California HealthCare Foundation

Ten Years of California's Independent Medical Review Process:
A Look Back and Prospects for Change

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by
Kelch Associates

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About the Authors

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About the Foundation

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I. Introduction

For more than a decade, California has been among the states requiring state-regulated health plans to provide consumers with the opportunity for an independent external review of coverage denials. Referred to in California law as Independent Medical Review (IMR), external review is available to consumers in coverage provided through health plans regulated by the California Department of Managed Health Care (DMHC) and through health insurers regulated by the California Department of Insurance (CDI), hereafter referred to collectively as "health plans."[1] Together, CDI and DMHC regulate health care coverage for over 24 million Californians, with each department overseeing the IMR process for the health coverage products under its jurisdiction.

The federal Affordable Care Act (ACA) mandates independent external review for all coverage, including not only state-regulated health coverage products but also self-insured group plans subject primarily to federal oversight. The ACA allows health plans to meet the external review requirement through state-established review processes that meet specific standards. The federal government has determined that California's IMR program (hereinafter CA-IMR) meets those standards.[2]

Given the expansion of external review under the ACA, and more than ten years of IMR cases in California, it is timely to examine the California experience for lessons learned and potential program improvements. This review of California's IMR program relies on data from both CDI and DMHC for all IMR cases from the program's inception through 2010.[3] This report presents findings from that data, describes the current California IMR statute and program rules, and compares California's IMR law to the external review process required under the ACA. The report also suggests several ways to improve the quality, consistency, and credibility of IMR in California and the effectiveness of IMR oversight by policymakers and regulators.

II. Background

Prior to Mandatory IMR

Before California adopted an IMR requirement, most California consumers did not have a formal right to have health plan coverage denials examined by independent clinicians. California law had imposed other requirements, which remain in force, intended to ensure that health plans make appropriate medical decisions. For example, health plans regulated by DMHC are required to ensure that medical decisions be made by qualified medical staff, "unhindered by fiscal and administrative management."[4] Also, under both DMHC and CDI, health plans that conduct medical necessity reviews must develop, file with the respective regulator, and update annually their medical review policies and procedures, which must be based on clinical standards.[5] In addition, health plans must meet other statutory requirements related to medical necessity reviews, including that decisions to deny or modify coverage based on medical necessity can only be made by a licensed health care professional competent to evaluate the specific clinical issues involved.[6]

Prior to mandatory IMR in California, some larger health plans had voluntary programs to evaluate emerging technologies through internal and/or external expert medical review panels, such as the Medical Care Ombudsman Program, which health plans used to secure independent reviews, primarily for breast cancer treatment coverage denials.[7] Most health plans today have some internal process or program for gathering medical and scientific information to inform health plan coverage policies and individual coverage decisions.

Imposition of Mandatory IMR

During the early and mid-1990s, a number of high-profile cases involving emerging expensive treatments raised serious concerns among the public and policymakers about the lack of scrutiny of health plan coverage decisions (see "The Early Case for IMR," page 4). In response to the increased public and media attention, California and many other states established statutory IMR requirements.[8] California's IMR law evolved in two phases:

- **IMR for experimental treatments.** In 1996, California required that health plans arrange for independent, external medical review of coverage decisions involving experimental or investigational therapies for enrollees with terminal conditions in cases where standard treatments were not effective.[9] This early program applied to experimental treatment decisions made after July 1, 1998. It required health plans to establish an external review process conducted by an impartial, independent entity accredited by a private nonprofit agency under contract with the Department of Corporations, predecessor to DMHC, in consultation with CDI.
- **IMR for coverage denied based on medical necessity.** In 1999, California enacted the CA-IMR statute now in place, which extended the right to an IMR to any person with coverage regulated by DMHC or CDI, not just those with terminal conditions.[10] A primary purpose of this new IMR law was "restoring consumer confidence in [California's] health care system by requiring a fully independent, outside review when HMOs deny care."[11] The new CA-IMR

made external review available to any enrollee for whom coverage was denied, modified, or delayed, in whole or in part, on the basis that the treatment or service was not medically necessary, as well as those seeking access to experimental treatments. CA-IMR assigned DMHC and CDI, rather than health plans, responsibility for contracting with an external independent review organization (IRO) for coverage denials beginning January 1, 2001. CDI initially contracted with DMHC to manage IMRs for cases under its jurisdiction but currently has a separate contract with MAXIMUS, Inc., which is also the IRO for DMHC.

The Early Case for IMR: Treatment for Advanced Breast Cancer

California's existing IMR process followed in the wake of media and public scrutiny of health plan decision processes. A publicly visible example spurred much debate within the health care community and highlighted the tensions between medical decision-making and health care coverage: high dose chemotherapy followed by autologous bone marrow transplantation (HDC/ABMT) for treatment of late stage breast cancer. In the early 1990s, after a few encouraging preliminary reports, breast cancer patients and advocates began demanding the treatment. Some state legislatures responded by mandating that insurance companies pay for the intensive procedure, which at the time cost up to $100,000 per case, much more than conventional treatments.[12] High-profile court cases over denial of coverage for this treatment yielded some of the highest legal judgments to date against health plans. By mid-decade, more people were receiving the treatment for breast cancer than for any other cancer.[13]

A 2001 review of the medical literature from 1990 to 2000, however, revealed that while public and physician enthusiasm for HDC/ABMT increased steadily over the decade, clinical evidence of the treatment's effectiveness went from promising to equivocal to disappointing.[14] The HDC/ABMT experience cautioned against allowing either the political process or the courts to resolve disagreements over coverage for emerging treatments and interventions.[15]

At about the same time as the HDC/ABMT controversy, health plans also denied coverage for some promising treatments they deemed experimental or investigational but which later proved to be clinically efficacious. For example, in the 1980s and 1990s, health plans resisted covering a number of new drugs for HIV/AIDS on the basis that these treatments were experimental, and in some cases not yet approved by the federal Food and Drug Administration for HIV/AIDS treatment. Many of these drugs were later proven to be effective at prolonging and improving the quality of life for individuals with HIV/AIDS and eventually became mainstream treatments for the disease.

These and other similar experiences precipitated an increase in state adoption of IMR requirements elevating the use of medical and scientific evidence and establishing an independent forum for coverage appeals.

III. Structure of the California IMR System

Types of Cases Covered by CA-IMR

CA-IMR provides for independent review of three types of health plan decisions: medical necessity, urgent/emergency care, and experimental/investigational treatment. The rules governing each type of case are described below.

Medical Necessity

Most IMRs are triggered when a health plan denies, delays, or modifies a request for coverage of a service based on the health plan's finding that the service is not medically necessary. There is no definition of "medical necessity" for private health care coverage in California law or regulations, or in the IMR contracts DMHC and CDI have with their current IRO, MAXIMUS. Instead, health plans establish contractual definitions of medical necessity for the coverage they offer, which results in different definitions from plan to plan.[16]

CA-IMR differentiates medical necessity cases from coverage decisions; coverage decisions are reviewed directly by CDI and DMHC rather than through IMR. CA-IMR defines a coverage decision as a finding that a particular service or treatment is included or excluded as a covered benefit under the contract or policy for all covered persons, while a medical necessity decision determines whether to authorize treatment for a specific, individual patient.[17] CDI and DMHC have the final authority to decide whether a health plan's decision is a coverage decision or a medical necessity decision.

Urgent and Emergency Care

Payment denials related to urgent and emergency care are a subset of medical necessity cases eligible for IMR. In these cases, health plans deny or modify coverage for urgent or emergency services a plan enrollee has already received, where the health plan determines the enrollee did not require emergency care and reasonably should have known that an emergency did not exist, even if the provider determined the care was medically necessary.[18] In such IMR urgent care cases, physician reviewers consider: (1) whether an emergency was present that justified the enrollee's access of an emergency or urgent care provider; (2) whether the enrollee reasonably should have known that an emergency did or did not exist; and/or (3) whether the enrollee could have waited to receive services from a participating plan provider or during regular business hours. Since 2008, DMHC has tracked and reported emergency care IMR cases separately, whereas CDI does not.

Experimental and Investigational Treatments

Also eligible for CA-IMR are cases in which health plans deny coverage for enrollees with life-threatening or seriously debilitating conditions on the basis that the proposed treatment or service is experimental or investigational. In these cases, the patient has access to IMR if:

- The enrollee has a life-threatening or seriously debilitating condition.
- The enrollee's physician certifies that the enrollee's condition is one for which standard therapies have not been effective or would not be medically

appropriate, or for which there is no more beneficial standard therapy covered by the plan.

- The enrollee's physician has recommended, or the physician or enrollee has requested, a treatment or therapy which, based on two sources of medical and scientific evidence (see below), is likely to be more beneficial than available standard therapy.
- The plan denied coverage of the service or treatment requested.
- The treatment or service would be a covered benefit for the enrollee but for the health plan's determination that it is experimental or investigational.[19]

CA-IMR requires decisions in IMR experimental cases to be based on "medical and scientific evidence" and specifies what sources meet that definition, including specified medical journals, peer-reviewed scientific studies, and listed medical compendia developed by federal agencies and professional bodies, as detailed in the statute.

Standards for CA-IMR Case Reviewers

Because improving consumer confidence was an important goal of the IMR law, CA-IMR places a number of important duties and restrictions on contracting IROs to facilitate impartial reviews by qualified reviewers.

Impartiality

CA-IMR requires an IRO to be independent of any health plan doing business in the state and to prohibit its employees from having any material professional, financial, or familial affiliation with any of the parties involved in the disputed service. Further, health plan employees and board members cannot serve on the board of an IRO. These restrictions also apply to staff and board members of trade associations that represent plans and providers. CA-IMR further requires that the IRO choose individual medical reviewers who are similarly free from conflicts of interest.

Knowledge

CA-IMR requires IROs to ensure that clinician reviewers are appropriately qualified to render decisions in the cases under their review. Specifically, a reviewer must have no history of disciplinary action or sanctions, must be knowledgeable in the treatment of the enrollee's medical condition, and must be familiar with the guidelines and protocols in the area of treatment under review.

Decisions Guided by Statutory Standards

CA-IMR imposes specific criteria for IMR decisions and requires reviewers to document which of the criteria are used to uphold or overturn a health plan's decision. Different criteria apply for experimental IMRs than for medical necessity IMRs. Table 1 summarizes the major differences in these criteria.

