DEFINING MEDICAL NECESSITY: AN EXPLORATORY STUDY

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EXECUTIVE SUMMARY

INTRODUCTION

In response to rising health care costs, states have been seeking ways to reduce their Medicaid budgets. One approach is to restrict services that are not medically necessary. This approach requires an understanding of what constitutes medical necessity and a mechanism to implement that understanding. Despite an increasing body of commentary on medical necessity, there is little agreement in the literature on what the guiding principle or overriding conceptual approach should be, and there is no universally accepted or applied definition.

Purpose of the Present Study

The purpose of this study is to provide information to the Washington State Medical Assistance Administration (MAA) and the Washington State Health Services Commission (HSC) about the definition and use of medical necessity from several different perspectives. The goals of the project are to:

- Review the MAA’s current definition of medical necessity and how that definition is implemented in program operations
- Review other Washington State public and private payers to determine how they define and implement medical necessity
- Review other state Medicaid agencies to determine their medical necessity criteria for authorizing services
- Assess whether and how MAA’s current definition of medical necessity could be revised
- Provide information to assist the state policymakers

Study Methods

To achieve the above research goals, we conducted a series of semi-structured interviews in Washington State with MAA personnel and other governmental officials. We also met with representatives of advocacy organizations, commercial insurers, and managed care plans. We
conducted similar interviews in Oregon. We also collected data and conducted telephone interviews with Medicaid officials in Utah, Minnesota, and New Jersey.

THE MAA'S DEFINITION AND IMPLEMENTATION OF MEDICAL NECESSITY

The current definition of medical necessity used by the MAA is relatively open-ended, and appears to be less restrictive than most other definitions we examined. Advocates of the definition argue that its flexibility allows physicians to provide a wide range of services to those least able to afford them and to accommodate the special needs of severely disabled and chronically ill patients. Respondents who would like to change the definition maintain that the definition's open-endedness makes it difficult to deny services, providing Medicaid clients with levels of care above what is provided by private insurance.

To implement the definition, the MAA maintains an extensive formal process that is codified in the Washington Administrative Code (WAC). Requests requiring prior authorization are reviewed first by nurses, often based on explicit criteria. Denials can then be appealed to physician consultants or to the medical director. Although initial denial rates are at the high end of available denial rates from other state Medicaid programs, Medicare carriers, and managed care plans, denial rates decrease as they are appealed to and overturned by higher levels within MAA. Data are generally not available to estimate the final denial rates for particular services.

Clients are also permitted to appeal care denials to a fair hearing. Our review of the cases suggests that Administrative Law Judges (ALJs) defer to the examining physician's recommendations and appear to place the burden on MAA to show medical necessity. Few ALJs explain why a particular treatment or piece of equipment is medically necessary, even when the denial is overturned.

Our interviews suggest that a more restrictive definition of medical necessity definition would lead to higher denial rates, but we could not estimate the potential fiscal impact of changing the definition in this study. Our interviews also suggest that advocacy organizations will not be receptive to changes in the medical necessity
definition or implementation. The state should anticipate legal challenges to any changes, although our preliminary legal analysis suggests that a more restrictive definition would survive legal scrutiny.

OTHER WASHINGTON STATE PAYERS

Our interviews with other Washington State payers indicate widely varying medical necessity definitions and methods of implementation. Respondents held widely varying opinions about the purpose of any definition of necessity and some even doubted that defining medical necessity served any useful purpose whatsoever.

We found general disagreement over how to build upon any but the most basic elements included in the various medical necessity definitions. But most respondents agreed that a standard of appropriateness should be incorporated into the definition, and clauses mandating the lowest reasonable level of service also received widespread support. Almost all the other elements lacked anything approaching consensus. Most respondents agreed that the contractual wording of the definition of medical necessity would have little effect on cost in the absence of rigorous implementation procedures.

Perhaps more important than the construction of the definition are realistic expectations of the cost savings resulting from any change. Much larger forces than the definition of medical necessity appear to be driving medical costs. The experiences of our respondents suggest that, as capitated arrangements become more common, the role of the definition of medical necessity will change from limiting costs devoted to unnecessary overutilization of procedures to protecting patients from underutilization of needed care.

THE OREGON HEALTH PLAN

The state's general definition of medical necessity rarely plays a definitive role in determining health care for Medicaid patients enrolled in Oregon's Demonstration Project. The state acts as an insurer and provides a legislatively-derived explicit benefits package (the funded portion of the Prioritized List) from which per capita payments to capitated health plans are calculated. Although the state
defines medical necessity, it does not appear to be implementing the
definition, relying instead on the Prioritized List to control costs.
As a practical matter, the medical necessity definition is subsumed by
what is funded on the Prioritized List. Case-specific medically
necessary care will only be defined for the few remaining fee-for-

service patients.

The determination of medical necessity and appropriateness is
mostly left to the individual plans. However, most plans do not have
definitions of medical necessity or appropriateness. Even those that do
use a medical necessity definition essentially rely on an unstructured
approach and on managed care incentives to ensure that providers
minimize wasteful spending. Thus, general definitions of medical
necessity appear to play a negligible role in shaping managed care
practitioners' decisions.

In addition, the state has decentralized case-specific oversight to
managed care plans under the Medicaid demonstration project. But few
data are available on plan denial rates. Our respondents indicated that
denial rates ranged from 5-8%, although they were reluctant to share the
actual data.

The state and managed care plans are using or developing explicit
quality assurance methods to guide care toward what is considered to be
appropriate and necessary. These quality assurance methods are often
directly taken from or modified from already available published models.

OTHER STATE MEDICAID AGENCIES

We analyzed the definition and implementation of medical necessity
in the Utah, Minnesota and New Jersey Medicaid programs. Some prior
authorization of services to determine medical necessity currently is
required in all three states, although to differing degrees. Very
little data regarding rates of medical necessity denials or utilization
of services by Medicaid recipients are collected by any of these state
programs.

The Utah Medicaid program has adopted the most aggressive approach
to medical necessity review of these states, requiring prior
authorization for many expensive inpatient surgical procedures
explicitly as a means to control program costs. In Minnesota, the state Medicaid agency also has in place a formal medical necessity review program, although fewer services require prior authorization and many of them, such as nutritional services and sleep studies, would not be reimbursable in other states. The New Jersey medical necessity review program is the least formal and least comprehensive of the states analyzed in this section. Whereas the Utah Medicaid program relies on detailed, written medical necessity criteria for many services, the New Jersey program relies primarily on the medical judgment of consultant reviewers. What little data on denial rates are available suggest that the MA has generally higher denial rates than in these states.

All three states plan to require the majority of the Medicaid population to enroll in capitation-based managed care plans in the next one to three years in order to control program costs and increase access to medical care. In each of these states, our respondents indicated that case-by-case medical necessity review of claims will be dropped except for those patients who continue to be cared for by fee-for-service providers.

MAJOR FINDINGS

The major findings from this study can be summarized as follows:

1. There is no general definition of medical necessity that will resolve all of the issues confronting the MA and HSC.
2. Our interviews reveal little consensus on the purpose of the definition or how medical necessity should be defined and implemented, except for including appropriateness as part of the definition.
3. Implementing medical necessity requires a great deal of labor-intensive oversight.
4. The MA’s current medical necessity definition appears to be less restrictive than most other definitions we examined. A more restrictive definition is likely to save costs by providing fewer medical services and the sentinel effect, but there does not appear to be evidence to suggest that savings
under the other medical necessity definitions we examined have been substantial.

5. The other states we examined expect to rely primarily on capitated managed care rather than medical necessity to control costs, and Oregon also relies on its Prioritized List to constrain services.

6. We observed two different implementation patterns. Commercial insurers and state Medicaid agencies use a structured process of medical necessity review. Capitated plans use a decentralized physician-based process, relying more on financial incentives than on medical necessity review.

7. The shift to capitated managed care is likely to change the MAA's role from preventing overutilization to monitoring for underutilization.

8. There are limited data on medical necessity denial rates and cost savings, either from other state Medicaid agencies, managed care plans, or Medicare carriers. Available data suggest that the initial MAA denial rates are within the range observed in other programs, and considerably higher than denial rates at managed care plans.

CONCLUSIONS

Among the many options available to Washington State policymakers, four approaches in particular could be considered. First, the state could retain the current MAA definition. Second, the state could develop a more restrictive definition of medical necessity, similar to what the HSC is now considering. Third, the state could develop an alternative approach that focuses on eliminating equivocal or marginally beneficial services, as not being medically necessary. Fourth, the state could consider limiting the range of covered services now offered to Medicaid patients.

Elements of a more restrictive definition could focus on: appropriateness; effectiveness; and, the least costly, equally effective alternative. Experimental or investigational care, as well as convenient or cosmetic care could be excluded. Making the medical
necessity definition more restrictive, implementing it consistently, and shifting the Medicaid population into capitated managed care should result in cost savings to the state.

The focus of the alternative approach would be to define necessary care restrictively as care that is explicitly shown to provide substantial benefits. The goal would be to eliminate altogether services that are not beneficial through the use of explicit clinical criteria. Several different methods are already in use for developing the explicit criteria for making these decisions, including: cost-effectiveness analyses; formal consensus panel ratings on appropriate and necessary care; evidence-based recommendations by recognized professional organizations; and, developing a process of obtaining consensus between the state and physicians.

Any medical necessity definition is only as good as its implementation. Whatever definition is adopted should be implemented to meet the explicit criteria established by the Department of Social and Health Services (DSHS). Care that fails to meet the definition and criteria should be denied, and the burden should be on the physician or client to provide justification for the requested service.

Constraints

In thinking about the specific medical necessity definition to implement, it is important to consider the internal and external constraints facing Washington State policymakers. These constraints are likely to create bounds on what a change in the definition is able to achieve.

Internal constraints on implementing a more restrictive definition include: staffing and resource limitations; differing philosophies about the MAA's role in providing services to Medicaid clients, especially for the severely disabled patient population; and the implications of the shift to Medicaid managed care. External constraints on cost savings include the potential effects of a restrictive definition on provider participation rates, federal mandates, and the effects of advocacy group challenges.
There are several potential legal barriers to a more restrictive definition of medical necessity. Our initial legal analysis suggests that the state can develop and implement a more restrictive medical necessity definition without violating current law.
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DEFINING MEDICAL NECESSITY: AN EXPLORATORY STUDY

SECTION 1: INTRODUCTION

In response to rising health care costs, states have been seeking ways to reduce their Medicaid budgets. One approach, underway in Oregon, is to limit the scope of covered services. Another approach is to shift Medicaid clients into capitated managed care systems. A third approach is to restrict services that are not medically necessary. The latter approach requires an understanding of what constitutes medical necessity and a mechanism to implement that understanding.

Despite an increasing body of commentary on medical necessity, there is little agreement in the literature on what the guiding principle or overriding conceptual approach should be, and there is no universally accepted or applied definition (Mariner, 1994). As we discuss below, there does not even appear to be agreement on what elements (such as appropriateness, cost-effectiveness, etc.) should constitute the concept of medical necessity. Instead, many managed care plans, state Medicaid agencies, insurance companies, and third party reviewers use their own definitions to determine whether to provide or pay for care.

Further complicating matters, one group of Blue Cross managed care plans recently suggested that it is no longer desirable to define medical necessity, concluding that it means "...too many things to too many different people and [is] too misunderstood to be helpful" (NICCM, 1994). Other groups, such as the American Society of Internal Medicine, have been unable to agree on the elements of a medical necessity definition, while insurance company definitions are changing constantly (see, e.g., Hall and Anderson, 1992).

No definition of medical necessity is likely to be self-executing. That is, under the best of circumstances, medical necessity must be determined and implemented on a case-by-case basis. Thus, it is difficult to separate the definition from its implementation. Both aspects need to be considered when developing a medical necessity program.
PURPOSE OF THE PRESENT STUDY

The purpose of this study is to provide information to the Washington State Medical Assistance Administration (MAA) and the Washington State Health Services Commission (HSC) about the definition and use of medical necessity from several different perspectives. The HSC is responsible for assuring access to health care for all Washington State residents under the Washington State Health Services Act of 1993, through the establishment of a set of uniform health services and the uniform benefits package (UBP). MAA administers the Medicaid program and the state funded medical program for eligible low-income people. A little less than ten percent (approximately 592,000 people per month in fiscal year 1994) of Washington State's population receive medical assistance program services based on MAA's medical necessity criteria.

Washington State's 1994 legislation included two provisos in the Supplemental Budget which directed both the HSC and the MAA to study the definition of medical necessity. The Legislature expressed concern that the current MAA definition of medical necessity is driving the MAA budget. This study is designed to assist the MAA and HSC in thinking about the medical necessity problem, rather than to redefine the concept of medical necessity.¹ The goals of the project are to:

- Review the MAA's current definition of medical necessity and how that definition is implemented in program operations
- Review other Washington State public and private payers to determine how they define and implement medical necessity
- Review other State Medicaid agencies to determine their medical necessity criteria for authorizing services
- Assess whether and how MAA's current definition of medical necessity could be revised
- Provide information to assist state policymakers

The central policy question underlying the study is whether the current definition and implementation of medical necessity impede MAA from providing safe and effective medical care at the lowest cost. If

¹For various theoretical articles about medical necessity, see Lang (1991), Mariner (1994), Hall and Anderson (1992), and Kahan et al. (1994).
so, the question is whether a change in the medical necessity definition
would result in significant cost savings without the loss of essential
care. To date, very little empirical research has been conducted to
understand the relationship between a particular definition of medical
necessity and the level and type of services delivered pursuant to that
definition.

This research is not designed to answer these policy questions
directly. In particular, time and resource constraints prevent us from
fully addressing the fiscal implications of various medical necessity
definitions. Instead, our research focuses on understanding the MAA’s
medical necessity program, defining the links between implementation and
the definition, placing the issue in the context of what other states
are doing, and comparing it to how other Washington State payers
approach the problem. In doing so, we will establish the parameters
within which major changes to the definition must be evaluated.

STUDY DESIGN

Study Methods

To achieve the above research goals, we conducted a series of
semi-structured interviews in Washington State with MAA personnel and
other governmental officials. We also met with representatives of
advocacy organizations, commercial insurers, and managed care plans. We
conducted similar interviews in Oregon. We also collected data and
conducted telephone interviews with Medicaid officials in Utah,
Minnesota, and New Jersey. These states were selected by MAA and HSC as
presenting similar problems to those confronted by Washington State.
The individuals interviewed within Washington State, described more
fully in Section 3, were identified by the investigators in conjunction
with MAA and HSC personnel.

The Interviews. Most interviews lasted between one and two hours.
When possible, interviews in Washington State and Oregon were conducted
in person, but some interviews were conducted by telephone. We
developed an interview protocol (attached as Appendix A), and a data
request (attached as Appendix B). The interview questions were adapted
to reflect the type of information any particular individual could be
expected to provide.
The interview guide consisted of semi-structured questions designed to elicit participants' characterization of how their organization defines and implements medical necessity. The interviews focused on the following issues: 1) how the organization defines medical necessity, what the underlying purpose of the definition is, perceived strengths and weaknesses of the definition used, and what changes the respondent would like to see in the definition; 2) how the organization implements the definition, including the process for patient appeals; 3) how information about medical necessity is conveyed to physicians; 4) what data the organization collects to estimate denial rates and cost savings based on medical necessity; and, 5) other methods, such as utilization review or physician profiling, the organization uses to ensure the provision of appropriate care.

Data Collection. We asked each managed care plan or commercial insurer to supply data on: 1) the types of services requiring prior authorization; 2) overall denial rates based on medical necessity; 3) data on denial rates and costs for the ten most expensive procedures; 4) data on denial rates and costs for experimental or investigational procedures; 5) data on denial rates for durable medical equipment (DME); 6) data on realized or anticipated cost savings through the use of medical necessity; and 7) any analyses conducted of medical necessity.

Study Limitations

Some limitations to this study should be noted. First, time and resource constraints limited the number of states, plans, and insurers that could be interviewed, as well as the number of persons within plans. Also, we did not interview a random sample within sites, but spoke to selected individuals at various levels of the organization. Thus, our sample may not be generalizable to a broader set of states, managed care plans, or commercial insurers.

Second, there were limited data available from respondents. In many cases, plans do not routinely maintain the types of data needed to provide insight into medical necessity denial rates or costs saved through medical necessity review. In other cases, plans were reluctant to share proprietary data.
Terminology Used in This Study

The concept of medical necessity is just one of several ways to control health care quality and reduce costs. Other ways include appropriateness reviews, coverage determinations, and physician profiling. Before describing the results of our study it is important to set forth our understanding of key concepts.

Medical Necessity. Medical necessity is an inherently imprecise term that is used by providers and payers in different ways (Lang, 1991; Mariner, 1994). Medical necessity is, first, a concept of only providing medical care that a patient needs. Second, it is also a process of determining whether a particular procedure or treatment should be provided for a given medical condition. And, third, it forms the contractual basis between providers and subscribers for making medical care decisions. Medical necessity is often determined in advance on a case-by-case basis. Reviewers and medical consultants may develop criteria to determine medical necessity for a given treatment request.

Our review of the literature and discussions with providers in Washington State and Oregon suggest a wide range of definitions, from stringent to open-ended. Some of the definitions are listed below; others will be noted in the following sections of the report.

As one example, RAND defines medical necessity as crucial care based on four factors: 1) appropriateness; 2) improper care not to provide the service; 3) reasonable chance of benefit from the procedure; and, 4) benefit to patient is not small (Kahan et al., 1994). Similarly, a physicians' group in Washington State defines medical necessity as "...indispensable in that a medical condition...could not have been diagnosed or relieved without the medical service or supply in question."

A typical commercial insurance contract defines medical necessity as "...a service, supply, and/or setting that the company deems is required for diagnosis or treatment of sickness or injury and is: 1) consistent with the symptoms, diagnosis, and treatment of the beneficiary's condition; 2) not primarily for the convenience of the beneficiary or provider; 3) the least costly of the alternative levels of service...that are adequate and available....The fact that a
physician or other provider has prescribed, ordered, recommended, or approved a service, supply, or setting, does not, in itself, make it medically necessary."

Congress mandates that Medicare services must be "reasonable and necessary", but does not define medical necessity (42 U.S.C. Section 1395y(a)(1)(A)). In a 1989 Notice of Proposed Rulemaking (NPRM),\(^2\) the Health Care Financing Administration defined the statutory phrase reasonable and necessary "...to mean that a service is safe, effective, noninvestigational, and appropriate." A procedure is considered to be safe and effective if it is based on authoritative evidence or is generally accepted in the community as being safe and effective. The NPRM also proposed including cost-effectiveness as a criterion for determining medical necessity, meaning that patients receive improved outcomes that justify additional expenditures.

As an example of a more open-ended approach, Utah determines that care is medically necessary if it is "...reasonably calculated to prevent, diagnose, or cure conditions that endanger life, cause suffering, cause physical deformity or malfunction, or threaten to cause a handicap." In addition, seven criteria must be met. For example, there must be no equally effective course of treatment that is more conservative or substantially less costly. The treatment must be safe, non-experimental, and of proven medical value. This definition is similar to the MA's current definition (as set forth in detail below), with the exception that Utah law requires denial of a claim that fails to meet these criteria.\(^3\)

In an attempt to move beyond medical necessity, the National Institute for Health Care Management (NIHCM, 1994) would require health plans to cover interventions based on the following criteria: 1) used for a medical condition; 2) sufficient evidence to draw conclusions about the effects on health outcomes (including the quality of life); 3) evidence that the intervention will produce the intended effects; 4) beneficial effects outweigh the harmful effects; and, 5) the

\(^2\)Federal Register, Vol. 54, No. 18, January 30, 1989, pp. 4302-4318. The NPRM has never been issued as a final rule. Under 42 C.F.R. Section 230(d), states are permitted to place limits on services that are not based on medical necessity criteria.

\(^3\)Utah Administrative Code, Sec.R414-13x-1 (1994).
intervention is the most cost-effective method available to address the medical condition. The NICHM makes no attempt to define medical necessity.

**Covered Services.** Covered services are those medical procedures and treatments that a provider or third party insurer agrees to provide to a subscriber or beneficiary. Most providers and payers require that a treatment must be both covered and medically necessary before it will be provided.

**Utilization Review.** Utilization review or utilization management can be retrospective or prospective review of services provided by a health plan, hospital, physician, or other health care provider. Utilization review may be based on clinical practice guidelines or criteria and is an attempt to monitor over- and underutilization of health care services.

**Physician Profiling.** Physician profiling is the use of statistical indicators, such as the amount and types of services ordered for a particular patient, to compare over- and underutilization between physicians. Physician profiling is usually a retrospective review of a physician’s decisions.

**Appropriateness.** Appropriateness, in the RAND definition, is a determination of whether the benefits of a medical intervention outweigh the risks (Kahan et al., 1994). Inappropriate care is when the risks outweigh the benefits. Another way to consider appropriateness is care that is consistent with the symptoms or treatment of a medical condition that is safe and effective. Appropriateness and medical necessity are conceptually similar, but Kahan et al. define appropriateness as exclusionary (do not use if inappropriate) and medical necessity as inclusionary (must be used if necessary). In this construct, medical necessity is a more restrictive concept than appropriateness. For example, consensus panels rated 2,905 indications as appropriate for cataract surgery, but only 1,303 were rated as necessary (Lee et al., 1993).

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4HCFA defines appropriateness as services furnished in a setting commensurate with the patient’s medical needs and condition and furnished by qualified personnel. Federal Register, Vol. 54, No. 18, January 30, 1989, pp. 4302-4318.
Investigational or Experimental Treatment. HCFA considers most drugs and devices that have not been approved by the Food and Drug Administration (FDA) as experimental, as are services provided according to a research protocol. Other services are considered experimental or investigational if they are not widely provided because there is inadequate evidence of their safety and effectiveness.

