

**DEPARTMENT OF MANAGED HEALTH CARE
CALIFORNIA HMO HELP CENTER
DIVISION OF PLAN SURVEYS**

FINAL REPORT

**NON-ROUTINE MEDICAL SURVEY
OF
KAISER FOUNDATION HEALTH PLAN, INC.
A FULL SERVICE HEALTH PLAN**

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**Final Report of a Non-Routine Medical Survey
Kaiser Foundation Health Plan, Inc.
A Full-Service Health Plan**

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EXECUTIVE SUMMARY

Pursuant to Section 1341(a) of the Knox-Keene Act (“Knox-Keene” or the “Act”), the Department of Managed Health Care (the “Department”) is charged with enforcing the provisions of the Act and the Rules issued under the authority of the Act¹. The Knox Keene Act was enacted to require health care service plans to provide enrollees with access to quality health care services and to protect and promote the interests of the enrollees. The Department’s Division of Plan Surveys conducts medical surveys² to ensure health plans meet their Knox-Keene obligations.

A NON-ROUTINE SURVEY: OVERSIGHT OF KAISER’S QUALITY MANAGEMENT SYSTEM

The Department began an investigation of the adequacy of Kaiser’s (the “Health Plan”) oversight system for the San Francisco Kidney Transplant Program (the Transplant Program) in May 2006. The San Francisco Medical Center’s mishandling of the Transplant Program’s administration, inclusive of enrollee complaints and grievances, raised Department concerns regarding the level of Health Plan oversight for Programs administered at the Medical Center level.

The close media attention given the Transplant Program led to a series of newspaper articles linking Kaiser to other quality of care problems, suggesting the Health Plan’s mishandling of enrollee and physician reported concerns potentially extended beyond the Transplant Program. The Transplant Program issues, coupled with the progeny of complaints reported in close proximity to this incident, formed a basis of good cause justifying a non-routine survey of Kaiser Foundation Health Plan’s Quality Assurance Program as mandated by Section 1370 and associated Rules. Specifically, the survey assessed the Health Plan’s system of oversight of programs designed to monitor and evaluate care provided to members and the effectiveness of the Medical Center quality programs, inclusive of Peer Review.

The Director authorized review of peer review proceedings and records conducted and compiled pursuant to Section 1370 of the Act. Where medical review has been authorized, the survey team is required by law to ensure the confidentiality of the records and information reviewed along with the peer review proceedings.

ANALYSIS

The Health Plan’s inability to establish a system of governance of Medical Center and regional quality activities hinders its ability to ensure local Medical Center programs consistently identify

¹ References made throughout this report to “Section” are to sections of the Knox-Keene Health Care Service Plan Act of 1975, as amended (California Health and Safety Code Section 1340 *et seq.* [“the Act”]). References to “Rule” are to the regulations promulgated pursuant to the Act (Title 28 of the California Code of Regulations).

² Surveys can be a routine general examination (scheduled on a recurrent basis) or non-routine (specific examinations) for issues or deficiencies identified pursuant to Rule 1300.82.1. An examination or survey is additional or non-routine for good cause for the purposes of Section 1382(b) when the plan has violated, or the Director has reason to believe that the plan has violated, any of the provisions of Section 1370. (Rule 1300.82.1(a)(2))

and resolve problems in the delivery of health care and services. The problems in oversight stem from two health plan guiding principles: 1) To allow substantial variation among and between the Medical Center Quality Management (QM) programs, in both regions and 2) To grant discretion and deference to physicians to set local QM peer review policy. These principles, however, create barriers to the Health Plan's ability to form a comprehensive oversight system of Kaiser's 29 Medical Centers, and clinical departments and to ensure early Health Plan notification of significant changes, administrative decisions and serious problems in quality of care when they arise.

The Health Plan relies on Medical Center QM programs, inclusive of peer review, to identify and solve problems in care and services delivered to Kaiser enrollees. The Medical Centers must be held accountable to the Health Plan for maintaining the integrity of these critical quality review programs. The Health Plan, in turn, is held accountable to its enrollees and must eliminate program variation and oversee rather than defer to Kaiser Physicians' peer review decisions.

The Health Plan's system of governance over the Medical Centers and medical groups requires the establishment of a single set of Health Plan review standards for use by all 29 Medical Centers and multiple clinical departments. A set of standards and a change to a "checks and balances" relationship between the Health Plan, Medical Center and physician groups are necessary changes to ensure the integrity and quality of Kaiser's system of care.

SURVEY TEAM

The Department used seven experienced surveyors/reviewers for this survey:

1. Three physicians with extensive clinical, managed care administration and utilization and quality management experience including previous participation in the Department's routine and non-routine medical survey process;
2. Two registered nurses with critical care nursing, managed care and regulatory survey experience;
3. One epidemiologist/quality management specialist; and,
4. One research analyst and one health care management professional to provide quality management and analytical expertise.

The Department evaluated the Health Plan's QM oversight processes by:

1. Performing interviews with Health Plan regional staff in both Northern and Southern California,
2. Examining related Health Plan documents, and,
3. Reviewing case files broadly selected from the Health Plan's Medical Centers and offices.

The Department selected nine Medical Centers: four from Kaiser Permanente Southern California (KPSC) and five from Kaiser Permanente Northern California (KPNC), as a representative sample to assess the Health Plan's QM oversight program for its 29 Medical Centers as well as the quality programs administered at the Medical Center level.

This non-routine survey also included specific case investigations. The cases came to the Department's attention by way of member complaints, referrals from Health Plan physicians, the Medical Board and related media news articles. The Survey Team traced these cases to evaluate the handling of the issues through the respective Medical Center QM programs and also in relation to the Health Plan's oversight of the Medical Center's QM review. (Refer to Appendix C for a description of the Survey Methodology.)

SURVEY RESULTS

Summary of Deficiencies and Final Department Determination

Health Plan Oversight - Governance

The Survey Team concluded the Health Plan lacked an effective Quality Program oversight system, evidenced by:

1. A lack of monitoring and evaluation of the care provided by the system of providers and facilities.

STATUS: The Plan has initiated remedial action and is on its way to achieving acceptable levels of compliance.

2. A failure to inform providers and facilities of the scope of the QM responsibilities or how it will be monitored by the Health Plan.

STATUS: CORRECTED

3. A lack of sufficiently detailed QM reports to the Health Plan's governing body and the delegated quality oversight committees to identify those components presenting significant or chronic quality of care issues.

STATUS: CORRECTED

Peer Review and Quality Programs— Operations Systems

The Survey Team concluded that the variation among all of the Medical Center QM programs, extending to and including the system of peer review formed a basis for the following deficiencies:

1. The Medical Center Peer Review processes are not designed to consistently ensure all quality of care problems are identified and corrected for all provider entities.

STATUS: The Plan's completed corrective actions and the corrective actions to be summarized and submitted in its Supplemental Report, due October 1, 2007, are sufficient to demonstrate the Plan is on the way to achieving acceptable levels of compliance.

2. The Medical Center QM programs are not designed to consistently ensure all quality of care problems are identified and corrected for provider entities.

STATUS: The Plan's completed corrective actions and the corrective actions to be summarized and submitted in its Supplemental Report, due October 1, 2007, are sufficient to demonstrate the Plan is on the way to achieving acceptable levels of compliance.

The Department issued a Preliminary Report to the Health Plan on March 13, 2007. The survey report referenced five deficiencies; three deficiencies involved Health Plan oversight responsibility for the quality program at the regional level; and two deficiencies involved the local Medical Center's administration of its quality programs and peer review processes.

Based on the Department's findings, on or within 30 days following notice to a plan of a deficiency, the Health Plan was instructed to:

1. Develop and implement a corrective action plan for each deficiency, and
2. Provide the Department with evidence of the Plan's completion of or progress toward implementing those corrective actions.

The Department granted the Health Plan a one month time extension for submitting a corrective action plan. On May 12, 2007, the Health Plan delivered a corrective action plan to the Department that addressed each of the five deficiencies.

Pursuant to CCR, Section 1300.80.10, where deficiencies may be reasonably adjudged to require long-term correction or to be of a nature which may be reasonably expected to require a period longer than 30 days to remedy, the Department may accept evidence of initiated remedial action which is reasonably designed to lead to an acceptable level of compliance.

The Department relied on Section 1300.80.10 of the regulations to form final deficiency determinations because the changes needed to comply with the Act constitute a fundamental restructuring of Kaiser Health Plan's quality review oversight system and the relationships between the Health Plan, the Hospital and the Permanente Medical Groups. The corrective actions presented by the Health Plan have been initiated; however, complete integration and implementation will continue over a period of weeks, months and years.

CORRECTIVE ACTIONS

The Department acknowledges the work the Health Plan has begun to address the oversight concerns raised in this survey. The following changes have been initiated and will be implemented over a period of weeks, months and years:

1. A reporting process that will allow the Health Plan to review and monitor, on an ongoing basis, health care delivery system changes instituted on the Medical Center level;

2. A robust business plan process that provides for the Health Plan's Regional President review and approval of all new or modified clinical services instituted on the Medical Center level;
3. A Peer Review Performance Improvement Project that will establish a uniform set of peer review standards, define and establish a common case severity leveling system and revise case referral and review processes to ensure physicians participating in peer review activities within any clinical department, in either region, conducts a diligent and objective quality review of the appropriateness of physician services and to improve documentation of rationale, conclusions and recommended corrective actions;
4. Training at all 29 Medical Centers to educate and orient physicians participating in peer review on new Health Plan standards, criteria and processes in support of changes to the peer review system and to promote consistency throughout Kaiser's clinical departments.
5. Regular ongoing Health Plan audits of its Medical Centers' processes for evaluating and correcting Potential Quality Issues (PQI) to ensure implementation of program changes and ensure Medical Centers follow new policy;
6. Regular ongoing audits of clinical department-level based peer review programs to confirm changes have been implemented and adhere to both process and content standards, ensuring a standard level of professional practice.
7. New system-wide policies and procedure for the 29 Medical Centers to improve the timely handling and appropriate review and analysis of complaints relating to the quality of care (objective peer review), systems issues or administrative problems.
8. Regularly scheduled semi-annual presentations, including standard reporting, by Medical Center leaders to their respective regional Health Plan Quality Committees providing a comprehensive overview, and a mechanism to begin comparisons among Medical Centers; and
9. A Member Concerns Committee (MCC) for its Medical Centers in Southern California will report on member complaint and grievance processes, and in time, trended information (by region, by facility, and by department) from the Southern Region. This Committee mirrors the activities already underway in Northern California.
10. Revised business requirements, re-configurations of computer software and development of an access database to standardize quality review tracking systems in both Northern and Southern California by the end of the year. The Health Plan has committed to the purchase and installation of a new quality review tracking system in Southern California by 2009.

CONCLUSION

The Department found the Health Plan to be in violation of Section 1370 of the Act and implementing Rule 1300.70.

A COPY OF THIS REPORT HAS BEEN REFERRED TO THE DEPARTMENT'S OFFICE OF ENFORCEMENT.

Refer to Section II for further details on deficiencies and findings identified during the survey.