As discussed above, the standards for IMR reversal of coverage denials for experimental treatments are somewhat higher than in medical necessity cases. CA-IMR requires that reviewers consider whether an experimental treatment is likely to be more beneficial than standard therapy, based on specific scientific and medical evidence. In addition, experimental treatment cases require three reviewers, with the decision based on the majority opinion. For cases involving medical necessity, on the other hand, CA-IMR requires independent reviewers to consider available practice standards and clinical guidelines but allows them to overturn a health plan's decision if the reviewer believes that the service the enrollee is seeking is likely to benefit the enrollee, and does not require them to base their decision on specific scientific evidence.

Table 1. CA-IMR Requirements for Experimental and Medical Necessity Cases

	EXPERIMENTAL IMR	MEDICAL NECESSITY IMR
Services Eligible for Review	• Enrollee has life-threatening or seriously debilitating condition • Standard therapies are not effective • Enrollee's physician recommends experimental therapy as being more beneficial than standard therapy • The carrier has denied coverage for the therapy on the basis that it's experimental or investigational	Any health care service that is denied, modified, or delayed by a carrier on the basis that it is not medically necessary. This category includes denials for care already provided in emergency or urgent care settings that the health plan determines did not need to be provided in such a setting.
Standards for Reviewers in Determining Whether to Uphold a Health Plan's Decision	Therapy is likely to be more beneficial than standard therapy based on: • The enrollee's specific medical condition • Relevant documentation • Medical and scientific evidence "Medical and scientific evidence" includes peer-reviewed scientific studies or literature such as defined medical journals, enumerated professional compendia, and findings from studies or research conducted by specified federal agencies.	Service is medically necessary based on the specific medical needs of the enrollee and any of the following: • Peer-reviewed scientific and medical evidence • Nationally recognized standards • Expert opinion • Generally accepted standards of medical care • Service likely to provide a benefit when other services are not efficacious
Number of Independent Reviewers Required	Three, with decision reflecting majority opinion	One

Source: CA-IMR [California Health and Safety Code, Article 5.5 (commencing with Section 1374.30) and California Insurance Code, Article 3.5 (commencing with Section 10169)]

Enrollees Covered by CA-IMR

CA-IMR is available to enrollees in health plans under DMHC and CDI jurisdiction, including those enrolled in certain government-funded programs, such as Medi-Cal managed care and Healthy Families. In addition to or instead of appealing through CA-IMR, Medi-Cal managed care enrollees can request a Medi-Cal "fair hearing" before an administrative law judge when a health plan denies coverage for a treatment or service. Approximately 24 million of the estimated 32 million Californians with health care coverage are eligible for CA-IMR.[20] Enrollees with coverage through fee-for-service Medi-Cal and Medicare have appeals processes through those programs that are similar but not identical to the state's IMR process. With enactment of the ACA, individuals with coverage through self-insured employers will also be guaranteed access to independent external review, but unlike CA-IMR, generally the appeals will be adjudicated by IROs that contract with the self-insured employer's plan rather than with a government regulator or agency.

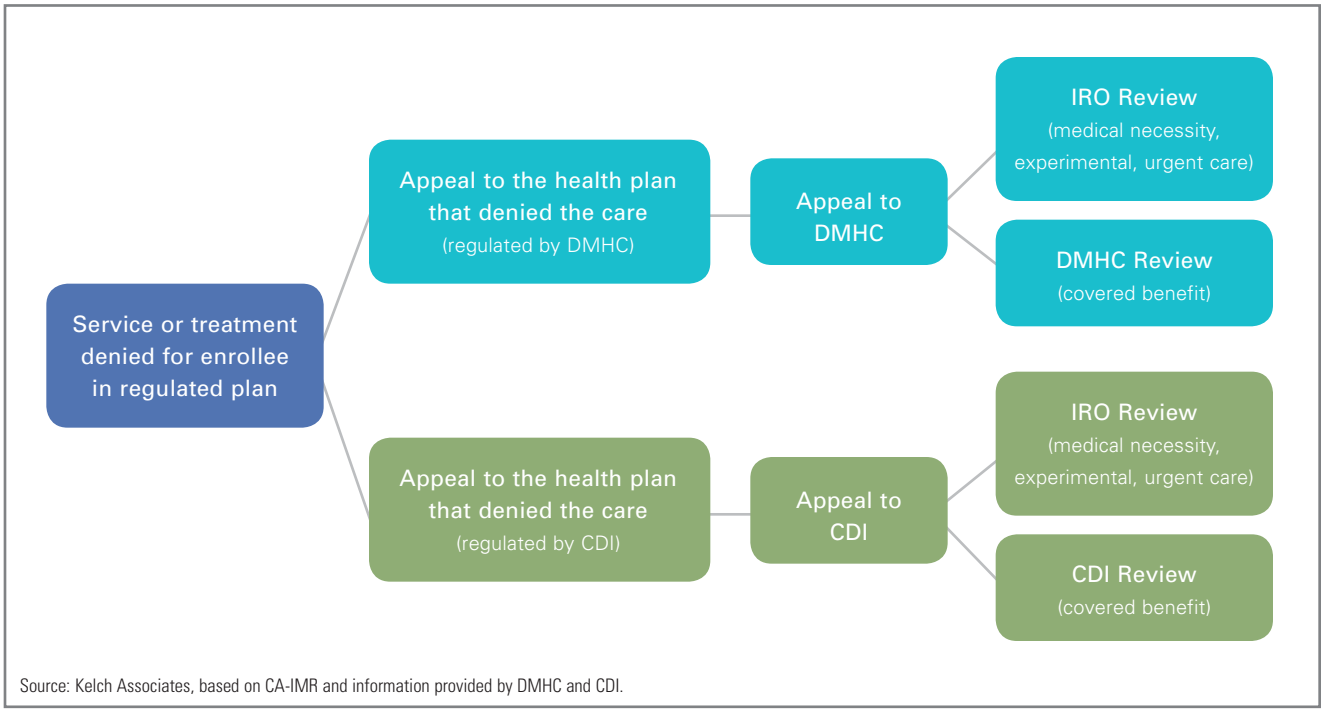
The CA-IMR Process

CA-IMR requires an enrollee to attempt to resolve his or her dispute through the plan's internal appeal or grievance process before seeking external IMR.[21] Disputes that remain unresolved after appeal to the health plan's internal process (or that are not resolved within 30 days) can then be appealed to DMHC or CDI. DMHC and CDI have the responsibility to determine if an appeal qualifies for IMR or if the dispute instead turns on whether the service is a covered benefit under the policy or contract, an issue reviewed and adjudicated directly by DMHC or CDI.

DMHC and CDI review enrollee complaints to identify whether there is an issue appropriate for IMR, regardless of whether the enrollee has specifically requested IMR. Also, prior to submission of a case to IMR, DMHC and CDI review the file to make sure the enrollee and health plan have provided the information required. At DMHC, an IMR review team comprised of an attorney, nurse, and program analyst conducts this review. At CDI, the review team is comprised of insurance compliance officers and CDI management. In some cases, the departmental review might find that the case need not go to IMR, for example if there is a statutory mandate for coverage of the service or treatment irrespective of proof of medical necessity. Both departments also review the case findings following IMR and communicate the results to the health plan and the enrollee.

Figure 1 outlines the process that an enrollee in a California-regulated health plan would follow when coverage for a medical service is denied.

Figure 1. Process Enrollees Must Follow for California Independent Medical Review



Source: Kelch Associates, based on CA-IMR and information provided by DMHC and CDI.

IV. Profile of CA-IMR Cases, 2001–2010

California has maintained de-identified data on virtually all IMR cases since 2001, providing an opportunity to examine trends and changes as the program has evolved. The analysis conducted in this section is based on data from all IMR cases obtained for this project from DMHC and CDI.[22] For a fuller explanation of data sources and methods, see the Appendix to this paper.

Types of Cases

Between 2001 and 2010, nearly 12,000 Californians obtained an IMR overseen by CDI or DMHC. Table 2 shows the total number of IMR cases by type of decision. Over two-thirds involved whether the care requested was medically necessary. About a quarter of all cases involved whether an experimental or investigational service should be covered; these cases make up a significantly greater portion (33%) of IMRs overseen by CDI than by DMHC (25.3%). Less than 2% of IMR cases are categorized as urgent or emergency care, in part because only DMHC tracks and reports this category separately, which it has been doing since 1998.

Table 2. IMR Decisions By Type, 2001 – 2010

	CDI	DMHC	TOTAL
Medical Necessity	1,095 (66.7%)	7,483 (72.6%)	8,578 (71.7%)
Experimental/ Investigational	544 (33.1%)	2,613 (25.3%)	3,157 (26.4%)
Emergency/ Urgent Care	4 (0.2%)	215 (2.1%)	219 (1.8%)
Total	**1,643**	**10,311**	**11,954**

Source: DMHC and CDI.

Previous Research Regarding CA-IMR

California's IMR process has been in existence for over 13 years, with several published studies reviewing the program's impact and effectiveness. In 2001, the California HealthCare Foundation undertook a review of the early cases related to experimental and investigational treatments, based on a survey of the participating enrollees and physicians.[23] Findings from the survey included the following:

- Neither the enrollees nor the physicians surveyed were very familiar with the IMR process or the legal protections put in place to ensure its validity.
- Enrollees were not confident that the independent reviewers thoroughly considered all the information that was available.
- Enrollees were suspicious that health plans were influencing the reviewers and that, as a result, the process was not really independent.
- The degree to which enrollees were satisfied with the IMR process was highly dependent upon whether they obtained the treatment they had sought.[24]

In 2004, researchers at the University of California, San Francisco, evaluated all IMR cases from 2001 and 2002, when the IMR process was evolving from one in which IROs contracted directly with health plans to the present system in which state regulators contract directly with an IRO.[25] This research analyzed 1,400 IMR cases and found that:

- The most common disputes arose around cancer, endocrine, metabolic (including treatments for obesity), orthopedic, and neurologic care.
- Surgery and pharmacy services accounted for over half of all IMRs.
- IMR upheld 58% of carrier decisions in the first two years.[26]

