JOINT INFORMATIONAL HEARING
ASSEMBLY HEALTH AND JUDICIARY COMMITTEES
Tuesday, March 12, 2002
1:30 p.m. to 4:00 p.m.
State Capitol, Room 4202

BACKGROUND

AGENDA – Part II

Implementation of Independent Medical Review

Independent Medical Review (IMR) is a way for patients to appeal to physicians and other health care professionals outside the patient's health plan to make an independent decision about their health care. IMR programs provide an independent review of a health plan's decision to deny, modify, or delay 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, IMR programs are used by most states and in the private sector. IMR is 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. IMR, also known as external review, is widely cited as a fair, impartial, and usually expeditious and cost effective way to resolve disputes,[i] and is used by more than 35 states.[ii]

Enacted through the Friedman-Knowles Experimental Treatment Act of 1996,[iii] California's initial IMR law required health plans to establish a reasonable external, independent review process to examine health plan coverage decisions regarding experimental or investigational therapies for individual enrollees who were terminally ill and met other specified criteria.

In 1999, the California Legislature passed and Governor Davis signed into law a package of HMO reforms. Included in those reforms was AB 55 (Migden and Thomson), Chapter 533, Statutes of 1999, which established, effective January 1, 2001, the Independent Medical Review System[iv] for health plan denials based on medical necessity, and SB 189 (Schiff), Chapter 542, Statutes of 1999. SB 189 broadened eligibility for the Friedman-Knowles Experimental Treatment Act from terminally ill patients to patients with life-threatening or seriously debilitating conditions and required the health plans' regulator (either the Department of Managed Health Care or the Department of Insurance) to contract with the independent review organization (IRO), instead of the plan contracting with an IRO directly.[v]

After an overview of IMR by Daniel Zingale, Director of the Department of Managed Health Care (DMHC), the members of the Assembly Health and Judiciary Committees will hear testimony from patients, consumer advocates, researchers, and physicians on how IMR is working in California. The following discussion questions were sent to panel participants in advance of the hearing.

Discussion Questions

1) What is Independent Medical Review (IMR) and why is IMR important?

2) What types of cases go to IMR? What is the criteria used to determine eligibility for IMR?

3) What appear to be the principal complaints about IMR being expressed by patient users?

4) How do California's results compare to the rest of the nation? Can any conclusions be drawn from the data to date?

5) If a patient pays for and obtains a service after the health plan denies it as not medically necessary, is the denial eligible for IMR? If not, should it be?

6) In a delegated medical group, are patients being made aware of their right to IMR if the patient is denied care by the medical group? What is being done to monitor and enforce notice requirements and the right to IMR when the service denial is from a delegated medical group?

7) If an independent review panel requires a health plan to cover a particular treatment or therapy, is the decision binding on the plan for other enrollees with the same condition or is it limited to that particular enrollee?

8) What percentage of the applications for IMR actually went through and completed the IMR process? What were the reasons for the other applications not being eligible for IMR or not completing the IMR process?

9) What oversight exists regarding the IMR contractor's (Center for Health Dispute Resolution [CHDR] performance? How will DMHC and the Legislature know if CHDR is doing a good job?

10) How does CHDR determine the composition of its expert panels? Are differences in subspecialty, training, knowledge and biases taken into consideration?

11) How do patients learn about the IMR process? Is there a need for additional enrollee education?

12) Is DMHC starting to see trends in the types of cases that go to IMR and health plan denials of care?

13) Should there be greater public disclosure of the clinical issues and health plan involved in each IMR case?

Who is Eligible for IMR?

Individuals eligible for IMR include those enrolled in "full service" health care service plans (generally HMOs such as Kaiser Foundation Health Plan and HealthNet) and managed behavioral health plans (such as Managed Health Network) regulated by DMHC, health insurers regulated by the Department of Insurance (such as Hartford Life and Accident Insurance Company and CalFarm), and Medi-Cal managed care plans providing health care coverage to Medi-Cal beneficiaries (such as the Health Plan of San Mateo).

