

Regulating Medical Necessity Decision Making by Health Maintenance Organizations

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Abstract

Medical necessity and external review have become subjects of regulatory and legislative attention. National surveys of regulators and managed care plan medical directors provide a map of regulatory oversight in these areas, information about the influence of state external review regulation on health maintenance organizations, and insight into differences in opinion between these key stakeholders. Results show significant variation and clear differences between regulators and medical directors. Regulators concern themselves primarily with the decision-making process while plans focus more on clinical practice and on the scientific evidence in support of or against particular medical necessity judgments. Results suggest that better communication between regulators and medical directors could improve policies and compliance.

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The dramatic expansion of managed care has prompted both federal and state governments to take a more active role in overseeing health plan activities in recent years.¹ Medical necessity decision-making, in particular, has been the focus of both controversy and variation, and—as a result—legislative and regulatory attention.^{2,3,4} External review has been the principal way in which state legislatures and regulators have been drawn into the medical necessity issue in recent years. Variation in the way states have approached this and other forms of managed care oversight, however, has made it difficult for consumers, purchasers, providers, and health plan administrators to appreciate the effect of different government initiatives on quality and cost of care. Increasing calls for evidence-based medical care,⁵ and renewed pressure to contain health care costs,⁶ highlight the importance of appropriate legislation.

A number of studies have attempted to compare different states' approaches to overseeing major areas of medical necessity and other managed care activity.^{7,8,9} However, researchers have tended to rely on a review of recent state laws rather than examining the efforts of state regulatory agencies to implement and enforce such legislation. As a result, these studies have ignored the role of state regulators in promoting effective care management.

Our study examined the way state regulators monitor decision-making activities of health maintenance organizations (HMOs) and the way they enforce state regulations relating to medical necessity. We surveyed state regulators directly in order to assess their

priorities and perspectives in regulating different health plan activities. While we were interested in state laws in so far as they guided regulators' actions, we did not seek information that could be obtained more directly from an examination of legislation.

Our goal was to create a detailed description of state medical necessity and coverage oversight across the United States from the regulators' perspective.¹⁰ By combining the results of this survey with data from a separate survey of managed care plan medical directors, we also aimed to evaluate the influence of state external review regulation on HMOs throughout the country and differences in opinion between regulators and medical directors regarding medical necessity and coverage decisions. We believed that identifying differences among states and between states and HMOs, could facilitate the bridging of these differences and a reduction in unwanted variations.

Methods

We developed two survey instruments; one for regulatory agencies and another for managed care organizations. Both surveys asked multiple-choice questions; the regulator survey allowed some open-ended comment.

Questions for the regulator survey were divided into the following subject areas: (1) defining coverage and medical necessity, (2) general organizational characteristics, (3) strategies for managing utilization and quality, (4) contractual medical necessity standards (clinical evidence and cost-effectiveness criteria), (5) the timing of decisions, (6) coverage guidelines, (7) denial letters, and (8) external review process. Questions

prompted respondents to distinguish between their regulation of different managed care products (HMO, PPO, POS, indemnity, etc.); this article presents information relevant to state oversight of HMOs but not necessarily other products. While PPOs are now the dominant form of managed care in the U.S., HMOs are most heavily regulated. The regulator survey was designed to correspond to the survey of health plan medical directors, which we fielded at approximately the same time. Questions from the medical director survey directly addressed the first four areas studied in the regulator survey and indirectly addressed the remaining areas. We also asked medical directors about the impact of state statutes and regulations on their plan decision-making. The medical director survey similarly asked respondents to distinguish between product types if their treatment differed.

We identified a total of 65 state managed care regulatory agencies in 49 states and the District of Columbia responsible for monitoring or enforcing activity for commercial health plans in one or more of the areas addressed in the survey.¹¹ Surveys were mailed to regulators in these agencies from February to April 2001, and responses were accepted until June 2001. We also identified 346 managed care organizations operating in the 50 states and the District of Columbia. Surveys were mailed in mid-January 2001, and responses were accepted until May 2001. Details about the development, sample, and results of the medical director survey are reported elsewhere.^{12,13}

We examined responses to each section of the regulator survey in order to compare regulation of HMO decision-making by state. For states with more than one eligible agency, data from all agencies were consolidated into combined state “cases” that

reflected the total regulation in those states. We used cross tabulations to compare relationships of regulatory activity by state with related legislation, using the χ^2 test to assess statistical significance. We also analyzed responses of medical directors to relevant sections of the medical director survey to enable comparison of HMO regulatory and health plan activity and comparison of regulator and medical director opinion. .

