by medical group medical directors was the same as the plans -- *cost effectiveness*. This was followed by *community standards*, *diagnosis and treatment*, and *effective use of group resources.*

We analyzed a variety of definitions supplied by our interviewees, in addition to model definitions being proposed by various advocacy organizations and statutory definitions, both existing and proposed.[83] We determined that most criteria fell into five content categories for determining *medical necessity*: *authority* for decision making; *purpose* of an intervention; *scope* of service*; standards of evidence*; and *value* (by which we meant tradeoffs between marginal cost and benefit, or what some call "cost effectiveness" analysis). It was clear that most definitions have criteria that address purpose and scope, and closely following those criteria in frequency are criteria about authority and evidence. Few definitions addressed value or cost effectiveness.

We could not discern any particular pattern of criteria or any consistency in definitions linked to plan size. Some of the largest plans in California used a contractual definition without an evidence-based criterion, and only two plans specified the type of evidence to

[83] See appendix T for criteria from contract, purchasers and statute.

be used in making *medical necessity* decisions. Two plans included *cost effectiveness* criteria: a small plan and a large well-established plan.

In the definitions we analyzed from outside California, we did not find any particular pattern of criteria either. Medicaid statutory definitions were often bolder than private contractual definitions in that some Medicaid agencies were willing to address cost effectiveness,[84] while the private insurance industry would not. There was also an increasing focus nationally on the authority component of the definition, with support by physician associations for deleting the "in the sole discretion of the plan" clause in many contractual definitions.

Our interviews revealed many concerns about these definitions from the perspectives of consumers, legal experts, and medical experts. Consumer advocates were most concerned about the following: the desire for the definition to reinforce the prevention and maintenance of health aspects of insurance and to emphasize the importance of the individual patient's characteristics; the ability of the physician to have input into the final decision; the inability to meet effectiveness criteria due to lack of evidence for populations such as children, cancer patients, and consumers with diseases for which no clinical trials have been conducted; and the potential outcome of a decision driven by cost considerations. Legal experts felt courts were the wrong place to decide *medical necessity* disputes because of the length of time it takes to resolve issues; and the fact that courts would not break new ground or devise their own definitions of *medical necessity.* They were also concerned about the legal dichotomy whereby "coverage" issues are governed by contract law but medical decisions are the responsibility of the physician with a legal duty to the patient under tort law. Physicians felt that the burden on them to show “proof" of effectiveness for their treatment requests was unrealistic given their resources to do the required research. Plan and group medical directors felt an absence of guidance or support for making evidence-based decisions from existing definitions; their current contractual language is vague and unhelpful. The Department of Corporations had not previously been supportive of the inclusion of evidence-based language or a cost-effectiveness criterion in definitions proposed by two of our plan interviewees.

E. While several aspects of the DOC request for assistance (RFA) process are generally consistent, there are also some variations.

1. The DOC’s decision in a dispute was almost always consistent with the consultant's recommendation.

Of the 22 RFA cases in the sample reviewed by staff, the DOC upheld the health plans’ decisions in 13 of them. There was only one instance in which the DOC’s final disposition was different from the consultant’s recommendation. In this case, the consultant’s recommendation contradicted an opinion the consumer had solicited from

[84] Several states have cost effectiveness criteria in their Medicaid statutory definitions, including Massachusetts (recently introduced); Florida (Fla Admin. Code. Ann. r. 10C-7..040 (1992); Minnesota (Minn.R. 9505.0210); and South Dakota (S.D. Admin R.67:16:01:06:02).

the Center for Health Dispute Resolution, the independent review agency used for Medicare appeals. In all the other cases, there was no documentation of opinions considered besides that of the physician consultant. While this pattern may vary depending on the physician consultant, the DOC staff interviewed confirmed that they almost always accept the consultants' recommendations, since they don't feel qualified to make medical judgments.

2. The types of documents included in the RFA files were generally consistent from case to case.

Every RFA file included an initial complaint form, an RFA control sheet, a record of the dates the case was opened, assigned to a consultant and closed, a letter from the physician consultant reviewing the case, either or both a demand letter to the health plan and a closing letter to the consumer, correspondence between the health plan and consumer, and relevant portions of the consumer's medical record. In all the files, the only overall summary of the case was the physician consultant's summary of events, pieced together from the documents given to him, included in his letter to the DOC.

3. There was generally little communication between the DOC and the plan or consumer, and the communication exhibited large variations in the amount of information provided about the decision and the decision making process.

The DOC wrote demand letters to the health plan and closing letters to the consumer to inform them of the DOC decision. In most files, however, only one (not both) of the letters to the plan or consumer was included. When both letters were included, they differed in level of detail provided and in degree of sophistication. A substantial portion of every letter was form letter language that gave the same information to the consumer or health plan in every RFA. However, while some demand and closing letters consisted only of the form letter language, a few contained various amounts of more detailed explanation specific to the case.

In the demand and closing letters, the DOC almost never included information on how it defined *medical necessity* or the reasoning behind the decision. Occasionally, the DOC included a quote or two directly from the consultant review, which provided some insight into the *medical necessity* criteria considered. DOC personnel interviewed indicated that as of September 1998 the DOC is making a greater effort to provide rationale for decisions, typically by including consultants' comments. One letter had extensive quotes from the consultant review, including a definition of *medical necessity* and the reasons why this definition was or was not met. There was no apparent correlation between the amount of explanation and any other characteristics of the RFA, including the DOC reviewer whose name was signed on the letter, or the complexity of the case. In one case when the DOC decided to uphold the health plan denial of care, the consumer wrote an angry letter to the DOC demanding to receive an explanation of the criteria used; no reply correspondence was found in the file.

4. Questions asked of the physician consultant did not define terms or specify evidence criteria, and varied with case details

The DOC always asked the physician consultant to answer from two to five questions pertaining to the RFA, but these questions varied from case to case and included terms like "*medically necessary"* and "*professionally recognized standards of care*" without specific definitions. The DOC, upon sending an RFA to the physician consultant for review, would include a list of questions for the consultant to answer specifically. The questions varied from case to case, depending on the nature of the dispute. For example, the DOC often asked the physician consultant to determine whether:

- the health plan's refusal to do the procedure was a denial of *medically necessary* services required under the Knox-Keene Act;
- the care was consistent with professionally recognized standards of care;
- it was *medically necessary* and consistent with professional standards of practice and only a certain out-of-plan physician was capable of performing the procedure.

It appeared that the questions asked in each case were different in order to be more specific to the circumstances of the case. However, the questions were consistently vague from case to case. For example, none of the letters to the consultant included a definition of "*medically necessary*" or "professional standards of practice" for the consultant to use. Nor were there any stipulations that scientific evidence or literature should be used to support the consultant's opinions.

5. The term *medical necessity* was applied in different ways by the DOC, the consultant, and the plans and was seldom defined.

The DOC almost always used the term *medically necessary* in the list of questions sent to the consultant, the demand letter to the health plan, the closing letter to the consumer, and other correspondence to the health plan.

In most cases, at least one of the questions to the consultant was whether the treatment requested was a "basic health care service that was *medically necessary*." In using the term "basic health care services," the DOC referred to the Knox Keene Act, subdivision (b) of section 1345 which defines a list of basic service categories—physician services including consultation and referral, hospital inpatient services and ambulatory services, diagnostic laboratory and diagnostic and therapeutic radiologic services, home health services, preventive health services, and emergency health care services.

