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External Review of Health Plan Decisions: An Update

Prepared for the Kaiser Family Foundation by:

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INTRODUCTION

External review programs provide an independent review of a health plan's decision to deny, reduce or terminate care. Devised initially by insurance regulators in a handful of states, by Medicare, and by some managed care plans to help resolve disputes over difficult cases, external review programs are proliferating across states and in the private sector. They are meant to address concerns about managed care incentives that might lead to the inappropriate denial of care, and to help restore public confidence in managed care. External review is widely cited as a fair, impartial, and usually expeditious and cost effective way to resolve disputes.¹

Even as the concept catches hold, however, it is evolving. As more states create external review programs, as more private health plans adopt the practice voluntarily, and as federal legislation is considered to establish the protection nationwide, there are more variations on the theme. This issue brief provides an update on external review, including an examination of some trends developing in the design of these programs and a closer look at what goes on during the external review process. It also looks at the variation in key features of these programs across the nation and raises some questions to consider as public and private decision-makers continue to expand the application of external review.

The information in this policy brief was obtained from interviews with key independent review organization staff and state regulators, and a review of surveys of state external review laws.²

BACKGROUND

In 1998, the Kaiser Family Foundation released a report prepared by Georgetown University on external review programs in 13 states and the Medicare program.³ Most external review programs studied in the Kaiser report shared the following features:

Independence: External review is conducted by experts who are independent of both disputing parties; the external reviewer or review entity generally is selected by state regulators who also are independent of both disputing parties;

Clinical expertise: External review relies on recognized clinical experts in the field of medicine most closely related to the case being considered;

¹ Karen Pollitz, Geraldine Dallek, and Nicole Tapay, "External Review of Health Plan Decisions: An Overview of Key Program Features in the States and Medicare," prepared for the Kaiser Family Foundation, November 1998. (See the Kaiser Family Foundation website at www.kff.org or call the Publication Request Line at 1-800-656-4533)

² The following surveys were reviewed: Hayes Inc. and Duane, Morris & Heckscher LLP, *Insurance Coverage Denials: External Review (HAYES Legal Precedent Directory)*, 1999; American Association of Health Plans, "State External Review Laws and Regulations as of July 30, 1999," 1999; Molly Stauffer, "Consumer Grievance Procedures: Internal and Independent Appeals," Health Policy Tracking Service, 1999.

³ Pollitz, Dallek, and Tapay, "External Review of Health Plan Decisions."

Timely reviews: State external review laws include timeline requirements to ensure that decisions are rendered promptly and, when needed, expeditiously;

Fairness: External review programs are widely regarded as fair and useful in strengthening consumer confidence in managed care;

Cost: External review programs generally are cost effective;⁴ and,

Seldom used: External review programs are used infrequently by consumers.

More than one year after the publication of the Kaiser report, the number of state external review programs has more than doubled to include 32 states and the District of Columbia (Table 1). In addition, many private health plans (including Aetna U.S. Healthcare, UnitedHealthcare, Health Net, PacifiCare Health Systems, and the California Association of Health Plans) have announced that they will voluntarily provide their enrollees access to external review when care is denied.

Further, the National Committee on Quality Assurance (NCQA), a private body that accredits HMOs, has expanded its accreditation standards to require plans to make available external review of medical necessity denials, effective in July 2000. In October 1999 the American Accreditation Healthcare Commission/URAC, another private accrediting body, announced its intention to accredit external review organizations to encourage their voluntary use by private health plans. Finally, in Congress, the House and Senate passed different bills in 1999 providing a federal right to external review for some or all Americans enrolled in private health plans. Resolving differences between these bills is on the Congressional agenda this year.

⁴ States have generally kept the cost of reviews low, although cases requiring multiple reviewers cost significantly more.

**Table 1. State External Review Laws
(as of March 13, 2000)**

State	Effective Date(s)
Michigan	1978
Florida	1985
Pennsylvania	1991 (amended in 1998)
Missouri	1994 (codified and amended in 1997)
Vermont	1996 (mental health and substance abuse) July 1999 (cases other than mental health and substance abuse)
Rhode Island	1997 (amended in 1999)
New Jersey	1997
New Mexico	1997
Texas	1997
Connecticut	1998
Arizona	1998
California	1998 (experimental therapies) January 2001 (all cases including experimental therapies)
Hawaii	1998
Ohio	1998 (experimental therapies) May 2000 (all cases including experimental therapies)
Maryland	January 1999
Tennessee	January 1999
Delaware	February 1999
District of Columbia	April 1999
Georgia	July 1999
Indiana	July 1999
New York	July 1999
Montana	October 1999
Illinois	January 2000
Iowa	January 2000
Kansas	January 2000
Oklahoma	February 2000
Minnesota	April 2000 (3 month extension possible with commissioner approval)
Colorado	June 2000
Virginia	June 2000 (or 90 days after regulations promulgated)
New Hampshire	September 2000
Louisiana	January 2001
Utah	January 2001
Washington	June 2001

SUMMARY OF TRENDS

This issue brief examines five key features and issues relating to the external review process, including the following trends in the development of these programs:

- ***Barriers to consumer access.*** Barriers to consumer access are appearing more frequently in state external review laws.
- ***Disputes subject to external review.*** Some new state and voluntary efforts are restricting the scope of external review only to cases involving medical necessity, potentially leaving consumers without an avenue for resolving other kinds of disputes.
- ***External review entities and the review process.*** Most state and voluntary external review programs depend on organizations known as Independent Review Organizations (IROs) to conduct reviews. There is great diversity among IROs and the way they conduct reviews. In addition, to the extent these IROs are paid to do other kinds of work for private health plans, the definition of “conflict of interest” and how to regulate it may merit further study.
- ***Coordination between state, voluntary, and Federal review programs.*** The variability across state, voluntary, and Federal external review programs requires attention to issues of coordination.
- ***Other uses of external review.*** State regulators are using aspects of external review to address other problems in the health care system.

BARRIERS TO CONSUMER ACCESS

The 1998 Kaiser report examined potential barriers to consumer access to external review as one possible reason to explain the infrequent use of these programs. In assessing any external review program, it helps to consider the kinds of consumers who might need to appeal a claims denial—including, for example, patients undergoing chemotherapy, extensive surgery, or severe mental illness, or terminally ill patients seeking experimental therapies. What might not seem a serious barrier to healthy consumers could be viewed as more daunting by those who are sick.

The 1998 report reviewed features that might pose barriers to consumer access. Lack of public awareness about external review was cited frequently by state regulators. The length of the entire appeals process – from initial denial to two levels of internal appeals to external review – might also lead to consumer attrition. Few of the state programs studied in 1998 had built in additional barriers to consumer access (such as filing fees), and regulators generally saw little need to create such barriers in light of small caseloads. Nevertheless, such barriers are appearing more frequently in newly enacted laws. (See Table 2)

Table 2. Examples of Barriers to Access to State External Review Programs

Filing Fees	Filing Deadlines	Claims Threshold	Denials ineligible for review
\$25 (Indiana, Minnesota, Pennsylvania, Tennessee, Vermont)	15 days (Pennsylvania) 30 days (D.C., Hawaii, Maryland)	\$100 (Vermont – non-mental health claims only)	Therapies determined to be experimental (Tennessee) Retrospective denials of care involving claims payment issues and experimental and investigational therapies (Texas)
\$50 (New York, Oklahoma, Virginia)	45 days (Illinois, New York) 60 days (Colorado, Ohio, Tennessee) 90 days (Vermont)	\$500 (Georgia, Ohio, Tennessee, Virginia) \$1000 (Oklahoma)	

Filing Fees – Three of the state external review programs studied in 1998 charged consumers a fee to file for external review. In two states, the fee is \$25 and can be waived for certain low-income applicants. In a third state, consumers are required to pay half of the cost of an external appeal – a sum that can reach several hundred dollars. In 1998-99, at least eight more states passed laws requiring consumers to pay a fee for external review, ranging from \$25 to \$50.

Claims Thresholds – Claims thresholds (a minimum dollar value of the claim involved) – ranging from \$100 to \$1000 – are a new barrier that at least six states have recently adopted. None of the 13 programs previously studied imposed such thresholds.

Filing Deadlines – Tight filing deadlines may pose a barrier for consumers in at least nine new state external review programs. In one state, a consumer must file for external review within 15 days after the final plan denial notice, and eight other programs impose filing deadlines of 60 days or less. By contrast, in the 14 programs previously studied, half imposed no filing deadline on consumers, two states set deadlines of 1-2 years, and five states required consumers to act within 60 days or fewer.

Other Limits on Eligibility – As discussed below, a number of state laws and voluntary programs limit review to cases of “medical necessity,” precluding contract or benefit disputes from review. Since 1998, two states limited the types of medical necessity claims denials that are eligible for external review. Tennessee will not review denials based on a health plan’s finding that a service is experimental or investigational. Recently, Texas has reinterpreted its law to limit external review to claims denied on a prospective or concurrent basis (for example, denial of a request for prior authorization of elective surgery, or denial of a request for additional hospital days). Retrospective denials are not eligible for external review unless they underwent prospective or

concurrent review at an earlier time.⁵ Two other states expanded the scope of external review in 1999. California and Ohio, which previously had provided external review only for denials of services determined to be experimental, now will review all medical necessity decisions.

Exhaustion of Internal Appeals Process – Most states continue to require consumers to first exhaust two levels of plan internal appeals before applying for external review. Several states permit exceptions to this rule in urgent situations or where the plan has failed to meet internal appeals timelines.

Consumer Assistance – Even without these barriers, pursuing an external appeal is often difficult. Patients who are struggling with serious illness or disability often need assistance in navigating the appeals process. A growing number of states have created health care consumer ombudsman offices to help people in a variety of ways, including through the external review process.⁶ In Maryland, for example, the health care ombudsman program is established in the Office of the Attorney General. The ombudsman assists residents in state-regulated plans first by contacting the health plan when there is a denial or dispute to see if the problem can be resolved informally. If not, the ombudsman will help the consumer through the internal appeal process and then on to external review. State regulators credit this office with helping to minimize the need for external review through its effective early intervention.