A health plan enrollee can apply for an IMR when he or she meets one of the following conditions:

1) the enrollee's provider has recommended a health care service as medically necessary;

2) the enrollee has received urgent care or emergency services that a provider determined was medically necessary; or,

3) the enrollee, in the absence of a provider recommendation or the receipt of urgent care or emergency services by a provider, has been seen by an in-plan provider for the diagnosis or treatment of the medical condition for which the enrollee seeks independent review.

To be eligible for IMR, a health plan enrollee must also meet one of the following conditions:

1) Had medical services or treatment denied, modified or delayed by the plan or one of its contracting medical providers based in whole or in part on a finding that the proposed health care services are not medically necessary. In most cases, the patient must first complete the health plan's grievance process or participate in the plan's grievance process for at least 30 days;

2) Had medical services or treatment denied for a life-threatening or seriously debilitating condition because it was determined to be experimental or investigational; or,

3) Had received emergency or urgent medical services or treatment, but the health plan denied reimbursement on the grounds the service was not medically necessary.

Medical Necessity vs. a Coverage Decision

To be eligible for IMR, a patient's case must involve a "disputed health care service." A disputed health care service means any health care service eligible for coverage and payment under a health plan contract that has been denied, modified, or delayed by a decision of the plan, or by one of its contracting providers, in whole or in part due to a finding that the service is not medically necessary.

Health plan coverage decisions are not subject to IMR. A "coverage decision" is defined as the approval or denial of health care services by a plan, or by one of its contracting entities, substantially based on a finding that the provision of a particular service is included or excluded as a covered benefit under the terms and conditions of the health plan contract. If a plan, or one of its contracting providers, issues a decision denying, modifying, or delaying health care services, based in whole or in part on a finding that the proposed health care services are not a covered benefit under the contract that applies to the enrollee, the statement of decision is required to clearly specify the provision in the contract that excludes that coverage.

The health plan's regulator is the final arbiter when there is a question as to whether an enrollee grievance is a disputed health care service or a coverage decision.

DMHC contracts with Maximus/Center for Health Dispute Resolution (CHDR) to administer the IMR program. CHDR has handled external reviews for the Medicare program since 1988 and reviews cases for 23 other states.

Criteria Used by the Medical Reviewers

Upon receipt of information and documents related to a case, the medical professional reviewer or reviewers selected to conduct the review by the independent medical review organization (CHDR) is required to promptly review all pertinent medical records of the enrollee, provider reports, as well as any other information submitted to the organization.

Following its review, the reviewer or reviewers determine whether the disputed health care service was medically necessary based on the specific medical needs of the enrollee and any of the following:

- Peer-reviewed scientific and medical evidence regarding the effectiveness of the disputed service;
- Nationally recognized professional standards;
- Expert opinion;
- Generally accepted standards of medical practice; or,

- Treatments that are likely to provide a benefit to a patient for conditions for which other treatments are not clinically efficacious.

The organization is required to complete its review and make its determination in writing, and in layperson's terms to the maximum extent practicable, within 30 days of the receipt of the application for review and supporting documentation, or within less time as prescribed by the plan's regulator. The medical professionals' analyses and determinations are required to state whether the disputed health care service is medically necessary. Following a decision, the plan's regulator is required to immediately adopt the determination of the independent medical review organization, and to promptly issue a written decision to the parties that is binding on the plan.

After removing the names of the parties, including, but not limited to, the enrollee, all medical providers, the plan, and any of the insurer's employees or contractors, decisions adopting a determination of an independent medical review organization are made available by the regulator to the public upon request. DMHC provides on its web site a database of IMR decisions that contains a brief summary of the case and that is searchable by diagnosis category or treatment category. The following two cases are from DMHC's database. The first case falls under the diagnosis category of "prevention" and the treatment category "diagnostic imaging/screening" in which the health plan decision was upheld, and the second case falls under the diagnosis category "mental disorder" and the treatment category "mental health" and involves a health plan being overturned.

Case Details

Reference ID #	**Type**
MN01-000132	Medical Necessity
Prevention	Diagnostic Imaging / Screening

Upheld Decision of Health Plan

Case Details:

A 60-year-old female requested a colonoscopy as a cancer screening. The health plan denied the request indicating the requested procedure is not medically necessary, and the health plan recommended a sigmoidoscopy and a fecal occult blood test. The Review Organization's Physician Consultant examined the medical records submitted and determined there is no indication that this patient is at increased risk for colon cancer. The Health Plan’s denial should be upheld.

