

State-by-State Compendium of Medical Necessity Regulation

Survey of State Managed Care Regulators

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Background and Methodology

Background

The dramatic expansion of managed care in recent years has prompted both federal and state governments to take a more active role in overseeing managed care plan activities. Variation in the way states have approached managed care oversight 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.

Recently, a number of state-by-state guides to managed care legislation have been published by researchers attempting to compare the way states approach managed care oversight.ⁱ These guides have tended to rely on a review of recent state laws, however, rather than exploring the role of state regulatory agencies in enforcing managed care legislation and promoting quality of care over and above legislative mandates.

Our research group aimed to create a state-by-state guide that emphasized the regulatory initiatives putting state laws into effect. We surveyed state regulators about their efforts to monitor health plans' decision-making activities and enforce regulations relating to medical necessity and coverage. While we were interested in state laws in so far as they guided regulators' activities, we did not focus our study on information that could be obtained directly from an examination of written legislative materials.

Research goals

Our goal was to gather information about oversight of medical necessity and coverage decision-making in health plans that would enable us to

- 1) create a detailed, comprehensive “map” of medical necessity and coverage oversight activity in every state plus D.C.;
- 2) gain insight into the influence of regulation on the decisions of medical directors in managed care plans.

Development of the questionnaire

We developed a written survey instrument for regulators drawing upon previous research about medical necessity decision-making and oversight. Questions were primarily multiple-choice with some open-ended short-answer follow-up and were organized into six subject areas: strategies for managing utilization and quality, contractual medical necessity standards, timing of decision-making, coverage guidelines, denial letters, and external review processes. Questions about two of the subject areas were designed to correspond to questions in the medical director survey in order to facilitate integrated analysis of our data. The survey was pre-tested with two state

ⁱ See, for example, Milbank Memorial Fund. *Tracking State Oversight of Managed Care*. October, 1999; and Stauffer M and Morgan RB. *2001 State by State Guide to Managed Care Law*. Panel Publishers, 2001.

regulators in January 2001 and revised before distribution to regulators starting in February 2001.

Recruitment of regulators

Our previous research indicated that the department of health or the department of insurance (or both) would be likely to regulate the types of managed care activities of interest to us in each state, except in some states where a third agency might be involved (e.g., the California Department of Managed Health Care).ⁱⁱ Telephone calls or e-mails were made to the departments of insurance and health (or their nearest equivalent) in every state to determine if the agency in question was eligible for our study, and, if so, which individual within that agency was most knowledgeable about medical necessity regulation.

Agencies were considered eligible only if they were responsible for monitoring and enforcement activity for commercial health plans in one of the six areas addressed in the survey. Agencies that either 1) handled insurance rates and form filings only, 2) regulated Medicaid or Medicare plans exclusively, or 3) were involved in policy research but not enforcement activity, were excluded from participation in the study.

Where our discussions revealed that a different agency was charged with regulating some or all of the medical necessity activities, calls were made to that agency to identify appropriate individuals to participate. For some states, the names and contact information of appropriate personnel were initially supplied by contacts from the National Association of Managed Care Regulators (NAMCR) and the National Association of Insurance Commissioners (NAIC); however, research staff always confirmed this information through telephone calls or e-mails to state regulatory personnel. For a significant proportion of states, we identified multiple agencies operating within a single state that were appropriate to participate in our survey.

Collection of data

From February to April 2001, surveys were sent by e-mail, fax, or regular mail to individuals recruited from each eligible regulatory agency. Regulators were encouraged to pass the survey to other staff people or to get input from other regulators whenever they found it necessary to answer our questions. Telephone and/or e-mail reminders were made to all non-responding regulators at 10-day intervals after the first wave of survey mailing. Additional surveys were mailed only when requested by individual regulators.

In some cases, regulators realized that their agencies were not appropriate to participate after performing a preliminary review of the survey instrument. A total of 65 regulators from 49 states plus the District of Columbia were found to be eligible after the first mailing (See end of section for agency names and responsibilities). Only one state, Alaska, did not have any agency that performed at least one of the types of activities that were the focus of our research. **Surveys were received from 100% of targeted agencies by June 2001.**

ⁱⁱ Our previous study of medical necessity in California is described in: "Singer SJ and Bergthold LA. Prospects for improved decision making about medical necessity. *Health Affairs*. 2001;20:200-6."

Data cleaning and consolidation

When information provided in written surveys was incomplete or unclear, research staff contacted regulators by phone or e-mail in order to clarify their answers. Additional documents about state legislation or regulation were consulted only when regulators suggested that they were important; research staff did not systematically attempt to confirm regulators' answers using outside sources. Data collected from the returned surveys and from clarification e-mails/phone calls and supplemental documents were entered into a central database for all state regulatory agencies. For states with more than one eligible agency, data from all agencies were consolidated into combined state "responses" that reflected the total regulation in those states as of February 2001.

Development of state-by-state HMO guide

Information furnished by regulators suggested that some regulations did not apply equally to all managed care products in their states (i.e., HMO, PPO, POS, indemnity). Our final database contains information about regulation that was definitely relevant to HMOs but not necessarily other products in every state. The information contained within this compendium reflects state oversight activities mainly for HMO products (except for the section on "Conducting an External Reviews Process," which contains some additional information about product applicability).

Discrepancies between this guide and other sources

Results from this survey may appear to conflict with information provided in other studies about oversight about managed care for a number of reasons:

- 1) We relied upon individual regulators' descriptions of regulatory activity in their states; although we encouraged regulators to consult with other staff to verify information, it is possible that some of their responses reflected an inaccurate understanding of their state's regulatory context.**
- 2) We did not systematically verify regulators' answers using outside sources such as state legislative or regulatory documents, although we did examine applicable legislation in cases where answers were obviously contradictory.**
- 3) Regulatory activity is constantly changing; the results of this survey apply only to regulatory activity taking place between February and June 2001.**

List of eligible state agencies:

Alabama Department of Public Health
Arizona Department of Insurance
Arkansas Department of Insurance
Arkansas Department of Health
California Department of Managed
Health Care
Colorado Division of Insurance
Colorado Department of Public Health
and Environment
State of Connecticut Insurance
Department
Delaware Division of Public Health
D.C. Department of Health
Florida Agency for Health Care
Administration
Georgia Insurance and Safety Fire
Commissioner's Office
Georgia Division of Public Health
Georgia Department of Community
Health
Hawaii Division of Insurance
Idaho Department of Insurance
Illinois Department of Insurance
Illinois Department of Public Health
Indiana Department of Insurance
Iowa Insurance Division
Kansas Insurance Department
Kentucky Department of Insurance
Louisiana Department of Insurance
Maine Bureau of Insurance
Maryland Insurance Administration
Maryland Department of Health and
Mental Hygiene
Massachusetts Division of Insurance
Massachusetts Department of Public
Health
Michigan Office of Financial and
Insurance Services
Minnesota Department of Health
Mississippi Department of Insurance
Mississippi Department of Health
Missouri Department of Insurance
Montana Insurance Division
Montana Department of Public Health and
Human Services
Nebraska Department of Insurance
Nevada Division of Insurance
Nevada State Health Division
New Hampshire Insurance Department
New Jersey Department of Health and
Senior Services
New Mexico Division of Insurance
New York State Insurance Department
New York State Health Department
North Carolina Department of Insurance
North Dakota Department of Insurance
Ohio Department of Insurance
Ohio Department of Health
Oklahoma State Department of Health
Oregon Insurance Division
Pennsylvania Department of Health
Rhode Island Department of Health
South Carolina Department of Insurance
South Dakota Department of Insurance
Tennessee Department of Commerce and
Insurance
Texas Department of Insurance
Utah State Insurance Department
Vermont Department of Banking, Insurance,
Securities, and Health Care
Administration
Virginia Bureau of Insurance
Virginia Department of Health
Washington Office of Insurance
Commissioner
Washington State Department of Health
State of West Virginia Insurance
Commission
Wisconsin Office of the Commissioner of
Insurance
Wyoming Insurance Department

Distribution of Responsibilities Among State Agencies

| State | Areas of Regulation | | | | | |
|-------|---|---|---------------------------|-------------------------|------------------|---------------------------|
| | Strategies for Managing Utilization and Quality | Contractual Medical Necessity Standards | Timing of Decision-Making | Coverage Guidelines | Denial Letters | External Review Processes |
| AL | D.O.H. | D.O.H. | D.O.H. | D.O.H. | D.O.H. | ----- |
| AK | ----- | ----- | ----- | ----- | ----- | ----- |
| AZ | D.O.I. | ----- | ----- | D.O.I. | D.O.I. | D.O.I. |
| AR | D.O.I. D.O.H. | D.O.H. | D.O.I. D.O.H. | D.O.I. D.O.H. | ----- | ----- |
| CA | D.M.H.C. | D.M.H.C. | D.M.H.C. | D.M.H.C. | D.M.H.C. | D.M.H.C. |
| CO | D.O.I. D.O.H. | D.O.I. D.O.H. | D.O.I. | D.O.I. D.O.H. | D.O.I. | D.O.I. |
| CT | D.O.I. | D.O.I. | D.O.I. | ----- | D.O.I. | D.O.I. |
| DE | D.O.H.(minor) | ----- | D.O.H. | ----- | D.O.H. | D.O.H. |
| DC | D.O.H. | D.O.H. | D.O.H. | D.O.H. | D.O.H. | D.O.H. |
| FL | D.O.H. | ----- | ----- | ----- | D.O.H. | D.O.H. |
| GA | D.O.I. D.O.H. | D.O.I. | D.O.I. | D.O.I. D.O.H. | D.O.I. | D.C.H. |
| HI | D.O.I. | D.O.I. | D.O.I. | D.O.I. | D.O.I. | D.O.I. |
| ID | D.O.I. | D.O.I. | D.O.I. | D.O.I. | D.O.I. | ----- |
| IL | D.O.I. D.O.H.(minor) | D.O.I. | D.O.I. | D.O.H. | D.O.I. | D.O.I. |
| IN | D.O.I. | D.O.I. | D.O.I. | D.O.I. | D.O.I. | D.O.I. |
| IA | D.O.I. | D.O.I. | ----- | D.O.I. | ----- | D.O.I. |
| KS | ----- | ----- | ----- | D.O.I. | ----- | D.O.I. – |
| KY | D.O.I. | D.O.I. | D.O.I. | D.O.I. | D.O.I. | D.O.I. |
| LA | D.O.I. | D.O.I. | D.O.I. | D.O.I. | D.O.I. | D.O.I. |
| ME | D.O.I. | D.O.I. | D.O.I. | D.O.I. | D.O.I. | D.O.I. |
| MD | D.O.I. | D.O.I. D.O.H. | D.O.I. | D.O.I.(minor) D.O.H. | D.O.I. D.O.H. | D.O.I. |
| MA | D.O.I. D.O.H. | D.O.I. D.O.H. | D.O.I. | D.O.H. | D.O.I. | D.O.H. |
| MI | D.O.I. | D.O.I. | ----- | ----- | ----- | D.O.I. |
| MN | D.O.H. | D.O.H. | D.O.H. | D.O.H. | D.O.H. | D.O.H. |
| MS | D.O.I. D.O.H. | D.O.I. D.O.H. | ----- | D.O.I. D.O.H. | D.O.I. | ----- |
| MO | D.O.I. | D.O.I. | D.O.I. | D.O.I. | D.O.I. | D.O.I. |
| MT | D.O.I. D.O.H. | D.O.I. | D.O.I. D.O.H. | D.O.I. D.O.H. | D.O.I. D.O.H. | D.O.H. |
| NE | D.O.I. | D.O.I. | D.O.I. | D.O.I. | D.O.I. | ----- |
| NV | D.O.I. | D.O.I. | D.O.I. | D.O.I. | D.O.I. | ----- |
| NH | D.O.I. (minor) | D.O.I. | D.O.I. | D.O.I. | D.O.I. | D.O.I. |
| NJ | D.O.H. | ----- | ----- | D.O.H. | D.O.H. | D.O.H. |
| NM | D.O.I. | D.O.I. | D.O.I. | D.O.I. | D.O.I. | D.O.I. |
| NY | D.O.I. D.O.H. | D.O.I. | D.O.I. D.O.H. | D.O.I. D.O.H. | D.O.I. D.O.H. | D.O.I. D.O.H. |
| NC | D.O.I. | D.O.I. | D.O.I. | D.O.I. | D.O.I. | ----- |
| ND | D.O.I. | D.O.I. | D.O.I. | D.O.I. | D.O.I. | ----- |
| OH | D.O.I. D.O.H. | D.O.I. | D.O.I. | D.O.I. D.O.H. | D.O.I. D.O.H. | D.O.I. |
| OK | D.O.H. | D.O.H. | D.O.H. | D.O.H. | D.O.H. | D.O.H. |
| OR | D.O.I. | D.O.I. | D.O.I. | D.O.I. | D.O.I. | ----- |

| State | Strategies for Managing Utilization and Quality | Contractual Medical Necessity Standards | Timing of Decision-Making | Coverage Guidelines | Denial Letters | External Review Processes |
|-------|---|---|---------------------------|---------------------|------------------|---------------------------|
| PA | D.O.I. D.O.H. | D.O.I. D.O.H. | D.O.H. | D.O.H. | ----- --- | D.O.H. |
| RI | D.O.H. | D.O.H. | D.O.H. | D.O.H. | D.O.H. | D.O.H. |
| SC | D.O.I. | ----- | D.O.I. | ----- | ----- | D.O.I. |
| SD | D.O.I. | D.O.I. | D.O.I. | D.O.I. | D.O.I. | ----- |
| TN | D.O.I. | D.O.I. | D.O.I. | D.O.I. | ----- | D.O.I. |
| TX | D.O.I. | D.O.I. | D.O.I. | D.O.I. | D.O.I. | D.O.I. |
| UT | D.O.I. | ----- | ----- | D.O.I. | D.O.I. | D.O.I. |
| VT | D.O.I. | D.O.I. | D.O.I. | D.O.I. | D.O.I. | D.O.I. |
| VA | D.O.H. | D.O.I. D.O.H. | D.O.H. | D.O.H. | D.O.I. D.O.H. | D.O.I. |
| WA | D.O.I. | D.O.I. | D.O.I. | D.O.I. | D.O.I. | D.O.I. D.O.H. |
| WV | D.O.I. | ----- | D.O.I. | D.O.I. | D.O.I. | ----- |
| WI | D.O.I. | D.O.I. | ----- | D.O.I. | D.O.I. | D.O.I. |
| WY | D.O.I. (minor) | ----- | ----- | D.O.I. | ----- | ----- |

| | |
|----------|---|
| D.O.I. | = Department of Insurance or nearest equivalent |
| D.O.H. | = Department of Health or nearest equivalent |
| D.M.H.C. | = Department of Managed Health Care |
| D.C.H. | = Department of Community Health |