Growth in Number and Rate of Cases

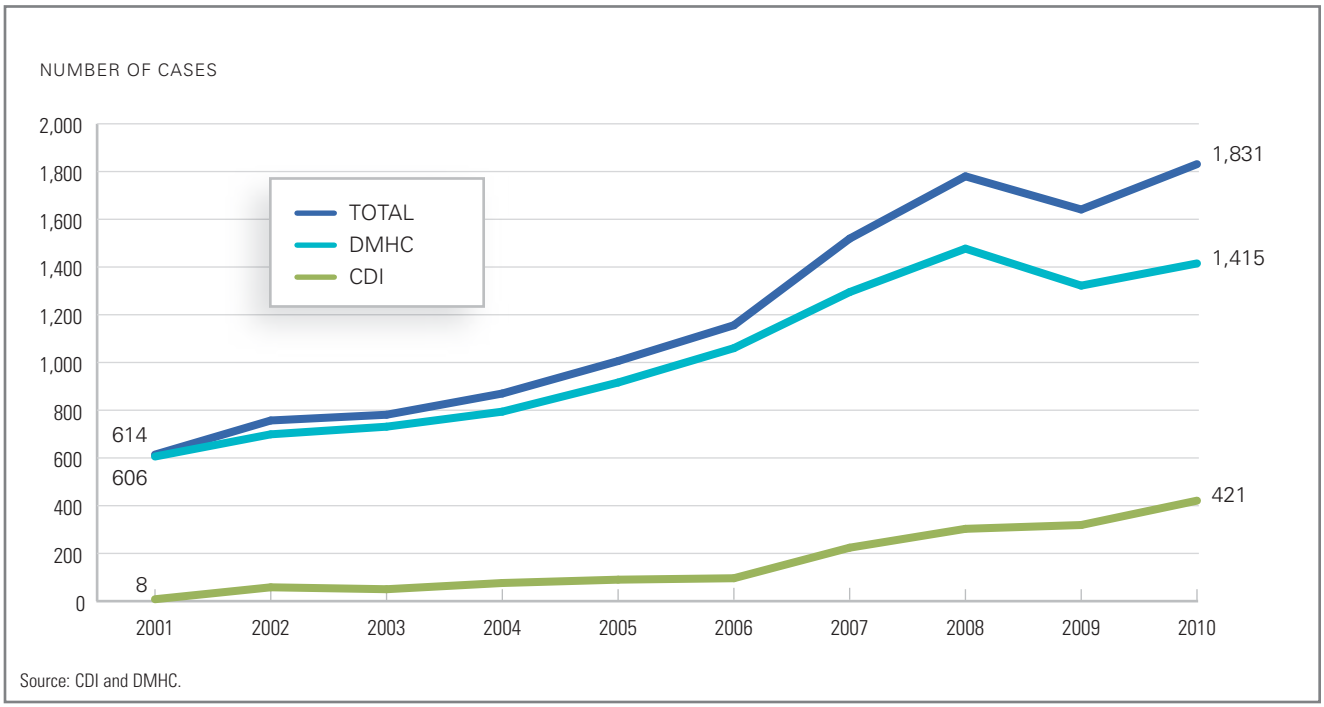
Figure 2 shows the trend in IMRs over time. Between 2001 and 2010, the annual number of IMR cases tripled, from 614 to 1,831, with DMHC overseeing many more IMRs than CDI. This disparity is likely due primarily to two factors. Most notably, CDI oversees health plans with only about 12% of the enrollees as those under DMHC: In 2009, there were 2.6 million people in CDI-regulated plans and 21.6 million people enrolled in DMHC-regulated plans.[27]

Second, health plans regulated by DMHC are required by law and regulation to cover basic health care services if medically necessary, while there is no similar requirement for health plans regulated by CDI. Thus, CDI health plans may exclude some basic services in a health insurance policy that might otherwise be medically necessary, such as physician office visits or hospital days above a limit specified in the policy.

The number of IMR cases in CDI-regulated plans has been increasing more rapidly in recent years: a four-fold increase between 2006 and 2010. The data does not demonstrate with certainty the reasons for the increase in CDI IMR cases. Some have suggested that the increase could reflect greater awareness by consumers and providers about the availability of IMR.[28] According to CDI, it has increased its efforts to make consumers accessing the CDI hotline and website aware of the IMR program. The increase in CDI cases could also be partly explained by market consolidation and administrative standardization among the state's largest health plans, which all have products regulated by both CDI and DMHC, and which are likely to administer one internal system for utilization review regardless of the regulator involved.

Despite the increase in IMR cases over time, the IMR rate remains relatively low compared to the number of insured Californians who

Figure 2. Total IMR Cases Reviewed, CDI and DMHC, 2001 – 2010



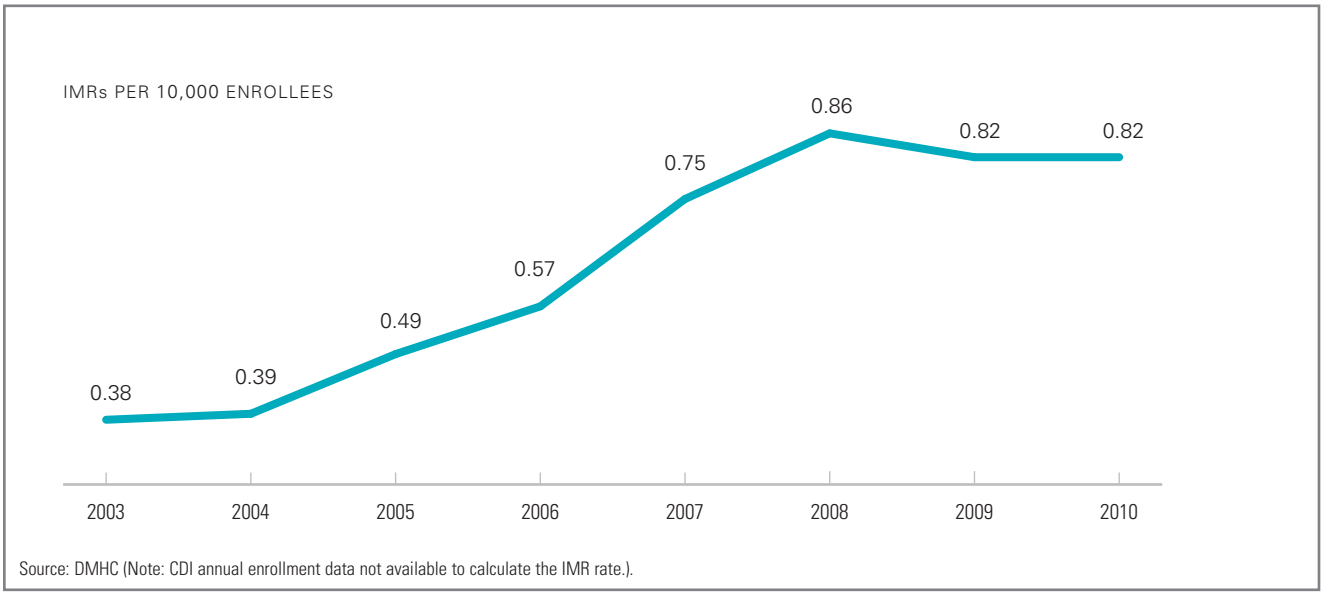
Source: CDI and DMHC.

could access IMR (see Figure 3). The number of enrollees in DMHC plans has dropped slightly (from 18.9 million in full-service plans in 2003 to 18 million in 2010) while the IMR rate has increased from 0.38 per 10,000 covered enrollees in 2003 to 0.82 in 2010.[29–31] (CDI IMR rates cannot be calculated because CDI does not publicly report the number of enrollees insured in products under its jurisdiction.)

Previous research has suggested that California's IMR rate is lower than in some other states. Specifically, in a 2006 review of 37 states where consumers have a right to IMR, the rate of appeals per 10,000 covered enrollees ranged from 0.03 per 10,000 in Missouri to 3.2 per 10,000 in Maryland. Appeal rates were higher than California's in 22 states.[32, 33] Comparisons among states are hard to interpret, however, because:

- The rates are highly dependent upon the denominator, which is the number of insured consumers in a state — a figure that is not always accurately or consistently reported.
- Rates of IMR may be influenced by the prevalent type of coverage offered in a state. States where the prevalent type of coverage is traditional indemnity insurance or PPO coverage may have a lower rate of service denials than states with higher HMO enrollment, since HMOs generally offer more comprehensive benefits combined with utilization management processes to monitor medical necessity and control costs.
- Rates of IMR may be influenced by other remedies available to consumers in other states, including non-IMR appeal rights and access to litigation or arbitration.

Figure 3. IMR Rate DMHC-Regulated Health Plans, 2003 – 2010



Source: DMHC (Note: CDI annual enrollment data not available to calculate the IMR rate.).

Demographic Characteristics of CA-IMR Appeals

The demographic characteristics of health plan enrollees participating in CA-IMR has generally reflected California's overall population. Geographic distribution of IMRs tracked population distribution closely, with only minor and inconclusive variations. IMR cases also appear to have closely mirrored health care utilization patterns. For example, women tend to use more health care services than men, and people tend to use more health care services as they age.[34, 35] The profile of consumers who participated in IMR generally matched these utilization patterns. In 56% of the IMRs, the appeal was requested for a female, while in 44% it was for a male. California's IMR cases also increased by age, peaking in the 41- to 60-year-old age bracket and then declining as consumers move into Medicare, which has its own appeals process. Table 3 shows the breakdown by age group for those regulated by CDI and DMHC.

Table 3. Age of Individuals Who Appealed to IMR, 2001–2009

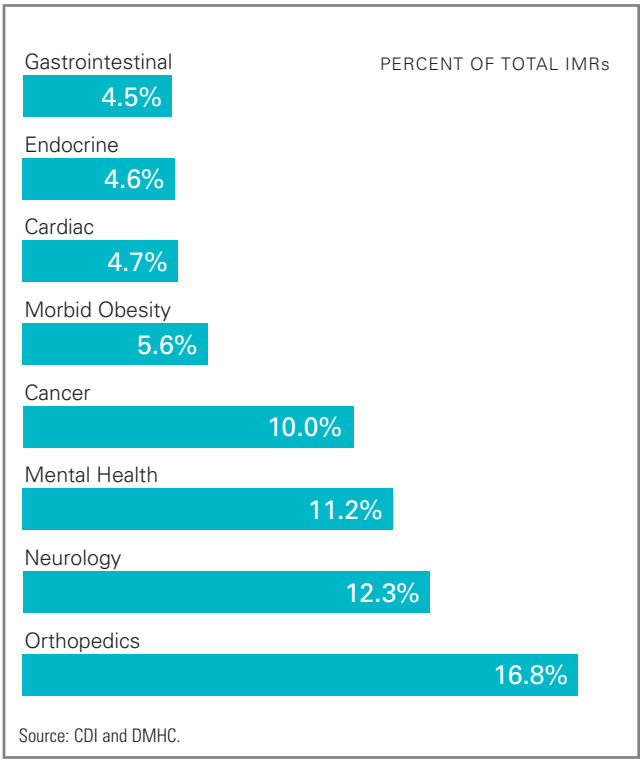
AGE GROUP	CDI	DMHC	TOTAL
0 to 10 years	6%	10%	9%
11 to 20 years	8%	10%	10%
21 to 40 years	16%	21%	20%
41 to 60 years	34%	47%	46%
61+ years	8%	11%	11%
No information	27%	0%	4%

Source: DMHC and CDI.