Refer to Appendix A for Time Line for Completing Corrective Actions

Refer to Appendix B for Quality Management (QM) System Overview

Refer to Appendix C for Survey Methodology

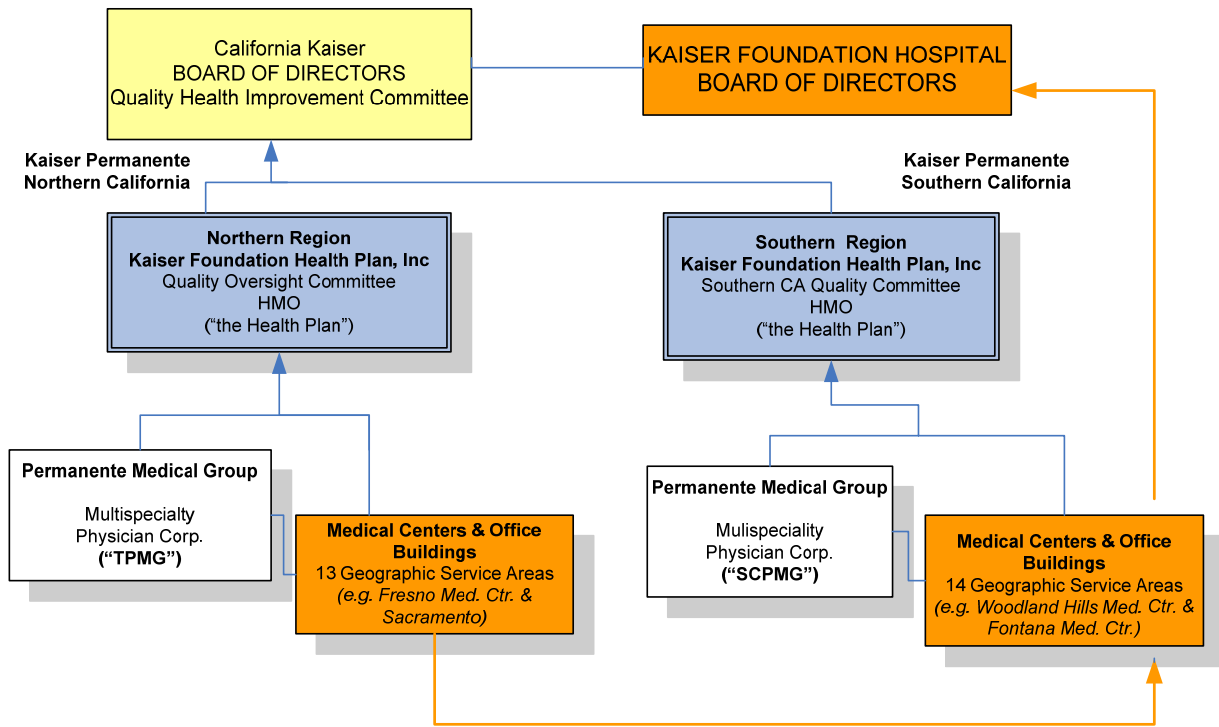
Refer to Appendix D for Summary of Files Reviewed.

Refer to Appendix E for a list of applicable Knox-Keene statutes and regulations.

Refer to Appendix F for a list of Acronyms used throughout this report.

SECTION I. OVERVIEW OF PLAN STRUCTURE

Kaiser Foundation Health Plan (the “Health Plan”), a DMHC licensed non-profit health care service plan, provides and arranges for medical and health care services for over six million members. The Plan offers a comprehensive and integrated health care delivery system, including ambulatory care, preventive services, hospital care, behavioral health, home health care, hospice, rehabilitation services, and skilled nursing services. The Health Plan divides its operation into two geographic service areas, the northern California region, headquartered in Oakland, California and the southern California region, headquartered in Pasadena, California.



NORTHERN CALIFORNIA REGION

Kaiser Permanente Northern California (KPNC) consists of three separate legal entities: (1) the Kaiser Health Plan, (2) the Kaiser Foundation Hospital (KFH) (“Medical Center”), a 13-hospital system and (3) The Permanente Medical Group (TPMG) (“Medical Group”), a multi-specialty physician corporation. Each entity has an independent Board of Directors. The Health Plan contracts with the Medical Center and the Medical Group to provide medical and other health care professional services to over 3.3 million Northern California members and relies on their quality review programs to identify and resolve problems within the local centers.

The Medical Centers are in a campus design that generally includes a hospital and medical buildings and offices for out-patient services. Each of the northern California Medical Centers has a Quality Department, responsible for the administration of the quality review program and a Medical Center Quality Committee (MCQC) responsible for reviewing the quality of care and services delivered by the Center.

Each service area has a Senior Vice President/Service Area Manager (appointed by the Plan’s Board of Directors), a Medical Group Physician-in-Chief (appointed by TPMG’s Board of Directors), and a Medical Center Director of Hospital Operations (appointed by KFH’s Board of Directors). These individuals serve on the Medical Centers Quality Committees and are jointly responsible for the administrative oversight of the Northern California Medical Centers activities.

Each MCQCs reports to its local Medical Center Executive Committee (MEC) and to the regional Quality Oversight Committee (QOC), which is responsible for all quality programs administered throughout Northern California Medical Centers. The QOC reports to the Quality Health Improvement Committee (QHIC), a sub-committee for the national Kaiser Foundation Health Plan/Kaiser Foundation Hospital Board of Directors.

SOUTHERN CALIFORNIA REGION

Similarly, Kaiser Permanente Southern California (KPSC) consists of three separate legal entities: (1) the Kaiser Health Plan, (2) the Kaiser Foundation Hospital (KFH) (“Medical Center”), a 14-hospital system and (3) The Permanente Medical Group (SCPMG) (“Medical Group”), a multi-specialty physician partnership. Each entity has an independent Board of Directors. The Health Plan contracts with the Medical Center and the Medical Group to provide medical and other health care professional services to over 3.3 million Southern California members and relies on their quality review programs to identify and resolve problems within the local centers.

Each of the southern California Medical Centers has a QM Department and a Medical Center Quality Committee (MCQC) responsible for reviewing the quality of care and services delivered by the Center. The Southern California Quality Committee (SCQC) is responsible for oversight of the quality programs at all Southern California Medical Centers to ensure that the programs are effective in identifying and correcting quality of care and service issues. Consistent with the north, the SQOC reports to the Quality Health Improvement Committee (QHIC), a sub-

committee for the national Kaiser Foundation Health Plan/Kaiser Foundation Hospital Board of Directors.

SECTION II. DISCUSSION OF PLAN DEFICIENCIES

This non-routine survey identified five deficiencies, referenced in Tables 1 and 2 below. Table 1 identifies deficiencies at the Health Plan (regional) level relating to governance; quality oversight activities and responsibilities. Table 2 identifies deficiencies at the local Medical Center/Medical Group operations level relating to quality and peer review processes.

On March 13, 2007, the Plan received a Preliminary Report outlining these deficiencies. The Health Plan was instructed to:

1. Develop and implement a corrective action plan for each deficiency, and
2. Provide the Department with evidence of the Plan’s completion of or progress toward implementing those corrective actions.

The “Status” column describes the Department’s findings regarding the Plan’s corrective actions.

**TABLE 1
 QM PROGRAM OVERSIGHT AT THE HEALTH PLAN LEVEL**

SUMMARY OF SURVEY DEFICIENCIES		
#	HEALTH PLAN DEFICIENCY STATEMENT	STATUS
1	In regard to the Health Plan’s oversight of QM activities: The Health Plan failed in “establishing a program to monitor and evaluate the care provided by each contracting provider group [both Medical Centers and Medical Groups] to ensure that the care provided meets professionally recognized standards of practice.”[Section 1370 and Rule 1300.70(b)(2)(C)]	The Plan has initiated remedial action and is on its way to achieving acceptable levels of compliance. [Rule 1300.80.10]
2	In regard to the Health Plan’s delegating its oversight of QM activities to its contracted Medical Centers and Medical Groups: The Plan failed to: (1) “inform each provider [Medical Center and Medical Group] of the plan’s QA program, of the scope of that provider’s responsibilities, and how it will be monitored by the Plan and (2) “have ongoing oversight procedures in place to ensure that providers [Medical Centers and Medical Groups]are fulfilling all delegated QM responsibilities.”[Section 1370 and Rule 1300.70(b)(2)(G)(1), Rule1300.70(b)(2)(G)(3)]	CORRECTED

3	<p>The Health Plan failed to ensure that [QM] “Reports [from its Medical Centers and Medical Groups] to the plan’s governing body [were] sufficiently detailed to include findings and actions taken as a result of the QA [QM] program and to identify those internal or contracting provider components that the QA program has identified as presenting significant or chronic quality of care issues.” [Section 1370 and Rule 1300.70(b)(2)(C)]</p>	CORRECTED
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**TABLE 2
 PEER REVIEW AND
 MEDICAL CENTER QM PROGRAMS**

SUMMARY OF SURVEY DEFICIENCIES	
#	MEDICAL CENTER DEFICIENCY STATEMENT
1	<p>The Medical Center Peer Review processes are not designed to consistently ensure the “level of care meets professionally recognized standards of practice” and that “quality of care problems are consistently identified and corrected for all provider entities.” [Section 1370 and Rules 1300.70(a)(4)(D), 1300.70(b)(1)(A,B)]</p> <p>STATUS: The Plan’s completed corrective actions and the corrective actions to be summarized and submitted in its Supplemental Report, due October 1, 2007, are sufficient to demonstrate the Plan is on the way to achieving acceptable levels of compliance.</p>
2	<p>The Medical Center QM programs are not designed to consistently ensure that the “level of care meets professionally recognized standards of practice is being delivered to all enrollees” and “quality of care problems are consistently identified and corrected for provider entities.” [Section 1370 and Rules 1300.70(a)(4)(D), 1300.70(b)(1)(A,B)]</p> <p>STATUS: The Plan’s completed corrective actions and the corrective actions to be summarized and submitted in its Supplemental Report, due October 1, 2007, are sufficient to demonstrate the Plan is on the way to achieving acceptable levels of compliance.</p>

The following discussion of the deficiencies summarized above in Tables 1 and 2 provide: (1) a summary of the Survey Team’s findings, (2) the Plan’s corrective actions to remedy the five deficiency findings, and (3) the Department’s assessment of the Plan’s compliance efforts.

TABLE 1 QM PROGRAM OVERSIGHT AT THE HEALTH PLAN LEVEL
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As the Knox-Keene licensee, the Health Plan is ultimately responsible and accountable to its members and the Department for the quality of care and services provided through Kaiser's integrated system of care. The Survey team reviewed the Plan's regional level structures and processes, including policies, procedures, staffing, committees, reports, and resources, designed to monitor the quality review activities performed at the local Medical Centers and clinical departments. The deficiencies in this section describe the shortfalls and demonstrate the Health Plan lacks a system to ensure effective oversight of these local programs.

Deficiency #1: In regard to the Health Plan's oversight of QM activities: The Health Plan failed in "establishing a program to monitor and evaluate the care provided by each contracting provider group [both Medical Centers and Medical Groups] to ensure that the care provided meets professionally recognized standards of practice."

Criteria: Section 1370 and Rule 1300.70(b)(2)(C)

Conditions: The Survey Team found the Health Plan's oversight system lacked sufficient information from the various Medical Center quality programs to adequately ensure an awareness of the effectiveness of each Medical Center's quality management system. The Department based this finding on the following:

- A single Health Plan level oversight audit report, a Survey Readiness Audit (prepared by the Health Plan Regulatory Services Department (HPRS), assesses specific measures tracked by the QM programs of the various Medical Centers. The Readiness Audit Report examines complaints and grievances annually (e.g., seven to 41 cases per Medical Center with four Medical Centers not included in the study) and whether cases meeting criteria for quality referral are in fact referred and acknowledged by the QM departments.
- Case referral compliance rates in 2006 varied significantly between Medical Centers from 63 percent to 100 percent in the northern region and from 25 percent to 100 percent in the southern region.³

³ The HPRS audit covers both member grievances and complaints, which the Plan defines as follows:

- Complaint – expression of dissatisfaction
- Grievance – expression of dissatisfaction for which the member seeks referral, provision of or reimbursement of services, supplies or other financial resolution.

