Independent Medical Review Experiences in California, Phase I: Cases of Investigational/Experimental Treatments

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by

The Institute for Medical Quality

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The Institute for Medical Quality (IMQ) is a 501(c)(6) non-profit organization dedicated to improving the quality of care provided to patients across the continuum of health care. IMQ offers a wide range of educational, accreditation, consultation, and certification programs.

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Executive Summary

In 1998, a new California law allowed patients to receive an independent medical review when HMOs denied treatment for specific types of cases. Each review was to be conducted by three medical experts who would evaluate the merits of a requested course of treatment for a particular patient using documented scientific data. The legislation was motivated, in part, by public concern that HMOs might be approving or denying treatment on the basis of cost rather than medical appropriateness.

The Knox-Keene Act of 1975, which governs HMOs in California, historically provided only an informal process through which an HMO enrollee who was denied coverage of a desired treatment could appeal to the health plan's internal review process. If the consumer was not satisfied with the internal decision, he or she could file a complaint with the state's Department of Corporations. Although some health plans voluntarily offered independent external review of denials, the availability was not universal, and there was no oversight of the external review process. The Friedman-Knowles Act of 1998 amended that law. It required HMOs to provide external and independent medical review for specific classes of patients who requested investigational or experimental treatments that were denied by their health plan.

IMQ conducted this study to assess the impact of California's mandated independent medical review process during its initial two-year implementation, from January 1999 to December 2000. The goal of California's State Legislature in mandating the availability of this formal process was to assure that appropriate and equitable decisions were made regarding access to care and to increase public confidence in managed care and health plans' decision-making processes. It was hoped that study results would be useful to consumers, regulators and health plans, all of whom have an interest in the processes through which these decisions are made and the outcomes of the decisions.

Areas addressed included:

- Patients' perception of the independent medical review process;
- Physician involvement in the independent medical review process;

- Valued attributes of the independent medical review process;
- Changes in health plans' medical policies as a result of independent medical review; and
- Effect of the Friedman Knowles legislation on the operations of health plans and independent review organizations.

The study included interviews with patients/families, physicians, health plan representatives, and the principals of the independent review organizations (IROs) responsible for conducting the independent external reviews. Study participants shared their impressions of the process and its effectiveness. They were questioned about their satisfaction with the review process, the adequacy of information provided before and after the reviews, and the extent to which they believed that the independent medical review process resulted in each case receiving a fair and objective review.

Principal findings include:

- *Lack of awareness of the availability of the process.* Neither patients nor physicians showed high levels of awareness of the process.
- *Lack of awareness of safeguards to the process.* Neither patients nor physicians were aware of safeguards such as accreditation used to assure the validity of he process.
- *Lack of confidence in experts' review criteria.* A majority of patients did not feel confident that the experts thoroughly considered and reviewed all available scientific information.
- *Lack of confidence in independence from plans.* Many believed that health plans had influence over the review panel; i.e., the process was not truly independent.
- *Satisfaction heavily linked to outcome of process.* Patients/families' satisfaction with the process appears to be significantly influenced by the outcome of the review—those whose treatments were approved were generally more positive about the value and more confident about the positive effect the process would have on others.

This report reviews the study findings and makes recommendations for consumers, physicians and physician organizations, independent review organizations, DMHC and health plans.

Independent medical review continues to evolve in California. Recent legislation expanded the definition of cases eligible for review. As of January 1, 2001, eligible cases include those in which treatment or care was denied coverage by health plans as "not medically necessary." Under this new and expanded scope of independent medical review, patients must first appeal a denial with the health plan through the plan's internal grievance process. If the denial is upheld or the dispute remains unresolved after 30 days, the patient has the right to request independent medical review. Requests for IMR go directly to the California Department of Managed Health Care (DMHC). DMHC, as successor to the Department of Corporations, regulates access to independent medical review and contracts directly with independent review organizations.

Current guidelines require the independent review organization to complete its review within 30 days.

Phase II of this study will review the effectiveness of independent medical review in 2001, under the new legislation. Phase II findings should be available by the end of 2002. For more information about independent medical review, visit the California Department of Managed Health Care online (**www.dmhc.ca.gov**). For more information about this study, see the Institute for Medical Quality contact information at the beginning of this document.

I. Introduction

In 1998, a new California law allowed for an independent medical review (IMR) when HMOs denied treatment for specific types of cases. Each review was to be conducted by three medical experts, who would evaluate the merits of a particular course of treatment for a particular patient using documented scientific data. The legislation was motivated, in part, by people who felt that HMOs might be approving or denying treatment due to concerns about costs rather than based on medical appropriateness.

At the beginning of the program, independent medical review was available to patients with "life threatening" conditions. In 2000, patients with "seriously debilitating" conditions also had the option of independent medical review. Effective January 1, 2001, the scope of independent medical review was broadened to include denials based on "medical necessity."

Purpose

The purpose of this study was to determine how the IMR process affected the patients, health plans, physicians, and the independent review organizations (IROs) that engaged in it from January 1999 through December 2000. Areas that were addressed include:

- Patients' perception of the IMR process;
- Physician involvement in the IMR process;
- Valued attributes of the IMR process;
- Changes in health plans' medical policies as a result of IMR; and
- Effect of the Friedman-Knowles legislation on the operations of health plans and independent review organizations.

The balance of this report documents our findings and includes recommendations for future program improvements.

Background

During the study period, January 1999 to December 2000, 263 independent medical reviews were conducted pursuant to the Friedman-Knowles legislation: 75 in 1999 and 188 in 2000. The 150 percent increase in the frequency of reviews is attributable to the expansion of the criteria under which one could obtain an independent medical review to include seriously debilitating conditions in addition to life threatening conditions.

At the outset of the study, we thought that increased awareness of the option to request an independent medical review might have contributed to the increased activity. That is unlikely, however, since only 34 percent of the respondents reported that they knew about independent medical review prior to having one.

In this sample of 263 cases, health plan denials were upheld for 60 percent of the cases and overturned in 40 percent of the cases. Following are more detailed data extracted from clinical information recorded by IROs that profile those people who had independent medical reviews.

Table 1. Distribution of Clinical Conditions

Condition	Number	Percent of Total
Cancer diagnosis	191	73
Other diagnoses		
Spinal / Lumbar	23	9
Cardiac	13	5
Neurological	10	4
Gynecological	5	2
Pulmonary	3	1
Miscellaneous	18	6
Total	**263**	**100**

Table 2. Proposed Treatments

Treatment	Number	Percent of Total
Thalidomide	45	17
Clinical trial / study	45	17
Stem cell procedure	38	14
IDET	19	8
Miscellaneous	116	44
Total	**263**	**100**

Table 3. Distribution by Plan

Plan	Number of Reviews
Health Net*	94
PacifiCare	53
Blue Cross	45
Blue Shield	32
Kaiser	19
Cigna	6
Aetna / Prudential †	4
Lifeguard	2
Health Plan of Redwoods	1
Key Health Plan	1
National Health Plan	1
One Health Plan	1
Principal	1
SCAN Health Plan	1
United	1
Universal	1
Total	**263**

* Health Net adopted a policy of 100% review of the Friedman-Knowles cases.

† During the study period, these two companies merged.

Table 4. Source of Review

Source	Number	Percent of Total
Enrollee or physician	125	47.5
Health plan*	88	33.5
Not known†	50	19.0

* Health Net routinely refers for Independent Review as part of initial process; $N = 78$.

† IROs were not identifying source in initial data submissions.

Methodology

Organizing and Orienting the Advisory Panel

From the outset of the study, we endeavored to create a body that would represent the points of view of all parties to this process, and be small enough to be an effective working body. The Advisory Panel assisted in framing the operating principles for the study and served as our review body for the survey instruments. We were fortunate to have had a group of individuals with a broad base of expertise participating on this panel. The 18 members are distributed as follows:

Table 5. Advisory Panel Membership Distribution

Group Represented	Number of Members
Health Plans	6
Consumers	6
Physicians	2
DMHC	2
IROs	2

The membership roster is included in Appendix A.

Health Plan Participation

Due to patient confidentiality issues, the Institute for Medical Quality (IMQ) was not able to contact patients or their families directly. Therefore, it was critical to obtain health plan support for, and active involvement in, this effort by making the initial contact with patients and families to introduce the study and to distribute consent forms. We gratefully acknowledge the support and participation of Blue Cross of California, Blue Shield of California, Health Net, Kaiser Health Plan, and PacifiCare of California. These health plans accounted for 243 reviews conducted during the study period, or 93 percent of the total. It would have been impossible for us to complete this project without their efforts.