In the demand and closing letters, the DOC's decision stated that the surgery either was or was not a *medically necessary* basic health care service that should have been provided. In cases of dispute over referral to an outside provider, the DOC's decision stated whether or not it was *medically necessary* for an out-of-plan provider to perform the procedure instead of an in-plan provider. In the demand and closing letters, the DOC sometimes said simply that there was or was not sufficient evidence to establish that *medically necessary* services were or were not provided. The DOC letter did not define "sufficient evidence".

In a DOC letter notifying the health plan of the RFA filed by the consumer, the DOC said that the health plan had to demonstrate that it provided all *medically necessary* basic health care services, as indicated by the medical condition. Again, *medically necessary* was not defined in the letter.

6. **The DOC never defined *medical necessity* internally though sometimes quoted the consultant's definitions; the consultant's definitions varied**.

In some cases, the DOC defined *medical necessity* by quoting the consultant's definition of *medical necessity*, which was case-specific. For example, several procedures were deemed by the consultant, and therefore the DOC, to be *medically necessary* (and not cosmetic) because they relieved pain. In another instance, the DOC demand and closing letters stated that the consultant had determined surgery was *medically necessary* based on the patient's condition, since the lesion, though small, was growing in size and disfiguring. In this case, the DOC stated, "the surgery is *medically necessary* based on her condition." Other of the consultant's criteria cited in the demand and closing letters included *presence of symptoms, accordance with accepted medical practice, demonstrated effectiveness of the treatment in alleviating symptoms*, and *the correction of an anatomical defect that interfered with physiological function*. Another example of the way the consultant and the DOC defined *medical necessity* was that a procedure was *medically necessary* because the consumer suffered from a severe congenital deformity causing a defect of anatomical function that was grossly abnormal. In general, the DOC lifted phrases out of the consultant report directly and did not include substantial explanation.

7. The DOC consultant's criteria for medical necessity varied.

When requested by the DOC, the consultant determined the *medical necessity* of the procedure in each RFA. However, the criteria the consultant used varied from case to case.

In some instances the consultant used the health plan definitions of *medical necessity* because the Evidence of Coverage document was supplied to him. In other instances, he used criteria but did not cite any source. In two cases he cited anonymous colleagues' opinions, and in another, he referenced a journal article.

The consultant's own criteria for *medical necessity* varied:

Criteria, ranked approximately by frequency of use	**Criteria used: F=in favor of surgery, O=in opposition to surgery, B=both**
Significant/insignificant pain and symptoms caused by the condition	B

Significant/insignificant functional impairment caused by the condition	B
Potential benefit of surgery (effectiveness of procedure in restoring function)	F
Presence/absence of "abnormality"	B
High/low cost-benefit ratio of treatment, (i.e., what is the potential benefit of a procedure vs. risk of complication from surgery, such as infection)	B
Health plan EOC	F
Other specialists' opinions (i.e., from medical records or from colleagues of the consultant)	F
Potential progression of disease	F
Psychological impact of condition (i.e., impairment of mental function)	F
Disfigurement caused by the diagnosis	F
Marginal cost-effectiveness of treatment (e.g., trade-off between cost of breast implant vs. cost of more expensive mental health care)	F
Urgency/lack of urgency of condition (e.g., cancer)	B
Clearly accepted medical practice and within professionally recognized standards (undefined)	F
"Cosmetic" (undefined)	O
Cost of treatment (e.g., whether nipple tatooing should be included in what is covered by the health plan because it is relatively inexpensive)	F
Treatment requested was/was not for complications from previous procedure or continuation of previous procedure	B
Geographic accessibility of treatment (i.e., whether a provider is close enough to make it *medically necessary* to go to an out-of-plan provider)	O
Medical literature	F
Consumer compliance with treatment	O
Practicality of treatment, given lifestyle considerations	O
Presence of contraindications to surgery	F

The presence of *pain* and *functional impairment* were the criteria most often used in more than a third of the RFAs. When the consultant felt the medical records presented convincing evidence for the presence of pain caused by the diagnosis, he considered it a compelling argument for *medical necessity*. If he felt evidence was insufficient, he considered the lack of pain an argument against *medical necessity*. In about four cases, the consultant emphasized the importance of psychological impact. He sometimes considered functional impairment of mental processes caused by medical condition as a relevant criterion for *medical necessity*, especially in cases of breast surgery. He considered the urgency of the case and the need to have a procedure performed quickly due to the nature of the diagnosis as a criterion. In one instance, he decided that this criterion supported a consumer's need to go to an out-of-plan provider when the in-plan

provider refused to perform the surgery. In another case, he decided that a rupture of a breast implant was not an emergency, and therefore it was not *medically necessary* for the consumer to go to an out-of-plan provider who could see her sooner than an in-plan provider. In this case, he also stated that patient did not appear to have made enough effort to find in-plan providers.

8. Health plans interpreted their Evidence of Coverage criteria differently from the consultant.

In the health plans' denial letters to consumers, there was almost always a statement that the procedure in question was not *medically necessary* according to the definition in their Evidence of Coverage (EOC) documents. The general definition of *medical necessity* was very similar in the EOC documents of a variety of health plans. The difference between reconstructive surgery, which was considered *medically necessary* and therefore a covered benefit, and cosmetic surgery, not a covered benefit, was stated explicitly in the EOCs. Reconstructive surgery, specifically, was considered *medically necessary* when it was necessary to improve a functional impairment. Reconstructive cosmetic surgery which did not improve functional impairment was generally not covered, except for some plans when it was incidental to a several-stage treatment plan following a trauma for which the surgery was necessary to improve functional impairment, or for a *medically necessary* mastectomy.

The consultant used the health plan definition of *medical necessity* to evaluate a few cases, when the health plan's EOC document was included in the RFA. However, although all parties generally agreed on the diagnosis, disagreement arose regarding whether there was actually functional impairment, and what treatment was best for the patient. In one case, the health plan and doctors claimed that good hygiene was the most clinically effective treatment for a skin disorder, while the patient and consultant claimed that surgery was most clinically effective. Neither provided scientific evidence to support their opinions.

9. Consumers and their physicians referred to *medical necessity* with few references to explain what they understood or meant by the terms.

Consumers often sent letters to the DOC and health plan stating that the procedure in question was *medically necessary* and therefore should be covered by the health plan. Physicians would sometimes write letters to the health plan on behalf of the consumer, requesting that a procedure be covered because it was *medically necessary*.

Medical necessity criteria to which physicians referred in writing included whether a diagnosed condition caused an *anatomical functional deficit* and whether the therapeutic procedure was *appropriate to restore this function*. Consumers did not define *medical*

necessity, but generally stated that the procedure was necessary because the diagnosis impaired their physical and/or mental functioning.

10. The most common source of evidence was the clinical or personal judgment of the consultant.

a) To determine *medical necessity*, the consultant relied almost exclusively on his own clinical and personal judgment as an expert in the field.

In one case he quoted a journal article and in two other cases he referred to colleagues' opinions, which he had solicited.

b) The definitions of terms in *medical necessity* criteria were subject to the consultant's judgment.