The HPRS audit was pilot tested in the 4th Quarter of 2004 and was fully implemented in 2005. HPRS assesses the appropriateness of the member services' receipt, investigation, resolution and documentation of enrollee complaints and grievances. With reference to QM, the audit evaluates:

- whether complaints/grievances that meet quality referral criteria were appropriately identified and referred to QM;
- whether the referral to QM was timely; and
- Whether QM confirmed receipt of the referral.

- A lack of formal aggregate audit reports available to the Health Plan: (1) detailing the administrative activities of the QM programs, (2) reflecting the volume, tracking, resolution of QM cases/issues, or (3) evaluating the overall performance of the QM programs.

The Survey Team found only a few Medical Center reports, filed with the Health Plan, designed to track and evaluate key aspects of the Medical Center's QM programs or the effectiveness of Peer review activities.

The QM systems varied within each of the Medical Centers surveyed. Each Medical Center establishes its own protocol for quality of care investigations. The Survey Team found substantial variation in:

- Staff organization and reporting structures within the QM programs and QM Committee structure and membership, internal audit programs and whether and how frequently QM processes were audited.
- Processes and criteria to consistently identify quality issues from all sources, administrative, services or quality of care and escalation processes to assign the proper level of review.
- Threshold criteria for identifying cases for peer review and the structure of peer review, including: consideration of provider history, case severity levels and decision criteria for severity assignments, circumstances warranting a focus review of provider practice, case review documentation and assignment and follow-up of corrective actions.

As a result, the Survey Team found significant barriers to Health Plan oversight secondary to the variation in Medical Center based QM processes and structure and the absence of:

- Standard screening criteria to identify quality of care complaints; important to ensure appropriate evaluation of peer review eligibility.
- A policy to ensure the assignment of quality of care complaints to reviewers at a level commensurate with the seriousness of the allegations (e.g., whether the case warranted,

The 2006 audit of grievances found that in most Medical Centers, greater than or equal to 90% of the issues that meet referral criteria are being identified and referred to the QM Department; three Medical Centers were exceptions at 67%, 73% and 88%. The percentage of referrals to QM that had confirmation of receipt ranged from 33% to 100% with only five Medical Centers having greater or equal to 84%.

The 2006 audit of complaints found that in most Medical Centers, greater than or equal to 86% of issues meeting quality referral criteria are being identified and referred to QM Department; two exceptions showed 25% and 73%. The percentage of referrals to QM that had confirmation of receipt ranged from 0% – 100% with only six centers having a percentage of greater than or equal to 84%. When asked whether these results have been addressed, the Director of the HPRS stated that the results have not been reported and no corrective action has yet been recommended or undertaken.

non-physician clinical staff, single physician, clinical department-level committee, regional/Health Plan-level committee).

- A system to audit peer review decisions on a regular basis by individuals responsible for peer review oversight to ensure:
 1. Peer reviewers consistently assign the appropriate severity level and develop and implement effective corrective actions for confirmed quality of care problems.
 2. Peer reviewers consistently document the rationale for peer review decisions.
 3. The timely completion of peer review activities and consistency and accuracy of data entry of peer review determinations for tracking and trending.

The Survey Team found variation in how cases were audited by QM Directors. Several Medical Center QM Directors stated they read some or most of the QM review results (i.e., peer reviewer summaries/conclusions) returned by the peer reviewers. A few QM Directors occasionally re-reviewed cases (i.e., examining medical records and/or other case documentation) to assess results. Such efforts in general, however, were not formalized, quantified or tracked in order to evaluate peer reviewer performance.

In recent months, the northern California region has started to compare the number of cases undergoing peer review, identification of quality of care issues and the assignment of severity scores between Medical Centers. The minutes of northern California's QOC and QHIC on April 19, 2006, and May 10, 2006 meetings, respectively, documented that the Health Plan was notified of the variation in peer review activities and results among the various Medical Centers. The QOC minutes state that "there are many aspects of peer review that would benefit from attention." The report comparing peer review activities among the Medical Centers showed:

1. Significant (i.e., 20-fold) variation in the number of cases going to peer review among the northern California Medical Centers (questions remain as to the basis for the variation, data capture issues or differences in screening and case referrals).
2. Variation in the source of referral to peer review among the Medical Centers;
3. Variation in severity level assignment (questions remain as to the basis for the variation, different criteria used in scoring or true variation in the quality of care);
4. Variation in the rate of unnecessary referrals from Member Services, and variation in time taken to close cases.

The variation among the northern California centers precludes consistent identification of quality of care problems that may exist system-wide, within northern California. The Health Plan's process of evaluating each Medical Center on an individual basis, rather than in aggregate, precludes the ability to gauge trends or patterns in this integrated system.

The Medical Centers in southern California rely on a variety of data systems (many with limited data collection and reporting capabilities) to store, track and report on peer review activities and

a variety of severity scoring systems to categorize review. SCQC meeting minutes in southern California do not reflect audit or other oversight activities. In contrast to northern California, the Survey Team found no evidence of comparative reports or other means to review the southern region's comparative performance.

Implications: The Health Plan represents itself as an integrated delivery system; however, the Survey team's examination reveals that the value of the Plan's integration is seriously undermined by the significant variation in the QM and peer programs among its 29 Medical Centers. While the Health Plan may make use of the quality of care programs established at its local Medical Centers to ensure the delivery of high quality services and care to its members, the Plan must first ensure that these programs are substantively comparable and eliminate the substantial variation among these programs. So long as substantial variation exists in these programs, the Plan lacks an objective basis to gauge the effectiveness of the QM programs at local, regional and system levels and cannot verify that its members are consistently receiving health care services that are consistent with professionally recognized standards.

Plan's Compliance Effort: The Department acknowledges the Health Plan's significant efforts, initiated immediately after the completion of the survey in November 2006, to create standards, criteria and process changes to support a robust QM oversight system. While substantial progress has been made, the Plan will continue to work through 2009 to fully implement all the changes needed to achieve proper integrations and consistency in the QM and Peer Review programs and associated reports and audits for the Health Plan and Board of Directors review.

To begin the compliance effort, the first step was to establish and set standards for quality review to ensure uniformity among the hospitals, inclusive of the approach and system of peer review for both northern and southern California. The Health Plan accomplished this goal.

The Health Plan instituted process changes to ensure that quality issues are identified and addressed effectively and promptly by the KFHs and PMGs. The changes also address the Health Plan's need to receive regular detailed reporting of all QM and peer review activities so the Plan can: (1) evaluate the adequacy of the clinical review process; (2) assess the efficacy of the quality improvement activities; and (3) confirm that the corrective actions taken are appropriate. To that end, the Health Plan has instituted and the Medical Centers and Medical Groups are implementing the following:

1. Standardize quality review criteria and processes;
2. Standardized reports to increase consistency of information provided by the KFH hospitals and PMGs to the Health Plan; and
3. Additional monitoring and auditing procedures by the Health Plan to ensure new standards and processes are fully implemented.

1. Standardization throughout the two California Regions

The Health Plan worked to establish process standards and uniform case screening criteria to be used when reviewing potential quality of care issues. These new process standards

and screening criteria will be used by all Medical Center quality departments, quality committees, professional staff committees, and clinical departments within the Kaiser system.

The Health Plan has developed the following process standards:

1. Uniform screening criteria for Member Service Departments to use to determine if a member complaint should be forwarded for a QM review. This corrective action also requires all Member Service Departments to have clinical staff to assist in the correct detection and referral of quality care issues for review.
 2. A uniform “severity leveling” system to gauge and label the seriousness of the quality of care complaints that will be used by all physician reviewers as part of their peer review analysis.
 3. Uniform criteria for all Quality Departments to use to determine if a member complaint or referral from another Department related to a clinical, ancillary or administrative service should be forwarded for a QM review.
 4. A standard scoring system to screen and rate system issues (non-clinical quality concerns) to be used by the quality, clinical or administrative review committees. If these reviewers find a serious system issues, it is scored a “2” and referred to the Medical Center’s risk manager for tracking and escalation to the appropriate operational unit.
 5. The Health Plan is developing a consistent on-line data collection and tracking system for both regions and all 29 Medical Centers. Since this is a long-term goal, the Plan has initiated an interim step, a manual data collection process for all southern California Medical Centers to track in a consistent fashion with the automated system in use by northern California Medical Centers.
- 2. Content of Additional Reports the Quality Departments Provide to the Health Plan**
- The Health Plan has developed specific report requirements for all quality departments allowing the Health Plan to monitor quality activities designed to ensure the delivery of quality care to all members and patients. For example, reports will include the number of peer reviewed cases scoring a particular level at each Medical Center, the number of member appeals overturned by the Health Plan’s regional appeals committee due to the quality, service or access issues and the volume and trends by type of complaint, grievance and appeal.

Reports will be sent quarterly, semi-annually and annually to the regional (Health Plan) level quality committees to track patterns and trends in quality issues across all Medical Centers. Reporting changes facilitate the Plan’s ability to oversee and provide a “checks and balance” for quality reviews conducted at local Medical Centers and Medical Group level. (See Deficiency #3 for Board Report information.)

3. Auditing and Monitoring

The Health Plan has formalized a four-level audit process to evaluate the implementation of new process standards and uniform case screening criteria and in ensure the integrity of the quality review processes at each Medical Center:

1. Each Medical Center's quality department will commence a self auditing process;
2. The Health Plan will commence a bi-annual "audit validation" process, performing a second review of the same quality cases examined in the Medical Centers quality department self-audit process. The Plan's initial focus will be to verify the Medical Center's implementation of new process standards and the uniform case screening criteria;
3. PMG physicians from outside of California will audit peer review files in each region twice a year to verify the implementation of new process standards (content of case review) and the uniform case screening criteria.
4. The Health Plan will commence an annual "continuous survey readiness," process that will include a PMG physician audit of peer review determinations to confirm that appropriate severity levels were applied and that suitable corrective actions were assigned and completed.

Audit reports will be reviewed by the respective Medical Center's quality committees, the Health Plan's regional quality committees, and the Health Plan's Board of Directors.

Department's Finding Concerning Plan's Compliance Effort:

STATUS: The Plan has initiated remedial action and is on its way to achieving acceptable levels of compliance. [Rule 1300.80.10]

The Department accepts the corrective action plan related to Deficiency #1 because the Plan:

1. Developed, administratively appropriate policies and procedures that if effectively implemented and monitored, should result in "establishing a program to monitor and evaluate the care provided by each contracting provider group [both Medical Centers and Medical Groups] to ensure that the care provided [to its members] meets professionally recognized standards of care," and
2. Initiated remedial action and has provided a detailed timetable for completing implementation, demonstrating full operations of corrective actions to ensure care provided [to Kaiser members] meets professionally recognized standards of care. (See Appendix A)

Deficiency # 2: In regard to the Health Plan's delegating its oversight of QM activities to its contracted Medical Centers and Medical Groups: The Plan failed to: (1) "inform each provider [Medical Center and Medical Group] of the plan's QA program, of the scope of that provider's responsibilities, and how it will be monitored by the Plan and (2) "have ongoing oversight procedures in place to ensure that providers [Medical Centers and Medical Groups]are fulfilling all delegated QM responsibilities."