Standard of Care. The legal standard of care refers to the level and type of care that is customary and usual medical practice. Each physician must exercise the degree of skill ordinarily applied, under similar circumstances, by members of the profession.

Overview of the Medical Necessity Process

The following is a truncated description of the general medical necessity process, shown schematically in Figure 2 (Section 2). The initial determination in providing non-emergency medical care is usually to decide whether the service is covered under the patient’s benefits (for example, the Uniform Benefits Package in Washington State). Many benefits packages, for example, exclude investigational or experimental therapies. Once that determination is made, most providers and payers decide whether the service is medically necessary. Based on the elements of a particular definition of medical necessity (such as appropriateness, or the least costly most effective alternative), a physician determines whether the service for the patient’s condition is medically necessary.

Medical necessity is conceptually distinct from whether or not a particular service is covered by Medicaid. What constitutes medical necessity is a more subjective determination than determining whether a service is covered. Thus, medical necessity can be viewed along a continuum which varies depending on clinical circumstances, while covered/noncovered can be viewed as a dichotomous variable. But as noted below, interpreting covered services, such as determining what constitutes “aids to mobility”, can also be subjective.

Both concepts, however, can be used to limit coverage to program beneficiaries, and should thus be seen as complementary. For example, one state may limit the range of services it will cover, but flexibly define medical necessity to allow most covered services to be provided.
another state may provide a wide range of covered services, but narrowly define medical necessity to exclude all but essential services to be provided. In analyzing the definition of medical necessity, it is important to keep in mind its complementary relationship to covered services (shown in Figure 3, Section 6).

This means that we are generally concerned with four policy "spaces": covered services that are either medically necessary or not medically necessary, and noncovered services that are either medically necessary or not medically necessary. In theory, it should not be a problem to determine when services should be provided—that should only occur when a covered service is medically necessary. In practice, these distinctions can be hard to apply. For example, there may be pressure to allow an exception to policy (WAC 388-200-1150) in individual cases, especially when a public program is the patient's last resort.

No definition of medical necessity operates in isolation. When thinking about whether to redefine the term, it is also important to think about how the definition will be operationalized. Operational issues include prior authorization for services, levels of review to obtain approval or denial of services, the criteria (implicit or explicit) for determining whether a particular service is medically necessary, and the ways in which medical necessity decisions will be monitored. Criteria development could include the use of clinical practice guidelines, reviewing the medical literature to determine the service's effectiveness, or convening consensus panels. Monitoring could include utilization management and physician profiling.

In public programs, a structured process for appealing denials is usually available. In private plans, the appeals process may not be as structured. As an example in public programs, a denial might be appealed from the initial review, to medical consultants, and then to the medical director. If the denial is not overturned, the patient may seek a fair hearing by an Administrative Law Judge (ALJ).

These interactions are depicted in Figure 1. A service that is covered and necessary, box A, should be provided. A service that is covered but not necessary (perhaps a transplant), box C, will most likely be denied. That denial may be appealed to challenge the medical necessity determination or the client may request an exception to
policy. A service that is not covered but necessary, box B, may result in a request for an exception to policy, or the coverage decision (perhaps defining an aid to mobility) may be challenged. A service that is neither covered nor necessary, box D, will not be provided.

Figure 1

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<thead>
<tr>
<th>Medically Necessary</th>
<th>Covered</th>
<th>Not Covered</th>
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<tbody>
<tr>
<td>Not Medically Necessary</td>
<td>A</td>
<td>B</td>
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<tr>
<td></td>
<td>C</td>
<td>D</td>
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Organization of the Report

The remainder of this report is organized as follows. In Section 2, we review the MAA’s current definition and implementation of medical necessity. In Section 3, we review the experience of other payers in Washington State. In Section 4, we describe our findings from Oregon. In Section 5, we describe our findings from Minnesota, Utah, and New Jersey. In Section 6, we provide an economic model for assessing potential cost savings based on changes in the definition of medical necessity. In Section 7, we provide our findings and conclusions, and discuss the legal and other constraints that should be considered in defining medical necessity.
SECTION 2: THE MAA'S DEFINITION AND IMPLEMENTATION

COVERED SERVICES

To begin with, beneficiaries receiving medical assistance through MAA do not receive unlimited medical benefits; there are limits on the scope of medical program services offered. These limits are set forth in the Washington Administrative Code (WAC), which describes those services that MAA will cover (see, generally, WAC 388-Chapter 86). For example, MAA pays only for equipment, supplies, and services that are listed as covered in MAA published issuances, including the WAC, billing instructions, certain memoranda, and bulletins. In cases where the items or services are within the scope of an eligible client's medical care program, they must also be medically necessary, within accepted medical standards, consistent with a diagnosis, reasonable in amount and duration of care, treatment or service, and not specifically excluded at WAC 388-86-200(1).

Thus, a beneficiary can only receive MAA reimbursable services for medical care that is covered under the WAC and is determined to be medically necessary. An individual's eligibility for services is decided by the Community Services Office (CSO). WAC 388-86-200(2)(b) excludes from covered services those “Services, procedures, treatment...which the department or HCFA consider investigative or experimental on the date the services are provided.”

MEDICAL NECESSITY

The MAA's Definition

The current definition of medical necessity used by MAA was originally formulated in a 1978 consent decree settling the case of Mead v. Burdman, King County Superior Court, No. 818663, Consent Order for Declaratory and Injunctive Relief (1978) for inpatient care. The definition was reaffirmed in another consent decree in Bowers v. Thompson, Thurston County Superior Court, Case No. 89-2-00553-8, Stipulation and Agreement and Consent Order (October 15, 1990), applying the definition to durable medical equipment (DME). At this point, the
definition is applied to all MAA services. The definition, as codified in WAC 388-500-0005, is as follows:

- "Medically necessary" is a term for describing requested service which is reasonably calculated to prevent, diagnose, correct, cure, alleviate or prevent the worsening of conditions in the recipient that endanger life, or cause suffering or pain, or result in illness or infirmity, or threaten to cause or aggravate a handicap, or cause physical deformity or malfunction, and there is no other equally effective more conservative or substantially less costly course of treatment available or suitable for the recipient requesting the service. For the purpose of this section, "course of treatment" may include mere observation or, where appropriate, no treatment at all.

The MAA has not issued any policy statements interpreting any of these terms. For many individual procedures, however, the MAA has developed explicit medical criteria to determine when a particular treatment is medically necessary. For example, the following criteria must be met to receive approval for a bone marrow transplant: 1) the transplantation must be the most effective medical treatment, when compared to other alternatives, in prolonging life expectancy to a reasonable degree; 2) the client must have a maximum probability of a successful clinical outcome; and, 3) all alternative treatments with a one year survival rate comparable to that of bone marrow transplantation must have been tried or considered. The definition itself makes no reference to experimental or investigational treatment, since this is dealt with in the context of covered services.

Purpose of the Definition. The MAA definition of medical necessity serves several practical purposes, but an overriding purpose or objective does not appear to have been stated. Nor does there appear to be an agreed-upon purpose for the definition beyond providing a bound on the amount and level of services to be provided. In practice, those who advocate for providing expansive services cite the definition's open-ended provisions and implicit deference to treating physicians,
while those who argue for greater restrictions use the definition to try to limit services. The consent decree in *Mead v. Burdman* explicitly prohibits the MAA from denying medical care based on fiscal considerations.

**The Definition's Strengths and Weaknesses**

According to advocates, the current definition has several strengths they would like to retain. First, it is flexible, allowing physicians to provide needed services. Second, and closely related, the definition defers to the treating physician who knows the most about what particular patients need. Third, it provides a wide range of services to those least able to afford them. Fourth, it is flexible enough to accommodate the special needs of the SSI population.

From a different perspective, however, the definition has several serious weaknesses according to our respondents. First, it is so broadly written that it can be difficult to justify and support a denial of services based on medical necessity once they are covered. Our interviews, for instance, focused repeatedly on the phrases "reasonably calculated", "alleviate the worsening of conditions", and "substantially less costly course of treatment" as allowing for unlimited benefits. The perception is that, over time, the definition operates so that everything is approved. Critics of the definition argue that the result is to provide Medical Assistance clients with amounts and levels of care that are often above what private insurance would provide.

Second, the expansiveness of the language arguably contributes to rising Medical Assistance Program costs because it is difficult to deny benefits, hence blocking the MAA's ability to provide safe and effective care at the lowest cost. Third, some observers also argue that the current definition leads to inconsistent ALJ rulings in similar cases. Fourth, the language is so ambiguous, making a denial hard to sustain, that the definition lacks any sentinel effect. That is, the looseness of the language encourages claims for reimbursement instead of acting as a sentinel to discourage all but the most appropriate claims. Finally, not only does the definition defer to the treating physician, it has the effect of placing the burden on the MAA to justify a denial, rather than
placing the burden on the physician or beneficiary to justify the treatment.⁵

Critics of the current definition cite, as paradigmatic cases driving Medical Assistance Program costs, the difficulty of limiting extensive add-ons to wheelchairs or second wheelchairs to individual recipients, of denying transplants even when MAA medical criteria are not met, and of supplying generic pharmaceuticals instead of brand names. A recent example deals with lifelines, a noncovered service which ALJs are generally requiring MAA to provide as medically necessary. In general, our interviews suggest a two-fold concern: that MAA clients receive "Cadillac" equipment and services (such as rehabilitation) not available under private insurance; and that marginally beneficial DME is being provided as medically necessary care.⁶ In part, this appears to result from the difficulty of defining coverage criteria when each case is so different.

IMPLEMENTING THE DEFINITION

The Implementation Process

The formal MAA process for implementing the medical necessity definition, as set forth in WAC 388-Chapter 81 and shown schematically in Figure 2, is pyramidal, with most of the denials occurring at the initial review stage according to established policies and criteria. As a case moves up the pyramid, fewer denials appear to be sustained. Supplementing the formal process, a more informal process (in the sense that criteria or guidelines for granting an exception to policy have not been established) allows the medical director to issue an exception to policy when he or she believes that MAA should provide the requested service despite established policies or criteria.

⁵By contrast, the proposed HCFA definition in the NPRM places the burden on the beneficiary to show medical necessity.
⁶Several people argued that DME expenditures and MAA's workload have expanded as a result of the Bowers v. Thompson consent decree, but supporting data are not available.
Figure 2

Medically Necessary Process Overview of The

Provider Requests Service

Is service covered?

Yes

No

Provider Requests Service

Is service med. nec.?

Yes

No

Appeal to Med. Director

Not provided

No

Yes

Recipient Request for Fair Hearing

Recipient Request for Fair Hearing
**Prior Authorization.** Prospective review of medical necessity only occurs through the process of prior authorization. Certain services cannot be reimbursed by MAA unless a provider receives prior authorization for the request. For example, transplants, Magnetic Resonance Imaging (MRIs), and some DME all require prior authorization. During 1993, 218,119 services required prior authorization, constituting less than 1% of all MAA funded services. Over time, however, MAA has reduced the number and types of services requiring prior authorization, primarily, according to our interviews, because of staff reductions, general trends in denial rates, and the definition of medical necessity. For instance, prior authorization is no longer required for outpatient physical therapy or enteral nutritional therapy. Nor is prior authorization required for C-Sections or Coronary Artery Bypass Graft (CABG) surgery. Thus, in 1994, 171,225 services required prior authorization.

Prior authorization requests are submitted either in writing or by telephone to the Authorization Section. The Authorization Section, consisting largely of nurses, makes an initial determination as to whether the requested service is covered and medically necessary.

An integral aspect of this review is to determine the least costly alternative. Most high cost items are reviewed based on criteria established by MAA. For example, MAA has developed a list of preliminary indications for using MRIs (such as acoustic neuroma for a brain scan), along with key questions regarding specific symptoms for approval (such as cranial nerve compression or degeneration for acoustic neuroma). These indications and symptoms are reviewed periodically and updated. Similar criteria have been developed to guide prior authorization for transplants. For some procedures, provision of care is restricted to a specific site. For example only previously approved transplant centers may provide transplant services.

Under WAC 388-81-038(4), MAA may only deny a request for medical assistance services for one of three reasons: the service is not

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7See Appendix C for the full list of services requiring prior authorization.
8See Appendix D for a list of services no longer requiring prior authorization. Federal regulations require utilization review, not prior authorization.
covered by the Medical Assistance program, it is generally considered experimental or unacceptable treatment, or it is not medically necessary. Often, the Authorization Section will request additional information from the physician or beneficiary, leaving the file open as pending. If the request is denied, MAA is required under WAC 388-81-038(6) to provide written notice within five working days of the denial. The written notice must include: (1) the WAC references used as a basis for the decision; (2) a summary statement of the specific facts the MAA relied upon for the decision; and, (3) an explanation of the reasons for denial, including the reasons why the specific facts relied on did not meet the requirements for approval. Advocates complain that denial notices often do not specify why the requested service is not medically necessary, a finding also noted by Administrative Law Judges (as discussed below).

**Medical Consultants.** If a physician or client wishes to challenge an Authorization Section denial, he or she may appeal the decision to the next level, physicians who act as medical consultants to MAA. No data on the number of denials overturned by the medical consultants are maintained. Our interviews suggest that there is wide variation among medical consultants in upholding or overturning Authorization Section decisions. Some medical consultants defer to the treating physician, while others apply the review criteria more stringently. In part, this may represent different philosophies about the level and extent of services to be provided to program clients.

**Medical Director.** If a denial is upheld by the medical consultants, a physician or beneficiary may appeal to the medical director. The medical director makes the final decision on behalf of MAA regarding the claim. The medical director also has broad authority to grant a request as an exception to policy where a denial would otherwise be indicated based on existing departmental policy (WAC 388-501-0160, and 388-200-1150). As an example, the medical director can

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9 This has the effect of shifting the burden to the provider or beneficiary to provide supporting documentation. Because a pending file is only reconsidered if the requested information is provided, a pending request is tantamount to a denial.

10 Absent a specific federal or state law, the medical director can grant an exception to policy under WAC 388-200-1150(4) when: a) the client’s circumstances differ from the majority or are peculiar; b) it would ease
agree to cover a transplant for an out-of-state resident that would otherwise not be covered. Data are not available on the number of denials overturned by the medical director, but our interviews suggest that most transplant denials are overturned by the medical consultants or the medical director. Recent MAA data on client-requested exceptions to policy indicate that 72% of the requests are approved (203 approved out of 281 requests).

**Fair Hearings.** If a denial is sustained by the medical director, the physician or beneficiary can seek a fair hearing (called an initial hearing) before an Administrative Law Judge (ALJ) pursuant to WAC 388-526-2610. Either party can then request a second hearing (called a review) before a different ALJ.

One general perception from our interviews is that hearings favor the Medical Assistance client, but MAA's statistics show a more ambiguous outcome (Fair Hearing Status Report, January 1994). From 1991 through May 1994, MAA won most of the cases actually brought to an initial hearing, although most cases were settled before the hearing with an MAA approval, or the client withdrew. In 1992, for instance, 74 fair hearings were held out of 317 requests. The MAA prevailed in 52% of the hearings, the client prevailed in 31%, the client did not appear in 10%, and there was no issue in the remaining 7%. After a request for a fair hearing was filed, however, the MAA approved 43% of all requests, while the client withdrew 32% of the requests. On appeal from the initial decision, MAA did even better, winning 78% of review cases. Only 3% of all hearings are appealed to Superior Court; those results are not available. These figures fluctuate considerably from year-to-year.

A second general perception is that ALJs use the medical necessity definition to require MAA to provide noncovered services. Many respondents perceive that ALJs will order MAA to provide medically necessary services regardless of whether they are covered by the client’s Medical Assistance Program, especially DME items such as aids to mobility. Our review of the cases (noted below) provides some support for this perception. For example, some ALJs have required MAA...
to provide services such as environmental equipment, including air
purifiers, and lifelines, when they are medically necessary even though
MAA argued that they are noncovered services.

Project staff reviewed more than 100 fair hearings decisions and
selected 65 of the decisions from 1989 through September 1994 for more
in-depth analysis. These cases were selected through a cursory review
of all available ALJ decisions during this time frame that involved the
definition of medical necessity. The purpose of the review was to
ascertain how ALJs interpret the definition and the reasoning used to
reach particular results. Perhaps because the clients win a higher
percentage of medical necessity cases, the cases analyzed oversample
client successes and may not be representative of all fair hearings
decisions. Nevertheless, the review suggests certain consistent
patterns and reasons why ALJs overturn MAA denials that the department
should consider in the future.

First, ALJs defer to the examining physician’s determination of
medical necessity. The department is required by WAC 388-81-038(3) to
give substantial weight to objective medical evidence and conclusions
provided by an examining physician. The department, pursuant to WAC
388-81-038(a), may reject an examining physician’s conclusion that the
requested item is medically necessary only on the basis of sound medical
practice and specific objective medical evidence.

Second, there appear to be few cases where the department presents
sufficient evidence to offset the examining physician’s testimony. For
the most part, ALJs appear to discount the department’s physician
testimony as based on a review of the record rather than based on
patient observation or treatment.

Third, in our sample, the burden of persuasion appears to be
placed on the department to support its denial, despite WAC 388-501-
0165(4)(c) which appears to place the burden on the client to
demonstrate medical necessity. This trend also contradicts the
unpublished Washington State Court of Appeals case of Beal v. DSHS, No.
5789-1-11, Division Two, August 4, 1983, holding that “There is no
dispute that where the proposed service is denied, the plaintiff has the
burden of demonstrating that the proposed service is medically
necessary." HCFA places the burden on the recipient to show medical necessity.

Fourth, although the definition is always repeated verbatim, ALJs are not expansive in their reasoning as to why a particular treatment or piece of equipment is medically necessary. They simply rely on the phrase "calculated to alleviate or prevent the worsening..." without analyzing what the terms mean in the particular case. In the 1992 case of In Re: Paul J. Flores, Docket No. 0492 A-257, however, an ALJ stated that "An objective reading of the definition makes it clear that the standard to be applied is more accurately one of probable medical benefit." If this standard is widely applied by ALJs, either explicitly or implicitly, this would provide strong support for the MAA's concerns that the definition forces them to provide marginally beneficial care that is not necessary.

Fifth, many of the cases appear to be brought by severely disabled people (both children and adults) for whom the MAA is truly the payer of last resort. Thus it is difficult to generalize the results to a different patient population.

Sixth, costs or the cost-effectiveness of treatment were not often discussed in the decisions. When raised, costs were usually discussed in a general context of whether additional spending would reduce subsequent expenditures without explicit cost analyses.

Seventh, the extent to which ALJs used medical necessity to compel MAA to provide non-covered services seems to be mixed, with only a few cases directly requiring MAA to provide non-covered services. (At least two of these were reversed on review.) In some cases, ALJs seemed to enlarge covered services, by reading, "aids to mobility" or medical necessity in a more expansive way than MAA recommended. In a case involving a workhorse tricycle for a severely disabled child, for example, the ALJ determined that the item fell within MAA's general scope of service and should be provided.

Because the decisions reviewed offer so little guidance on how ALJs interpret the medical necessity definition, it is difficult to speculate on whether a more restrictive definition would produce substantially different results. At a minimum, MAA needs to consider the cost-effectiveness of having its medical consultants actually
examine patients prior to the hearing. If the severely disabled population continues to dominate fair hearings requests, even patient examinations might not make much of a difference. Nor is there any assurance that ALJs will not find ways around a more restrictive definition.

It is not clear how a change in the definition would affect the fair hearings request rate. But indications from interviews with advocacy organizations suggest that they will respond to the level of denials. If a change in either the definition or its implementation results in increasing numbers of denials, MAA should expect a corresponding increase in fair hearings requests. In 1994, DME denial rates based on medical necessity rose substantially (see Table 1), as did the number of fair hearings requests for DME and wheelchairs. So far in 1994, DME and wheelchairs constitute 56% of all fair hearings requests, up from 36% in 1992.

Table 1
Overall DME Denial Rates: Percent by Quarter

<table>
<thead>
<tr>
<th>Quarter</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>2nd Quarter 1994</td>
<td>15.3</td>
</tr>
<tr>
<td>1st Quarter 1994</td>
<td>11.5</td>
</tr>
<tr>
<td>4th Quarter 1993</td>
<td>11.5</td>
</tr>
<tr>
<td>3rd Quarter 1993</td>
<td>9.4</td>
</tr>
<tr>
<td>2nd Quarter 1993</td>
<td>5.1</td>
</tr>
<tr>
<td>1st Quarter 1993</td>
<td>5.7</td>
</tr>
<tr>
<td>4th Quarter 1992</td>
<td>5.5</td>
</tr>
<tr>
<td>3rd Quarter 1992</td>
<td>6.6</td>
</tr>
<tr>
<td>2nd Quarter 1992</td>
<td>10.0</td>
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<tr>
<td>1st Quarter 1992</td>
<td>8.5</td>
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<td>4th Quarter 1991</td>
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<tr>
<td>3rd Quarter 1991</td>
<td>6.4</td>
</tr>
<tr>
<td>2nd Quarter 1991</td>
<td>9.5</td>
</tr>
<tr>
<td>1st Quarter 1991</td>
<td>9.6</td>
</tr>
</tbody>
</table>

SOURCE: MAA–DME Unit

But fair hearings requests declined from 1991 through 1993, as did the number of hearings held, despite an increase in DME denial rates in the last two quarters of 1993 (Fair Hearing Status Report, January 1994). And the number of fair hearings requests for 1994 appears to be at or slightly below the 1993 rate, both of which are considerably lower than the 1992 rate. At the same time, if a more restrictive definition
results in overturning fewer denials, the number of fair hearings requests should decline over time, as a result of the sentinel effect. But medical necessity is just one of many factors affecting denial rates and fair hearings outcomes.