DISPUTES SUBJECT TO EXTERNAL REVIEW

Disputes between consumers and health plans can arise for different reasons. Many involve denials of coverage based on judgments that care is not medically necessary or appropriate. Disputes or denials can be based on other reasons, such as benefit/coverage limitations in the health insurance contract.⁷

Some external review programs handle only disputes involving medical necessity or other clinical judgments. This raises three important issues.

First, when external review is available only for medical necessity denials, consumers may not have an avenue for resolving other kinds of disputes. This situation

⁵ Texas Department of Insurance (TDI) staff will send a “retrospective” denial to the IRO if the documentation shows that prospective or concurrent review was actually performed, and the plan “re-reviewed” the case as a retrospective review after the initial denials were issued. The TDI staff make it clear to plans that they may not “re-review” retrospectively for medical necessity after performing prospective or concurrent review in order to avoid compliance with the law.

⁶ Some states, including Connecticut, Florida, Illinois, Maine, Maryland, Massachusetts, New Mexico, Rhode Island, Texas, Utah, Vermont, and Virginia, have or will soon establish a health care consumer ombudsman office to educate the public about health care rights and responsibilities and to help people answer questions they may have about their health plans.

⁷ Coverage denials may be based on clearly delineated benefit limits (e.g., the managed care organization covers only 21 days of psychiatric inpatient hospital days) or on less defined contract issues (e.g., whether a plan member can seek out-of-plan care because no *qualified* network provider is available; whether plastic surgery is cosmetic and thus not covered by the plan, or is medically necessary and thus a covered benefit; or how does a managed care organization define “deluxe” when it excludes “deluxe durable medical equipment” from coverage).

can arise in voluntary external review programs if health plans do not make other kinds of disputes eligible for review. Bills pending in Congress would make external review available for medical necessity cases, but do not provide for review of other kinds of denials. By contrast, Medicare and a few states have a single external review program for all member disputes with health plans, including those relating to benefit/coverage issues. In most other states that have established external review for medical necessity issues, insurance regulators will still help consumers resolve other kinds of disputes. Recently, however, an insurer has challenged one state's authority to resolve disputes regarding benefit/coverage issues.⁸ (See accompanying box.)

**Vermont Blue Cross Challenges State's Authority
to Interpret Insurer Contracts**

In November of 1999, Blue Cross Blue Shield of Vermont filed suit challenging the state's authority to resolve coverage disputes. Vermont law provides for external appeal to an independent review organization (IRO) for disputes relating to medical necessity. Regulations specify that IRO decisions be confined to clinical issues and not have the effect of changing the terms of coverage under a health benefit plan. However, regulations also require the state to determine whether a service reasonably appears to be covered under the contract.

Earlier in 1999, Blue Cross denied a request for prior approval for a medical device that would help a disabled child to communicate. Regulators determined the device would reasonably be a covered service under the contract, then assigned the case to an IRO that ruled the device was medically necessary. Blue Cross does not dispute the IRO's finding, but has challenged the authority of regulators to determine whether a service is reasonably covered under its contract. In its suit, Blue Cross cites language in its contract that states,

“In accepting your Contract, you agree that we have the exclusive right to use our discretion and authority in ruling on all questions of coverage and eligibility. We also reserve full discretion and authority to interpret and apply the provisions of your Contract.”

Blue Cross goes on to argue that the device does not qualify as a medical device or prosthesis as these terms are defined under its contract.

As the Vermont case may ultimately demonstrate, distinguishing between medical necessity and other coverage disputes may give an insurer the opportunity to argue that different kinds of denials are eligible for different levels of protection.

⁸ See *Blue Cross and Blue Shield of Vermont vs. Vermont Department of Banking, Insurance, Securities and Health Care Administration*, (Vermont Superior Court filed November 23, 1999).

Second, it is not always easy to tell what a dispute is about. Medical necessity issues can be hard to distinguish from other kinds of contractual coverage issues, and sometimes a denial can be based on both. The example that follows is based on a real case, but has been modified to summarize key facts and protect the identity of the patient.

Medically Necessary or Cosmetic?

Billy's parents sought authorization for strabismus surgery to correct his crossed eyes. The plan denied authorization because it determined the surgery to be cosmetic. The plan contract defined cosmetic as surgery "from which no improvement in physiologic function can be expected."

Billy's doctor argued that the procedure was medically indicated to promote the child's well-being and physical and emotional development, and only cosmetic to the extent that it would change his appearance. Billy's doctor also argued that the strabismus was the result of a congenital condition and noted language in the plan contract exempting correction of congenital conditions from the cosmetic surgery exclusion.

In Billy's case, the nature of the dispute – and the distinction between medical necessity and coverage – is blurred. The IRO was asked to determine the nature of the dispute first to see whether the case was eligible for external review. To make this determination, reviewers eventually had to examine other provisions in the contract that modified the coverage exclusion (in this case, to permit an exception for congenital conditions). At this point, they could move on to examine the medical necessity of the procedure for this child. The IRO decided that the procedure was both eligible for coverage under the terms of the health plan contract and medically necessary for Billy.