Patient Consent Process

IMQ staff worked with the Advisory Panel and health plan representatives to develop the procedures that would facilitate distribution of the consent forms and follow-up with non-respondents. Following are the key elements of this collaboration:

- The health plans' principal interaction with the patients was to secure their consent to participate in the study.
- The consent was between IMQ and the patient because IMQ conducted the study. Therefore, completed consent forms were sent directly to IMQ.
- In order to contact physicians, patients had to provide the contact information and authorization for IMQ contact; the health plan could not release that information.

The five participating health plans distributed a description of the study and consent forms to patients/families in April and May. As discussed in previous progress reports, the elements delineated above are a modification of the original study design, which would have directed patients to return consent forms to their plans. PacifiCare chose to stay with the original design and directed patients to return their consent forms back to them. In addition, potential PacifiCare participants received a draft survey with the consent forms. We believe that either or both of those factors resulted in the lower participation rate of PacifiCare members as shown in Chapter 2.

Some of the plans made follow-up telephone calls to nonrespondents to encourage them to return the consent forms, but that seems to have had minimal impact on the response rate.

Expansion of Study to Include Physicians

Although the original proposal did not include a physician component, the scope of the study was expanded to include physicians whose patients had independent medical reviews. Seventeen participants provided names, addresses, and telephone numbers of their physicians and authorized IMQ to contact them. Those physicians received a copy of an article regarding the study that was published in the *Western Journal of Medicine*, a letter explaining the study in more detail, and a survey.

Questionnaire Development and Administration

Questionnaires for each study segment (patients, physicians, health plans, and IROs) were developed in consultation with Susan Radius, Ph.D., CHES, Professor and Master's Program Director, Department of Health Sciences, Towson University, who has expertise in drafting survey instruments. Dr. Radius's role was to assure that our questions were clear and accessible to the respondents; that the documents maintained a logical flow, regardless of responses to questions; and that the questions would lead to unambiguous responses. Because we were working with small numbers, we used the Advisory Panel to review and "field test" each survey.

II. Results

Patients

Although it was our goal to include all 263 of the patients/families who had an independent medical review, the plans that had a low volume of reviews were not responsive to our invitation to participate in the study. (All reviews conducted are included in Table 3, Chapter 1.) Table 6 summarizes by plan the distribution of patients/families who participated in the study.

Table 6. Distribution by Plan of Patients/Families Who Participated in the Study

Plan	Independent Medical Reviews 1999–2000	Percent of Total*	Consent Forms Returned	Number in Study	Percent of Plan Patients Participating
Blue Cross	45	17.1	10	10	22.2
Blue Shield	32	12.1	8	5	15.6
Health Net†	94	35.7	31	15	15.9
Kaiser	19	7.2	8	6	31.5
PacifiCare	53	21.8	NA	3	5.6
Total	**243**			**39‡**	**15.6**

***** This is a percent of the total number of reviews conducted (263).

† Health Net of California adopted a policy of 100% review of all Friedman-Knowles cases.

‡ An additional patient returned her questionnaire with a note indicating that she "realized that she had not had an independent medical review" after reviewing the survey. In fact, she did have an independent review and the treatment was approved, but this was not apparent to her.

The participants were evenly split between those whose treatments were approved (*N*=20) and those whose treatment denials were upheld (*N*=19). On a percentage basis, 51.3 percent of the study group had treatments approved and 48.7 percent had the denials upheld. This differs from the results of all the reviews, which was 40 percent approvals and 60 percent upholding the denial. The respondents included seven relatives, all of whom felt that their responses "were close" to how the patient would have responded (see Appendix B). Because only about 15

percent of patients/families who had an independent review participated in the study, respondents may represent a biased review.

Knowledge of Independent Medical Review Prior to Event

Most of the participants (66 percent) were not aware of independent medical review prior to their directly experiencing the process.

When they did become aware of independent medical review, patients' most prevalent sources of information were health plan denial letters and the Evidence of Coverage (EOC) issued by the health plan.

None of the respondents used the Department of Corporations/Department of Managed Health Care as a source of information regarding independent medical review.

When asked to select from a list of items all that the respondent knew about independent medical review by the time the case was referred out for review, eleven people could not identify anything. For the remaining 28 participants, following are the most frequent responses (with the number of responses in parentheses):

- That health plans are required to pay for treatment if the IMR finds it beneficial (19);
- That reviews must be supported by medical and scientific evidence (14);
- That IMR is governed by legislation (10);
- That independent review organizations manage the reviews (10); and
- That independent review organizations select the experts (10).

Very few, if any, respondents were aware that (1) the IMR process was defined by state legislation and regulations; (2) IROs had to be approved by an independent accrediting organization; (3) IRO performance was monitored by an independent professional organization; or (4) medical expert findings were subject to specific conflict-of-interest provisions. Nonetheless, most believed the features would be important to an IMR process.

Experience of the Process

Overall, the outcome of the independent medical review, either approving the requested treatment or upholding the health plan denial, appears to be the determinant that most affects the perception of one's own IMR experience.

In order to assess satisfaction with logistical matters such as timeliness and clear explanation of the process, we asked only those patients who had initiated the reviews (N=26), and who would be more aware of the process to complete the relevant survey section. Because respondents were directed to check every statement that reflected their experience, the total number of responses exceeds the number of people who completed the section.

Clarity regarding the process. Approval/denial of the proposed treatment appears to influence the perception of navigating through the process.

Table 7. Patients/Families' Responses Regarding Explanations of the Process

	Total	Approved	Denied
I received the information in a timely fashion	8	6	2
The process clearly explained; I knew what to expect.	3	1	2
I knew how long the review would take	5	4	1
It was difficult to find out how to proceed	9	3	6
The process was difficult to understand	10	1	9
I was unclear about how long it would take	11	4	7

Clarity regarding the time frames. The actual time that elapsed for the review appears to be less influential than the outcome of the review with respect to the perception of timeliness.

Table 8. All Responses to the Question: "How satisfied were you with the amount of time it took to receive the results of the independent medical review?"

	Total	Approved	Denied
Very satisfied	1	1	0
Satisfied	8	5	3
Somewhat satisfied	7	4	3
Not at all satisfied	10	1	9

Even among the 15 people who reported the least elapsed time (two months or less) for the review, the approval/denial of the treatment appears to affect the perception of the timeliness of the review.

Table 9. Responses of Only the Patients/Families Reporting Two Months or Less for the Review to the Question: "How satisfied were you with the amount of time it took to receive the results of the independent medical review?"

	Total	Approved	Denied
Very Satisfied or Satisfied	6	6	0
Somewhat Satisfied or Not Satisfied	9	3	6

A minority of patients reported providing documentation to support their case. Among them, those whose treatments were denied suspected that the material never got to the medical experts. Apparently they believed that if the reviewers, in essence, "heard from them," they would have approved the treatment.

Response to Treatment Approval

All 20 people whose treatment denials were overturned by the independent medical review went ahead with treatment. No one reported any negative consequences of proceeding with treatment.

- Eleven reported that the treatment enabled them to live longer and improved their quality of life;
- Five reported an improved quality of life;
- Three reported that the treatment allowed them to live longer; and
- Two did not answer.

Response to Upheld Denial

It appears that participating in the process, in and of itself, did not "rationalize" a treatment denial in the minds of most of the patients whose treatment denials were upheld. Of these nineteen respondents

- Twelve thought they should have the treatment and followed through with it in the absence of health plan payment;
- Five thought that they "should receive" treatment, but did not pursue it;
- Seven described themselves as "angry" about the process, either alone or in combination with another response; and
- Three understood the reasons that the treatment was not approved.

Patients' Receipt of Clinical Information

The patients who received copies of the medical experts' reports or summaries (or both) were more likely to report that they understood the medical basis for the approval/denial of treatment.

- Of the 19 patients who received clinical information, 68 percent affirmed that they understood the clinical basis for the independent medical review result.
- Of the 20 patients who did not receive clinical information, 35 percent affirmed that they understood the clinical basis for the independent medical review result.
- Of the 20 respondents who did not receive any clinical information, 9 said that they would have liked it.

Understanding the Outcome

Both the outcome of the review and the provision of clinical information appears to have an effect on whether the respondent reports that he/she understands the clinical rationale for the decision, as demonstrated by the responses to the following question:

Table 10. Responses to: "Overall, do you feel you understand the medical basis for the approval/denial of the proposed treatment?"