In some cases the consultant had to decide whether the diagnosis was impeding "normal anatomical function." In one case, he decided that normal skin function was limited by the disease, while the health plan had decided that function was not affected. In another case he stated that reconstructive breast surgery might be *medically necessary* even if the breast was capable of producing milk, because producing milk was not the only function of the breast.

To make clinical judgments, the consultant used information from the medical records in the RFAs. In one case he could not find any documentation of specific symptoms caused by the diagnosis, so he concluded that the surgery was cosmetic. In another case, based on the medical records, he made a diagnosis different from that of the patient's physician. He also used common sense, e.g., determining that a cosmetic and a reconstructive procedure should be done at the same time, but that only the reconstructive portion should be billed to insurance.

The consultant was sometimes asked by the DOC to consider whether some treatment "was consistent with professionally recognized standards of care". He would state what he considered to be a clinical standard. For example, he considered a procedure that removed more that seven pounds of breast tissue a mastectomy, rather than a breast reduction. However, neither the DOC nor the consultant referenced any evidence-based standards of care or any guidelines provided by professional organizations or medical literature.

c) Evidence from medical literature was only used in one case by the health plans, DOC or the consultant.

In this case, the health plan cited four journal articles, including one from the Journal of the American Medical Association (*JAMA)*, to support its decision to deny surgery. In response, the consultant cited an article from *Plastic Surgery* which he used to support his opinion in opposition to the health plan decision. The health plan decision was

overturned by the DOC, which questioned the validity and rigor of the evidence used by the health plan, but did not provide contradicting evidence.

F. There is variation in the way courts interpret *medical necessity*.

Review of the California and Ninth Circuit cases related to *medical necessity* decisions confirmed several of the conclusions previously found in research by Hall[85] and Sage[86]. First, "the number of coverage disputes generating written opinions has increased markedly during the past decade."[87] The Hall study found a "geometric increase" -- from 36 cases during all of the 1970s to more than 200 between 1990 and 1996.[88] Of the total cases in the present study, only ten (about one-third) were decided or arbitrated before 1990. In fact, there was only one case in the 1970s and seven in the 1980s. All Ninth Circuit *medical necessity* cases were adjudicated after 1990.

The increase in reported federal cases may be explained, at least in part, by the growing number of ERISA controlled plans. ERISA requires injured plaintiffs to bring suit in federal rather than state courts, and federal courts more frequently publish their decisions. However, this jurisdictional shift alone seems insufficient to explain the enormous increase in recent published cases.[89] Rather, it seems to support the conclusion that our health care system is, in fact, becoming more adversarial.

In our analysis, like Hall's, plaintiffs tended to fare better in state rather than federal appellate courts. In California, plaintiffs with private (i.e. non-Medi-Cal) insurance were awarded coverage in fifty percent of state appellate court cases but they were denied coverage in all Ninth Circuit appellate decisions.

This distinction between state and federal court outcomes applies only at the appellate level. In federal district courts, (the equivalent of a state trial court,) the plaintiff prevailed and obtained coverage in three of five cases, or sixty percent of the time. These federal district cases are bench trials, decided by a judge. In them, the judge assumes the role of the jury and acts as "fact finder." Since the federal district judge is not limited to a decision based on law (as is his federal appellate counterpart) sympathy for the plaintiff may play a role in these decisions. By way of contrast, in federal appeals courts under ERISA, the court is limited to an abuse of discretion standard of review whenever the plan expressly reserves discretion to the plan administrator.[90] In other words, to reverse the decision of the lower court (and find in favor of the plaintiff) the court would have to find that the trial court made a serious mistake of law. The application of this rigorous standard makes it uncommon for a plaintiff to win on appeal.

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[85] Hall op-cit
[86] Sage, op-cit
[87] William M. Sage, *Judicial opinions Involving health Insurance Coverage: Trompe L'oeil or Window on the World*, 31 IND. L. REV. 49, 68 (1998).
[88] *See* Mark A. Hall et al *Judicial Protection of Managed Care Consumers: An Empirical Study of Insurance Coverage Disputes,* 26 SETON HALL L. REV. 1055, 1059 (1996).
[89] *See* Hall et al, *supra* note 1, at 1059.
[90] 29 U.S.C. §1001 et seq. (1994).

Finally, the Hall study found that patients who sought treatment for a life-threatening condition were more likely to prevail than those who had less serious diseases. The data in our study suggested the same conclusion for state appellate and federal district cases but not for federal appellate cases. In the four appellate cases where the ERISA preemption doctrine did not apply, the court found in favor of the defendant and denied coverage even when the plaintiff was critically ill. The most likely explanation of this trend has already been discussed; namely, the court could not find for the plaintiff because it had to apply an abuse of discretion standard. However, there is another common thread among these cases, albeit a superficial similarity. Most of the plaintiffs sought therapies that were unusual, unorthodox and costly. Whether this relates to the tendency to pursue cases only when large amounts of money are at stake or whether disputes over lower cost treatments are settled at an earlier stage is not clear.

In this study decisions most often seemed to turn on facts unique to each consumer's particular situation. Because of the small sample size and methodological limitations, the California and Ninth Circuit analysis cannot be considered statistically significant. We must also acknowledge that many *medical necessity* disputes never reach a judgment on the merits because they are dismissed on procedural grounds. Another observation that we can confirm is that many judicial outcomes in *medical necessity* cases seem idiosyncratic and fact specific.[91] We could discern little judicial precedent and consequently no policy directive or useful interpretation of *medical necessity* criteria or decision making from the courts.

G. Summary

This research was able to identify a number of common steps in the "black box" of coverage decision making that consumers can expect medical groups and plans to follow. We have identified several common steps in the process of approving or denying a request for authorization by a physician or provider, as well as general processes for both internal and independent review of these decisions. We were also able to identify and help to clarify how plans use coverage guidelines and policies to inform their decisions, what types of guidelines and policies are used and how physicians are informed and educated about them.

The most problematic variations in the decision making process occur in the way coverage guidelines and policies are developed, distributed, and applied; the way different organizations attempt to manage physician behavior through pre-authorization processes; and the many ways in which information and decisions are communicated among health plans, medical groups, physicians, and consumers. Although most requests submitted for authorization are approved, the number of denials varies as do the reasons for those denials and the communication between medical groups and plans about what denials should be upheld or overturned. Finally, the definitions and criteria of *medical necessity* themselves vary, as do their usefulness in practical terms. The way in which the Department of Corporations evaluates appeals and the way in which the courts handle

[91] Karl Llewellyn, THE CASE LAW SYSTEM IN AMERICA, 79 (Paul Gewirtz ed. & Michael Ansaldi trans., 1989).

appeals cases has also been inconsistent and variable, providing little guidance to consumers or other stakeholders about how to resolve their disputes.

The information that we collected through our interviews, review of documents, and prior research, provided a basis for discussion at the Decision Maker Workshop which we describe in the next section (Section V).

V. Research data provided recommendations for improvement. A Decision Maker Workshop validated and refined the recommendations.