A third issue is who decides whether a case is eligible for external review? For health plans that voluntarily offer external review to their enrollees, it may be the plan that decides. When the nature of the dispute is in controversy, some plans forward the case to an external reviewer for screening. Other plans do the screening themselves and forward for external review only those denials they decide are eligible. A health plan that offers external review on a voluntary basis would be able to turn down Billy's appeal as ineligible.

NCQA external review standards, effective July 1, 2000, require plans to send only medical necessity cases for review. However, the proposed standards require plans to send all cases to review where the line between medical necessity and benefits/coverage is indistinct:

"If the requested service or procedure is something that could be considered a covered benefit, it must be evaluated against medical necessity criteria. Experimental treatments, cosmetic procedures and access to out-of-network practitioners or providers are examples of the types of services which could be considered a

covered benefit. Denials of these services fit the medical necessity definition because they may or may not be considered covered benefits.”⁹

EXTERNAL REVIEW ENTITIES AND THE REVIEW PROCESS

This section analyzes the characteristics of external review organizations and the review process. All external review programs ultimately rely on practicing physicians and/or other kinds of experts in the community (such as attorneys) to perform review. However, some programs rely on independent review organizations (IROs) to arrange for these expert reviews, while others do not.

Independent Review Organizations (IROs) – IROs are used by most, though not all, of the original state programs studied to perform external review.¹⁰ Examples of state external review programs not based on the IRO model include Vermont’s mental health appeals program, which relies on a state-appointed panel of mental health practitioners, and New Mexico, where the insurance commissioner appoints a panel of two physicians and one attorney to review each appeal. With a few exceptions, more recent state external review laws use the IRO model. No study has been conducted to compare the quality of IRO reviews and those conducted by other state dispute resolution programs.

“IRO” is not a term of art. Rather, it is used here to describe private organizations that contract with states (and, increasingly, with private health plans) to conduct external reviews.¹¹ These organizations in turn contract with practicing physicians from many specialties who agree to be available to review cases. IROs vary in their structure and activities. Some IROs are for-profit and some are non-profit. Some IROs were established to conduct internal and external reviews for health plans or to review and evaluate other aspects of health plans or health care institutions. Others were established for different purposes. Some IROs focus primarily or exclusively on providing independent external medical reviews. For others, external review is only one of many activities they perform for health plan and states and the federal government. For example, some states contract with Peer Review Organizations/Quality Improvement Organizations (PRO/QIO) to conduct independent external reviews in addition to the work they do for Medicare monitoring the quality of care in hospitals and other settings. In other states, academic medical centers can be IROs. Some specialize in certain types of reviews – for example, an IRO might review only mental and substance abuse cases, or concentrate primarily on high technology cases – while others handle a broad range of cases.

⁹ National Committee on Quality Assurance, *2000 MCO Surveyor Guidelines*, p. 293.

¹⁰ For example, Vermont appoints a standing panel of mental health professionals to review the medical necessity of mental health and substance abuse services. In Michigan, a seven-member task force, including two physician members, hears all non-expedited appeals. Florida uses a panel of state employees to conduct reviews with medical expert advisors as needed. In Arizona, plans choose from a list of state-approved IROs or individual physicians, while in New Mexico, the Department of Insurance appoints an independent review board with two physicians and one attorney.

¹¹ Some IROs now prefer to be called “external review organizations,” or EROs.

IRO procedures vary by IRO, by state requirements, and, sometimes, by the type of case. However, IROs generally share a number of common features. Most have medical directors and formal protocols to evaluate the quality of the review process. IROs collect and organize external review case files to send to clinician reviewers (who are not on staff) based on the characteristics of the case and the reviewer's qualifications. Many, but not all, IROs include a list of questions with the case file for the reviewer(s) to answer. Some IROs will also conduct a medical literature review for cases requiring supporting documentation (see the following discussion on types of reviews). However, most IROs depend on their reviewers to provide appropriate cites to the medical literature.¹²

IRO staff also assess reviewers' reports to ensure that they are thorough, well written, provide clear answers to the questions, and, depending on the case, cite appropriate references. Most IROs send a standardized report to the interested parties which incorporates the reviewer's decision, others attach the reviewer's report to the IRO's standardized report, while a few send only the reviewer's report.

Two private accrediting organizations – NCQA and URAC – are moving forward to provide for private accreditation of IROs to encourage their voluntary use by private health plans. Over time, this process may lead to greater uniformity among IROs in their structure and activities.¹³

External Reviewers – Because many state external review laws require IROs to handle the full range of appealable issues, most IROs have agreements with a broad spectrum of practicing physicians and other clinicians to conduct reviews in their field of expertise. Many have expanded their contracting network to include non-physicians (e.g., acupuncturists, physical therapists, psychologists, etc.). Some IROs also employ or contract with health benefits experts who have experience reading and interpreting coverage language in health insurance contracts.¹⁴

At a minimum, IROs require that medical (as opposed to benefit) reviewers meet the following requirements:

- Board certification;
- Active practice (full or part-time) for a minimum number of years;
- Practice in a different medical market than the case under review;¹⁵ and
- Free of other conflicts of interest (see following discussion).

¹² California's external review program for experimental/investigational therapies requires literature citations in all cases.