**Utilization Review.** As an adjunct to the medical necessity regime, MAA has instituted a utilization review program to identify inappropriate treatment based on retrospective data analyses and monitoring. The program is in its early stages, and relies on cost savings through audits of items flagged for review, rather than on physician profiling. At this point, there are no standards to measure or estimate rates of inappropriateness, but MAA is mandated to review a certain percentage of cases each quarter.

According to information supplied by the Division of Utilization Services in MAA, utilization review recoups annually approximately $5 million from providers and an estimated $7 million through cost avoidance. Current data systems, however, are unable to separate recoupment between inappropriate billings and medical necessity.

**Data**

**Data Availability.** State Medicaid expenditures are rising for many reasons; medical necessity is one of many factors affecting MAA costs. Between FY 1990 and FY 1993, the MAA non-nursing home budget rose from $656 million to $1.2 billion, a 90% increase. But total client eligibles rose 40% from 394,991 to 553,186, accounting for a significant portion of the increased expenditures. Rising inpatient, outpatient, and physicians services account for nearly 45% of the additional expenditures between 1990 and 1993. In addition, federal Medicaid mandates to provide maternal and child care above the poverty level also contribute to increased expenditures. Thus, it is difficult to determine the extent to which the current program contributes to these costs and whether a more restrictive definition would reduce the rate of increase. We discuss these issues in Section 6.

Equally important, there do not appear to be any data on denial rates at various points in the process, except at the Authorization Section level. No computerized system is in place to determine the end result of a request or to analyze exceptions to policy. As a result, it
is difficult to determine eventual denial or approval rates without following each individual case through the system. There are also no data available to document exceptions to policy.

Data Analysis. No analyses or estimates of money saved or expended based on medical necessity denials appear to have been conducted. Nor are there any estimates of potential savings from changing the definition of medical necessity. We address this issue further in Section 6 below.

Denial Rates. Before considering the available data on denial rates, it is important to note that there is no “gold standard” for what an optimal denial rate should be, and our study was not designed to determine an optimal denial rate for MAA. As noted in a recent General Accounting Office (GAO, 1994, p. 14) report on medical necessity denial rates for Medicare,

“...although low denial rates are desirable from the standpoint that they imply less trouble for providers and beneficiaries, they are only desirable insofar as providers appropriately bill for what is medically necessary. If providers are inappropriately billing Medicare, high denial rates are desirable.”

Data on overall MAA denial rates based on lack of medical necessity are not available. However, data on denial rates in selected MAA programs, at least at the Authorization Section level, provide some basis for comparing MAA denial rates to other programs. The most comprehensive data on denial rates are from the DME and transplantation programs. DME data have been collected since late 1990 in compliance with the Bowers v. Thompson consent decree.

As shown in Table 1, overall DME denial rates (calculated by RAND based on MAA data) have increased dramatically at the Authorization Section level following the second quarter of 1993, to 15.3% in the second quarter of 1994. To reiterate, these are initial denial rates at the Authorization Section; there are no currently available data to determine the percentage of denials as an end result. In Table 2, we show denial rates based on selected high volume DME requests in the
first quarter of 1991-1994, and compare these individual denial rates to the overall rates in the same quarters. There do not appear to be any consistent patterns to these denial rates.

In Table 3, we show denial rates at the Authorization Section for transplantation requests in 1994. The overall denial rate is 23%. (In reality, the denial rate is probably much lower, as our interviews indicate that many transplants are eventually approved.) Bone marrow transplants represent 49% of all transplant requests, and 48% of all approved transplants. Other MAA data corroborate that bone marrow is the largest single category for transplant requests. Between FY 1991 and FY1993, bone marrow transplants constituted 33% of all MAA funded transplants and 59% of MAA transplant expenditures in FY 1993.

Table 2

<table>
<thead>
<tr>
<th>1st Quarter</th>
<th>Manual</th>
<th>Repair</th>
<th>Power</th>
<th>Ortho</th>
<th>Pros</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>1991</td>
<td>9.5</td>
<td>8.1</td>
<td>2.9</td>
<td>0(^{b})</td>
<td>3.7</td>
<td>9.6</td>
</tr>
<tr>
<td>1992</td>
<td>5.5</td>
<td>11.3</td>
<td>5.3</td>
<td>0(^{a})</td>
<td>3.1</td>
<td>8.5</td>
</tr>
<tr>
<td>1993</td>
<td>3.9</td>
<td>5.0</td>
<td>2.3</td>
<td>10.4</td>
<td>6.5</td>
<td>5.7</td>
</tr>
<tr>
<td>1994</td>
<td>13.4</td>
<td>2.9</td>
<td>8.8</td>
<td>9.9</td>
<td>8.5</td>
<td>11.5</td>
</tr>
</tbody>
</table>

\(^{a}\) Only 1 request  
\(^{b}\) Only 9 requests  
SOURCE: MAA--DME Unit

Table 3

Transplantation Approvals and Denials\(^{a}\)

<table>
<thead>
<tr>
<th>Type</th>
<th>Approvals</th>
<th>Denials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart</td>
<td>14</td>
<td>3</td>
</tr>
<tr>
<td>Heart/Lung</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Kidney</td>
<td>14</td>
<td>2</td>
</tr>
<tr>
<td>Liver</td>
<td>25</td>
<td>2</td>
</tr>
<tr>
<td>Pancreas</td>
<td>9</td>
<td>5</td>
</tr>
<tr>
<td>BMT</td>
<td>95</td>
<td>31</td>
</tr>
<tr>
<td>BMH</td>
<td>22</td>
<td>6</td>
</tr>
<tr>
<td>BM Search</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Lung</td>
<td>13</td>
<td>5</td>
</tr>
<tr>
<td>Cornea</td>
<td>14</td>
<td>1</td>
</tr>
<tr>
<td>Bowel</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

\(^{a}\) These may have been overturned but no way to know without going over each of the auth $s$.  
SOURCE: MAA--Authorization Section
The available data suggest that denial rates have increased between 1992 and 1994, consistent with increases in DME denial rates. For example, data indicate that MRI denial rates were 14% in 1993, but 25% in 1994. In addition, denial rates for bone marrow transplants were 22% in 1994 (including 7% that are pending further information), compared to 7% in 1993 (including 1% pending).

Although our interviews suggest that a more restrictive medical necessity definition will lead to higher denial rates, there is no way to estimate such effects. As we discuss in Section 7, there are external constraints that limit MAA flexibility. To take just one example, the federal Office of Personnel Management recently decided that all plans participating in the Federal Employees Health Benefits Program cover bone marrow transplants for certain types of cancers. This will undoubtedly put pressure on other programs to offer similar coverage, despite conflicting evidence of medical effectiveness. On the other hand, a more restrictive definition, and corresponding higher denial levels, should act as a sentinel by sending signals to physicians that requests for marginally beneficial care will be denied.

**Medicaid Managed Care**

The above discussion is predicated on implementing a medical necessity program based largely on a fee-for-service system. But Washington State, like many other states, is in the process of shifting its Medicaid clients into managed care. At least 50% of the Medicaid population is already enrolled in either primary care case management or in capitated systems. Eventually, all Medicaid clients will be enrolled in capitated managed care plans, regardless of whether the HSA is fully implemented.

Indeed, one of the structural changes anticipated under the HSA is that all Washington State residents will receive health care through managed care arrangements based on the uniform benefits package (UBP). Thus, the discussion of medical necessity in Washington State must take into account the likelihood that direct implementation of medical necessity will shift from MAA to managed care plans. As a result, MAA’s role will shift from monitoring overutilization of unnecessary services to monitoring underutilization of necessary services. That is, the MAA
role shifts from a primary concern with cost containment to a primary concern for access. In turn, implementation of the medical necessity definition will shift to managed care plans. This shift may also affect MAA’s staffing and resource needs, and the mix of staff required to monitor health plans.

Therefore, any changes in medical necessity need to take into account the differences between managed care and fee-for-service. This is especially true for those enrolled in capitated systems. To put the change another way, in a fee-for-service system, the physician and patient are aligned to maximize the availability of services. In Medicaid managed care, the patient and MAA are aligned to ensure that all medically necessary services are provided.

An important concern is that managed care plans have little experience with the types of problems confronted by the SSI population. As our review of fair hearings suggests, the SSI population (which has not yet been shifted to managed care) presents managed care plans with a fundamentally different set of problems than a non-disabled population. For example, the palliative care required by a chronically ill population is not well-suited to a restrictive definition of medical necessity. Some respondents also raised concerns that a more restrictive definition would result in reduced access to specialized care for severely or developmentally disabled clients.
SECTION 3: OTHER WASHINGTON STATE PAYERS AND PROVIDERS

INTRODUCTION

Because the MAA provides only about 11% of the population in Washington State, most of the care in the state is delivered under other definitions of medical necessity. Private insurance plans, physician groups, health maintenance organizations, and other public agencies have developed their own definitions and methods of implementation. Sharing the same geography, population base and legal and institutional milieu does not ensure comparability, particularly as the MAA's service population and organizational goals as a public provider of care to the indigent may vary greatly from those of private plans. Nonetheless, these organizations' experience still sheds some light on the strengths and weaknesses of the MAA's definition of medical necessity. The experience of managed care organizations should prove especially useful as the MAA and the rest of the state moves to managed care regime. To collect data on that experience, we interviewed key respondents from a broad variety of such plans and payers throughout the state.

This section is organized into four parts. In the first, we note the methods we used to select and interview respondents. In the second, we summarize our findings with regard to the formal definitions of medical necessity operating throughout the state. We review respondents' perspectives on the purposes and elements of their organizations' definitions of medical necessity. The third contains an overview of common implementation processes. Lastly we draw some implications for the MAA's definition in the coming managed care era.

Methods

With the assistance of the MAA staff, we collected a list of experienced informants from prominent Washington State health care organizations. Through group discussion, two investigators assembled a sample from that list that represented commercial fee-for-service insurers, commercial managed care insurers, staff model health maintenance organizations, claims management companies, public insurers,
and representatives of provider groups. The size of the populations covered ranged from ten thousand to several hundred thousand and the organizations spanned the state from the Kitsap Peninsula to Spokane. Within any given organization, we tried to identify a variety of perspectives. For example, at plans we tried to interview the medical director, an administrator responsible for utilization review, and a practicing physician.

We sent a project summary letter to all potential respondents. The letter described the purpose and methods of the project. We then contacted the respondents by telephone and arranged a period of about an hour for the interview. Actual interview times ranged from 35 minutes to 2 hours. To ensure honest and forthright replies, respondents and the organizations they represented were promised confidentiality. Almost all the interviews took place in the respondents’ offices around the state, though a few took place by telephone because of scheduling conflicts. We conducted 24 interviews at 11 organizations in all.

The interviewer used a semistructured protocol (Appendix A) and data request form (Appendix B) to gather information on the definition and implementation of medical necessity, though questions were adapted to reflect the type of information any particular individual could be expected to provide. All organizations but one were able to provide copies of at least one operating definition of medical necessity, and most were able to provide example guidelines, preauthorization lists, and flow charts. Unfortunately, data on denial rates and cost analyses were most often unavailable, either because the organization had not compiled them or the respondents felt they were proprietary information.

**DEFINITION OF MEDICAL NECESSITY**

Respondents provided a total of 19 different definitions that their organizations employed. A fairly typical one reads as follows:

Medically Necessary (or Medical Necessity)--the service or supply meets all of the following criteria:

1. It is required to diagnose or treat the condition, and the condition could not have been diagnosed or treated without it.
2. It is consistent with the symptom or diagnosis and treatment of the condition.
3. It is the most appropriate supply or level of service that is essential to the employee's or dependent's needs.
4. When applied to an inpatient, it cannot be safely provided on an outpatient basis.
5. It is appropriate with regard to good medical practice.
6. It is not primarily for the convenience of the employee or dependent or provider.

The fact that a service or supply may have been furnished, prescribed, recommended, or approved by a physician or other provider does not, of itself, make it medically necessary. A service of supply may be medically necessary in part only.

Definitions were generally drawn from coverage contracts between insurance carriers and policyholders. Health maintenance Organizations (HMOs) sometimes had no formal definition of medical necessity.

**Purpose**

Respondents held widely varying opinions about the purpose of any definition of necessity and some even doubted that defining medical necessity served any useful purpose. Insurance company administrators and medical directors had perhaps the clearest point of view. They saw the definition as drawing boundaries around the sort of claims that the plan risked paying. The purpose of the definition is to communicate those boundaries to the patients and physicians with whom the company contracts to serve as legal protection in case of disputes. As one administrator put it, "Insurance is all about risk. If the carrier is going to assume some risk, it has to know what it is at risk for and so do the policyholders. That is what the definition of medical necessity does."

Conceiving of medical necessity restrictions as a form of carrier cost control is the logical extension of this viewpoint. Yet most of the respondents were hesitant to attribute that purpose to the definitions they employed. Even line physicians of managed care plans often said cost was external to the concept of medical necessity.
However, when pressed, most respondents thought that administrators with their eye on the bottom line could and did use medical necessity as a mechanism of cost control. Interestingly, skepticism abounded as to the effectiveness of limiting overall costs by denying unnecessary care. Even many utilization review staff thought that this at best shifted the care elsewhere in the medical care system, often to services for which the individual carrier was still liable. Instead, they saw the much larger forces of increasing technologic intensity and an aging population as driving costs.

Other respondents thought the purpose of the definition was to protect patients from receiving unwarranted, unnecessary, and potentially dangerous services. They pointed to the usual exclusion of experimental and investigative procedures as evidence. One utilization review nurse said, “Sick patients are really quite vulnerable to the promise of a cure, whether that promise is really there or not. The definition [of medical necessity] makes sure we don’t pay for promises that the provider can’t keep.”

Many respondents were quite cynical about whether a general definition of medical necessity could serve any useful purpose. Though admitting that the theoretical purpose was to communicate the boundaries of risk, they pointed out that few providers or patients had any familiarity with the contractual definition of medical necessity that governed their interactions. Even an occasional plan administrator admitted that he or she was not nearly as familiar with the general definition as with the implementation procedures. Nurse and physician reviewers routinely reported ignoring the very general provisions of the definition in favor of procedure-specific guidelines. Some said that the definition only came up during appeals and litigation and noted that courts tended to interpret the definitions broadly regardless of their wording.

One operations manager at a large commercial insurance carrier thought it was time to do away with the term medical necessity entirely. She thought the term was “overloaded and counterproductive” and should be replaced with noncoercive guideline development. She cited a definition developed by National Institute for Health Care Management that replaces the term with outcome-based standards of coverage (NIHCM,
1994). Several staff members from the HMO that operated without a
formal definition echoed this sentiment: "[The] general definition has
to rely on the evaluation of process, and we want to be responsible for
outcomes."

Elements

Though most respondents did agree upon a very few basic elements
of the definition medical necessity (though what they meant by those
elements seemed to vary somewhat), there was widespread disagreement
over how to build upon these basic elements. Elements mentioned
included appropriateness, patient preference, costs, cost-effectiveness,
community standard of care, level of service, decision-making authority,
exclusion of investigational procedures, and preventive care exclusion.
Despite some conceptual overlap, we address each in turn.

Appropriateness. Virtually all the respondents agreed that any
definition of medical necessity should exclude procedures that were
inappropriate, though few provided their own definition of
appropriateness. Most researchers take appropriateness to mean that the
medical benefits outweigh the risk, specifically excluding financial
considerations (Kahan, 1994). Some respondents thought that
appropriateness was all that any definition should include. One managed
care medical director said that physicians at his plan thought of
"medical necessity as a pristine medical concept, very much in the
doctor's realm and not the administrator's."

Language in the definitions themselves usually addressed this
element only tangentially with phrases like "consistent with the
symptoms, diagnosis, and treatment of the patient's condition," or "it
is required to diagnose or treat the condition, and the condition could
not have been diagnosed or treated without it." None of the definitions
addressed the standard of scientific evidence that should be applied in
evaluating a procedure's appropriateness or effect on outcome.

Patient Preference. Some respondents felt strongly that patients
should have a voice in determining the necessity of a procedure and
others felt just as strongly that they should not. One primary care
physician practicing primarily in a fee for service setting pointed out
that the utility of many procedures was strongly modified by patients'
preferences regarding health states. He gave the example of an airline pilot with a cataract that only marginally affected his night vision. Removing the cataract might be judged unnecessary for most patients, but necessary for the pilot. Respondents with the opposing point of view pointed out that patients should pay for preferences that exceeded a more objective medical necessity standard. The language of the definitions we collected most often addressed patient preference only the negative sense, e.g., "not primarily for the convenience of the patient."

Cost. Many respondents were quite vehemently opposed to including cost in the consideration of medical necessity as illustrated in the medical director's comments above. Such respondents were often surprised to find that the contractual definition included cost as an element. Usually the definitions subordinated cost to appropriateness or effectiveness. Typical wording might characterize a medically necessary service as the "least costly of the alternative levels of service or supplies that are adequate and available" or "the least costly of equally effective procedures."

Cost-effectiveness. A common point of view among several utilization review nurses held that considering cost alone does not go far enough. A slightly less effective but much less costly procedure should qualify as medically necessary over the slightly more effective but much more costly one. The use of magnetic resonance imaging (MRI) when computed tomography (CT) might suffice was a frequently cited example. Several respondents cited with approval Oregon's plan to limit the provision of marginally cost-effective services to Medicaid patients, though as we will see in Section 4, this probably represents a misunderstanding of the Oregon process. None of the definitions we reviewed included any language that explicitly addressed cost effectiveness.

Community Standard of Care. Several respondents, particularly medical directors, thought that the most important element in defining medical necessity was a reference to the community standard of care. Typical contractual wording might state that a necessary service must be "generally performed or accepted by the medical profession" or be consistent with "good medical practice." They felt such standards
preserved the autonomy of the medical profession as a group while allowing for imposition of reasonable standards upon individual practitioners ordering unnecessary procedures.

**Level of Service.** Most definitions specify that a procedure is unnecessary if it can safely and effectively be performed at a lower level of service. Such provisions apply to a variety of circumstances. They can preclude hospitalization where less expensive outpatient services would have sufficed or they may be used to deter referrals to specialists where primary care providers could deliver the desired service. Sample criteria include: "When applied to an inpatient, [the service] cannot be safely provided on an outpatient basis," or "[the service] is the most appropriate level...essential to the patient’s needs."

**Decision-making Authority.** The more stringent definitions of medical necessity reserved the final authority for determining whether particular services met the standard outlined to the carrier. Weaker provisions simply remove such authority from the providing physician, while stronger ones further reserve the right to make the determination in the office of the medical director. For example, "The fact that a service or supply may have been furnished, prescribed, recommended, or approved by a physician or other provider does not, of itself, make it medically necessary....The...Medical Director has final authority to determine medical necessity."

**Investigational Procedures.** Service contracts regularly exclude coverage of investigational procedures. However, medical necessity did not always form the basis of the exclusion. Provisions barring experimental therapies sometimes appeared as part of the definition, sometimes appeared independently, and sometimes were incorporated into the list of covered and noncovered services. Almost all respondents agreed that coverage should exclude experimental therapies, but like the contract language, they disagreed as to why. Quite a few thought many such procedures represented necessary care in desperate circumstances, but that insurance carriers, public or private, should leave their funding to research programs. Others, particularly those that strongly believed in the community standard of care element of the definition, conceived of necessary services as the minimum level of care accepted by
the local medical community. Such respondents saw experimental and investigational procedures as frills that exceeded any reasonable community standard.

**Preventive Services.** Some service contracts exclude the coverage of preventive services. When they do, the reasoning for the exclusion may rely upon wording in the definition of medical necessity. One publicly funded carrier's medical director pointed out that the definition requires the carrier to pay for the care necessary to treat a condition, and preventive care does not treat a condition. Other respondents, particularly those that worked in managed care organizations, disagreed. They felt that the word condition should be interpreted broadly to mean even nascent illnesses or genetic predispositions and that preventive care was necessary to treat such conditions.

It is difficult to integrate these elements into a single commonly accepted definition of medical necessity operating across the state. Some standard of appropriateness seems the favored candidate for such a title, though clauses mandating the lowest reasonable level of service also received widespread support. Almost all the other elements lacked anything approaching consensus. Even where there was a consensus that carriers should not pay for certain classes of procedures, for example investigational procedures, there was no consensus as to whether medical necessity provided the rationale for denying such claims. Cost and cost effectiveness divided respondents sharply. Many administrators thought that working financial considerations into the definition would provide their organization with more flexibility in controlling abuse, while many providers, including medical directors, opposed such an approach as an intrusion upon professional autonomy. While many of the advocacy groups had expressed a strong desire to include patient preference in the definition, plan and provider groups were deeply divided on this point as well.

In the midst of this lack of a consensus, there was one area of agreement. Interviews revealed a near unanimity of opinion that the individual elements of the definition of medical necessity had become more stringent with time. Particularly over the last 5 years, carriers and plans had begun inserting clauses that increased the contractual
basis for denying claims, and decreased the grounds for appeal on the part of the patient or provider. Most, however, doubted that the definitional changes had any effect, per se, on reducing costs or reducing the rate of unnecessary claims. Instead, our respondents thought that if any monetary savings accrued from medical necessity review, the savings had instead arisen from changes in implementation procedures.