Study Highlights

- There is significant variation in the way regulators understand and apply terms such as *medical necessity* and *coverage* in their oversight of plans.
(*33% of regulators find our definitions to be “very consistent” with the way they use them; 49% find them “somewhat consistent”; and 18% find them “not at all” consistent.*)
- The majority of states do not regulate the way health plans define and apply terms such as *medical necessity* in their standard contracts.
(*Only 11 states have laws specifying a standard definition that plans must use; only 18 states require plans to submit their definitions to state agencies for approval.*)
- Few states require health plans to use scientific evidence as a source of information about the clinical effectiveness of interventions in medical necessity determinations.
(*Only 4 states require plans through regulation to include “effective as demonstrated by scientific evidence” as a criterion in their contractual definitions, as opposed to 14 states that require “generally accepted principles of professional medical practice.”*)
- States do not currently regulate whether health plans include cost-effectiveness criteria in their contractual definitions of *medical necessity*.
(*Only 1 state explicitly requires plans to include cost-effectiveness criteria in their contracts; only 1 state explicitly prohibits plans from including such criteria in their contracts.*)
- The majority of states do not regulate any additional ways in which health plans take cost into consideration when evaluating interventions for coverage.
(*Only 2 states prohibit plans from taking cost into consideration in one of the additional ways proposed by our research group.*)
- Few states directly regulate medical groups and networks that share financial risk and decision-making authority with health plans.
(*Only 6 states directly regulate delegated entities, although 36 regulate these entities indirectly through their regulation of plans.*)
- Although accreditation organizations are widely seen as upholding quality of care standards, very few states actually require health plans to obtain accreditation.
(*Only 5 states explicitly require plans to obtain accreditation, although 26 states provide some more indirect incentive for plans to seek accreditation.*)
- The majority of states place some restrictions on the way in which health plans use primary care gatekeeping to control patients’ access to specialists.
(*Forty-two states regulate primary care gatekeeping in some way, such as requiring that some patients have direct access to certain specialists.*)

- Few states attempt to review the clinical practice guidelines that health plans develop to guide the management of specific medical conditions.
(Only 8 states review guidelines for compliance with statutory requirements).
- The majority of states review health plans' coverage guidelines (also known as medical policies) for compliance with relevant statutory requirements.
(Thirty-seven states review coverage guidelines under some circumstances.)
- The majority of states place some restrictions on plans' use of preauthorization requirements to control members' access to medical services.
(Forty states restrict plans' use of preauthorization in some way, such as prohibiting plans from requiring preauthorization in certain situations [e.g., emergency care].)
- The majority of states restrict the amount of time that health plans may take when making prospective medical necessity decisions; however, specified time limits vary substantially from state to state.
(Thirty-three states set at least some time limits for prospective decisions; time limits for non-urgent cases may vary from 2 days to 45 days .)
- Although the majority of states regulate the information that health plans include in letters to patients when they deny coverage for interventions, the actual information required by state law can be quite different from state to state.
(Thirty-nine states have laws that specify information that plans must include in denial letters; the required items vary considerably by state.)
- While the majority of states have legislatively-mandated external review processes, reviewers are rarely required to consult rigorous scientific evidence of effectiveness in their case-by-case determinations.
(Thirty-eight states have a legislatively-mandated external review process; only 7 of these require reviewers to use randomized controlled trials.)
- Overall, compliance and enforcement activity increased across all categories of regulation of managed care during the past 2 years.
Regulation increased most often for external review regulation (25 states), followed by denial letters (23 states) and timing of decision-making (22 states).

Defining *Medical Necessity* and *Coverage*

Our previous research about medical necessity in California suggested that there was widespread confusion about the meaning of terms such as *coverage* and *medical necessity*. To gain insight into the way state regulators use these terms, we asked regulators whether the following definitions are “very consistent,” “somewhat consistent,” or “not at all consistent” with the way they understand and apply them in their states:

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

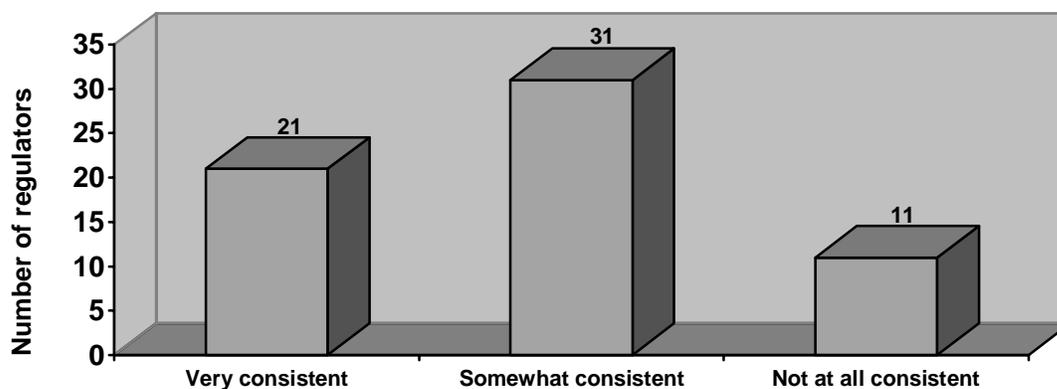
- A **medical necessity decision**, which is a decision about coverage of an intervention¹ for an individual patient.²
- A **coverage decision**, which is a decision about coverage of an intervention for a group of patients with specific medical indications.

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.

There was considerable variation in regulators’ responses to this question; in some cases, responses varied even among regulators within the same state. Of the **63** regulators that responded to this question, **21** reported that these definitions are “very consistent” with the way they understand and apply these terms, **31** reported that they are “somewhat consistent,” and **11** reported that they are “not at all consistent.”ⁱ

Regulators' Responses to Proposed Definitions



ⁱ Because regulators’ responses to this question sometimes varied even within the same state, we have reported our findings by number of regulators rather than number of states. Two of the 65 state regulators surveyed did not provide us with a response to this question.

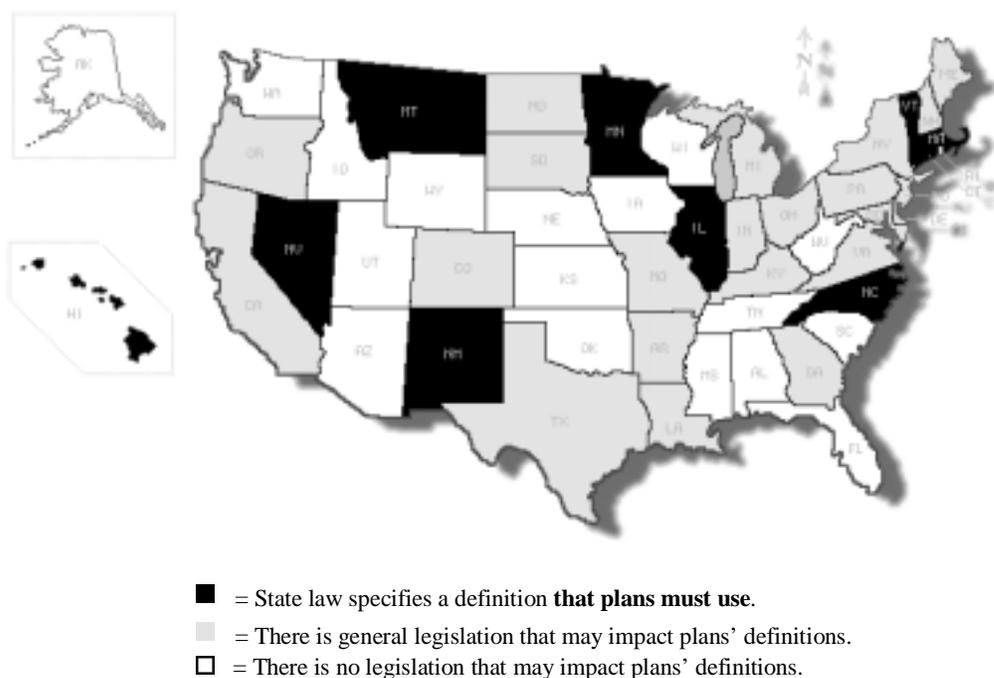
Regulators' responses to this question suggested that there is significant variation in the way that state agencies use the terms *medical necessity* and *coverage*. For example, regulators disagree with the proposed definitions for all of the following reasons:

- Some regulators believe that *medical necessity* decisions are decisions about coverage of specific interventions for *both* individual patients *and* groups of patients with certain medical indications.
- Some regulators believe that *medical necessity* refers to whether or not a treatment is appropriate for a condition, while *coverage* refers exclusively to whether or not the enrollee's evidence of coverage contract provides payment for it.
- Some regulators believe that *medical necessity* refers to decisions about the level of treatment or the setting in which a treatment is provided, once it is established that a treatment is covered for members of a plan.

Regulating Contractual Definitions of *Medical Necessity*

We asked regulators to describe any **legislation** in their states that might impact the way health plans define terms such as *medical necessity* in their contracts.¹ We also asked regulators to describe the ways in which their agencies review, monitor, or otherwise **regulate** plans' contractual definitions of *medical necessity*.

Regulators from **11** states indicated that their states' laws specify a standard definition of *medical necessity* **that health plans are required to use**. Regulators from **23** states reported that general legislation in their state might impact plans' definitions of *medical necessity* even though there is no state-mandated definition. According to our respondents, **16** states do not have any legislation that might impact plans' definitions (not including Alaska, which was not included in our survey).



States also regulate plans' contractual definitions of *medical necessity* in varied ways, according to regulators. **Forty** states regulate plans in ways we inquired about in our survey. Only **18** states require plans to submit their definitions to regulators for approval. However, **6** states require plans to "file and use" definitions with a state agency; **30** states review plans' definitions indirectly by reviewing plans' contracts; and **14** states require plans to make their definitions publicly available. When asked about the amount of change in compliance and enforcement activity regarding contractual definitions during the past two years, regulators from **20** states reported that activity had

¹ We did not specify whether the legislated definitions might apply to Medicaid or commercial products, although follow-up calls confirmed that regulators were responding mainly about commercial products.

increased, regulators from 1 state reported that activity had decreased, and regulators from another 21 reported that activity had stayed the same.

| State | State laws on definitions | Require plans to submit definitions for approval | Require plans to file and use definition | Regulate definitions through review of contracts | Require plans to make definitions publicly available | Change in regulatory activity |
|-------|---------------------------|--|--|--|--|-------------------------------|
| AL | ó | ✓ | | ✓ | | ↔ |
| AZ | ó | | | | | ↔ |
| AR | □ | ✓ | | | | ↑ |
| CA | □ | ✓ | ✓ | ✓ | ✓ | ↑ |
| CO | □ | | | ✓ | ✓ | ↑ |
| CT | ■ | | | ✓ | | DK |
| DE | □ | | | | | DK |
| DC | ■ | | ✓ | ✓ | | ↑ |
| FL | ó | | | | | ↔ |
| GA | □ ¹ | ✓ | | ✓ | ✓ | ↓ |
| HI | ■ ² | | | | | DK |
| ID | ó | ✓ | ✓ ³ | | | ↑ |
| IL | ■ | ✓ | | | | ↑ |
| IN | □ | | | ✓ | | ↑ |
| IA | ó | | | ✓ | ✓ | ↑ |
| KS | ó | | | | | DK |
| KY | □ | ✓ | ✓ | ✓ | ✓ ⁴ | ↔ |
| LA | □ | | | ✓ | | ↑ |
| ME | □ | ✓ ⁵ | | | | ↑ ⁶ |
| MD | □ | | | ✓ | | ↑ |
| MA | ■ | ✓ | | | ✓ | ↔ ⁷ |
| MI | □ | ✓ | | ✓ | | ↑ |
| MN | ■ | ✓ | | ✓ | ✓ | ↔ |
| MS | ó | | | ✓ | | ↔ |
| MO | □ | ✓ | | ✓ | | ↔ |
| MT | ■ | ✓ | | | | ↑ |
| NE | ó | | | ✓ | | ↔ |
| NV | ■ | | | ✓ | ✓ | ↑ |
| NH | □ | ✓ | | | | DK |
| NJ | □ | | | | | ↔ |
| NM | ■ | | ✓ | ✓ | ✓ | DK |
| NY | □ | | | ✓ | ✓ | ↑ |
| NC | ■ | ✓ | | ✓ | ✓ | ↔ |
| ND | □ | ✓ | | ✓ | | ↔ |
| OH | □ | | | ✓ | | ↔ |
| OK | ó | | | ✓ | ✓ | ↔ |
| OR | □ | ✓ | | | | ↑ |
| PA | □ | | ✓ | ✓ | ✓ | ↑ |
| RI | □ | ✓ | | | | ↑ |
| SC | ó | | | | | ↔ |
| SD | □ | | | ✓ | | ↑ |
| TN | ó | | | ✓ | | ↔ |
| TX | □ | | | ✓ | | ↔ |
| UT | ó | | | | | ↔ |
| VT | ■ | | | ✓ | | ↔ |
| VA | □ ⁸ | | | ✓ | | ↑ |
| WA | ó | | | | ✓ | DK |
| WV | ó | | | | | DK |
| WI | ó | | | ✓ | | ↔ |
| WY | ó | | | | | ↔ |

| | |
|----|---|
| ■ | = State law specifies a standard definition of <i>medical necessity</i> that plans must use. |
| □ | = There is general legislation that may impact plans' definitions of <i>medical necessity</i> . |
| ó | = There is no legislation that has any impact on plans' definitions of <i>medical necessity</i> . |
| ✓ | = State regulates contractual medical necessity standards in this way. |
| ↑ | = Regulator reports increase in compliance/enforcement activity over the past 2 years. |
| ↓ | = Regulator reports decrease in compliance/enforcement activity over the past 2 years. |
| ↔ | = Regulator reports no change in compliance/enforcement activity over the past 2 years. |
| DK | = Regulator does not know if compliance/enforcement activity has changed. |

¹ Regulators from the Georgia Department of Health noted that state law specifies a definition of *medical necessity* that plans must use for emergency services, but not necessarily other services.

² Regulators from the Hawaii Division of Insurance noted that although their state has a statutory definition of *medical necessity*, and although regulators require plans to apply the state's *medical necessity* standard in external review determinations, plans are not specifically required to incorporate this definition into their contracts.

³ Regulators from the Idaho Department of Insurance reported that in Idaho, "managed care organizations" are required to submit their definitions to their agency for approval. Indemnity plans need only "file and use" their definitions.

⁴ Regulators from the Kentucky Department of Insurance reported that they require plans to make their contractual definitions publicly available primarily through plans' certificates of coverage.

⁵ Regulators from the Maine Bureau of Insurance reported that it is empowered to disapprove health plans' definitions of *medical necessity* even though there is no state standard set in statute.

⁶ Regulators from the Maine Bureau of Insurance attributed this increase to the increase in the number of appeals, grievances, and complaints that it has received relating to medical necessity determinations.

⁷ Regulators from Massachusetts reported that their state had just passed a new managed care law on January 1, 2001, but the regulations pursuant to this law were not promulgated until March 30, 2001, so enforcement and compliance activity had been unchanged as of the date of this survey.

⁸ Regulators from the Virginia Department of Health noted that although their state has a statutory definition of medical necessity, they do not explicitly require plans to include it in their contracts. However, they expect that most plans will do so.

Regulating Clinical Effectiveness Criteria in Contractual Definitions

We were interested in determining whether states regulate, over and above legislation addressing definitions, the types of clinical effectiveness criteria that appear in health plans' contractual definitions of *medical necessity*. Previous research into health plans' contractual definitions indicated that the following clinical effectiveness criteria sometimes appear in their standard contracts:

An intervention is medically necessary if (among other things)...