Case Details

Reference ID #	**Type**
MN01-000300	Medical Necessity

Mental Disorder	Mental Health

Overturned Decision of Health Plan

Case Details:

A 54-year-old female requested weekly cognitive therapy by an out-of-network provider for treatment of behavioral problems. The Health Plan denied the request indicating the service can be provided in-plan consistent with weekly group therapy, monthly visits with an LCSW and consults with a psychiatrist every two months for medication review. The Health Plan has a brief treatment model using cognitive and behavioral techniques, through group therapy, and when necessary individually. Individual treatment occurs on a frequency of two to four weeks between sessions. The Review Organization's Physician Consultant examined the medical records submitted and determined the enrollee has multiple problems; depression, post-traumatic stress disorder (PTSD), anxiety as well as serious psychodynamic cognitive and behavioral issues. The mode of therapy, i.e., cognitive, behavioral or psychodynamic or a combination in a group setting or individual setting can vary depending upon assessment of the enrollee at a given point in time. The enrollee is described as a very high suicidal risk, which would exacerbate if continued treatment with the out-of-network provider was disrupted. Therefore, the health plan's denial should be overturned.

Upon receiving a decision adopted by the health plan's regulator that a disputed health care service is medically necessary, the health plan is required to promptly implement the decision. In the case of reimbursement for services already rendered, the health plan is required to reimburse the provider or enrollee, whichever applies, within five working days.

The health plan's regulator is required to establish a reasonable, per-case reimbursement schedule to pay the costs of IMR organization reviews, which can vary depending on the type of medical condition under review and on other relevant factors. The costs of the independent medical review system for enrollees are required to be borne by health plans pursuant to an assessment fee system established by their regulator.

Disclosure to Health Plan Enrollees

To notify patients of their right to IMR, every health plan is required to prominently display information concerning the right of an enrollee to request an independent medical review on the following documents:

- every health plan member handbook or relevant informational brochure;
- in every health plan contract;
- on enrollee evidence of coverage forms;
- on copies of health plan procedures for resolving grievances;
- on letters of denials issued by either the health plan or its contracting organization;
- on grievance forms; and,
- on all written responses to grievances.

Report to the Legislature and Annual DMHC Audit

The director of DMHC is required to submit to the Legislature by March 1, 2002, a report on the initial implementation of IMR which includes a description of assessments imposed on plans to implement IMR, increased staffing and other resources attributable to these new responsibilities, and any redirection of existing staff and resources to carry out these responsibilities.[vi]

Additionally, the director is required to perform an annual audit of IMR cases for the dual purposes of education and the opportunity to determine if any investigative or enforcement actions should be undertaken by DMHC, particularly if a plan repeatedly fails to act promptly and reasonably to resolve grievances associated with a delay, denial, or modification of medically necessary health care services when the obligation of the plan to provide those health care services to enrollees or subscribers is reasonably clear.[vii]

Clinical Advisory Panel

AB 78 (Gallegos), Chapter 525, Statues of 1999, created DMHC and established in DMHC a Clinical Advisory Panel (CAP).[viii] The CAP consists of five members appointed by the director, three of whom are professors of medicine from California's public and private medical schools and two of whom are practicing physicians. CAP is required to meet quarterly, and its purpose is to:

- Provide expert assistance to the director by ensuring that the external independent review system is meeting the quality standards necessary to protect the public's interest.

- Assist the director with other clinical issues as needed, such as recommending approaches to globally reduce clinical errors, improving patient safety, increasing the practice of evidence-

  based medicine, and catalyzing clinical studies when a clear need for additional clinical evidence becomes evident.

- Review the decisions made in external review to ensure that the decisions are consistent with best practices, and to make recommendations for improvements where necessary.