		Received Clinical Documentation		Treatment	
	Total	**Yes**	**No**	**Approved**	**Denied**
Understood	21	14	7	16	5
Didn't understand/ Don't know	16	5	11	4	12

Of those 21 respondents who said that they understood the medical basis, 66 percent received clinical information and 76 percent of them had their treatments approved. Of those who said they either didn't understand or didn't know, 31 percent received clinical information and 75 percent of them were denied treatment. The sample is just too small to determine the relative contribution of each variable.

Evaluation of Process

In general, the outcome of the review determined the confidence level/satisfaction with the process. The fact that the IMR process exists does not , in and of itself, appear to have had a significant impact on this population.

This finding may be heavily influenced by the lack of information about how the process worked. The majority of patients did not feel that all of the significant information regarding their case reached the IRO and were not clear on the procedures to get it there.

Trust and Confidence in the Process

The responses to the following series of questions demonstrate the relationship between approval/denial of the treatment and the perception of trust and confidence in the IMR process.

Table 11. Responses to Trust and Confidence Questions

	Total Responses	Number Approved	Number Denied
To what extent has the independent medical review process increased people's trust in their health plans?			
Increased a great deal	15	13	2
Increased somewhat	2	2	0
No difference	14	4	10
Reduced trust	7	0	7
How confident are you that the patient's specific medical issues were considered?			
Very confident	12	11	1
Confident	7	6	1
Somewhat confident	1	1	0
Not at all confident	18	1	17
How confident are you that the medical experts conducted a fair and impartial review?			
Very confident	10	9	1
Confident	7	7	0
Somewhat confident	4	2	2
Not at all confident	17	1	16
How confident are you that the medical experts thoroughly considered available scientific information?			
Very confident	6	5	1
Confident	5	4	1
Somewhat confident	7	6	1
Not at all confident	17	1	16

Perception of the Extent to Which Health Plans Influenced the Process

It is noteworthy that 36 of 39 respondents either believe or are not sure whether the plan had a role in selecting the medical experts. Medical experts who are independent of health plans are the premise of this entire enterprise, and yet, it appears that skepticism prevails.

Table 12. Responses to Questions About Extent of Health Plan Influence

	Total Responses	Number Approved	Number Denied
Do you think that the health plan played a role in selecting the medical experts who participated in the independent medical review?			
Yes	18	5	13
No	3	3	0
Don't know	18	12	6
Do you think the health plan played a role in the medical experts' final decision?			
Yes	15	1	14
No	16	15	1
Don't know	8	4	4

Clearly, the outcome of the independent medical review significantly influenced the patients' perceptions of the role and influence of health plans in what is truly an independent process.

What Worked Well/What Should Be Improved?

Each participant was given the opportunity to tell us "what worked well" and "what should be improved" about the process in his/her own words. With just a couple of exceptions, the positive and negative responses were directly associated with whether the treatment was approved or denied. Health plan processes or procedures do not seem to have effect on how the process was perceived. No health plan, each of which presumably treats all patients in the same way, had a consistent performance profile. Appendix B includes all of the responses to each of these questions, sorted by outcome of the review.

Physicians

The survey package was sent to 17 physicians. IMQ received four completed surveys, one blank survey, and a telephone message from a physician who said that because the health plan did not advise him or involve him in the independent medical review, he would not have any contribution to make.

The fact that we received responses from a very small number of physicians, and only one of them appeared more than marginally familiar with independent medical review suggests that, overall, physicians were not well integrated into the process. This may have been particularly true when a health plan initiated a review.

The data are too limited to report conclusive results.

Health Plans

The five health plans that participated in the study, Blue Cross, Blue Shield, Health Net, Kaiser, and PacifiCare, accounted for 93 percent of the independent medical reviews during the study period. (See Appendix C for the tabulated responses from the health plan representatives.)

Integration of Independent Medical Review with Plans' Internal Operations

First level review. During the study period, four of the five plans initially reviewed all proposed Experimental/ Investigational treatments at the plan level rather than at medical group/IPA level. (The fifth plan is following that practice now.)

Supporting documentation provided by the patient. All plans reported that they forwarded all material provided by a patient to the IRO to be triaged and included in the information given to the medical experts. However, as previously noted, a number of patients who provided material reported that they did not think it was considered. It appears that the health plans could/should have confirmed this process step back to the patients.

Patient communication following review. There was variability among plans regarding communication with the patients following an independent medical review.

- All of the plans provided patients with a letter stating the outcome of the independent medical review (i.e., approval/denial of the treatment).
- Three plans routinely made telephone calls to inform patients of the results.
- Two of the three plans that routinely made telephone calls did not provide any clinical information to the patient.
- Two plans provided both the aggregated summary of the medical experts' findings prepared by the IRO, as well as a copy of each medical expert's report.
- One plan included a summary only, prepared by internal staff.

The plans that sent all of the clinical material felt that the patients had a right to the information; the plans that did not provide clinical information made that decision based on the belief that the material was too technical and/or emotionally charged to be useful to the patient.

An interesting note is that in the two plans that reported sending a complete package of information, fewer than half of the patients reported receiving the material.

Physician communication following review. All of the plans sent physicians duplicates of whatever material was sent to their patients. In addition, those plans that did not routinely provide clinical information to patients said that they would provide it to physicians upon request. Unfortunately, due to the low level of participation, we do not have corroborating data from physicians.

Monitoring Results. At a minimum, all of the plans tracked the proposed modalities and whether the plan decision was upheld or overturned. Medical directors at four plans reviewed each independent medical review.

Integration with medical policy. Two plans reported that there was a direct mechanism to incorporate results from independent medical reviews into policy formation, while the other three reported that independent medical review results indirectly influenced policy. In a less formal fashion, plans shared important findings that emanated from independent medical reviews with their contracting IPAs and medical groups in a variety of formats. These included physician newsletters, operations and policy manuals, and communications to IPA/Medical Group Medical Directors.

Dissemination of information. There was no clear sense among plan respondents as to whether practicing physicians would use the results of independent medical reviews (if they were readily available) in recommending treatment options. There were two opinion poles: (1) that physicians who were inclined to practice "evidence-based medicine" would welcome the information and would adjust their practice accordingly and (2) that those physicians who had a vested interest in pursuing and recommending particular treatment modalities would do so without regard to independent medical review trends.

Evaluation of Process

Plan perception of independent medical review. The interviewees characterized their plans' views of the independent medical review process during the study period as follows:

- Four saw it as supporting the internal review process;
- Three felt that it provided both public relations protection and functioned as a tension release valve for patients; and
- One saw independent medical review as adding unnecessary bureaucracy, but also felt that it provided new information and knowledge.

Cost/benefit. None of the plan representatives could quantify the cost/benefit of independent medical review beyond the obvious cost of reviews and the assumption that the process could help to avoid costly legal action.

Independent medical review impact on trust. On balance, the health plan representatives believe that independent medical review may have increased trust "somewhat" in that people may appreciate having the opportunity for their cases to be reviewed by parties outside of the health plan. However, there were concerns about the extent to which the public understands the relationship between independent medical review (organizations) and plans. One health plan representative believes that people may not truly understand the intent of the process and that independent medical review could undermine the health plan's clinical credibility with its members. Another, whose plan routinely referred cases to independent medical review in the spirit of advocating for the patient, believed that their high number of independent medical reviews could be misconstrued by the public as the result of their initially denying more treatments than other plans.

Independent Review Organizations

Principals of both of the independent review organizations that were managing the reviews during the study period were interviewed. In general, they reported that the Friedman-Knowles legislation and the performance standards that were generated had a positive effect on their internal operations and on the independent medical reviews that they performed for all their clients. Other significant findings are as follows:

Adequacy of Material to Support Reviews

Over the two-year period, the quality and completeness of supporting documentation provided by health plans steadily improved. IROs working directly with plans seemed to be advantageous in expediting receipt of additional material. A chronic problem was securing treatment protocols from the provider institutions, which often claimed that such information was proprietary.

Expedited Reviews

During the study period, there were 52 "expedited" reviews (19.7 percent) which were to be completed within five days. Many of these required extensions to gather additional material for the medical experts. The IRO respondents feel that there should be strict criteria for what can be labeled "expedited" and who can make that determination. One suggested that there be "consequences" for physicians who request expedited reviews when there is no clear medical reason to do so. This is because expedited reviews are much more costly to perform. In addition, they believe that it takes a minimum of 5 days to complete a credible review, assuming that all materials are available. (On the patient side, there was no observable link between "satisfaction" measures and having had an expedited review.)