At the conclusion of the research phase of the project, with the co-sponsorship and collaboration of the Integrated Healthcare Association, we conducted an in-depth Decision Maker Workshop to review the research findings and determine areas of consensus and disagreement with respect to processes related to coverage decision making and proposed model language. The goal of the workshop was to seek recommendations for an improved decision making process, consensus from the clinical and legal decision-makers on a model contractual definition of *medical necessity,* and commitments from physician groups and plans to implement recommended changes.

A. The medical necessity workshop was organized under the auspices of the Integrated Healthcare Association.

The workshop was designed as an intense, 2.5 day working retreat. It included consumers, treating physicians, health plan legal directors, purchasers, a regulator, and plan and medical group medical directors directly involved in various aspects of *medical necessity* decision making. Observers were a representative from the California legislature; representatives of the California HealthCare Foundation and the Sierra Health Foundation; Stanford staff; and selected consultants. David Eddy, MD, PhD, assisted by Linda Bergthold, PhD and Sara Singer, MBA, facilitated the sessions.

Participation in the interview process was a prerequisite for participation in the workshop. Participants were selected for their knowledge of the process, their breadth of perspective, and their experience with coverage decision making.

The agenda for the workshop was structured so that the first day included introductions, definition and clarification of terms (see discussion in Section IV), and presentation of the recommendations for a model decision making process developed from the research findings. While as a first step in the process it might have been appropriate to start the workshop with a discussion of the definition of *medical necessity,* we determined that it was important to begin with process for several reasons:

- how decisions are made and by whom they are made is as or more important than how *medical necessity* is defined in contract;
- we thought process recommendations would be less contentious than the definitional issues, and we hoped to build some relationships in the first day;
- discussing language is an endless task and will expand to fit the time allotted; therefore, by placing language second, we provided a self-imposed "deadline" of noon on Saturday to reach consensus.

The second day of the workshop was structured around the model language based on the research findings and presented by staff for discussion. The last morning was devoted to the prioritization of recommendations, discussion of follow-up initiatives and next steps, and a dissemination plan.

B. Our research suggested recommendations for a model decision making process.

Based on our interviews and secondary research, staff compiled over 60 different recommendations for ways the process of decision making could be improved, related to the three key variations in the process (development of guidelines, the process of authorization, and the communication among all parties) and a miscellaneous category. We organized these findings into a series of recommendations for consideration by the workshop participants. [92]

After the research findings for each category of variation were introduced, there was a discussion about the recommendations proposed to solve the "problems" that were causing these variations. Each set of recommendations was displayed on butcher paper on the walls surrounding the participants.

Workshop participants were then asked to rate each set of process recommendations on the basis of potential impact and feasibility, using either a green, yellow or red dot to indicate high, medium, or low respectively. Participants had a short amount of time and a large number of recommendations to consider. We were seeking their initial reactions to these recommendations and some high level priorities, not a thorough analysis. In addition, with 30 total participants, the small number of each type of stakeholder was not representative. Therefore, while general trends and patterns can be observed in the priorities they identified, the results should not be over-interpreted. The priorities represent only those of the participants in the room.[93]

Some overall trends can be deduced from the dot exercise. First, participants rated impact much more highly than feasibility for every one of the recommendations. This trend suggests that while people believe that many process suggestions are potentially helpful, they perceived them as being difficult to implement.

Other trends can be identified by looking at patterns of response among stakeholder groups. In general, consumers and the regulatory representative were much more likely to score recommendations as both high impact and high feasibility. In contrast, health plan and physician group representatives, purchasers and treating physicians were more likely to score the recommendations lower, particularly on feasibility. This difference may be explained by the relatively low degree of risk and responsibility for action that consumers and regulators share versus that of plans, physician groups, purchasers, and treating physicians.

[92] See Appendix L for Summary Recommendations Based on Interviews with All Stakeholders.
[93] See Appendix U for dot exercise results

Several process suggestions were thought to have the potential for positive impact among all stakeholder groups. These included recommendations about authorization, communication, education, and guidelines.[94] None of the recommendations was rated as highly feasible by everyone. In some cases, however, recommendations were unanimously considered to have at least high or medium feasibility.[95]

Most of the recommendations were thought to have at least some potential for positive impact. Of the sixty ranked, only 5 recommendations were considered to have low impact potential, and two of these referred to an expanded role for the legislature in determining what plans should do regarding definitions in contract.

Because responses were collected in aggregate by categories of stakeholder type and not coded by individual, it is impossible to identify trends of disagreement within stakeholder groups. Perhaps the most interesting thing to note is that the participants responded, basing their priorities on individual experience and perceptions, not necessarily their "membership" in any stakeholder group.

Based on the dot exercise prioritization, along with the overall research findings, staff put together a more comprehensive document after the workshop representing a **model process** for improvements in decision making.[96] This model process incorporates several dozen recommended priorities that the workshop participants considered having high impact and medium to high feasibility.

After presentation and discussion of the model process, Workshop participants were asked to choose two process improvements that would be most helpful in creating a better decision making process. Staff tabulated these recommendations and cross-referenced them against existing requirements of the Knox Keene Act (KKA) and NCQA accreditation standards to determine the overlap between what participants though was most important to do and what was already being required. Participants selected 21 process changes as their highest priority. Of the 21 selected, 5 (24%) were already required either by statute or for accreditation.

The five overlapping priorities included:

- Consumers are informed of requests, decisions, and reasons in a timely manner. (Communication)
- Provide consumers with timely and full information about ability to appeal, internal and external assistance and second opinions. (Communication)
- Notify consumers of decision makers and their qualifications. (Communication)
- Denial letters should include the reason for the decision, the *medical necessity* definition and guideline applied, the guideline criteria not met, sources of evidence, and alternatives. (Communication/ Guidelines)

[94] See Appendix U for examples.
[95] See Appendix U for examples.
[96] See Appendix A for Model Process.

- Involve practicing physicians with the appropriate skill and credentials who are contracted with the Plan in the development of coverage policies/medical policies as well as clinical practice guidelines. (Guidelines)

This overlap between stakeholders' priorities and existing requirements may reflect the problems of implementation.

Of the twenty-one highest priorities at the Workshop, the following process steps were voted to have the highest impact and highest feasibility for implementation:

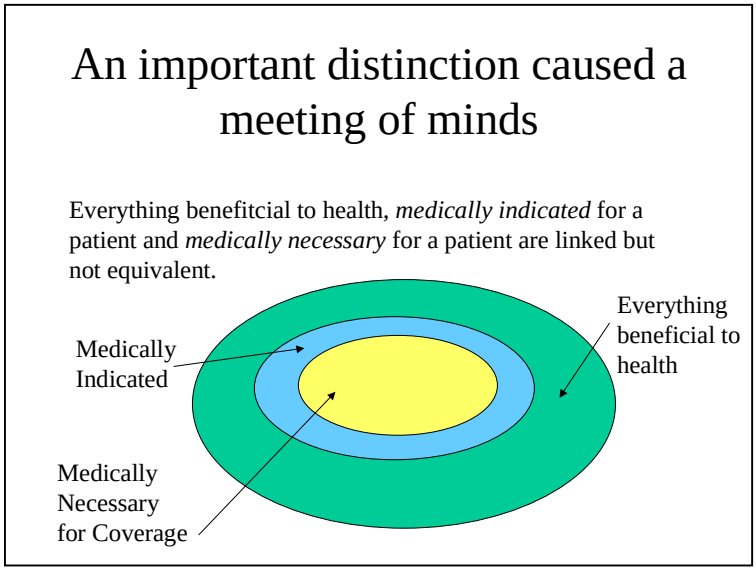
- Create risk sharing arrangements between plans and medical groups that reduce conflict;
- Distribute guidelines on-line to all;
- Pre-approve low cost/low controversy treatments based on data;
- Refer any unresolved questions about authorization to clinical personnel immediately;
- Require plans and groups to track numbers and types of denials and their reasons, for use in quality improvement and for comparison among organizations; and,
- Communicate more information more effectively.