Types of Diagnoses and Treatments Reviewed by CA-IMR

California IMR reviewers are asked to review cases involving a wide variety of diagnoses. However, just over half of all IMR cases involved one of four diagnosis categories: orthopedics, neurology, mental health, or cancer. The data are similar to earlier findings regarding California's IMR process, although when the IMR process was still limited to experimental/investigational treatments, 73% of cases involved cancer care. Figure 4 shows the most common diagnosis categories for which IMR was requested in California.[36, 37]

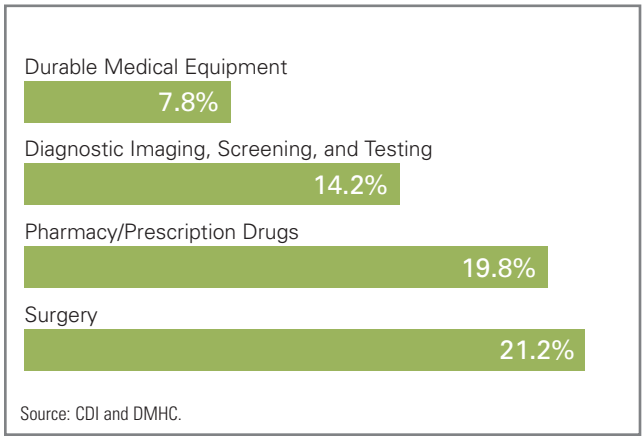
Figure 4. Most Common Diagnosis Categories, 2001–2010



The treatments and services requested by enrollees appealing to IMR also varied widely, but the most common interventions fell into one of four major categories: surgery, pharmacy, diagnostic

imaging, and durable medical equipment. As Figure 5 shows, these four categories accounted for about two-thirds of all IMRs. The remaining IMRs requested were spread across a wide range of services and treatments, though no other category accounted for more than 5% of total cases.

Figure 5. Most Common Types of Services Sought in CA-IMRs, 2001 – 2010

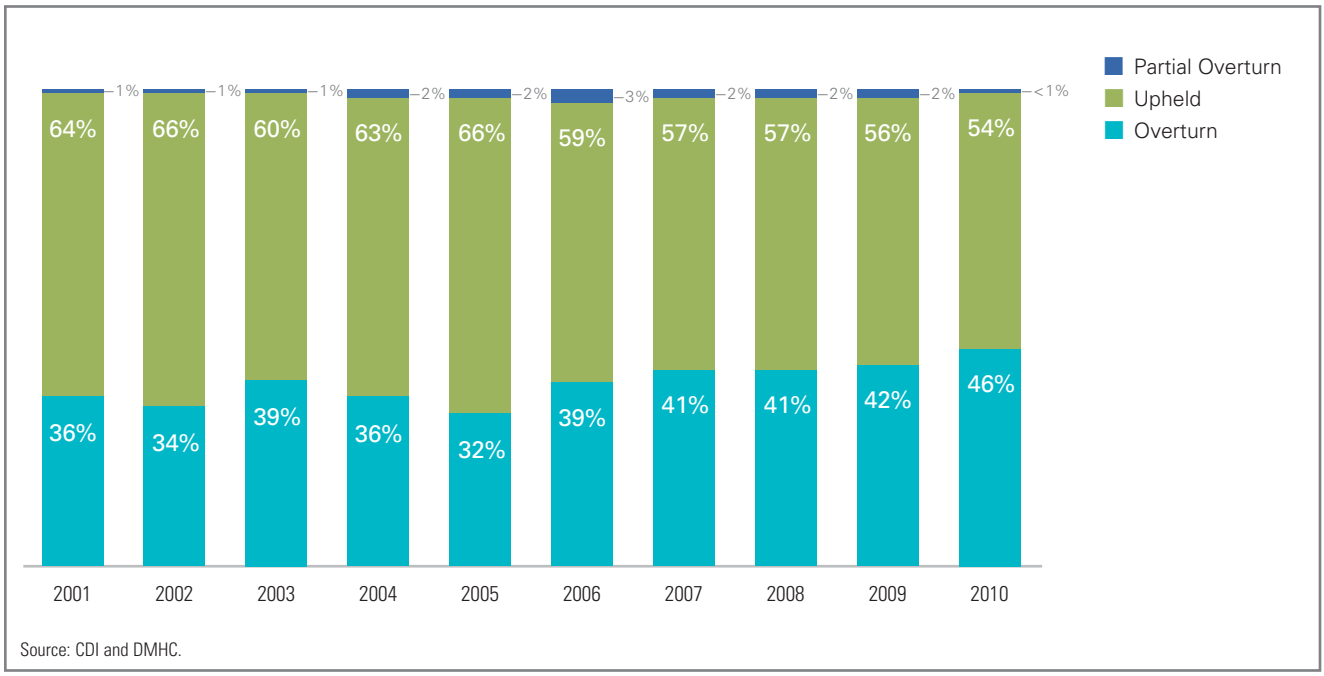


Source: CDI and DMHC.

Rate of CA-IMR Reversals of Health Plan Decisions

National data suggest that enrollees who appeal their health plans' denial of care have a reasonable chance of getting that decision reversed. For example, a recent study by the federal Government Accountability Office found that between one-quarter and one-half of appeals submitted to IMRs in six states were overturned.[38] In California, the data show that in 46% of all IMR cases (2010), the independent reviewers overturned the original decision and required the health plan to provide coverage for the care sought by the enrollee. (In rare instances — less than 1% in 2010 — reviewers partially overturned a health plan's denial, such as a case involving a 14-day inpatient facility stay denied coverage by the health plan but later approved in IMR for seven days.) CA-IMR case data, as illustrated in Figure 6, also show that the share of

Figure 6. IMR Decisions, All Cases, 2001 – 2010

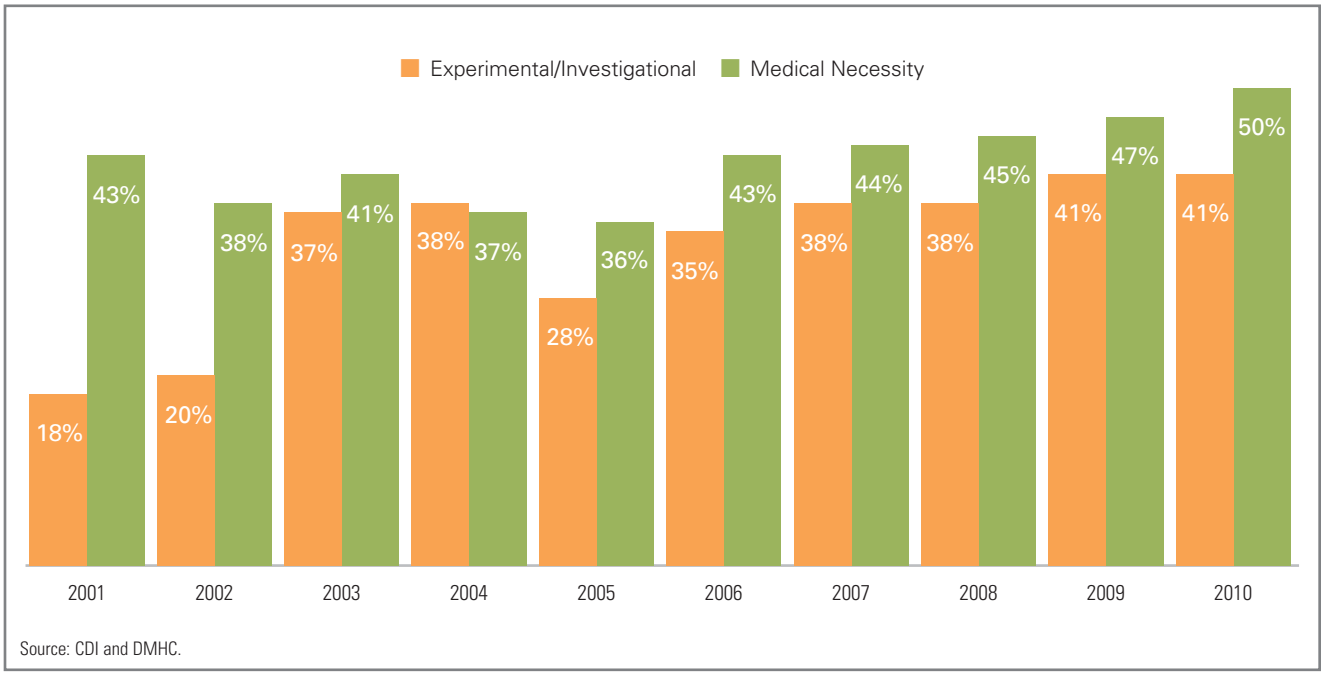


Source: CDI and DMHC.

cases where the health plan's decision is overturned has grown by about 10% over the last decade.

Reviewers in IMR cases involving experimental procedures have been more likely to uphold the original decision to deny coverage for the treatment or service than have reviewers in medical necessity cases, although that gap has narrowed. As Figure 7 shows, in 2001 reviewers in experimental IMRs overturned a health plan's denial in about 18% of the cases, but by 2010 reviewers found in favor of the enrollee in 41% of experimental IMRs. The rate of health plan decisions overturned in medical necessity IMRs fluctuated over time, running between 36% and 50%, but was consistently higher than in experimental IMR cases.

Figure 7. Percent of IMR Cases Overturned or Partially Overturned, by Type of Case, 2001–2010



Source: CDI and DMHC.

V. Analysis of the DMHC IMR Case Database

Although not required to do so by law, DMHC has for some time made available an online searchable database of all IMR cases, since the program began, for enrollees in health plans under its jurisdiction. In addition to basic information about the type and disposition of the cases, the DMHC database offers search capability by diagnosis and treatment types and a brief summary of each case, including the reviewer findings. The DMHC database offers a detailed glimpse of California's IMR program and makes possible the analysis presented in this section of the paper. CDI just recently established a similar online database, starting with cases resolved in 2011, and expects to add case summaries in the future.

IMR Influence on Health Plan Decision-Making

IMR cases often involve new and emerging types of treatments or services. This review of the detailed DMHC case descriptions revealed that IMR cases cluster around situations where identifying the best treatment for a particular disease is an unsettled issue in the medical community. Discussion between this paper's authors and health plan medical staff confirmed that areas where the state of medical knowledge is still evolving tend to drive more requests for IMRs. Similarly, IMRs for emerging treatments decline as medical knowledge and practice evolve and there is greater agreement about those treatments among the medical and health plan communities.