Findings

Response Rate

We received responses from regulators in all 65 (100%) of the targeted agencies and states. Of the 346 plans surveyed, we obtained responses from 228, or 65.9%. Survey responses represented covered lives in all 50 states and the District of Columbia. The total number of covered lives represented by responding plans was approximately 119 million, or 77% of the covered lives represented by our universe of eligible plans (estimated at 155 million). A third (33%) of responding plans reported their greatest enrollment in IPA/network HMO products and another 16% reported their greatest enrollment in group/staff model HMOs, an artifact of the directory sources we used to identify the sample (i.e., mainly HMO or managed care directories).

State Medical Necessity and Coverage Oversight

Regulatory Responsibility. We identified variation in the way states delegate responsibility for regulating managed care organizations. In most states responsibility is housed in either the Department of Insurance (28 states) or the Department of Health (8 states). In some instances authority is shared between both agencies (13 states), and in

two states a separate agency is given authority (Department of Managed Health Care in California or the Department of Community Health in Georgia).

We also identified variation in the scope of state regulation of medical necessity and coverage decisions. While there is some medical necessity regulation in nearly all states, there is also no regulation in 24 states in one or more of the areas of regulation we studied. At the time of our survey, 38 states had already implemented regulations regarding the newest form of medical necessity regulation, external review.

Validity of responses. To assess the validity of regulator responses to our survey questions, we compared information we obtained from regulators about the existence of external review legislation in their state to information available in published guides about external review legislation. We also compared regulators' responses about the existence of state laws on contractual definitions of medical necessity to available guides on state medical necessity legislation.¹⁴ In order to address the potential for secondary sources to be out of date, where discrepancies emerged we searched for state legislation directly through state legislative websites.

Table 1.

As indicated in Table 1, regulator responses were more often consistent with secondary sources regarding external review laws than secondary sources regarding laws defining medical necessity. The greater inconsistency regarding medical necessity definitions legislation may have been due to differences in terminology and scope of the questions

in our survey compared to the secondary analysis.¹⁵ In the one state where the regulator and secondary source did not agree about the status of external review legislation, a new law was pending at the time of our survey.

Legislative versus regulatory activity. We also used information obtained from compendia of state managed care legislation to examine the extent to which regulatory activity is driven explicitly by statute rather than the independent discretion of regulators. We compared information we obtained through secondary sources about the date of enactment of legislation of external review processes to regulator response to questions about how the amount of compliance and enforcement activity in this area in their state has changed in the past two years. We found that of the 39 states reported by the Blue Cross Blue Shield Association compendium to have external review legislation, 21 enacted laws during 1999 and 2000. In comparison, 25 regulators reported an increase in compliance and enforcement of external review processes during this period. Regulators reporting an increase in compliance and enforcement were significantly more likely to represent states where external review legislation had been passed in the previous two years ($p < .05$).

In areas where specific laws were less likely to be passed in the two years prior to our survey, regulators also reported increased regulatory activity, albeit at slightly lower rates. For example, regulators from 19 states report increased compliance and enforcement activity over the last two years with respect to preauthorization requirements. Similarly 20 regulators report increased regulation regarding contractual standards of medical necessity and coverage guidelines.

While these findings indicate that regulatory activity is clearly responsive to the dictates of legislation, regulators also suggested they are paying attention to medical necessity decision making, even in areas where legislatures may not be involved.

Regulating contractual medical necessity standards. We asked regulators to describe the ways in which their agencies review, monitor, or otherwise regulate health plans' contractual definitions, and to report any specific clinical or cost-effectiveness criteria that they require or prohibit in these definitions.

Table 2.

As shown in Table 2, regulation of medical necessity definitions is more often indirect than direct. Forty states provide some indirect oversight of definitions, including requiring plans to submit their definitions for approval, requiring plans to file the definition, reviewing plan definitions, or requiring plans to make definitions publicly available. In contrast, only 11 states specify a standard definition. Similarly, only 18 states require specific clinical-effectiveness criteria, and only two states maintain regulations about cost-effectiveness criteria.