Delegation is defined as a group of persons chosen to represent others. The Knox-Keene Act recognizes that medical groups or other provider entities may have active quality assurance programs which the Health Plan may use to review the care and services provided within individual Medical Centers; nevertheless, "In all instances, the plan must retain responsibility for reviewing the overall quality of care delivered to plan enrollees, "and "inform each provider of the plan's QA program, of the scope of that provider's QA responsibilities, and how it will be monitored by the plan."

Criteria: Section 1370 and Rules 1300.70(b)(2)(G)(1), 1300.70(b)(2)(G)(3)

Conditions: The Health Plan has delegated a variety of QM program responsibilities (e.g., peer review, data analysis, and corrective actions) to its Medical Centers and Medical Groups.

While the Health Plan has service agreements/memorandums of understanding with medical groups in both the northern and southern California regions, the Survey Team found no documents or other evidence of an agreement between the Plan and the local Medical Center or Medical Group detailing: (1) the Plan's QM policies, (2) the physician's QM responsibilities, (3) reporting requirements established to monitor performance of those responsibilities or (4) the allocation of the QM responsibilities between the parties. The Team found no documentation describing the required QM audit activity, or the process or frequency for QM reporting from the local levels to the Plan's regional level.

While QM-related activities are conducted by different bodies within the Medical Center such as peer review committees and Medical Center QM departments supporting the hospitals and medical offices, there was insufficient evidence the Health Plan instituted processes to oversee these activities and that it retained responsibility and accountability for these programs. Further, in the event the Plan found Medical Center QM activities unsatisfactory or peer review programs ineffective, the plan offered no protocol of corrective action it would institute to resolve the performance issues.

Implications: An effective delegation of responsibility for quality of care review to the Medical Center and clinical departments requires the Health Plan provide a clear delineation of the scope of the responsibilities and of the reporting requirements. The Plan's failure to clearly stipulate these responsibilities and reporting requirements in a written QM delegation agreement, policy or other document has led to a system of reporting based on (1) discretion rather than established standards and (2) local level independence rather than coordinated Plan oversight.

Plan's Compliance Effort: The Health Plan developed, formalized and executed an agreement which delineates respective roles and responsibilities between the Plan, Kaiser Foundation Hospitals and the Permanente Medical Groups, including how the Health Plan will monitor quality review performed by the hospitals and physicians.

The agreement, signed by the three parties, acknowledges the Health Plan's responsibility and accountability to oversee the quality of care delivered to Kaiser Enrollees by monitoring the quality of care review and evaluation of health care system issues performed by KFH and the PMGs on the Plan's behalf. The Health Plan's oversight creates a checks and balance relationship to ensure accountability to the Health Plan for hospital and medical group adherence to quality review standards set by the Plan.

Department's Finding Concerning Plan's Compliance Effort:

STATUS: CORRECTED

During a scheduled follow-up review, the Department will evaluate how the Plan informed providers and hospitals of the delegation agreement, outlining respective roles, responsibilities and their accountability to the Health Plan for the performance of quality review.

The delegation agreement confirms the Health Plan's reliance on and delegation of quality review to each hospital and medical group, however, the hospitals and providers must understand that the Health Plan and maintains ultimate accountability for setting standards and maintaining a level of involvement that ensures the delivery of care in accordance with professionally recognized standards of practice.

The Department will verify that Regional QI Program Descriptions are revised to ensure these documents are consistent with accountabilities referenced in the delegation agreement. The Department will consider these revisions as one mechanism the Plan has used to communicate the Plan's oversight responsibilities and associated Hospital and Medical Group roles and responsibilities.

Deficiency #3: The Health Plan failed to ensure that [QM] "Reports [from its Medical Centers and Medical Groups] to the plan's governing body [were] sufficiently detailed to include findings and actions taken as a result of the QA [QM] program and to identify those internal or contracting provider components that the QA program has identified as presenting significant or chronic quality of care issues."

"To the extent that a plan's QA responsibilities are delegated within the plan or to a contracting provider, the plan documents shall provide evidence of an oversight mechanism for ensuring that delegated QA functions are adequately performed." Rule 1300.70(b)(2)(B).

Any delegated entity must maintain records of its QA activities and actions, and report to the plan on an appropriate basis and to the plan's governing body on a regularly scheduled basis, at least quarterly, which reports shall include findings and actions taken as a result of the QA program.

Criteria: Section 1370 and Rule 1300.70(b)(2)(C)

Conditions: While the Health Plan routinely analyzes and provides aggregate performance report cards to the local Medical Centers and medical Groups, information from the local Medical Center quality review, flowing from the Plan's Medical Centers to the Health Plan, is less predictable. The lack of consistency is linked to the absence of clear criteria informing the QM departments of reporting standards and content required for Health Plan reporting.

Based on the lack of uniform standard protocols or criteria for peer review analysis and reporting, Medical Centers enjoy broad discretion in setting quality review policy. The clinical department chiefs and department-level committees, in each Medical Center, exercise unfettered discretion to decide which cases and/or issues from their departments will be reported in detail to the Medical Center QM Department and to higher level committees.

The Plan's policy to grant extensive discretion to individual Medical Centers to decide whether a peer reviewed case, a serious system or administrative problem reaches the Plan's regional levels serves to relinquish Plan's responsibility to be aware of serious problems and its duty to Kaiser Members to take swift corrective action and to guard Kaiser's system of care. Some Medical Centers report cases above a given severity assignment, but other centers without multi-tiered severity levels, rely on subjective decision-making. The reporting deficit to the regional Plan level extends to the Health Plan's Board of Directors where case specific discussion is rare.

Minutes of the Plan's Board meetings showed Medical Center QM reports lacked sufficient detail of quality findings and corrective actions. The BOD minutes reflected minimal discussion, evaluation or inquiries of care issues identified through the local QM programs.

Remarkably, the Health Plan and BOD received extensive reports on population-based measures (e.g., HEDIS measures, satisfaction rates); however, absent were detailed Medical Center-specific reports or comparative studies on the patterns and trends of quality issues confirmed through peer review activities or from the local QM hospital programs. When the Medical Center staff was asked to describe the type of case information elevated to the Health Plan level, answers varied among those interviewed.

In addition to inconsistent case information, the Plan's regional-level Quality Committees and the Plan's Board of Directors receive no reports on the operational and administrative challenges facing individual clinical or service departments. Medical Centers located in southern California provide the regional committee (SQOC) a bi-annual operational/administrative overview, however, the Medical Centers in northern California have only recently commenced plans to report similar information.

Kidney Transplant Program

This non-routine survey evaluated the Plan's oversight of San Francisco's Kidney Transplant Program. The Survey Team found no regular reports from the Kidney Transplant Program Director to the regional Plan level even though the Program received several grievances raising significant administrative capacity issues including the length of time to obtain a live donor blood type and cross match with the transplant candidate's/member's blood.

Although recurrent complaints about treatment delays and the lack of follow-up with members existed, neither the Plan's regional quality committees' or its Board of Director's meeting minutes acknowledged or addressed these chronic problems.

The Survey Team conducted staff interviews and reviewed documents, to assess the level of information afforded the Plan regional levels regarding the Kidney Transplant Program, with the following results:

1. None of the program officers filed a formal Business Plan with the Health Plan prior to establishing the Program. (Plan officers reasoned because the Program did not require any new capital investments, a Business Plan was not required.)
2. Although general information about the start-up of Kaiser's SF Kidney Transplant Center existed, the Plan did not monitor any of the Kidney Program's key implementation and rollout dates. The Health Plan did not measure the effectiveness or adequacy of the Program's start-up process or monitor the transition and timely access to transplant services as patients moved to Kaiser's new SF Kidney Transplant Center.
3. The Kidney Program's Chief of Staff stated that oversight focused on quality and that possibly greater emphasis was needed on administrative and regulatory oversight. However, the Survey Team found no documentation suggesting that any administrative or regulatory deficiencies were reported to the Plan; and
4. The Kidney Program officers failed to demonstrate to the Plan that safeguards or processes to control patient flow into Kaiser's Kidney Transplant Program had been established.

Implications: The Health Plan's failure to require and standardize the information and data analysis from QM programs at the local centers, including peer review activities, results in the Plan receiving insufficient detail to recognize, understand and address individual or potential system-wide quality and access issues. This lack of knowledge, effectively denies the Plan's ability to meet its oversight obligations, which includes the prompt institution of corrective action when warranted.

While Medical Centers must have some flexibility to address local needs, a Plan's grant of unfettered local policy discretion is never warranted. Where the Plan operates in multiple locations, the Plan must insist on a reasonable amount of standardization (in performing quality

review, data collection/reporting and severity leveling) so it can conduct a valid comparative analysis and objectively quantify the quality of care that is being delivered to its members.

The variation and unfettered discretion granted the individual Medical Centers resulted in the Health Plan failing to establish “a program to monitor and evaluate the care provided by each contracting provider group to ensure that the care provided meets professionally recognized standards of practice” is a violation of Rule 1300.70(b)(2)(C).

Plan’s compliance Effort: The Health’s Plan Board of Directors currently receives detailed information on critical events and aggregate reports on quality issues from both Health Plan regional quality oversight committees, QOC in the North and SQOC in the South. The Plan’s Board of Directors also established the Quality Healthcare Improvement Committee, an oversight committee for both regions, to review the quality assurance functions of both the Medical Centers and the Medical Groups. This Committee utilizes a quality system in an electronic dashboard format to provide standardized and consistent report of quality data. All of the Medical Centers and Medical Groups contribute and collaborate in the development of the Committee’s “Big Q” report. The Big Q report has a “drill-down” option to allow Board Members to ascertain the specific metrics for a regional or individual hospital.

The Health Plan will provide additional detailed reports and information to its Board of Directors concerning significant provider and quality of care issues to allow the Board to properly evaluate the seriousness of quality issues and assist in the development of appropriate corrective action. The new reports include:

1. Documentation of the analyses and decisions to assume responsibility for a clinical service [rather than outsourcing or subcontracting]. This will require review by the Health Plan’s Regional President and the PMG’s Executive Medical Director or their designees, and approval of the related business case by the Health Plan Area Manager/ Executive Director and the Regional President.
2. Complaint data, including significant complaint patterns and trends related to quality issues.
3. Case data of critical events, with enumerated criteria and identified trends.
4. Reports of any adverse findings by Lumetra, the designated California Quality Improvement Organization for the Centers for Medicare & Medicaid Services.
5. Enhanced practitioner performance review and oversight reports to include complaint data, number of practitioners reviewed, and the number of practitioners whose credentials and privileging were approved.
6. Statistics on National Compliance Office hotline complaints related to quality concerns.

The first three reports were reviewed and discussed during the Plan's Board of Director's meeting in April 2007. The last three reports were reviewed during the June 26, 2007 Board of Director's meeting.

Department's Finding Concerning Plan's Compliance Effort:

STATUS: CORRECTED

The Department acknowledges the Plan's efforts to identify and institute additional reporting requirements covering provider performance and quality case assessments. These new reports should contain sufficient detail including the findings and actions taken by the various QM programs to allow the Plan's Regional Quality Committees and its Board of Directors to identify and remedy significant or chronic quality of care issues. At the time of the posting of this Final Report, the Plan will have reported all six of the additional quality reports to its Board of Directors.