C. The workshop participants achieved a degree of consensus on a model contractual definition of *Medical Necessity*.

Using a similar approach to the presentation of findings about process, research staff presented findings to the workshop participants about the analysis of how *medical necessity* is defined and used. We described our methodology and approach to the analysis of contractual definitions; how the interviewees perceived the various criteria and their usefulness in practice; and how we constructed the model language that we presented to them on the night of the first day.

Before we could have a full discussion of the language, we found we needed to clarify the considerable confusion that still existed over what distinguishes a coverage decision from a *medical necessity* decision. An additional insight into the medical necessity decision making process helped move the discussion forward. The treating physicians at the workshop, like those we interviewed, were troubled that what had been the province of the physician in the past, deciding what is *medically necessary* for a specific patient, had now become linked to coverage and payment, and the authority to decide necessity must be shared with plan decision makers. While the physicians agreed that there are some interventions that may be *medically necessary* in the physician's view but definitely not covered (e.g. infertility treatments) in the benefit package; there are too many other interventions that the physician would view as necessary and might seem to be covered, but would not be reimbursed by the plan/group because they were not deemed to be necessary by the plan/group's medical director. It is the sharing of power over this decision between physician and plan or group that has caused major friction.

Therefore, for purposes of the workshop discussion, we agreed to characterize the universe of decisions in the following way:



The outer circle represents all interventions that could possibly affect health (but are clearly not covered and will not be reimbursed): vitamins, exercise, yoga classes, fresh vegetables and fruit, etc. The middle circle represents all interventions that a physician might consider to be necessary or indicated for an individual but that may not be covered as part of the contractual agreement with the purchaser (e.g. dental care, alternative therapies or interventions, lifestyle enhancing treatments, etc.) or are not considered to be necessary by the plan/group medical director, because of lack of evidence of effectiveness. This middle circle would be called *medically indicated* to demonstrate that the physician finds the intervention important enough to prescribe it even though the plan/group may not cover it or find sufficient evidence of its effectiveness. The inner circle, which group members suggested was not much different in size from the middle circle, would be interventions that the physician recommended and that the plan/group could agree were *medically necessary for coverage*; that is, these interventions, prescribed or requested by a health professional, were also covered under the policies and guidelines of the plan/group.

While these distinctions clarified the way interventions may be recognized in actual practice, the fact that the treating physician was not the final decision maker in all requests continues to trouble physicians and their associations. The workshop participants, however, felt that they could not solve these larger problems and that these distinctions could move the discussion ahead in a constructive way. Unfortunately, the consensus within the workshop does not translate into general consensus. The terms "coverage" and "medical necessity" continue to be used in confusing ways and to be the source of a considerable amount of conflict at the plan/group level and at the legislative level.

Dr. Eddy led participants through a discussion of each of the component categories of a model definition: **authority, purpose, scope, evidence and value**. The entire second day was spent discussing such issues as what "treat" means; what a "medical condition" covers; how to distinguish requests that are *medically indicated* from those that are *medically necessary for coverage;* what evidence standards should be included and in what order; who should have final authority for making the decision and with what input; and finally, what cost effectiveness means, in theory and in practice. There was vigorous debate and too little time to reach consensus on every issue. Staff compiled complete and detailed notes of the language discussions, which they characterized as a "federalist papers" approach to describing the content of the discussions. This paper was circulated to workshop participants for their review after the workshop and is included in this report. [97]

On Saturday morning, we came back to some of the more problematic language issues, and finally concluded that while there was consensus on the main criteria, the more finely tuned definitions of terms in footnotes needed further work. Dr. Eddy and staff were asked to provide workshop participants some suggested definitions for the footnotes and engage the participants in a fax-back discussion over the following two weeks. Statutory applications of the language were also deferred until consensus could be achieved on the details of the contractual language, most likely in a telephone conference call for interested participants in the following weeks.

The last few hours of the Saturday session were devoted to a prioritization of recommendations for follow-up action. Participants indicated their interest in various projects, and we identified specific people with responsibility for next steps.[98]

D. Outcomes of the workshop were described in a press release two weeks after the workshop concluded, along with the distribution of the consensus model language, process documents, and recommendations on statutory applications.

The process by which staff worked with participants to finish the work involved the following steps:

Dr. Eddy and staff proposed clarifications of the footnote definitions for the model language and faxed these clarifications out to all workshop participants. An iterative process developed over a two-week period that included several faxes and a number of lengthy telephone calls. Different participants had different concerns about the language as it was being defined, and because the whole group could not meet to discuss each suggested change, several faxes were sent to the entire group that proposed changes that required feedback. The only changes to the main criteria were relatively minor editorial

[97] See Appendix V for Federalist Paper summary of pre and post workshop discussion on language.
[98] See Appendix W for Follow-Up Initiatives.

changes. The substantive discussion all took place 'below the line' regarding the footnotes and how terms would be defined. The most difficult issues had to do with **cost effectiveness** and how the individual patient's characteristics would be included in the analysis; **evidence**, and what standards would be used to judge the effectiveness of new interventions for which there was little or no scientific evidence; how **quality of life** would be evaluated; and of course, how the language would be represented to the public and distributed for discussion. While minor editorial changes were incorporated without much discussion, staff did not incorporate any substantive changes into the language without giving participants the opportunity for feedback.

On the evening of March 30th, the last disagreement over language was resolved with some refinements to the cost effectiveness definition, specifying that the **individual patient's characteristics had to be determinative** in a decision that applied cost effectiveness analysis.[99] In the tradition of good consensus building, no one was completely satisfied with the final product. Most agreed that the cost effectiveness description and definition was the weakest part of the model language and that considerable work needed to be done to improve it. Some participants felt that the inclusion of a value component was a significant contribution in and of itself, even if it did require more elaboration.

On March 31st, a statement was released to the press describing the consensus and work of the Decision Maker Workshop.[100] We made the model process and model language available upon request, so that we could use the request as the opportunity to talk to the media in more depth about what the recommendations meant, how the recommendations were developed, their shortcomings, and their potential implications. As a result of the Press Release, approximately a dozen interviews were conducted with local and national press about the workshop and the project.

The model process and model definition were presented to a briefing of stakeholders on April 6, 1999, at Stanford University, and to numerous other stakeholders in California and nationally in a variety of presentations and discussions.

On April 28th, 1999, a subgroup of workshop participants who had indicated an interest in the statutory applications of the contractual language, met by telephone to discuss how or if the group should take a position on the use of the language in legislation. The nine conference call participants agreed that *medical necessity* should not be defined in statute if at all possible; however, if a definition were to be used, the participants recommended the use of the workshop language as being superior to any other proposed language. The results of this discussion were sent by email to all workshop participants, but there was no disagreement about this conclusion.