Specialty Panel Composition

Some patients believed that the composition of the specialty panel determined the outcome of their reviews and some health plan representatives agreed that it is possible that panel composition *could* bias the outcome. In response, IRO representatives reported that, insofar as possible, they attempted to balance panels in terms of geography and institutional affiliation. That is, they would not include more than one reviewer from the same institution, from an institution that competes with the one where the proposed treatment would be provided, or from an institution that routinely refers to the one where the treatment would be rendered. They acknowledge that, in the case of unique treatments provided by a limited number of institutions, it is difficult to consistently meet the above conditions.

The aggregate results of certain often-controversial therapies reflect a pattern of findings by specialty (i.e., specialists whose colleagues provide the treatment would recommend approval, while those who do not recommend against it). Obviously, the weighting of a given panel would/could directly influence the outcome of the independent medical review. One of the IRO respondents stated that the "weight" of the panel would favor those specialties that have long-term responsibility for a patient rather than the specialty that has a financial interest.

Provision of Review Information to Patients

Both of the IRO respondents believe that patients should receive (blinded) copies of each medical expert's review. While they did acknowledge that the findings are written for a clinical audience and might be difficult for a layperson to understand fully, they believe that it is preferable for an individual to have the material and confer with his/her physician as appropriate.

Impact of Specific Mandates

Performance Standards

For the most part, health plan representatives did not see the performance standards embedded in the Friedman-Knowles legislation as materially affecting the performance of IROs or the quality of the reviews. Nonetheless, the IRO respondents were in general agreement that the performance standards that emanated from the legislation contributed to improvements in their respective internal systems and processes. The IRO principals believe that these standards, which were more rigorous than those of other accrediting bodies or government agencies, "raised the bar" and positively affected the quality of their work.

Legislative Attributes

Both patients and health plan representatives were asked to characterize the importance of selected legislative attributes of independent medical review. All of the patient respondents, except one, rated the requirement that *plans must pay for treatment recommended by an independent medical review* as "very important." This quality ranked first among ten legislative attributes for the patient segment (see Appendix D).

The *conflict-of-interest* and *medical/scientific evidence* provisions topped the rankings of the attributes by plan representatives and the few physicians who responded. These attributes ranked numbers three and four for patients—following the obligation for plans to pay for treatment and IRO responsibility for selecting medical experts.

Accreditation and Oversight

Patients, plan representatives, and IROs endorsed accreditation and oversight of IROs as a means to assure quality control and adherence to certain principles. In particular, accreditation/oversight was seen as the vehicle to assure that reviewers have no conflicts of interest and that their recommendations are supported by medical and scientific evidence. Although oversight was considered very important by most patients, few knew that it existed.

Standard Questions

In general, patients, plan representatives, and the IRO representatives endorsed the concept of applying a standard set of questions to each review to achieve consistency. However, there was a sense that the questions should pertain to a category of review, such as medical necessity or experimental/investigational, and that there should be an opportunity to customize the review to suit the particular situation if necessary.

III. Discussion and Recommendations

Discussion

Fundamental questions regarding independent medical review emerge from this study.

- What is the purpose of independent medical review?
- Is there a common understanding of the purpose and "value" of independent medical review?
- Should there be?
- How will we know if it achieves its goal?

As stated in the Introduction, the impetus for the original legislation was the perception that health plans were making medical decisions based on financial, rather than clinical, criteria. In response, the independent medical review process was legislatively memorialized to assure that a patient could have an "objective" hearing of his/her case. In theory, the existence of the system, in and of itself, would translate into higher levels of patient satisfaction and a better understanding of why treatments were denied.

The health plans individually and through their state and national associations endorsed the concept. In fact, a recent paper published by the American Association of Health Plans characterizes independent medical review as providing "peace of mind" for consumers and as "a strong foundation for their plans' multifaceted efforts to build consumers' confidence in this area ... by providing reassurance to consumers that their health plans are held accountable…" (See *Independent Medical Review of Health Plan Coverage Decision: A Framework for Excellence*, American Medical Association of Health Plans, April 2001.)

Do the patients and family members see it that way? It appears that the more appropriate characterization of the patient perspective during this time period was of independent medical review as the "court of last resort." It was seen as an opportunity to plead one's case and when one did not "win," the disappointment was palpable. As demonstrated in Chapter 2, simply going through the process did not appear to engender confidence or a sense of health plan

accountability in the participants. The outcome of the independent medical review was the most common shared element among those who shared similar recollections of the quality of the experience. With one exception, those patients whose treatment denials were upheld did not express appreciation for having gone through the process. They instead felt somewhat betrayed because they were not heard.

It is not clear from this phase of the study whether patients would perceive independent review differently if they had more information about it and understood it better. For example, many believed that health plans had influence over the review panel and were not aware of the steps taken to avoid conflicts of interest. They also believed it would be important to have the IRO's performance monitored by an independent professional organization but did not know that such monitoring occurred. Many were unsure that the review panel received all appropriate information about their appeal. Patients expressed a desire to present evidence to the IRO, but were unsure how to gather evidence, and what type of documentation would support their case. Patients found gathering information themselves to be time consuming and difficult to do in the absence of clear guidelines. Also, many did not understand the reasons for the IRO's findings. Perhaps patients' confidence would be higher if they know of the protections that were in place and they all received complete reports from the IROs.

Although each case is considered on its own merits, what will happen when independent medical review results are widely disseminated? Will the information generated by reviews contribute to increased consistency among the determinations of the plan physicians and the IRO physicians, and subsequently reduce the number of requests for independent review? Alternatively, will there be a shift in the types of cases requesting reviews? For the process to be successful, patients must see the independent review as a final objective review of one's case considering the merits of the requested treatment, not as a "court of last resort."

It is incumbent upon the DMHC and/or the legislature to clearly articulate the purpose of independent medical review and to set appropriate expectations for enrollees and their physicians before they need/want an independent medical review. Many of the study participants stated that they should have received the disputed treatment because their physician recommended it, and that neither the health plan nor the independent medical reviewers could make that determination without seeing them. "If my physician thinks I ought to have this treatment, how can someone who doesn't know me and has never seen me possibly be in a position to know more than my doctor?" Of course, there are legitimate reasons to deny coverage; the underlying process and rationale should be more effectively communicated to the patients and families who engage in the process. They need to understand that the IRO looks at their particular case and not just at trends in reviewing their case.

It is not clear how or whether the addition of the Department of Managed Care into the process will infuse more trust and confidence in the system. While no one in our study used the DOC or DMHC as a resource regarding independent medical review, the DMHC plays a significant role in the current conduct of the independent medical review program. This structure may clarify the separation between the health plans and the IROs in the minds of the consumer, but it also could reinforce the perception that a case is sent for an independent medical review because the health plan has a priori done something wrong. Finally, our results suggest that patients benefit when there are opportunities for personal communication with knowledgeable staff. It may be valuable

to study whether concentrating all of the liaison functions in the DMHC rather than distributing communications among the health plans affected the extent to which staff were able to "special handle" patients when necessary. Did patients feel they got better information and assistance as a result of the change?

Finally, there clearly is a significant role for physicians whose patients go through the independent medical review process—particularly for experimental/investigational cases. These cases are often complex and involve significant illness and/or disability. Certainly there are instances when physicians are very engaged. There is, however, the potential that patients will be left to navigate difficult territory alone. This phase of the study indicated that many physicians have little or no understanding of the independent review process, and therefore may be compromised in their ability to assist their patients. This may suggest that educational efforts should be directed toward physicians to enable them to better assist their patients.

Recommendations

Patients

There is a need to better inform health plan enrollees regarding the nature and purpose of independent medical review. Specific actions that can be taken by health plans, the DMHC, and contracted independent review organizations include:

General Information for All Health Plan Members

- Providing a clear explanation of independent medical review, including the purpose, how it applies to different situations such as medical necessity or Experimental/Investigational treatment, and representative timetables to set specific and realistic expectations
- Using standard language and text by all parties, i.e., DMHC, health plans, and IROs, to establish consistency of message
- Providing clear definitions of the roles and responsibilities of each party, emphasizing the delineation between plans, IROs, and DMHC.
- Providing what types of information can be considered and how patients and physicians can submit the material.