Of note, Nevada is the only state that claims to take an active role in encouraging plans to incorporate cost-effectiveness considerations into discussions about medical necessity. Regulators from this state require plans to include in their definitions a statement that an intervention is medically necessary if (among other criteria) "it is furnished in the most cost-effective manner that may be provided safely and effectively to

the member.” On the other hand, Minnesota is the only state that claims to prohibit plans from directly considering cost in medical necessity decisions or referencing cost in their definitions. Regulators from this state acknowledge, however, that plans may indirectly consider cost when determining appropriate level, setting, type, or duration of care for members. In practice, the approaches taken by Nevada and Minnesota may not differ dramatically.

Contractual definitions are a source of concern for some health plan administrators and consumer advocates. While there appears to be significant oversight of plan’s definitions of medical necessity, the majority of states do not regulate the specific language.

Regulating the decision-making process. We asked regulators to describe their regulation of a variety of aspects of the coverage and medical necessity decision-making process. Several discrete aspects of decision-making appeared to be a focus of legislative and regulatory activity in the majority of states. According to regulators, 42 states regulate primary care gatekeeping in some way, 40 states restrict plans’ use of preauthorization in some way, 38 states regulate the external review process, and 33 states place restrictions on the amount of time that plans may take when making preauthorization decisions. Similarly, regulators from 39 states specify information that plans must include in denial letters.¹⁶ This level of regulatory activity contrasts markedly with the lower level of activity surrounding contractual medical necessity standards outlined above.

These findings suggest that states are more likely to develop regulations focused on process issues rather than definition and application of terms such as clinical evidence and cost effectiveness. Plans, in contrast, focus extensively on these issues.

Regulating coverage and clinical management. We asked regulators whether they place any restrictions on plans' coverage guidelines, defined in our survey as "also referred to as coverage or medical policies, formal guidelines that plans issue to specify the circumstances under which they will pay for a medical intervention for a group of patients with specific medical indications." We also asked them if they regulate the way plans use clinical practice guidelines, which we defined as "authoritative recommendations for the clinical management of specific conditions."

While regulators from 37 states reported that they review coverage policies under some circumstances, regulators from only nine states reported that they review clinical practice guidelines for compliance with statutory requirements. Similarly, 30 states require plans to make their coverage policies publicly available, while only 10 states require such disclosure of clinical practice guidelines.

Sources of information for external review. We asked regulators from the 38 states with a legislatively-mandated external review process about the sources of information they require the reviewer to consider in reviewing the clinical effectiveness of interventions requested. We also asked if the mandated review process permits the reviewer to take cost into consideration. Regulators from only half of the states reporting external review laws (19) indicated that the external review process for medical necessity denials in their

state requires reviewers to use any specific sources of information. Of these, almost all require use of multiple sources of information; only three do not. Professional guidelines and expert opinion were the most often cited sources; 15 states and 13 states respectively require consideration of these. Of the 19 states that specify sources, 12 require consideration of either randomized controlled trials (RCTs) or technology assessments (7 RCTs, 8 technology assessments), the most rigorous sources of evidence, where available. Of states that require consideration of only one source, one state requires consideration of expert opinion. No state requires reference only to community standards of care, the least rigorous standard. Regulators from 23 states indicated that reviewers are prohibited from considering cost when conducting external reviews; 12 permit the reviewer to consider cost.

While an increasing number of states have mandated external review for medical necessity and often other decisions, sources of information that should be considered in a review are often left unspecified. This lack of specificity may come from legislation or regulation; we did not review statutes in order to make this determination. Where states do specify sources for use in external review, they often do not include the most rigorous forms of scientific evidence. While more states specify whether they permit consideration of cost in external reviews, there is considerable variation regarding this issue.

Regulators in Contrast to Medical Directors

Defining Key Terms. We introduced both surveys by proposing a way to differentiate the terms medical necessity and coverage (See Figure 1). We did this both to establish

common terminology for key terms in the survey, and because we wanted greater insight into the way the terms themselves have become sources of confusion and dispute at the state and federal level.

Figure 1.

We asked both groups how consistent these definitions were with the way their agency or plan understands and applies them. Table 3 shows that the percent of regulators reporting that our definitions were not at all consistent with the way their plans defined and applied these terms was nearly twice the percent of medical directors with this response.

Table 3.

The substantial differences between regulators and medical directors in their understanding of these terms is significant because of the potential for litigation over denials on the basis of whether or not they represent a coverage decision or a medical necessity decision.