During a scheduled follow-up review, the Department, at a minimum, will evaluate:

1. Whether the Plan has consistently received and provided its Board of Directors with the additional quality and provider reports identified above;
2. Whether the reports sufficiently detail QM program findings and actions and whether the actions taken were appropriate;
3. Whether the Plan's Board of Director meeting minutes reflect that the Board: a) reviewed and evaluated the findings and actions contained in these reports, (b) assessed and understood the seriousness of the issues presented and (c) participated in the development of corrective action strategies, and (d) verified, thorough appropriate follow-up, that all serious quality issues were promptly remedied.

TABLE 2 PEER REVIEW AND MEDICAL CENTER QM PROGRAMS

The following two deficiencies reflect failures in the design of the QM system as administered by the Plan's network of Clinical Departments and Medical Centers.

BACKGROUND: PEER REVIEW

Each Medical Center's QM department has established a peer review system to monitor professional conduct and medical decision-making that utilizes other physicians within the same specialty to review case files for quality issues. Once a physician reviewer accepts a QM case for review, he is responsible to ensure that:

1. The case investigation is completed,
2. The case is assigned a severity level, and
3. The appropriate level of corrective action is developed and reconciled against the medical decision-making and/or conduct issues identified.

The first level of peer review may be conducted by a multi-department committee, a single-department committee (most often the department in which the practitioner works), or one designated physician (generally the Chief of the clinical department or Chief of Service or his/her designee). Cases deemed to be of sufficient severity may undergo a second level of peer review, generally by a committee. The QM departments are responsible to oversee the peer review activities performed by clinical departments.

When peer review determines a case falls below a standard of care, results are sent to the Medical Center's QM Department which is generally responsible for the development, implementation and follow-up of corrective actions. If case review reveals a serious quality issue, the case may be escalated to the Medical Center's Medical Executive Committee (MEC), the highest level Medical Center oversight. Peer review referrals, outcomes, and identified issues are tracked and trended by the QM Department.

Deficiency #1: The Medical Center Peer Review processes are not designed to consistently ensure the "level of care meets professionally recognized standards of practice" and that "quality of care problems are consistently identified and corrected for all provider entities."

Criteria: Section 1370 and Rules 1300.70(a)(4)(D), 1300.70(b)(1)(A,B)

Conditions: The individual(s) responsible for peer review varied considerably among the nine Medical Centers. Often, the peer review process varied among clinical departments within a single Medical Center and/or between Medical Centers. The Survey Team's evaluation of peer review revealed:

- Inconsistent determination and identification of cases that merited peer review;
- Inconsistent application of criteria when selecting providers to screen cases (focused review) to determinate eligibility for peer review;
- Substantial variation in the criteria used to judge case severity levels;
- Inconsistent understanding of the application of the severity levels among per reviewers; and
- The failure to ensure impartial physician reviewers in the peer review process resulting in the physician's co-worker or supervisor making the peer review determination.

Case Identification: The Medical Center QM departments follow a variety of processes in handling peer review case referrals. A Medical Center Quality Director stated that "screening of cases is based on judgment." While most Medical Centers use a Quality Physician(s) to decide which cases warrant peer review, some Centers allow a registered nurse (RN) to make this determination.

Medical Centers use several portals to identify cases offering potential opportunities for improvement in care or service. The percentage of cases referred to the QM departments and ultimately forwarded to peer review varied among the nine Medical Centers from a low of 20% to a high of 33%.

It is important to note that cases identified for peer review did not consistently reach the QM Department. Even though the Health Plan had criteria to guide Member Services in deciding to refer a case for quality review, QM and clinical departments did not consistently apply or utilize these criteria in their case reviews.

Generally, Medical Centers do not provide formal peer review case referral criteria to non-physician medical professionals. In one quality of care case, Member Services received an increasing number of member complaints reported over several months; however, this trend did not trigger a quality review. The Plan explained that the gauge for case referral (what circumstances distinguish a serious quality of care problem from a minor issue) did not consider physician behavior or communication style a trigger for physician review.

Case Screening: In the event a quality of care case was identified and referred to the QM program, QM Department screening and peer review referral protocols varied among the nine centers. The Survey Team found several case examples of problems in the QM Department case screening process for peer review. In one case, the file lacked documentation to confirm the case was screened by an RN or other qualified clinical staff for peer review referral, or physician-level peer review had occurred (either by QM Department physicians or by clinical department chief).

Often the file reflected a factual summary of the complaints, rather than a quality review. In a sub-set of cases, the clinical review of quality issues occurred only after the case was selected for

the Department's survey, even though these cases had been referred for a quality review more than 120 days prior to the Department's case selection notice.

Peer Review Decision – Assignment of Severity Levels: A severity scoring system applies a consistent measure to each case in an effort to identify and track medical practice patterns that are not consistent with professionally recognized standards of care. A severity level assignment weighs the physician's medical decisions against the clinical facts and patient outcome. Severity scores can also be used to gauge administrative and service problems. When an organization uses a consistent severity score rating system, the Plan is in a position to receive reasonable and timely notice of:

1. Providers who need an in-depth focused review or additional training;
2. System or practice protocols that need to be addressed or revised; and
3. Accurate data necessary to develop appropriate corrective actions.

The Survey Team examined numerous case files to evaluate the assigned severity level in conjunction with case review documentation; to gauge the thoroughness and rationale for the peer review decision; however, Peer review files did not consistently document the rationale behind case severity determinations.

Case severity assignments ranged between "no problem" to cases assigned the highest severity level. The proportion of case assignments (low to high severity levels) varied significantly among the Medical Centers. Some Medical Centers had a much higher proportion of cases assigned "no problem" as compared to other Medical Centers.

The variation raised two important questions, whether the variation reflected genuine performance differences among physicians, or whether reviewer skill and diligence accounted for the variation. Either condition would qualify as a serious concern for the Health Plan.

The Survey Team assessed peer review training programs in each of the nine Medical Centers with varying results. Four out of nine QM departments provided formal peer review training. Two Centers mentioned using a peer review orientation packet while another Medical Center was planning a "boot camp" to examine peer review process and train peer reviewers.

Impartial v. Potentially Biased Peer Review: Most Medical Centers assign the initial case review to the Chief of the clinical department (Chief of Service) in question or to the Chief's quality designee. Concerns related to a reviewer's objectivity can arise when the Chief of Service or a department committee reviews a case involving a physician staff member without also assigning an impartial, uninvolved party. The potential for bias stems from a lack of anonymity between the practitioner under review and the peer reviewer.

Medical Centers rarely use neighboring Medical Centers and/or non-Plan peer reviewers to conduct a "blind" peer review analysis which would ensure objectivity in the process. The

Medical Centers had a varied response when asked about accessing outside peer review, summarized below:

1. The case requires the expertise of a specialist not available at the “home” Medical Center;
2. Personality or personnel issues exist between the practitioner and the peer reviewer;
3. The quality of care complaint has the potential of receiving a level 3 severity assignment;
4. The case involves not only a medical care issue but also a potential legal issue; or
5. The quality of care complaint involves the Chief of Service.

It is worthy to note, when a case was referred for a blinded peer review, the review focused on the “in-house” peer review conclusion. The blind peer review did not screen the case to ensure the “in-house” process captured all quality issues. In contrast, an unbiased blinded review should involve a thorough “de novo” review of the quality complaint.

In cases in which the in-house peer reviewer found no quality of care problem, the option of outside review was never used to verify results, even in cases in which the peer reviewer was also involved in the care in issue. The Survey Team found case examples where the peer reviewer was either a treating physician or otherwise involved in the care of the patient, however, no independent assessment was arranged.

The Survey Team found no case review audit protocols from either the Medical Center or Health Plan for reviewing decisions made by clinical department chiefs or department-level committees, therefore, no ability to validate the objectivity of the peer reviewers, the appropriateness of findings or the recommended corrective action. Neither the Medical Centers nor their Clinical Departments could identify a policy or a standard process to confirm the impartiality of assigned peer reviewers.

Implementation of Corrective Action Plans and Evaluation of Final Outcome: The Medical Center QM programs did not consistently evaluate the corrective action assignment or verify completion or the long term effectiveness of peer review recommended corrective actions. In northern California Medical Centers, a severity level 2 indicates a significant deviation from the standard of care and corrective actions to educate or improve provider performance would be expected. However, the Survey Team found a number of cases assigned a severity level of 2 or higher, with no evidence that any corrective action was assign or implemented. In 14 other cases with identified quality problems and assigned corrective actions, no documents confirmed completion or effectiveness of corrective actions.

Consideration of the Provider’s History in Case Determinations: The majority of peer reviewed cases failed to consider the provider’s complaint history when formulating the recommended corrective actions. Similarly, there was no evidence suggesting the Plan ever considered the provider’s complaint history when evaluating the adequacy of the peer reviewer’s recommended corrective actions. Survey Team interviews confirmed two of nine Medical Centers routinely review the provider’s complaint history when assigning corrective actions.

Two Centers review complaint history in the event the case receives a high severity level assignment. The Health Plan explained that quality complaint histories are reviewed at the time of physician re-credentialing which occurs every three years.

Results of File Review: The Survey Team examined 228 peer review files from nine Kaiser Medical Centers.

TABLE A

Identification of Quality of Care Issues

FILE TYPE	# OF FILES REVIEWED	SURVEY FOCUS	# COMPLIANT	# DEFICIENT
Internal QM referrals	65*	Were all quality issues/problems identified and determination rationales documented?	43	22

*Subset of cases from the 228

TABLE B

Adequate Case Review Documentation

FILE TYPE	# OF FILES REVIEWED	SURVEY FOCUS	# COMPLIANT	# DEFICIENT
Internal QM referrals	65	Did the peer review file contain thorough, accurate, legible documentation?	46	19

TABLE C

Assignment and Follow-up of Corrective Actions to Address Quality of Care Issues

FILE TYPE	# OF FILES REVIEWED	SURVEY FOCUS	# COMPLIANT	# DEFICIENT
Peer review cases that found a quality of care issue. *	57	Was a Corrective Action Plan (CAP) assigned?	48	9
		Did the file contain sufficient documentation to verify that the CAP was implemented and/or a followed-up assessment conducted?	43	14

Peer review cases that found serious quality of care issue.	17	Was a Corrective Action Plan (CAP) assigned?	14	3
		Did the file contain sufficient documentation to verify that the CAP was implemented and/or a followed-up assessment conducted?	11	6
Peer review cases that found provider-specific problems	50	Was the provider's complaint history reviewed to assist in designing and appropriate CAP?	12	38
Peer review cases that found serious provider-specific problems	17	Was the provider's complaint history reviewed to assist in designing and appropriate CAP?	5	12

TABLE D

Timely review of quality of care cases

FILE TYPE	# OF FILES REVIEWED	SURVEY FOCUS	# COMPLIANT	# DEFICIENT
Peer review a cases that included internal QM referrals and member complaints & grievances filed with the Plan and DMHC's	228*	Was the quality of care issue referred to Medical Center's QM Department within 30 days of identification?	194	34
		Was the quality of care referral initially review by a medical professional (chief of service, QM physician, etc.) within 30 days of the case referral?	179	49

Help Center.		Was the quality of care issue handled in a timely manner? This examination took into consideration the time from issue identification to final peer review determination?	155	73
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Implications: Individual clinical departments work independently to establish quality review policies without input or approval from the Medical Center, from other “like specialty”⁴ clinical departments, or the Regional Quality Committees of the Health Plan. A system that holds not only the Hospital, but the physicians accountable to the Health Plan level is essential to providing oversight of Kaiser’s system of care. The local clinical department peer review systems are further flawed by the lack of safeguards to ensure an objective peer review process. The peer review system is the cornerstone of the system’s quality review program and must be designed to ensure the level of care delivered to Kaiser Enrollees is in keeping with acceptable levels of professional practice and standards.