- It is in accordance with prevailing community standards of care.
- It is consistent with generally accepted principles of professional medical practice.
- It is effective in improving health outcomes as determined by scientific evidence
- It meets nationally recognized standards of care.
- The treating physician determines that it should be provided.

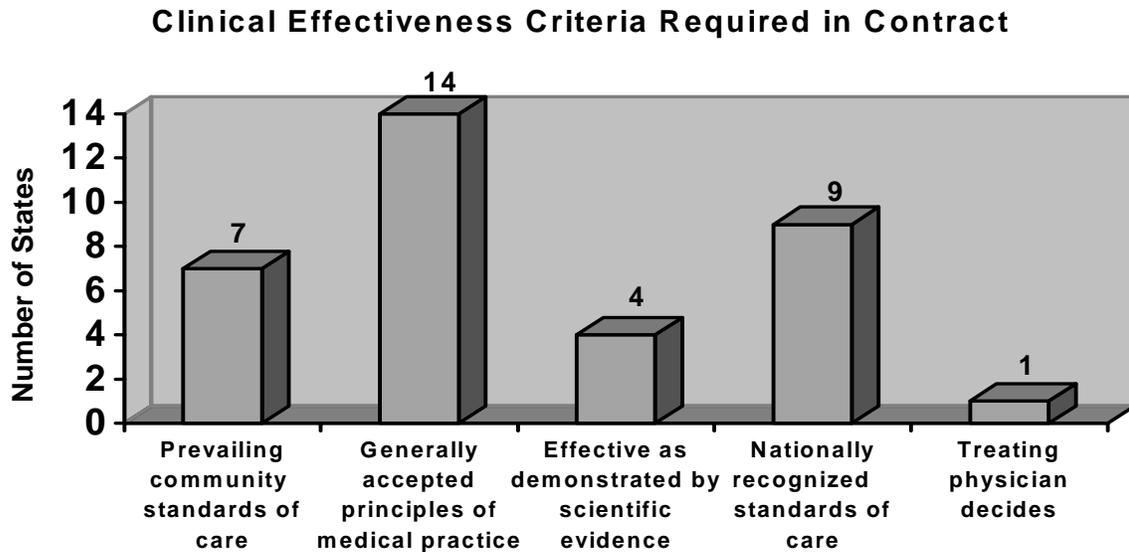
We asked regulators to indicate 1) if their agencies **require** plans to include any of the above clinical effectiveness criteria in their standard contracts; and 2) if their agencies **prohibit** plans from including any of these same criteria in their contractual definitions.ⁱ

Regulators from **18** states indicated that they require plans, through regulation, to include at least one of the above clinical effectiveness criteria in their standard contracts. Regulators from **8** states indicated that they require only one of the above criteria to be included, while regulators from **10** states indicated that they require multiple criteria to be included.

Of those states that require only one of the above criteria to be included, Hawaii is the only state that requires prevailing community standards of care. Furthermore, Illinois is the only state that requires that the treating physician's opinion be observed. Specifically, in Illinois, regulators indicated that if the treating physician disagrees with a plan's determination that an intervention is not clinically effective, then the plan's determination is automatically referred to third-party review. In this way, regulators ensure that neither the treating physician's judgment nor the health plan's administrators are permitted to dominate the decision process in difficult cases.

ⁱ We did not specify whether the legislated definitions might apply to Medicaid or commercial products, although follow-up calls confirmed that regulators were responding mainly about commercial products.

Overall, the most commonly required criteria cited were “generally accepted principles of professional medical practice” (14 states), “nationally recognized standards of care” (9 states), and “prevailing community standards of care” (7 states). Only 4 states regulate whether plans include the most scientifically rigorous criterion, “effective as demonstrated by scientific evidence,” in their contractual definitions, according to regulators:



Of note, in no states did regulators report that they prohibit health plans from including any of the above clinical effectiveness criteria in their contractual definitions of *medical necessity*. Furthermore, in no states did regulators appear to regulate whether health plans include any clinical effectiveness criteria other than the ones presented to them in our survey.ⁱⁱ

ⁱⁱ As noted in the section, “Regulating Contractual Definitions of *Medical Necessity*,” regulators from 11 states indicated that their state laws specify a standard definition of *medical necessity* that plans are required to use. However, none of these regulators indicated that they prohibit plans from including any specific clinical effectiveness criteria in their contractual definitions of *medical necessity*. It is possible that some regulators may require plans to use a legislatively-mandated definition as a starting point, but also permit plans to incorporate additional clinical effectiveness criteria as desired. It may also be that some regulators **effectively** prohibit certain clinical effectiveness criteria by requiring plans to use state definitions; however, they do not think of themselves as formally prohibiting any of these criteria.

The following chart provides a state-by-state breakdown of regulators' responses:

| State | In accordance with Prevailing community Standards of care | Consistent with accepted principles of medical practice | Effective in improving outcomes as determined by scientific evidence | Meets nationally recognized standards of care | Treating physician Determines that it should be provided |
|-----------------|---|---|--|---|--|
| AL | | ✓ | | | |
| AZ | | | | | |
| AR | | ✓ | | | |
| CA | | | | | |
| CO | | | ✓ | ✓ | |
| CT | | | | | |
| DE | | | | | |
| DC | | ✓ | | | |
| FL | | | | | |
| GA | | | | | |
| HI ¹ | ✓ | | | | |
| ID | | | | | |
| IL | | | | | ✓ |
| IN | | | | | |
| IA | | | | | |
| KS | | | | | |
| KY | | ✓ | | | |
| LA | | | | ✓ | |
| ME | | | | | |
| MD | | ✓ | | ✓ | |
| MA | | | | | |
| MI | | | | | |
| MN | ✓ | ✓ | | ✓ | |
| MS | | | | | |
| MO | | | | | |
| MT ² | ✓ | ✓ | | ✓ | |
| NE | | | | | |
| NV | | ✓ | | ✓ | |
| NH ³ | | ✓ | ✓ | ✓ | |
| NJ | | | | | |
| NM | ✓ | ✓ | | ✓ | |
| NY | | | | | |
| NC | | | | | |
| ND | | | | | |
| OH | | ✓ | | | |
| OK | | | | | |
| OR | | | | | |
| PA | | | | | |
| RI | ✓ | ✓ | ✓ | ✓ | |
| SC | | | | | |
| SD | | | | | |
| TN | ✓ | ✓ | ✓ | | |
| TX ⁴ | | | | | |
| UT | | | | | |
| VT | ✓ | ✓ | | | |
| VA | | | | | |
| WA | | | | | |
| WV | | | | | |
| WI | | | | | |
| WY | | | | | |

✓ = State requires plans to include this criterion in contractual definitions.

¹ Regulators from the Hawaii Division of Insurance noted that although their state has a statutory definition of *medical necessity*, plans are not specifically required to incorporate the state's definition into their contracts. However, plans are required to include "community standards of care" as a clinical evidence criterion in their own contractual definitions of *medical necessity*.

² The "managed care network adequacy and quality assurance" section of the Montana Insurance Code specifies only one clinical evidence criterion for medical necessity: "according to accepted standards of medical practice" (MCA 33-36-103). However, the "health utilization review" chapter of the Code indirectly specifies 2 other clinical evidence criteria for medical necessity, by requiring that all health plans adopt utilization review criteria that 1) are "based on nationally recognized criteria, standards, and procedures" and 2) "reflect community standards of care" (MCA 33-32-103).

³ The "utilization review" section of New Hampshire's Managed Care Law indirectly specifies three clinical evidence criteria for medical necessity, by requiring that health carriers and their designated utilization review entities use clinical review criteria that 1) are "developed in accordance with the standards of national accreditation entities," 2) are "based on current, nationally accepted standards of medical practice," 3) "if practicable, be evidence-based" (XXXVII.420-J:6).

⁴ Regulators from the Texas Department of Insurance indicated that they do not require plans to include any specific clinical evidence criterion in their standards contracts. However, its utilization review law states that decisions must be made "in accordance with currently accepted medical or health care practices, taking into account special circumstances of each one that may require deviations from the norms stated in the screening criteria."

Regulating Cost-effectiveness Criteria in Contractual Definitions

We were interested in whether state agencies regulate (again over and above legislation addressing definitions) the cost-effectiveness criteria in health plans' contractual definitions of *medical necessity*. Previous research into contractual definitions indicated that the following cost-effectiveness criteria sometimes appear in health plans' standard contracts:

An intervention is medically necessary if (among other things)...

- It is furnished in the most cost-effective manner that may be provided safely and effectively to the member.
- There is no other equally effective course of treatment available which is less costly.
- It provides the same or greater benefit at the same or lower cost, compared to the next best alternative.
- The benefits and harms relative to costs for the treatment represent an economically efficient use of resources for patients with this condition compared to alternative treatments.

We asked regulators to indicate 1) if their agencies **require** plans to include any of the above cost-effectiveness criteria in their standard contracts; 2) if their agencies **prohibit** plans from including any of these criteria in their contracts.ⁱ

According to regulators, **Nevada** is the only state that requires health plans to include any of the above cost-effectiveness criteria in their contractual definitions.ⁱⁱ Nevada regulators require plans to include 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." Regulators from this state can therefore be seen as taking an active role in encouraging health plans to incorporate cost-effectiveness considerations into their approach to evaluation interventions for coverage.

According to regulators, **Minnesota** is the only state prohibiting plans from directly considering cost in medical necessity decisions; state regulators do not allow any of the criteria listed above to be included in plans' standard contracts. However, they acknowledge and accept that plans may indirectly consider cost when determining appropriate level, setting, type, or duration of care.

Regulators from several other states indicated that language related to "cost effectiveness" may be prohibited if it appears that a fiscal process is hindering medical decisions, but stated that no specific criterion was prohibited from contract.

ⁱ We did not specify whether the legislated definitions might apply to Medicaid or commercial products, although follow-up calls confirmed that regulators were responding mainly about commercial products.

ⁱⁱ Regulators from the Hawaii Division of Insurance noted that cost-effectiveness is statutorily defined in their state, and that their agency evaluates plans in external reviews to ensure that the statutory definition is applied. However, plans are not otherwise required to incorporate cost-effectiveness criteria into their contractual definitions.

Additional Ways of Regulating Health Plans' Consideration of Cost

We were interested in determining whether states regulate the way health plans take cost into consideration apart from regulating contractual definition criteria. We asked regulators whether they **prohibit** plans from taking cost into consideration when evaluating interventions in any of the following ways:

- Using formal cost-effectiveness analysis where available.
- Selectively applying preauthorization to high-cost interventions.
- Establishing explicit coverage policies for high-cost interventions.
- Requiring application of less costly, equally effective interventions first.

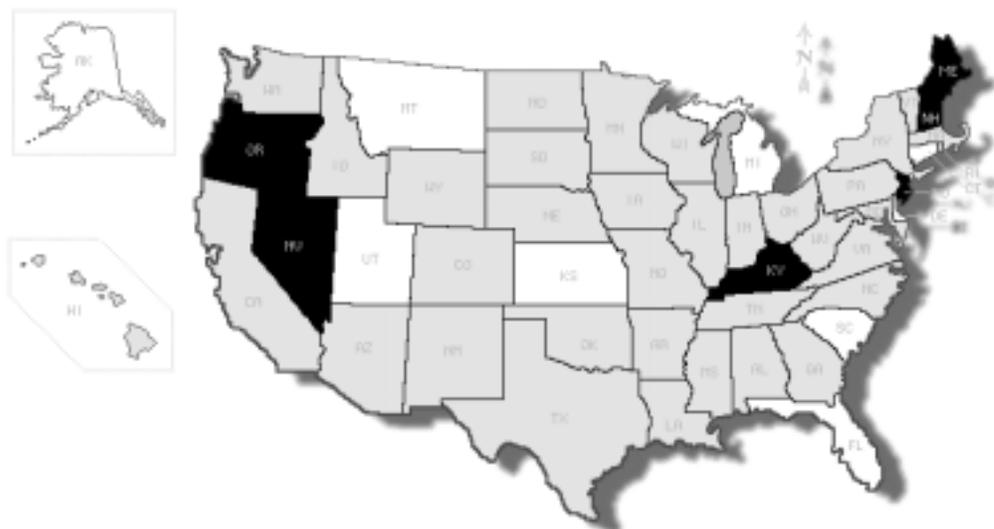
No regulators indicated that they prohibit plans from taking cost into consideration in any of the ways described above. However, some regulators indicated in their comments on this question that they regulate plan's consideration of cost in other ways that were not explicitly described by our survey.

For example, California regulators reported that they require that plans' financial and administrative considerations be distinct from medical review and decision-making processes. Regulators from North Dakota, Pennsylvania, and Vermont commented that plans in their states cannot provide financial incentives for providers to provide less than medically necessary care. Texas regulators noted that cost considerations may not violate any insurance law that mandates a specific benefit (e.g., HMO basic health care service plans must cover physician visits without limitations as to time and cost. We recognize that other states may also regulate cost consideration in these ways, even if their regulators did not choose to provide this additional information in our survey.

Regulating Delegated Entities

Our research in California revealed that many health plans delegate financial risk and medical necessity decision-making authority for some services (e.g. hospital, professional, pharmaceutical, biological, or transplant services) to medical groups or networks. These delegated entities are in the position of weighing clinical and cost-effectiveness considerations in making initial medical necessity decisions for plans' members.

We asked regulators to indicate whether their agencies regulate the activities of medical groups or networks accepting full or shared financial risk from plans. According to their responses, only **6** states directly regulate risk-sharing medical groups or networks, **36** states indirectly regulate risk-sharing groups or networks through their regulation of plans,ⁱ and **8** states do not regulate delegated entities in any way (not including Alaska, which was not selected to participate in our survey):ⁱⁱ



- = State directly regulates risk-sharing medical groups and networks.
- = State regulates risk-sharing medical groups and networks indirectly through their regulation of health plans.
- = State does not regulate medical groups or networks in any way.

ⁱ Regulators from the California Department of Managed Health Care indicated in response to our survey that they regulate risk-sharing medical groups and networks indirectly through their regulation of health plans. However, we also note that California's Senate Bill 260, which was signed into law in September 1999, includes a requirement that risk-bearing provider organizations in California, including some medical groups and networks, provide accounting information to external parties for state grading purposes. This suggests that California is starting to regulate delegated entities more directly in some areas.

ⁱⁱ During our preliminary telephone screening of state agencies, we asked state regulators about their regulation of managed care plans only, not about their regulation of risk-sharing medical groups or entities. Some agencies may have been excluded from participation in our study during this initial screening process, even though they performed some oversight of delegated entities. We cannot be certain, therefore, that our study detected all states that regulate delegated entities.