¹³ NCQA's proposed IRO requirements can be found on their website at <http://www.ncqa.org/pages/main/iro.htm> or by calling 202-955-5697.

¹⁴ There are differences among IROs about the expertise needed for benefit reviews—some IROs argue that lawyers with medical backgrounds are needed, while others rely on persons experienced with benefit reviews.

¹⁵ Some states' IRO laws require that contracting reviewers hold a medical license in the state. In small states or those with low population density and limited providers in some specialties, requirements that reviewers practice in the same state may undermine conflict of interest protections.

IROs require reviewers to be of the same or similar specialty as appropriate for the case under review, as well as have extensive experience in the type of case under review.

All IROs credential their reviewers.¹⁶ Because of the small number of cases in some specialties and sub-specialties, IROs have determined that it would be impractical to require reviewers to handle a minimum number of cases each year.

Some IROs conduct relatively informal telephone training on how to conduct a review, while others use a more standardized and extensive approach to reviewer training. IRO internal quality assurance programs include oversight of all reviewer decisions for format and content. Reviews that lack clarity, fail to answer the relevant questions or, when appropriate, cite relevant literature are returned for revisions. Reviewers who do a poor job are simply not sent additional cases.

Depending on the type of case and state requirements, IROs will assign one or more reviewers to a case. In cases involving experimental or investigational procedures/therapies/drugs, three reviewers are often used. More than one reviewer may be assigned to high technology cases and cases involving co-existing illnesses or with both a medical and psychiatric component. Multiple reviewers may be assigned to “contentious cases.” In highly complex cases, reviewers with academic medical appointments are used. Cost is an important consideration in assessing the number of reviewers needed for a particular case.

Conflict of Interest Requirements – For reviews to be independent, IROs and their contracting reviewers must be free of any conflicts of interest with the managed care plan and the case under review. State laws generally prohibit IROs and reviewers from having material professional, familial, or financial affiliation with the plan, the treating physician or physician’s medical group, the appellant, the institution at which the therapy would be provided, or the development or manufacture of the drug, device, procedure or other therapy proposed for the appellant.

Two issues may give rise to questions about conflicts of interest under new external review programs, especially those programs adopted voluntarily by health plans.

The first has to do with who chooses the IRO. Under most state programs created prior to 1999, regulators select and contract with one or more IROs to handle all external reviews for that state. Some states, such as Connecticut, New Jersey, Texas, and Vermont, contract with multiple IROs and assign cases on a rotational basis. If a conflict of interest arises, that IRO is skipped over in the rotation. However, under several recently passed state external review laws (and under pending Congressional bills), health plans are permitted to select and hire the IRO—usually from an approved list.¹⁷ When health plans voluntarily provide external review, their choice of IROs is not governed by

¹⁶ Credentialing includes checks on reviewer’s state medical license, state disciplinary action information, Drug Enforcement Agency registration, hospital privilege status, and evidence of a national practitioner data bank query.

¹⁷ Arizona, Indiana, Iowa, Ohio, Oklahoma, Tennessee, and Virginia. See Hayes Inc. and Duane, Morris & Heckscher LLP, *Insurance Coverage Denials: External Review*, 1999.

any rules, although NCQA will be requiring plans they accredit to contract with an approved IRO. However, the independence of the IRO may be diminished somewhat when it is selected by and contracts directly with the health plan.¹⁸

A second issue has to do with the performance of multiple tasks by the IRO for health plans. Several IROs we interviewed regularly contract with health plans to conduct such tasks as advisory, pre-determination reviews (to assist health plans to make coverage decisions), internal appeals, quality of care studies, development of clinical protocols, data validation, and medical technology assessments. These IROs also contract with the same health plans to conduct external review.

Some IRO representatives argue that these other activities (including conducting internal reviews for a plan) do not pose a conflict of interest because their external review process is independent of their other business activities and their reviewers are also independent and free of any conflict of interest. By contrast, other IROs we interviewed said their practice is to never conduct external reviews for health plans with whom they have other contractual arrangements. Some state programs, such as Connecticut, Texas, and Vermont, also prohibit such conflicts. In an attempt to address potential conflicts when plans choose IROs, a new California law requires IRO-health plan contracts to specifically state that the health plan must not influence or attempt to influence the IRO's selection of experts to review the case.

The mere presence of a contract between the health plan and the IRO may raise questions about independence. This is not to say that external reviews performed under such circumstances are necessarily biased; but they are inherently less independent because the IRO formally works for one of the disputing parties. Some IROs argue that if they are prohibited from contracting with managed care organizations for other work, they will forgo external review contracts because of the small number of reviews. Companies would be unable to stay in business providing only external reviews. This issue brief does not assess the degree to which a conflict of interest statement prohibiting any non-IRO business with plans might impact the number or quality of organizations conducting external review.

Contracting IRO reviewers are required to submit a detailed conflict of interest declaration for themselves, spouses and other close relatives. Most IROs also require reviewers to sign a supplemental conflict of interest form with each review relating to any conflicts of interest with the treating provider, patient, health plan, technology manufacturer, drug company, hospital, etc.

Types of Reviews – As discussed above, the number and expertise of reviewers depends on the type of review in question. Only a minority of reviews are “evidence based,” requiring specific medical/scientific evidence to support the reviewer's decision.