Plan’s Compliance Effort: Beginning in February 2007, the Plan initiated a process to develop uniform peer review policies and procedures and to standardize the peer review process across all of its 29 Medical Centers. To avoid the potential for bias, the Plan expanded the criteria for referring quality issues to an external peer review body. The Plan developed a delegation agreement (See Deficiency #2.) to ensure that the Plan retains the ability to participate in establishing peer review policies and to limit the unfettered discretion previously granted individual Clinical Departments and Medical Centers.

The Health Plan has developed a system of audits to ensure: (1) peer review policies and procedures are consistently followed, (2) peer review activities are appropriately documented and (3) peer review activities are designed to ensure that the care delivery in their Medical Centers meets professional standards of practice. The first audits begin February 2008.

In April 2007, the Plan conducted a “Pilot” training program to begin educating its physicians on the new requirements and expectations for peer review activities. The Plan estimates November 2007 for completion of peer review training and the rollout of the new peer review system across all medical centers and regions will occur by the end of December 2007.

⁴ “Like Specialty” Each Medical Center has a number of clinical departments such as Medicine, Pediatrics, General Surgery. When a clinical department, for example Pediatrics, sets quality review policy in one of the medical centers, there is no review or approval of the policy by other “like specialty” Pediatric clinical departments either in neighboring medical centers or across regions to Pediatric clinical departments between North and South.

Department's Finding Concerning Plan's Compliance Effort:

STATUS: The Plan's completed corrective actions and the corrective actions to be summarized and submitted in its Supplemental Report, due October 1, 2007, are sufficient to demonstrate the Plan is on the way to achieving acceptable levels of compliance.

While the Plan has worked to develop standards, processes and criteria to provide a uniform peer review infrastructure and has collaborated with its provider partners to address serious limitations in its peer review process, associated changes in accountabilities and adherence to Health Plan standards requires a fundamental restructuring of relationships between the Permanente Medical Group, the Medical Centers and the Health Plan, in accordance with the delegation agreement. This is to ensure not only a sound peer review system is established by the Medical Groups, but that accountabilities to the Health Plan are established and observed.

On or before October 1, 2007, the Plan will submit a supplemental report detailing the additional remedial actions and implementation activities undertaken to place into operation the revised standards, policies and procedures and case review. The Supplemental Report shall include a final timetable for instituting the Plan's revised policies and procedures in all of its 29 Medical Centers.

At the Plan's invitation and in accordance with the Department's follow-up objectives, the Department will institute a "no notice" spot check audit of a sampling of case files from a select Medical Center(s), to begin after November 1, 2007.

The Department anticipates completing a follow-up survey to verify that all of the Plan's proposed correctives actions are fully operational in the fourth quarter of 2008.

Deficiency #2: The Medical Center QM programs are not designed to consistently ensure that the "level of care meets professionally recognized standards of practice is being delivered to all enrollees" and "quality of care problems are consistently identified and corrected for provider entities."

Criteria: Section 1370 and Rules 1300.70(a)(4)(D), 1300.70(b)(1)(A,B)

Conditions: Generally, the Medical Centers' quality tracking systems seriously limit the ability to collect and trend quality program activities and findings. Data reports failed to include information confirming and tracking the implementation, completion and results of required corrective actions when assigned.

If the QM Committee performs a case review, the committee minutes usually verify whether the required corrective action has been completed. If the case is reviewed by a clinical department chief, the chief is responsible for verifying that required correction action is completed. Medical Center QM departments, however, do not require or verify that clinical departments document

the tracking and completion of corrective action. In practice, department chiefs rarely memorialize their efforts in confirming implementation and completion of required corrective actions assigned to physicians.

The Survey Team found case examples in which the case screening process failed to identify all quality issues, hence, the case review was incomplete. These cases generally fell in one of four categories:

1. Cases involving systems issues (problems resulting from the established policies and procedures);
2. Cases including a request for reimbursement of services or charges;
3. Cases where appropriate care coordination was lacking; and
4. A general category, for all other cases.

Timely Case Review: While most Medical Centers have established goals for completing case reviews (90 to 180 days from receipt of referral to case closure), only four of nine centers tracked the percentage of completed reviews within the goal time frames. The QM Department staff acknowledged their awareness of case review timeframes, however, Medical Centers did not consistently complete the case reviews within the established time requirements.

Process to Ensure Proper Level of Physician Review: The Survey Team examined the “case escalation” process that ensures the review of serious cases by the proper level of physician or clinical department committee. Several case files should have received a higher level of review due to the seriousness of the issue or implications of system-wide problems, however, no documentation confirmed this review, suggesting these cases were not appropriately escalated to the requisite level of physician review.

In one case, the Pediatrics Peer Review Committee instituted a corrective action plan (“CAP”) for a provider who received a score of “3” representing “unacceptable standard of care.” Although the Pediatric Peer Review Committee department conducted a timely and thorough peer review, there was no documentation to suggest that the case was referred to the Medical Executive Committee of the Medical Center, where Medical Center policy required review of the most serious cases.

Variation Among Centers in Case Tracking: Only one of nine Medical Centers prepared reports on the number and percentage of quality of care cases by category/topic of problem. One other Center prepared a limited report detailing the number/rate of cases falling into various peer review severity levels. The extent of variation in the comprehensiveness of tracking reports between the surveyed Medical Centers illustrates the level of autonomy and detachment under which they operated.

Variation Between Regions: Computer Systems Used to Support Medical Center Quality Programs: All Medical Centers in the northern region use the MIDAS computer system to

collect, track, and analyze data on cases identified/referred for quality investigation. The system also allows the northern region to conduct comparative studies.

Southern region Medical Center QM departments use a variety of data systems that collect disparate data fields and use coding systems. This multiplicity results in information that cannot be easily combined or compared and prevents Plan-wide comparative performance reports. In addition, QM departments throughout the Kaiser System use varied criteria for deciding which cases to include in databases.

Implications: An integrated and consistent data system to track, trend and resolve member-reported problems (a key focus of this non-routine medical survey) is a fundamental prerequisite for a comprehensive and effective quality improvement program. Reporting variations and the inability for Medical Centers and the Plan to effectively exchange and compare information results in missed opportunities for systematic quality of care improvements and perpetuates practices patterns that are inconsistent with professional standards. The information sharing that does occur is minimal and inefficient. For example, while one QM department revealed efforts to change from multi-department committees to single clinical department-based committees, another QM department revealed a plan to change from single-clinical department-based committees to a multi-department committee.

The Health Plan delegates the responsibility for quality of care review to the local Medical Center QM programs, inclusive of peer review. However, the survey revealed that in addition to each Medical Center functioning independently, similar medical Departments (e.g., orthopedics, pediatrics) operate differently among the Medical Centers and often completely independent from the Plan.

Inconsistent identification, reporting and tracking of quality issues renders meaningful comparisons between clinical departments/Medical Centers impossible; and may result in the under reporting of quality issues. The Health Plan must: (1) address the level of independence, discretion and lack of accountability that currently exist between the individual Medical Centers and the Plan, (2) develop consistent standards for addressing quality of care complaints and provider issues and (3) require that all QM programs in all Medical Centers implement these standards and regularly account to the Plan for the quality of care it renders

Plan's Compliance Effort: The Health Plan has initiated process and system changes in its Medical Centers and Medical Groups to ensure that quality issues are identified and addressed effectively and promptly. These changes will standardize the quality review programs among all Centers and between regions. These changes will include the:

1. Standardization of quality of care review criteria and processes;
2. Standardized reports to increase consistency of information that Medical Centers and Medical Groups provide to the Health Plan; and
3. Additional monitoring and auditing activities by the Health Plan to ensure that the new standards and processes are properly implemented. (See Deficiency #1)

The Health Plan has committed to purchasing a long term data system solution for Southern California no later than the end of 2009. In the interim, the Plan has begun developing the business requirements for the new data system and identifying the necessary system modifications.

Department's Finding Concerning Plan's Compliance Effort:

STATUS: The Plan's completed corrective actions and the corrective actions to be summarized and submitted in its Supplemental Report, due October 1, 2007, are sufficient to demonstrate the Plan is on the way to achieving acceptable levels of compliance.

The Plan's corrective actions (also referenced in Deficiency #1) involve two separate phases of organizational work: 1) developing a strategy for oversight of the quality of care activities performed at the local Centers and 2) ensuring the implementation of proposed new standards, processes and criteria among its 29 Medical Centers and their clinical departments. To address the first phase of its Corrective Action, the Plan established protocols for a uniform case screening criteria, a case severity level system and quality of care oversight process at the Plan level. The second phase requires that these new policies and procedures be implemented and practiced by the Plan's 29 Medical Centers. The Plan is just beginning education process necessary to ensure consistency, eliminate variation and improve tracking systems for all of the 29 Medical Centers.

The Department will monitor the implementation of process changes and review results of planned audit activities represented in the Plan's corrective action plan (See Deficiency #1.); however, more importantly, the Department must verify on an ongoing basis the implementation status of Plan's corrective actions through 2008.

On or before October 1, 2007, the Plan will submit a supplemental report detailing the additional remedial actions and implementation activities undertaken to place into operation the revised standards, policies and procedures and case review. The Supplemental Report shall include a final timetable for instituting the Plan's revised policies and procedures in all of its 29 Medical Centers.

At the Plan's invitation and in accordance with the Department's follow-up objectives, the Department will institute a "no notice" spot check audit of a sampling of case files from a select Medical Center(s), to begin after November 1, 2007.

The Department anticipates completing a follow-up Survey to verify that all of the Plan's proposed correctives actions are fully operational in the fourth quarter of 2008.

SECTION III. RECOMMENDATIONS

The Department recognizes that the Plan has considered and is adopting most of the recommendations from the Survey Team's initial observations. The Survey Team continues to offer the following two recommendations to advise and assist the Plan in its ongoing quality improvement efforts. The Department encourages the Plan to review, evaluate, and take action, as appropriate, on these recommendations.

Recommendation #1: The Plan should develop mechanisms: (1) to identify members who file multiple complaints related to a single episode of care or ongoing treatment and (2) to conduct an aggregated review these multiple complaints to determine whether member /family needs special attention or whether there are any patterns or trends that precipitate the filing of multiple complaints.

Recommendation #2: The Plan should implement a process to ensure that all member complaints involving requests for a co-payment refund be screened to determine whether the refund requests stems for a potential quality of care issue. If a potential quality of care issues is identified, the complaint should be process as a quality of care issue.

SECTION IV. SURVEY CONCLUSION

The Department has completed its non-routine medical survey of Kaiser Health Plan and has determined that the Plan has violated Section 1370 of the Act and corresponding regulations pertaining to peer review and oversight of QM activities. The Department has accepted the health plan's corrective action plan addressing system changes to remedy each deficiency. The Department will closely monitor the integration of change over the next several months which will include "no-notice" on-site review of quality of care case files, review and feedback on interim submissions pursuant to the health plan's timeline for correction and concluding in a follow-up survey toward the end of 2008.

A P P E N D I X A

A. TIME LINE FOR COMPLETING CORRECTIVE ACTIONS

In accordance with the Plan's representations, the Plan will submit to the Division of Plan Surveys evidence of the following by the date indicated:

By October 1, 2007:

- The Plan will complete the hiring of a triage nurse (RN) for each Member Service Department and the training of all Member Service Department personnel.