IMPLEMENTATION OF THE DEFINITION

As we noted when discussing the MAA's definition, no definition of medical necessity operates in isolation. For the definition to have an effect, it must engender a detailed set of procedures to follow for the staff charged with implementation. The relationship of the definition to the implementation process varied dramatically across organizations. Some definitions referred explicitly to a set of guidelines or committees responsible for guideline production. Similarly, definitions occasionally referred directly to an appeals process to resolve disputes or for defining experimental therapies. In others, the review process seemed to operate completely independently of the definition. Indeed, one organization had an extensive review process in the absence of any formal definition.

Respondents agreed that the degree of stringency of the definition had little to do with the stringency of the implementation procedures. In fact, the most stringent definition we discovered in our research was supported by a very open-ended implementation. This particular organization covered a small population relative to the others and had little staff devoted to medical necessity evaluation. Only a small proportion of all claims were evaluated at all and denial rates for those that were evaluated were reportedly quite low.

Overall, two different but not mutually exclusive patterns of implementation procedures emerged from our interviews, a claims-based review and a physician-based approach. We consider each pattern separately, though a few organizations employed hybrid implementation techniques.
Claims-based Review

The first pattern was a claims-based approach in which reviewers attempted to evaluate individual claims or services to generate a decision as to their necessity. The MAA implementation process falls into the claims-based review category, as do the processes of most of the traditional fee-for-service commercial carriers. Essentially, this approach employs a pyramidal review system to either review requests for services before the service is rendered (preauthorization) or retrospectively (utilization review). Successive levels of reviewers apply standard criteria to judge whether a particular claim meets the standard of medical necessity. Most denials emerge at the lower levels and often result from procedural considerations (e.g., insufficient information on the indications for the requested procedure). As the claim ascends the hierarchy of review from software to nurse reviewer to physician consultant to medical director, the rate of denials decreases. A sample flow chart is appended (Appendix X). Proponents of this system of implementation tout its thorough and consistent approach. Opponents criticize its bureaucratic complexity.

Criteria Development. The process for development of the criteria that the various levels employ varies greatly in sophistication and rigor. A few of the smaller organizations relied predominantly on implicit review. Nurses or physicians collect information about a particular claim and judge its necessity based on their expertise alone without the aid of specific agreed upon criteria. This was less common in larger organizations. Instead, most of the organizations we surveyed employed written review criteria for at least some procedures. Medical directors usually took the lead in the development of criteria, often but not always with the assistance of outside consultants. For larger carriers, the guidelines often originated at the national level and underwent modification locally. Medicare maintains a CD ROM database of policies for local carriers to use when constructing their own criteria. In no case did we encounter written criteria based upon formal metanalyses or appropriateness panels, though one organization used a software package from Value Health Sciences that incorporates the results of several appropriateness panels. Criteria development often did include a less rigorous review of the relevant literature, however.
Preauthorization. The list of services requiring preauthorization tended to include costly procedures and those with the potential for abuse. A typical list is attached as (Appendix E). For example, certain carriers required preauthorization for all elective admissions because these were viewed as much more costly than the alternative outpatient care. Weight reduction programs and plastic surgery often appeared on preauthorization lists. Carriers wished to reduce the rate of potential abuse for such procedures, as patients often desire them for cosmetic purposes that ignore medical necessity criteria. The review process for procedures on the preauthorization list was often quite similar to that for retrospective claims reviews that reach the nurse reviewer level (detailed below).

In general, respondents thought that the proportion of procedures denied preauthorization was declining due to a cumulative sentinel effect. Line physicians reported that they had realized the nature of the criteria that individual carriers apply and had restricted their requests to those that satisfy the criteria. In many cases, preauthorization forms that incorporate the review criteria have hastened this sentinel effect. In other cases, informal discussion between physician reviewers and providers who frequently ordered the test had a similar effect.

Utilization review. For claims reviewed retrospectively, the first evaluation of medical necessity is often a set of software screens. These software packages can be purchased commercially (Claimcheck is common brandname) and perform functions that go beyond evaluating medical necessity (e.g., claims bundling or coverage issues). With regard to medical necessity, the software often screens for obvious violations of the definitional element of appropriateness by searching for a mismatch between diagnosis and procedure. For example, the software may mark a claim for a cardiac catheterization for further review in the absence of diagnostic codes indicating heart disease.

Utilization review staff examine claims for a selected subset of procedures and apply either their own expertise or written criteria sets to render a judgment of medical necessity. The proportion of all claims reviewed for medical necessity is probably less than 10%. The first level usually consists of utilization review nurses who usually
only deny claims based on procedural grounds. For example, one criteria set for breast reduction surgery asked for copies of the medical record of 2 visits at least 2 months apart in which the patient is documented to complain of back, neck, or breast pain. If the claim is not accompanied by such documentation, the nurse reviewer may send it back for more information. In some larger organizations, there may be a second level of nurse reviewers who issue more substantive denials.

However, in most organizations, substantive denials based on medical necessity criteria are the province of physician consultants who review the recommendations of this first level before any notice is sent to the claimant. Our respondents felt that less than 15% of the claims that nurse reviewers examined were referred for consultant reviews. The medical consultants often review claims only within their clinical specialty. The medical consultants are almost always familiar with the written criteria sets pertinent to the procedures in their usual scope of activities, but they have the latitude to stretch the criteria if they see fit. Many consultants routinely called the claimant’s physician to informally discuss aspects of the cases that might have escaped initial evaluation. Like the MAA medical consultants, our interviews suggest that physician consultants’ rate of upholding the decisions of the lower levels varies greatly. Estimates from various respondents ranged from a 30% to 70% reversal rate of denials.

The medical director usually supervises the work of both the nurse reviewers and physician consultants. In smaller plans, the medical director does much of the application of medical necessity review criteria. In larger plans, the director confines his or her activities to deciding appeals. Appeals usually arise after a denial by one or sometimes two different physician consultants and make up less than 0.1% of all claims. In some plans, an appeals board’s consideration either precedes or oversees the medical director’s judgments. All plans have a state-mandated appeals process that allows patients or physicians to appeal denials based on medical necessity to an outside panel of experts. Appeals of decisions of public plan administrators go through a similar process of administrative law judge (ALJ) review as the MAA. Our respondents felt the ALJs frequently reversed the denials by plan administrators, but no data were available.
Reasonable data on denial rates by category were unavailable. Respondents either said they did not collect the data or that proprietary rules forbade their disclosing it. The only exception was Medicare denial rates discussed in Section 2. Nonetheless, it was a common subjective impression that denial rates were decreasing with time. Some attributed the decline to a sentinel effect as described for procedures requiring preauthorization. Others felt that physician capitation had changed the incentives for providing care so as to make the provision of unnecessary care unprofitable.

Cost Savings. Little quantitative data are available on the cost savings that claims-based review yields Washington payers. One claims review company estimated that every dollar spent on their utilization review process saved $3-$5 for programs not previously subject to any review and $1.50 to $2 for established programs. A large commercial insurance carrier estimated that its review process saved the company about $100,000 each month out of a volume in the tens of millions of dollars annually. The methodology behind these estimates was proprietary information so it is difficult to assess the reliability of the estimates or to know whether they took into account the paperwork burden imposed upon patients and providers.

Physician-based Review

As managed care and capitated payment arrangements proliferate, traditional pyramidal review systems of the sort just described have begun to give way to the more decentralized physician-based approach. Plans operating under this paradigm involved physicians in the development of guidelines for medical necessity evaluation. Plans then profile physician practices to determine how well the physicians in the plan follow the proposed guideline.

Guideline Development and Dissemination. The purpose of this activity is very similar to the development of review criteria in the claims-based paradigm, but the process of development differs. A group of physicians selected by the medical staff review the literature and suggest a guideline for evaluating the necessity of a certain procedure. They may also base the guideline on models from other organizations. The organization then circulates the guideline to the entire medical
staff for comments. After revision, the medical staff approves the
guideline. In practice, a few physician-administrators’ conception of
medical necessity can dominate this seemingly democratic process. The
guidelines are then disseminated through conferences, newsletters, and
orientation to new providers. Even organizations that rely primarily on
the claims-based approach may still use these educational activities to
disseminate medical necessity information.

Physician Profiling. This process varied greatly in purpose and
 sophistication between plans. Some plans simply calculated charges per
patient and compared physician cost profiles to one another without
regard to medical necessity. Others still relied on cost profiling but
controlled for physician specialty, and patient age and sex. Physicians
with high cost profiles may suffer financial penalties. Perhaps the
most relevant sort of profiling involved ranking physicians by the rate
at which they complied with a particular clinical dictum, for example,
influenza immunization rates for their panel of patients. These rates
are then either compared against an ideal standard (e.g., 100% immunization of patients over 65) or to the performance of other
similarly situated physician practices.

Incentives. The incentive structure for physicians sharply
distinguishes the two paradigms. Physician-based review essentially
never denies an individual service requested by a given patient and
physician. Physicians may order whatever service they personally deem
medically necessary. Some plans rely on physicians’ desires to practice
medicine in a manner similar to their colleagues. “Doctors are
conservative people. In general, they don’t want to be the odd man out.
It doesn’t take much feedback to get them to regress to the mean,” said
one managed care administrator. Others rely on more explicit goal
setting and/or financial incentives. This set of incentives for
reducing the rate of unnecessary procedures contrasts with the claims-
based regime’s reliance on the “hassle factor” of justification and
repeated denials. Proponents make much of physician-based paradigm’s
allegiance to the Total Quality Management (TQM) ideas so popular in
general business management. They claim that this approach maximizes
physician and patient autonomy while minimizing bureaucratic costs.
Opponents claim that it places physicians in the morally conflicted
situation of determining medical necessity when they possibly have a financial stake in the outcome of that determination.

We found great variation both in the formal definition of medical necessity and its implementation. Respondents could not agree upon common elements that should comprise any general definition. Many doubted the utility of a general definition of medical necessity given the complexity of the implementation process and preferred to rely on more specific clinical practice guidelines. A large majority saw utilization review as a method of implementing the definition of medical necessity fading in importance as more and more patients throughout the state received their care under capitated arrangements. Instead, they anticipate that capitated physician groups will implement their own concept of necessity by monitoring their own utilization.

IMPLICATIONS

Our investigation of Washington State payers' and providers' definitions of medical necessity and their implementation revealed several disparate trends. There was little consensus beyond appropriateness as to what elements constituted the proper definition of medical necessity. Carriers' attempts to incorporate more restrictive clauses into that definition have had little obvious effect on the stringency of its implementation. This is not to say that the implementation has been irrelevant. At the same time, two different implementation paradigms with strongly contrasting structures, processes, and incentives have arisen. Proponents of neither regime can produce reliable data that show it to be more effective than the other at reducing unnecessary care, promoting necessary care, or even at saving money.

In such an environment, the implications for MAA's definition are not entirely clear. If policymakers take a middle road in the construction of a new definition of medical necessity, it would not be unreasonable to include clauses addressing the elements of appropriateness, level of care, and exclude investigational procedures. A clause making clear that a physician's prescription does not guarantee medical necessity would certainly be in the mainstream of current
practice. So would one precluding physician or patient convenience as a primary argument for medical necessity.

Perhaps more important than the constitution of the definition are realistic expectations of the effect of any change. Our interviews revealed little relationship between the definition itself and cost or quality of care. Indeed, one successful HMO operated without any awareness of a definition entirely. Much larger forces than the definition of medical necessity drive medical costs. Though our economic analysis (Section 5) can only scratch the surface with available data, it is clear from our interviews of other payers that expectations of large cost savings based upon a more restrictive definition alone are probably unrealistic.

Choosing an implementation strategy will probably have a greater effect on both cost and quality than the formal definition. Again, the intersection of the two paradigms makes drawing implications difficult. What many payers around the state have chosen is a hybrid regime that reviews individual claims for a few expensive or sensitive procedures and promulgates guidelines and physician profiling for the vast majority of care rendered. Our analyses would suggest that as capitated arrangements become more and more common, physician financial risk assumption places the incentive squarely in favor of not ordering necessary tests on the margin. Such a transition will probably make intricate and extensive claims-based utilization review less and less relevant. Claims-based review is primarily designed to detect unnecessary overutilization rather than the opposite threat of underutilization posed by capitation.

As a final note, it is also important to remember that the organizational goals of MAA may be very different from the predominantly private payers and providers surveyed. The MAA is an insurer of last resort with a large population of disabled clients. Policymakers must realize that this population is particularly vulnerable to the threat of underuse of necessary medical services when deciding upon a medical necessity definition and implementation policy.
SECTION 4: OREGON HEALTH PLAN

INTRODUCTION

The health care system serving Oregon’s Medicaid population provides a unique environment for studying how the concept of medical necessity influences clinical practice. The system combines three components not found in any other Medicaid program: (1) a formal definition of medical necessity by the State; (2) a benefits package based on explicit prioritization of services; and (3) a delivery system that depends almost solely on managed care. How these factors interact determines what care is given. It is not clear, however, how the concept of medical necessity influences managed care plans which receive capitated payments and are obligated to provide a predetermined benefits package. Since Washington State desires to expand their Medicaid program, while simultaneously using a managed care delivery system and a State-level definition of medical necessity to constrain costs, it is important to evaluate Oregon’s experience in how providers determine medically necessary services. In the following section, we will look at the Oregon Demonstration Project and how the State, managed care plans, and individual providers define and implement the concept of medical necessity.

The Oregon Medicaid Demonstration Project

The Oregon Medicaid Demonstration Project was designed to expand Medicaid eligibility to Oregon residents with family incomes below the Federal Poverty Level and pregnant women and children under age six with incomes up to 133% of the Level. The Project, adding about 120,000 covered persons to the Medicaid rolls, was part of a more comprehensive solution to providing health insurance to Oregon’s uninsured population, estimated in 1991 to include a total of 400,000 to 450,000 persons. Both the private and public sector were to be affected by five inter-related state legislative acts:
1. The Oregon Medicaid Demonstration (SB 27) extending Medicaid eligibility by explicitly prioritizing benefits for legislatively determined coverage and by increasing access to care through enrolling Medicaid patients in pre-paid health plans or through utilizing primary care case managers.

2. The Health Insurance Partnership Act (SB 935) initially encouraging and later requiring employers to provide health coverage to employees and dependents.

3. The State Health Risk Pool Act (SB 534) for persons who are unable to obtain private health insurance due to pre-existing conditions and who are not eligible for Medicaid.

4. The Health Resources Commission Act (SB 1077) establishing a review commission to control health care costs.

5. The Health Insurance Reform Act (SB 1076) establishing rate bands and limiting rate increases in small group plans in order to make health coverage more affordable to small businesses.

To date, the Oregon Medicaid Demonstration, the Health Insurance Partnership Act, the Health Insurance Reform, the State Health Risk Pool Act, and Health Resources Commission Acts have been implemented. The Insurance Partnership Act was passed by the Legislature and may possibly be implemented in 1996 if an ERISA exemption is given by the Federal Government.

Prior to implementing the Demonstration Project, Oregon had about 180,000 Medicaid patients in managed care. Beginning in February 1994, 120,000 additional patients were expected to enter the system over eighteen months. Within 6 months, nearly 90,000 had done so. Another 60,000 to 65,000 aged and disabled patients, already covered by the state’s Medicaid program, will begin to enter the managed care system in 1995. Eventually, nearly 350,000 patients will be enrolled. At present, approximately 255,000 Medicaid eligibles are in the OHP managed care program.

Under the Demonstration Project, Oregon’s Medicaid population receives health coverage, which includes an explicit benefits package, and health services within a capitated managed care system. The benefits package is defined from a prioritized list of
condition/treatment pairs. The state legislature determines the extent of covered benefits and this overall funding decision sets the benefit package and provides the method for calculating capitated premiums. The health plans in the managed care system are either fully capitated health plans (FCHP’s) or partially capitated plans known as physician care organizations (PCO’s). Capitated plans are available in all but eight counties. Patients choose their own managed care plan based on availability within a geographic area. The choice is assisted by and done through HealthChoice, a non-profit firm which is not financially involved with any of the health plans. In areas where neither type of managed care plan is available, patients may enroll under a Primary Care Case Manager (PCCM). As of June 30, 1994 the Oregon Health Plan system had 16 FCHP’s serving nearly 162,000 OHIP patients, 4 PCO’s with nearly 16,000 patients, and 442 PCCM’s with about 2,700 patients. Dental Care Organizations (DCO’s), currently serving about 50,000 persons, are also part of the managed care system.

A major component to Oregon’s Medicaid managed care system is the oversight provided by the state. The Office of Medical Assistance Programs (OMAP) is responsible for ensuring that enrollees can access health care when needed and for determining whether the care is appropriate and necessary. This latter determination is difficult for a number of reasons including: (1) the inherent ambiguity in the medical necessity definition; (2) whatever definition exists must be implemented by the individual plans with state oversight; (3) it is unclear how individual plans implement medical necessity; and (4) it is unclear how to measure compliance with the existing definition of medical necessity. Moreover, state oversight of plans requires a new perspective within the framework of managed care, given a structured benefits package. It is unknown to what degree the concepts of medical appropriateness and necessity, which were originally developed to constrain services and ensure quality within an indemnity-based health delivery system, will influence provider behavior under managed care.

This project is not meant to be a comprehensive analysis of the Oregon Health Plan but rather will focus on the changing nature of medical necessity and its influence on care at the state and plan levels. We looked first at how the state and plans define medical
necessity. We then examined how the state and plans implement their definition(s) and how implementation has influenced denials and appeals and legal challenges. This section will also briefly discuss how the Demonstration Project has affected access to health care and whether care received by OHP patients within the managed care system is different from that received by commercially insured patients. Finally, we briefly describe (1) how plans promote cost-effective behavior and (2) problems emerging for plans and providers under the Demonstration Project.

STUDY DESIGN

Using the semi-structured interview guides noted earlier, we conducted interviews with health plan medical directors (or their representatives), health plan utilization review personnel, and state employees in the Office of Medical Assistance Programs (OMAP). Information was collected by phone or direct interviews during September, October, and November of 1994. OMAP provided the interviewer with a list of all fully-capitated (FHCPS) and partially capitated care plans (PCOs) that serve Medicaid patients (n = 20). Primary Care Case Managers (PCCMs), because they are not members in fully or partially capitated plans, were not included in interviews. Interviews were completed with seventeen Medical Directors or their representatives. Two plan directors did not return phone calls and one plan director was unable to complete an interview due to time constraints. The 17 plans participating in our study cover nearly 90% of all OHP patients enrolled in managed care. Many of the directors are primary care physicians in the health plans that they direct. Interviews were also conducted with employees of the Oregon Medical Physician Review Organization (OMPRO), with the director of Oregon's Medicare Claims Administration and with members of the Health Services Commission.

DEFINITION OF MEDICAL NECESSITY

At the State Level. The Office of Medical Assistance Programs codifies that which is "Medically Appropriate" 11 as:

11 Oregon Health Plan Administrative Rules, p.4.
*Services and medical supplies, including dental services and supplies, which are required for prevention, diagnosis or treatment for sickness or injury and which are:

(a) Consistent with the symptoms of a medical condition or treatment of a medical condition;

(b) Appropriate with regard to standards of good medical practice and generally recognized by the medical scientific community as effective;

(c) Not solely for the convenience of an Oregon health Plan Client or a provider of the service or medical supplies; and

(d) The most cost effective of the alternative levels of Medically Appropriate service or medical supplies which can be safely provided to an OMAP Member or PCCM Member in Contractor’s or Primary Care Case Manager’s judgment.*

"Medically Necessary Services and Items" are defined in the Department’s General Rules12 as:

"Those services and items that are required for diagnosis or treatment of illness, or injury, and which, in the judgment of the Medical Assistance Program, are:

(a) Consistent with the diagnosis and treatment of the patient’s condition, and

(b) Appropriate with regard to standards of good medical practice, and

(c) Not primarily for the convenience of the patient or a provider of services or supplies, and

(d) The least costly of the alternative supplies or levels of service which can be safely provided to the patient, and

(e) Will significantly improve the basic health status of the client.

"The fact that a licensed practitioner or other professional or provider prescribes, orders, or recommends, or approves a service or item does not, in itself, make the service or item medically necessary."

12General Rules, p.36
Interviews conducted with representatives from OMAP indicate that the current definitions of appropriateness and necessity are perceived as inadequate for an explicit benefits package administered within a managed care system. The definitions were originally developed to control for overuse in an indemnity payment system, and interviewees pointed out that any new definition (or at least its implementation) must focus on ensuring that plans do not overly economize and restrict access to care or deprive enrollees of needed care. Thus, under a capitated environment, the functional definitions must address the theoretical and practical issue of underuse. It is for this reason that the state is defining specifically what care is necessary for plans to administer (e.g., immunizations, preventive care) so that monitoring of the plans can be based on established guidelines (see implementation, below).

The potential problem of underuse is particularly worrisome because exceptional-needs patients (e.g., the physically and mentally disabled) are due to enter the OHIP system early next year. Issues such as the need to foster independent living are not well-addressed by current definitions of medical appropriateness and necessity. State officials are concerned that individual plans may skimp on needed supplies or durable medical equipment or not show enough flexibility in allowing the patients access to such services. One official illustrated the problem in discussing wheelchair allocation: although a patient is usually allowed one wheelchair (i.e., an electric wheelchair), an exception may be made for a second (nonmotorized) wheelchair if that allows a patient to remain independent within his or her house rather than renovate the entire house to allow mobility with the electric wheelchair. Clearly, this type of decision is not one of medical necessity and is more an issue of social independence. Thus, at issue is how to define and implement "socially-necessary" care, which as one interviewee put it is "care that allows a patient to remain independent within their community".

While state representatives indicated that there are no indications that plans are promoting underuse, OMAP is working with the plans to define in practical terms what basic services are to be given to current state enrollees and to future exceptional needs patients (see
below). Also, the state and plans are working together to provide a database on service access issues and on patient satisfaction. These practical measures are explicit and take precedence over the general definition of medical necessity because the general definition does not provide sufficient guidance in a managed care system. The state is working with the plans to develop consensus on what care to provide.