Regulators' comments to this question suggest that there is significant variation in the specific ways that agencies regulate delegated entities, however:

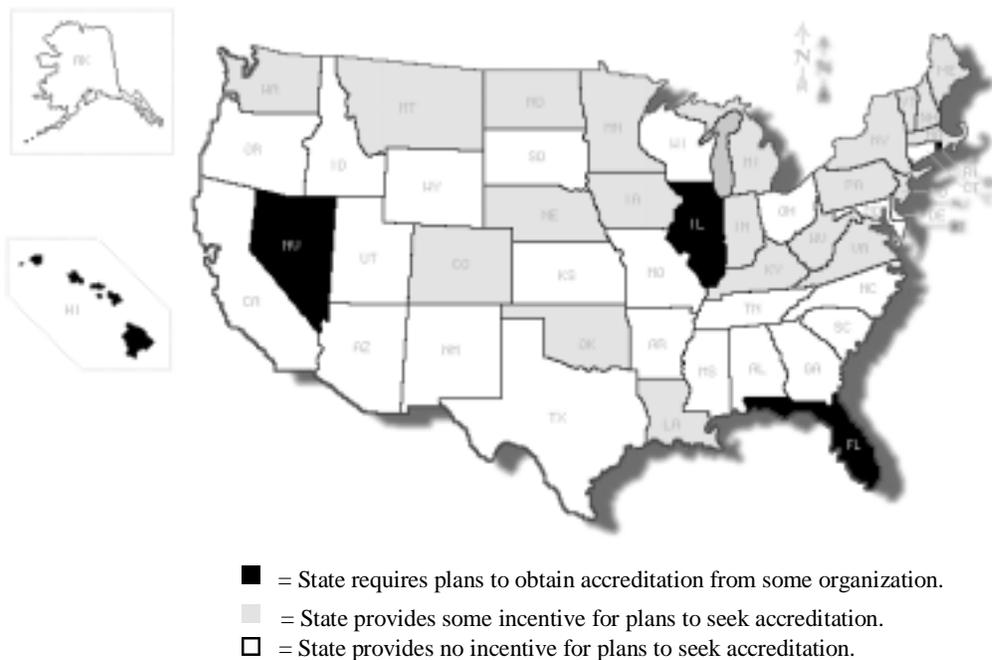
- Regulators from New Jersey reported that they require delegated entities to be licensed. The state recently passed a more extensive Organized Delivery Systems Act, but the rules pursuant to this have not yet been promulgated.
- Regulators from New York reported that their state is in the process of promulgating a regulation that would require financial security on the part of risk-sharing provider groups or provider intermediaries such as IPA-model HMOs.
- Regulators from Oregon reported that their oversight of risk-sharing medical groups or networks takes the form of market conduct audits of delegated entities.
- Regulators from Vermont reported that they regulate mental health review agents directly; comprehensive care groups and networks are not directly regulated, however.
- Regulators from Washington reported that they deem medical groups and networks to be “downstream entities” for which the insuring organization is held responsible.
- Regulators from Wyoming reported that their regulation of risk-sharing groups or networks depends on how much risk is shared by the insuring plan.

Regulating Accreditation

Accrediting organizations such as the National Committee for Quality Assurance (NCQA), American Accreditation HealthCare Commission (URAC), Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and Accreditation Association for Ambulatory Healthcare Organizations (AAAHC) are thought by many industry experts to uphold more rigorous standards for medical necessity decision-making and other utilization and quality management activities than state regulators. Our research group asked regulators whether their agencies provide incentives for plans to obtain accreditation from NCQA, URAC, JCAHO, and AAAHC, such as:

- Directly requiring plans to obtain accreditation from some organization.
- Requiring plans to undergo review by an accrediting organization.
- Automatically exempting accredited plans from some filing requirements.
- Encouraging plans to obtain accreditation in other ways.

According to their responses, only **5** states (Florida, Hawaii, Illinois, Nevada, and Rhode Island) explicitly regulate whether plans must obtain accreditation, but at least **26** states provide some form of incentive for plans to seek accreditation:



Some regulators indicated they encourage plans to obtain accreditation in other, similar ways:

- Permitting accredited plans to apply for exemption from some regulatory filing requirements
- Taking accreditation status into consideration when performing their own agency audits
- Requiring plans to meet the standards set by an accreditor without actually requiring accreditation

The following chart provides a state-by-state breakdown of regulators' responses:

| State | Require plans to obtain accreditation | Require plans to be reviewed by accreditor | Exempt accredited plans from some requirements | Provide other incentives for seeking accreditation ¹ |
|-----------------|---------------------------------------|--|--|---|
| AL | | | | |
| AZ ¹ | | | | |
| AR | | | | |
| CA | | | | |
| CO | | | | ✓ |
| CT | | | | |
| DE | | | | |
| DC | | | | |
| FL | ✓ | | | |
| GA | | | | |
| HI | ✓ | | | |
| ID | | | | |
| IL ² | ✓ | | ✓ | ✓ |
| IN | | | ✓ | |
| IA | | | ✓ | |
| KS | | | | |
| KY | | | ✓ | |
| LA | | | ✓ | |
| ME | | | | ✓ |
| MD | | | | |
| MA | | | ✓ ³ | |
| MI | | | | ✓ |
| MN | | | | ✓ |
| MS | | | | |
| MO | | | | |
| MT | | | ✓ ⁴ | |
| NE | | | | ✓ |
| NV | ✓ | | | |
| NH | | | | ✓ |
| NJ | | ✓ | | |
| NM | | | | |
| NY | | | | ✓ |
| NC | | | | |
| ND | | | | ✓ |
| OH | | | | |
| OK | | ✓ | | |
| OR | | | | |
| PA | | ✓ | | |
| RI | ✓ | | | |
| SC | | | | |
| SD | | | | |
| TN | | | | |
| TX | | | | |
| UT | | | | |
| VT | | | ✓ | |
| VA | | | ✓ | |
| WA | | | | ✓ |
| WV | | ✓ | ✓ | |
| WI | | | | |
| WY | | | | |

✓ = State provides this incentive for seeking accreditation.

¹ There may be additional states that provide other incentives for plans to obtain accreditation, even though regulators from these states may not have checked the “other” category in response to this question.

¹ Regulators from the Arizona Department of Insurance reported that they are in the process of developing regulations pursuant to Arizona's new HMO law which may allow accredited plans to be exempt from some regulatory requirements – expected July 1, 2001.

² Regulators from the Illinois Department of Insurance reported that they require plans that engage in determinations of medical necessity to register as utilization review organizations and obtain URAC accreditation. JCAHO and NCQA accreditation are voluntary, however.

³ Massachusetts regulations as of March 30, 2001: 1) Carriers accredited for URAC or NCQA PPO standards are exempt from on-site surveys of Quality Assurance, Utilization Review, Credentialing, and Preventive Health Services processes. 2) Carriers with score of 80% or greater in NCQA's QA/UR scores are exempt from on-site surveys of QA and UR; carriers with score of 80% or greater in NCQA's Preventive Health Service scores are exempt from on-site surveys of Preventive Health Services; carriers with score of 80% or greater in NCQA's credentialing scores are exempt from on-site surveys of credentialing.

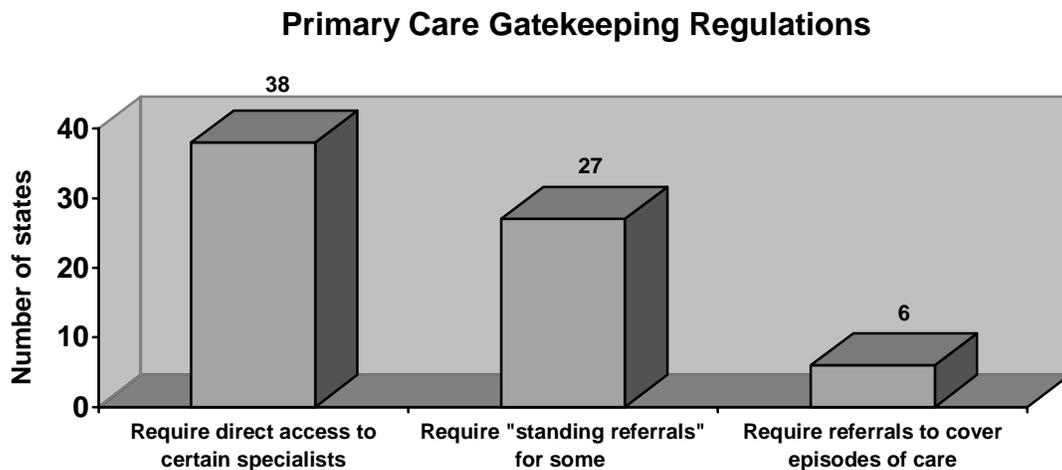
⁴ The Montana Code of Administration 33-36-301 specifies, "If the department finds that the standards of a nationally recognized accrediting organization meet or exceed state standards and that the health carrier has been accredited by the nationally recognized accrediting organization, the department shall approve the quality assurance standards of the health carrier."

Regulating Primary Care Gatekeeping

Primary care gatekeeping (i.e., requirements that patients obtain permission from primary care providers before seeing specialists) is one important strategy used by health plans to manage patients' utilization of specialty services. We asked regulators whether they place any of the following restrictions on the ways in which plans use this strategy:

- Requiring that all patients have direct access to certain types of specialists (e.g., OB/GYNs, chiropractors).
- Requiring that some patients have direct access to certain types of specialists (e.g., “standing referrals” for patients with chronic conditions).
- Requiring that referrals from primary care providers cover episodes of care rather than individual visits.

Regulators from **42** states reported that they regulate plans' use of primary care gatekeeping in one of the ways described above, such as requiring that all patients have direct access to certain types of specialists (**38** states), requiring that some patients receive “standing referrals” (**27** states), and requiring that referrals from primary care providers cover episodes of care (**6** states):



Some regulators suggested that some of the other activities performed by their agencies might result in indirect regulation of primary care gatekeeping. For example, some state agencies maintain requirements about access to primary care providers or enforce continuity of care and coordination of care protections that might indirectly influence the way that plans use primary care gatekeeping.

The following chart provides a state-by-state breakdown of regulators' responses:

| State | Require direct access to certain specialists | Require "standing referrals" for some patients | Require coverage for "episodes of care" |
|-------|--|--|---|
| AL | ✓ | | |
| AZ | | | |
| AR | ✓ | | |
| CA | ✓ | ✓ | ✓ |
| CO | ✓ | ✓ | |
| CT | ✓ | | |
| DE | ✓ ¹ | | |
| DC | ✓ | ✓ | |
| FL | ✓ | ✓ | |
| GA | ✓ | | |
| HI | ✓ | ✓ | |
| ID | ✓ | | |
| IL | ✓ | ✓ | ✓ |
| IN | ✓ | ✓ | |
| IA | ✓ | | |
| KS | | | |
| KY | ✓ | ✓ ² | |
| LA | | | |
| ME | ✓ | ✓ | |
| MD | ✓ | ✓ | ✓ ³ |
| MA | ✓ | ✓ | |
| MI | ✓ | | |
| MN | ✓ | ✓ | |
| MS | ✓ | | |
| MO | | ✓ | |
| MT | ✓ | ✓ | |
| NE | ✓ | | |
| NV | ✓ | | |
| NH | | | |
| NJ | | | |
| NM | ✓ | | ✓ |
| NY | ✓ | ✓ | |
| NC | ✓ | ✓ | |
| ND | | | |
| OH | ✓ | ✓ | |
| OK | | ✓ | |
| OR | ✓ | ✓ | |
| PA | ✓ | ✓ | |
| RI | ✓ | | |
| SC | ✓ | | |
| SD | | | |
| TN | | ✓ | ✓ |
| TX | ✓ | ✓ | |
| UT | ✓ | ✓ | ✓ |
| VT | ✓ | ✓ | |
| VA | ✓ | | |
| WA | | ✓ | |
| WV | ✓ | ✓ | |
| WI | ✓ | ✓ | |
| WY | | | |

✓ = State regulates primary care gatekeeping in this way.

¹ Regulators from the Delaware Department of Health and Social Services provided information for this state. However, they were able to point us to the parts of the Delaware Insurance Code that related to this issue.

² Regulators from the Kentucky Department of Insurance reported that Kentucky health plans must permit “standing referrals” for patients with chronic conditions for certain time periods only.

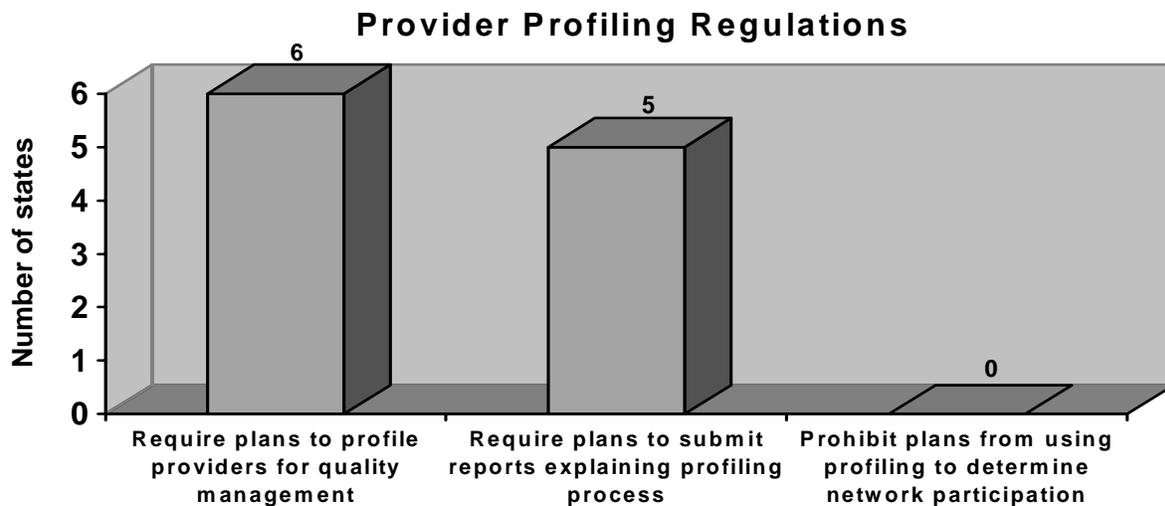
³ Regulators from the Maryland Insurance Administration reported that they require referrals from primary care providers to cover episodes of care for pregnancy cases only.

Regulating Provider Profiling

Provider profiling (i.e., comparisons of physicians' performance relative to their peers) is one strategy used by health plans to manage utilization and quality by encouraging participating providers to practice in a way that is consistent with their peers. We were interested in determining whether states regulate the way health plans use provider profiling in any of the following ways:

- Requiring plans to profile providers as part of quality management efforts.
- Requiring plans to submit reports explaining their profiling process.
- Prohibiting plans from using profiling to determine network participation.

Regulators from only **10** states indicated that they regulate provider profiling in one of the above ways. Regulators from **6** states reported requiring plans to profile their providers as part of their quality management efforts, and regulators from **5** states reported requiring plans to submit reports explaining their profiling process. No states prohibit plans from using profiling to determine network participation, according to regulators.