By November 1, 2007:

- Use of revised case screening and referral process for Member Services
- Completion of Northern California system modifications and configuration development.
- Development and implementation of access database for Southern California.
- Complete training related to peer review and department review processes.

By December 1, 2007:

- Use of revised case screening, referral process for Peer Review
- Use of revised criteria, standards and processes related to quality review in the clinical and administrative departments.
- Use of new criteria, standards and processes for the identification and referral of systems issues.

By December 31, 2007:

- Availability of modified MIDAS system to all Northern California medical centers, regional offices for purposes of peer review and department review documentation and reporting.
- Availability of the access database to all Southern California medical centers and regional offices for purposes of peer review and department review documentation and reporting.
- Submit self audit criteria for the medical centers.

After May 2008:

- Subject to Plan Survey verification: Meeting minutes from regional oversight committees, reflecting documented review and evaluation of new Health Plan required content in medical center reports.

February 28, 2008:

- Sample results of self-audits.

After May 2008:

- Subject to Plan Survey verification: Evidence of Health Plan validation audit.
- Subject to Plan Survey verification: Evidence of Content audit of peer review files performed by PMG physicians outside of California.

After October 2008:

- Subject to Plan Survey verification: Evidence of Continuous Readiness Survey.

A P P E N D I X B

B. QUALITY MANAGEMENT SYSTEM OVERVIEW

MECHANISMS FOR HEALTH PLAN REGIONAL OVERSIGHT OF THE QM SYSTEM

The Health Plan's, Service Area Managers and/or Quality Directors, serve on the local Medical Center Quality and Credentialing Committees where provider-specific quality issues are discussed. The Plan representative reports to the respective regional quality committee, the QOC in the North or the SQOC in the South, any serious provider issues they feel are not being addressed and/or of which they feel the Plan should be made aware.

QHIC is responsible for overseeing quality of care and service statewide across all Plan programs. This committee reviews and approves the regional quality committee's quality program descriptions, work plans and evaluations as well as QOC and SCQC minutes and reports. It establishes quality goals, oversees regional performance and investigates allegations of deficiencies in quality.

Plan oversight of the local Medical Centers peer review processes is limited to participation on the individual Medical Center's Medical Executive Committees. There is no formal Plan-level monitoring of the effectiveness of the peer review processes.

Each of the 29 Kaiser Medical Centers has a Quality Management (QM) Program designed to identify, investigate, and take appropriate actions in response to quality of care concerns reported by any of the facilities in the local Medical Center system, such as the hospital's medical and surgical departments, outpatient clinics and medical offices.

IDENTIFICATION OF POTENTIAL QUALITY OF CARE ISSUES

Each Medical Center has a Member Services Department (Member Services) that follows standard procedures in processing enrollee complaints including database entries and creation of case files. Member Services is required to refer quality of care concerns to the QM Department which is responsible for tracking all potential quality of care issues received through:

1. Anonymous compliance hotlines,
2. Inter/intra departmental referrals,
3. Risk management referrals,
4. Patient surveys,
5. Employee surveys,
6. Sentinel events,
7. Potentially compensable events,
8. Significant events,
9. Medical-legal referrals,
10. Issues referred by another practitioner,

11. Utilization management and quality indicators established by each Medical Center service area (e.g., return to operating room, readmission within 30 days, frequent emergency department visits, unexpected death).

QUALITY MANAGEMENT DEPARTMENT STRUCTURE

The QM Department within each Medical Center is responsible for reviewing and arranging for peer review of all potential quality of care concerns. If peer review confirms that a quality issue exists, the QM Department is responsible for ensuring implementation of appropriate and timely corrective action and assessing the effectiveness of that action. Because each Medical Center establishes its own protocol for case quality of care investigations, QM Department structures and processes vary widely throughout Kaiser's 29 Medical Centers. The Survey Team found substantial variation in:

1. Staff reporting structure
2. Staff organization within the QM systems, including salary source (e.g., Health Plan, Hospital, Medical Group-South, Medical Group-North)
3. QM Committee structure and membership
4. Processes to identify quality issues including clinical thresholds/triggers that would identify whether a physician needed a focused review
5. Case review processes
6. Case severity gauges, rating models and assignments
7. Methods to identify system problems
8. Case escalation criteria and processes
9. Whether physician histories are considered in peer review and corrective actions
10. Case documentation
11. Decision criteria, designated decision makers and triggers for peer review
12. Internal audits, including whether and how frequently QM processes are audited

Generally, each QM department consists of a Quality Improvement Director, Quality Physician and RN QM coordinators. While each Medical Center tracks potential quality of care concerns in a database, the quality of the database and data fields vary. The northern California Medical Centers all utilize a standard database, the Medical Information Data Analysis System (MIDAS). Southern California Medical Centers use a variety of databases; including an Access[®] database developed by one of the local Medical Centers. The substantial variation in database systems impedes an effective aggregated analysis of system issues at the Health Plan level.

If the QM Department concludes no quality of care problem exists in the case, it is closed. If the case raises a quality concern, depending upon the Medical Center and/or the severity of the quality issue, responsibility for assigning a corrective action may fall to the clinical department Chief of Service, the QM Department or a committee who has the discretion to handle the matter informally or forward to peer review. The QM Department tracks and trends case review outcomes and reports to the local Medical Center's quality oversight committee. Peer review

results on each physician are compiled in the Provider's Profile, which is provided to the Medical Center's (local level) credentials and privileges committee at the time of re-credentialing.

The QM departments also monitor individual practitioner practices against a list of quality indicators, including the number of;

1. Members filing quality of care and service complaints,
2. External quality of care complaints,
3. Significant events reported,
4. Negative peer review findings, and
5. Medical record delinquency.

Each Medical Center establishes its own thresholds for quality indicators that, if exceeded, will trigger a focused review of the practitioner. If the need for a provider focused review is identified, it is provided as part of the peer review process.

PEER REVIEW

Each Medical Center's QM department has established a peer review system to monitor professional conduct and medical decision-making that utilizes other physicians within the same specialty to review case files for quality issues. Once a physician reviewer accepts a QM case for review, he is responsible to ensure that:

1. The case investigation is completed,
2. The case is assigned a severity level, and
3. The appropriate level of corrective action is developed and reconciled against the medical decision-making and/or conduct issues identified.

The first level of peer review may be conducted by a multi-department committee, a single-department committee (most often the department in which the practitioner works), or one designated physician (generally the Chief of the clinical department or Chief of Service or his/her designee). Cases deemed to be of sufficient severity may undergo a second level of peer review, generally by a committee. The QM departments are responsible to oversee the peer review activities performed by clinical departments.

When peer review determines a case falls below a standard of care, results are sent to the Medical Center's QM Department who is generally responsible for the development, implementation and follow-up of corrective actions. If case review reveals a serious quality issue, the case may be escalated to the Medical Center's Medical Executive Committee (MEC), the highest level Medical Center oversight. Peer review referrals, outcomes, and identified issues are tracked and trended by the QM Department.

PEER REVIEW REFERRAL

The Member Services Departments in the southern California Medical Centers forward cases to the Chief of Service (or designee) assigned to the department cited in the complaint, unless the Chief of Service is directly involved with the care and then the case is referred to the Chief's Medical Director. Member Services also notifies the QM Department of the potential quality issue and forwards copies of investigative forms to the practitioner named in the complaint, soliciting his response to the issue(s) referenced in the complaint. At the end of 14 days, the physician reviewer forwards the completed peer review documents to the Medical Center QM Department for review and approval.

In Northern California, Member Services forwards potential quality of care issues to the Quality Department where the cases are generally screened by an RN coordinator or the Physician Chief of Quality to decide whether a case merits peer review. If so, the case is forwarded to the Chief of clinical service for determination. The review concludes with an assignment of a severity level, routed back to the Quality Department and "closed" in the computer tracking system. Quality Physicians, assigned to and who work in the QM Departments, may review peer review determinations. If disagreement with the assigned severity level exists, the case may be forwarded to an external peer reviewer (e.g., peer reviewer from another Medical Center or outside the Plan).

ASSIGNMENT OF LEVELS OF SEVERITY -- SOUTHERN REGION

In the southern region, medical centers use various severity levels. The following provides an example from one of the medical centers reviewed:

1. "Opportunity for improvement vs. no opportunity for improvement,"
2. "No opportunity for improvement predictable event, opportunity for improvement standard of care not met, and standard of care was met but with learning opportunity," and.
3. "Predictable event/no opportunity to improve care, opportunity to improve care by the practitioner, opportunity to improve care system/process of care related."

ASSIGNMENT OF LEVELS OF SEVERITY -- NORTHERN REGION

While the severity levels are standard among all Northern California medical centers, the criteria used to determine severity level varies. For example, the case review factors constituting an "Improvement Opportunity" in one medical center may not be the same in another. Each center in Northern California, however, uses the same list of severity designations:

- E – Excellent Care: Clinical practice excellent in a difficult case
- 0 – Care Appropriate: Clinical practice acceptable and appropriate
- 1 – Improvement Opportunity: Practice within standard of care (SOC) with opportunity for improvement
- 2 – Significant Deviation: Clinical practice showed significant deviation from SOC
- 3 – Unacceptable Care: Care provided definitely not acceptable

Depending on the process used at the individual Medical Center, severity level 2 and 3 cases may be escalated to the Medical Center's Medical Executive Committee for discussion. Medical Center determinations for Provider Focused Reviews also vary and can be based on the provider's severity level scores, number of complaints and medical-legal referrals (e.g., a single score of "3" or three or more scores of "2" in 24 months.).

A P P E N D I X C

C. SURVEY METHODOLOGY

The Department evaluated the Health Plan's QM processes subject to the Act by:

1. Conducting interviews,
2. Examining Plan documents, and
3. Reviewing case files broadly selected from the Plan's Medical Centers and offices.

To permit an in-depth study of activities, the Department selected four Medical Centers from KPSC and five from KPNC to serve as a representative sample of the Plan's 29 Medical Centers:

Kaiser Permanente Southern California (KPSC)

- Woodland Hills
- Fontana
- Baldwin Park
- West Los Angeles

Kaiser Permanente Northern California (KPNC)

- Sacramento
- San Rafael
- South San Francisco
- Fresno
- San Francisco

1. Interviews

The Survey Team formally interviewed KFHP, KFH, SCPMG and TPMG management and staff to obtain a thorough understanding of Plan policies and procedures related to identification, investigation and resolution of potential quality of care issues. Informal discussions also occurred during the case file review to clarify plan documents and processes, especially when inconsistencies were identified between actual procedures and written policies. The Survey Team also interviewed officers (physician and non-physician) and staff from the nine Medical Center QM Departments listed above to obtain a thorough understanding of the quality review processes used at these locations and the Plan's oversight and response to specific complaints of poor quality of care.

2. Document Review

The Survey Team reviewed regional and local Medical Center quality program descriptions, work plans, and annual evaluations to gain an understanding of how potential quality of care issues are identified, investigated, and resolved. The Team also reviewed policies and written procedures that describe Health Plan and Medical Center processes for quality management,

focusing on those that addressed the identification, investigation, and resolution of potential quality of care concerns. The Team also reviewed a number of reports that the Plan and Medical Centers use to monitor quality of care and assessed committee meeting minutes to determine (a) whether identification, investigation, and resolution of quality of care concerns were appropriate and timely; and (b) whether quality of care issues were reported to the appropriate level relative to the seriousness of the quality issue.