Litigation Involving IMR

United States Supreme Court

The U.S. Supreme Court has under review *Rush Prudential HMO Inc. v. Moran* after hearing oral arguments in January 2002. The case raises the issue as to whether the independent physician review provision of an Illinois law, similar to California law and laws adopted in 36 states and the District of Columbia, is preempted by the Employee Retirement Income Security Act of 1974 (ERISA). The impact of the court's decision in this case will be the future viability and enforcement of current state laws, which are designed to help patients deal with denials of care by HMOs or their contracting entities. The court's decision will ultimately determine any state's ability to regulate managed care, and material modifications of managed care agreements may be necessary after the decision is rendered.

The case involves an Illinois woman, Debra Moran, who decided to pay for a $94,841.27 operation herself after her HMO, Rush Prudential, refused coverage. Moran sued the insurer and won a state court order that required Rush Prudential to submit to independent physician review as mandated by the Illinois HMO Act. The insurer complied but denied, as medically unnecessary, Moran's request for full coverage of the surgery by the outside surgeon.

Superior Court of the State of California - Sacramento County

In September, 2001, a Blue Shield enrollee's physician submitted a request to Blue Shield requesting that the enrollee's prescription for the weight loss drug Xenical be covered by Blue Shield under one of their outpatient prescription drug benefit plans.[ix] Outpatient prescription weight loss drugs are specifically excluded from the enrollee's plan. Blue Shield denied the enrollee's physician's request for coverage for Xenical, informing the enrollee that outpatient prescription drugs for weight loss are specifically excluded.

The enrollee then appealed Blue Shield's denial of coverage, and that appeal was denied on the ground that weight loss medications are not a covered benefit under the enrollee's outpatient prescription drug benefit package. The enrollee applied for an IMR of Blue Shield's decision not to provide coverage for the enrollee's Xenical prescription, CHDR performed an IMR and determined that the medication Xenical was medically necessary for the treatment of the enrollee's medical condition. CHDR accordingly decided that Blue Shield's denial of coverage for Xenical should be overturned. DMHC adopted this decision on October 26, 2001, finding that because CHDR had determined Xenical was "medically necessary" for the treatment of the enrollee's medical condition, Blue Shield was required to provide coverage for the medication. Blue Shield refused to comply with DMHC's decision but continued to provide the drug pending the outcome of the case.

On November 16, 2001, DMHC filed an accusation against Blue Shield seeking to impose a $100,000 administrative penalty against Blue Shield and an additional penalty of $5,000 per day from November 2, 2001 until Blue Shield provides coverage for the enrollee's outpatient prescription of Xenical. In December 2001, Blue Shield sought a declaratory judgment that the denial of coverage for outpatient prescription drug benefits based on an exclusion of coverage is not subject to an IMR and that, in such cases, DMHC may not approve enrollee's requests for an IMR or adopt, rely upon, or consider the conclusions of any such IMR. Additionally, Blue Shield sought a permanent injunction to enjoin (prohibit) DMHC from authorizing an IMR for Blue Shield outpatient prescription drug benefit coverage decisions, when those coverage decisions are not based, in whole or in part, on a finding that an outpatient prescription drug is not medically necessary, and a permanent injunction to enjoin DMHC, from adopting, relying upon, or considering the results of any IMR of Blue Shield outpatient prescription drug benefit coverage decision under IMR, when those coverage decisions are not based, in whole or in part, on a finding that the outpatient prescription drug is not medically necessary, absent an express statutory mandate.

On January 15, 2002, a Sacramento Superior Court judge issued a preliminary injunction enjoining DMHC from authorizing an IMR for Blue Shield's outpatient prescription drug benefit coverage decisions when those decisions are not based on a finding that the outpatient prescription drug is medically necessary. Additionally, the judge enjoined DMHC from adopting the results of any IMR review of Blue Shield outpatient prescription drug benefit coverage when those coverage decisions are not based on a finding that the outpatient prescription drug is not medically necessary, absent an express statutory mandate.[x] Blue Shield has continued to provide the drug to the enrollee whose case went to IMR and to enrollees who requested the drug prior to January 15th but is not authorizing the drug for other enrollees since the judge's injunction.