Medical Consensus Reduces IMRs: The Example of Bariatric Surgery

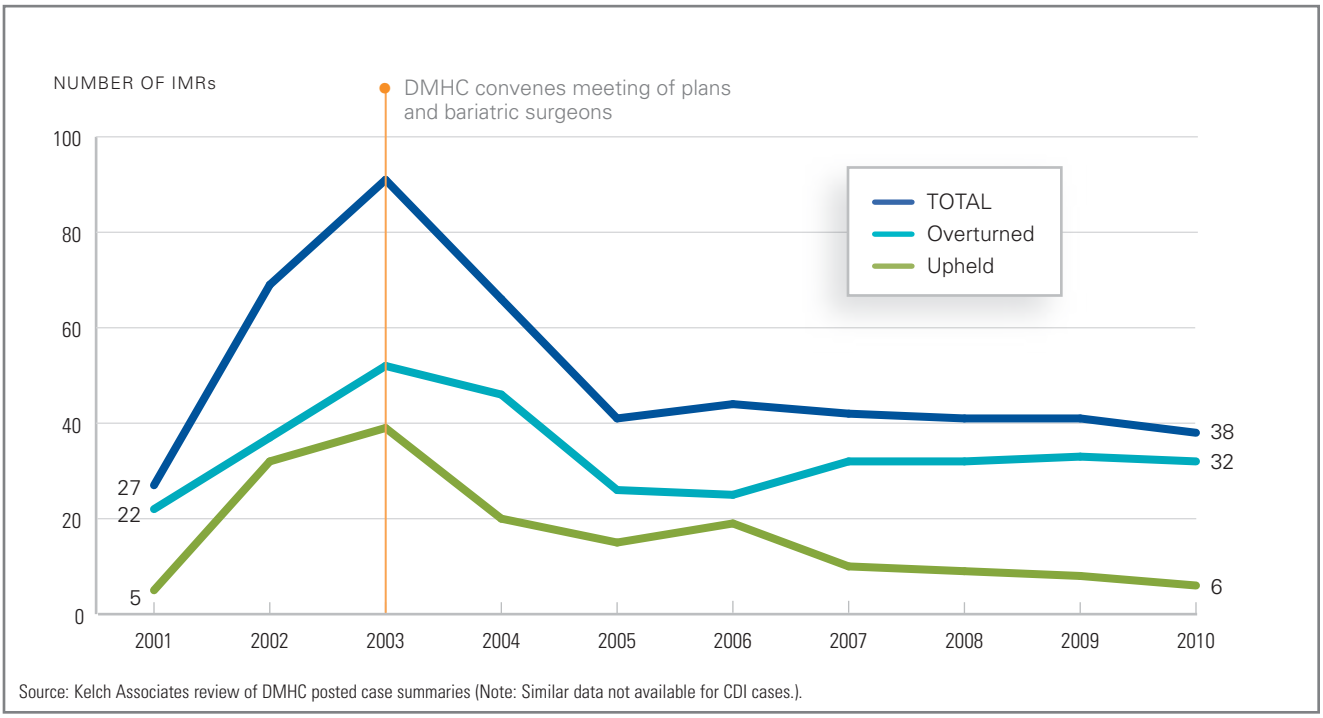
Figure 8 illustrates the evolution of IMR decisions in cases involving bariatric surgery from 2001 to 2010. (See page 16.) Bariatric surgery is a term for several different types of surgical procedures used to treat obesity by either reducing the size of the stomach or re-routing a portion of the small intestine.

IMRs involving bariatric surgery grew rapidly early in the decade, from 27 in 2001 to 91 in 2003. During the same time, IMR results overturning health plan denials grew from 22 to 52. After 2003, though, the number of IMRs for bariatric surgery declined and has since remained steady at roughly 40 per year since 2005.

The peak of IMRs involving bariatric surgery cases most likely reflected unsettled medical practice and evolving health plan internal policies regarding which patients should be candidates for bariatric surgery, whether patients should be required to participate in some other form of weight loss treatment prior to or instead of surgery, and which type of surgery should be performed. For example, during that period some health plans required patients to diet prior to approving surgery, while others applied protocols that called for alternative medical therapies, such as prescription drugs. In 2003, however, the DMHC stepped in, convening a meeting with health plans and bariatric surgeons in which the surgeons presented findings from different clinical studies to support and clarify the appropriate uses of bariatric surgery.

The steep increase in IMR cases drove health plans to look more closely at the bariatric procedures, according to health plan medical staff

Figure 8. IMRs Involving Bariatric Surgery by Year and Disposition, 2001–2010



Source: Kelch Associates review of DMHC posted case summaries (Note: Similar data not available for CDI cases.).

who were interviewed for this report. Ultimately, the combination of IMR findings, additional research, and increased regulatory scrutiny served to inform the medical dialogue and health plan decision-making. In 2005, the American College of Physicians (ACP) published a treatment protocol outlining national standards of care regarding the appropriateness of bariatric surgery as a treatment for obesity. This protocol synthesized findings from a number of important studies confirming the value of this treatment for certain patients. Bariatric surgery is now a commonly accepted treatment routinely approved by health plans for morbid obesity in cases meeting medical guidelines.

Despite the substantial medical consensus reflected in the ACP protocol and the fact that bariatric surgery IMR appeals are overturned about 75% of the time, some enrollees whose physicians believe they would benefit from bariatric surgery are still denied coverage. Figure 8 shows that a small number of IMRs involving bariatric surgery has persisted since 2005. Some of these cases involve disagreements about the specific type of bariatric surgery being requested, not whether bariatric surgery should be covered at all. For example, one health plan medical director interviewed for this report offered that his health plan believes that a type of bariatric surgery called "gastric bypass" is clinically superior to another type of surgery called "duodenal switch." Other bariatric surgery cases still going to IMR involve disagreements about the provider or the facility where the surgery is to be performed, when the health plan only covers the procedure if performed by a limited panel of providers within the plan's network. Finally, some IMR cases continue to involve disputes about whether the enrollee would be better treated through diet, exercise, or other non-surgical medical intervention.

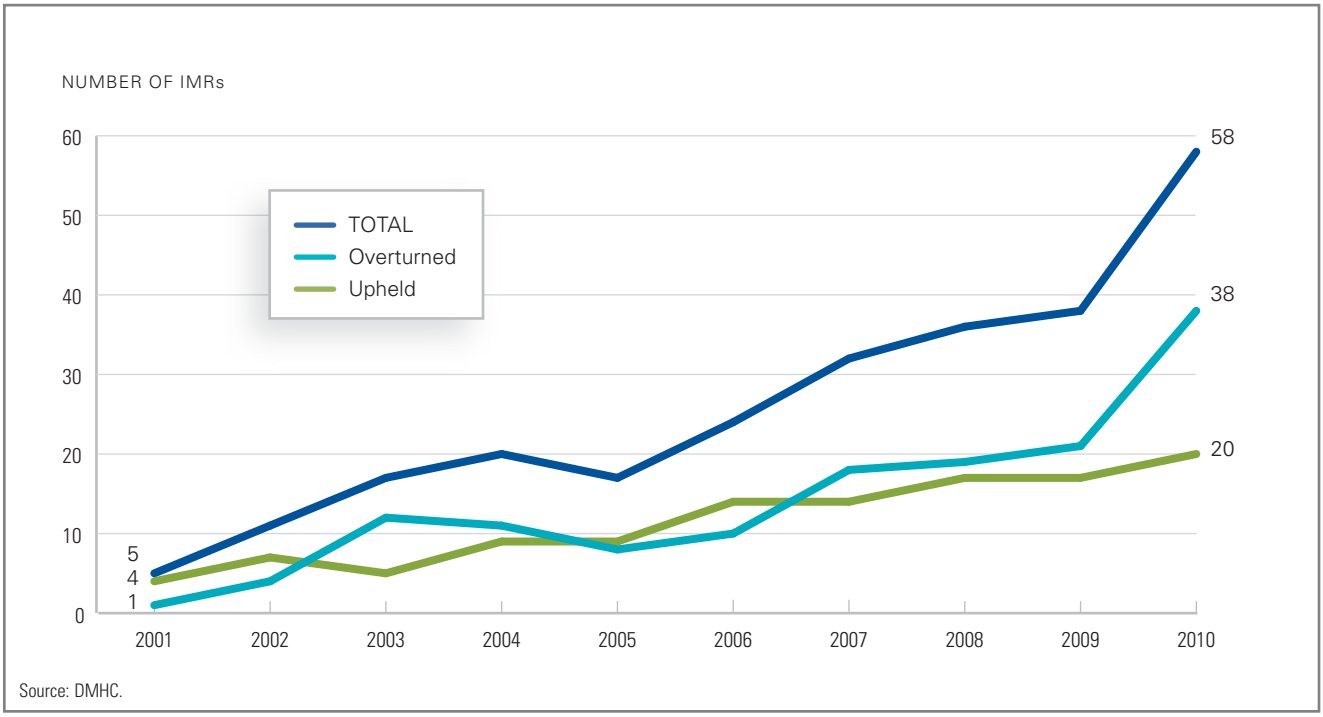
No Medical Consensus Means More IMRs: The Example of Botox for Migraines

Another example where unsettled or inadequate medical evidence and practice appears to have led to an increase in IMR cases is the use of Botox for migraines. Most commonly thought of as an aesthetic treatment to remove unwanted wrinkles, Botox is also prescribed by some physicians for certain types of migraine headaches, as well as for other central nervous system disorders. A review of the DMHC IMR cases shows that health plans that typically denied the Botox migraine treatment did so on the basis that the scientific evidence regarding its efficacy in migraine cases was lacking or because other, more standard treatments had not been tried. As Figure 9 shows, IMRs involving Botox — though still small in absolute terms — have been increasing. In 2010, DMHC oversaw 58 cases involving Botox, of which 38 (65%) were overturned by IMR reviewers.

The Botox cases and the summaries of the reviewer decisions in those cases appear to reflect the emerging and still evolving nature of medical practice related to the use of Botox for some central nervous system disorders. Enrollees with debilitating chronic conditions such as migraines continue to look for new treatments in the hope of obtaining relief, while health plans are reluctant to revise their treatment guidelines in the absence of more compelling or consistent evidence regarding efficacy.

Results in Botox IMR cases also suggest that, during a period when scientific evidence and medical practice are evolving, IMR reviewer decisions are inconsistent. For example, similarly situated patients — middle-aged women who suffer from chronic migraines that do not respond to other forms of treatment — received disparate IMR results; in some cases the patient's request for Botox coverage was approved, in others denied. "Does Botox Work for

Figure 9. IMRs Involving Botox, DMHC Cases, 2001 – 2010



Source: DMHC.