Information/Processes to Support Reviews

- All patients should receive copies of the medical experts' reviews.
- Patients, particularly those requesting reviews for experimental/investigational treatment, should have a personal contact available within the DMHC.
- The DMHC should consider whether to institute "special handling" procedures for patients whose treatment denials were upheld (e.g., telephone calls from a clinician).
- DMHC should clearly define what types of material will be passed on to the reviewers, andhow to submit information to the IRO, and should confirm that appropriate material is received and passed on to the reviewers.

Physicians

There is a need to define the role of and to actively involve physicians in the independent medical review process. Potential activities include:

- Physician education through the DMHC, health plans and the CMA
    - A core message would be disseminated by all parties, including articulating the role of the physician in supporting his/her patient through the independent medical review process.
    - IPA and medical group medical directors should receive consistent information through manuals, newsletters, and other media.
    - The CMA communication channels should be used to disseminate information regarding independent medical review.
- Dissemination of clinical outcome data of independent medical reviews recognizing that the findings are patient specific.

Independent Review Organizations

- Although under the current structure, the IROs' primary relationship is with the DMHC, there should be communication to health plans regarding the conduct and outcome of independent medical reviews.
- Standard questions should be developed for specific types of reviews and used when appropriate; similarly there should be guidelines for crafting and applying specific questions to address the needs of a particular case. The standard questions and criteria for specific questions should be made known to health plans and patients who engage in the independent medical review process.
- When patients submit material for consideration, the IROs should send a letter to the patient confirming that the material was received and verifying what was passed on to the reviewers.

DMHC

- The DMHC should organize data by type of review and track the uphold/overturn rate by type.
- Expedited reviews should be tracked regarding frequency of request, "legitimacy" of request, and frequency of extensions.
- DMHC should ensure that there is adequate oversight of the IROs and make physicians and patients aware of those protections.

Health Plans

Health Plans, in concert with the DMHC, should agree on a consistent approach to payment for those services that are mandated as a result of an independent medical review and which would be excluded from payment by virtue of the EOC or medical group agreements. Appropriate language would be included as standard in capitation agreements with IPAs and medical groups.

Further Study

The following areas should be considered for further study:

1. Survey 2001 participants, differentiating between categories of review (e.g., medical necessity and experimental), and track whether the outcome is a determinant of the patient's perception of the process.

2. Assess whether there are substantive differences in patient perception between those whose treatments were denied based on "medical necessity" and "experimental/investigational" criteria.

3. Evaluate the reviews based on "medical necessity" and identify trends in treatments brought forward for review, distribution across health plans, and outcomes (and underlying criteria) of reviews, with the goal of developing a definition of "medical necessity" that is used for the purpose of independent medical review.

4. Evaluate whether centralizing the independent medical review process within the DMHC, rather than distributing it among the health plans, contributes to higher confidence levels for the participants. Also evaluate whether centralization contributes to improving processes and procedures over time.

5. The DMHC's Clinical Advisory Panel or delegated auditors should:

    a. Track the outcomes of reviews with multiple reviewers to determine whether outcomes of similar reviews were determined by the panel composition and, if trends are identified, to assess whether the composition and distribution of medical specialties systematically introduced any bias into the process.

    b. Monitor the expedited review data to determine possible "abuse" and institute criteria for requesting and/or consequences for inappropriate use, if appropriate.

Legislation

Based on the outcome of the activities described under "Further Study," the legislature might:

- Consider redefining "expedited" review as having a five-day turnaround time to assure quality reviews and adequacy of material. It also might consider penalties for "abusers."

- Consider including an accreditation and/or oversight requirement in amended legislation.

Appendix A

Advisory Panel

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Appendix B

Additional Patient Comments and Reactions to the IMR Process

Denied by IRO, but ultimately paid by health plan

Spouse answered; attorney was involved and ultimately health plan paid even though the independent medical review upheld the denial. Felt that the process did not work well.

"My spouse had a rare [disease] and the independent medical review physicians did not have knowledge of it; two denied the treatment and one approved…. [With the attorney's intervention] the plan approved it even though independent medical review denied. It saved my husband's life and cost health plan less money in the long run."

"The doctors reviewing need to be familiar with the diagnosis and treatment."

Denied by IRO

"Nothing [worked well] – it was a long process and I do not believe a fair one."
"The patient's health and well being should be the primary factor. The review panel should be open to new treatments and attempt to understand how they work before denying them. My treatment was approved for two years – then suddenly denied. Health care companies are just trying to cut costs at the patient's expense!"

Denied by IRO

"Those doctors used by the IROs should be audited for the percentage of denials versus the percentage of approvals. My referring physician is the head of the [X] Cardiopulmonary Department. I think that makes him especially qualified to request this procedure. Also, please note that the denials did NOT address the benefits of the procedure, which has been proven to save lives of CHF patients. I was denied this procedure and now my condition is so bad I am on disability with a left ventricle output of 19% (50% is normal). In my opinion, based upon the data, the three IROs were quacks."

Denied by IRO

"The review is futile if the review is not *immediate*. It does *no* good to get a panel of experts together to rule on something that needs immediate attention. That decision should be made by the attending physician. This should be true if the treatment is for therapeutic *or* palliative reasons."

Denied by IRO

Interviewed on the telephone. Very skeptical; really angry; lost a lot of time. Feels that "everything" should be changed about process. Didn't like that he didn't know who the medical experts were so that he could challenge findings. "What is the health plan doing? Should be made easier without a maze and layers of bureaucracy." Plan docs couldn't answer questions.

Felt that he got a major runaround. Ended up where he began at the end of the process. "Fraudulent" time frame. This "hassle" lasted one and a quarter years.

Doubted that there ever was a review at all. He never got any documentation or analysis. He is angry and puzzled that the procedure was approved for someone enrolled in another health plan offered by employer but his plan [and the reviewers] insisted on treating it as experimental.

Appendix C

Health Plan Phone Interviews: Questions and Responses

This appendix specifies the questions asked of the health plans and reports their responses. This part of the study, conducted in a blind method, identifies individual plans by letter designations A- E. Plan responses are indicated by their letter designation next to the chosen response. If a plan did not respond, then its corresponding letter is not noted.

Section 1: Organizing the reviews

1. *Did your plan provide delegated medical groups with a definition of patients who would meet Friedman-Knowles criteria and be eligible for an independent medical review?*

   A D: Yes
   B: Plan's message to delegated medical group: If you are inclined to deny something as investigational, send to us; certain technologies, send to us; early 1999, told groups about the law; plan wanted to see these cases first and would make determination (communication was more informal rather than clearly delineated policy)
   C: Before the legislation, medical groups not allowed to review potential Investigation/Experimental treatment

2. *For all mandated Friedman-Knowles reviews, who conducted the first level review for cases with proposed "experimental/investigational" treatment?*

   A: Delegated medical group
   B C D E: Internal plan staff

3. *Who conducted the first level review of proposed "Experimental/Investigational" treatment for cases that did not meet the Friedman-Knowles criteria?*

   A C: Delegated medical group
   D E: Internal plan staff (go to Question 5)
   B: Send everything here, we'll send back as appropriate

4. *If the delegated medical group had responsibility for first level review of "experimental/ investigational" treatments, did your plan provide any guidelines/criteria to be applied to the review?*

   A D: Yes
   A: occasionally

5. *If plan staff had responsibility for first level review of "experimental/investigational" treatments, did your plan provide guidelines to delegated medical groups that defined the type of cases that should be referred directly to the plan?*

D: Yes
B: Send everything here, we'll send back as appropriate
C: Anything investigational/experimental to go to plan

6. *When the plan reviewed "experimental/investigational" treatment requests, either first level or upon appeal, was there a specific procedure for handling cases that met the Friedman-Knowles criteria?*

   B C D: Yes
   B C D: Medical directors statewide within each plan handle the cases that met the Friedman-Knowles criteria

7. *At what point in the process was it determined that the patient's condition qualified him/her for a Friedman-Knowles review?*

   A: Plan review upon appeal
   B C D E: First level review

8. *What was the position and title of the person(s) who determined that an individual qualified for a review under Friedman-Knowles?*

   A: Medical director
   B: Medical directors
   C: Dedicated individual; Nurse/ benefits interpretation process; collected info and communicated internally and with the treating M.D.
   D: At medical group

9. *What sources of patient information discussed the availability of independent medical review to patients who met the Friedman-Knowles criteria?*

   A B C D E: Evidence of Coverage (EOC)
   A B C D E: Denial letters
   A D E: Newsletters
   Other (please specify):
   C: Member handbook; payroll stuffers
   E: annual handbook

10. *Once a Friedman-Knowles patient was engaged in the independent medical review process, was a principal contact person, e.g., a case manager, identified for that patient?*

    A: No
    B: Medical Policy "home" for Friedman-Knowles; nurse with fax and phone number given; customer service and internal appeals unit clued in to process
    C: Yes, see #8
    D: Quality Intervention subunit: nurse and/or appeals staff person
    E: Senior consultant who works on cases

Section 2: Operations

(The following questions pertain to the study period, January 1999–December 2000, the initial implementation of the independent medical review processes required by the Friedman-Knowles legislation.)