Department of Managed Health Care IMR Data

Calendar Year 2001	Beginning Balance	IMRs Received	IMRs Not Eligible	IMRs Resolved IMRO	IMRs Resolved Other*	Ending Balance
January	0	30	17	1	0	12
February	12	82	34	9	2	49
March	49	134	88	36	0	59
April	59	119	61	54	5	58
May	58	173	58	59	10	104
June	104	200	106	49	24	125
July	125	146	109	67	24	71
August	71	208	112	47	15	105
September	105	171	105	53	5	113
October	113	195	145	62	1	100
November	100	153	86	69	8	90
December	90	117	63	59	12	73
Year-to-Date Totals		**1,728**	**984**	**671**		

In 2001, of the 1,728 IMR requests received, 984 or 57% were not eligible for IMR. 671 of the 1,728 IMR requests were resolved (39%), with 84% of the cases resolved being resolved through IMR.

* IMR Requests that did not go to the IMR organizations because the DMHC made a mistake in its original review of the issue, the patient withdrew, the health plan withdrew, or the issue was resolved through the Department's HMO Help Center.

Source: Department of Managed Health Care

Department of Managed Health Care IMR Data

Month	Balance	Sent		Upheld		Overturned		Withdrawn*	Pending
		E/I	MN	E/I	MN	E/I	MN		
January	0	4	1	1	0	0	0	0	4
February	4	4	18	3	4	0	2	2	15
March	15	21	45	9	14	3	10	0	45
April	45	18	33	17	23	2	12	5	37
May	37	12	39	15	24	5	15	2	27
June	27	17	64	5	26	3	15	7	52
July	52	11	36	13	29	1	24	2	30
August	30	14	50	9	18	5	15	8	39
September	39	14	45	11	26	2	14	4	41
October	41	14	60	11	21	3	27	5	48
November	48	19	55	14	24	3	28	8	45
December	45	5	51	11	26	0	22	5	37
Subtotals		153	497	119	235	27	184	48	
Year-to-Date Totals		**650**		**354**		**211**			

E/I – Experimental/Investigational
MN – Medical Necessity

* Withdrawn means withdrawn from the review process as a result of the health plan reversing its decision, the DMHC's action or at the enrollee's request.

In 2001, of the 650 IMR requests sent to IMR, the health plan was upheld in 354 cases (54%) and overturned in 211 (32%), with the remainder being withdrawn or still pending. Of the 650 IMR requests, 153 were experimental/investigational requests for IMR. For the 153 cases sent to IMR involving experimental/investigational treatment, the plan was upheld in 119 cases (78%) and overturned in 27 (18%), with the remainder being withdrawn or still pending. Of the 650 IMR requests, 497 were medical necessity requests for IMR. For the 497 cases sent to IMR involving medical necessity, the plan was upheld in 235 cases (47%) and overturned in 184 (37%), with the remainder being withdrawn or still pending. The DMHC's report contains different numbers because it excludes from the 650 cases sent to IMR the 37 still pending.

Source: Department of Managed Health Care

Department of Managed Health Care IMR Data
IMR Requests Not Eligible / Not Qualified

For the period January 1 to December 31, 2001, there were 1,728 requests for Independent Medical Review. Of the applications received, 984 did not qualify. IMR requests are rejected as: not being eligible/qualified; withdrawn by the enrollee, health plan or department; or closed due to a rendered review organization determination.

DISPOSITION	Number
Non-jurisdictional (1)	59
Non-response to request (2)	64
Reimbursement (3)	272
Enrollee died	1
Not completed grievance	111
Health plan/patient reversal (4)	58
Medicare	22
Medi-Cal (5)	3
Coverage	249
Service already rendered	13
Enrollee terminated from the health plan	13
Quality of care	6
Dental (6)	15
Request to pay	4
Duplicate Request (case opened twice)	18
2000 denial letter (7)	6
Invalid (case opened that is not eligible for IMR)	9
Referred to standard complaint	36
Condition not life threatening or serious debilitating (8)	3
Resolved	16
Six month deadline (9)	6
TOTAL	**984**

(1) Non-jurisdictional - Health plan under jurisdiction of another agency.

(2) Enrollee/physician non-response to info request – Requested documentation not received.

(3) Reimbursement/Service already rendered – Includes medical services obtained by enrollee out-of-network; enrollee not obtaining a prior authorization. Request reviewed through standard complaint process.

(4) Reversal of request – Health plan or patient reversed the request.