At the Plan Level. Interviews conducted with seventeen medical directors indicate that definitions of medical necessity and appropriateness have little influence over their daily activities. Only three medical directors (or plan representatives) knew of a formal written definition available to them. None actively used the definition in most contacts with plan physicians. Only two directors stated that a formal definition was given to providers or members. Some plan directors, however, did mention that a definition might be "somewhere in a legal contract" between themselves and the various insurers.

The available definitions were similar in most respects to the state's definition. The medical directors stated that any formal definition generally addressed legal contractual obligations and aimed to allow insurers (including plans) to exclude services determined to be experimental, cosmetic, or self-serving (for provider or patient). An example from one of the plans follows:

"Medically Necessary: Services and supplies which, in the judgment of (the Plan), are required for diagnosis or treatment of sickness or injury and which are:

a. Consistent with the Symptoms or diagnosis and treatment of a medical Condition;

b. Appropriate with regard to standards of good medical practice and generally recognized by the medical-scientific community as effective;

c. Not solely for the convenience of a Member or a provider of the services or supplies;

d. The least costly of the alternative supplies or levels of service which can be safely provided a Member in (the Plan's) judgment. For a Hospital Inpatient, it means that services or supplies are essential and cannot be safely provided in other than a Hospital
inpatient setting without adversely affecting the Member’s Condition or
the quality of medical care rendered; and

e. For the treatment of an existing disease or existing health
problem."

A second example, similar to the definition from a large
commercial insurer, is as follows:

Services, treatments, procedures, prescriptions or supplies that are:

1. appropriate and necessary for the treatment of symptoms,
diagnosis or treatment of an illness, disease, accidental bodily injury
or condition harmful or threatening to the member’s life or health;

2. provided for the diagnosis or direct care and treatment of an
illness, disease, accidental bodily injury or condition harmful or
threatening to the member’s life or health;

3. within the standards of good medical practice within the
organized medical community;

4. not primarily for the convenience of the member, the member’s
physician or another provider; and

5. the most appropriate supply or level of service which can be
safely provided.

While the definitions provided some guidance, the medical
directors who knew of such definitions, noted that the terms used to
define appropriateness and necessity are not well-defined themselves.
Such terms as “safe”, “cost-effective”, “standards of good medical
practice” and even “cosmetic” and “experimental” are interpreted
differently from physician to physician and plan to plan. In practical
terms, it requires case-by-case management to define what constitutes
medical necessity for a given patient with a specific set of clinical
problems or further study to determine when a new technology transmitted
from being experimental to being a “standard of care”. Further
confusing the practical applications of the definition, for example, was
that even if a new technology was not experimental for one type of
service (i.e., autologous bone marrow transplant for certain leukemias), it might be considered experimental for another type of service (i.e., autologous bone marrow transplant for stage 4 breast cancer). General definitions of appropriateness and necessity do not provide much guidance on such complicated issues.

In those plans lacking a formal definition of appropriateness and necessity, medical directors cited essentially the same reasons as given above for not having a definition. What is interesting about this is that, in fact, all plans who enroll OHP patients are governed by OMAP's definition. Clearly, however, the definition plays a negligible role in defining services. In effect, the state does not appear to be using its own medical necessity definition. In discussing this with plan directors, the consensus was that general definitions, whether from the plan or state, are inadequate at best for helping plans decide what care to give. That decision is primarily a function of physicians acting prudently (which in most cases they are assumed to do) within the constraints of specific insurance contracts. Only relatively infrequently do the medical directors need to research "medical necessity" for a proposed service or patient. In the case of state patients, the benefits package spells out exactly what is covered and what is not. Thus, in most instances, medical necessity remains undefined and services are rendered under contractual obligations.

IMPLEMENTATION OF MEDICAL NECESSITY

At the State Level

State officials noted that, in practical terms, any definition of appropriateness and necessity was subsumed by what was funded on the Prioritized List. Even such services as transplants and coronary artery bypass grafting were determined at the plan level. The representatives further stated that OMAP was "going out of the business" of defining case-specific medically necessary care, except for the small number of patients still in the indemnity delivery sector.

The Prioritized List was developed using the following underlying characteristics as a guide: (1) prevention of death; (2) cost of alternative treatments; (3) alphabetical prioritization (equally effective condition/treatment pairs were prioritized by which came first
in the alphabet); and (4) public values. Effectiveness was not a component because in initially determining what constituted "effective" treatment, survey participants were asked to compare completely healthy states to partially healthy states (those with some form of disability) and the results were challenged under the Americans with Disabilities Act. In constructing the List, cost considerations were generally important but some conditions warranted expensive treatments because alternative managements were not considered as effective in preventing death. Specifics regarding the creation of the List are beyond the scope of this document and further details are available from OMAP.\textsuperscript{13}

The Prioritized List acts as a treatment guide. It codifies condition/treatment pairs, listing them from highest to lowest expected benefit, and allows rational dollar allocation based on legislatively derived decisions on how much medical care can be covered.\textsuperscript{14} Yet, while the funded portion of the Prioritized List defines coverage, it is a proxy for, but does not truly define, appropriateness and necessity. Just because a service is covered does not mean it is appropriate or necessary for every patient and just because a service is not covered does not mean that it is not appropriate or necessary for some patients. An example frequently given is treating a paraplegic patient's sprained arm (not usually covered for OHP patients). However, the state covers this treatment under its "co-morbidity" clause because non-treatment might decrease independence (and lead to complications from being bedbound). Thus, some nonfunded ("below the line") items may be medically appropriate for some patients.

Since the implementation of the Demonstration project the state has operated a Benefit RN Hotline for providers and plans. Three registered nurses answer a total of approximately 80 calls per day. Between April and June 1994, 97\% of questions were about where a condition/treatment pair was to be found on the list.

The state now primarily depends on capitated plans to implement needed care and the general perception is that managed care's financial incentives will ensure minimal wasteful health expenses. By

\textsuperscript{13} See Waiver Application, Oregon Medicaid Demonstration Project submitted by the Oregon Department of Human Resources. August 1991. 
\textsuperscript{14} The 1995/1997 per capita costs and capitation rates are being calculated by a public accounting firm, Coopers & Lybrand.
decentralizing case-specific oversight, the state has freed up considerable human and capital resources. Since retrospective review and preauthorization of services are no longer done, except for patients with Medicaid indemnity insurance, resources are now being shifted to quality assurance (QA). The emphasis in QA is in developing total quality improvement (TQI) methods to identify and correct problems. Methodologies will include surveys, chart audits, and site visits. The state will also review contractors' written procedures and criteria for OHP enrollees. Aspects of care to be reviewed include provision of preventive care\(^1^5\), adequacy of record-keeping, referral procedures, medication reviews, appointment system and after-hours call-in system, arrangements for emergency services and out-of-plan utilization. In addition, OMAP will monitor patient complaints and certain adverse or unexpected outcomes for OMAP members.\(^1^6\) OMAP has also contracted with the Oregon Medical Professional Review Organization (OMPRO) to assess quality of and access to medical and dental care in managed care delivery systems\(^1^7,1^8\).

According to OMAP officials, the above issues will be even more important as Oregon incorporates Phase II patients with “exceptional needs” into the managed care system. This patient population includes children under foster care and those with special needs, as well as elderly, physically disabled, and blind Medicaid recipients. Mental health and substance abuse patients will also be covered. Many of these patients will need services that will allow them to live or work independently, that is, “socially-necessary care”. For these populations, OMAP and the plans have begun to define protocols for ancillary services (see Appendix 2) and durable medical equipment.

\(^1^5\)Details on adult and child preventive services can be found in the Oregon Health Plan Medicaid Demonstration Project Quarterly Report: April - June 1994; Appendix: Tables 1 - 5.
\(^1^6\)For more detailed information, see Oregon Health Plan Medicaid Demonstration Project Quarterly Report: April - June 1994; attachment 17.
\(^1^7\)Op Cit., attachment 16.
\(^1^8\)Services to be monitored include obstetric care (c-sections, low birthweight babies, addicted mothers, fetal deaths), diabetic care, children and adults with special needs, adult preventive services (mammograms, pap smears), children preventive services, emergency room use, chemical dependency screening, mental health (medications), and child and adult encounter care.
Whether these protocols will succeed in properly serving the Phase II population is unknown.

At the Plan Level

Since most medical directors are unaware of any formal definitions of medical appropriateness and necessity, it is reasonable to assume that few plan physicians are familiar with or are using a formal definition in their clinical decision-making. Plan medical directors universally stated that they, as plan physicians, and their colleagues judge what is medically appropriate and necessary on a case-by-case basis.

When a question arises about a specific case decision, the usual method is to determine first if the insurer covers the service and then ask if the service is necessary for the particular patient. In other words, plans determine appropriate care by allowing case-specific management within explicit contractual obligations. Since providers generally know what is contractually available to a patient, clinical decisions often include the first step of the process and the clinical pathway continues unimpeded.

Almost every medical director noted that when there is a question of coverage, personnel familiar with the contract (either at plan or insurer level) review the request for service. Non-covered services are denied. Covered services are either assumed to be appropriate and are accepted (no review) or undergo prospective utilization review (e.g., preauthorization). This relatively unstructured process occurs regardless of whether the insurer is Oregon or is commercial. Alternatively, services are reviewed retrospectively and determination is reached whether the service was covered. If the practitioner who gave the service is outside the plan (e.g., a subspecialist consultant or an emergency room) the service may not be reimbursed. Within the health plans, however, retrospective review is used more for education and training purposes. It is worth noting that non-capitated practitioners and services are more closely monitored and are often subject to preauthorization.

Not all services are either clearly covered or not covered by the written specifications of the contract. In this case, the insurers or
health care plan first decide whether or not the service is appropriate and/or necessary for the patient. If the service is determined to be necessary then the next question is whether the contract can be used to cover that decision. This general technique seems to be used by almost every health plan, although the method for reaching the decision may differ between health plans.\footnote{For instance, one area where the question of coverage frequently emerges is in the use of "experimental" technologies. Two of the largest fully capitated plans use a regional committee to decide when a new technology (e.g., autologous bone marrow transplant for stage-four breast-cancer patients) is no longer experimental. Another large health plan formally specifies the process that a Director must take to determine whether a technology or procedure is appropriate. The process was described as follows: (1) collect patient's medical records; (2) assess all contract language relevant to case; (3) review subject literature through MEDLINE and library search; (4) review any literature provided by patient and/or patient representative; (5) Consult with local or national experts if appropriate; (6) Assess medical and legal information on the issue; (7) Document decision and reasons for decision in writing in file; and (8) keep claim file and all medical literature for future review.}

In some instances, providers will determine that a service is medically necessary even though it is not covered by the contract. According to the medical directors who described this scenario, any among the following might occur: (1) an exemption in the contract is found prior to providing service; (2) a plan covers the service itself; (3) the plan refuses to provide the service; or (4) the patient pays for the treatment. This process occurs regardless of who is the insurer, although OHP patients may take the decision to arbitration (see below, under denials and appeals).

Apart from defining contractual obligations, plans vary on how they constrain physician behavior to ensure that services are appropriate and necessary, at least as cost-effective as possible. Some plans strongly constrain behavior through numerous prospective and retrospective utilization reviews (UR), while other plans have minimal organized oversight. Although it is beyond our scope to describe each plan’s utilization review methods an overall view may be helpful.

Most medical directors stated that their plan has some form of review process. Several plans use written standard-of-care protocols (e.g., for diabetes, hypertension, elevated cholesterol) based on national and/or local consensuses. About half the plans use
preauthorization procedures for day surgery, referrals and a variety of diagnostic or therapeutic procedures. About one-third of respondents stated that utilization review criteria are derived from actuarial firms, such as Milliman & Robertson, InterQual, and OMPRO. Some plans focus on areas that are prone to overuse (e.g., laboratory testing, certain radiological procedures such as CT or MRI scans, sleep studies, and cardiac procedures). Other areas include drug utilization, especially for medications that may be misused, are expensive, or are given out in high volume; examples given include nonsteroidal anti-inflammatory drugs for muscular and arthritic pains, ulcer medications (particularly H2-Blockers such as Tagamet or Zantac), nicotine patches, growth hormone, and Vitamin B12 injections.

Most plans look carefully at surgical procedures that have a cosmetic component. Examples include blepharoplasties (eyelid surgery) and breast reduction. These are not entirely excluded from coverage but providers must detail medical reasons for doing the procedure. Almost every plan monitored or required authorization for outside non-capitated consultants, laboratory tests, and therapeutic procedures.

While most plans use utilization management techniques, according to many directors the incentives inherent in a capitated environment are prompting a change in the way UR is conducted. A central theme that emerged from interviews was that plans are moving away from preauthorization of procedures and tests and toward using practice guidelines, provider education, and provider profiling (e.g., calculating cost per patient per month) to implement change and limit unnecessary or inappropriate services. Plans are also relying more on quality improvement programs with provider participation and with feedback to improve overall care and cut costs.

DENIALS AND APPEALS
At the State Level

As the state has moved from an indemnity payment plan to a managed care system with defined coverage, quality management has shifted away from reviewing cases and denying coverage. In the small fee-for-service sector that remains, OMPRO representatives note that the denial rate for services remains similar to the rate prior to implementation of the
Demonstration project. That rate is approximately 1%\textsuperscript{20} and is apparently not dependent on whether retrospective or prospective review is used nor on the stringency of the review protocol. The low rate is probably due to: (1) an educational effect where physicians learn what is considered appropriate or necessary; (2) a sentinel effect of having a review process; and (3) a gaming effect where physicians learn how to bypass the system; and (4) the difficulty in second guessing providers about what is medically necessary without actually seeing the patient. The low rate does not mean that utilization review based on Oregon's current definition of medical necessity is unhelpful in controlling costs, however, because the educational and sentinel effects may reduce the rate of unnecessary services. But the size of this hypothesized effect is unknown.

State-issued denials have been rare because there have been few appeals to OMAP to overturn plans' decisions. As of June 30, 1994, OMAP had received only four requests for coverage of a noncovered condition involving comorbid problems; two requests were denied. Thirty-four requests were received for "grandfathering" and twenty-seven were approved. Legal challenges (see below) have been few, as well.

\textbf{At the Plan Level}

There are few official denials because most managed care plans do not have a formal, wide-reaching review processes, and fewer still actually quantify their denial rates (or were willing to give them to us). Most directors, when directly asked, stated that fewer than 5% of requests are denied. One plan, with very aggressive prospective utilization review methods, did not have more than a 7% to 8% denial rate. These overall percentages include contractual denials which, according to most directors, are about half of the total. No medical director was willing to disaggregate the percentages or provide actual numbers of denials based on medical necessity alone.

The official rate may underestimate the true number of services that are denied to patients because of educational or sentinel effects. We also cannot estimate which denials are appropriate and which are not.

Furthermore, almost every director clearly stated that economic incentives inherent in managed care minimize the number of cases that need formal review and consequently actual denial rates may underestimate the overall effect of a capitated environment on reducing unnecessary services. Almost every director stated that real savings in Oregon accrue because of managed care, not because of the Prioritized List and not because they or their providers use a general definition of medical necessity.

It is unclear what the denial rate is for OHP patients because it is unclear what denial means, in the context of an explicit benefits package; If we assume that every request made by a practitioner to provide a service that is not covered is denied, then the rates are probably high. This is because many condition/treatment pairs that are not covered (e.g., lower back pain, common cold) are often treated symptomatically for commercially insured patients. Many directors pointed out that their providers sometimes had a hard time turning down patient requests for these and other similarly noncovered services, and instead deferred the decision to not treat to the plan. This rate, however, would not include denials made directly from a provider to a patient. So, informal “denials” may be high even though plans or providers may simply be adhering to the funded portion of the prioritized list.

LEGAL CHALLENGES

At the State Level

Challenges to a coverage denial are not necessarily a legal dispute, but in almost every case represent a perceptual dispute between plans and patients on what constitutes appropriate and/or necessary care. Even if a plan and OMAP deny a service, patients can appeal the decision and request a hearing on whether the service is necessary in their case. According to state officials, there have been no court challenges as of October 1994. However, as of June 30, 1994 there were thirty hearings requested by OHP patients enrolled in the managed care system. The following table\(^\text{21}\) summarizes the information.

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\(^{21}\)Modified from Oregon Health Plan Medicaid Demonstration Project Quarterly Report. April - June 1994; p.34.
To date all the above and all newer cases have been adjudicated at the Department of Human Resources' hearings.

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<thead>
<tr>
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<th>January 1 - June 30, 1994</th>
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<tbody>
<tr>
<td>No. of Requests Received</td>
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<tr>
<td>No. of Hearings Held</td>
<td>12</td>
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<tr>
<td>No. of Hearings Pending</td>
<td>11</td>
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<tr>
<td>No. of Hearings Dismissed</td>
<td>15</td>
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<td>Claimant no show</td>
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<tr>
<td>Claimant Withdraw</td>
<td>1</td>
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<tr>
<td>Plan Withdraw</td>
<td>12</td>
</tr>
<tr>
<td>No. of Hearings Affirmed</td>
<td>2</td>
</tr>
<tr>
<td>No. of Below Line Issues</td>
<td>19</td>
</tr>
</tbody>
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A recent challenge regarding whether circumcision is necessary for an asymptomatic child merits review because of its potential impact on covered services. This case was settled by a hearings officer in favor of the claimant on the basis that circumcision (not covered for asymptomatic males) reduces the risk of future cancer of the penis. The hearings officer stated that the service should be covered under preventive care. If upheld on appeal, this decision may eventually cause adjustment to covered services under the Prioritized List.

At The Plan Level

Although several directors complained of state interference with how plans decide coverage (based on the List), there is no indication that the state is reversing a large number of provider decisions. In addition, directors all stated that they knew of no court challenges against their plan or any other plans.

Other Methods of Controlling Costs

At the State Level

The state is limited in how it can control its costs under the managed care system. Currently, it does so through the explicit benefits package from which provider payments are calculated. In the future, the state can choose among four primary methods to reduce costs, including: (1) reduce the number of Medicaid eligibles; (2) reduce the reimbursement rate to providers; (3) reduce the number of funded items on the Prioritized List; or (4) generate revenues through co-pays and deductibles. As the state increases its Medicaid eligibles, it will be
left with choosing from among the latter three options. However, choosing the second option may force plans to opt out of the OHP managed care network for financial reasons. The third option may or may not be politically tenable. However, reducing what is covered will almost certainly increase the denial rate at the plan/provider level. This may raise the number of appeals if patients or providers do not agree with the new cut-off point for care.

At the Plan Level

Apart from formal utilization review, there are other means used to control costs. Although a general review is beyond the scope of this study, we present some of the methods stated by medical directors. These include: (1) contracting for specific outside services (e.g., two plans stated that they contract out coronary artery bypass grafting to hospitals that charge a set rate for the entire package); (2) restricting the drug formulary (fairly common among plans) which may include preauthorization for certain expensive drugs, limiting certain medications to specialists, only carrying one or two drugs of a specific class of medications, and generic substitution; (3) limiting services for physical and occupational therapy; (4) comparing physician utilization patterns (profiling) to identify and correct the clinical behavior of physicians who overuse laboratory tests, radiological procedures and durable medical equipment.

For OHP patients, plans may decrease potential catastrophic costs by purchasing a catastrophic insurance plan from the state. The policy, available at several different levels of deductibles, protects plans from overwhelming costs generated by one or many severely ill patients (outliers). Many plans have opted for catastrophic insurance but some of the large plans are self-insured.

It is important to recognize that financial incentives within managed care tend to emphasize "wellness". In other words, keeping patients well means less money spent on costly acute care. This may increase upfront costs to, say, better control a diabetic or hypertensive patient or to spend extra effort on child care and immunization programs. However, managed care programs should in theory benefit from these upfront costs by avoiding future acute problems or
late complications of various diseases. There are sparse data on whether this actually is the case.

PROBLEMS AND POTENTIAL EFFECTS

At the State Level

Several unwanted systemic effects may occur because of implementation of the Oregon Demonstration project. First, the number of Medicaid eligibles may increase as persons from other states move to Oregon to benefit from coverage. There is to date no indication that this is occurring to any large degree. Second, employers who provide health care coverage to low-wage workers may drop insurance coverage if their workers and families are covered by the Oregon Health Plan. Alternatively, employees who have the option of receiving state insurance coverage or employer coverage may opt for the OHP if their wages are higher without the employer benefit. The Department of Human Resources is currently evaluating the extent of this problem. Third, without implementation of the Health Insurance Partnership Act, Medicaid eligibles may become caught in a "welfare trap". Workers may opt away from taking low-paying jobs that raises a family above the eligibility limit but causes the loss of subsidized health care coverage.

Several other potential unwanted effects should also be mentioned. First, it was initially feared that the combination of limited primary providers and large numbers of new patients might strain available services, particularly in rural areas where physician density is generally lower than in urban areas. This has not been the case, but extending OHP to exceptional-needs patients may yet prove problematical and overtaxing to providers and/or plans. Second, by creating a Contract (Funded portion of the List) the state might inadvertently cause a two-tiered system with care differences between commercially-insured and state-insured managed care patients. Every medical director, however, stated that they believe that care is essentially the same (although contractual obligations necessitate some minor differences). Most directors also stated that differences in coverage are somewhat offset by the fact that OHP patients are fully covered with no deductible or co-pay. Some directors felt this might actually
provide unequal access in favor of OHP patients. There are no data to support this supposition.

