DEPARTMENT OF HEALTH & HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES
Consortium For Quality Improvement and Survey & Certification Operations
Western Consortium – Division of Survey & Certification

Refer to: WCDSC--FOIA--DH (SAN FRANCISCO REGIONAL OFFICE)

February 1, 2008

Vickie Travis, President
The Managed Care Reform Council
P.O. Box 900591
Palmdale, California 93590

Dear Ms. Travis:

This is in response to your Freedom of Information Act request of January 31, 2008 to the Centers for Medicare & Medicaid Services (CMS) for a copy of CMS' October 25, 2007 survey report on Kaiser Foundation Hospital Fresno, the facility's plan of correction, and correspondence associated with the survey.

All records within the scope of your request (i.e. 71 pages) possessed by the San Francisco Regional Office of CMS are hereby released and none are withheld.

Please note that the enclosed plan of correction was not accepted. A new plan of correction is due to CMS on February 8, 2008.

There is no charge for processing this request.

Please let us know if the San Francisco Regional Office of CMS may be of further assistance. You may contact Dan Hersh at (415) 744-3731 for additional information.

Sincerely,

Charlotte Yeh
Acting Regional Administrator

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES
WESTERN CONSORTIUM
DIVISION OF SURVEY AND CERTIFICATION

FILE COPY

January 3, 2008

Administrator
Kaiser Foundation Hospital – Fresno
7300 North Fresno St
Fresno, CA 93720

Re: Medicare Provider Number 05-0710

Dear Administrator:

Hospitals accredited by the Joint Commission on Accreditation of Healthcare Organization (JCAHO) are "deemed" to meet Medicare Conditions of Participation (COPs) with certain exceptions, not pertinent here. See 42 C.F.R. § 488.4 (a). However, if a validation survey results in a finding that the hospital is out of compliance with one or more of the COPs, the hospital will no longer be deemed to meet any COP. See 42 C.F.R. §488 .7(d).

The California Department of Public Health (CDPH), the State Medicare survey agency, reported serious deficiencies from the October 25, 2007 complaint validation survey of your hospital, authorized by this office. Specifically, you do not comply with the following Condition of Participation:

42 C.F.R. 482.12	Governing Body
42 C.F.R. 482.21	QAPI
42 C.F.R. 482.22	Medical Staff

Consequently, effective the date of this letter we are removing your status as a provider deemed to meet Medicare COPs and placing you under the CDPH survey jurisdiction until you demonstrate full compliance. See 42 C.F.R. §488 7(d). This means that the hospital is now subject to all applicable participation and enforcement requirements and may be subject to termination of its Medicare provider agreement.

A description of the deficiencies found by the October 25, 2007 survey is set forth on the enclosed Statement of Deficiencies, Form CMS-2567.

You may submit evidence documenting actions you have taken to correct these deficiencies. Please submit your evidence of correction to address the survey findings to **this San Francisco**

office and the Fresno DO, CDPH, by close of business, within ten (10) days of receipt of this letter.

The evidence of correction is to be entered on the right side of Form CMS-2567, opposite the deficiency, and must be signed and dated by the administrator or other authorized official.

The evidence of correction of each item must contain the following:

1. How the correction was accomplished, both temporarily and permanently for each individual affected by the deficient practice, including any system changes that must be made.
2. The title of position of the person responsible for correction, e.g. Administrator, Director of Nursing or other responsible supervisory personnel.
3. A description of the monitoring process to prevent recurrences of the deficiency, the frequency of the monitoring and the individual(s) responsible for the monitoring.
4. The date when the immediate correction of the deficiency will be accomplished. Normally this will be no more than thirty (30) days from the date of the exit conference.

If we determine that the submission is timely, credible and otherwise acceptable, we may authorize CDPH to conduct a resurvey. If this survey finds that the hospital meets all applicable Medicare Conditions, deemed status will be restored. See 42 C.F.R. §488.7(e). If we do not receive an acceptable, timely submission, or if a resurvey finds that the hospital is not complying with any COP, we will notify you that we are initiating action to terminate the facility's Medicare provider agreement. See 42 C.F.R. §488.7(d). In the meantime, the removal of deemed status does not limit your ability to bill Medicare, nor does it affect JCAHO accreditation.

Copies of this letter are being sent to JCAHO, the CDPH and Medicaid agency.

If you have any questions, please contact Leslie Royall of my staff at 415-744-3417 or Maureen Calacal at 415-744-3727.

Sincerely,

Rufus Arthur, Manager
Hospital and Community Care Operations Branch
Division of Survey and Certification

Enclosure

KAISER PERMANENTE®

Susan A. Ryan
Senior Vice-President/Area Manager
Varoujan Altebarmakian, MD
Physician-in-Chief
Jose J. De Anda
Medical Group Administrator

Kaiser Permanente Fresno Medical Center
7300 North Fresno Street
Fresno, California 93720-2942
(559) 448-4500

January 18, 2008

Rufus Arthur, Manager
Hospital and Community Care Operations Branch
Division of Survey and Certification
Department of Health & Human Services
Centers for Medicare & Medicaid Services
90th 7 Street, Suite 5-300 (5W)
San Francisco, CA 94103-6707

RE: Medicare Provider Number 05-0710
Complaint Number: CA00129602

Dear Mr. Arthur:

Kaiser Foundation Hospital-Fresno is responding to the Statement of Deficiencies received from your office on January 10, 2008. This was follow-up from a CMS Validation Survey conducted at our hospital in October, 2007.

Attached for your review is our response to the Statement of Deficiencies. Preparation and execution of this Plan of Correction does not constitute admission or agreement by Kaiser Foundation Hospital-Fresno of the truth of the facts alleged or conclusions set forth in the Statement of Deficiencies.

Please contact Debrah Prewit, Director of Accreditation Regulation & Licensure, at (559) 448-5997 should you require any additional information. A copy of this report will also be forwarded to the Department of Public Health-Fresno Licensing and Certification office as well as The Joint Commission Office of Quality Monitoring.