(5) Medi-Cal – Enrollee participated in the Fair Hearing Process or not a covered benefit.

(6) Dental issue – Not a covered benefit.

(7) Health plan denial letter dated 2000 – Health plan denial letter has to be issued in 2001 to be eligible for an IMR.

(8) Expirmental/Investigational qualifications not met – Physician certification information disqualifies request.

(9) The enrollee did not respond within the six month period to file an IMR.

Expedited IMR Requests for 2001

Experimental/Investigational – 70
Medical Necessity – 29

Source: Department of Managed Health Care

Department of Insurance
Health Insurance Related Inquiries and Complaints

Statistical Data - Calendar Year 2001

Category	Totals
Telephone calls to Consumer Communications Bureau (CCB) (Hotline)	454,205
Health insurance related telephone calls to the Hotline	10,853
Health insurance related written consumer complaints	3,003
Health insurance related written consumer complaints on Claim Issues (CSB)	2,893
Total health insurance related written consumer complaints on Rating & Underwriting issues (RUSB)	110
Total complaints received in CSB as potential medical necessity issues (Potential IMRs) *	120
Total complaints where the IMR program was initiated	59
Total complaints actually sent to the IMR program	22

* These cases had the potential to be placed into the IMR program if they qualify.

Source: Department of Insurance

Total IMR Cases Received in the

Department of Insurance's Claims Services Bureau (CSB) 2001-02

Status of Cases	CY - 2001	CY - 2002
Potential cases eligible for IMR	***120***	***52***
Cases placed into the IMR program	***64***	***29***
IMR offered to insured, pending response	22	17
IMR offered to insured, no response - case closed	19	2
IMR request sent to insurer - pending insurer response	1	3
IMR process completed, case closed, IMRO found for the insured	5	0
IMR process completed, case closed, IMRO upheld insurer position	8	0
Cases not placed into IMR program	***56***	***23***
Standard regulatory review only, pending *	2	1
Claim approved prior to IMR process	8	1
Standard regulatory review only, case closed *	11	0
No jurisdiction - referred to another state	6	2
No jurisdiction - referred to Federal Benefit Program	2	0
No jurisdiction - referred to US Department of Labor (self-funded)	16	2
No jurisdiction - referred to DMHC	7	1
Closed - complaint did not qualify **	4	0
Informational only, no action requested	0	16
Total recoveries to date	**$52, 169.00**	**n/a**

Note: Due to a pending response from the IMRO, the insurer or the insured, not all data is recorded. It is recorded immediately upon DOI's receipt of such information.

* Standard Regulatory reviews are cases classified as medical necessity related cases that either did not qualify for the program or cases where the complainant requested a standard review rather than the IMR program. The law allows a standard regulatory review for ineligible IMR cases (CIC Section 10169(d).

** Disqualified complaints encompass circumstances such as contractual disputes, consumers who withdrew their complaints, and providers who withdrew complaints.

Source: Department of Insurance

[i] 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.

[ii] Geraldine Dallek and Karen Pollitz, "External Review of Health Plan Decisions: An Update," prepared for the Kaiser Family Foundation, May 2000.

[iii] AB 1663 (Friedman and Knowles), Chapter 979, Statutes of 1996.

[iv] Article 5.55 (commencing with Section 1374.30) of Chapter 2.2 of Division 2 of the Health and Safety Code, and Article 3.5 (commencing with Section 10169) of Chapter 1 of Part 2 of Division 2 of the Insurance Code.

[v] SB 189 (Schiff and Migden), Chapter 542, Statutes of 1999.

[vi] Health and Safety Code Section 1374.36.

[vii] Health and Safety Code Section 1374.34.

[viii] Health and Safety Code Section 1347.1.

[ix] Complaint for Declaratory and Injunctive Relief and Notice of Related Case Filed Concurrently Herewith), Quinn Emanuel Urquhart Oliver & Hedges, LLP, Steven G. Madison, J.D. Horton, Brian D. Henri, Attorneys for Plaintiff California Physicians' Service dba Blue Shield of California.

[x] Order Re Plaintiff's Motion for A Preliminary Injunction by Joe S. Gray, Judge of the Superior Court, Superior Court of the State of California For the County of Sacramento, January 15, 2002.