**At the Plan Level**

Various problems were noted by plan directors, although few problems dominated all discussions. Some problems were described by a majority of directors. These included: (1) a higher emergency room (ER) use rate by OHP patients, probably because many OHP patients used this delivery method prior to having health insurance; (2) the delay between when an OHP patient enrolls in a plan and when the plan can begin education and assign a primary provider (this may promote early ER use for which the plan must pay); (3) patients not re-enrolling in the plan every six months, which means that the plans cannot reap the benefit of receiving capitated payments while the patient is well (service needs are biased toward sick patients who need more services); and (4) cultural and educational differences have at times made the transition from episodic care to continuous care more burdensome to plans.

**CONCLUSIONS**

1. Oregon has definitions of medical necessity and appropriateness but these provide almost no guidance as to what care should or should not be given. Rather, the explicit coverage package provided by the covered portion of the Prioritized List subsumes the definitions.

2. Few health plans have definitions of appropriateness and necessity. For the most part, providers decide what is appropriate and necessary in an unstructured manner.

3. Provider decisions are constrained by insurers’ contractual obligations and, to varying degrees, by plans’ utilization management methods. In the case of OHP patients, contractual obligations are specified by the funded portion of the Prioritized List.

4. Official denial rates under managed care are low (< 5%). This is probably due to economic incentives in managed care that tend to implicitly constrain resource use.

5. The denial rate for OHP patients is unknown because many denials are merely “explanations” that the service is not covered.
6. Although cost-savings based on the formal denial rate may be
low, the sentinel and education effects from utilization management
methods may have some impact. The size of such effects is unknown and
potential savings cannot be calculated from available data.

7. According to plans' directors, managed care incentives
generate far more savings than relying on the Prioritized List or on
definitions of medical necessity.

8. Under the paradigm of managed care, Oregon is becoming
cconcerned with defining medical necessity to prevent underuse of
services.

9. In areas where the state feels medical necessity needs
defining and monitoring, they and the plans have worked to implement
explicit guidelines. These guidelines are often based on specific
methodologies or guidelines found in the medical literature.
SECTION 5: MEDICAL NECESSITY IN UTAH, MINNESOTA, AND NEW JERSEY

This section describes and assesses the approaches to medical necessity that are being utilized by three state Medicaid programs, Utah, Minnesota and New Jersey. RAND researchers made initial contacts with officials at each state Medicaid program and obtained the current definition of medical necessity as well as detailed documentation regarding how the concept of medical necessity is implemented in program operations. A written request for further information then was sent to the state, a sample copy of which is enclosed as Appendix F. RAND project members received and analyzed documentation regarding medical necessity and then conducted telephone interviews with at least two Medicaid program officials in each of these states, including those responsible for maintaining or implementing the concept of medical necessity in program operations. Researchers also contacted representatives from the state medical associations to obtain further information regarding the evolution and implementation of medical necessity review in the Medicaid program. Finally, follow-up interviews were conducted with officials in each state to assess how the definition and implementation of medical necessity in the state Medicaid program is likely to evolve in the near future.

UTAH

Medical Necessity Definition

The following definition of medical necessity is utilized by Utah Medicaid (Utah Administrative Code, Sec. R414-13x-1, 1994).

"A provider must furnish or prescribe medical services to the recipient only when, and to the extent that, it is medically necessary. A service is 'medically necessary' if it is (1) reasonably calculated to prevent, diagnose, or cure conditions in the recipient that endanger life, cause suffering or pain, cause physical deformity or malfunction, or threaten to cause a handicap; and (2) there is no other equally effective course of
treatment available or suitable for the recipient which is more conservative or substantially less costly."

Implementation and Analysis

The Utah Medicaid program is statutorily mandated to monitor medical necessity of services under the Medicaid program. This mandate is articulated in the Utah Code Annotated, Section 26-18-2.3(1): "The division shall deny any provider claim for services that fail to meet criteria established by the division concerning medical necessity appropriateness. The division shall place its emphasis on high quality care to recipients in the most economical and cost-effective manner as possible, with regard to both publicly and privately provided services."

In response to the above state mandate, Utah has implemented formal and rigorous medical necessity review program that focuses on controlling utilization of costly services via prior authorization. Explicit, written utilization review criteria are utilized primarily for high cost, inpatient surgical procedures. These medical necessity criteria for each service specify whether providers must call in for prior authorization via telephone or submit paper documentation regarding medical necessity. Services requiring prior authorization include arthroscopic surgery, hysterectomy, laparoscopy, carpal tunnel surgery and organ transplants. Finally, detailed written guidelines are utilized by the agency to monitor appropriateness of inpatient admissions and continued stays.

Medical necessity criteria in this program were developed to control utilization of high expense services. However, Department officials indicated that there have been some problems enforcing denials for medical necessity because some courts have recognized a presumption in favor of the attending physician’s medical judgment concerning medical necessity, regardless of whether the Department’s criteria for medical necessity were met. A July 24, 1994 internal memo from the Division’s legal counsel explains that this problem stems from the ambiguity and subjectivity surrounding the term “medical necessity.” For example, a recent Utah state court decision (863 P.2d 44 [Ut. App. 1993]) reversing the Department’s denial on the grounds of medical necessity stated that "the decision of whether or not certain treatment
or a particular type of surgery is 'medically necessary' rests with the individual recipient's physician and not with clerical personnel or government officials."

That said, the Utah Department of Human Services has stated its intention to continue using explicit medical necessity criteria to the extent that Medicaid recipients continue to receive services under the fee-for-service system. The Department also has reiterated the importance of closely adhering to its written guidelines to minimize the probability that denials will be overturned as a result of legal challenges. This strict reliance on published medical criteria in Utah stands in contrast to other state Medicaid programs such as New Jersey that rely primarily on the medical judgment of medical consultant reviewers.

The Utah program does not cover investigational services. But because of financial constraints, the program is unable to conduct independent evaluations to determine which services are investigational; instead, the Department relies on Medicare's list of investigational services.

The Utah Medicaid program intends to move the vast majority of its Medicaid population to capitation-based managed care within the next two years. Case-by-case medical necessity review will be discontinued except for those patients who continue to receive fee-for-service care.

Data

The Department does not collect or utilize any data regarding rates of medical necessity denials in the state Medicaid program. Further, there are very little data that has been collected either by the Department or outside groups to assess or compare utilization of medical services by Medicaid recipients. The Department has generated some data showing that savings would result from strict enforcement of its medical necessity criteria for such high expense services as bone-marrow transplants; however, RAND was unable to obtain this information from the Department. The Department has not collected, and is unaware of, any data that might indicate a differential impact on access or service utilization across categorical programs or compared to the general population. Department officials did note, however, that the
rates of appeals for medical necessity denials are relatively low, and are mostly generated by state legal aid societies.

The Shift to Managed Care

Despite its relatively aggressive attempts to control utilization of high expense services via medical necessity review, the Utah Department of Health has published detailed plans to convert the majority of its Medicaid population to capitation-based managed care in the near future. As of December 1994, 18% of Utah's Medicaid population was enrolled in capitated managed care plans, with an additional 42% enrolled in a primary care case management program.

According to officials at the Utah Department of Human Services, the Department's regulatory role will shift dramatically in the near future with the shift to capitation-based managed care. The Department intends to carefully monitor managed care systems’ prior authorization and quality assurance systems to ensure against withholding of medically necessary services. The Department intends to rely on its current definition of medical necessity in its monitoring efforts. However, its focus will shift away from “outlier-based profiling” that has been the hallmark of fee-for-service utilization review, and toward promotion of guideline-based profiling that attempts to shift the entire utilization distribution of physician services toward quality benchmarks using total quality improvement techniques.

MINNESOTA

Medical Necessity Definition

The Minnesota Department of Human Services uses the following state regulatory definition of medical necessity as the basis for determining coverage of services in the Medicaid Medical Assistance program.

“A medically necessary service must be ‘consistent with the recipient’s diagnosis or condition and:

A. [be] recognized as the prevailing standard or current practice by the provider’s peer group; and
B. [be] rendered in response to a life-threatening condition or pain; or to treat an injury, illness, or infection; or to treat a condition that could result in physical or mental disability; or to care for the mother and child through the maternity period; or to achieve a level of physical or mental function consistent with prevailing community standards for diagnosis or condition; or
C. [be] a preventative health service."

The Minnesota Health Care Programs Provider Manual goes on to state that, to be covered by Medicaid, a health service must "be appropriate and effective for the medical needs of the recipient, meet quality and timeliness standards, and be the most cost-effective health service available for the medical needs of the recipient."

As part of its state health system reform activities, the Minnesota Department of Human Services currently is in the process of developing a recommendation for a new definition of appropriate and necessary care to propose to the state Legislature. The new definition would be used as the basis for a new mandatory standard benefit package for all Minnesota insurance programs (including the privately insured, the Medicaid population and newly insured populations).

Implementation and Analysis

According to a spokesperson at the Minnesota Department of Human Services, the main purpose of the Medicaid medical necessity definition is for use as a framework for benefits coverage. The definition has not been viewed by the Department as a primary method for cost-containment; rather, the Department has been committed since the mid-1980's to shifting the entire Medicaid population to capitated managed care plans to control costs.

The Minnesota Medicaid program relies primarily on prior authorization to "safeguard against the unnecessary use of health care services....The goal of prior authorization is to assure that the proposed health service is actually needed, that all appropriate, less expensive alternatives have been given consideration, and that the
proposed services conform to commonly accepted community standards of
the profession or health specialty involved."

The Department uses various methods to monitor and control
utilization under its fee-for-service program, including coordination of
benefits, prior authorization, provider credentialing, case management
for select recipient groups, pre-certification of hospital admissions
and second surgical opinions. The Department also uses a "Health Care
Access Line" whereby nurses provide information to Medicaid recipients
calling in via telephone on how to treat minor medical problems, when
and where to seek medical care, and how to access transportation
services.

Services that require prior authorization in the Minnesota
Medicaid program include hospital beds, acupuncture, chiropractic care,
durable medical equipment, home health agency services, nutritional
services, case management services, psychotherapy, treatment of obesity,
pain management, private duty nursing, sleep studies, elective plastic
and reconstructive surgery and out-of-state services. A number of these
services would be noncovered and nonreimbursable in other states, such
as Utah, and the Minnesota program only will allow reimbursement if the
services are deemed to be medically necessary.

The agency requires prior authorization for services that are
considered investigational. The agency considers investigational
services primarily to be those identified by Medicare or Minnesota Blue
Cross and Blue Shield as investigational procedures.

Data

The Department does not collect or utilize any data regarding
rates of medical necessity denials in the state Medicaid program. The
Department also does not collect data to compare the utilization of
services across categorical programs or with the general population.
Nor are there any data showing potential differences in utilization that
might arise from changing the definition of medical necessity.

One Department official did note that implementation of a prior
authorization program for physical therapy services after utilization
thresholds are exceeded appears to have resulted in a reduction in
payments for unnecessary care. Although there were associated increases
in administrative costs to process prior authorization as well as a dramatic increase in the number of appeals for these services, the cost savings have, in the Department's view, justified the costs. The Department did cite low participation by dentists as a problem--further research is needed to determine whether implementation of prepayment medical necessity review for dental services may have contributed to these access problems.

The Department has conducted a general review of its available utilization data and testified that "in recent years, [state Medicaid] cost increases appear to be attributed more to increases in price, rather than increases in utilization. The state currently is investigating to what extent changes in the Medicaid population have influenced the utilization of services (e.g., whether eligibles in the higher income groups use services at a lower rate)." This testimony by Minnesota Medicaid officials is consistent with their stated belief that the purpose of medical necessity review is determine coverage benefits, not to control escalating Medicaid program costs.

Although RAND was unable to obtain data to confirm or quantify the trend, there is growing concern in Minnesota over the amount spent on services for persons with developmental disabilities. This system is highly regulated in an attempt to encourage providers to control costs and assure high quality service. However, the Department believes that the biggest area where improvement can be made is in reducing duplication of effort and services among agencies and providers via enhanced coordination rather than reducing provision of medically unnecessary care. The Department is working to develop an alternative service delivery system that would coordinate a broad range of services including medical care, and residential, habilitative, and support services.

The Shift to Managed Care

The Minnesota Department of Human Services has been working with the State Legislature for several years to convert the entire Medicaid population to capitation-based managed care. The state envisions that by the end of 1996, virtually all Medicaid recipients would be required to enroll in a prepaid managed care plan in areas of the state where
health plan networks exist. As of December 1994, 30% of the state’s Medicaid population was already enrolled in capitated managed care plans. These efforts currently are underway as the State Legislature contemplates statewide health care reform to expand access to the state’s uninsured via savings from converting to a mandatory managed care system.

Medical necessity review under capitation-based managed care in Minnesota is conducted to determine whether Medicaid managed care plans are fulfilling their contractual obligations to provide covered services to recipients. No prepayment or postpayment review is conducted under capitation, and prior authorization will largely be discontinued (except for the few remaining fee-for-service patients). According to Department officials, the new role of medical necessity review will be performed largely by managed care providers in the form of case management and utilization review rather than the Department itself. The role of the Department’s Quality Assurance Unit is to contract with personnel to review managed care organizations’ patient records, physician utilization profiles, immunization rates, etc., and ensure that medically necessary services are not withheld. The Department will largely no longer be concerned with overutilization, and the focus will shift to monitoring for high quality and ensuring that underutilization does not occur.

NEW JERSEY

Medical Necessity Definition

The New Jersey Division of Medical Assistance and Health Services regulations for Medicaid “apply the concept that a medically necessary service, admission, or item is that which is required for the diagnosis or treatment of a disease, injury or condition.” Further, the state regulations mandate that:

“Any service limitations imposed will be consistent with the medical necessity of the patient’s condition as determined by the attending physician or other practitioner and in accordance with standards generally recognized by health professionals and promulgated through the New Jersey Medicaid program.”
Implementation and Analysis

The New Jersey medical necessity program is fairly limited compared to the relatively aggressive approach taken in such states as Utah. The program does not rely on medical necessity as a primary means to control program costs, and the medical necessity program is conducted in a less formal manner than in the other state programs analyzed during this study. The agency relies primarily on individual determinations of medical consultants rather than formal, written criteria.

According to the Chief Medical Consultant for the New Jersey Medicaid program, the underlying purpose of the medical necessity definition is to determine benefits coverage and to make sure medically unnecessary services are not reimbursed. Medical necessity in the program is implemented by utilizing employed physicians, medical consultants, and other professional staff within their scope of practice to review cases and make determinations on the medical necessity of services in relation to the client’s diagnosis. The New Jersey program also utilizes computer system edits to deny claims based on the logic programmed into the claims processing system. These computer system edits replaced prior authorization review for several services.

Prior authorization for the following services is required under the New Jersey Medicaid program: out-of-state non-emergency hospital services, cosmetic surgery, vision care services, some podiatry services, and private duty nursing. In addition, prior authorization is conducted after utilization thresholds have been exceeded for durable medical equipment, mental health services, prosthetics and orthotics, and personal care assistance. The agency also conducts prescreening of nursing home admissions to ensure medical necessity.

Only those transplantation services provided in out-of-state hospitals require prior authorization under the program. In-state transplantation services do not require prior authorization. High expense services such as Magnetic Resonance Imaging (MRI) do not require prior authorization.

The determination of what constitutes an experimental procedure is currently based on a case-by-case review by medical consultants who conduct literature reviews, technology assessments, and communicate with centers of excellence across the country.
It is evident that the New Jersey Medicaid program officials are interested in revising the program's medical review activities. During interviews with the agency's Chief Medical Consultant, information was requested from RAND personnel by the consultant regarding appropriate contacts at other state Medicaid programs or the Health Care Financing Administration (HCFA) who could assist the agency in updating its approach to medical necessity review. The official was particularly interested in gaining access to any information technology that would allow the agency to track and compare utilization patterns of physicians for particular services.

The New Jersey Department of Human Services intends to mandate that the majority of its urban Medicaid population move to capitation-based managed care in 1995, with the rest of the state close behind. Although this is a dynamic area, the Department does not envision changing its definition of medical necessity at this time. Although the definition may remain the same, the Department intends to drop its prior authorization activities for the managed care population and rely on primary care physician case managers to ensure that only medically necessary services are provided.

The New Jersey Medicaid program appears to have relied primarily on restrictions on prices of Medicaid services to discourage utilization by providers rather than attempting to implement stringent controls on the quantity of services provided to Medicaid recipients. Although the Department has not formalized how medical necessity implementation would evolve under a capitation-based system, officials plan to shift responsibility for direct medical necessity review to primary care physician case managers in managed care networks, who would be responsible for authorizing virtually all referrals to specialists. The Department also is considering developing report cards, physician profiles, and monitoring utilization of such services as immunizations to ensure against underprovision of care.

Data

The Department does not collect or have any data available regarding utilization of medical services in the state Medicaid program. Further, the Department does not collect or utilize any data regarding
rates of medical necessity denials. Nor does it collect data to compare utilization of services across categorical programs or with the general population. Finally, there are no data showing potential differences in utilization that might arise from changing the definition of medical necessity.

The shift to capitated managed care has been much slower in New Jersey than in Utah or Minnesota. As of December 1994, only 8% of the New Jersey Medicaid population was enrolled in capitated managed care plans.

**DISCUSSION**

The three state Medicaid programs analyzed in this section have embraced different approaches to ensure the medical necessity of services. The Utah Medicaid program has implemented the most aggressive approach to medical necessity review of the three states via strict reliance on detailed, written medical necessity criteria for high expense services as a means to control program costs. The Minnesota Medicaid program also has in place a formal medical necessity program, although the agency reports that its program is primarily meant to determine which services qualify for coverage, and is not meant as a means to control escalating program costs. The New Jersey program is less comprehensive and less formal than the other states analyzed in this section, and is not used as a primary cost control tool. The New Jersey Medicaid program also apparently has relied on low prices for individual services as a means to control costs and utilization.

All three states utilize prior authorization, particularly for hospital procedures and out-of-state services. However, the types of services targeted for prior authorization in each state differ markedly. In-state physician services are largely exempt from prior authorization in all three states. In addition to prior authorization, two states (Minnesota and New Jersey) have implemented second opinion reimbursement for outpatient procedures as a means to control utilization. Both Minnesota and Utah have excluded coverage for many experimental procedures and cosmetic surgery rather than relying on medical necessity review to control utilization. The three states also differ regarding coverage of such high expense services as organ transplants, with Utah
excluding coverage for lung and pancreas transplants and New Jersey excluding coverage of any transplants for its medically needy Medicaid population.

Despite these differences, all three states have embraced mandatory capitation-based managed care for the Medicaid population as an attempt to control costs. Officials in each state responded that medical necessity will continue to play an important role in the Medicaid program, but they stated that the implementation of the concept of medical necessity will change dramatically in the near future. Officials in these states indicated they intend to discontinue prior authorization programs except for patient populations that are explicitly exempt from managed care arrangements. As the financial incentives for providers are reversed, the focus of the regulatory process will shift toward ensuring that managed care plans have adequate quality assurance mechanisms in place to ensure that medically necessary services are provided. This approach is in direct contrast to the current focus on ensuring that medically unnecessary services are not provided.
SECTION 6: FRAMEWORK FOR AN ECONOMIC ANALYSIS

INTRODUCTION

The potential economic consequences of changing the definition of medical necessity may be an important consideration in deciding what changes to make. However, it was beyond the scope of this study to assess the fiscal implications of a revised medical necessity definition or alternative standard. Instead, we set forth in this section a conceptual framework for conducting a subsequent in-depth fiscal analysis.

Economic Considerations

As noted in Section 1, most services can be precisely classified as either covered or non-covered. Each of these classifications includes some medically necessary and some unnecessary services. If the number of covered services is decreased, the space of uncovered services will increase. But the effect on total cost will depend on how medical necessity fits within covered and non-covered service spaces. Medical necessity requirements must decrease the number and volume of procedures included in the space of reimbursable services in order for savings to be realized. In the absence of severe service restrictions, it is unlikely that savings will be significant.

Figure 3 below illustrates this concept.
Requirements for prior authorization of medical procedures are expected to decrease the cost of providing medical services to the Medicaid population in the state of Washington. It is thus important to develop economic models of service utilization and cost to aid in determining how much could be saved by controlling access to care with medical necessity and how sensitive the amount of savings might be to the specific definition employed. Below we develop a framework for considering the effect of utilization containment policies on costs. We also describe the types of data which would be required to conduct a detailed cost analysis.

**Macro-economic Framework**

Total cost of services is identically equal to the price of each service multiplied by the quantity of services used and summed over the space of services offered. Total Medicaid costs are equal to the cost of medical services plus the administrative cost of review and reimbursement systems. Authorization requirements for medical necessity would directly affect the quantity of services performed and the cost of reviewing additional claims, but not necessarily the unit price of medical services. Indeed, here we can take the price of medical service to be exogenous since it is determined through a state-mandated Medicaid reimbursement rate. Authorization requirements may vary systematically with service price. For example, one approach might focus on requiring authorization only for very high cost procedures. However, the price per unit of service delivered remains unchanged regardless of the specific definition employed.

In a traditional economic model, the price and total quantity of medical services used is determined by the population's demand for medical services and the institutional willingness to supply such services. Conceptually, the introduction of medical necessity review for Medicaid claims would curtail the supply of some services, resulting in new equilibrium levels of price and quantity, as illustrated with the backwards shift in supply from S-1 to S-2 in the figure below.
Thus, a decrease in supply, all other things equal, would reduce the quantity of services used and thus, all other things equal, lower the overall cost of service provision. The size of the supply shift depends implicitly on how strictly medical necessity is defined. For example, FY93 spending on DME was $25.7 million. DME currently requires prior authorization, and 5.7% of claims were denied in 1993. Assuming equal average costs per claim, denial of DME resulted in savings of $1.5 million. Medical necessity would ostensibly increase this denial rate, and thus incur savings. But by how much? If denials increased by 5% (to 10.7% of total claims) savings would be $2.9 million. If they increased by 10% (to 15.7%) savings would be over $4.2 million. Since DME already requires prior authorization one might expect that medical necessity review would not increase denial rates as substantially as requiring authorization for items which were previously unreviewed. (These calculations are hypothetical and based only on the assumption that medical necessity review will increase the number of claims which are denied).