A dissemination plan was developed after the workshop in order to ensure the distribution of workshop and research findings to a broad group of stakeholders.[101] Project staff have made presentations to a number of different associations, beginning

[99] See Model Definition, Appendix B.
[100] See Appendix X for Press Release.
[101] See Appendix Y for Dissemination Plan.

with the April 6, 1999, Stakeholder briefing; National Independent Practice Association Coalition (NIPAC)(May12, 1999); the National Health Policy Forum in Washington D.C. (May 11, 1999); Integrated Healthcare Association (April 29 and July 29, 1999); a coalition of consumer advocates in Washington D.C. (May 11, 1999); the Pacific Business Group on Health's Medical Advisory Council (June 17, 1999); and the Medical Technology Advisory Forum (May 24, 1999). Other presentations will be scheduled as necessary, including a session with legislative staff in Sacramento if requested.

VI. Discussion of Findings and Implications for Change

A. In Section III we described our three main policy goals for this project:

1) to describe how medical groups and plans define and use *medical necessity*; 2) to understand what works and what does not and to make concrete recommendations for change that will benefit consumers and all stakeholders in California; and 3) through those recommendations to reduce variation and inconsistency in the decision making process in California.

The following discussion will address the way in which this research achieved those goals, to what degree our research hypotheses were answered through the research, and what further research and action may be needed to answer these questions more thoroughly.

Our project hypotheses were answered in the following ways:

We expected to confirm prior findings that the term medical necessity would no longer be considered a useful tool by California decision makers and that guidelines, utilization review procedures, and organization structure would have a greater impact on medical necessity decisions than contractual terminology.

Our research findings were very consistent with prior research and our own hypotheses about the usefulness of contractual definitions of *medical necessity* in daily coverage decision making. Interviewees were nearly unanimous in agreeing that the current definitions and lack of specificity of the meaning of *medical necessity* no longer aided decision makers in determining what to cover or not cover. Coverage policies and guidelines were much more important as influences over coverage decisions, although there is still confusion over how these terms are defined and used. These findings did not vary by organization type, size, or geography.

The detailed analysis of the Department of Corporation process of external review reveals that, while *medical necessity* is invoked frequently by all parties to the dispute, the lack of definition and specificity renders it nearly meaningless. Although one might expect the meaning to be applied differently by different parties, the DOC analysis reveals that the

terms and criteria are also inconsistently applied by the same consultant to the DOC, suggesting that the variability in expert judgment is a problem not confined to plans or medical groups but also to external review processes.

The discussion about language, in the interviews as well as the workshop, touched the values that underpin medical decision making in a very deep way, provoking controversy and intense debate. They also exposed the growing conflict between physicians and managed care plans over who will have final authority over individual decisions, whether they are called "coverage" or "medical necessity" decisions.

What emerged from the Decision Maker Workshop was model language for a contractual definition of *medical necessity* that, while still being debated, is regarded by most as better than any of the contractual definitions currently in use. It is considered to be better because it takes on the underlying issues of decision making: who should make the decision, with what input, on what basis, and for what purpose. Although the workshop language has never been tested, it is interesting to note that some participants feel the language is too lax (i.e. would allow more interventions to be covered), while others feel it is too restrictive (i.e. would result in more denials of care for lack of evidence of effectiveness). Its length attests to the difficulty of defining terms precisely enough to be applied consistently. The danger in this, however, is that what is gained in specificity may be lost by jeopardizing its ease of use.

At least two stakeholder groups have declared some support for the inclusion of this definition by purchasers in all contracts.[102] The ability to test the language on real cases is partially constrained by the reluctance of the Department of Corporations to allow the use of this definition in contract in California until it has been tested on a retrospective sample. Until there is a statutory mandate, research, or political pressure by the purchasers to show the impact of this new language, it will remain a "model" for discussion but perhaps have no real impact. The only practical application of the language may be a growing understanding among consumers and providers alike, that interventions that cannot be proven to work should not be offered to consumers, and certainly should not be paid for by purchasers, unless the situation is life-threatening and good evidence is simply not available. In the latter situations, medical directors will continue to rely on trial and error, and expert opinion, and will react to the many marketing pressures to approve treatments "just in case they work."

Future research and action should focus on understanding the way in which practice guidelines and coverage guidelines mediate between the contractual definition and the daily practice of decision makers; building consensus on the evidence and values that shape coverage guidelines to promote more consistent decision-making; determining what impact the model language would have had on approvals or denials; and comparing our findings to practices in other regions and nationally.

[102] The National IPA Coalition (NIPAC), northern and southern California groups, voted in May to endorse the use of the workshop model definition in contract and, if necessary, in statute. The Health Services Advisory Committee of the Pacific Business Group on Health is in the process of considering the endorsement of part or all of the model language for use by the negotiating alliance of PBGH.

There would be differences in the use and availability of resources related to the size of the organization and the beneficiaries served by those organizations.

The research supports this finding quite clearly. The size of an organization is related to the expertise and resources of the organization to do something as complex as develop evidence-based guidelines or complex coverage policies. Although our sample of medical groups does not allow us to generalize findings to the universe of medical group decision making, the larger plans do develop and craft their own guidelines and policies, in contrast to the smaller plans and those serving Medi-Cal. Those plans tend to buy their guidelines "off the shelf", use local or expert opinion, or in the case of Medi-Cal rely on the State to issue policy directives.

The larger private plans have access to national sources of evidence through their national corporate headquarters; smaller plans and plans that serve mainly a Medi-Cal population simply do not have the same resources. One exception was one of the larger Local Initiative Medi-Cal plans that did use proprietary evidence sources and outside guidelines for their more complex decisions, much the same as their private counterparts.

A proliferation of guidelines is not necessarily desirable unless it results in greater acceptance and use by practicing physicians. Multiple guidelines may be undesirable if they result in contradictory directives and therefore reduced use as was suggested by many interviewees.

Future research and action should further identify the uses and impact of coverage guidelines and policies in relation to organization type and structure.

There would be differences in denial rates by geographic region and organization type.

We found no evidence that denial rates vary by region in California. The only suggestion of a difference in organization type came from the comparison of plan denial rates and overturns vs. those of delegated medical groups. The data showed that some medical groups' denial rates were clearly higher than most plans would tolerate, as indicated partially by the high overturn rates of some group decisions. Respondents from medical groups also would have denied treatment in our hypothetical cases more often than respondents from health plans. However, our medical group sample was too small to determine whether medical groups are generally more restrictive in their decision making than plans.

We consistently heard misperceptions about who makes the denial decisions in managed care organizations. Almost none of the consumers we interviewed were aware that physicians must make those decisions, per NCQA standards and KKA requirements.[103] We also found reported denial rates to be consistent with other research and relatively low compared to the public's perception of them. Nevertheless, because of the difficulty

[103] NCQA, *Surveyor Guidelines for the Accreditation of Managed Care Organizations*, July 1, 1998-June 30, 1999.

in quantifying the rates precisely, we cannot make substantive generalizations about denial rates in managed care in California.