Chronic Migraines?" below, compares two recent cases to illustrate this point. [Note: In late 2010, the federal Food and Drug Administration approved Botox injections as a treatment for migraines in certain patients.[39]]

The problem of inconsistency in IMR decisions is complicated by the fact that identical treatments — such as Botox for migraines — are sometimes processed as experimental IMRs and sometimes as medical necessity IMRs, depending on the reason the health plan gives for the denial. IMR appeals related to Botox identified in Figure 9 fall into both the medical necessity and experimental IMR categories, each classification triggering a different appeals process. Experimental IMRs have three reviewers and must meet review criteria tied to scientific and medical evidence. Medical necessity IMRs, on the other hand, are reviewed by only one reviewer who can overturn or uphold a health plan's decision based on criteria that are not necessarily scientifically based, such as a conclusion that the treatment may benefit the patient.

Does Botox Work for Chronic Migraines?

Below are case summaries involving two similar patients who suffer from chronic migraines. The description of each case is taken verbatim from the DMHC IMR website, with some detail omitted for the sake of brevity. In both cases, the patients appealed their health plan's denial of coverage for Botox as an experimental treatment for migraines. These two cases also demonstrate that even when multiple independent reviewers are involved — as with experimental/investigational treatment cases like these — consistency from case to case is not always achieved. In the first case in 2009, the reviewers cited specific emerging evidence of the potential efficacy of Botox for treatment of chronic migraines; in the second case, a year later, the reviewers concluded that despite some evidence that Botox works, the evidence was not compelling enough to justify its use over conventional therapies.

Botox Approved for Chronic Migraines: "A 51-year-old female enrollee has requested Botox injections for treatment of her chronic headaches with migraines. Findings: Two physician reviewers found that recent evidence has shown that botulinum toxin also blocks the neuronal release of nociceptive mediators such as substance P, glutamate, and calcitonin gene-related protein. In a recent study, Frietag et al. suggested that botulinum toxin may be an effective treatment in chronic migraine without medication overuse. Mathew, et al. and Silberstein, et al. also suggested the efficacy of Botox as a prophylactic treatment for chronic daily headaches. Mathew, et al. (2008) also opined that chronic migraine patients respond better to Botox than chronic tension-type headaches."
Plan decision to deny Botox coverage overturned (case number EI 09-9214).

Botox Denied for Intractable Migraines: "A 38-year-old female enrollee has requested Botox for treatment of her intractable migraines. Findings: Three physician reviewers found that Botox injections for episodic, chronic, tension type headaches may provide substantial improvements in symptoms for some patients who are refractory to pharmacotherapy. Despite this contention, the current scientific data does not demonstrate statistically significant outcomes between Botox treatment groups and placebo. The references confirm that Botox treatment of migraine headaches remains in the experimental stage and is not FDA approved for this indication. In addition, it is not preventative of migraine headache and has not been established through well designed clinical trials to be more effective than standard treatments that are proven, first-line therapies… the patient's migraine headaches may well be managed with conventional, proven alternative treatment modalities. For these reasons, the requested Botox treatment remains investigational and experimental for management of this patient's condition."
Plan decision to deny Botox coverage upheld (case number EI 10-11627).

Reviews and Reviewers Do Not Always Meet CA-IMR Standards

One of the primary goals of California's IMR law was to improve consumer confidence by providing access to independent reviewers who: (1) are knowledgeable in the treatment being appealed and (2) base their decisions on criteria established in law. IMR data provided by both CDI and DMHC revealed that the reviewers do not always meet one or the other of these standards.

Independent Reviewers Often Do Not Document Reasons for Their Decisions

The DMHC online IMR case summaries facilitated examination for this report of the extent to which independent reviewers documented their use of the decision criteria mandated by state law.[40] Kelch Associates conducted a text analysis and divided IMR cases into the following categories:

- The reviewer cited a study of any sort in the decision.
- The reviewer cited any professional body — such as the American Academy of Pediatrics or the National Institutes of Health — in the decision.
- The reviewer stated that the treatment or service was commonly provided for the diagnosis identified, without providing any additional, specific documentation to support this conclusion.
- The reviewer indicated that the treatment sought was mandated to be covered under California law.
- The reviewer provided no reason for the decision.

Lack of Provider Input Can Hamper IMR Appeals

Although the law permits an enrollee to appeal to IMR without the direct assistance of a provider, the clinical information submitted by a provider is one of the essential elements of the case evaluated by IMR reviewers. The DMHC data show that health plan denials are sometimes upheld simply because the treating provider failed to submit information showing why the health plan decision should be overturned. For example, a panel of independent reviewers summarized a 2011 case as follows:

> "A 50-year-old female enrollee has requested Botox injections for treatment of her intractable migraine. Findings: Three physician reviewers found that Botox injections are not likely to be more beneficial for the treatment of the patient's chronic daily headaches than any available standard therapy…. With respect to this patient, there was no documentation by the treating physician that the patient's headache frequency was substantially reduced by the end of the initial trial. Therefore, the Health Plan has appropriately denied the patient's request for authorization for Botox as the records fail to suggest that it is likely to be more beneficial for treatment of her condition than conventional modalities." (case number EI 11-12261)

In this case, the enrollee's physician had prescribed Botox for an initial trial period but failed to provide documentation that the enrollee benefitted from the trial. Lack of provider documentation has resulted in a health plan's denial being upheld in other types of IMR cases as well.

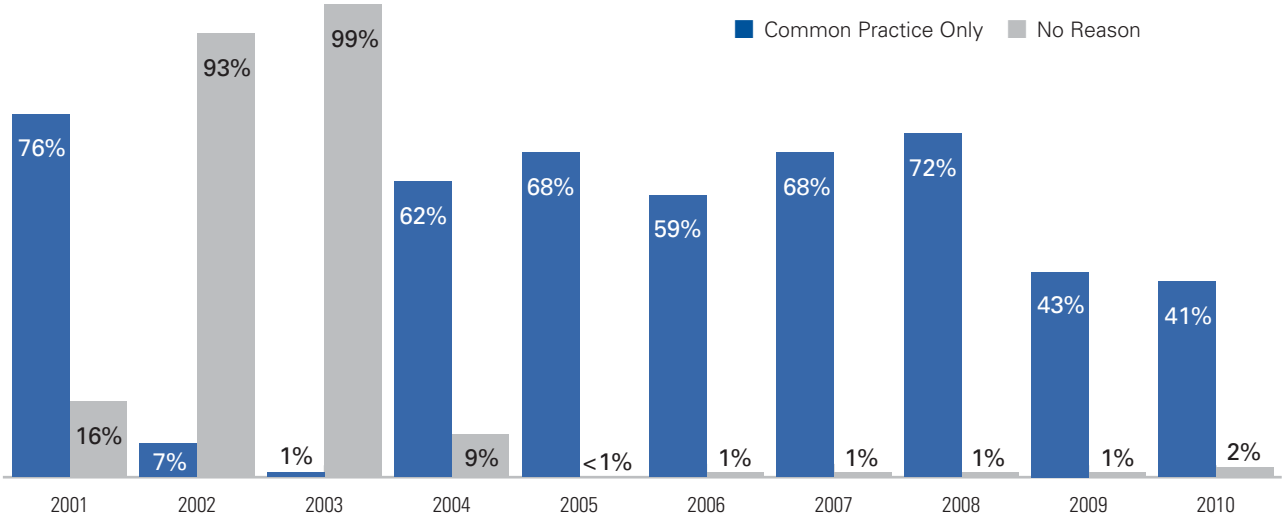
Figure 10 presents reasons cited by IMR reviewers across all DMHC cases. In almost half of the cases, the only reason given for the decision was that the treatment sought was a common and accepted practice for the disease or condition identified; no studies or other data sources were specifically identified. However, in some instances, such support may be implied — for example, it is such common practice to administer chemotherapy as a treatment for cancer that citing a study to justify its use might seem unnecessary. The next most frequent (23.9%) reason cited was that either a professional body or study recognized the benefit of the treatment sought. However, in 12% of the cases, reviewers cited no reason at all.

As Figure 11 shows, while IMR reviewers in over 40% of cases still cite common practice without reference to scientific or medical studies, reviewers improved over time with respect to documenting the reasons for medical necessity IMR decisions. Since 2003, significantly fewer medical necessity IMRs have no reason cited. Although there is no data or

Figure 10. Reasons Cited by Independent Reviewers for All DMHC Cases Combined, 2001–2010

Source: DMHC (Note: CDI case summaries not available.).

Figure 11. DMHC Medical Necessity IMRs Citing Only Common Practice or No Reason, 2001–2010



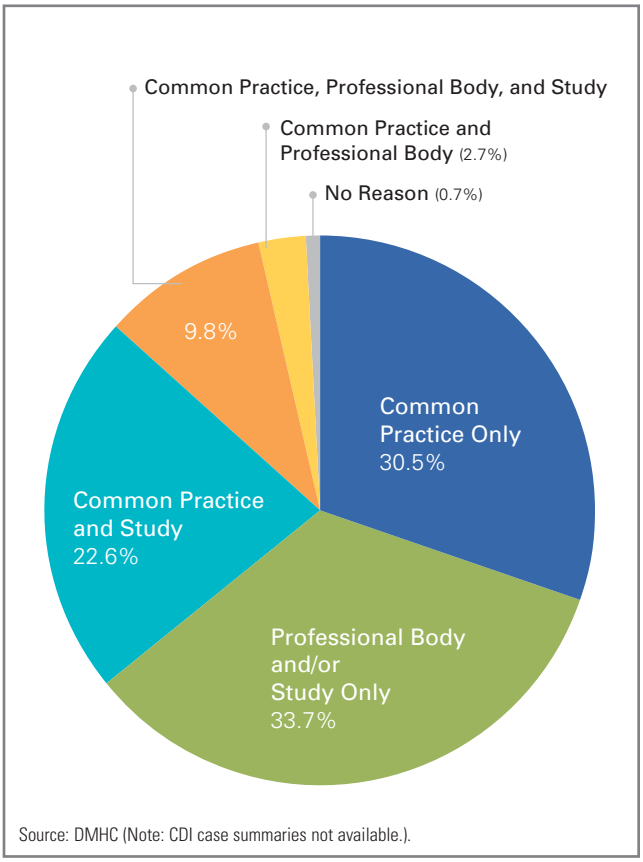
Source: DMHC (Note: CDI case summaries not available.).

formal information available to explain the changes, there are several possible sources of this improved documentation. DMHC staff may have improved at noting and including the rationale for decisions in the summaries posted online. Also, IMR reviewers may have improved the documentation they offer in issuing a decision. In addition, the greater use of more definitive reasons could reflect changes in the field of medicine, in particular an overall increase in the use of evidence. For example, during the 1990s and early 2000s, clinical practice guidelines evolved to favor recommendations grounded primarily in evidence, after centuries of being based largely on expert judgment.[41] There were also dramatic increases in the availability of medical studies and clinical trials in the United States during this time.[42]

Given the greater specificity and scientific rigor required by law for experimental IMRs — that is, the requirement that the reviewer document some scientific and medical evidence — it would be reasonable to expect that reviewers in these cases would provide more specific and detailed rationales for the decisions. However, Figure 12 reveals that a high percentage of experimental IMR decisions cite common practice as either the only reason or one of the reasons for the IMR decision. Between 2001 and 2010, reviewers failed to cite medical and scientific evidence in about one-third of all experimental IMRs, relying instead on common practice as the sole rationale.