Similarly, about 23% of organ transplants are initially denied at the authorization level (though some of these denials are eventually overturned through appeal). FY93 expenditures on transplants totaled $9.1 million. If we take the initial denial rate for transplants as a baseline and assume equal costs per transplant, FY93 denials could have resulted in savings of approximately $2.7 million. Doubling the denial rate for transplants would save the state $5.4 million. While these figures are not trivial, it seems unlikely that substantial savings will be achieved through traditional medical necessity, even when based on
large increases in denials.

It is quite likely that medical necessity review would have effects other than simply to reduce supply. Indeed, the demand for medical services may respond to progrannmatic changes as well, and the direction of this response is not certain. For example, users may ask for more services in hopes that "something at all will be provided." Alternatively, one might observe physicians actually submitting fewer medically unnecessary claims as denials increase. This possibility is commonly termed the sentinel effect—that fewer claims will be submitted the greater the rate of denial for payment and thus demand would be reduced. Evidence of the sentinel effect has been demonstrated in many studies of physician behavior (for a survey of this literature, see Nyman, 1990).

It is likely that both physicians and beneficiaries will adjust their behavior in response to stricter authorization requirements. For example, physicians may "upcode" symptoms to make them appear more serious than is actually the case to better the odds that a treatment is authorized. It is also conceivable that both bundling and unbundling of services could be used to increase the probability that reimbursement is approved. The potential for gaming the system was explicitly noted by many Washington State physicians who were interviewed for this study. Behavioral responses to the introduction of medical necessity review will ultimately determine the size and direction of the cost response. Savings from stricter authorization requirements will only be realized if costs due to beneficiaries' and physicians' system gaming are smaller than direct savings from denial of payment for procedures deemed unnecessary.

Authorization requirements may also affect individuals' use of the public health system as well as physicians' willingness to provide services to the Medicaid population. Utilization restrictions may discourage beneficiaries from seeking care, and difficult review requirements may induce physicians to cease provision of Medicaid services. The effect of medical necessity review on participation in the Medicaid system by both beneficiaries and physicians and the various implications of such effects must also be considered in the final analysis.
Micro-Economic Model

Here we develop an empirical model which can track Medicaid costs over time as a function of changes in the definition of medical necessity while controlling for characteristics of the Medicaid population which are related to health care utilization. This model is similar to that used to analyze the effect of policy on healthcare utilization in the RAND Health Insurance Experiment (Keeler, et al. 1988).

In the model below the dependent variable is cost. Cost can be measured many ways, though most studies have found that it is best represented as a natural logarithm for estimation purposes. Costs could be analyzed from either the perspective of the beneficiary or that of the physician, by using individual or physician costs as the unit of analysis. The independent variables in such an analysis would include demographics (changing population), time, covered vs. non-covered and necessary vs. unnecessary services. One would thus like to estimate equations of the form

\[
\log Y_{jt} = \alpha_t + \beta_1 X_{jt} + \beta_2 S_{jt} + \beta_3 N_{jt} + \epsilon_{jt}
\]  

(1)

Where

- \(Y_{jt}\) = user or physician cost
- \(X_{jt}\) = patient demographic characteristics
- \(S_{jt}\) = proportion of covered vs. non-covered services
- \(N_{jt}\) = level of medical necessity review
- \(\epsilon_{jt}\) = random error term

and \(\alpha_t\), \(\beta_1\), \(\beta_2\), and \(\beta_3\) are regression coefficients. The coefficient \(\beta_3\) represents the impact of medical necessity review on log costs as \(N_{jt}\) measures the strictness of medical necessity review standards. In other words, estimation of the equation above will yield information on the relationship between cost and the necessity requirement while controlling for other characteristics such as patient age which is also directly related to health care utilization and cost.
More information can be gleaned by examining cost and utilization over time since such an approach can measure the change in cost resulting from a change in policy. Thus, it would be more useful to use time series data to further estimate equations of the form

$$\Delta \log Y_{jt} = \beta_1 \Delta X_{jt} + \beta_2 \Delta S_{jt} + \beta_3 \Delta N_{jt} + \epsilon_{jt} \quad (2)$$

where $\Delta$ denotes first differences. The structure of equation (2) is similar to that used in other studies of the effect of program changes on health and education outcomes (see, for example, Gruber (1992), Model (1993), Angrist and Krueger (1994), and Currie and Gruber (1994), among others). The results of estimating equation (2) can determine if the advent of medical necessity review (as measured with the coefficient $\beta_2$) is related to significant savings in Medicaid costs while controlling for other characteristics related cost and service utilization. Since (2) uses first differences the results can measure how cost responds to changes in policy over time.

In addition, a number of other factors may be important in determining the success of medical necessity review at controlling costs. First, medical necessity review will likely not affect outlier utilization. Outlier services (e.g., very high cost, very low volume) are generally price insensitive. Also, since other variables in the system are changing, the overall effects of medical necessity review on cost cannot be theoretically determined. A less healthy population, for example, would use more services, all other things equal. In addition, some service provision decisions are covered by federal mandates and thus are entirely out of the scope of control by medical necessity review. Federal mandates provide an effective lower bound on states’ level of service provision.

Medical necessity review would unambiguously introduce new administrative costs for healthcare. Contrary to current policy, the introduction of medical necessity review for all covered services would directly increase the overall cost of claims review. Thus, one must also compare and contrast utilization savings with the increase in costs of administration to determine the overall cost-effectiveness of incorporating medical necessity review into Medicaid service provision.
Data Requirements

Calculation of overall system costs requires data on the price and volume of services provided. Thus, it is necessary to measure the number of services of each type that are approved and denied, the price per service, and the administrative cost of claims review and reimbursement. It is also essential to fully describe the system of service approval/denial and its associated costs, e.g., variation in the number of reviewed procedures and the staff required for such review. The survey contained in Appendix B provides a description of the macro variables which would be useful for analyzing changes in overall costs.

The data which would be necessary to conduct a behavioral analysis of costs, i.e., to estimate the micro-economic equations (1) and (2) in the section above, are not currently assembled in a comprehensive form and may include elements which are not currently measured systematically. Estimation of the cost models obviously requires data on cost at the individual beneficiary, physician, and system levels. In addition to information on costs, the analysis requires information on the demographic characteristics of beneficiaries including (but not limited to) age, sex, and race, and any other health-relevant data which can be gleaned. Lastly, accurate data on the specifics of the authorization program are essential. Information on which services are covered vs. not covered, the specific definition of medical necessity employed, and the nature of the review/authorization process can then be combined into empirical measures of the authorization system. With these data, the models above can then be used to determine the overall effect of changing systems of authorization on program costs.
SECTION 7: FINDINGS AND CONCLUSIONS

MAJOR FINDINGS

The major findings from this study can be summarized as follows:

1. There is no general definition of medical necessity that will resolve all of the issues confronting the MAA and HSC. No definition we examined is sufficiently specific to eliminate case-by-case interpretation.

2. Our interviews reveal little consensus on the purpose of the definition or how medical necessity should be defined and implemented, except for including appropriateness as part of the definition. There appears to be no generally accepted definition for MAA and HSC to consider adopting.

3. Implementing medical necessity requires a great deal of labor-intensive oversight. Regardless of the stringency of the medical necessity definition, day-to-day implementation requires a process with explicit or implicit criteria to determine health care approvals or denials.

4. The MAA’s current medical necessity definition appears to be less restrictive than most other definitions we examined. A more restrictive definition is likely to save costs through reduced services and the sentinel effect, but there does not appear to be evidence to suggest that savings under the mainstream medical necessity definitions we examined have been substantial.

5. The other states we examined expect to rely primarily on capitated managed care rather than medical necessity to control costs, and Oregon also relies on its Prioritized List to constrain services. In the states we examined that have shifted the Medicaid population to managed care, primary responsibility for implementing medical necessity also shifts to the plans.
6. We observed two different implementation patterns. Commercial insurers and state Medicaid agencies use a structured process of medical necessity review. Capitated plans use a decentralized physician-based process, relying more on financial incentives than on medical necessity review.

7. The shift to capitated managed care is likely to change the MAA's role from preventing overutilization to monitoring for underutilization.

8. There are limited data on medical necessity denial rates and cost savings, either from other state Medicaid agencies, managed care plans, or Medicare carriers. But available data suggest that the initial MAA denial rates are within the range observed in other programs, and considerably higher than denial rates at managed care plans.

CONCLUSIONS

The MAA's definition of medical necessity dates from 1978. Health care delivery has changed dramatically since then, though the definition remains unchanged. Thus, it would seem to be an appropriate time to revisit the definition to determine whether it retains its validity or should be changed. Most medical necessity definitions (including the MAA's) were formulated to reduce overutilization in an acute care, fee-for-service environment. The shift to Medicaid managed care and the large chronic care population served by MAA present different problems that a revised definition should take into account.

In deciding whether the definition needs to be changed, the following questions arise. What new definition should be considered? What does the state want to achieve through medical necessity? What can the state reasonably expect a change in the definition to achieve? As part of the reconsideration, does the state also need to revisit the level and types of services now covered by Medicaid?

Purpose of the Definition

Our results suggest little agreement on the purpose of the medical necessity definition among commentators, providers, and payers. No general definition of medical necessity will be able to specify what is
medically necessary for any given condition. But a general definition can reflect the broader goals that medical necessity will help achieve, much like an organization's mission statement.

As a payer of last resort, MAA faces the conundrum of serving patient populations with often extraordinary medical needs while simultaneously meeting taxpayer expectations about how state funds will be spent. If the primary goal is to reduce costs by limiting services, then the state should consider a more restrictive definition that defines medically necessary care as crucial or indispensable care. If the primary goal is to encourage a broad array of services, then an open-ended definition, similar to the current MAA definition, should be considered. If the goal is to provide the best quality care with the least expenditure of public funds, the definition should provide the state with flexibility to constrain overutilization while retaining sufficient ability to prevent underutilization.

**Changing the Definition of Medical Necessity**

Among the many options available to Washington State policymakers, four approaches in particular could be considered. First, the state could retain the current MAA definition. Second, the state could develop a more restrictive definition of medical necessity, similar to what the HSC is now considering. Third, the state could develop an alternative approach that focuses on eliminating equivocal or marginally beneficial services. Fourth, the state could consider limiting the range of covered services now offered to Medicaid patients, perhaps similar to Oregon's approach (as discussed in Section 4). We will only discuss the first three approaches, as the fourth option is beyond the scope of this study.

Our results show that the current MAA definition is less restrictive than most definitions currently being used. If Washington State wishes to increase its ability to deny services, the definition should be made more restrictive. Bringing the definition into the mainstream of more restrictive medical necessity definitions, implementing it consistently, and shifting the Medicaid population into capitated managed care should result in cost savings to the state. A more restrictive definition may also reduce the probability of a
successful legal challenge to care denials. As such, the main
difference between a more restrictive definition and the current MAA
definition may be one of degree—the ability to sustain a denial.

But as noted in Section 6, even doubling denial rates will not
substantially reduce state expenditures. Cost savings from a more
restrictive definition are not automatic. As shown in Sections 4 and 5,
cost savings will most likely emerge from managed care incentives rather
than from the ways in which medical necessity is usually implemented.

To have a major impact on Medicaid expenditures, an alternative
approach is needed that attacks what many commentators view as the crux
of the cost problem, the provision of too many equivocal or marginally
beneficial services. The result of using most current medical necessity
definitions is to limit the number of certain services provided; in the
alternative approach, the goal is to eliminate altogether services that
are marginally beneficial. While the up-front costs of the alternative
approach are higher than implementing the mainstream definition, the
potential savings are far greater.

**Retaining the Current Definition.** For the reasons discussed above
in Section 2, retaining the current definition is unlikely to meet the
state’s cost control goals, even with rigorous enforcement. The primary
benefits to retaining the current definition are that it provides
clients with access to a broad range of services and that it
accommodates the chronic care needs of the SSI population. However, the
MAA definition appears to be more open-ended than other definitions,
making it harder to sustain denials of care. Except for advocacy
organizations, the MAA definition is widely perceived to be too broad to
be an effective cost control mechanism.

**Developing a More Restrictive Definition.** Our study reveals no
generally accepted definition nor a generally accepted format for a
definition. The following components are often used in describing
medical necessity, and can be used as the basis for a more restrictive
definition. These elements are not currently in the MAA definition
(some are included separately in the WAC), but are consistent with the
current definition being suggested by the HSC.\textsuperscript{22}

\textsuperscript{22}Quality of life indicators do not appear to be included as part of
medical necessity in the definitions we examined. Because the
First, most definitions seem to define necessity based on appropriateness, and most of the managed care plans we interviewed focus their medical care decisions on appropriateness. What constitutes appropriateness, however, is rarely specified in the definitions we examined. (As noted in Section 1, in RAND’s terminology, appropriateness is a broader term than necessity.) Defining appropriateness is thus the first step in restricting care. Many definitions appear to equate appropriate care with sound medical practice and with an established course of treatment, but it is unclear who is making these judgments or what criteria they use. This should be made explicit. The burden of demonstrating appropriateness would be on the provider or client, either of whom could be required to produce evidence from recognized scientific and medical literature that a service is appropriate in their case.

Second, many definitions state that services must be effective. Again, it is not clear in whose judgment and on what criteria this would be determined. One way to restrict care is to define effective services as those where the costs are low relative to its benefits. By contrast, ineffective care is a high cost service with a marginal benefit, and would not be provided. One problem in including cost considerations is that these are primarily constraints on the level of services and have little to do with exercising medical judgment in an individual case. On the other hand, the state could insist that for equally effective services, the least costly alternative must be used unless the provider or client could show otherwise. For example, the state could require using generic prescriptions unless supporting evidence is offered for the need to provide a proprietary name.

Third, most definitions exclude experimental care, but do not define the terms or provide the criteria used to determine whether a service is experimental. To restrict care, the state could tightly define experimental care as that which is neither FDA-approved nor has been shown in properly conducted clinical trials to substantially benefit the process of care or patients’ outcomes.

evaluation of quality of life requires inherently subjective measures, it seems beyond the scope of what medical necessity is designed to achieve.
Fourth, many definitions exclude convenient or cosmetic care. Again, it is important to specify what constitutes a convenient or cosmetic service.

As a primary consequence of developing a more restrictive medical necessity definition, clients will be likely to receive fewer services. In a managed care environment, a concern is that clients will receive fewer services than needed. This problem may be exacerbated by restricting the definition of medical necessity. Thus, a traditionally-based definition of medical necessity, as discussed above, should also include means to ensure that services shown to be effective (e.g., certain preventive measures) must be offered.

An Alternative Approach. The focus of the alternative approach would be to define necessary care restrictively as care that is explicitly shown in the medical literature to provide substantial benefits. The state would need to set forth explicit clinical criteria for determining the benefits of the proposed treatment for a given condition. As part of the contract with managed care plans, the plans would be permitted not to provide equivocal or marginally beneficial care. And, as with a general definition of medical necessity, experimental or investigational therapy would not be considered necessary.

Several different methods are already in use for developing the explicit criteria for making these decisions. The state could consider any one or a combination of these methods to implement this approach. It must be stressed that this approach is on the "cutting edge" and has not been systematically attempted in other states. Thus, there is no current model to adopt and no easy way to estimate savings relative to the current medical necessity program or to a more restrictive definition. Given the likely costs of implementing this approach, savings may not be immediate. From the MAA's perspective, this approach might be viewed as an investment in long-term cost savings.

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23 For instance, supporting data from the medical literature would be derived, in order of preference, from: (1) randomized control trials, (2) consensus protocols (national, state, or local), (3) nonrandomized but prospective trials (cohort and registry studies), (4) retrospective cohort studies (adjusted and unadjusted) and (5) observational studies.
First, Eddy (1992) has developed methods for estimating the cost-effectiveness of certain procedures and treatments. For example, he analyzed evidence on the cost-effectiveness of low osmolar contrast agents (LOCAS) relative to high osmolar contrast agents (HOCAs), and advised Kaiser-Permanente to provide LOCAs only to high-risk patients. Kaiser-Permanente has implemented the recommendation, saving millions of dollars per year (Jacobson and Rosenquist, 1994).

Second, RAND has developed methods for obtaining consensus ratings on appropriate and necessary indications for various conditions. The general RAND methods involve extensive literature reviews, consideration of specialty society practice parameter recommendations, and convening consensus panels to define and rate the appropriateness and necessity of the critical indications for a particular procedure. In this model, panelists first define indications for appropriateness and then define indications that are necessary. As noted in Section 1, RAND defines medical necessity as crucial care meeting four criteria: 1) appropriateness; 2) improper care not to provide the service; 3) reasonable chance of benefit from the procedure; and, 4) benefit to patient is not small (Kahan et al., 1994). In most of the appropriateness ratings, consensus panels have rated far fewer procedures as necessary than appropriate, as noted in the cataract extraction example in Section 1.

Third, evidence-based recommendations issued by recognized professional organizations, such as the U.S. Preventive Services Task Force, can be followed. For example, this Task Force recommends mammography for women beginning at age 50. Absent strong justification, mammography prior to age 50, while possibly appropriate, would not be considered necessary and would not need to be provided except in certain limited circumstances. But mammography beginning at age 50 would be medically necessary care.

Fourth, where there is no clinical evidence of cost-effectiveness or benefits in the literature, a process for developing a consensus between the plans and the state could be devised. One possibility is to enlist Washington State physicians and other providers in a process of defining clinical criteria based on observed outcomes from their clinical experience. This method is similar to the NIH consensus model.
of implicit review and to the methodology recently used in developing the heart failure guideline for coronary revascularization (add refs), and is designed to "fill in the gaps" in research-based evidence concerning expected outcomes from various interventions.

For example, the heart failure guideline panel identified several key questions that were not well addressed by published studies and obtained input from clinicians around the country concerning their observations and experiences. During the process, the panel identified conservative approaches from clinicians who tended to test and treat less often than their colleagues. The panel considered these conservative approaches as the "default" management strategy absent good evidence for more aggressive use of the procedure.

To implement this approach, the state would still need to define its goals and the level of benefits to be provided. It would also need to define appropriate and necessary, but the focus would be on developing explicit clinical criteria to implement the definitions. As with other aspects of implementing the HSA, such as determining data requirements, a public-private partnership could assume responsibility for establishing the criteria development process.

A potential advantage of the alternative approach is that it may provide greater protection against subsequent legal challenges. By developing a rigorous process for determining whether certain procedures, therapies, supplies, or treatments provide benefits for a range of conditions, MAA may be in a stronger position to defend a denial than by focusing on the restrictiveness of the definition as applied to individual cases. Another advantage is that it brings providers directly into the process of determining which procedures are beneficial and should be provided. In the long run, obtaining some consensus should reduce the number of requests for equivocal or marginally beneficial care. A third advantage is that it is consistent with the current emphasis on continuous quality improvement management systems. Finally, it builds upon the process already being implemented by MAA to develop explicit review criteria.

But a potential disadvantage, aside from the up-front costs and labor-intensive nature of the process, is that this approach might not be directly applicable to the severely disabled and chronic care
populations, where problems often deal with social necessity, such as keeping people independent. The process may also be used to deal with socially necessary care, as in Oregon, but it is premature to judge how well the method will function. Thus, additional data need to be collected to determine how to apply these principles to the SSI population. Another disadvantage is that there are currently limited outcomes data available to measure the benefits of various treatments or procedures (Enthoven, 1994).

**Implementation**

Any medical necessity definition is only as good as its implementation. That is, no change in the definition matters absent a commitment to implement a more restrictive definition in a consistent manner. Whatever definition is adopted should be implemented so that the request must meet the explicit criteria established by MAA. Care that fails to meet the definition and criteria should be denied, and the burden should be on the physician or client to provide justification for the requested service.

Perhaps the most important attribute of implementing any definition is the process of specifying explicit criteria for determining when a specific treatment is necessary for a given condition. The methods described above for the alternative approach can be adapted to the definition under consideration by the HSA.

Our results suggest that implementing the medical necessity program in a managed care environment may require a substantially different approach than the current fee-for-service environment. With the shift to managed care, the MAA’s role could shift from a focus on preventing overutilization to a focus on preventing systematic underutilization. Monitoring should be similar under any of the three options raised. For example, one of the state’s monitoring functions could be to measure whether immunization targets are being met.

MAA might consider whether its current structure will suffice to meet the different role expected when the shift to managed care is completed. In particular, the prospective prior authorization review under medical necessity requires different staffing, information, and technical capabilities than the retrospective appropriateness review.
undertaken by many managed care plans. The latter focuses on physician profiling to identify inappropriateness rates and targeting resources to reduce those rates. If so, the MAA and HSC might consider working with managed care plans to develop a more extensive physician profiling system so that they can identify physicians who may not be following the new definition.

**Changing Implementation.** Our review suggests several potential areas for changing implementation that MAA might consider. First, clear guidance on what the terms of the definition mean and how they should be interpreted could assist the medical necessity review process. Second, a data system for determining the numbers of appeals based on medical necessity to the medical consultants and to the medical director, along with the results (approval, denial, additional information requested) at each stage would be helpful. Third, communication between the Authorization Section, the medical consultants, and the medical director could facilitate the consistent application of criteria to a medical necessity determination. Currently, there is no system for transmitting information about the medical consultants’ and medical director’s decisions to the authorization staff, and there is little documentation of decisions reached by the medical consultants or the medical director. Fourth, a systematic analysis of exceptions to policy would be helpful. With what frequency are they occurring, and for what types of conditions or eligibility categories?