Regulators suggested that they regulate provider profiling in other ways, such as:

- Requiring that plans make their profiling reports available to providers either periodically or upon their request
- Requiring that plans make allowance for case mix and severity of illness when profiling providers
- Requiring that plans profiling procedures are initially developed in consultation with plan providers
- Prohibiting plans for publishing data which identifies particular providers, including any performance tracking data, without prior notice

The following chart provides a state-by-state breakdown of regulators' responses:

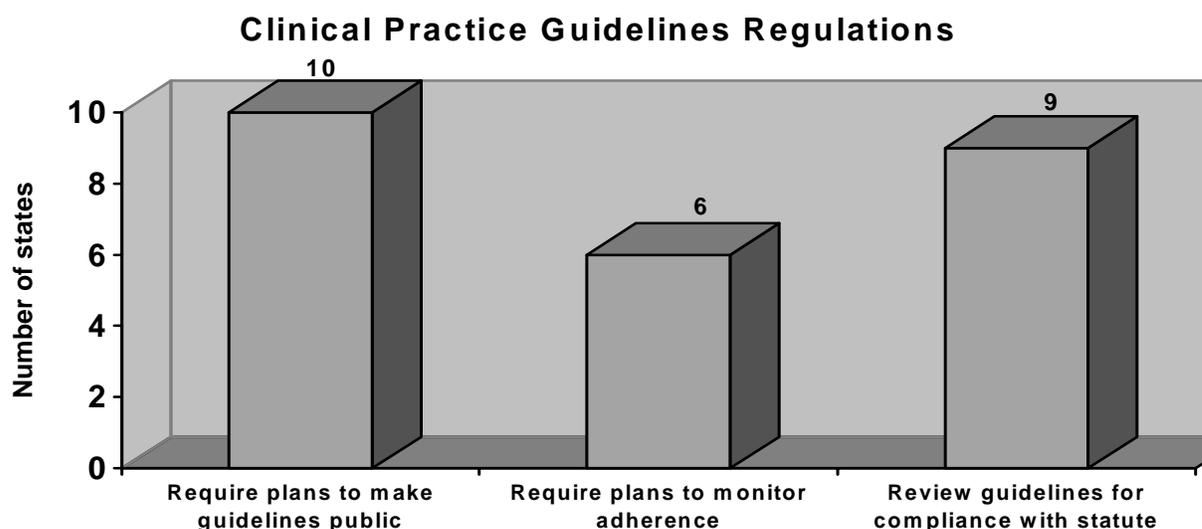
| State | Require plans to profile providers | Require plans to submit reports about their profiling process | Prohibit plans from using profiling to determine network participation |
|-------|------------------------------------|---|--|
| AL | | | |
| AZ | | | |
| AR | | ✓ | |
| CA | | ✓ | |
| CO | | | |
| CT | | ✓ | |
| DE | | | |
| DC | | | |
| FL | | | |
| GA | ✓ | | |
| HI | | | |
| ID | | | |
| IL | | | |
| IN | | | |
| IA | | | |
| KS | | | |
| KY | | | |
| LA | | | |
| ME | | | |
| MD | | | |
| MA | ✓ | ✓ | |
| MI | | | |
| MN | | | |
| MS | | | |
| MO | | | |
| MT | | | |
| NE | | | |
| NV | | | |
| NH | | | |
| NJ | ✓ | | |
| NM | | | |
| NY | | | |
| NC | ✓ | | |
| ND | | | |
| OH | | | |
| OK | | | |
| OR | | | |
| PA | ✓ | | |
| RI | | ✓ | |
| SC | | | |
| SD | | | |
| TN | | | |
| TX | | | |
| UT | | | |
| VT | ✓ | | |
| VA | | | |
| WA | | | |
| WV | | | |
| WI | | | |
| WY | | | |

Regulating Clinical Practice Guidelines

We asked state regulators if their agencies regulate the way health plans use clinical practice guidelines (i.e., authoritative recommendations for the clinical management of specific conditions) in the following ways:

- Requiring plans to make their guidelines available to the public.
- Requiring plans to monitor physicians' adherence to guidelines.
- Reviewing guidelines to ensure compliance with statutory requirements.

According to regulators, **18** states regulate clinical practice guidelines in one of the above ways. **Ten** states require plans to make their guidelines publicly available, **6** states require plans to monitor physician adherence to guidelines, and **9** states review guidelines for compliance with statutory requirements:



Many other regulators reported regulating clinical practice guidelines in other ways, including:

- Requiring plans to have programs to have quality improvement programs; these programs may specify the way that practice guidelines should be applied.
- Reviewing plans' utilization review criteria periodically or under special circumstances (e.g., when examining a complaint from an enrollee) to ensure that they apply their own practice guidelines).
- Some agencies require that plans develop clinical practice guidelines for certain conditions only (e.g., substance abuse).

The following chart provides a state-by-state breakdown of regulators' responses:

| State | Require plans to make guidelines publicly available | Require plans to monitor physicians' adherence | Review guidelines to ensure compliance with statute |
|-----------------|---|--|---|
| AL | | | |
| AZ | | | |
| AR | | | ✓ |
| CA | ✓ | ✓ | ✓ |
| CO | | | ✓ |
| CT | | | |
| DE | | | |
| DC | | | |
| FL | | | |
| GA | | | ✓ |
| HI | | | |
| ID | | | |
| IL | | | |
| IN | | ✓ | |
| IA | | | |
| KS | | | |
| KY | ✓ | | |
| LA | | | ✓ |
| ME | | | |
| MD | | | |
| MA | ✓ | ✓ | ✓ |
| MI | | ✓ | |
| MN | | | |
| MS | | | |
| MO | | | |
| MT | | | |
| NE | | | |
| NV | | | |
| NH | | | |
| NJ | | | ✓ |
| NM | ✓ | | |
| NY | | | |
| NC | ✓ | | ¹ |
| ND | | | |
| OH | | ✓ | |
| OK | ✓ | | ✓ |
| OR | ✓ | | |
| PA | | | |
| RI | ✓ | | |
| SC | | | |
| SD | ✓ | | |
| TN | | | |
| TX | | | |
| UT | | | |
| VT | | | |
| VA | | | |
| WA ² | | | |
| WV | ✓ | ✓ | ✓ |
| WI | | | |
| WY | | | |

✓ = State regulates health plans' use of clinical practice guidelines in this way.

¹ Regulators from North Carolina stated that they do not regulate clinical practice guidelines in this way except that substance abuse treatment guidelines must conform to certain criteria.

² Regulators from Washington state noted that their new Patient Bill of Rights, which was not scheduled to take effect until July 1, 2001, requires plans to make their guidelines publicly available and to monitor adherence.

Regulating Coverage Guidelines

Coverage guidelines, commonly also referred to as coverage or medical policies, are formal guidelines issued by health plans specifying the circumstances under which they will pay for a medical intervention for a group of patients with specific medical indications. We were interested in determining whether state agencies are regulating plans' coverage guidelines.

We asked regulators whether their agencies require the plans under their jurisdiction to make their coverage guidelines publicly available (i.e., at least to current and potential enrollees), and whether they ever review plans' guidelines for compliance with relevant statutory requirements. We also asked regulators to indicate the way in which compliance and enforcement activity related to coverage guidelines has changed during the past two years.

Regulators' comments about these questions indicated that there was some confusion about the term "coverage guidelines," despite our attempts to define it in our survey. Some regulators recognized that we were referring to detailed guidelines that plans develop to describe the specific circumstances under which interventions are considered appropriate for certain patients (e.g., guidelines specifying that electric bone growth stimulation is appropriate for patients whose long bone fracture have failed to show signs of healing for at least 9 months but not 6 months). Other regulators, however, initially confused this term with "certificates of coverage," documents in which plans describe the broad categories of medical interventions that are included in or excluded from enrollees' benefit packages (e.g., documents noting that osteogenesis stimulation treatments in general are covered where appropriate). Where possible, we attempted to clarify these distinctions in our follow-up calls to regulators.

Nevertheless, regulators indicated that there is variation in the degree to which their agencies are aware of and concerned about coverage guidelines as we defined them. They also indicated considerably more regulation of plans' coverage guidelines than of clinical practice guidelines. Regulators from **30** states, for example, require plans to make their coverage guidelines publicly available (i.e., to current and/or potential enrollees) under some circumstances, compared to **10** states which require the same for clinical practice guidelines. Regulators from **37** states sometimes review plans' coverage guidelines for compliance with relevant statutory requirements, compared to **9** states for clinical practice guidelines. According to regulators' responses to the survey, compliance and enforcement activity about these guidelines has increased in **20** states, decreased in **2** states, and stayed the same in **19** states over the past two years. The following chart provides a state-by-state breakdown of regulators' responses to these questions:

| State | Require plans to make coverage guidelines publicly available | Review guidelines for compliance with statutory requirements | Change in compliance/enforcement activity |
|------------------|--|--|---|
| AL | | ✓ | ↔ |
| AZ ¹ | ✓ | ✓ | DK |
| AR | ✓ | ✓ | ↑ |
| CA | ✓ | ✓ | ↑ |
| CO | | ✓ | ↓ |
| CT | 2 | | DK |
| DE ³ | | | DK |
| DC | ✓ | ✓ | ↑ |
| FL | | | ↑ |
| GA | | ✓ | ↔ |
| HI | ✓ | ✓ | ↑ |
| ID | ✓ | ✓ | ↑ |
| IL | ✓ | | ↑ |
| IN | ✓ | ✓ | ↑ |
| IA | ✓ ⁴ | | ↔ |
| KS | | ✓ | ↔ |
| KY | ✓ | ✓ | ↑ |
| LA | | ✓ | ↑ |
| ME | ✓ ⁵ | ✓ | ↑ |
| MD | ✓ | ✓ ⁶ | ↔ |
| MA | ✓ ⁷ | | ↔ |
| MI | | | DK |
| MN | | ✓ | ↑ |
| MS | ✓ | ✓ | ↔ |
| MO | | ✓ | ↔ |
| MT | ✓ | ✓ | DK |
| NE | ✓ | ✓ | ↔ |
| NV | ✓ | ✓ | ↑ |
| NH | ✓ | ✓ | DK |
| NJ | ✓ ⁸ | | DK |
| NM | ✓ | ✓ | ↑ |
| NY | ✓ | ✓ | ↑ |
| NC | ✓ | ✓ | ↔ |
| ND | | | ↔ |
| OH | ✓ ⁹ | ✓ | ↔ |
| OK | ✓ | ✓ | ↔ |
| OR | ✓ ¹⁰ | ✓ | ↓ |
| PA | | | ↔ ¹¹ |
| RI | ✓ | ✓ | ↑ |
| SC | | | DK |
| SD ¹² | | | ↑ |
| TN | | ✓ | ↔ |
| TX | | ✓ | ↑ |
| UT | ✓ | ✓ | ↔ |
| VT | ✓ ¹³ | ✓ | ↔ |
| VA | ✓ | ✓ | ↑ |
| WA | 14 | | DK |
| WV | ✓ | ✓ | ↑ |
| WI | | ✓ | ↔ |
| WY | | ✓ | ↔ |

- ✓ = State regulates coverage guidelines in this way.
- ↑ = Increase in compliance/enforcement activity over the past 2 years.
- ↔ = No change in compliance/enforcement activity over the past 2 years.
- ↓ = Decrease in compliance/enforcement activity over the past 2 years.
- DK = Regulator does not know if compliance/enforcement activity has changed.

¹ Regulators from the Arizona Department of Insurance indicated that legislation passed in 2000 provided them with statutory authority for reviewing plan coverage guidelines and requiring guidelines to be made publicly available. However, compliance and enforcement activity had not started at the time of the survey.

² Regulators from the Connecticut Insurance Department note that plans in their state are required to make their coverage guidelines available only to providers, and only at their Connecticut offices upon request after a denial.

³ Regulators from Delaware Division of Public Health reported that no one has performed on-site surveys of health plans or of their coverage guidelines for several years, because the relevant regulatory position within their agency has been vacant.

⁴ Regulators from Iowa reported that although they do not have a formal requirement for plans to make their coverage guidelines publicly available, they would “tell the HMO to provide them” if anyone asked to see them.

⁵ Regulators from the Maine Bureau of Insurance noted that plans under their jurisdiction are required to make their guidelines available to plan members, plan providers, and regulators, but not necessarily to other individuals not associated with the plan.

⁶ Regulators from the Maryland Insurance Administration note that their agency reviews health plan coverage guidelines only occasionally, and usually in the setting of a member complaint.

⁷ Regulators from the Massachusetts Department of Public Health noted that legislation passed in 2000 requires plans to reveal their clinical review criteria to enrollees when denying coverage for an intervention. Compliance and enforcement activity related to this legislation had not begun at the time of this survey, however.

⁸ Regulators from the New Jersey Department of Health and Senior Services noted that they usually use the term “coverage” to refer to a benefit or service that is covered under a plan member’s policy or contract. If the plan determines that it is medically appropriate for this member to have the service, it authorizes that service for coverage. If not, the plan denies coverage, and the member can appeal the denial.

⁹ Regulators from the Ohio Department of Health report that plans are required to make coverage guidelines publicly available during open enrollment periods only.

¹⁰ Oregon Revised Statute 743.804 states that all insurers offering a health benefit plan must provide enrollees with general information about “services provided, access to services, charges and scheduling applicable to each enrollee’s coverage;” upon request, insurers must provide enrollees with “a written summary of information that the insurer may consider in its utilization review of a particular condition or disease to the extent the insurer maintains such criteria.”

¹¹ Regulators from Pennsylvania indicated that legislation affecting regulation of coverage guidelines was recently passed in their state, but regulations pursuant to that legislation had not yet been promulgated at the time of the survey.

¹² Regulators from the South Dakota Division of Insurance reported that their managed care statutes became effective in July, 1999, resulting in a significant increase in compliance and enforcement activity. However, these statutes empower regulators to review guidelines for specific medical conditions only, such as mental illness.

¹³ Regulators from the Vermont Department of Banking, Insurance, Securities, and Health Care Administration noted that health plans must provide to recipients of adverse determinations, upon request, the specific criteria used to make the determination.

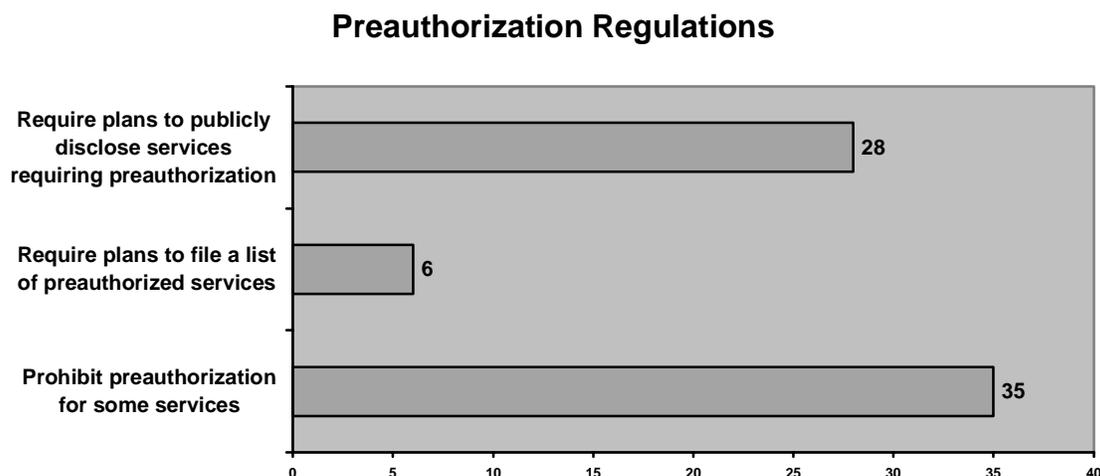
¹⁴ Regulators from Washington state indicated that their new Patient Bill of Rights included requirements for coverage guidelines, but this legislation was not scheduled to go into effect until July 1, 2001, several months after our survey was fielded.