Sincerely,

Susan A. Ryan
Hospital Administrator/Sr. Vice-President

cc: Department of Public Health-Fresno
The Joint Commission

Enclosure – Form 2567

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050710	A. BUILDING _____ B. WING _____	10/25/2007

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
KAISER FOUNDATION HOSPITAL - FRESNO	7300 NORTH FRESNO ST FRESNO, CA 93720

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 000	INITIAL COMMENTS The following reflects the findings of the Department of Public Health during a COMPLAINT VALIDATION SURVEY. Complaint Number: CA 00129602 Category: Quality of Care/Treatment Inspection was limited to the specific complaint investigated and does not represent the findings of a full inspection of the facility. Representing the Department of Public Health: Beverly Griffin, RN, HFEN, Everett Davis, M.D.,	A 000	Kaiser Foundation Hospital – Fresno ("Hospital") underwent a CMS Validation Survey from October 18, 2007 through Thursday, October 25, 2007. When asked by the Hospital the reason for this survey, the surveyors stated the survey was initiated in response to an article published in the Los Angeles Times. They stated when articles, such as this appear, it is necessary a regulatory investigation of the event mentioned in the article occurs. This article referenced the death of two infants; one infant expired in 2004; the second infant expired in 2005. Both of these infants' cases were subject to the Hospital's peer review process at the time of their occurrence. The Hospital appreciates the opportunity to respond to the allegations noted in the Statement of Deficiencies. After its review of the allegations, the hospital: 1) has identified information which requires clarification and; 2) will exercise its right to provide this clarification and/or corrections in response to the surveyors' summation. Preparation and execution of this plan of correction does not constitute admission or agreement by Kaiser Foundation Hospital – Fresno of the truth of the facts alleged or conclusions set forth in this Statement of Deficiencies. All exhibits referenced in this Plan of Correction are available on site at the hospital.	
A 043	482.12 GOVERNING BODY The hospital must have an effective governing body legally responsible for the conduct of the hospital as an institution. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body. This CONDITION is not met as evidenced by: Based on staff interviews, credentialing files, and administrative document review; the hospital failed to have an effective Governing Body legally responsible for the conduct of the hospital as an institution as evidenced by: 1. The hospital failed to ensure the governing body verified that the medical staff operated under the medical staff bylaws and the medical staff rules and regulations when the current proctoring was not done as set forth in the Bylaws. (A 48)	A043	**Refer to attached pages 1a through 1 c**	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Susan D. Ryan — TITLE: Hospital Administrator — (X6) DATE: 1/18/08

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

ID Prefix TAG	Providers' Plan of Correction	Lead and Completion Date
A043	The Hospital has an effective Governing Body that is legally responsible for the conduct of the Hospital as an institution. The Hospital has clearly defined roles and responsibilities of its leadership team that identifies the individuals who are responsible for the conduct of the hospital operations. Additionally, the Kaiser Foundation Hospital Board of Directors ("Board"), the Hospital's Governing Body, appointed a new Hospital Administrator with an effective date of August, 2005. The Hospital has a matrix of committees that have functional and operational relationships with accountability to the leadership team, including the Hospital Administrator and Medical Executive Committee (MEC) with escalation of important matters to the Board as required by the Professional Staff Bylaws and consistent with legal requirements. **A043(1) Proctoring Process** The CMS Conditions of Participation (CoP) for Hospitals do not require the performance of proctoring. The CoP require that the Medical Staff has a process to assess the competence of medical staff members. The Medical Staff is accountable to the Hospital Governing Body for assuring that there is a process for assessment of medical staff members' competencies. The KFH Fresno Professional Staff Bylaws, which were approved by the Hospital Governing Body, delineate such processes including the requirement for proctoring in Section H-2. The Hospital has an active Medical Staff that is competent in specialty and subspecialty services provided to its patients. Although proctoring is a part of the process to assure that quality physicians serve on its medical staff, an entire host of activities act as a check and balance to ensure that the most competent and experienced medical staff provide care to patients. Other processes to ensure that all Hospital medical staff are competent were not explored by the surveyors but should be mentioned. The Hospital ensures initial competence for all newly appointed medical staff in a variety of ways. The Hospital has an extensive process for verifying the credentials of initial applicants, as documented both in the Professional Staff Bylaws, Article B and in its credentialing policies and procedures. Each practitioner's file includes documentation of education, training, licensure, past and current practice, and liability history.	08/01/05 Leads: Assistant Administrator Quality & Safety (AAQS), Chief of Quality, Hospital Administrator

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A043	Practitioners are also required to submit evidence to substantiate their request for privileges specific to their practice; e.g. surgeons must provide evidence of cases performed in training or in recent practice at facilities where their affiliation is verified to be in "good-standing". Residency training program directors are asked to verify competence as are peers of the practitioner. Once a practitioner has been granted privileges, a physician member of the hospital clinical department is assigned to provide proctoring and assist with orientation as needed. The proctoring process, which includes medical review, is conducted within the initial 12 months of medical staff membership as required in the Bylaws. No practitioner is advanced from provisional staff status until proctoring has been completed. In addition to the initial evaluation period (Provisional Staff status), the practitioner is also subject to the quality department's ongoing monitoring process, as is every practitioner with hospital privileges, regardless of their length of service on the medical staff. Described below is the redesigned proctoring process, with clear lines of escalation for noncompliance with requirements for proctoring. This process meets the intent of the Bylaws. The surveyor reviewed a list of 90 physician files for evidence of proctoring, not 50 as stated in the report. The number of files without proctoring on file was 45 at the time of the survey. Therefore, the number should have been based on 45 of 90, not 45 of 50 as alleged in the Statement of Immediate measures initiated during the validation survey in October, 2007 include: 1. Reduction of number of physicians with no proctoring in file from 45 out of 90 to 5 as of January 16, 2008. A report on these physicians' proctoring status will be presented at the February, 2008 Credentialing and Privileging (C&P) Committee for review and action. 2. Beginning 10/18/07, a new monitoring process to oversee timely completion of proctoring was implemented. It entails sending monthly updates of progress on proctoring to the Chief of Staff and Assistant Administrator Quality and Safety (AAQS). These updates are reflective of each month's current proctoring activities and include practitioners that are newly appointed to the	10/18/07 02/05/08 10/18/07 and ongoing