Sources of information for decision-making. We compared the tendency of states to require specific sources of information in external review evaluations (described above) to the tendency of health plans to use these sources in preliminary decision-making. While external review requirements do not dictate plan medical necessity decision-making, they are related; where decision-making criteria differ, plan decisions may be overturned upon appeal to an external review. Using the same set of choices, we asked medical directors to indicate which sources of information about clinical effectiveness they use most often, second most often, and third most often when evaluating new

interventions for coverage. We weighted medical director responses chosen as first, second, and third most often used source by 3:2:1, respectively.

Figure 2.

As can be easily seen in Figure 2, the most striking difference between medical directors and regulators is in their reported use of technology assessment reports. While 71% of medical directors report using TAs, only 15% of regulators report that their state external review law requires use of this source of information. Similarly, many more regulators report requirements for use of community standards and observational studies than medical directors report use of these sources for decision-making.

These findings suggest that regulators do not consider it their role to promote rigorous sources of evidence to be used in medical necessity decisions, nor do they value at least one source of information (i.e., technology assessments) that is clearly used and preferred by health plans.

Discussion

Results from this regulator survey may appear to conflict with results from other studies about oversight of HMOs for a number of reasons. First, the findings of this study rely on accurate self-reporting of regulatory activity. We did not independently attempt to confirm the accuracy of regulators' responses or to examine systematically differences between laws and regulations as written and as they are interpreted and enforced by

regulators; such comparisons are appropriate for further research. Our comparison of survey findings to available secondary sources suggests that regulator's answers to our questions were generally accurate. Regulatory activity is constantly changing. The results of this survey apply only to regulatory activity taking place between February and June 2001. Despite some differences with legislation and regulation, the 100% response rate of this study of regulators' perceptions and the care taken to identify appropriate regulatory agencies has created a comprehensive, and perhaps unique, view of areas of state oversight where prior research is lacking.

Regulator survey results show substantial variation among states in the type and extent of regulatory oversight of medical necessity decision-making. The comparison of responses by regulators and medical directors demonstrate clear differences in the frameworks that state regulators and medical directors use when making medical necessity and coverage decisions. Variation can cause confusion for consumers and health plans, especially where health plans operate in multiple states with contradictory regulation. It is unclear whether differences described benefit consumers or whether these benefits are worth the costs of compliance. Efforts to enhance uniformity in the regulation of medical necessity decision-making could be beneficial to regulators, plans and consumers.

Findings from a previous study of medical necessity decision-making in California involving broad stakeholder input¹⁷ suggested that regulation of medical necessity processes was more appropriate and potentially much more helpful than others forms of

regulation. Our results suggest that states do, in fact, focus on regulation of process issues.

Our findings also suggest that states view “insurance” practices as a more appropriate target of regulatory intervention than clinical practice. Health plans attempt to draw clear distinctions—often in court—between coverage decisions and clinical practice. Strategies managed care plans use to control utilization, however, often involve management of clinical aspects of care. In reality, coverage policies typically discuss clinical issues. Similarly, clinical practice guidelines often convey clear implications for appropriate coverage.

With respect to an external review in the case of an individual patient, many states specify no or non-rigorous standards of evidence. Often sources specified contrast those used and preferred by health plans regarding coverage policy decisions applicable to populations of patients with specified conditions. As a result, many health plans’ initial determinations could be reversed upon external review. The fact that several states require plans to reference community standards of care indicates that state regulation may actually be promoting plan use of less rigorous standards, the result of which could ultimately be harmful to consumers. Efforts need to be taken to align the types of evidence used by regulators and health plans to promote more informed decision-making based on the highest standards of scientific evidence. These efforts should also conform to the regulation and administration of external review processes to promote a more effective and efficient appeals process for medical necessity determinations.

Differences between regulators and medical directors in understanding key terms represent more than a simple semantic issue. We found, for example, most state regulation of definitions does not dictate specific language or criteria. Similarly, state legislation permitting external review for health plan denials made on the basis of medical necessity does not typically define or explain this term. Different understandings of these terms among regulators, health plans, and consumers set up potential conflict and inevitable feelings of inequity. The need to reach consensus over terminology is of primary importance, since any attempt at clarification and improvement of the medical necessity decision-making process cannot be undertaken until all stakeholders at least understand and use words in the same way.