Regulating Preauthorization Requirements

Preauthorization requirements (i.e., requirements that patients obtain prior approval from health plans for certain medical interventions) are an important way in which plans control members' access to certain services. We asked state regulators if they regulate plans' use of preauthorization requirements in any of the following ways:

- Requiring plans to disclose the interventions that require preauthorization to the public.
- Requiring plans to file a list of the interventions that require preauthorization with a state agency.
- Prohibiting plans from requiring preauthorization for certain types of services (e.g., emergency services).

Regulators from **40** states indicated that they regulate preauthorization in one of the above ways; **28** states require plans to publicly disclose the interventions requiring preauthorization; **6** states require plans to file a list of the interventions requiring preauthorization; and **35** states prohibit plans from requiring preauthorization for certain services:



Many regulators reported regulating preauthorization in other ways, such as:

- Setting time limits for plans to make preauthorization decisions (see “Regulating Timing of Decision-Making”).
- Prohibiting plans from retrospectively denying coverage for preauthorized services.
- Requiring that preauthorization decisions be made by qualified health care professionals.

According to regulators, compliance and enforcement activity increased in **20** states, decreased in **1** state, and stayed the same in **21** states. The following chart provides a state-by-state breakdown of regulators' responses to our questions:

| State | Require disclosure of preauthorized services | Plans must file a list of preauthorized services | Prohibit preauthorization for some services | Change in activity |
|-----------------|--|--|---|--------------------|
| AL | | | | DK |
| AZ | | | | ↔ |
| AR | | | ✓ | ↔ |
| CA | ✓ | | ✓ | ↑ |
| CO | | | ✓ | ↑ |
| CT | ✓ | | ✓ | ↑ |
| DE | | | | DK |
| DC | | | ✓ | ↑ |
| FL | | | ✓ | ↔ |
| GA | ✓ | ✓ | ✓ | ? |
| HI | | | ✓ | DK |
| ID | | | ✓ | ↑ |
| IL | ✓ | | ✓ | DK |
| IN | ✓ | ✓ | | ↔ |
| IA | ✓ | | ✓ | ↔ |
| KS | | | | DK |
| KY | ✓ | ✓ | ✓ | ↑ |
| LA | | | ✓ | ↔ |
| ME | ✓ | | ✓ | ↑ |
| MD | ✓ | ✓ | ✓ | ↑ |
| MA | ✓ | | ✓ | ↔ ¹ |
| MI | | | ✓ | ↑ |
| MN | ✓ | | ✓ | ↔ |
| MS | ✓ ² | | | ↔ |
| MO | | | ✓ | ↔ |
| MT | ✓ | | ✓ | ↑ |
| NE | ✓ | | ✓ | ↓ |
| NV | ✓ | ✓ | ✓ | ↑ |
| NH | | | | DK |
| NJ | | | ✓ | ↑ |
| NM | ✓ | | | ↑ |
| NY | | | ✓ | ↑ |
| NC | ✓ | | ✓ | ↔ ³ |
| ND | | | | ↔ |
| OH | ✓ | | ✓ | ↔ |
| OK | ✓ | | ✓ | ↑ |
| OR | ✓ | | | ↑ |
| PA | ✓ | | ✓ | ↔ |
| RI | ✓ | ✓ | ✓ | ↑ |
| SC | ✓ | | | ↔ |
| SD | ✓ | | ✓ | ↑ |
| TN | | | | ↔ |
| TX | ✓ | | ✓ | ↔ |
| UT | ✓ | | ✓ | ↔ |
| VT | ✓ | | ✓ | ↔ |
| VA | | | | ↑ |
| WA ⁴ | | | | DK |
| WV | ✓ | | ✓ | ↑ |
| WI | | | ✓ | ↔ |
| WY | | | | ↔ |

✓ = State regulates plans' use of preauthorization requirements in this way.
 ↑ = Regulators report increase in compliance/enforcement activity in past 2 years.
 ↔ = Regulators report no change in compliance/enforcement activity in past 2 years.
 ↓ = Regulators report decrease in compliance/enforcement activity in past 2 years.
 DK = Regulators do not know if compliance/enforcement activity has changed.
 ? = Regulators' responses to this question were not reconcilable.

¹ Regulators from Massachusetts reported that their state passed a new managed care law on January 1, 2001, but the regulations pursuant to this law were not promulgated until March 30, 2001, so enforcement and compliance activity had been unchanged at the time of this survey.

² Regulators from the Mississippi Department of Insurance reported that Mississippi HMOs are required to set forth preauthorization requirements in their evidence of coverage documents.

³ Regulators from the North Carolina Department of Insurance noted that nearly all of their managed care plans and regulations were enacted in 1996. While compliance and enforcement activity increased significantly from 1997-1998, activity remained more constant from 1999-2001.

⁴ Regulators from Washington noted that their new Patient Bill of Rights, which was not scheduled to take effect until July 1, 2001, prohibits plans from requiring preauthorization for some services, will require plans to file a list of the interventions that require preauthorization, and will require plans to disclose the interventions that require preauthorization to the public.

Regulating Timing of Decision-Making

We were interested in determining whether states require health plans to make prospective medical necessity (i.e., preauthorization) decisions within specific time limits. We also wanted to know whether states specify different time limits for urgent versus non-urgent cases¹ or apply them equally to all types of authorization decisions.

Additionally, we wanted to know if state regulators require plans to report when they fail to make decisions within specified limits, and if state agencies are empowered to take any disciplinary actions in these situations. Regulators were asked to describe any change in the amount of compliance and enforcement activity related to timing of decision-making in their states over the past two years.

Regulators from **33** states reported that their agencies set at least some time limits for prospective medical necessity decision-making in health plans. Their answers indicated that some states set different time limits for urgent and non-urgent cases, while other states do not make any distinctions between type of case. Limits for non-urgent cases range from 2 to 45 days; limits for urgent cases range from 24 to 72 hours.

Some regulators indicated that they specify special time limits for appeals decisions, although our questions were primarily directed at initial authorization decisions. Furthermore, some regulate the amount of time that plans may take to notify patients once decisions have been made, without setting time limits for decision-making itself.

Twelve states require plans to report when they fail to decide a case within the specified time limit, according to regulators' responses. Regulators are empowered to take a variety of actions when plans fail to make preauthorization decisions in a timely manner:

- Issue a warning to plans that fail to meet time limits (**22** states).
- Publicly report the proportion of cases not decided in time (**11** states).
- Impose a penalty on plans that fail to meet time limits (**26** states).
- Freeze enrollment in plans that fail to meet time limits (**13** states).
- Suspend or revoke plans' licenses or certificates of quality (**22** states).

Some regulators also noted that they require plans to provide and adhere to a corrective action plan or provide the patients involved with access to an appeal process for adverse determinations when time limits are exceeded.

Regulators from **23** states reported that compliance and enforcement activity in their states has increased significantly in the past two years, while regulators from another **20** reported that activity in their states has not changed. The following chart provides a state-by-state breakdown of regulators' responses to these questions:

¹ An urgent case is one in which patients face an imminent and serious threat to their health, such as the potential loss of life, limb, or other major bodily function.

| State | Set time limits for prospective determinations? | Require plans to report failure? | Enforcement Actions | | | | | Change in compliance/enforcement activity |
|-----------------|--|----------------------------------|------------------------|--------------------------|-------------------------|----------------------------|----------------------------------|---|
| | | | Issue warning to plan? | Publicly report failure? | Impose penalty on plan? | Freeze enrollment in plan? | Withdraw license or certificate? | |
| AL | 7 calendar days or "a time period that accommodates the clinical urgency of the situation." | ✓ | ✓ | | | | | ↑ |
| AZ | | | | | | | | DK |
| AR | 30 days for claims submitted electronically; 45 days for claims submitted by other means. ¹ | ✓ | ✓ | | ✓ | ✓ | ✓ | ↑ |
| CA | - Non-urgent: 5 business days. - Urgent: 72 hours. | | ✓ | ✓ | ✓ | ✓ | ✓ | ↑ |
| CO | 2 business days. | | ✓ | ✓ | ✓ | ✓ | ✓ | ↑ |
| CT | 2 business days after receipt of all necessary information. | | ✓ | ✓ | ✓ | | ✓ | DK |
| DE ² | | | | | | | | ↔ |
| DC | - Non-urgent: 30 business days. - Urgent: 48 hours. | | ✓ ³ | ✓ | | | | ↔ |
| FL | | | | | | | | ↔ |
| GA ⁴ | | | | | | | | ↔ |
| HI ⁵ | | | | | | | | ↑ |
| ID | 2 business days after receipt of all necessary information, "unless circumstances warrant longer." | | ✓ | | | ✓ | | ↔ |
| IL ⁶ | Decisions to be made in a "timely and prospective basis." | | | | ✓ | ✓ | ✓ | ↑ |
| IN ⁷ | | | | | | | | ↑ |
| IA | | | | | | | | ↔ |
| KS | | | | | | | | ↔ |
| KY ⁸ | - 24 hours after request for preadmission review of hospital admission unless additional information is needed. - 24 hours after request for continued hospital stay or preauthorization of treatment when already hospitalized. - 2 business days after request for other treatment, drug, or device. | ✓ | | | | | | ↑ |

| State | Set time limits for prospective determinations? | Require plans to report failure? | Enforcement Actions | | | | | Change in compliance/enforcement activity |
|------------------|---|----------------------------------|------------------------|--------------------------|-------------------------|----------------------------|----------------------------------|---|
| | | | Issue warning to plan? | Publicly report failure? | Impose penalty on plan? | Freeze enrollment in plan? | Withdraw license or certificate? | |
| LA | 30 days after request unless the patient agrees to an extension. ⁹ | ✓ | | | ✓ | | | ↑ |
| ME | 2 working days. | ✓ ¹⁰ | ✓ | ✓ | ✓ | ✓ | ✓ | ↑ |
| MD | 2 working days. | ✓ | ✓ | | ✓ | | ✓ | ↑ |
| MA | 2 working days after obtaining necessary information. ¹¹ | | | | ✓ | ✓ | ✓ | ↔ ¹² |
| MI | | | | | | | | DK |
| MN | - Un-expedited: 10 business days after request. - Expedited: 72 hours. | | | | ✓ | | ✓ | ↑ |
| MS ¹³ | | | | | | | | ↔ |
| MO | 2 working days - initial determination. 24 hours - determination to certify an admission, procedure or service. | ✓ | ✓ | ✓ | ✓ | | ✓ | ↔ |
| MT ¹⁴ | | | | | | | | ↑ |
| NE | | | | | | | | ↑ |
| NV ¹⁵ | | | | | | | | ↑ |
| NH | 72 hours for expedited review. | ✓ | | | ✓ | | ✓ | DK |
| NJ | All determinations shall be made on a timely basis, as required by the exigencies of the situation. | | ✓ | ✓ | ✓ | ✓ | ✓ | ↑ |
| NM | Non-urgent: 5 days, or extended to 10 days under appropriate circumstances. | ✓ | ✓ | | ✓ | | ✓ | ↑ |
| NY | - Non-urgent: 3 days. - Urgent: 48 hours. - Continuing care: 24 hours. | | ✓ | | ✓ | | | ↑ |
| NC | - Non-expedited: 3 business days. - Expedited: 4 business days. | | ✓ | ✓ | ✓ | ✓ | ✓ | ↔ |
| ND | 2 business days. | | | | ✓ | | ✓ | ↔ |
| OH | 2 business days after obtaining all necessary information, "unless the seriousness of the medical condition of the enrollee requires a more timely response." ¹⁶ | | ✓ | | ✓ | ✓ | ✓ | ↔ |
| OK | 5 business days except in situations in which the normal time frame could jeopardize a patient's life or health. ¹⁷ | | ✓ | | ✓ | ✓ | ✓ | ↔ |

| State | Set time limits for prospective determinations? | Require plans to report failure? | Enforcement Actions | | | | | Change in compliance/enforcement activity |
|------------------|---|----------------------------------|------------------------|--------------------------|-------------------------|----------------------------|----------------------------------|---|
| | | | Issue warning to plan? | Publicly report failure? | Impose penalty on plan? | Freeze enrollment in plan? | Withdraw license or certificate? | |
| OR | 30 days unless the period of time is too long to accommodate the clinical urgency of a situation. ¹⁷ | 18 | ✓ | ✓ | | | | ↔ |
| PA | 2 business days. | | ✓ | ✓ | ✓ | ✓ | ✓ | ↔ ¹⁹ |
| RI | - Non-urgent: 7 business days of receipt of all necessary information. - Urgent: 1 business day of receipt of all necessary information. | ✓ | ✓ | | ✓ | | | ↑ |
| SC | 2 working days of receipt of all necessary information. | | | | ✓ | | ✓ | DK |
| SD | Initial review - 2 working days. Concurrent review - 1 working day. | ✓ | | | | | | ↑ ²⁰ |
| TN | 2 business days -- PPO, indemnity plans, HMOs. 72 hours - urgent cases | | | | ✓ | | ✓ | ↔ |
| TX | 1 working day when patient is hospitalized, 3 working days when patient is not hospitalized, within 1 hour when denying post-stabilization care after emergency | 21 | ✓ | | ✓ | | ✓ | ↑ |
| UT | | | | | | | | ↔ |
| VT | - Non-urgent: 3 business days of receipt of necessary information. - Urgent: 24 hours from the time service is requested. | ✓ | ✓ | ✓ | ✓ | | | ↔ |
| VA | Urgent: 24 hours. Also, immediate expedited review for decisions about alleviation of cancer pain. | | ✓ | | ✓ | ✓ | ✓ ²² | ↑ |
| WA ²³ | | | | | | | | DK |
| WV | Follow time limits established by accreditors, e.g., NCQA and URAC | | | | | | | ↑ |
| WI | | | | | | | | ↔ |
| WY | | | | | | | | ↔ |

| | |
|----|---|
| ✓ | = One or more state agencies performs this monitoring/enforcement action. |
| ↑ | = Regulators report an increase in compliance/enforcement activity over the past 2 years. |
| ↔ | = Regulators report no change in compliance/enforcement activity over the past 2 years. |
| DK | = Regulator does not know if compliance/enforcement activity has changed. |

¹ Regulators from the Arkansas Department of Insurance reported that although their rules do not specifically address "urgent" cases, it is "standard policy" for plans to review urgent cases "immediately."

² Regulators from the Delaware Division of Public Health reported that Delaware sets specific time limits only for appeals determinations, not for first-time prospective medical necessity determinations.

³ Information about timing regulations in the District of Columbia was provided by the D.C. Department of Health. This agency indicated that it could request further disciplinary action on the part of the D.C. Department of Insurance and Securities Regulation, an agency with broader enforcement powers, if necessary.

⁴ Georgia regulators indicated that they do not require plans to make determinations within specified time limits, but they do require plans to notify patients/providers in a timely manner once determinations have been made. Regulation 120-2-58-.05, "Requirements for Utilization Review," states "(a) When an initial determination is made to certify... [w]ritten notification shall be transmitted within two (2) business days of the determination. (b) When a determination is made not to certify, the attending physician and/or other ordering health care provider or facility rendering service shall: 1. Be notified by telephone within one (1) business day. 2. Be sent a written notification within one (1) business day, which also shall be sent to the enrollee."

⁵ Regulators from the Hawaii Division of Insurance indicated that their state sets specific time limits for appeals determinations, although not for initial determinations.

⁶ Regulators from the Illinois Department of Public Health report that their agency set additional explicit time limits for appeals determinations.