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A043	medical staff. 3. Information is also sent to every Department Chief that includes a list of practitioners and their proctoring requirements. 4. A monitoring report related to practitioner proctoring status is sent monthly from the C&P Committee to Medical Executive Committee (MEC). 5. The C & P Committee has responsibility for revising the proctoring process and assuring implementation of the revised process. The revised process was approved by the C&P Committee on 12/4/07 and was approved by MEC on 12/19/07. Implementation began on 12/19/07. 6. The revised process requires a "Proctoring Plan" for each new applicant before granting of temporary privileges. The plan will specify the type of proctoring required. 7. One-on-one education is provided on the revised proctoring process by Medical Staff Office to Chiefs of Departments which currently have practitioners pending completion of proctoring. Assistance will be provided for development of a proctoring plan for each of the practitioners who are pending completion of proctoring. 8. Education will be provided to all chiefs and clinical managers at the physician chief meeting on 1/23/08 to reinforce one-on-one training and promote communication between physicians and hospital clinical managers. **A0043 (1) Monitoring Process:** 1. C&P Committee is responsible for oversight of proctoring process. 2. Proctoring plan will be provided by the Department Chief to the C&P Committee for each applicant before a recommendation is made to grant temporary privileges. 3. Update on status of each individual's proctoring will be provided monthly to respective Department Chief and the C&P Committee.	12/04/07 12/19/07 01/23/08

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A 043	Continued From page 1 2. The hospital failed to ensure that the medical staff was accountable to the governing body for the quality of care provided to two of 23 patients (Patient 1 and 2) when: a. Physician A failed to provide quality of care to two patients during delivery. b. The hospital failed to implement their quality of care policies and procedures. (A49) 3. The hospital failed to ensure the governing body verified one of the criteria for selection to the medical staff was competency when: a. There was no objective evidence of current and timely proctoring in three of 35 credentialing files reviewed. b. Forty five of 50 provisional physicians were not completely and/or timely proctored. (A50) 4. The hospital failed to ensure the governing body appointed a chief executive officer who was responsible for managing the hospital when Physician A was not held accountable to follow High Risk Rounds with Perinatologist administrative guidelines. (A 57) The cumulative effect of these systemic practices resulted in the failure of the hospital to deliver statutorily mandated compliance with the Condition of Participation: Governing Body, CFR §482.12	A 043	**Refer to attached pages 2a through 2f** **Refer to attached page 3a** **Refer to attached page 4a**	
A 048	482.12(a)(4) MEDICAL STAFF - BYLAWS AND RULES The governing body must approve medical staff bylaws and other medical staff rules and regulations.	A 048	**A048: Governing Body-Medical Staff** The surveyor reviewed a list of 90 physician files for evidence of proctoring, not 50 as stated in the report. The number of files without proctoring on file was 45 at the time of the survey. Therefore, the number should have been based on 45 of 90, not 45 of 50 as alleged in the Statement of Deficiencies. **Please refer to Proctoring process as outlined in A043(1).**	Leads: AAQS, Quality Chief

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A043 (2)	**A043(2): Patients 1 and 2** The following demonstrates that the Medical Staff is accountable to the Governing Body and that the peer review actions taken in the cases of Patient 1 and Patient 2 were consistent with the Professional Staff Bylaws and legal requirements that were applicable at the time of the incidents described in this Statement of Deficiency. **2(a).** The cases identified for this Validation Survey occurred in 2004 and 2005. All "significant events" are investigated through department (system process) review, peer review, or both. The department managers and supervisors assist in the investigation and the formulation and implementation of necessary action plans. The review of "significant events" is the accountability of the Risk Management Committee, a multi-disciplinary group of directors, physicians and hospital senior leaders. This committee reviews the findings of the investigation and recommends corrective action plans. The MEC reviews a monthly report of "significant events" submitted by the Chief of Risk, who is a member of the MEC. Individual practitioner concerns are addressed through peer review. The MEC also reviews system issues relevant to patient quality of care and patient safety. Risk management data is reported to the Governing Body through established reporting mechanisms. Listed below is a summary of actions performed by the Hospital and Medical Staff at the time the Quality Department was notified of the cases involving Patient 1 and Patient 2. Each of these cases triggered peer review. Each case, with peer review findings, was reported to the MEC action in 2004 (Patient 1) and 2005 (Patient 2). **Patient 1 Case (January, 2004):** 1. Perinatal Peer Review occurred 02/12/2004, 06/24/2004, 07/28/2004. 2. Peer Review Follow-up to MEC 9/22/2004, 12/07/2004, 12/15/2004. ***Patient 2 Case April, 2005 :*** 1. Reported to Risk Management and identified as a "significant event". Reported to Hospital Leadership team with concurrent referral to Risk Management Committee and Peer Review.	Leads: AAQS, Quality Chief, Quality Director, Assistant Administrator Patient Care Services (AAPCS) 7/28/04 12/15/04 4/22/05

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A043 (2)	**2.** Root Cause Analysis (RCA) completed by Risk Department on 5/19/05 with recommended actions implemented through 12/2005. The surveyor reviewed the RCA documentation and commented on the good work accomplished in follow-up to the event involving Patient 2.	5/19/05
	3. On-call roster responsibilities of Physician A ceased.	05/25/05
	4. Perinatal Patient Safety Project Committee (PPSC) was implemented in 03/01/2005. Multidisciplinary group consisting of staff, physicians and departmental managers. During meetings held from 03/05 through 10/05, issues addressed included but were not limited to: Chain of Command policy reviewed and revised, Perinatal Department and Neonatal escalation algorithms developed and implemented, SBAR communication and Human Factor training completed.	03/01/05 through 10/05
	5. 05/27/05 - Communications from Department Manager, Nursing Executive, and Interim OB Chief to all staff and physicians educating on Patient Advocacy and Chain of Command, enforcement of the Perinatal Department Escalation Algorithm and Request for a Perinatology Consult.	05/27/05
	6. Perinatal Peer Review Meetings occurred on 5/25/2005, 6/09/2005, 7/12/2005.	7/12/05
	7. Peer Review Follow-up to MEC 7/20/2005 and 07/26/2005.	7/26/05
	8. Fetal Heart Monitor "Train the Trainer" for both physicians and RN staff completed in July. 2005.	07/05
	9. Critical Events Training focusing on communications and team effectiveness for staff and physicians completed in 10/05.	
	10. Audited all deliveries which required use of a vacuum delivery system for six months after event in 2005 – no other injury events of this type occurred during this review period.	10/05
	11. Staff received re-education on reporting medical errors via the Responsible Reporting Form (RRFs) or through the OOPS line from 06/05 through 11/05 at staff meetings.	10/31/05
	12. Vacuum Assisted Delivery Policy revised and education completed by 11/05.	11/05
	13. The current OB inpatient chief was designated by the Interim Department Chief to lead performance improvement activities with departmental manager in 2005 (Also serves as one of the co-chairs of Perinatal Service Performance Improvement Committee).	11/05
	14. Departmental Structure Standards updated 12/06. Section 2(F) – Consultation of Medical Staff outlines responsibilities of consulting and on-call physicians.	12/06