1. *During the internal appeals process, did the plan collect all of the necessary medical records/documentation that an IRO needed to conduct a Friedman-Knowles independent medical review?*

   A D E: Yes
   D: for the most part
   B: What they collected as sufficient for their purposes wasn't always enough for Friedman-Knowles (they knew quite a bit about technology for example). If the technology was not well known, they would collect info and package would be more complete.
   C: Competence grew over time as they did more and more reviews; felt they had it down pretty well by the time that Friedman-Knowles rolled out.

2. *Beyond material discussed in Question 2.6, did the plan include information that was provided by the patient to support the proposed treatment option?*

   A B C D E: Yes
   A B C D E: No
   B: Anything received was sent to the IRO
   C: Benefit interpretation nurse spoke with all and sent to IRO
   E: "Absolutely"

3. *At the conclusion of a Friedman-Knowles review, the patient always received:* ***(Please mark all that apply)***

   A B C D E: A letter from the plan that included a general statement re: approval or denial of the treatment
   D E: A telephone call from the plan that included a general statement re: approval or denial of the treatment
   A B: Phone call on occasion
   C: Generally received a call
   D: A letter from the IRO
   A B C: A summary of the 3 medical experts findings (go to Question 6)
      A: Summary prepared by tech in Appeals Unit
      B: MCOP put together a summary and included blinded copies of reviewers' results
      C: sent IRO summary
   B C: Copies of each medical expert's findings (go to Question 6)

4. *What was the rationale for the plan's decision to not provide the medical expert findings in some form or another?*

   D: Not required; copies sent to requesting M.D. who was asked to discuss with patient; technical considerations, fraught with emotion
   E: Didn't like to send out because members might not understand; maybe in concert with M.D. discussion

5. *Did the plan provide the medical experts' findings to patients who requested them?*

   A E: Yes
   D: Case by case

6. *Once the plan received the results of a Friedman-Knowles independent medical review, how soon was the patient notified of the review's findings?*

   A: Immediately
   B: Quickly; goal: within 24 hours
   C: Very quickly; call that day; letter within a day or two
   D: Expedited, that day; regular within 24 hours
   E: First talk with medical director then patent within 24 hours

7. *Did the same amount of time as reported in Question 6 apply to voluntary independent medical reviews?*

   A B C D E: Yes

8. *Did the same amount of time as reported in Question 6 apply before the Friedman-Knowles legislation?*

   A B C D E: Yes

9. *At the conclusion of a Friedman-Knowles review, the patient's physician always received:* ***(Please mark all that apply)***

   D E A: Letter from the plan that included a general statement re: approval or denial of the treatment
   ____ Telephone call from the plan that included a general statement re: approval or denial of the treatment
   ____ On occasion
   ____ Letter from the IRO
   A: A Summary of the three medical experts' findings (Go to Question12)
   D E: Copies of each medical expert's findings
   E: Both to PCP and specialist
   B C: Same material as patient

10. *What was the rationale for the plan's decision to not provide the medical expert findings in some form or another?*

A: Not required

11. *Did the plan provide the medical experts' findings to physicians who requested them?*

A: Yes

12. *Medical experts addressed these questions for every Friedman-Knowles independent medical review:*

- Is the requested therapy likely to be more beneficial for the enrollee than any available standard therapy?
- Are the medical records and accompanying information sufficient to answer the question above?
- Is there any other treatment not under consideration that can reasonably be expected to be more beneficial for the patient?

(a) Were you aware that this standard approach existed?
A B C D E: Yes

(b) Do you believe that standard questions should be uniformly applied to all cases?
A: Would be helpful if they had a standard way of responding; no room for additional information; "line getting fuzzy"
B: Yes, by and large
C: Yes; standard for a type of review
D: In theory yes; the questions are appropriate based on the legislative intent. Usually one would customize questions for an M.D. to make a decision.
E: No. Believes in consistency, however there isn't an opportunity to identify other relevant material; feels weighted toward patient who can submit anything while plan cannot; currently, with Medical Necessity, it plays out differently; consistent questions for complex, Experimental cases, may be a good thing but for benefit driven matters, no.

(c) Do you think that these questions elicit an objective review?
C: Yes
E: Don't know
A: Some of the time
B: Most of the time
D: No. Reviews inherently subjective, "likely to be more beneficial"; the results have nothing to do with questions

13. *Did you or a designee personally review the medical experts' findings for each Friedman-Knowles independent medical review?*

A: No

B C D E: Yes
B: Medical director looked at them to monitor quality of reviews; trends in services; policies
C: Overturns were reviewed with the policy review committee made up of internal and external M.D.s
E: Medical director

14. *In your opinion, did the specialty composition of each panel influence its findings? If so, how?*

A: Sure it does – both "good" and "bad" biases
B: They could…flaw in process, particularly for certain services, e.g. uterine artery embolization
C: On occasion; there are different ways of approaching things
D: IDET and Uterine Artery Embolzation given as examples; interventional radiologists likely to skew; alternative practitioners
E: [Former IRO] good at getting right type of specialists; process not good at CHDR

15. *Friedman-Knowles requires that if two out of three medical experts approve of a given treatment, the plan must provide the treatment. What did you do when there was one approval, one denial, and one undecided medical expert?*

A: Covered it
B: That was the IRO's job and they had guidelines on the statute; IMQ involved in resolving cases; abstention counts as a "yes"
C: Covered it
D: Looked to [IRO] or IMQ for guidance; this is the law and we are following the rules
E: Covered it

What did you do when there was one approval and two denials?

A B D E: Did not cover
C: Covered it

16. *Did the Medical Group/IPA have the financial responsibility to pay for treatments required as a result of the independent medical review?*

A: Yes
B C D E: Depended on the situation
B: This was a problem that could use a uniform approach; conflicting contract terms; e.g., payment requirements "under appeal process" and liability for care as described in the EOC
C: Not experimental then the IPA; experimental but beneficial, plan
D: Whichever party would have responsibility under the DFR

If Yes, did you ever encounter resistance from the group re: proceeding with treatment (example: patient who required angioplasty with brachytherapy)

A: Sure, they wouldn't argue the treatment, they argued the payment
B: Push back from group regarding payment
C: Yes, but they worked them out
D: All the time
E: Worked it out

17. *As a result of the Friedman-Knowles legislation, did the plan's internal voluntary independent medical review policies/procedures change in terms of:*
(Please mark all that apply)

____ panel size
____ specialty composition of panels
____ conflict of interest requirements
____ communications with patients
____ rigor re: scientific documentation
____ rigor re: time frames for completing reviews

Comments on changes: _____

A: Large influence; entire process changed
B: They tracked together
C: NA – they had a highly functioning process prior to Friedman-Knowles
D: Only had two during period; no ability to judge
E: They tracked together; Plan into IMR prior to legislation

Section 3: Application of independent medical review processes to internal operations

1. *Did the plan develop a database of the Friedman-Knowles cases?*

A B C E: Yes
B: Trended on spread sheet
D: A list

2. *Did a single individual have the responsibility to monitor the results of Friedman-Knowles reviews? If Yes, what was the title and qualifications?*

A B C D E: Yes

A: Clinical Coordinator; Clinical staff in appeals unit
B: Physician
C: Nurse
D: AA
E: Senior Consultant in Appeals Unit

3. *If Yes, please indicate what was included:*
(Please mark all that apply)

A E: Presenting conditions
A B C D E: Proposed treatment modalities
E: Referring specialties
A B C D E: Plan decisions upheld and overturned
_____ Other (please identify)
D: Really used as a tracking sheet for review itself
E: Reason for overturn

4. *Did the results of the Friedman-Knowles reviews influence the plan's development of medical policy during the study period, January 1999–December 2000?*

A: I think so
B C: Yes (please identify):
B: Feedback to Policy committee
C: example of bariatric surgery where plan had set policy based on old data; disagreement regarding standard of care and B I; once they modified, no more denials.
D: Indirectly resulted in more in depth documentation and review of benefit structure; added to knowledge base; feedback from reviewers regarding protocols that came up on a number of occasions, particularly with respect to cancer treatments.