¹⁸ One IRO representative suggests that if plans are permitted to pick and choose among HMOs, they should be required to contract with several IROs and assign cases on a rotational basis to eliminate any real or perceived conflicts of interest. Another IRO representative believes that with “meaningful accreditation” that assures “quality, independence, and fairness,” it does not matter who selects the IRO.

Many reviews are simply a second (albeit, in many cases, binding) opinion by an independent expert based on prevailing standards of good medical practice.

One IRO categorizes reviews into five types:

- Evidence-based medical necessity and/or investigational/experimental exclusion reviews for terminally or seriously ill patients (high visibility cases).
- Evidence-based medical necessity reviews of a less complex nature.
- Criteria-based medical necessity reviews.
- Opinion only reviews.
- Benefit coverage reviews.¹⁹

The type of evidence required and number of reviewers depends on the type of case in question and state law. For example, evidence-based medical necessity and/or investigational/experimental exclusion reviews for terminally or serious ill patients often require a three-physician panel and citations from peer reviewed literature. Criteria-based medical necessity reviews use a single reviewer and rely on medical consensus as reflected by clinical practice guidelines, practice standards, and consensus statements of professional associations. Opinion reviews simply depend on the opinion of a knowledgeable physician/clinician where there is neither evidence nor criteria upon which to base a review decision.

New York categorizes reviews as:

- Clinical trial;
- Experimental/investigational treatment; or
- Medical necessity.

In clinical trial reviews, the decision is based on whether the trial is scientifically adequate, the patient is eligible to participate, and participation is the patient's best option. For experimental/investigational treatment denials, the decision is based on whether or not the patient can reasonably expect to receive more health benefit from the proposed treatment than any other (standard) therapy. For medical necessity cases, reviewers are asked to make a decision based on whether the proposed treatment could be expected to benefit the health of the patient. Decisions for experimental/investigational reviews are evidence based, while medical necessity reviews are based on the judgement of a qualified expert practitioner.

For cases involving clinical trials or experimental/investigational treatment, New York requires a minimum of three reviewers. In very complex cases with unique circumstances, up to five reviewers may be used. For medical necessity reviews, New York requires one reviewer unless the treatment of the patient's condition involves multiple specialties or the treatment involves a potential controversy over the provider's qualifications.

The following, from the files of one IRO, is an example of a complex case with unique circumstances requiring more than three reviewers:

¹⁹ Hayes Plus, "External Review or Appeal Services," (December 1999).

“Mentally challenged adult with sickle cell disease who was proposed for a liver transplant and for a bone marrow transplant and who had a history of alcoholism and depression and his guardian had raised issues about the ethics of the proposed care (reviewers’ assigned were experts in sickle cell disease, liver transplantation, bone marrow transplantation, psychiatry, medical ethics).”²⁰

Basis for External Review Decisions: Defining Medical Necessity – An emerging controversy is over whether state law, the reviewers/IROs, or managed care organizations should dictate the basis upon which medical review decisions are made. Who defines “medical necessity” and how that definition is interpreted by reviewers can determine the outcome of any appeal. Plans and purchasers argue that if non-plan definitions of medical necessity are used, they will lose their ability to determine what is and is not a covered benefit. Consumer advocates counter that external review is designed to resolve disputes over what is medically necessary, and so this definition ought not to be controlled by one of the disputing parties.

A recent study by Stanford University’s Center for Health Policy found a number of problems with the current use of medical necessity definitions. Definitions may be circular (medical necessity is what the plan says it is); vary by plan (what may be considered medically necessary by one plan is not by another); rest on outdated clinical guidelines; or fail to take the individual circumstances of a patient into account. Medical necessity definitions are also not interpreted uniformly by health plan medical directors. For example, when three medical directors were asked hypothetically whether they would approve or deny a treatment, all three had different answers and two responses contradicted their own plan’s coverage guidelines.²¹

On the uses and misuses of “medical necessity” definitions, Stanford researchers concluded that:

“Conflicting opinions and ambiguous evidence cause a standard of care based on *medical necessity* to break down. The idiosyncratic way that coverage decisions are made in health care organizations has led to variations that create inequity for consumers, greater cause for appeal of denials, and more litigation.”²²

In state programs, “medical necessity” can be defined by the state, the reviewers, or the plan.

Medical necessity defined by the state. At least six states define in law or regulation a standard for medical necessity that external reviewers should follow in evaluating cases.²³ California is an example of a state that imposes its own definition of

²⁰ Medical Care Management Corporation, (undated).

²¹ Stanford University Center for Health Policy, *Medical Necessity*, October 1999, p. 3.

²² Stanford University Center for Health Policy, *Medical Necessity*, p.1.

²³ California (for experimental therapies), Georgia, Minnesota, New York, Ohio (for experimental therapies), and Vermont. See Hayes Inc. and Duane, Morris & Heckscher LLP, *Insurance Coverage Denials: External Review*, 1999.

medical necessity. For experimental and investigational reviews in that state, IROs may not base their determination on the health plan's definition of experimental/ investigational, regardless of how the health plan may define this. In fact, IROs are prohibited from sending a plan's definition to reviewers. As long as the treatment is otherwise covered under the plan, reviewers are expected to answer only two questions:

1. Is the requested therapy likely to be more beneficial for the patient than any standard therapy?
2. Should the requested therapy be provided by the health plan?