⁷ Regulators from the Indiana Department of Insurance indicated that their state sets specific time limits for appeals determinations, although not for initial determinations.

⁸ Regulators from the Kentucky Department of Insurance note that their agency specifies different time limits for appeals determinations than for initial determinations; for example.

⁹ Also, Louisiana Department of Insurance regulators indicated that they require that in no less than 80% of initial determinations, a medical necessity review organization shall make the determination within 2 working days of obtaining any necessary information.

¹⁰ Health plans in Maine may notify patients and providers if they need more time due to their inability to obtain information from a non-contracted provider involved in the case, according to regulators.

¹¹ Massachusetts regulators reported that they also require that the provider responsible for providing the service be notified by telephone within 24 hours after the decision is made, with later written or electronic confirmation.

¹² Massachusetts passed a new managed care law on January 1, 2001, but the regulations pursuant to this law were not promulgated until March 30, 2001, so enforcement and compliance activity had been unchanged at the time of this survey.

¹³ Regulators from the Mississippi Insurance Department note that although their agency does not set specific time limits for plans to make decisions, they do expect plans to make decisions within "a reasonable time."

¹⁴ Montana does not require plans to make determinations within specified time limits, but it does require plans to notify patients/providers in a timely manner once determinations have been made. Administrative Rules of Montana 378.108.310, based upon the insurance section of the Managed Care Act, state that "A managed care entity shall notify an enrollee and the health care provider of any adverse determination within 10 calendar days from the date the decision is made if the decision involves routine medical care. A managed care entity shall notify an enrollee and the health care provider of any adverse determination within 48 hours from the date the decision is made, excluding Sundays and holidays, if the decision involves a medical care determination which qualifies for expedited review." Information about timing regulations in Montana was provided by the Montana Department of Health. This agency indicated that it was not empowered to take disciplinary action on its own, but it could recommend such action to the Montana Insurance Division, an agency with broader enforcement powers, if necessary.

¹⁵ Regulators from the Nevada State Health Division reported that they set specific time limits only for response to patient complaints, not for first-time prospective medical necessity determinations.

¹⁶ Ohio regulators reported that they also require that the provider or health care facility responsible for providing the service be notified within 3 business days after the decision is made.

¹⁷ Additionally, Oregon requires that once utilization review decisions have been made, health plans must notify patients or providers within seven days after making the decision, according to regulators.

¹⁸ Regulators from the Oregon Insurance Division reported that insurance carriers in Oregon are permitted to combine their utilization review processes and their grievance processes. If this is the case, then they must report their failure to meet utilization review time limits in the annual grievance report that they submit to the Oregon Insurance Division.

¹⁹ Regulators from Pennsylvania reported that additional legislation related to timing of decision-making has been passed, but compliance and enforcement activity related to that legislation has not yet begun.

²⁰ South Dakota Department of Insurance regulators indicated that their new managed care statutes became effective on July 1, 1999, and compliance and enforcement activity has increased significantly since then.

²¹ Regulators from the Texas Department of Insurance note that although they do not require plans to report when they have not decided a case within specified limits, they expect to learn about non-compliance through on-site exams, member complaints, and utilization review information audits submitted to their agency.

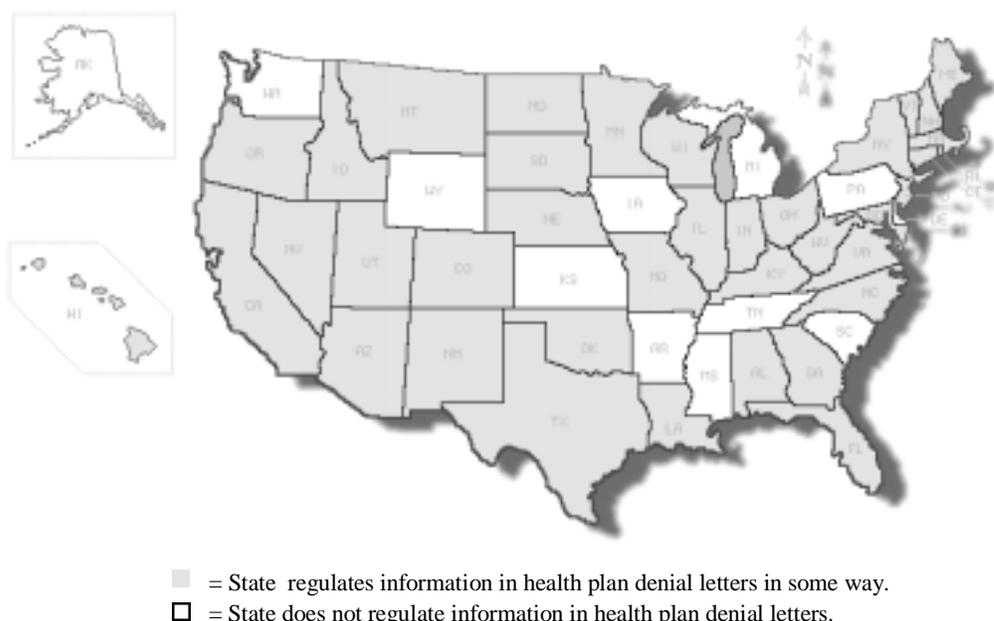
²² Revoking a plan's certificate of quality assurance is the responsibility of the Virginia Department of Health. All other disciplinary actions fall under the jurisdiction of the Virginia Bureau of Insurance.

²³ Regulators from Washington indicated that their new Patient Bill of Rights sets time limits for decision-making (non-urgent = 30 days, urgent = 72 hours), but this legislation were not scheduled to go into effect until July 1, 2001, several months after the fielding of this survey.

Regulating Denial Letters

Our research group was interested in whether states regulate the information that plans send in letters to patients when they deny coverage for an intervention. We asked regulators to confirm whether their state law contains requirements about the information that health plans must include in denial letters to patients.ⁱ

Regulators from **39** states indicated that their state laws contain at least some requirements about the information plans must include in denial letters to patients:



| State | Regulate information in denial letters? | Specific reasons for denial | Information about internal appeal | Information about external appeal | Description of evidence or criteria used in decision | Reference to medical necessary | Description of decision-maker's qualifications | Reference to contract provisions | Change in compliance/enforcement activity |
|-------|---|-----------------------------|-----------------------------------|-----------------------------------|--|--------------------------------|--|----------------------------------|---|
| AL | ■ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ↔ |
| AZ | ■ | | ✓ | | | | | | ↑ |
| AR | | | | | | | | | DK |
| CA | ■ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ↑ |
| CO | ■ | ✓ | ✓ | | | | | | ↑ |
| CT | ■ | ✓ | ✓ | ✓ | | ✓ | | | DK |
| DE | ² | | | | | | | | DK |
| DC | ■ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ↔ |
| FL | ■ | ✓ | ✓ | ✓ | ✓ | | ✓ | ✓ | ↔ |
| GA | ■ | ✓ | ✓ | ✓ | ✓ | | | | ↔ |
| HI | ■ | | | ✓ | | | | | ↑ |
| ID | ■ | ✓ | ✓ | | | | | | ↑ |
| IL | ■ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ↑ |
| IN | ■ | ✓ | ✓ | ✓ | ✓ | | | | ↑ |
| IA | | | | | | | | | ↔ |
| KS | | | | | | | | | ↔ |
| KY | ■ | ✓ | ✓ | ✓ | ✓ | | ✓ | ✓ | ↑ |
| LA | ■ | ✓ | ✓ | ✓ | | ✓ | ✓ | | ↑ |
| ME | ■ | ✓ | ✓ | ✓ | ✓ | | ✓ | | ↑ |
| MD | ■ | ✓ | ✓ | ✓ | ✓ | | ✓ | | ↑ |
| MA | ■ | ✓ | ✓ | ✓ | ✓ | | | | ↔ ³ |
| MI | | | | | | | | | DK |
| MN | ■ | ✓ | ✓ | ✓ | | ✓ | | ✓ | ↑ |
| MS | | | | | | | | | ↔ |
| MO | ■ | ✓ | ✓ | | | | | | ↔ |
| MT | ■ ⁴ | ✓ | ✓ | ✓ | | ✓ | | | DK |
| NE | ■ | ✓ | ✓ | | | | | | ↑ |
| NV | ■ | ✓ | | | | | | | ↑ |
| NH | ■ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | | DK |
| NJ | ■ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ↑ |
| NM | ■ | ✓ | ✓ | ✓ | ✓ | | ✓ | ✓ | ↑ |
| NY | ■ | ✓ | ✓ | ✓ | ✓ | ✓ | | ✓ | ↑ |
| NC | ■ | ✓ | ✓ | | ✓ | | | | ↔ |
| ND | ■ | ✓ | ✓ | | | | | | ↔ |
| OH | ■ | | ✓ | ⁵ | | | | | ↔ |
| OK | ■ | ✓ | ✓ | ⁶ | | ✓ | | | ↑ |
| OR | ■ | ✓ | ✓ | ⁷ | | | | ✓ | ↔ |
| PA | | | | | | | | | ↔ ⁸ |
| RI | ■ | ✓ | ✓ | ✓ | ✓ | ✓ | | | ↑ |
| SC | | | | | | | | | DK |
| SD | ■ | ✓ | ✓ | | | | | | ↑ ⁹ |
| TN | | | | | | | | | ↔ |
| TX | ■ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | | ↑ |
| UT | ■ | ✓ | | | | ✓ | | | ↔ |
| VT | ■ | ✓ | ✓ | ✓ | ✓ | | ✓ | | ↔ |
| VA | ■ | ✓ | ✓ | ✓ | ✓ | ✓ | | ✓ | ↑ |
| WA | ¹⁰ | | | | | | | | DK |
| WV | ■ | ✓ | ✓ | | ✓ | | | ✓ | ↑ |
| WI | ■ | ✓ | ✓ | ¹¹ | | | | | ↔ |
| WY | | | | | | | | | ↔ |

| | |
|----|---|
| ■ | = State regulates information in health plan denial letters in some way. |
| ✓ | = State requires plans to include this information in denial letters. |
| ↑ | = Regulators report an increase in compliance/enforcement activity in past 2 years. |
| ↔ | = Regulators report no change in compliance/enforcement activity in past 2 years. |
| DK | = Regulator does not know if compliance/enforcement activity has changed. |
| ? | = Regulators' answers to this question were not reconcilable. |

¹ Regulators from the Colorado Division of Insurance reported that information about patients' rights to external appeal is required in letters for appeal-level denials only, not initial denials.

² Regulators from the Delaware Division of Public Health reported that they regulate information in denial letters for appeal-level denials only, not for initial denials.

³ Massachusetts regulators reported that their new managed care law went into effect on January 1, 2001, and the regulations pursuant to that law were promulgated on March 30, 2001, but compliance and enforcement activity related to these regulations had not yet begun at the time of this survey.

⁴ Regulators from the Montana Insurance Department noted that they set additional requirements for denial letters specific to appeals determinations, as opposed to initial determinations.

⁵ Regulators from the Ohio Department of Insurance reported that information about patients' rights to external appeal is required in letters for appeal-level denials only, not initial denials.

⁶ Regulators from the Oklahoma State Department of Health noted that at the conclusion of any internal appeals process, Oklahoma HMOs must advise members that a request for assistance may be filed with the Department of Health. However, HMOs are not necessarily required to provide this information in denial letters following initial denials.

⁷ Oregon Insurance Division regulators noted that Oregon Revised Statute 743.804 requires insurance carriers to notify consumers of their right to seek assistance from the Oregon Insurance Division at any time; however, this requirement is not specific to denial letters.

⁸ Regulators from Pennsylvania indicated that legislation regarding denial letters was recently passed in their state, but regulations pursuant to that legislation have not yet been promulgated.

⁹ Regulators from the South Dakota Division of Insurance reported that their managed care statutes became effective in July, 1999, resulting in a significant increase in compliance and enforcement activity.

¹⁰ Regulators from Washington state indicated that their new Patient Bill of Rights included requirements for health plan denial letters, but this legislation will not go into effect until July 1, 2001.

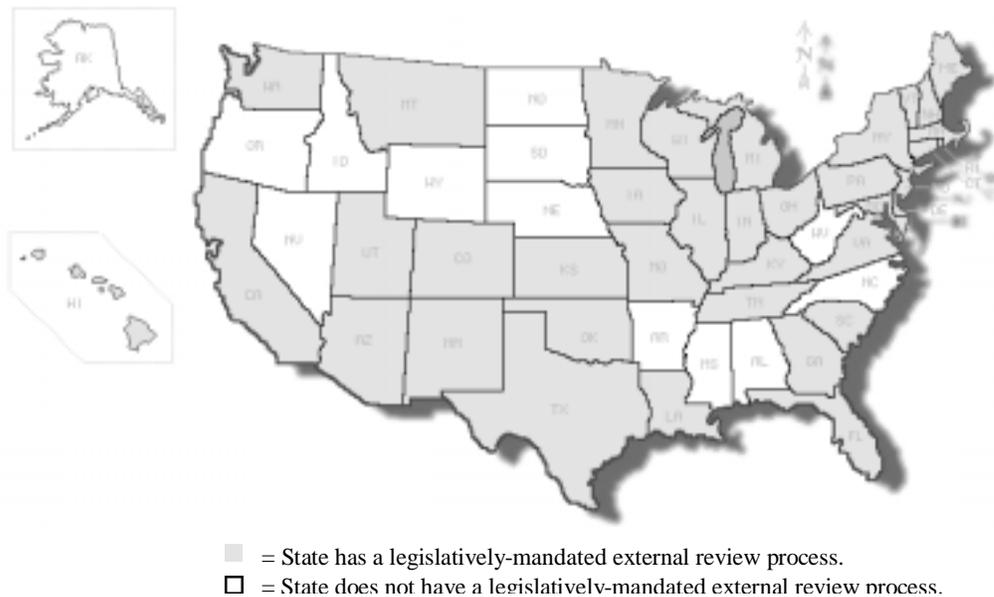
¹¹ Regulators from Wisconsin indicated that when administrative rules pursuant to their new external review law (passed in May, 2000) are finally promulgated, they will require insurers to include in denial letters a notification of the right to request an independent review, instructions for requesting an independent review, and a description the time within which the review must be requested.

Conducting an External Review Process

Prior research has documented the rapid increase in legislation specifying external review processes for medical necessity denials in health plans.ⁱ We asked regulators to confirm whether their state has a legislatively-mandated external review process and, if so, whether their agency plays any direct or indirect role in conducting reviews.

Where applicable, we asked regulators to describe the sources of information that reviewers are required to use when reviewing the clinical effectiveness of interventions; we also asked if the mandated review process permits the reviewer to take cost into consideration. Additionally, we asked regulators to describe the way that compliance and enforcement activity regarding external reviews has changed in the past two years.

Regulators from **38** states reported that there is a legislatively-mandated external review process for medical necessity denials (and sometimes for denials based on coverage or for denials of experimental/investigational treatments) in their state.ⁱⁱ



Regulators from **11** states reported that a state agency or its contracted representative actually conducts the reviews; regulators from **31** states indicated that one or more agencies certify or select the independent organizations that conduct reviews.ⁱⁱⁱ

ⁱ See Pollitz K, Dallek G, and Tapay N. “External Review of Health Plan Decisions: An Overview of Key Program Features in the States and Medicare.” Kaiser Family Foundation: November 1998; and Dallek G, Pollitz K. “External Review of Health Plan Decisions: An Update.” Kaiser Family Foundation: May 2000.