Future research and action should develop a methodology to define and quantify denials more precisely and consistently across plans and groups. One of the initiatives emerging from the Workshop is a proposal for such a study that would involve the Center for Health Policy, the RAND Corporation, the Integrated Healthcare Association, United Healthcare, Blue Cross, and PacifiCare among others.

There would be differences in process and definitions between organizations serving a commercial population and those serving primarily Medi-Cal beneficiaries.

The "public" plans, or those that serve primarily Medi-Cal beneficiaries (and we interviewed plans representing over 88% of the managed care enrollees in Medi-Cal) varied considerably among each other in the policies and procedures they implemented, some following Medi-Cal regulations quite strictly and others utilizing a broader range of policies and interventions that looked more similar to private sector organizations. On the other hand, the private plans that served Medi-Cal appeared to have the same decision making processes for their private client base as for their Medi-Cal client base and told us that specifically.

Medical directors of Medi-Cal managed care programs tended to think beyond the statutory definitions of *medical necessity* in their daily decision making, primarily because the statutory definition and regulations are so vague. They appeared to rely more on their own training and experience than any specific initiative or guideline from the state Medi-Cal office. Even though all of our Medi-Cal interviewees were risk-bearing organizations, cost was not a primary criterion for coverage decisions among those interviewed. It was definitely a consideration, but not the most frequently mentioned criterion in coverage decision making by any means.

There were no obvious differences between the policies or procedures of counties with County Organized Health Systems[104] and those of the Local Initiatives; in fact, all Medi-Cal plans must adhere to State defined policies, so the similarities and consistencies should be expected. However, there were differences between the plans related to their size. In the smaller counties, the medical directors definitely knew their providers and even their beneficiaries in a way that the larger counties could not match; conversely, in the larger counties, the decision making process involved more personnel with more layers of accountability. The medical directors in all of the Medi-Cal plans we interviewed gave numerous examples of innovative ways they would solve complex beneficiary problems. Whether their dedication was related to less pressure over cost containment, a different public "mission", the personality of the medical directors themselves, is impossible to sort out.

[104] Medical directors in the three counties with County Organized Health Systems (COHS) have a unique "franchise" on their population, in that their programs do not need to compete for enrollees; all Medi-Cal beneficiaries must enroll in a single program.

Future research and action should investigate more thoroughly the differences between plans serving public beneficiaries and those with private enrollees. Although we were told that private plans apply the same policies to both their commercial and public beneficiaries, we were not able to quantify those differences sufficiently in this research. It is also important that researchers understand and quantify the differences, if any, between the Medi-Cal plans and the private plans. Are the COHS and Local Initiatives better than their private competitors in any significant ways? Do they provide poorer service? There is evidence that their administrative costs are lower, but does that translate into higher beneficiary satisfaction levels, higher provider payments, better health outcomes, or any other quantifiable measures?

There would be variations in process and definitions among organizations, not attributable to specific organizational characteristics.

We expected to find variation in definitions of medical necessity and the ways in which various organizations applied it, and we did. Our findings identified hundreds of variations in the way decisions are made and terms are defined. We found no particular pattern of definitional differences related to the size of the organization, although most definitions of *medical necessity* relied on similar criteria.

Future research and action should investigate the variability in decision making in other regions and types of managed care to determine if the California findings are unique to this State or are typical of other areas.

There would be considerable variation in decisions about our hypothetical cases. The case and guideline findings in Section IV highlight the type of variations that our interviewees consistently identified. Although many of the process variations might be considered best practices, when decisions clearly would vary about the same case, the overall variation could be considered unacceptable. Also, the disconnect between the decisions over the hypothetical cases and the coverage policies governing these cases suggests an ignorance or disregard of these policies that should be disturbing to consumers, purchasers, regulators, accreditors and administrators, if not to the decision makers themselves. Perhaps the system has become so complicated and the contracts so numerous that no one person can be expected to be consistent or remember what policies say about specific conditions. However, the randomness of the decision making and the lack of knowledge of guidelines and policies is a finding that should not be ignored.

In the analysis of the case decisions, one finding stands out as hopeful. There was the most consensus about the case where the evidence of effectiveness was clearest (i.e. the patient population for which growth hormone is effective). This agreement may suggest that if the evidence is reasonably consistent about whether or not a treatment works, we can expect that medical directors will know about that evidence and apply it in a reasonably consistent way to individual decisions. Still, the variation in the growth hormone case suggests either that not all medical directors follow the literature closely or that marketing pressures may be forcing more approvals than would be warranted from the evidence itself.

The relationship between the plans and their medical groups demonstrates variability based on factors too numerous to analyze. However, the anecdotal evidence from our research, as well as the responses of the medical directors to the hypothetical cases, suggests that most plan medical directors are more lenient than the medical groups to which they have delegated risk, as indicated by the range of overturns (i.e. between 30% and 80% of decisions overturned). Once an appeal reaches the level of the plan, there are marketing and legal reasons to approve the request and overturn the medical group, particularly if the financial consequences are diluted by the delegated risk.

The differences in authorization logic and process did not seem to be attributable to organization size, geography or tax status of the plan. A more likely explanation of differences relates to the philosophy of the organization about how they work with their physicians (that is, do they believe that if left alone, physicians will do the right thing or do they believe that more control is required), and the type of organizational network, particularly the multi-specialty groups vs. the primary care only groups. The more closely affiliated the providers are to each other, the easier it should be to institute fast track referral processes within the group. Also, the more information gathered at the organizational level, the greater the ability of the organization to make pre-approval determinations.

Future research and action should attempt to identify differences between tightly managed medical groups and more loosely affiliated groups in terms of their level of risk, relationship to the plans, and other factors. The Integrated Healthcare Association is currently doing a study of the future of the delegated model in California, the findings from which will be available later in the summer.[105] Another initiative that has been strongly recommended by stakeholders is to develop a clearinghouse in California for existing coverage guidelines and policies; to make these guidelines more consistent; and to make them more comparable and fully available to providers and consumers through online distribution.

There would be enough dissatisfaction with the current variability to support the need for consensus around model language and process.

The outcome of the workshop and the follow-up dissemination discussions has demonstrated that there is considerable support for more consistency and that consensus is strong for better processes and more consistent definitions. Whether or not that consensus will hold without any "outside" pressure or threat, such as legislation or regulation changes, is not clear. However, as noted above, at least two of the stakeholder groups participating in this project have gone on record in support of a consistent definition of *medical necessity* for contractual purposes, and there have been many informal discussions about how to best implement process improvement recommendations.

[105] See the IHA website, www.iha.org for more information on this study when it is released.

Future research and action should concentrate on more ways for the stakeholders to meet together and discuss issues in a non-threatening environment. The degree of consensus that was achieved at the Workshop was related to a number of factors: the fact that the participants were not "spokespeople" for their stakeholder groups but for the most part actual decision makers; that the meetings were private and off-the-record; that the discussion was focussed on research findings and not just opinions; that there was time pressure and a sense that outsiders were watching the results; and the sessions were facilitated by a knowledgeable and credible expert. We have set up a way for Workshop participants to continue to communicate with each other via email, and we hope that other localities, organizations, and states will imitate this effort to achieve consensus by organizing their own workshops and discussion groups.

Although no formal hypothesis about communication issues was formulated, the research demonstrated that there is a great need for improvement in the communication of information among stakeholders.