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A043 (2)	**15.** A new Vacuum Assisted Delivery Perinatal Services Policy revised, effective 03/07. Staff educated on revisions.	03/07
	16. Physician A's privileges amended and approved by MEC and Kaiser Foundation Hospital Board 4/24/2007. Reports of restriction were made to the Medical Board of California and the National Practitioner Data Bank as required by Professional Staff Bylaws and legal requirements.	04/24/07
	In 2007, the following activities have occurred for staff and physicians to strengthen their knowledge of their responsibilities for reporting and escalating quality of care issues. These activities reflect the Medical Staff and Hospital's ongoing responsibility for assessment and reassessment of quality and peer review processes:	01/07 and ongoing
	1. Peer Review:	
	a. 06/01/07 through 11/30/07 – education to all physicians and administrative leaders on revised Peer Review process implemented 08/07.	11/30/07
	b. 08/06/2007 Revised Peer Review process implemented. This is to ensure the appropriate level of corrective action is developed and reconciled against the medical decision-making and/or conduct issues identified.	08/06/07
	2. Critical Events Training – 10/23/07 through 10/25/07 (This was scheduled prior to the Validation Survey). Perinatal staff and physicians participated with primary goal of improving communication and team effectiveness. Exercises included training on emergency delivery techniques.	10/25/07
	3. Highly Reliable Surgical Team (HRST) program implemented in 08/07 – Perinatal Services physicians and staff participating.	08/07 and ongoing
	Primary goals: Implement standardized communication techniques in every OR, every procedure, every day.	11/30/07
	4. Responsible Reporting Forms (RRF). Training and reporting of quality concerns and/or medical errors. Staff are continually re-educated on the importance of reporting medical errors and/or quality of care concerns via RRF reporting tools or utilizing the OOPS line for a verbal message. Data indicators, such as shift, care provider, outcomes, human factors, etc., are entered and tracked in the Risk database. Trends are reviewed, analyzed and presented to the Operations Performance Improvement Committee (OPIC) and MEC for review and action at least 4 times a year.	Ongoing

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A043 (2)	**5**. Significant Event education and reporting (including SB 1301, 1312). Education to physicians occurred 5/24/07 and 8/2/097 for SB 1301/1312 reporting guidelines. Additional education to staff at leadership, departmental and staff huddles to increase awareness for reporting requirements. Significant Event report presented at MEC each month by Chief of Risk Management.	08/02/07 and ongoing
	6. CME presentations – sample topics: Peer Review Training (6/26/07, 6/29/07, 7/31/07, 9/12/07, 10/17/07, 11/28/07) Patient Provider Interaction (3/15/07, 10/11/07, 10/18/07), Language Services to Support Quality Care (4/20/07), Safety Training (5/18/07, 5/25/07, 6/8/07), EMTALA annual review (8/10/07), Hospital Reporting Requirements (5/24/07, 8/2/07).	ongoing
	2.(b) The Hospital's Quality Program assesses and continuously improves the care and services the Hospital delivers to patients. The Hospital has a systematic, integrated approach to planning, designing, measuring, assessing, and improving the quality of care and services provided to patients. Performance improvement activities are prioritized by using criteria that include but are not limited to: Clinical Quality, Service and Access, Patient Safety, Risk Management, Performance Gaps, and High Volume Diagnoses and Procedures. Participation in performance improvement activities is multidisciplinary. Prior to July, 2007, the Quality Program held meetings one day a month (Quality Day) with a problem-focused agenda that involved the review of specific quality indicators on a rotating basis. Quality workgroups were assigned if system issues were recognized that required action.	ongoing
	Beginning July, 2007, the Quality Program was redesigned to enhance processes to identify system issues and provide corrective actions that could impact a variety of hospital departments on a more continuous basis. The Quality Program reports to the Operations Performance Improvement Committee (OPIC) which includes Hospital leadership and Medical Staff leaders. The OPIC reports its actions and recommendations directly to the MEC on a monthly basis. The MEC is accountable for reporting its activity to the Board through existing reporting mechanisms. As part of the Quality Program, the Quality Department staff completes an annual evaluation	07/07 and ongoing

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A043 (2)	of the previous year's Quality Program work plan and identifies areas of focus for the upcoming year. The Hospital offered to present the information described above with the surveyors during the October visit - the surveyors' schedules did not allow the opportunity for the Hospital to present the information at that time. Additional information about the redesigned Quality Program process is described below. Beginning in August, 2007, the Quality Program oversees the work of three service line performance improvement committees that report to the Operations Performance Improvement Committee (OPIC), a multi-disciplinary committee which includes Hospital leadership and Medical Staff Leaders. OPIC reports monthly on quality activities to the MEC. The three service line committees are: 1) Perinatal Service Line Performance Improvement Committee; 2) Surgical Service Line Performance Improvement Committee; 3) Medical Service Line Performance Improvement Committee. The purpose of these committees is to implement and maintain effective and efficient operational systems to ensure patient safety and quality improvement. Each of the service committees has defined quality indicators and areas of focus with action plans developed and implemented. Data are assessed for compliance and quality improvement. Results of action plans are tracked and reported to leadership to ensure the Hospital's quality goals are being met. If barriers to compliance in implementing action plans cannot be resolved by the service line committee, the issue is referred to OPIC for resolution. The Quality Program utilizes a variety of sources for monitoring hospital performance and identification of areas for improvement, including but not limited to: concurrent observational audits, medical record review, retrospective audits, patient care indicators, incident reports, infection control reports, and survey and/or complaint feedback from patients, staff and physicians. The program's assessment process is designed to secure information about patient outcomes, hospital	08/07

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A043 (2)	practice patterns, and quality of care performance. The information is evaluated and analyzed to drive efforts to improve patient care by: 1) determining if quality indicators are being met and sustained; 2) identifying barriers impacting performance improvement if quality indicators are not being met; 3) determining what corrective actions need to occur to resolve issues and improve patient care outcomes if system issues exist and; 4) sharing best practices among the service lines to achieve quality goals.	