3. Case File Review

The enrollee complaint logs and grievances with a potential quality of care concerns for the period of April 1, 2005 through March 31, 2006 were reviewed. During this time period, there were 27,284 enrollee complaints and grievances with a potential quality of care concern statewide. 7,414 of the 10,851 grievances filed included quality of care concerns relating to medical care provided by clinical staff. The Survey Team randomly selected and examined 79 of these cases. The Department's Help Center log was also used to identify and to select another 84 complaints in which members expressed dissatisfaction with the quality of care received for examination.

To capture cases identified through additional sources (e.g., employee referrals, data analysis), the Survey Team requested a log of all referrals between January 1, 2006 and March 31, 2006 made to the nine Medical Center QM selected for the Survey. The Survey Team selected six to nine cases from each Medical Center's logs, resulting in a total of 65 cases that reflected referrals primarily from risk management, patient safety, and other internal sources (i.e., case met quality indicator established by the service area). This sample was not random.

Finally, the Department reviewed four indexed cases that had come to its attention through the HMO Help Center and 14 complaints/quality referrals from the Kidney Transplant Program. The 14 kidney transplant program complaints were for the period January 2005 through March 2006. In total, the Survey Team reviewed 246 complaint files involving potential quality of care concerns to assess the Plan's handling of these PQMs.

The Plan compiled the following documents and materials related to each of the cases: Communications between the Plan and the enrollee (and/or his/her representatives) whether written, by telephone, e-mail or FAX;

1. Communications between the Plan and the involved provider(s) whether written, by telephone, e-mail or FAX;
2. Documents related to the enrollee's complaint/grievance, including telephone log information;
3. Relevant medical records;
4. Documentation evidencing the Plan's review of the relevant medical records;
5. Peer review documentation, including the Peer Review determination and rationale;
6. Documentation evidencing corrective actions;
7. Meeting minutes of any committees that reviewed the case; and,

8. Other documents that evidencing the Plan's investigation, and resolution of the issue(s).

Due to the more complex and diverse nature of the four indexed cases from the Department's HMO Help Center, these cases were reviewed against questions specific to each case rather than using a standard worksheet. The Department reviewed the remaining 242 complaint/grievance, Help Center, Kidney Transplant Program and QM Department files using a standardized file review worksheet. The worksheet collected descriptive data on the case (e.g., case identification date, level of review, corrective actions requested, etc.) and assessed Health Plan performance on key standards related to quality review and oversight. These key performance standards included:

1. Whether the case was appropriately identified and referred to the QM Department.
2. Whether the case was reviewed by a quality management clinician (RN or MD).
3. Whether the case was examined/reviewed at the appropriate level (i.e., RN, MD, Medical Center committee, Region, Board of Directors depending upon issues and findings).
4. If a problem was confirmed:
 - a) Whether corrective actions were recommended.
 - b) Whether corrective actions were appropriate to the issue.
 - c) Whether corrective actions were initiated and completed.
 - d) Whether follow-up was conducted
5. Whether the case was reviewed in a timely manner.
6. Whether results were communicated to the appropriate level committees/personnel.
7. Whether, overall, the case was handled appropriately.

The Department used seven experienced surveyors/reviewers to perform the case file reviews, including three physicians with extensive clinical experience, managed care administration experience, and experience performing utilization management and quality management review for the Department's routine and non-routine medical surveys; two registered nurses with critical care nursing, managed care and regulatory survey experience; one epidemiologist/QM specialist also conducted file reviews, and a research analyst and a health care management professional to provide quality management and analytical expertise.

Each file was reviewed by two surveyors. If these two surveyors concluded independently that the case revealed significant QM process findings, a third surveyor reviewed the case to validate the first two surveyors' concerns. If all three independent surveyors concluded significant concerns existed, then the file was included in the denominator of QM deficient files.

A P P E N D I X D

D. SUMMARY OF FILES REVIEWED

Type of Case Files Reviewed	
79	Grievances and Appeals
84	Help Center Cases
65	Quality Management Department Potential Quality Issue Database Cases
14	Renal Transplant Center-Specific Complaints, Grievances and Quality Management Department Potential Quality Issue Database Cases
4	Indexed Cases Coming to DMHC through the HMO Help Center

A P P E N D I X E

E. APPLICABLE STATUTES AND REGULATIONS

The following are the specific citations used in this report in identifying the deficiencies.

HEALTH PLAN LEVEL

Deficiency #1: In regard to the Health Plan's oversight of QM activities: The Health Plan failed in "establishing a program to monitor and evaluate the care provided by each contracting provider group [both Medical Centers and Medical Groups] to ensure that the care provided meets professionally recognized standards of practice.

Citations:

Section 1370

Every plan shall establish procedures in accordance with department regulations for continuously reviewing the quality of care, performance of medical personnel, utilization of services and facilities, and costs. . .

Rule 1300.70(b)(2)(C)

The plan's governing body, its QM committee, if any, and any internal or contracting providers to whom QM responsibilities have been delegated, shall each meet on a quarterly basis or more frequently if problems have been identified, to oversee their respective QM program responsibilities. Any delegated entity must maintain records of its QM activities and actions, and report to the plan on an appropriate basis and to the plan's governing body on a regularly scheduled basis, at least quarterly, which reports shall include findings and actions taken as a result of the QM program. The plan is responsible for establishing a program to monitor and evaluate the care provided by each contracting provider group to ensure that the care provided meets professionally recognized standards of practice. Reports to the plan's governing body shall be sufficiently detailed to include findings and actions taken as a result of the QM program and to identify those internal or contracting provider components, which the QM program has identified as presenting significant or chronic quality of care issues.

Deficiency #2: In regard to the Health Plan's delegating its oversight of QM activities to its contracted Medical Centers and Medical Groups: The Plan failed to: (1) "inform each provider [Medical Center and Medical Group] of the plan's QA program, of the scope of that provider's responsibilities, and how it will be monitored by the Plan and (2) "have ongoing oversight procedures in place to ensure that providers [Medical Centers and Medical Groups] are fulfilling all delegated QM responsibilities.

Citation:

Rule 1300.70(b)(2)(G)(1) and (3)

Medical groups or other provider entities may have active quality assurance programs which the plan may use. In all instances, however, the plan must retain responsibility for reviewing the overall quality of care delivered to plan members.

If QM activities are delegated to a participating provider to ensure that each provider has the capability to perform effective quality assurance activities, the plan must do the following:

- (1) Inform each provider of the plan's QM program, of the scope of that provider's QM responsibilities, and how it will be monitored by the plan.
- (3) Have ongoing oversight procedures in place to ensure that providers are fulfilling all delegated QM responsibilities.

Deficiency #3: The Health Plan failed to ensure that [QM] "Reports [from its Medical Centers and Medical Groups] to the plan's governing body [were] sufficiently detailed to include findings and actions taken as a result of the QA [QM] program and to identify those internal or contracting provider components that the QA program has identified as presenting significant or chronic quality of care issues."

Citations:

Section 1370

Every plan shall establish procedures in accordance with department regulations for continuously reviewing the quality of care, performance of medical personnel, utilization of services and facilities, and costs. . .

Rule 1300.70(b)(2)(C)

The plan's governing body, its QM committee, if any, and any internal or contracting providers to whom QM responsibilities have been delegated, shall each meet on a quarterly basis or more frequently if problems have been identified, to oversee their respective QM program responsibilities. Any delegated entity must maintain records of its QM activities and actions, and report to the plan on an appropriate basis and to the plan's governing body on a regularly scheduled basis, at least quarterly, which reports shall include findings and actions taken as a result of the QM program. The plan is responsible for establishing a program to monitor and evaluate the care provided by each contracting provider group to ensure that the care provided meets professionally recognized standards of practice. Reports to the plan's governing body shall be sufficiently detailed to include findings and actions taken as a result of the QM program and to identify those internal or contracting provider components, which the QM program has identified as presenting significant or chronic quality of care issues.

PERFORMANCE OF LOCAL QM FUNCTIONS: PEER REVIEW AND MEDICAL CENTER QM PROGRAMS

Deficiency #1: The Medical Center Peer Review processes are not designed to consistently ensure the “level of care meets professionally recognized standards of practice” and that “quality of care problems are consistently identified and corrected for all provider entities.”

Citations:

Section 1370

Every plan shall establish procedures in accordance with department regulations for continuously reviewing the quality of care, performance of medical personnel, utilization of services and facilities, and costs. . .

Rule 1300.70(a)(4)

. . . The Department's assessment of a plan's QM program will focus on:

(D) the level of activity of the program and its effectiveness in identifying and correcting deficiencies in care.

Rule 1300.70(b)(1)

To meet the requirements of the Act which require plans to continuously review the quality of care provided, each plan's quality assurance program shall be designed to ensure that:

(A) a level of care which meets professionally recognized standards of practice is being delivered to all enrollees;

(B) quality of care problems are identified and corrected for all provider entities;

Deficiency #2: The Medical Center QM programs are not designed to consistently ensure that the “level of care meets professionally recognized standards of practice is being delivered to all enrollees” and “quality of care problems are consistently identified and corrected for provider entities.”

Citations:

Section 1370

Every plan shall establish procedures in accordance with department regulations for continuously reviewing the quality of care, performance of medical personnel, utilization of services and facilities, and costs. . .

Rule 1300.70(a)(4)

. . . The Department's assessment of a plan's QM program will focus on:

(D) the level of activity of the program and its effectiveness in identifying and correcting deficiencies in care.

Rule 1300.70(b)(1)

To meet the requirements of the Act which require plans to continuously review the quality of care provided, each plan's quality assurance program shall be designed to ensure that:

- (A) a level of care which meets professionally recognized standards of practice is being delivered to all enrollees;
- (B) quality of care problems are identified and corrected for all provider entities;

Rule 1300.70(b)(1)

To meet the requirements of the Act which require plans to continuously review the quality of care provided, each plan's quality assurance program shall be designed to ensure that:

- (A) a level of care which meets professionally recognized standards of practice is being delivered to all enrollees;
- (B) quality of care problems are identified and corrected for all provider entities;

A P P E N D I X F

F. TABLE OF ACRONYMS

BOD	Board of Directors
CIWRS	Complaints Integrated Workflow Reporting System
CAP	Corrective Action Plan
EMR	Electronic medical record
ED	Emergency Department
ER	Emergency Room
KFHP	Kaiser Foundation Health Plan, Inc.
KFH	Kaiser Foundation Hospitals
KPNC	Kaiser Permanente Northern California
KPSC	Kaiser Permanente Southern California
KTP	Kidney Transplant Program
MCQC	Medical Center Quality Committee
MEC	Medical Executive Committee
MIDAS	Medical Information Data Analysis System
PQIs	Potential quality issues
QM	Quality Management
QMD	QM Department Director
QHIC	Quality and Health Improvement Committee
SFMC	San Francisco Medical Center
SAM	Service Area Manager
SCPMG	Southern California Permanente Medical Group

SCQC	Southern California Quality Committee
TPMG	The Permanente Medical Group
UCD	University of California at Davis Medical Center
UCSF	University of California at San Francisco Medical Center
UOR	Unusual Occurrence Reporting

PLANS APPENDED STATEMENT

The Plan has appended its response to this Report as authorized under section 1382(d) of the Act. To view that appended plan response, please access the link below:

[**Kaiser's Response to the Department's Report: Oversight of Quality Assurance Programs**](#)