ⁱⁱ As previously noted in the “Regulating Denial Letters” section, only 24 states require that plans provide information about the patient’s right to external appeal in denial letters for initial denials, even though 38 states report having a legislatively-mandated external review processes. Some regulators indicated that information about the patient’s right to external appeal is required in denial letters for internal appeals-level decisions instead. However, it also appears that some states have an inconsistent approach to external review; some states mandate an external review process without requiring notification of this process in denial letters.

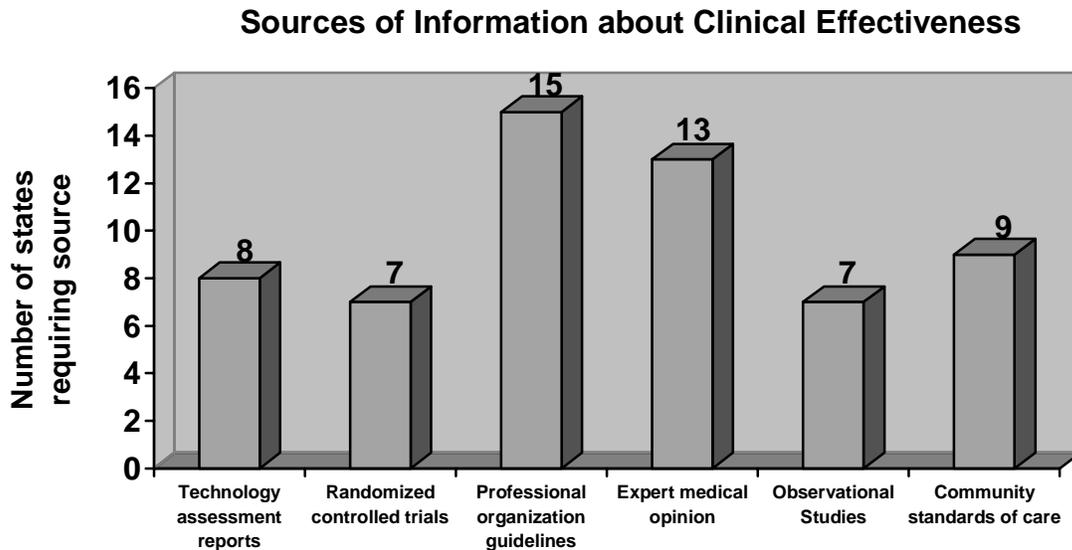
ⁱⁱⁱ Regulators from the California Department of Managed Health Care, Maryland Insurance Administration, New Hampshire Insurance Department, and New Mexico Division of Insurance reported their agency both conducts external reviews and selects/certifies other organizations that conduct reviews.

The following chart provides a state-by-state breakdown of responses:

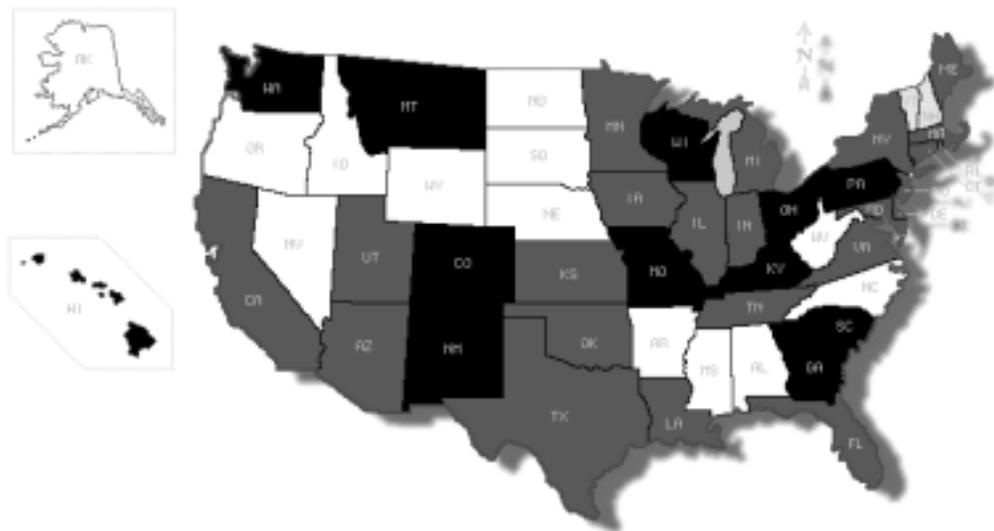
| State | State mandates a review process? | Product applicability | | | | State participates in review process? | Change in compliance/enforcement activity |
|-----------------|----------------------------------|-----------------------|-----|-----|-------|---------------------------------------|---|
| | | HMO | POS | PPO | Other | | |
| AL | | | | | | | |
| AZ | ✓ | X | X | X | X | ■ | ↑ ¹ |
| AR | | | | | | | |
| CA | ✓ | X | | | | ■/□ | ↑ |
| CO | ✓ | X | X | X | X | □ | ↑ ² |
| CT | ✓ | X | X | | X | ■ | ↔ |
| DE | ✓ | X | | | | □ | ↔ ³ |
| DC | ✓ | X | X | | X | ■ | ↑ |
| FL | ✓ | X | | | | ■ | ↔ |
| GA | ✓ | X | | | | □ | ↑ |
| HI | ✓ | X | | X | X | ■ | ↑ |
| ID | | | | | | | |
| IL | ✓ | X | | | | □ ⁴ | ↑ |
| IN | ✓ | X | X | | | □ | ↑ |
| IA | ✓ | X | X | | | □ | ↔ |
| KS | ✓ | X | X | X | X | □ | ↑ |
| KY | ✓ | X | X | X | X | □ | ↑ |
| LA | ✓ | X | X | X | X | □ | ↑ |
| ME | ✓ | X | X | X | | □ | ↑ ⁵ |
| MD | ✓ | X | X | X | X | ■/□ | ↑ |
| MA | ✓ | X | X | X | X | □ | ↔ ⁶ |
| MI | ✓ | X | | | | □ ⁷ | ↑ |
| MN | ✓ | X | X | | | □ | ↑ |
| MS | | | | | | | |
| MO | ✓ | X | X | X | | □ | ↑ |
| MT | ✓ | X | | | X | □ | ↑ |
| NE | | | | | | | |
| NV | | | | | | | |
| NH | ✓ | X | | X | X | ■/□ | DK |
| NJ | ✓ | X | X | X | X | □ | ↑ ⁸ |
| NM | ✓ | X | | | | ■/□ | ↑ |
| NY | ✓ | X | X | X | X | □ | ↑ |
| NC ⁹ | | | | | | | |
| ND | | | | | | | |
| OH | ✓ | X | X | | X | □ | ↔ ¹⁰ |
| OK | ✓ | X | | | | □ | ↑ ¹¹ |
| OR | | | | | | | |
| PA | ✓ | X | X | | | □ | ↑ |
| RI | ✓ | X | X | X | X | □ | ↑ |
| SC | ✓ ¹² | X | X | | X | □ | ↔ |
| SD | | | | | | | |
| TN | ✓ | X | X | | | ■ | ↑ |
| TX | ✓ | X | X | X | X | □ | ↔ |
| UT | ✓ | X | X | | X | □ | DK |
| VT | ✓ | X | X | X | X | □ | ↔ |
| VA | ✓ | X | X | X | | ■ | ↑ ¹³ |
| WA | ✓ ¹⁴ | X | X | X | X | □ | ↔ |
| WV | | | | | | | |
| WI | ✓ ¹⁵ | X | X | X | X | □ | ↔ |
| WY | | | | | | | |

| | |
|----|--|
| ✓ | = This state has a legislatively-mandated external review process. |
| X | = The external review process in this state applies to this managed care product. |
| ■ | = State agencies conduct reviews of medical necessity denials in this state. |
| □ | = State agencies do not conduct reviews of medical necessity denials, but they certify or select the independent organizations that conduct reviews in this state. |
| ↑ | = Regulators report an increase in compliance/enforcement activity in past 2 years. |
| ↔ | = Regulators report no change in compliance/enforcement activity in past 2 years. |
| DK | = Regulators do not know if compliance/enforcement activity has changed. |

When asked about the sources of information that external reviewers are required to use (if available) when evaluating the clinical effectiveness of requested interventions, regulators most often cited guidelines from professional organizations (**15** states). Also frequently required are expert medical opinion (**13** states) and community standards of care (**9** states). Less frequently required are technology assessment reports (**8** states), and randomized controlled clinical trials and observational studies (**7** states each). **Of note, regulators from 19 states reported that their agencies do not specify the sources of information that reviewers are required to use:**



Regulators from **23** states indicated that reviewers are prohibited from considering cost when conducting external reviews, as shown below:



- = Regulators report that reviewers are permitted to consider cost in reviews.
- = Regulators report that reviewers are not permitted to consider cost in reviews.
- = Regulators do not know if reviewers are permitted to consider cost.
- = State does not have a legislatively-mandated review process.

Regulators from Montana indicated that reviewers were permitted to take into account “reasonable costs,” for example, when conducting a review.

¹ Regulators from the Arizona Department of Insurance reported that there has been a large increase in compliance and enforcement activity in the past 3 years, and a somewhat smaller increase in just the past 2 years.

² Colorado’s external review law became effective in June, 2000, according to Division of Insurance regulators, resulting in a significant increase in the amount of compliance and enforcement activity related to external review.

³ Regulators from the Delaware Division of Public Health indicated that Delaware passed its new external review law in 2000, but the regulations pursuant to this law were still being developed by state agencies at the time of this survey, so compliance and enforcement activity had not yet begun.

⁴ Clarification: the Illinois Department of Insurance defines standards for independent organizations that conduct reviews of medical necessity denials, but does not actually select or certify these organizations.

⁵ Regulators from the Maine Bureau of Insurance noted that Maine’s Patient Bill of Rights, granting external review rights to health plan enrollees, was passed in 1999, and compliance and enforcement activity related to this legislation began in August, 2000.

⁶ Massachusetts regulators noted that their new managed care law went into effect on January 1, 2001, and the regulations pursuant to that law were promulgated on March 30, 2001, but compliance and enforcement activity related to these regulations had not yet begun at the time of this survey.

⁷ Although the Michigan Insurance Division directly conducts external review for coverage denials, it merely selects the independent organizations that conduct external reviews for medical necessity denials.

⁸ Regulators from the New Jersey Department of Health and Senior Services noted that external review determinations were declared binding on health plans in New Jersey on January 16, 2001, resulting in an increase in the amount of compliance and enforcement activity in this area.

⁹ Since completion of our survey, the 2001 session of the NC General Assembly passed a new law mandating an independent external review. This process will be available after the insured has exhausted the plan's two levels of internal review. This new law becomes effective July 1, 2002.

¹⁰ Regulators from Ohio noted that Ohio's external review law became effective on May 1, 2000, and state agencies have promulgated rules pursuant to this law, but they had not reviewed or enforced plans' adherence to these rules at of this survey.

¹¹ Regulators from the Oklahoma State Department of Health noted that Oklahoma's first external review law became effective on February 1, 2000, resulting in a significant increase in compliance and enforcement activity in this area.

¹² Regulators from the South Carolina Department of Insurance noted that their external review law is not scheduled to go into effect until January 1, 2002.

¹³ Virginia's external review law was passed in 1999, and the regulations pursuant to it were promulgated in May, 2000, resulting in a significant increase in compliance and enforcement activity in this area.

¹⁴ Regulators from Washington state noted that Washington's Patient Bill of Rights, which was signed into law in March, 2000, specifies an external review process, but compliance and enforcement related to this law had not begun at the time of the survey.

¹⁵ Wisconsin passed legislation relating to external review in May, 2000. The Office of the Commissioner of Insurance was still promulgating administrative rules to implement the law at the time of this survey.

Overall Change in Compliance & Enforcement Activity

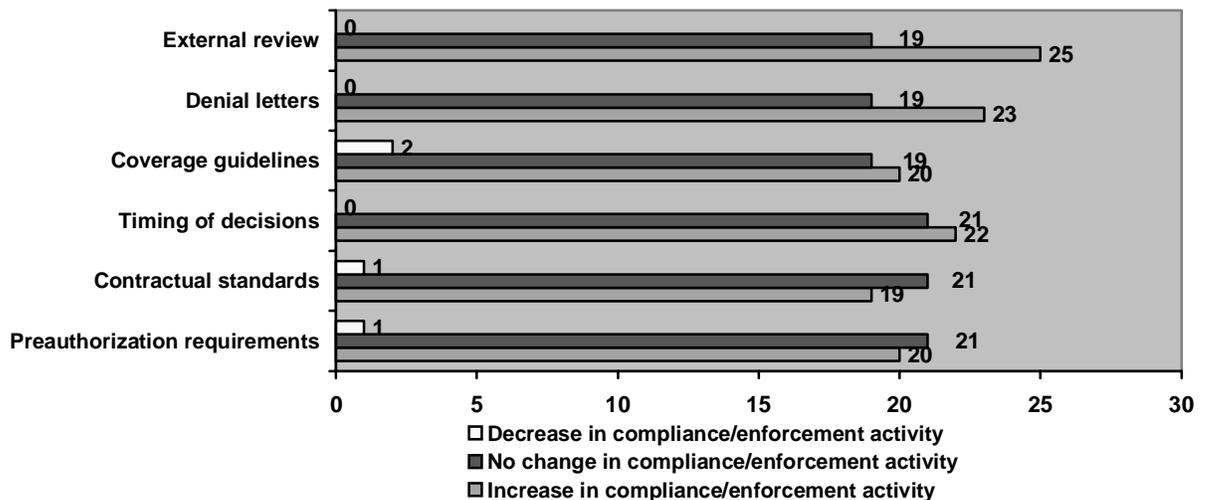
Prior research on managed care oversight has suggested that regulatory activity related to medical necessity decision-making has changed significantly in the past few years.ⁱ Our early conversations with state regulators indicated that managed care regulatory activity could be divided into three main phases:

- 1) Research performed for state legislators prior to the passage of new state laws;
- 2) Drafting and promulgation of regulations to carry out newly-passed state laws;
- 3) Compliance and enforcement activity following promulgation of regulations.

While all three types of activity are central to state regulators' work, we were primarily interested in the third phase, compliance and enforcement activity. This was because compliance and enforcement activity was the most likely to be detected by medical directors of health plans and to influence their medical necessity decision-making.

Reported compliance and enforcement activity increased across all categories of regulation we studied in 20 to 25 states. Regulators reported an increase in activity most often in external review regulation (**25** states), followed by denial letters (**23** states) and timing of decision-making (**22** states):

Change in Overall Compliance & Enforcement Activity



Regarding coverage guidelines, contractual standards, and preauthorization requirements, regulatory activity decreased or did not change at least as often as it increased. Regulators indicated that compliance and enforcement activity declined in

ⁱ See, for example, Milbank Memorial Fund. *Tracking State Oversight of Managed Care*. October, 1999; and Stauffer M and Morgan RB. *2001 State by State Guide to Managed Care Law*. Panel Publishers, 2001.

only 4 instances. Georgia regulators reported a decrease in activity relating to contractual standards; Nebraska reported a decrease in activity relating to preauthorization requirements; and Colorado and Oregon reported a decrease in activity relating to the regulation of coverage guidelines.