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A043 (3)	**A043(3) Selection Criteria for Competency** **Please refer to Proctoring process as outlined in A043(1).** Evidence of proctoring or of plan for completion of proctoring/verification of initial competency is present in every physician's credentials file. The surveyor reviewed a list of 90 physician files for evidence of proctoring, not 50 as stated in the report. The number of files without proctoring on file was 45 at the time of the survey. Therefore, the number should have been based on 45 of 90, not 45 of 50 as alleged in the Statement of Deficiencies.	Leads: AAQS, Quality Chief

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A043 (4)	**A043(4) Hospital Chief Executive Officer** The Hospital disputes this finding. There has been a Hospital Administrator since KFH Fresno commenced hospital operations in February 28, 1995. The current Hospital Administrator was appointed by the Board effective August 1, 2005. The Hospital Administrator is responsible for managing the Hospital. The "High Risk Rounds with the Perinatologist" memo is neither a Hospital or Medical Staff policy nor guideline as identified by the surveyor in the Statement of Deficiencies. The memo did not describe, nor was related to, the practitioner's privileges. The memo did not require notice, review or approval by the Hospital Administrator. Such a physician-to-physician memo does not require discussion with or the involvement of the Hospital Administrator. The memo from the Interim Chief of the Department to the practitioner explained the process that the nursing staff should use to contact the practitioner for orders and consultative services. The physician did not fail to make rounds as alleged in the Statement of Deficiencies because no such rounds with the Clinical Nurse Specialist were required as a condition of his practice.	Leads: AAQS, Quality Chief 08/01/05

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NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
KAISER FOUNDATION HOSPITAL - FRESNO	7300 NORTH FRESNO ST FRESNO, CA 93720

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A 048	Continued From page 2 This STANDARD is not met as evidenced by: Based on staff interviews and administrative document review; the hospital failed to verify that the medical staff operated under the medical staff bylaws, rules and regulations that had been approved by the governing body when: 45 of 50 provisional physicians proctoring was not done as set forth in the Bylaws, and three out of 35 credential files reviewed were inadequate and/or incomplete as set forth in the Bylaws when they failed to conduct appraisals. These failures placed patients at a potential risk of receiving care that was not in accordance with the medical staff bylaws and medical staff rules and regulations. Findings: On 10/18/07 at 4:45 p.m., during an interview with Physician D and Physician E, both stated that 45 of the 50 provisional (temporary) physicians on the medical staff roster had no documented evidence of proctoring (supervision) in their credential (met certain criteria by licensure) files. They both also stated that the current proctoring process was not in accordance with the process set forth in the The Bylaws of the Professional Staff for Kaiser Foundation Hospital. Physician D and Physician E stated that the current proctoring process did not allow for the assessment of competency in a timely manner as set forth in the Bylaws. The Bylaws contained documentation under Section H-2 that "the initial evaluation shall be for a period of one (1) year, unless extended by the Credentials and Privileges Committee for an additional period of up to one	A 048		

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A 048	Continued From page 3 year upon a determination of good cause. The general provisions of the hospital's proctoring protocol contained similar documentation regarding time frames that were not followed. On 10/18/07, the administrative document titled "The Bylaws of the Professional Staff for Kaiser Foundation Hospital" was reviewed. The Bylaws stated on page 57, I-1, "A. In addition to these Bylaws, the Professional Staff shall adopt such Rules and Regulations as may be necessary or desirable for the proper delivery of health care in the Hospital. B. Each department may establish policies and procedures for its specialized practice. They shall be consistent with the Bylaws and Rules and Regulations of the Professional Staff, and shall be subject to the approval of the Executive Committee." On 10/18/07, the Bylaws of the Professional Staff for Kaiser Foundation Hospital states on page 6, C 4, " To qualify for and continue membership on the Professional Staff a practitioner must: Perform a sufficient number of cases, and have sufficient patient care contact within the Hospital or another community hospital or health care setting to permit the Professional Staff to assess the applicant's current competency for all clinical privileges, whether requested or already granted, including completion of initial evaluation and proctoring as specified in Section H-2." The Bylaws of the Professional Staff for Kaiser Foundation Hospital contained documentation on page 38, D-3, " Chief of Staff. The Chief of Staff shall provide for general supervision of the medical care of Hospital patients. He or she shall be an ex officio member, with voice and vote, of all committees and shall perform such duties as	A 048		

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A 048	Continued From page 4 the Professional Staff or the Executive Committee shall designate. He or she shall appoint with Executive Committee approval, the chairpersons and committee members of all standing and special Professional Staff committees, except where otherwise provided by these Bylaws and Rules and Regulations. He or she shall act in coordination and cooperation with the Hospital Administration in matters of mutual concern within the hospital. He or she shall represent the views, policies, needs and grievances of the Professional Staff to the Hospital Administrator and the Board of Directors. He or she shall impart the policies of the Board of Directors to the Professional Staff in professional and public relations. The Chief of Staff shall supervise enforcement of these Bylaws and Rules and Regulations." On 10/22/07 at 8:00 a.m. during an interview with Staff I and Administrator H, Staff I produced a Summary of Progress on Proctoring dated 10/25/07 which established that 45 out of 50 provisional physicians had no documented evidence of current and timely proctoring in their credential files. Both Staff I and Administrator H stated that the proctoring was not being done as set forth in the The Bylaws of the Professional Staff for Kaiser Foundation Hospital. Staff I and Administrator H stated that the current proctoring process that was in use could not be found within the Bylaws. Both Staff I and Administrator H stated during the interview that the physician in chief, the chief operating officer of the hospital, members of the Executive Committee, and members of the Credentials and Privileges Committee were aware of the fact that proctoring was not being done as set forth in the the Bylaws. They were also aware of the fact that the current	A 048		