Unfortunately, our study of the other Medicaid state approaches provides little guidance for MAA. In Oregon, where the process is now dominated by reducing covered services, as well as in Minnesota, monitoring medical necessity is not seen as a priority. Instead, these states appear to be relying on capitation to monitor overutilization, and retrospective utilization review to monitor underutilization. In these states, prior authorization requirements are being reduced or eliminated. Our interviews with these agencies suggest a diminishing reliance on medical necessity to control or monitor utilization. Most of our respondents believe that cost savings will largely occur through the incentives inherent in capitated plans to reduce unnecessary medical services, irrespective of how medical necessity is defined and implemented. Thus, the other state Medicaid agencies we examined appear
to be decentralizing implementation to the plan level.

Both the second and third options suggested above can be operationalized, and choosing either alternative should permit the state to save money by narrowing the range of what constitutes necessary care. It is difficult to estimate whether denial rates would increase substantially if the definition of medical necessity were to be tightened. Perhaps more important, it is difficult to estimate the dollar value of a definitional change for a variety of reasons that we discuss below under Economic Considerations. In short, the answers depend on the implementation by managed care plans and the interactions between incentives under capitation and a more restrictive medical necessity definition.

DISCUSSION

In thinking about the specific medical necessity definition to implement, it is important to consider the internal and external constraints facing Washington State policymakers. These constraints are especially likely to create bounds on what a change in the definition is able to achieve. It is also important to estimate the economic consequences of changing the definition, as well as the legal implications.

Internal Constraints

The primary impediments to a more restrictive definition are staffing and resource constraints. Implementing medical necessity is time-consuming because it occurs on a case-by-case basis, requiring sufficient staff to evaluate requests. The inherent imprecision of the term medical necessity requires constant monitoring. To be effective, the number of procedures subject to prior authorization may need to be increased, reversing the current trend toward fewer prior authorization requirements, along with staff to process the requests. At least in the short run, a more restrictive definition, resulting in higher denial rates, will most likely increase the number of fair hearings requests and the need for MAA staff to testify. If a more restrictive approach has a sentinel effect over time, reducing requests for services, the lower number of requests may offset the need for increased staffing.
A second constraint suggested by our interviews is that there are widely differing philosophies about the MAA's role in providing services to Medicaid clients. Some clearly view MAA's responsibilities very broadly as a payer of last resort. In this view, medical necessity should be read expansively. Others, however, believed that Medicaid clients were inappropriately receiving a higher level of services than available under private insurance. In this view, medical necessity should be read narrowly. The result of the philosophical dispute is that there is no clear and consistent signal communicated to authorization staff, medical consultants, clients, and physicians as to MAA's approach.

As a payer of last resort, any public agency may be constrained in how much health care it can deny or limit. This is particularly true for the disabled and chronic care populations, who have no direct counterpart in private insurance and managed care plans. It is also important in a state with a traditional commitment to expansive coverage for indigent residents. As part of that commitment, the MAA has a broadly defined set of initiatives, including a Disabilities Initiative and a Family Policy Initiative. While there is nothing inherently contradictory between these initiatives and a more restrictive medical necessity program, it must be recognized that a more restrictive definition might well alter the type of care now provided to SSI clients.

External Constraints

Physician Participation. A constraint that is difficult to measure is the potential for fewer physicians to accept Medicaid patients if medical care requests are too closely scrutinized. The higher the denial rate, all else being equal, the lower the participation rate. As the Medicaid population is shifted to managed care, this may become less of a problem.

Federal Mandates. As a joint state-federal program, the MAA is affected by federal decisions. For example, the expansion of federal mandates will have an effect on the slope of MAA's budget increases, independent of a change in the medical necessity definitions. In addition, if HCFA issues a final rule for the proposed medical necessity
definition, the federal definition would be controlling unless the rule permitted the states to adopt different definitions.

Advocacy Groups. Our interviews suggest that advocacy organizations will not be receptive to changes in the medical necessity definition or implementation. For example, AIDS advocacy groups would oppose a medical necessity definition that would result in restricting home health care. The state should anticipate legal challenges to any changes, based on the legal issues discussed below.

Legal Considerations

There are several potential legal barriers to a more restrictive definition of medical necessity. Our initial legal analysis suggests that the state can develop and implement a more restrictive medical necessity definition without violating current law. However, it might be advisable to seek a more in-depth legal analysis from the State Attorney General’s Office.

Federal Statutes. An important legal consideration is whether a restrictive definition of medical necessity might violate the Americans With Disabilities Act (ADA) or Section 504 of the Rehabilitation Act of 1973 (Section 504).\(^2\) The issues likely to emerge are whether limitations on covered services or medical necessity would have a disparate impact on persons with disabilities, such as children with cerebral palsy and other chronic care patients, in violation of these statutes. At this point, there is no dispositive ruling or line of cases for the MAA and HSC to follow. The legal impact of these statutes remains unresolved.

Arguably, the United States Supreme Court’s decision in Alexander v. Choate, 469 U.S. 287 (1985), should provide some protection to state Medicaid agencies, at least in restricting covered services. In that case, the Supreme Court upheld a Tennessee Medicaid limitation on inpatient care to 14 days against a challenge based on Section 504. In a similar case dealing with the state’s ability to limit services to Medicaid clients, the Fifth Circuit Court of Appeals held in Rush v.

\(^2\)To the best of our knowledge, the Washington State Attorney General’s office has not undertaken an extensive legal analysis of the potential effects of these statutes on the definition and implementation of medical necessity.
Parham, 625 F.2d 1150 (5th Cir. 1980) that "...a state may adopt a
definition of medical necessity that places reasonable limits on a
physician's discretion." But in a recent case, Carparts Distribution
Center v. Automotive Wholesaler's Association of New England, __F.3d__
(1st Cir. 1994), the First Circuit Court of Appeals held that an insurer
could not exclude coverage for AIDS under the ADA because such an
exclusion would have a disparate impact on disabled persons. The AIDS
decision may affect coverage limitations rather than restricting the
medical necessity definition, but it suggests that courts may scrutinize
the definition's language to determine whether such restrictions have an
adverse impact on disabled persons.

Meeting the Standard of Care. A second legal consideration is the
extent to which implementing the definition of medical necessity will be
influenced by the legal standard of care. Physicians and plans might be
exposed to legal liability if they provide a level of care that differs
from the care provided on a given condition by other physicians and
plans. This does not mean that the services delivered must be
identical, but it does mean that what constitutes medical necessity will
be influenced by the care delivered by other providers in similar
circumstances.

A good example is with bone marrow transplants, as suggested in
the recent verdict against HealthNet for failure to provide a subscriber
with a bone marrow transplant. If, either as a result of the federal
coverage of certain types of bone marrow transplants or because other
providers have decided to cover such transplants, the failure to cover
them or to limit unduly the circumstances deemed to be medically
necessary could result in liability.

Contractual Language. Because the definition adopted by MAA and
HSC will amount to a contract with participating providers, it is
important to understand how courts have interpreted similar contractual
language. Numerous courts have considered challenges to benefit denials
based on a broad array of medical necessity definitions, but the
resulting case law is inconsistent. As a general rule, ambiguity in the
contractual language will be resolved against the insurer and in favor
of the subscriber. Thus, the language of the definition used by MAA and
HSC must be defined as precisely as possible.
Early cases appeared to favor individual litigants (see, e.g., Hall and Anderson, 1992), but recent cases appear more willing to allow the terms of the contract to control liability, hence favoring insurers. The ultimate result will depend on whether the courts defer to physicians in deciding what constitutes medical necessity or will rely primarily on contractual language between subscribers and insurers to make that determination. Because the Supreme Court has not attempted to define medical necessity (Mariner, 1994), whether the courts will eventually apply the Alexander v. Choate logic to limitations based on medical necessity remains to be seen. At present, the case results are too inconsistent to detect any trends.

Two recent cases illustrate the reality that the legal issues remain unresolved. Both cases determined whether the contractual agreement between the provider and subscriber required certain medical care to be provided. While neither case explicitly deals with the issue of medical necessity, the contrasting ways of interpreting related contractual provisions suggests the current lack of consistency across courts.

In Katskee v. Blue Cross/Blue Shield of Nebraska, 515 N.W.2d 645 (Neb. 1994), the defendant denied surgical coverage based on the conclusion that since the condition (asymptomatic breast-ovarian carcinoma syndrome) did not constitute an illness, the treatment (abdominal hysterectomy and bilateral oophrectomy) was not medically necessary under the contract. The Nebraska Supreme Court overturned the insurer’s denial because the condition constitutes an illness within the ordinary meaning of the contractual language of illness as a “bodily disorder or disease.” Once defined as an illness, the defendant was required to pay, although the court did not attempt to define medical necessity.

But in Barnett v. Kaiser Foundation Health Plan, Inc., ___F.3d___ (9th Cir. 1994), the 9th Circuit Court of Appeals ruled that Kaiser’s exclusion of liver transplantation coverage was consistent with the contractual language and with medical criteria established by Kaiser. The court upheld the exclusion as an experimental procedure, despite the

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25 Personal communication with Professor Wendy Mariner, August 17, 1994. See also, Mariner (1994).
fact that a transplant was the patient's only hope.

An issue on which the courts are split is who makes the medical necessity decision, physicians or the payer. The issue is important because many definitions include a proviso that the treating physician's determination of medical necessity is not binding on the payer. As Mariner (1994) notes, the court decisions are split, regardless of whether the payer is a state Medicaid agency or a private insurer. In one case, Cowan v. Myers, 232 Cal.Rptr. 299 (1986), the court ruled that states have the discretion to limit services based on its consideration of what constitutes medical necessity. It should be noted, however, that some cases have held the payer liable for medical malpractice where patients have been harmed by the payer's coverage decisions (see, e.g., Jacobson, 1991).
REFERENCES


Lang, D.A., "Medically Necessary Care is Not an Easy Concept to Define," LACMA Physician, April 8, 1991, pp. 19, 21, 23.


INTERVIEW GUIDE FOR PLAN ADMINISTRATORS, PROVIDERS, AND PAYERS

I. INTRODUCTION TO THE PROJECT

Responding to a legislative directive for the Health Services Commission (HSC) and the Medical Assistance Administration (MAA) of the Department of Social and Health Services (DSHS) to study the definition of medical necessity. (See attached summary.) Emphasize confidential nature of responses.

II. FORMAL DEFINITION

A. Does your organization have a formal definition of medical necessity? If so, try to obtain a copy.

1. Does it include: appropriateness/outcomes, costs, patient preference, or cost-effectiveness?

2. Is the definition linked to evaluations of appropriateness or effectiveness?

3. Has the program’s definition or implementation of medical necessity changed during the past five years? If so, when, why, and how?

4. What other elements of the definition did the organization consider?

5. What are the strengths and weaknesses of the current definition?

6. What aspects of the definition need to be changed? What changes would you recommend? Why?

7. What advice do you have for other organizations regarding the definition?

B. What is the definition’s underlying purpose (i.e., cost containment, appropriateness, etc.)? What assumptions underlie the definition?

III. IMPLEMENTATION OF DEFINITION

A. What is the process of implementing the definition?

1. Is there a written, formal process reviewers are instructed to follow? If so, try to obtain a copy.

2. Is there an informal process that actually occurs?

3. Is there a flow chart showing what happens at each stage—i.e., what happens when a procedure is denied or more information regarding medical necessity is requested?

B. Is there a separate utilization review process?
C. Are there written protocols or instructions for physicians or subsequent reviewers detailing criteria for determining medical necessity or inappropriateness?

D. In general, what information is relied on to determine medical necessity, inappropriateness, or effectiveness (i.e., patient indications, physician recommendations, guidelines, etc.)?

E. For what services is prior authorization required? Are there services that do not require prior authorization?

F. Denial rates
   1. Are data available on medical necessity denial rates (preferably by category of service) over the past five years?
   2. What percentage of claims are denied as medically unnecessary or inappropriate?
   3. Have denial rates changed over time?
   4. Are denial rates maintained by level of review (i.e., initial reviewers deny x%, medical reviewers deny y%, and the medical director denies z%)?

G. What is the process for patient appeals of medical necessity or inappropriateness denials?
   1. What is the percentage of denials overturned on appeal?
   2. Can physicians also appeal? Is the reversal rate different for physicians than for patient appeals?

H. Is there any information on legal challenges to medical necessity denials? What were the outcomes of these disputes, and how did your program respond to any such challenges?

I. What is the process for defining what constitutes an experimental or investigational procedure? Are there special processes for authorizing particularly expensive services (i.e. transplants, MRIs)?

J. Are there any data or analyses to show cost savings or expenditures generated as a result of the operational definition of medical necessity or inappropriateness?
   1. How do such cost savings or expenditures compare to those of other public and/or private insurance programs?
   2. Are there measurable sentinel effects from the medical necessity/inappropriateness process?

K. What barriers has the organization encountered in implementing the definition? How has it addressed the barriers?
   1. What aspects need to be changed?
2. What advice do you have for other organizations?

3. How can the medical necessity system be “gamed”?

IV. INCENTIVES FOR PROVIDERS TO ABIDE BY ANY DEFINITION

A. What incentives are in place for providers to abide by the medical necessity definition?

B. Physician profiling

1. Is there any physician profiling of utilization patterns to determine appropriateness or overutilization? If so, are results available? What actions are taken?

2. What are the dimensions measured?

C. Does your organization have any mechanism for educating providers as to the definition?

1. CME seminars

2. Orientation of new providers

3. Flyers/memos

V. QUESTIONS FOR THE MEDICARE CARRIER AND THE PRO

A. Similar questions about the definition and implementation of medical necessity, denial rates, and about savings realized or anticipated

B. Available policy decisions and documentation on medical necessity and appropriateness

C. Focus on process and data for determining inappropriateness

D. Dispute resolution process
APPENDIX B
DATA REQUEST

A. A list of all items/conditions removed from the prior authorization requirement
   1. Reason for removal
   2. Denial rates prior to removal

B. Data on denial rates (by type of procedure or treatment) over the past 5 years?
   1. At the initial review level
   2. By the medical review level
   3. By the medical director

C. Data on medical procedure or treatment for the 10 most expensive treatments/procedures
   1. Are clinical criteria/guidelines for appropriateness used for these procedures? If so, how were they determined?
   2. Is prior authorization required for these procedures
   3. Are there formal review criteria for these procedures?
   4. What are the denial rates for these procedures?
      (a) At the initial review level
      (b) By the medical reviewers
      (c) By the medical director
   5. How have denial rates changed over the past 5 years?
   6. Have exceptions to policy been granted for these procedures?
   7. What is the total number of each procedure performed?
   8. Has the list of the 10 most expensive conditions changed over the past five years?

D. Data on experimental or investigational procedures
   1. Definition of what constitutes an experimental or investigational procedure
   2. Appropriateness criteria
   3. Denial/authorization rates
4. What is the process for determining whether to cover experimental or investigational procedures?
   (a) Are there formal criteria?
   (b) How do the criteria interact with medical necessity?

5. Are medical necessity determinations for these procedures handled differently from other authorizations? If so, how?

E. Are non-covered services provided if medically necessary?
   1. If based on medical necessity, who makes the decision?
   2. Is there an available estimate of the number or costs of non-covered services provided as a result of medical necessity?

F. For C-Sections, coronary artery bypass grafts (CABG), and MRIs, if not covered above
   1. Is there information on appropriateness criteria, or on the process for determining when and whether to approve?
   2. What are the denial rates?
   3. How many are approved per year?
   4. Whether these were first denied as experimental or investigational, and if so, when and why that determination changed?

G. Does --- have any educational programs for participating physicians or medical consultants explaining ---'s concept of medical necessity?

H. Data on the following durable medical equipment: orthotics, prosthetics, manual wheelchairs, wheelchair repair, power wheelchairs
   1. Are clinical criteria/guidelines for appropriateness used for this equipment? If so, how were they determined?
   2. Are there formal review criteria for this equipment?

I. A list of all items/conditions removed from the prior authorization requirement for durable medical equipment
   1. Reason for removal
   2. Denial rates prior to removal

J. Are there any available data on high volume, low cost items such as laboratory tests
   1. Are clinical criteria/guidelines for appropriateness used for these procedures? If so, how were they determined?
2. Is prior authorization required?

3. Are there formal review criteria?

4. What are the denial rates for these procedures?
   (a) At the initial review level
   (b) By the medical reviewers
   (c) By the medical director

5. How have denial rates changed over the past 5 years?

K. Data on realized or anticipated cost savings through the use of medical necessity

L. Tracer conditions—lab tests, CABG, PTCA, etc.
Services Which Required Prior Authorization in FY 1993: MAA

Adult Apnea/Sleep Disorders Evaluation and Clinic Services
Apnea Monitoring
Chronic Pain Clinic (n req in 1991)
Dental (certain procedures)
Durable Medical Equipment (certain equipment/all rentals)
Elective Hospital Admissions (dental, medical and surgical)
Hearing Aids (second or less than 50 decibel loss)
Home Health (certain circumstances)
Hospital Length of Stay Extensions
Intravenous Therapy
Infant Phototherapy
Magnetic Resonance Imaging
Nonformulary Drugs
Nutrition Diet (weight loss program)
Organ Transplants
Orthotics and Prosthetics
Out-of-state Care
Pain Clinic
Physical Medicine and Rehabilitation
Physical Therapy (after initial 10 sessions)
Respiratory Services, Equipment, and Supplies
Specialized Eye Care
Speech Therapy (after evaluation and initial 12 treatments)
Supplemental Enteral Nutrition
Transportation (except for ambulance)
Ventilator Services
Exceptions to Covered Services

Source: Annual Report Fiscal Year 1993 Medical Assistance Administration, Washington State Department of Social & Health Services
Sample Preauthorization List

1. AICD Placement
2. ECMO (Extra Corporeal Membrane Oxygenation)
3. Ilizarov Procedure
4. Cochlear Implant
5. Stereotactic Radiosurgery
6. Chemotherapy
7. Reduction Mammaplasty
8. Augmentation Mammaplasty
9. Gastric/Intestinal Bypass
10. Abdominoplasty
11. Ventral Hernia Repair
12. Epilepsy (Seizure) Evaluations
13. Organ Transplants
   Kidney
   Heart
   Lung
   Heart-Lung
   Bone Marrow
   Liver
   Pancreas
14. Orthognathic Surgery
15. Temporomandiblar joint surgery
16. Rehab (includes Pain Clinic Programs)
17. Investigative/Experimental Procedures
Sample Preauthorization List

1. AICD Placement
2. ECMO (Extra Corporeal Membrane Oxygenation)
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10. Abdominoplasty
11. Ventral Hernia Repair
12. Epilepsy (Seizure) Evaluations
13. Organ Transplants
   Kidney
   Heart
   Lung
   Heart-Lung
   Bone Marrow
   Liver
   Pancreas
14. Orthognathic Surgery
15. Temporomandiblar joint surgery
16. Rehab (includes Pain Clinic Programs)
17. Investigative/Experimental Procedures
APPENDIX F
August 31, 1994

Dear Mr. ________: 

Thank you for the information you sent last week pursuant to our telephone conversation. It was extremely helpful. As you know, RAND is currently conducting a study of medical necessity in five state Medicaid programs, including the state of Utah. Upon completion of the project, we will be pleased to provide you with a copy of the final report.

This study will assess and compare each state Medicaid program’s definition and implementation of the concept of medical necessity. We are particularly interested in collecting any data showing differences in program utilization or expenditures that might result from changing the definition or implementation of medical necessity.

For your information, I am enclosing a summary of the project. To carry out the project, I am requesting the following information regarding the Utah Medicaid program (some of which you have already provided):

- A copy of the current state Medicaid definition of medical necessity. Is the definition of medical necessity determined by statute or regulation? Please provide any relevant citations. Is the definition linked to evaluations of appropriateness or effectiveness?

- Information detailing how medical necessity is implemented in program operations. Please provide any written protocols or instructions for reviewers detailing criteria for determining medical necessity. How are medically unnecessary services identified and denied? For what services is prior authorization required? Are there services that do not require prior authorization?

- Has the program’s definition or implementation of medical necessity changed during the past five years? If so, why and how?

- Any available data on medical necessity denial rates (preferably by category of service) over the past five years. What percentage of claims are denied as medically unnecessary? Have denial rates changed over time?

- Any available data on rates of medical necessity appeals—both at the reconsideration and fair hearing level. What percentage of denials are upheld or reversed? Have these rates changed over time?

- Any information on legal challenges or disputes to medical necessity denials. What were the outcomes of these disputes, and how did your state program respond to any such challenges?

- What is the process for defining what constitutes an experimental or investigational procedure? Are there special processes for authorizing particularly expensive services (i.e. transplants, MRIs)?

- Any available analyses that have been conducted to assess the impact of the medical necessity definition on Medicaid utilization and access to care across categorical programs.
• Are there any data or analyses to show cost savings or expenditures generated as a result of the operational definition of medical necessity? How do such cost savings or expenditures compare to those of other public and/or private insurance programs?

• Are there any data or analyses showing comparative service utilization patterns between the Medicaid and non-Medicaid patient populations?

Thanks again for your assistance in this project. Per our discussion, I will contact you again in the near future with several follow-up questions. In the interim, please feel free to contact me any time at (310) 393-0411, extension 6466 if you have any questions or wish to discuss this project in more detail. If I am not available, please contact Peter Jacobson at extension 6483.

Sincerely,

John B. Hernandez
Doctoral Fellow

Enclosure