All stakeholders universally expressed the problems of communication and information sharing, but the area of communication with the most conflict turned out to be between the medical directors of plans, medical groups, and treating physicians. It was the exceptional plan that made a policy of contacting the medical group medical director personally before every denial, and while some medical group medical directors claimed to call the plan medical director to double-check plan policies in advance of their own decisions to deny, most did not. Both sides claimed poor communication, and both sides are probably right. Certainly, neither side can claim consistently to meet best practices in this area. Relationships between plans and medical groups, as characterized by the number and types of contacts between the two types of organizations, seemed to be somewhat better for the smaller non-IPA medical groups, but that would be a "size" finding one would expect. The Medi-Cal managed care programs show no pattern of either collaboration or conflict, with the key to collaboration being the leadership style of the medical director.

In attempting to understand why the communication with consumers varied and was so inadequate, we were unable to isolate organization size, geography, or tax status as explanations. Even in most of the Medi-Cal plans, where the sense of public service and mission is supposedly strong, the communications and the letters sent to consumers were no better or worse than the plans serving privately insured beneficiaries. We must conclude that competition on the basis of service to consumers is not yet the driving force in managed care that the rhetoric would suggest, and that the issue of legal liability (i.e. if you give too much information to a patient you could be sued) as well as time constraints and a lack of evidence that good communication results in more enrollment and more satisfied consumers are the major reasons for the lack of good communication in managed care in California.

Communication between consumers, providers and the Department of Corporations was universally regarded as very poor. The DOC's review process is not clearly understood or communicated to either plans or consumers, and all stakeholders complained in detail

about the poor quality and quantity of DOC communication about its decisions and processes.

Future research and action suggests that improvement in communication will be useful. At least one initiative suggested from the Workshop supports ongoing education of consumers about the meaning of "cost effectiveness" and how it is applied and used in decision making. Given the support of Workshop participants for the many recommendations about communication, one hopes to see some of these recommendations initiated in California managed care plans in the near future. Nevertheless, it is perplexing that even though plans must demonstrate good communication practices for NCQA accreditation, there remains such a gap between policy and practice. Perhaps the problem is analogous to the maxim that a good marriage requires good communication, yet we all fail to some degree in that regard.

B. Researchers can provide information but advocates must make the changes.

1. Each Stakeholder group can play a role in distributing these findings to their constituencies.

This project has generated a great deal of information that could be useful to stakeholders and advocates, as well as to the managed care decision makers. Given the level of distrust by the public of managed care organizations, the need to educate the public about how decisions are made is greater than ever. There are a number of next steps that project staff and workshop participants have identified as high priority.

Each stakeholder group in the medical necessity decision making process has a set of unique concerns and responsibilities. Our research has attempted to define these various perspectives, the respective issues of importance, and opportunities for coalescing divergent interests into a better, clearer, more rational decision making process. However our role is to educate and stimulate fact-based debate with the goal of shaping public policy founded on evidence and effectiveness. It is the stakeholders to the decision making process: consumers, purchasers, providers, legal experts, medical groups, health plans, and regulators who are empowered to work together to implement change.

2. Given these collective priorities, the appropriate tasks for each stakeholder group might include, but are not limited to, the following:

Consumers and Consumer Advocacy Groups:

- Demanding that information be communicated completely, clearly and in a timely fashion;
- Becoming familiar with coverage decision making processes and policies;
- Advocating for more and better disclosure of the coverage process, including sharing of coverage guidelines and policies, describing reasons and bases for denial more

completely, including outlining sources of evidence and decision making; and making both the internal and external appeals processes clearer and more accessible;
- Acknowledging and accepting that some denials may be appropriate and beneficial to quality of care.

Purchasers and Purchasing Alliances:
- Ensuring that plans have clear and timely information available for consumers about the coverage decision making process;
- Educating their own personnel about the coverage process so they can better facilitate the process for employees.
- Reviewing EOCs to ensure that they are written as clearly as possible;
- Requiring plans and medical groups to disclose their definitions of *medical necessity* as well as criteria underlying those definitions;
- Advocating for the same definition of *medical necessity* to be applied in all contracts;
- Reviewing the model definition of *medical necessity* developed in the workshop to determine whether purchasers should support broader dissemination and use of the workshop language.

Providers:
- Participating more actively in discussions about how to improve the decision making process within their own organizations;
- Educating themselves about group and plan guidelines, policies, and procedures;
- Asking groups and plans to provide direct communication to the provider regarding potential denials and to give full reasons for any denial decision;
- Sharing in the process of providing evidence of effectiveness for treatments that involve new or emerging technologies;
- Explaining the coverage decision making process to patients when a request for authorization is required.
- Engaging patients in shared decision-making about treatment options.

Medical Directors of Groups and Plans:
- Providing full information in a clear and consistent manner to participating providers about coverage decision making policies and procedures;
- Ensuring that definitions of *medical necessity* are prominently displayed in all relevant documents and that criteria are defined as precisely as possible;
- Sharing coverage policies and guidelines with providers and consumers;
- Providing concrete incentives for treating physicians to participate fully in the development and use of guidelines and policies;
- Tracking and communicating information about approvals and denials to providers and consumers;
- Providing information about bases of evidence for decisions, including the types of experts involved in the decision, the policies or guidelines upon which decisions are based, the relevant scientific evidence or professional standards applied, if available;
- Providing opportunities for providers and consumers to participate fully in the internal appeals processes;

- Explaining the external appeals options fully and clearly;
- Otherwise implementing elements of the model process.

Legal Directors of Groups and Plans:

- Reviewing EOCs and other plan documents to ensure that they are written as clearly as possible;
- Ensuring that definitions of *medical necessity* are prominently displayed in EOCs and contracts and that criteria for applying the definition are also defined;
- Reviewing the internal and external appeals processes to be certain that consumers are offered the maximum opportunity to participate and that policies are clear about the rights of all parties;
- Reviewing the model definition of *medical necessity* developed out of the workshop to determine whether or not that definition should be promoted within the organization and with the Department of Corporations.

Regulators:

- Making the process of requests for assistance to the Department of Corporations easier to understand;
- Ensuring that all DOC staff follow a consistent process for responding to RFAs;
- Providing full information about the DOC review process to all consumers when an RFA is initiated, including the length of time for review, the type of provider who will do the review, and the bases for decisions about appeals;
- Allowing for discussion with plans and groups about problematic decisions;
- Involving medical directors of plans and groups in annual reviews of DOC policies and procedures;
- Promoting a more consistent and detailed definition of *medical necessity* by reviewing existing definitions and working with purchasers and groups/plans to improve existing definitions.
- Requiring scientific evidence to be used whenever available, and requiring consultants to list the sources of the evidence they use;
- Providing consultants with consistent and specific definitions of *medical necessity* to use in assessing the RFAs.

Some stakeholders have pledged to adopt certain aspects of the model process including some of the above recommendations. It is our hope that more stakeholders will step forward and assume responsibility for implementing these process changes. However, as we step back and think of the big picture context for this research and final report, it is the staff recommendation that each stakeholder become a better communicator about whatever he/she does. Open communication seems the most logical first step in allaying the current level of mistrust among and between stakeholders, and the need for more effective communication has been the strongest recommendation emerging from this research.