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A 048	Continued From page 5 proctoring process that was in use could not be found within the Bylaws. On 10/22/07 at 9:00 a.m. during an interview, Physician F stated he was a member of the Credentials and Privileges Committee. He stated he was aware of the fact that the current proctoring was not being done as set forth in the The Bylaws of the Professional Staff for Kaiser Foundation Hospital and he was also aware of the fact that the current proctoring process that was in use could not be found within the Bylaws. He stated that the Department chiefs within the hospital who were responsible for the proctoring and reporting to the appropriate committees were not in compliance with the Bylaws.	A 048		
A 049	482.12(a)(5) MEDICAL STAFF - ACCOUNTABILITY The governing body must ensure that the medical staff is accountable to the governing body for the quality of care provided to patients. This STANDARD is not met as evidenced by: Based on staff interview and administrative document review, the hospital failed to ensure that the medical staff was accountable to the governing body for the quality of care provided to two of 23 patients (Patient 1 and 2) when: 1. Physician B failed to provide quality of care to two patients during delivery which caused harm to them.	A 049	**A049: Governing Body-Medical Staff** The Statement of Deficiencies should have identified Physician A as the cited physician, not Physician B. **Please refer to "A043(2) Patients 1 and 2" above.** **1.** Physician A's privileges were restricted by the MEC and the restriction was subsequently approved by the Board 04/27/2007. Reports of the restriction were made to the Medical Board of California and the National Practitioner Data Bank. **2.** The Hospital and Medical Staff demonstrate accountability to the Board for quality of care by implementing the following policies: a) Chain of Command policy b) LDRP Escalation Algorithm guideline c) Vacuum Assisted Delivery policy	Leads: AAQS, Quality Chief, AAPCS 04/27/07

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A 049	Continued From page 6 2. The hospital failed to implement their quality of care policies and procedures. This failure resulted in negative health care outcomes. Findings: 1. On 10/23/07 at 9:30 a.m., Physician B was interviewed. Physician B worked with Physician A for ten years. Quality issues regarding poor judgment were identified in 2004 and Physician A was asked to improve. Physician B stated that Physician A only got upset and accused others. Physician B stated that Physician A continued to have problems, but "the governing body choose to reorganize the whole quality department instead of dealing with the deficiencies." Physician B stated that the quality department reviewed the delivery of Patient 1's baby in 2004 when the baby died months later, and found there was a "significant deviation" in Physician A's "competency". Physician B stated the quality department reviewed the delivery of Patient 2's twin babies in 2005 when the second twin was pronounced dead 22 minutes after birth, and found it to be a "Sentinel Event" (an indicator that should only occur on a rare basis in a hospital) with "adverse action" (caused harm). Physician B stated that the quality of care delivered by Physician A for Patient 1 in 2004 was unacceptable. Physician B stated that Physician A's general Obstetrical skills were poor. Physician B stated the quality of care delivered by Physician A for Patient 2 in 2005 was also unacceptable. Physician B was alarmed because of Physician A's poor judgement and poor obstetrical skills, but management refused to	A 049	**Please refer to "A043(2) Patients 1 and 2" above for corrective actions taken after the incident described in 2005 in the Statement of Deficiencies.** The surveyor reviewed the Root Cause Analysis (RCA) documentation and commented on the good work accomplished in follow-up to this event involving Patient 2.	

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A 049	Continued From page 7 listen. Physician B had no knowledge that the governing body did anything between 2004 and 2005 about the quality of care provided by Physician A. On 10/23/07 at 3:10 p.m., an interview was conducted with Staff 1. Staff 1 worked with Physician A for ten years. There were letters of complaints from the staff regarding Physician A as early as 1998 to the present time. Staff 1 stated that these letters were sent to the Nurse Executive (NE) at the time. The NE's job was to refer issues to administration and the medical staff. Staff 1 was a supervisor during the time Physician A delivered care to Patient 1 in 2004 and Patient 2 in 2005. Staff 1 was aware that there were quality of care issue regarding the care Physician A provided to both patients. Staff 1 stated that the policy titled "Chain of Command (Conflict Resolution)" in effect in 2004 and 2005 was not followed when quality of care issues were not addressed and resolved. Staff 1 stated that as a supervisor, she was told by staff that Physician A lashed out at the nursery nurse after Patient 2's baby was born dead. Physician A told the nurse that he "Only gave a gentle pull." Staff in the room during the vacuum extraction delivery of Patient 2 in 2005 told Staff 1 that Physician A "pulled with a jerk motion at the end." Staff 1 stated that Physician A violated the vacuum extraction policy and procedure by continuing to use the vacuum extractor on Patient 2's baby beyond what any other Obstetrical doctor would have. After the delivery of Patient 2's twins in 2005, the quality of care issue was brought to the attention of the NE immediately. Physician A was back on call two days after the incident. Staff 1 stated there was a Labor Delivery Recovery Postpartum (LDRP) Escalation Algorithm (set	A 049		

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A 049	Continued From page 8 rules) in place in 2005 when Patient 2's twins were delivered. Staff 1 stated that staff present during Patient 2's delivery "did not escalate the event" as set forth in the Algorithm when "It was taking too long" and the "vacuum pulls" were inappropriate. After the incidents during delivery with Patient 1 and 2, Staff 1 stated there was no feedback given about any effort that "Quality" addressed Physician A. 2. The QA program failed to ensure the following quality of care policies and procedures were implemented: a. On 10/23/07, the Chain of Command (Conflict Resolution) effective in 2004 and 2005 was reviewed. The policy contained documentation under Procedure: 1. When a problem was identified on the unit, the staff involved along with the physicians and other care providers would work towards resolution. 2. If the staff were unable to resolve the issue, the unit management team would be contacted to assist. 3. The unit management staff would then assess the situation and assist in solving the problem. 4. If the unit management staff was unable to resolve the problem, the nursing supervisor would be contacted. 5. The nursing supervisor would then assess the situation and assist in solving the problem. 6. If the nursing supervisor was not able to resolve the problem, the service director or nurse executive would be contacted for assistance. If the problem continued to be unresolved, the hospital administrator would be contacted. A medical staff call resource was available for assistance but was to only be called by the	A 049		