5. *If you observed a trend in the Friedman-Knowles reviews (for example, a given treatment was never approved) did you communicate that information to your contracting medical groups?*

A B C: Yes (if so how?)
A: Outcomes in M.D. newsletters
B: Communications to IPA medical directors; copies of appeals letters to doctors
C: Policy updates go to providers every six months; medical policy and Ops manuals on line
D: No trends identified

6. *If physicians had access to the results of all independent medical reviews, how likely do you think it is that such information would influence their recommendation for a particular treatment?*

C: Very likely
A: Likely
___ Somewhat likely
D B: Not at all likely
D E: I don't know

B: Not very likely; depends; some treatments are emerging and some docs will be interested; early adapters who have a vested interest won't change
C: Only way you get at standards of care; doctors are hungry for this

D: Physicians would continue to advocate for their point of view, e.g., tertiary oncologists engaged on clinical trials

Section 4: Assessment of independent medical review

1. *Please characterize how you think your plan viewed the independent medical review process during the study period:*
   (Please mark all that apply)

   A B E: Public relations protection
   A B E: Provided a tension release "valve" for patients
   A C: Provided access to expertise not otherwise available
   A D: Provided new information and knowledge
   A B C E: Supported the internal review process
   D: Added unnecessary bureaucracy to the process
   E: Hopefully this translated to an even more objective process in minds of members; didn't get any real education back

2. *Please characterize the impact of the Friedman-Knowles legislation in terms of observable costs and benefits to your plan.*

   A: Benefit: anecdotal denial stories disappeared; costs: can't really calculate, zero sum game.
   B: Cost of reviews and administrative cost of program apparent; offsets potential problems, legal costs. Cost of treatments hard to quantify and the cost of working through it. Noted mindset of getting "best possible treatment" which lowers threshold of what plans will cover without review.
   C: Negligible cost; nominal when you consider the expertise you are getting; also "cheap" compared to litigation
   D: Costs of reviews; provided defense [shield] against bad faith claims
   E: No benefits at this point: added administrative costs

3. *Please characterize changes in IRO performance that you would attribute to the Friedman-Knowles legislation*

   _____ Improved turnaround time
   _____ Improved documentation of findings
   C D E: No change
   _____ Got worse
   _____Other
   A: Can't say
   B: Can't say
   C: They did really well before and after

4. *Based on your independent medical review experience, how important was each of the following to having an effective independent medical review process?*

1 = Very Important
2 = Important
3 = A little important
4 = Not at all important

(a) That IROs were accredited specifically to meet standards developed to implement intent of the Friedman-Knowles legislation.

A: 2
B: 4
C: 2 (important that they be accredited, not necessary to be specific to Friedman-Knowles)
D: 1 (consistency)
E: 1 Average: 2.0

(b) That there was ongoing oversight provided by an independent professional organization.

A: 4
B: 4
C: 2
D: 2
E: 2
Average: 2.8

(c) That medical experts were subject to specific conflict-of-interest provisions.

A: 2
B: 2
C: 2
D: 1 (assuming the process worked)
E: 2
Average 1.8

(d) That medical expert findings had to be supported by medical and scientific evidence.

A: 2
B: 2 (not always followed)
C: 1
D: 3 (rarely surprised by the data provided)
E: 1
Average 1.8

(e) That IRO reviews were randomly audited by expert physicians to be sure that they meet clinical standards

A: 4
B: 3 (invisible)
C: 2
D: 3 (assuming this was done)
E: 2
Average 2.8

5. *In your opinion, to what extent has the independent medical review process increased members' trust in their health plans?*

____ Increased trust a great deal
A B: Increased trust somewhat
___ Has had no impact on patient trust
___ Reduced trust
C: Not sure that people really understand what is behind independent medical review; perception that MORE means the plan is "bad" rather than what they perceive is true, i.e., plan is advocating for patient and therefore sends more out.
D: Had no direct information or knowledge; assuming that the same principles apply as do in the internal Appeal and Grievance procedure, he assumes that they are appreciative of having the opportunity.
E: One respondent thought it increased trust; another thought it decreased trust in that it may have undermined the authority of the M.D.s who make the decision.

6. *Based on your experience, what worked well about the independent medical review process during the initial implementation of the Friedman-Knowles legislation (experimental/ investigational treatment for defined types of patients)?*

A: Always room for improvement; generally thinks it's a great deal.
D: Worked as it was intended to work. Worked reasonably well
E: Process went fairly well; good relationship with IRO, which isn't the case now; well thought out.

Comments/Information

Plan C

Felt that the IROs understood job and gave back thoughtful and timely reviews; difficulty in getting medical records. However, the sicker a patient, the easier is was to get the records.

Plan D

Plan D gave delegated groups the Friedman-Knowles conditions and instructed them to refer all Experimental/Investigational cases that came up for review to plan. There would be a review and if a denial was issued the patient was given the option of either another internal Plan D review under the Appeal/Grievance process or to have case sent for independent medical review.

If, when a case was referred for review as Friedman-Knowles, Plan D determined it was not Friedman-Knowles, it was returned to the medical group to make a determination.

Plan E

Has included M.D.s to a high degree; Staff person made presentation around the state to alert physicians to the law and the process. Prior to Friedman-Knowles Kaiser set up a voluntary process run by a designated physician.

Appendix D

Patient Questionnaire and Tally Responses

Instructions: This survey may be completed by the person who had the independent medical review ("the patient"), or by a representative of the person who had the independent medical review. "The patient" will be used throughout the questionnaire to refer to the person who had the independent medical review. If the person completing this form is "the patient," please answer accordingly. If the person completing this form is not "the patient," your answers should reflect your personal knowledge of and experience with the independent medical review conducted on behalf of the person named below.

Name of patient who had an independent medical review: _____

Name of person responding: _____

If you were not the person who received the independent medical review, which of the following best describes your relationship to the patient?

2 Spouse/Partner
Child
Parent
Sibling
9 No Response

Section 1: Initiating the Independent Medical Review Process

1.1 Before this case was referred for an independent medical review, did you know about the law that requires health plans to make an independent medical review available to certain types of patients?

13 Yes 24 No ***(Go to Question 1.3)*** 2 Not Sure ***(Go to Question 1.3)***

1.2 If "Yes," what was your first source of information about independent medical review? ***(Please mark all that apply. Then go to question 1.5.)***

1 Health plan newsletter
0 Health plan website
4 Health plan Evidence of Coverage (EOC)
1 Advocacy group
4 Physician
4 Other ***(Please identify)***

1.3 If "No ", when did you find out about independent medical review? ***Please mark only one response.***

4 When the medical group denied the proposed treatment
10 When the health plan denied the proposed treatment
0 When the health plan said that it was sending the case out for independent medical review
2 Other ***(Please identify)*** _____

1.4 How did you find out that this case would qualify for an independent medical review?

Possible sources of information about independent medical review are presented below. Within each general source (for example, health plan), specific sources are identified. Please review the entire list of general sources identified in bold. Place a check in the space provided beside each general source that informed you about independent medical review as an option for the patient. Then, for each general source, mark the specific source of your information. For example, if you learned about independent medical review in a denial letter from your health plan, you would mark Health Plan and Denial Letter(s).

25 Health Plan:
6 Evidence of Coverage
18 Denial Letter(s)
6 Conversation with Plan Staff

11 Doctor or Medical Group:
7 Specialist who was treating the patient
2 Patient's primary care doctor
___ Medical Group Medical Director
1 Nurse
3 Customer Service Representative

6 Institution where the proposed treatment would have been provided:
4 Doctor
0 Nurse
2 Program Coordinator or Case Manager
3 Other

2 **Advocacy Group**: ***(Please identify)*** _____

1 **Department of Corporations/Department of Managed Health Care**
1 Website
1 Customer Service Representative
___ Other

1 Friends and/or Acquaintances

3 Other *(Please identify)* Attorneys

1.5 Who initiated the independent medical review process?

22 The patient
The patient's:
2 Spouse/Partner
2 Parent
0 Child
0 Sibling
2 Other ***(Please identify)***
1 Primary care doctor
6 Medical specialist
1 Institution where the proposed treatment would have been provided
******If you marked any of the above, please go to Section 2******
11 Health plan

1.6 If the health plan initiated the independent medical review process, how did the patient find out that the case was referred for an independent medical review?