New York's statute requires reviewers to determine "Whether the health care plan acted reasonably and with sound medical judgment, and in the best interest of the patient." For medical necessity cases, one IRO under New York contract defines medical necessity as "health beneficial to the patient."

Vermont defines "medically necessary care" as:

"health care services including diagnostic testing, preventive services and aftercare appropriate, in terms of type, amount, frequency, level, setting, and duration to the member's diagnosis or condition. Medically necessary care must be consistent with generally accepted practice parameters as recognized by health cared providers in the same or similar general specialty to typically treat or manage the diagnosis or conditions and to: 1) help restore or maintain the member's health; or 2) prevent deterioration of or palliate the member's condition; or 3) prevent the reasonably likely onset of a health problem or detect an incipient problem."²⁴

Medical necessity defined by the reviewer/IRO. The reviewer's or IRO's definition of medical necessity is substituted for that of the plan in at least 14 states and the District of Columbia.²⁵ For example, New Jersey regulations require that an IRO, in determining whether the "member was deprived of medically necessary covered services," consider:

"all pertinent medical records, consulting physician reports and other documents submitted by the parties, any applicable, generally accepted practice guidelines developed by the Federal government, national or professional medical societies, boards and associations, and any applicable clinical protocols and/or practice guidelines developed by the HMO...."²⁶

Medical necessity defined by the plan. Currently, under at least eight state laws and many voluntary programs, IROs and their reviewers must make decisions based on

²⁴ Vt. Code R. 21-040-012, § 3(T).

²⁵ California, Colorado, Connecticut, the District of Columbia, Illinois (for experimental and investigational therapies), Indiana, Louisiana, Maryland, Michigan, New Jersey, New Mexico, Ohio, Rhode Island, Texas, and Virginia. See Hayes Inc. and Duane, Morris & Heckscher LLP, *Insurance Coverage Denials: External Review*, 1999.

²⁶ N.J.A.C. 8:38-8.7(g).

the managed care plan's definition of medical necessity.²⁷ In these cases, reviewers may be less likely to overturn a plan's decision. For example, one IRO we interviewed evaluates medical necessity for care against the plan's definition of what is medically necessary and upholds 90 percent of plan denials under this standard. It is not clear whether other IROs would have the same uphold rate under similar standards.

In other cases, the health plan's contract may be less specific and allow IROs more discretion. Some IROs require reviewers to find the plan's definition of medical necessity "reasonable" before making a decision based on it. Although the reviewer may not like the definition, as long as it is "reasonable," the reviewer must judge the case based on that definition.

Other Limits on External Review Decisions – At least one state—Connecticut—has circumscribed IROs' ability to reach nuanced decisions about what is and is not medically necessary. Connecticut requires IROs to either uphold or overturn a plan's decision in its entirety.²⁸ This precludes IROs from partially agreeing with a plan's denial. For example, if a patient is appealing the denial of a 5-day hospitalization, the IRO must find that all or none of the days are medically necessary; it cannot decide that a 3-day stay is appropriate.

External Review Reports and Reviewer Confidentiality – IROs use different formats for reporting review decisions to interested parties. Most state laws require IROs to send their decision to all affected parties: the appellant or his or her designated representative, the appellant's physician, and the plan. New voluntary external review programs initiated by plans also require reports to all stakeholders, as do draft NCQA regulations.

Most of the IROs send a decision report under their letterhead in a standardized format. Report formats vary. Some IROs provide only an appeal determination with a brief rationale, while others include the following information:

- a statement describing the IRO;
- the reviewer's decision;
- a summary review of the case (summary of facts/medical history);
- the reviewer's rationale for the decision; and
- the reviewer's qualifications.

Some states also require that reviewers propose any appropriate alternative treatments if the plan's denial is upheld. The question of whether reviewers should suggest alternatives to the proposed treatment is somewhat controversial. Some IRO representatives believe caution is in order as the reviewer is not the appellant's treating physician. Others believe that it serves both the appellant's and plan's interest to suggest alternative treatments when appropriate.

²⁷ Arizona, Illinois (for medical necessity cases), Iowa, Kansas, Missouri, Oklahoma, Pennsylvania, and Tennessee. See Hayes Inc. and Duane, Morris & Heckscher LLP, *Insurance Coverage Denials: External Review*, 1999.

²⁸ Conn. Agencies Regs. §38a-478n-3(f).

IRO reports vary in the amount of information provided about the reviewer. Some states, such as Maryland, require the release of reviewers' names. These states report no problems to date with this policy. However, most states do not require, and most IROs do not release, reviewers' names. IROs say that to do so would open reviewers to possible harassment by either an appellant's physician or the appellant. In addition, they argue that releasing the names of reviewers gives managed care organizations (MCOs) the option to "shop around," choosing IROs based on their reviewer panels. A number of IRO representatives say that releasing names would make it harder for them to recruit qualified reviewers.