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A 049	Continued From page 9 nursing supervisor or On-Call administrator. The procedure was not followed when administration and the medical staff failed to address and resolve problems regarding Physician A's behavior and competency during the deliveries of Patient 1 and 2's babies when they were identified. b. On 10/2307, the "LDRP (Labor Delivery Recovery Postpartum) Escalation Algorithm" guideline effective in 2005 was reviewed. The guideline contained documentation as follows: 1. For clinical practice issues, the Licensed Vocational Nurse/ Registered Nurse (LVN/RN) was to confer with peers and or the Clinical Nurse Specialist (CNS). 2. Then the Medical Doctor (MD) on-call was to be contacted. 3. Then then the consult with back-up MD was to be contacted. 4. Then Obstetrical (OB) Nursing Manager was to be contacted. 5. Then if the nursing manager was unavailable, the RN was to go upward to the OB Chief and to the Assistant Physician In Chief (APIC) or MD Administrator on-call. 6. Before the OB Chief was notified, the Service Director could be notified and the Perinatologist could be consulted as needed. The Algorithm was not followed during the delivery of Patient 2's twins when staff present during Patient 2's delivery "did not escalate the event" as set forth in the Algorithm when too much time elapsed between vacuum pulls and delivery, and the vacuum pulls were inappropriate.	A 049		

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A 049	Continued From page 10 c. On 10/23/07, The Vacuum Assisted Delivery policy dated March of 2004 was reviewed. The purpose was to clarify indications of use, procedure and contraindications of vacuum assisted deliveries. When to discontinue the use of the vacuum was as follows: 1. If progress was not being made with each contraction. 2. If the extractor becomes disengaged (disconnected) 3 times. 3. If 20 to 30 minutes elapsed without success. 4. If trauma (injury) of fetal scalp was observed. The policy was not being followed when progress was not made with each contraction, over two hours elapsed between the start of the use of the vacuum until delivery, and when injury was noted to the fetal scalp at birth. On 10/25/07 at 8:50 a.m., an interview was conducted with Administrator G and Physician C. Administrator G and Physician C stated they were aware of the incident in 2004 with Patient 1 where there was complete disorder in the operating room, prolonged labor with an untimely progression to a cesarean section, and no guidance for an escalation of concerns. They were also aware of the incident in 2005 with Patient 2's twin deliveries where there was complete disorder in the operating room, a prolonged vacuum extraction delivery of a non-viable twin , and quality of care policies and procedures that were not followed when concerns about Physician A were not communicated appropriately and/or addressed and resolved effectively.	A 049		
A 050	482.12(a)(6) MEDICAL STAFF - SELECTION	A 050		

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A 050	Continued From page 11 CRITERIA The governing body must ensure that criteria for selection are individual character, competence, training, experience, and judgement. This STANDARD is not met as evidenced by: Based on staff interviews, credentialing file reviews, and administrative document review; the hospital failed to verify that the governing body ensured that criteria for selection of both new medical staff members and selection of current medical staff members for continued membership must be based on competence when: 1. Three of 35 credentialing files were reviewed and there was no documented evidence of current and timely proctoring when the hospital failed to conduct appraisals. 2. 45 of 50 provisional physicians were not completely and/or timely proctored. This failure placed patients at risk of receiving poor health care from incompetent medical staff members. Findings: 1. On 10/18/07 at 3:00 p.m. credential files were reviewed with Staff I. Three files out of an initial 35 files were found to be inadequate and/or incomplete.	A 050	**A050: Governing Body-Medical Staff** The surveyor reviewed a list of 90 physician files for evidence of proctoring, not 50 as stated in the report. The number of files without proctoring on file was 45 at the time of the survey. Therefore, the number should have been based on 45 of 90, not 45 of 50 as alleged in the Statement of Deficiencies. The CMS Conditions of Participation (CoP) for Hospitals do not require the performance of proctoring. The CoP require that the Medical Staff has a process to assess the competence of medical staff members. The Medical Staff is accountable to the hospital governing body for assuring that there is a process for assessment of medical staff members' competencies. The KFH Fresno Professional Staff Bylaws which were approved by the Hospital Governing Body, delineate such processes including the requirement for proctoring in Section H-2. The Hospital has and continues to maintain an active medical staff that is competent in specialty and subspecialty services provided to its patients. As stated above, Section H-2 of the Professional Staff Bylaws states the requirement for proctoring. Although proctoring is a part of the process to assure that quality physicians serve on its medical staff, an entire host of activities act as a check and balance to ensure that a competent and experience medical staff provides care to patients. **Refer to A043(1) Proctoring Process for additional information.** The Hospital continues to ensure that criteria for selection of both new medical staff members and selection of current medical staff members for	Leads: AAQS, Quality Chief

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A 050	Continued From page 12 On 10/18/07, the Bylaws of the Professional Staff for Kaiser Foundation Hospital states on page 6, C 4, " To qualify for and continue membership on the Professional Staff a practitioner must: Perform a sufficient number of cases, and have sufficient patient care contact within the Hospital or another community hospital or health care setting to permit the Professional Staff to assess the applicant's current competency for all clinical privileges, whether requested or already granted, including completion of initial evaluation and proctoring as specified in Section H-2." 2. On 10/18/07 at 4:34 p.m., Staff I stated that 45 of 50 provisional physicians on the medical staff roster had no objective evidence of proctoring in their credential files. On 10/18/07 at 4:45 p.m. during an interview with Physician D and Physician E, both stated that 45 of the 50 provisional physicians on the medical staff roster had no objective evidence of proctoring in their credential files. They both also stated that the current proctoring process was not in accordance with the process set forth in The Bylaws of the Professional Staff for Kaiser Foundation Hospital. They both stated that the current process did not allow for the assessment of competency in a timely manner as set forth in The Bylaws. On 10/19/07 at 4:50 p.m., Staff I provided an administrative document titled "Summary of Progress on Proctoring" which was reviewed. The document substantiated that 45 of 50 provisional physicians had inadequate and/or incomplete proctoring.	A 050	continued membership are based on individual character, competence, training, experience and judgment.	