11 Received a letter or telephone call from the health plan
3 Received a letter or telephone call from a doctor
4 Other ***(Please identify)*** _____

1.7 If the health plan initiated the process, did the patient present information for the reviewers' consideration?

5 Yes
4 No
2 Don't know

Section 2: Patient or Doctor Initiated Independent Medical Review

This Section should be completed if the patient, family or a doctor initiated the independent medical review process. If the health plan initiated the independent medical review process, please go to Section 3.

2.1 If a doctor initiated the independent medical review, did the patient provide any information to send to the Independent Review Organization?

6 Yes
9 No
0 Don't know

2.2 Which of the following describes your experience with independent medical review? Please mark all that apply.

a 8 I received all of the information that I needed to initiate the independent medical review in a timely fashion.
b 9 It was difficult to find out about how to proceed with independent medical review.
c 3 The process was clearly explained and I knew what to expect.
d 10 The process was difficult to understand.
e 5 I knew how long it would take to receive the recommendations of the medical experts.
f 11 I was unclear as to how long the review process would take.
g 1 My physician discouraged me from proceeding with the independent medical review
h 2 My health plan discouraged me from proceeding with the independent medical review
i 3 Other ***(Please identify)*** _____

2.3 How much time passed from when the patient first decided to pursue the proposed treatment until the patient was notified of the final determination of the independent medical review?

4 One month or less
12 1 – 2 months
3 2 – 4 months
6 4+ months
2 N/A; I had the treatment before the review (go to Section 3)

2.4 How satisfied were you with the amount of time it took to receive the results of the independent medical review?

1 Very satisfied
8 Satisfied
7 Somewhat satisfied
10 Not at all satisfied

2.5 In your opinion, did it take too long for the patient to be notified of the final determination of the independent medical review?

13 Yes
7 No ***(Go to Section 3)***
1 Don't know ***(Go to Section 3)***

2.6 If you believe that it took too long to receive the final recommendation of the independent medical review, what do you think caused the delay? Please mark all that apply.

3 The Medical Group review of the treatment took a long time.
6 The health plan's review took a long time.
3 The medical experts who reviewed the case took a long time.
3 Other ***(Please identify)*** _____
5 Don't know

Section 3: Outcome of Independent Medical Review

3.1 The treatment option that was evaluated in the independent medical review was:

20 Approved
19 Denied ***(Go to Question 3.4)***

3.2 When the treatment was approved, did the patient receive the treatment?

20 Yes
0 No ***(Go to Question 3.5)***

3.3 In your opinion, having the treatment: ***Please mark all that apply. Then go to Question***

14 Enabled the patient to live longer
16 Improved the patient's quality of life
0 Did not observably change the patient's condition
0 Resulted in a decline in the patient's status
0 None of the above
0 Other ***(Please identify any other outcomes of having received the treatment)***

_____

_____

3.4 When the treatment was denied, the patient: ***Please mark all that apply.***

3 Understood the reasons why the treatment was not approved
0 Felt better about earlier denials of the proposed treatment
13 Believed that he/she should have received the treatment
12 Decided to go ahead with the treatment without the health plan paying for it
7 Felt angry that he/she had gone through the independent medical review
0 None of the above
4 Other ***(Please identify any other outcomes of having been denied the treatment)***

_____

_____

3.5 How was the patient informed of the results of the independent medical review?

3 Informed by a doctor
25 Letter from health plan
9 Telephone call from health plan
3 Other ***(Please identify)*** _____

3.6 Did the patient receive a written explanation of the clinical basis for the recommendation that resulted from the independent medical review?

19 Yes
16 No ***(Go to Question 3.11)***
1 Don't know ***(Go to Question 3.11)***

3.7 If you answered "Yes" to question 3.6, please identify which of the following provided the explanation: *Please mark all that apply.*

10 A copy of each medical expert's recommendation
11 A summary of the 3 medical experts' recommendations
4 A letter from the independent review organization
8 A letter from the health plan

3.8 Did the patient discuss the explanation with a doctor?

10 Yes ***(Please specify)***
0 Primary Care
8 Specialist
3 M.D. for proposed treatment
11 No
1 Don't know

3.9 How well did the patient understand the material?

14 Completely understood it upon first reading
1 Understood it after a doctor explained it
3 Partially understood it
1 Did not understand it
0 Don't know

3.10 If you answered "No" or "Don't Know" to Question 3.6, would it have been helpful for the patient to have received a written explanation of the medical experts' final recommendation?

10 Yes
1 No
1 Don't know

Section 4: Evaluation of the Independent Medical Review Process

4.1 How confident are you that the patient's specific medical issues were considered?

12 Very confident
7 Confident
1 Somewhat confident
18 Not at all confident

4.2 How confident are you that the medical experts conducted a fair and impartial review?

10 Very confident
7 Confident
4 Somewhat confident
17 Not at all confident

4.3 How confident are you that the medical experts thoroughly considered available scientific information?

6 Very confident
5 Confident
7 Somewhat confident
17 Not at all confident

4.4 Do you think that the health plan played a role in selecting the medical experts who participated in the independent medical review?

18 Yes
3 No
18 Don't know

4.5 Do you think that the health plan played a role in the medical experts' final decision?

15 Yes
16 No
8 Don't know

4.6 The following questions framed every independent medical review:

a) Is the requested therapy likely to be more beneficial for the enrollee than any available standard therapy?
b) Are the medical records and accompanying information sufficient to answer the question above?
c) Is there any other treatment not under consideration that can reasonably be expected to be more beneficial for the patient?

a) When the case was initially referred for an independent medical review, did the patient know that the medical experts' review of the proposed treatment would be based on these questions?

3 Yes
29 No
2 Don't know
2 Don't remember

b) Do you believe that these questions resulted in an objective review of this case?

13 Yes
13 No
8 Don't know

4.7 Presented below is a list of features that describe independent medical review. Which of these features did you know about at the time this case went to the Independent Review Organization? *Please mark all that apply.*

I knew:

a 10 That the independent medical review process was defined by State legislation and regulations.
b 10 That Independent Review Organizations (IROs), which are not affiliated with any health plan, managed the reviews.
c 4 That IROs had to be approved by an independent accrediting organization.
d 3 That IRO performance was monitored by an independent professional organization.
e 10 That medical experts were selected by the IROs and not the health plans
f 4 That medical experts were subject to specific Conflict of Interest provisions.
g 14 That medical expert findings had to be supported by medical and scientific evidence.
h 19 That the health plan was required to provide the treatment if the medical experts determined that it would be helpful.

4.8 Based on your independent medical review experience, how important is each of these features to having an effective independent medical review process? *In your reply, put a "1" beside something if you think it is very important; a "2" if it is somewhat important, and so forth. NUMBERS LISTED ARE FOR 'VERY IMPORTANT' REPLIES ONLY.*

1= Very important
2= Important
3= A little important
4= Not at all important

a 33 That the independent medical review process was defined by State legislation and regulations.
b 17 That Independent Review Organizations (IROs), which are not affiliated with any health plan, managed the reviews.
c 39 That IROs had to be approved by an independent accrediting organization.
d 36 That IRO performance was monitored by an independent professional organization.
e 17 That medical experts were selected by the IROs and not the health plans
f 19 That medical experts were subject to specific Conflict of Interest provisions.
g 28 That medical expert findings had to be supported by medical and scientific evidence.
h 3 That the health plan was required to provide the treatment if the medical experts determined that it would be helpful.
i 39 That the medical experts answered the same three standard questions during every independent medical review.
j 36 That medical experts' reviews were randomly audited by a panel of physicians to be sure that they met clinical standards.

4.9 In your opinion, to what extent has the independent medical review process increased people's trust in their health plans?

15 Increased trust a great deal
2 Increased trust somewhat
14 I don't think it has made a difference
7 Reduced trust

4.10 Overall, do you feel you understand the medical basis for the approval/denial of the proposed treatment?

21 Yes
13 No
7 Don't know

4.11 Based on your experience, what worked well about the independent medical review process?

4.12 Based on your experience, what should be changed about the independent medical review process?

If you were not the person who received the independent medical review, how closely do you think your answers reflect the way in which "the patient" experienced the independent medical review process?

7 Very close to how the patient would have responded
___ Somewhat close to how the patient would have responded
___ Not at all close to how the patient would have responded
0 I cannot say how the patient would have responded