Conclusion

Medical necessity decision making is a valuable management strategy for health plan administrators as well as an important regulatory issue for states, yet these two groups generally discuss the issue only as adversaries in confronting a potential breach a policy. The findings from this research suggest that medical necessity is an area in which regulators are involved, even when state legislatures are not. Regulators concern themselves with the decision-making process, especially regarding enrollee protections, more than with the definition of terms that dictate clinical practice. Regulators do not focus on the clinical evidence base for plan decisions, even with respect to external review programs. Health plans approach the problem of medical necessity differently than regulators in that they are more focused on clinical practice relative to process than regulators and they emphasize different evidence standards. Differences among states

and between states and HMOs are burdensome for multi-state health plans and confusing for consumers. For the sake of legal compliance and policy impact, better communication between regulators and medical directors, aimed at reducing unnecessary variation, must be a high priority.

Acknowledgements

The authors would like to thank Marcel Gemperli for his research assistance, the National Association of Managed Care Regulators (NAMCR) and the National Association of Insurance Commissioners (NAIC) for assistance in the development and implementation of the regulator survey, and The Robert Wood Johnson Foundation's Changes in Health Care Financing and Organization (HCFO) Initiative for their financial support.

Table 1: Agreement of Survey Responses with Secondary Sources

	Survey responses			
	Medical necessity definitions ^a		External review laws ^b	
	Survey indicates law exists	Survey indicates no law exists	Survey indicates law exists	Survey indicates no law exists
Secondary source indicates law exists	21	4	38	1
Secondary source indicates no law exists	2	23	0	11
Percent agreement	88%		98%	

a= Survey responses were compared to data collected by Mark Hall as part of "Assessing Patient Protection Laws," funded by the Robert Wood Johnson Foundation, currently underway.

b= Survey responses were compared to the Blue Cross Blue Shield Association *State Legislative Comparison* from 1999 and 2000.

Table 2: State Regulation of Medical Necessity Definitions



	No. of states
Direct forms of oversight	
State law specifies a standard definition of MN that plans must use	11
Agency requires plans to include at least one of 5 clinical effectiveness criteria in contracts	18
Agency requires plans to include at least one of 4 cost-effectiveness criteria in contracts	1
Agency prohibits plans from including any of 4 cost-effectiveness criteria in contracts	1
Indirect forms of oversight	
General legislation may impact plans' definitions of MN, but there is no state mandated definition	23
Agency requires plans to submit their definitions for approval by the agency	18
Agency requires plans to "file and use" their definitions with the agency	6
Agency regulates definitions indirectly through review of plan contracts	30
Agency requires plans to make definitions publicly available	14
 = Legislated requirement	
 = Regulated requirement	

Table 3: Percentage of medical directors and regulators who find proposed definitions of medical necessity and coverage decisions consistent with their own understanding and application

	State regulators	Medical directors
Very consistent	33%	53%
Somewhat consistent	49%	37%
Not at all consistent	18%	10%

Figure 1.

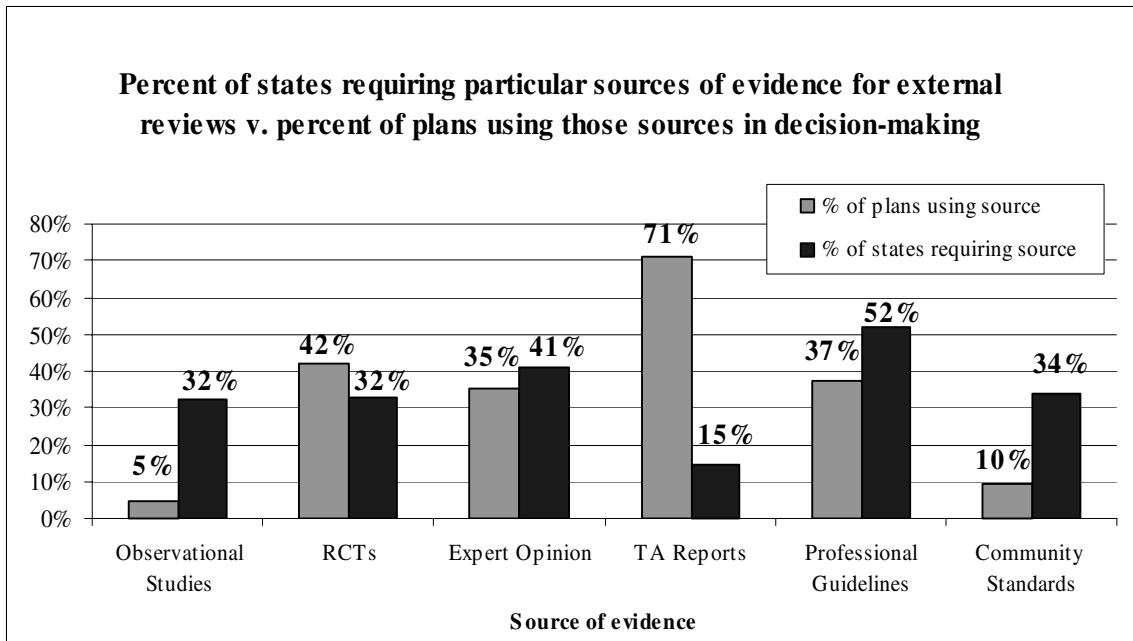
Medical necessity refers to the contractual standard applied to the following types of decisions:

- A **medical necessity decision**, which is a decision about coverage of an intervention¹ for an individual patient.²
- A **coverage decision**, which is a decision about coverage of an intervention for a group of patients with specific medical indications.

¹An intervention is an item or service (e.g., treatment, procedure, test, device, or drug) used to diagnose, prevent, or manage a medical condition.

²Some plans may use the term *medically appropriate* rather than *medically necessary* when referring to decisions about individual patients.

Figure 2.



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- ¹ A. Enthoven and S. Singer, "The Managed Care Backlash and the Task Force in California," *Health Affairs*, (July/August 1998): 95-110.
- ² S.J. Singer and L. Bergthold, "Prospects for Better Medical Necessity Decision Making," *Health Affairs*, (January/February 2001): 200-206.
- ³ L. Bergthold, "Medical Necessity: Do We Need It?," *Health Affairs* (Winter 1995): 180-190.
- ⁴ M. Stauffer, "Medical Necessity", Health Policy Tracking Service Issue Brief (Washington D.C.: 1 October 1999).
- ⁵ Institute of Medicine Committee on Quality Health Care in America, *Crossing the Quality Chasm: a new health system for the 21st century*. (Washington, D.C. : National Academy Press, 2001):337.
- ⁶ L. Levitt et al., *Employer Health Benefits: 2000 Summary of Findings*, (Menlo Park, California: Henry J. Kaiser Family Foundation and Chicago, Illinois: Health Research and Educational Trust, 2000).
- ⁷ See, for example, Milbank Memorial Fund. *Tracking State Oversight of Managed Care*. October, 1999.
- ⁸ M. Stauffer and R.B. Morgan, *2001 State by State Guide to Managed Care Law*. (Panel Publishers, 2001).
- ⁹ S. Laudicina, B. Losleben, and K. Pardo, *State Legislative Health Insurance Issues: Survey of Plans* (Washington, DC: Blue Cross Blue Shield Association, 1999 and 2000).
- ¹⁰ For detailed survey results, see State-by-State Compendium of Medical Necessity Regulation: Survey of State Managed Care Regulators, Stanford Center for Health Policy, 2001.
- ¹¹ Our preliminary research found that Alaska did not have any oversight of managed care plans; therefore, this state was excluded from our survey.
- ¹² See L. Bergthold et al., "Coverage and Decision Making in Managed Care" etc. [further information to be provided].
- ¹³ Huang A., et al., "Medical Necessity Decision-Making: The Case of Electrical Bone Growth Stimulation," etc. [further information to be provided].
- ¹⁴ Blue Cross Blue Shield Association, op-cit., M Hall, "Assessing Patient Protection Laws," unpublished study, 2002.
- ¹⁵ Mark Hall's study identified states with specific legislated or regulated definitions of medical necessity. In contrast, our survey asked whether there is specific or general legislation impacting plans' definitions of medical necessity. Since our survey questions allow for a broader interpretation, we did not consider inconsistent states unless (1) regulators reported a specific legislation in contradiction to Dr. Hall's findings, or (2) regulators reported no specific or general legislation where Dr. Hall identified a specific law.
- ¹⁶ Specifically, we asked respondents to indicate whether state law requires health plans to include the following: (1) A statement that the intervention is not medically necessary, (2) Specific reasons why the intervention is being denied, (3) Reference to contract provisions excluding the intervention from coverage, (4) Description of the evidence or criteria used to support the decision, (5) Description of the decision-maker's qualifications, (6) Information about the patient's right to internal appeal, (7) Information about the patients' right to external appeal, or (8) Other.
- ¹⁷ S.J. Singer and L. Bergthold, "Prospects for Better Medical Necessity Decision Making," *Health Affairs*, (January/February 2001): 200-206.