In lieu of providers' names, IROs provide varying amounts of information about the reviewer, but some of this information is quite cursory. For example, IRO decisions we have reviewed include the following reviewer descriptions:

- "physician cardiology review"
- "consultant physicians"
- "physician specialist (board certified in psychiatry)"
- "physician specialty consultant"
- "specialist reviewer"
- "board certified physician specializing in Otorhinolaryngology"

Some IROs provide a more detailed biographical sketch of the reviewer with each report, which includes information about training, academic appointments, and practice experience.

Finally, some IROs include in their decision reports a list of the reviewed materials. This helps reassure all parties that the reviewer's decision is based on all relevant information.

COORDINATION AMONG STATE, VOLUNTARY, AND FEDERAL REVIEW PROGRAMS

As noted above, NCQA, as part of its accreditation process, will be requiring HMOs to provide enrollees access to external review. The American Accreditation Healthcare Commission/URAC has proposed IRO accreditation standards. Both organizations have said that state law will preempt their voluntary programs. However, issues of coordination will remain.

For example, as noted above, a recent interpretation of Texas IRO law has led to the conclusion that retrospective cases (where services have been provided, but payment subsequently denied) are not eligible for external review. Thus, some cases may be ineligible for state mandated reviews but eligible for NCQA review, requiring two different notices and review processes. Coordination between any federally mandated external review program and state programs will also be important. Notice requirements, timelines, types of cases eligible for review, and the review process itself will likely differ depending on whether the member is eligible for state or federal review.

Finally, the question of when federal law preempts less protective state external review laws may require a feature-by-feature comparison and evaluation of laws.²⁹ For example, one of the external review proposals pending in Congress imposes no filing deadline or claims threshold on consumers, but does require a \$25 filing fee.³⁰ This bill defines in federal law a standard for determining medical necessity and requires non-urgent external review decisions to be made within 21 days.³¹ A state law, by comparison, might have no filing fee, impose a \$100 claims threshold, use a slightly different standard for medically necessity determinations, and require external review decisions within 15 days. In this example, some features of state law are more protective of consumers, some less, and one feature could be difficult to compare. States will need guidance from federal regulators on how to evaluate these differences if a federal law is enacted. This process would be less complicated if federal law were to require stronger consumer protections in most or all respects than states currently provide.

OTHER USES OF EXTERNAL REVIEW

In addition to individual reviews of health plan decisions, state regulators are using external review programs to address other problems in the health care system. Maryland, for example, has expanded the concept of external review and incorporated it into its market conduct examinations. State regulators have pulled a sample of claims denials from a large health plan and turned them over to an IRO as if each had been appealed by the consumer. The IRO was asked to review each denial and make a recommendation as to its appropriateness. Regulators used the process to identify and correct a troubling pattern of decision-making regarding denials for mental health services.

States are also using the external review process for quality improvement. For example, regulators use Vermont's external review process for mental health cases to examine the appropriateness of plans' mental health guidelines. Under voluntary external review programs, according to IRO representatives, review decisions can also prompt some plans to change procedures and improve care to members. The use of independent review also helps to standardize a process that many consumers believe is subject to random denials of needed care.

Finally, a few states have tied the external review process to the right of plan members to sue for malpractice. Texas and Georgia, for example, require (with some important exceptions) consumers filing suit against their health plan to first complete the external review process. Colorado requires that the external review decision creates a

²⁹ The bills that have passed their respective houses and are being considered at conference this year are the Senate amendment to H.R. 2990 (originally passed by the Senate on July 15, 1999 as the *Patients' Bill of Rights Plus Act*, S.1344) and H.R. 2990 as passed by the House on October 6, 1999 (which incorporates both the *Quality Care for the Uninsured Act of 1999*, Talent/Shadegg, and the *Bipartisan Consensus Managed Care Improvement Act of 1999*, Norwood/Dingell).

³⁰ See H.R. 2990 as passed by the House, § 1103(a)(4)(A) (filing fee requirement).

³¹ See *id.*, § 1103(b)(2)(B) through (D) (medical necessity); § 1103(b)(2)(H)(ii) (time limit on decisions).

rebuttable presumption in any subsequent legal action that may arise regarding the dispute.

CONCLUSION

Though external review is over 20 years old, the growth and evolution of these programs has been recent and rapid. External review seems poised to be almost universally accepted as part of our health care system. Even so, questions remain on how best to ensure accessible, unbiased, high-quality reviews. The growing acceptance of external review should not obscure the importance of these questions.

State external review laws differ on a number of important parameters: What issues are eligible for review? How easy is it for consumers to use the process? Who are the reviewers, what are their qualifications, and how are they chosen? How is medical necessity defined? What is the relationship between external reviews and plan liability? Variation among IROs and their contracting arrangements also raise a number of questions: How should reviewers be trained? What questions should be asked of reviewers? What review methodology should be used? What other work should IROs be permitted to do for plans without raising the appearance of a conflict of interest?

As the number of external review programs grows, more focus on their features is warranted. The details of what external review encompasses and how it works will have important implications for how fair and effective these programs will be. Data collection and oversight will be critical for policymakers deciding how to structure external review programs and how to evaluate access to and outcomes of review.



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