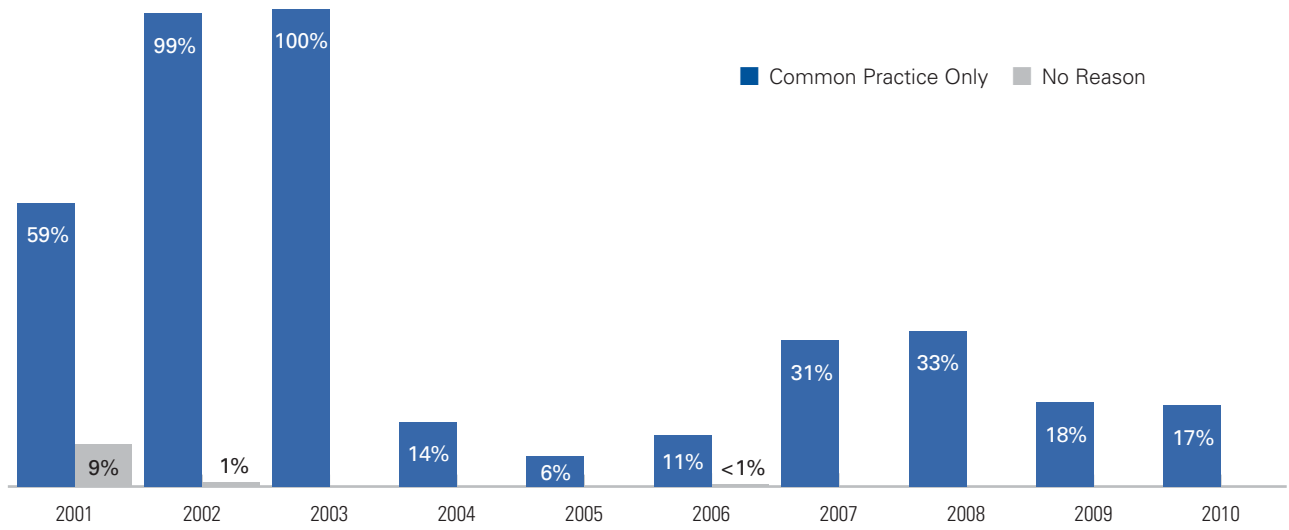
Figure 13 shows that publicly available case summaries demonstrate an improvement over time with respect to documenting the evidence used to reach conclusions in experimental IMRs (see page 22). However, in 2010, 17% of the publicly available case summaries did not include information related to specific scientific and medical evidence.

Figure 12. DMHC Experimental IMRs Reasons Cited, 2001 – 2010



Source: DMHC (Note: CDI case summaries not available.).

Figure 13. DMHC Experimental IMRs Where Reason Cited Was Common Practice Only or No Reason, 2001–2010



Note: Regarding the dramatic change in reviewers' cited reasons after 2003, reflected in this figure, see the discussion concerning the data in Figure 11.

Source: DMHC.

Independent Reviewers May Not Always Have Appropriate Credentials

CA-IMR specifically requires that independent reviewers be knowledgeable about the cases they review. However, the present analysis found that this is not always the case. Regardless of the department overseeing the review, in some instances the reviewer's expertise and the enrollee's disease or condition, or the treatment being considered, appeared mismatched, based on data provided to the authors by MAXIMUS. For example:

- A geriatric psychiatrist reviewed treatment for a child under ten with bulimia.
- A urologist reviewed treatment for an enrollee with temporal mandibular joint disorder.
- A hand surgeon reviewed treatment for an adolescent with a gender identity disorder.

While such obvious discrepancies seem to be the exception, some reviewers — such as the hand surgeon noted above — were used in a wide range of IMRs involving very different types of surgery. In response to this report, MAXIMUS later indicated that the specialists had multiple certifications.[43]

VI. Will Federal Health Care Reform Change California's IMR Process?

The federal ACA contemplates sweeping changes to the health care system. Among the many ACA provisions is the requirement that all health plans, state-regulated fully insured plans, and self-insured plans subject to federal oversight must afford enrollees the right to an independent, external review whenever a service is denied on the basis that it was not medically necessary, appropriate, or effective.

Under the ACA, state external review processes at a minimum must meet the consumer protections included in the National Association of Insurance Commissioner (NAIC) 2010 Uniform Health Carrier External Review Model Act.[44] If state processes do not meet these standards — and as of this writing, the federal Department of Health and Human Services (DHHS) has found 16 states to be in this category — then health plans in those states have the option either to choose an external review process administered by DHHS or to contract directly with an accredited IRO that meets federal standards.[45–47] To meet the federal external review requirement, non-grandfathered self-insured plans must contract directly with an accredited IRO or may opt to participate in a state-administered IMR. This means that Californians with coverage in self-insured plans will most likely have a different process than those in state-regulated health plans and that the process will be primarily subject to oversight by the self-insured plan rather than by regulators.

The requirements in the ACA are similar to CA-IMR and programs already in place in many other states. California is one of 23 states recently notified by DHHS that its IMR process meets the minimum federal requirements for external review. As a practical matter, this means that California will not need to amend its laws to conform to the ACA requirements. California enrollees in CDI- and DMHC-regulated health plans will continue to have access to the IMR process now in place.

While CA-IMR applies to Californians in health plans regulated by DMHC and CDI, it does not cover Californians in self-insured plans subject to federal oversight. Under the ACA, Californians in self-insured plans gained the right to an external review process governed by standards established by DHHS and the federal Department of Labor, based on NAIC guidelines. Rather than an IMR process with IROs selected by regulators, however, self-insured plans are able to contract directly with accredited IROs to perform external reviews. The following comparison of the two sets of standards highlights some of the differences that might come into play.

The major requirements of the NAIC Model Act include:

- Health plans must provide adequate notice of and information about appeal rights to their enrollees.
- The cost of IMR is borne by the health plan, other than nominal fees that may be charged to enrollees requesting IMR.
- Enrollees must be given at least four months from the time coverage is denied to appeal to IMR.
- IROs and their reviewers must be appropriately credentialed, qualified, and free from conflicts of interest.
- Enrollees must be permitted to submit documentation to support their appeals.

- IROs must notify health plans and enrollees of their decisions within 45 days.
- Enrollees must have access to expedited review within 72 hours if certain conditions are met — for example, if the time frame for standard review might seriously jeopardize the enrollee's life or health.

In many respects, California's IMR process is governed by rules more stringent than those established as a minimum under the ACA. For example, under CA-IMR, enrollees have six months from the date of a coverage denial to apply for an IMR rather than the four months permitted by the federal standards; health plans must respond to an IRO request for supporting documentation within three days rather than five; and the IRO must complete the review within 30 days of receiving sufficiently comprehensive information, rather than 45 days under federal standards.

In addition, federal IMR rules require health plans to provide language translation services for notices involving denied coverage in any county where more than 10% of the population is non-English speaking. In contrast, California law imposes on all health plans a more rigorous standard for translation. California requires, among other things, that all "vital" documents — which include not only notices of denials and appeal rights but also evidence of benefits and other information — be translated into "threshold" languages, defined as a language spoken by 0.75 to 5% of the health plan's enrollees, depending on the size of the health plan.

On the other hand, there are several areas where the NAIC Model Act is more rigorous than CA-IMR, including:

- **Standards for reviewer decisions.** California law allows independent reviewers to overturn a health plan's medical necessity denial based on any of five considerations, which include not only peer-review scientific and medical evidence but also generally accepted medical practice and treatments likely to benefit the patient where other treatments are not clinically efficacious. In contrast, the NAIC Model Act directs reviewers to consider the "most appropriate practice guidelines, which must include applicable evidence-based standards and may include any other practice guidelines developed by the federal government, national or professional medical societies, boards and associations." That is, the California criteria for medical necessity cases allow reviewers to rely on the relatively vague notion of "common practice," without consideration of scientific and medical evidence, while the NAIC Model Act calls for review and consideration of practice guidelines and evidence-based standards, to the extent available, in every case.
- **Qualifications for reviewers.** The federal standards appear to place greater emphasis on the selection of reviewers who have specific, expert knowledge about the issues in the case under review. California's IMR statute requires that independent reviewers be "knowledgeable" about the condition and the treatment being reviewed and "familiar" with the guidelines and protocols for the treatment. In contrast, the NAIC Model Act requires that independent reviewers be "expert" in the treatment of the covered person's relevant medical condition and "knowledgeable about the recommended health care service or treatment through recent or current actual clinical experience treating patients with the same or similar medical conditions."[48]

VII. Areas for Improvement

California now has a rich repository of data and information, developed since the CA-IMR program's inception, which formed the basis of the analysis presented in this report. The researchers in this project found that while the number of CA-IMR cases increases annually, only a small number of individuals enrolled in CDI- and DMHC-regulated plans have appealed to IMR. Most IMR cases involve treatments and services where the clinical standard is evolving and remains unsettled. Once there is industry-wide adoption or rejection of emerging and evolving treatments and technologies, IMR cases related to that particular treatment or service tend to decline. The extent to which IMR evolves with and embraces an emerging clinical consensus regarding coverage, or influences and alters the consensus on coverage, cannot be readily determined from the data available, but it is likely some combination of both.

At the same time, this review of the data from ten years of IMR cases reveals that there is: (1) inconsistent IMR case resolution for similar cases and enrollees; (2) lack of clarity and transparency regarding the basis for decisions made by IMR reviewers; and (3) evidence that the qualification and training of IMR reviewers may be poorly matched to the cases they review. Given these shortcomings, the following section identifies several areas in which the oversight and administration of California's IMR program might be improved.

More Transparent and Consistent Reporting of IMR Data by State Regulators

CA-IMR does not require DMHC and CDI to proactively make IMR program data available to the public but only to provide data upon request. Currently, DMHC and CDI both exceed the minimum data requirements in state law and provide online searchable databases for IMR cases. During the course of the research for this project, CDI for the first time posted IMR case data online and reports that ultimately it will also post IMR case summaries similar to those on the DMHC website. In many respects, the CA-IMR data currently available puts the state in a strong position to review and analyze the program.

Still, additional information about the IMR cases, process, and results would enhance the state's ability to monitor and adjust program effectiveness. For example, DMHC case summaries, while providing a robust source of information about IMR, in some cases lack sufficient detail regarding the criteria used by reviewers to decide the cases. Finally, neither department captures or reports race, ethnicity, or language information on enrollees, which could be a valuable resource for examining differences in health care access and health disparities.

Obtaining the full benefit of an effective IMR program for enrollees, providers, health plans, and policymakers requires timely and complete disclosure of IMR case data beyond what either department is currently providing. Transparency surrounding the IMR process and the medical and scientific bases for IMR decisions is essential for building public and provider confidence in the basic fairness of the program and for system learning about the

development of medical consensus on emerging treatments. Since there is only one contracted IRO administering all IMR cases in California, it should be technically feasible to provide consistent and complete case data for both DMHC and CDI cases.

In that regard, there are a number of steps the state could take to improve the available information about the program. Ideally, CDI and DMHC could collect and report the same complete and meaningful information through one common online, searchable database for all cases, including detailed case summaries. In addition to the case characteristics currently available online, it would be extremely useful for the common database to include, for each case, demographic profile information on participating enrollees, including age, gender, ethnicity, and county of residence; length of time to complete the IMR; credentials and qualifications of the reviewer; and which of the statutory criteria the reviewer used to make the decision, as outlined in Table 1 of this report. The case summaries could also include the specific standards, criteria, and medical and scientific evidence, if any, that led to the case decision. Finally, CDI could develop and report the annual rate of IMR among the total insured population for products under its jurisdiction and the number, type, and resolution of IMR cases by health plan, in the same way DMHC does now.

More Robust Regulatory Oversight and Review

CA-IMR includes a number of specific requirements regarding IROs, including that reviewers be appropriately credentialed for the cases they are assigned and that they document the basis for their decisions. This study found that these requirements are not always met. IMR has the potential to be a major source of feedback and guidance for policymakers, regulators, health plans, providers, and enrollees regarding the effectiveness of emerging medical treatments and coverage for them. IMR could encourage plans to adopt new treatments, affecting many more consumers than the relatively few enrollees who actually appeal denials to IMR. However, this potential for IMR to contribute constructively to the broader dialogue and clinical consensus is, to some degree, frustrated by the lack of consistency among reviewers' decisions. Further, to the extent that similar appeals result in disparate outcomes, confidence about the validity of IMR is diminished. For both these reasons, DMHC and CDI may wish to consider methods for monitoring and validating the consistency of IMR reviewer decisions for similarly situated cases.

CDI and DMHC could also more closely evaluate and monitor IMR results to identify instances where CA-IMR requirements are not met, and take steps to ensure that the state's contracting IRO complies with all CA-IMR standards and criteria. For example, the departments might together regularly evaluate and analyze IMR results to identify consistency problems, instances where the reasons cited for decisions are vague or inadequate, and cases where the reviewer's qualifications do not appear to closely match the clinical issues in the case. Regular joint analysis of IMR cases could also present opportunities for regulators to intervene and work with health plans regarding emerging medical treatments and medical consensus, as DMHC did in the case of bariatric surgery. Increased transparency of data, as discussed in the section immediately above, would facilitate such meaningful review and evaluation of the program in these areas.

Improved Consistency of Referrals

This review of detailed DMHC IMR data suggests that some similarly situated enrollees have their IMR appeals handled through different processes with different rules. Sometimes a dispute regarding a treatment is referred as an experimental IMR, subject to the more rigorous standards for those cases, while other times a dispute regarding the same treatment is referred as a medical necessity IMR. Consistency in referrals for similar cases is important because the number of reviewers on medical necessity and experimental IMRs differs, and the criteria for deciding the two categories of cases is different, as outlined in Table 1 of this report. (See page 7.) The way cases are currently referred generally flows from the justification provided by the health plan at the point of the initial denial. However, CDI and DMHC have the authority to review and assign cases to a specific category of review, regardless of the health plan's initial designation. By closely monitoring the cases presented, DMHC and CDI could provide guidance and criteria to direct more consistent health plan referrals and to intervene when necessary to ensure that similar cases are assigned to the same level of IMR.

VIII. Conclusion

California's IMR program has been in operation for more than ten years. The researchers in the present project analyzed extensive data on IMR cases to evaluate and consider what might be learned from the experience to date, particularly as IMR processes are now extended to all covered persons under the federal ACA, including people in self-insured coverage. The ACA will also dramatically change the environment and markets for health care coverage in California and significantly increase the number of people enrolled in health plans with access to IMR appeal rights. The federal DHHS has determined that California need not make any statutory changes to CA-IMR in order to comply with the ACA. This means that changes to CA-IMR, or to the way California administers and evaluates the program, will be state-driven. This report concludes that several primarily administrative improvements might be made in CA-IMR, which would position the state to more effectively deliver on the promise of a credible, transparent, and effective IMR program.

Appendix: Data Sources

The data analyzed for this report came from three sources. First, working through CDI and DMHC, Kelch Associates obtained data files containing de-identified information on all cases reviewed from 2001 through 2009 from California's IRO contractor, MAXIMUS. The files, in Excel format, include information on demographics (age, sex, county of residence), diagnosis, treatment under dispute, medical qualifications of the independent reviewers (area of board certification), and outcomes of the cases reviewed. This data is the source of the demographic analysis (age and geographic region) included in this report. Second, for the 2010 year only, Kelch Associates downloaded more general information — including diagnosis, treatment under dispute, and case disposition — directly from each department's website to update the original data through 2010. The 2010 data combined with the data provided by MAXIMUS is the source for analysis on the overall types of diagnoses and treatments that have been appealed to IMR and on the disposition of cases overseen by both departments from 2001 through 2010.

This combined data set, though exhaustive in some respects, lacked detail on the rationales behind IMR decisions. To gather this information, Kelch Associates consulted the online database of IMR case summaries posted on the DMHC website for all DMHC cases from 2001 through 2010, and conducted a text analysis of the summaries, which forms the basis for the findings in Figures 8 through 13 of this report. These detailed case summaries include descriptive information on the medical particulars of each case as well as any justification reviewers provided for the decision. CDI does not similarly report or make summary case information available online but plans to do so in the future.

This report summarizes findings from the Kelch Associates review of the data, with the goal of identifying potential areas for improvement in California's IMR program. The data files developed and coded for this project are extensive and could yield further insights based on additional analysis and review. CHCF is retaining the data files and will consider requests to make the data set available to persons interested in further analysis and research in this area.

Endnotes

1. For more information on California's dual system of health insurance regulation, see Kelch Associates, *Ready for Reform? Health Insurance Regulation in California under the ACA,* California HealthCare Foundation, June 2011 (www.chcf.org).
2. Center for Consumer Information and Insurance Oversight, letter to Department of Managed Health Care, July 29, 2011.
3. Kelch Associates obtained the data used in this report from two sources: (1) data publicly available on the DMHC web site and (2) data obtained and purchased from MAXIMUS, California's contracted IRO, through a Public Record Act request to CDI and DMHC. See the Appendix to this paper for a more detailed discussion of the data used in the report.
4. California Health and Safety Code §1367(g).
5. California Health and Safety Code §1367.01 and California Insurance Code §10123.15.
6. Ibid.
7. Richard A. Rettig et al., *False Hope: Bone Marrow Transplantation for Breast Cancer* (New York: Oxford University Press, 2007).
8. According to a 1998 report by the Georgetown University Institute for Health Care Research and Policy prepared for the Kaiser Family Foundation (KFF), *External Review of Health Plan Decisions: An Overview of Key Program Features in the States and Medicare,* Medicare established its external review program in 1989 (www.kff.org). KFF reported in 1998 that there were 13 states with external review programs, including California, which at the time provided for external review only in cases of denials for investigational and experimental treatments. As of July 2010, the United States Department of Health and Human Services reported that 44 states had some form of external review. See "Protecting Consumers and Putting Patients Back in Charge of Their Care" (www.healthcare.gov).
9. Chapter 979 (A.B. 1663), Statutes of 1995, California Health and Safety Code §1370.4 and California Insurance Code §10145.3.
10. Chapter 533 (A.B. 55), Statutes of 1999, California Health and Safety Code, Article 5.5 (commencing with §1374.30) and California Insurance Code, Article 3.5 (commencing with §10169).
11. Assembly Health Committee Analysis of A.B. 55, Chapter 533, Statutes of 1999 (April 13, 1999) (www.leginfo.ca.gov).
12. National Cancer Institute, *High-Dose Chemotherapy for Breast Cancer: History* (April 26, 2001) (www.cancer.gov).
13. Ibid.
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22. For a fuller explanation of the data files and how they were obtained, see the Appendix to this paper.
23. The Institute for Medical Quality, *Independent Medical Review Experiences in California, Phase I: Cases of Investigational/Experimental Treatments,* California HealthCare Foundation (2002) (www.chcf.org).
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40. CDI does not publicly report information disclosing the basis for IMR reviewer decisions.
41. Carolyn M. Clancy and Kelly Cronin, "Evidence-Based Decision Making: Global Evidence, Local Decisions," *Health Affairs* 24 (1) (2005).
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43. While the original data file did not contain data on multiple certifications, upon review of the examples cited, MAXIMUS said these independent reviewers held board certifications in more than one practice area. Specifically, MAXIMUS stated that the hand surgeon was also a board certified plastic surgeon and performed many different forms of plastic and reconstructive surgery; the urologist was also a board certified oral surgeon; and the psychiatrist referred to in the report had a sub-specialty certification in geriatric psychiatry, but was board certified in general psychiatry and treated patients of all ages.

44. 76 C.F.R. 37208 and NAIC "Uniform Health Carrier External Review Model Act," April 2010.

45. Centers for Medicare and Medicaid Services, Center for Consumer Information and Insurance Oversight, *Fact Sheet: Affordable Care Act: Working with States to Protect Consumers* (www.cciio.cms.gov).

46. California's IRO, MAXIMUS, is also the contracted IRO in the process administered by DHHS for Medicare and for states that do not have an acceptable state external review process.

47. Centers for Medicare and Medicaid Services, Center for Consumer Information and Insurance Oversight, *Fact Sheet: Affordable Care Act.*

48. NAIC Model Act, April 2010.

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