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A 050	Continued From page 13 On 10/22/07 at 8:00 a.m. during an interview with Staff I and Administrator H, Staff I produced The Bylaws of the Professional Staff for Kaiser Foundation Hospital and these were reviewed on 10/18/07. The Bylaws established the fact that 45 out of a total of 50 provisional physicians had no documented evidence of current and timely proctoring in their credential files. (The Bylaws contained documentation under Section H-2 that "the initial evaluation shall be for a period of one (1) year, unless extended by the Credentials and Privileges Committee for an additional period of up to one year upon a determination of good cause." The general provisions of the hospital's proctoring protocol contained documentation regarding time frames of one year that could be extended an additional year that were not followed. Both Staff I and Administrator H stated that the proctoring was not being done as set forth in the the Bylaws. Staff I and Administrator H stated that the current proctoring process that was in use could not be found within the Bylaws. Both Staff I and Administrator H stated during the interview that the physician in chief, the chief operating officer of the hospital, members of the Executive Committee and members of the Credentials and Privileges Committee were aware of the fact that proctoring was not being done as set forth in the Bylaws and they were also aware of the fact that the current proctoring process that was in use could not be found within the Bylaws. On 10/22/07 at 8:05 a.m., Physician F was interviewed. Physician F was a member of the Credentials and Privileges Committee. Physician F was aware of the fact that the current proctoring was not being done as set forth in the The Bylaws of the Professional Staff for Kaiser Foundation	A 050		

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A 050	Continued From page 14 Hospital and was also aware of the fact that the current proctoring process that was in use could not be found within the Bylaws. Physician F stated that the Department chiefs within the hospital who were responsible for the proctoring and reporting to the appropriate committees were not in compliance with the the Bylaws.	A 050		
A 057	482.12(b) CHIEF EXECUTIVE OFFICER The governing body must appoint a chief executive officer who is responsible for managing the hospital. This STANDARD is not met as evidenced by: Based on staff interviews and administrative document review, the hospital failed to ensure the governing body appointed a chief executive officer who was responsible for managing the hospital in 2007 when Physician A was not held accountable to follow the guideline titled "High Risk Rounds with Perinatologist." This failure placed patients at risk for receiving poorly managed health care. Findings: On 10/23/07 the High Risk Rounds with Perinatologist guideline was reviewed. Rounding (reviewing) time was to be from 8:30 a.m. to 9:30 a.m., Monday through Friday. Physician A was to notify the Birthing Center on the days not rounding. Upon arrival to the unit, Physician A was to contact Staff 1 or Staff 3 and contact the MD on call.	A 057	**A057: Governing Body-Medical Staff** **Refer to information in A043(4) Hospital Chief Executive Officer.** The Hospital disputes this finding. There has been a Hospital Administrator since KFH Fresno commenced hospital operations in February 28, 1995. The current Hospital Administrator was appointed by the Board effective August 1, 2005. The Hospital Administrator is responsible for managing the Hospital. The "High Risk Rounds with the Perinatologist" memo is neither a hospital or medical staff policy nor guideline as identified by the surveyor in the Statement of Deficiencies. The memo did not describe, nor was related to, the practitioner's privileges. The memo did not require notice, review or approval by the Hospital Administrator. Such a physician-to-physician memo does not require discussion with or the involvement of the Hospital Administrator. The memo from the Interim Chief of the department to the practitioner explained the process that the nursing staff should use to contact the practitioner for orders and consultative services. The physician did not fail to make rounds as alleged in the Statement of Deficiencies because no such rounds	Leads: AAQS, Quality Chief 08/01/05

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A 057	Continued From page 15 On 10/23/07 at 3:30 p.m., Staff 3 stated Physician A did not consistently arrive on the unit at 8:30 a.m., did not consistently make his presence known or contact Staff 3 or Staff 1, and did not consistently contact the (Medical Doctor) MD. Staff 3 stated Perinatology activities with Labor Delivery Recovery Postpartum (LDRP) included: reviewing policies and procedures, routinely reviewing and updating complicated patients prior to delivery, completing a comprehensive medical plan of care for the patient's clinical record, and updating new practice issues and changes twice monthly for the Perinatal Patient Safety Project. Staff 3 stated Physician A did not review policies and procedures. Staff 3 stated Physician A did not intermittently review and update complicated patients prior to delivery or consistently complete a comprehensive medical plan of care for the patient's clinical record. Staff 3 stated Physician A did not update new practice issues and changes twice monthly. On 10/24/07 at 8:30 a.m. during an interview, Administrator G was shown a copy of the administrative guideline titled "High Risk Rounds with Perinatologist" that was put in place to ensure the perinatal clinical nurse specialist could make rounds with Physician A. Administrator G stated acknowledgement of what it represented and that the high risk rounds guideline was put in place. Administrator G did not know that Physician A had been non-compliant with the high risk rounds guideline. Administrator G (senior vice president/area manager) stated that he was the responsible individuals who represented Medical Staff and governing body. Administrator G went on to say that Staff K (Director Quality Management) was the responsible individual within the administration who should have known	A 057	with the Clinical Nurse Specialist were required as a condition of his practice.	

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A 057	Continued From page 16 directly through the Quality Assurance Performance Improvement (QAPI) process that Physician A was non-compliant with the high risk rounds guideline. Administrator G stated that Staff K should have been the responsible individual within the administration to convey that information directly to the governing body. Administrator G acknowledged that there was no excuse for not being informed of Physician A ' s non-compliance with the high risk rounds guideline. On 10/24/07 at 9:05 a.m., during an interview with Physician C and Administrator G, both stated that they were the responsible individuals who represented Medical Staff and governing body, respectively. They both acknowledged that there was a high risk rounds guideline that had been put in place to ensure the perinatal clinical nurse specialist could make rounds with Physician A as he saw consult patients from 8:30 a.m. to 9:30 a.m., Monday through Friday. Both Physician C and Administrator G agreed that it was important to have such guidelines, and it was important that Physician A comply with the high risk rounds guideline without exception. Both Physician C and Administrator G replied that they were unaware of the fact that Physician A was non-compliant with the high risk rounds guidelines when it was brought to their attention. Physician C and Administrator G stated that Physician A's non-compliance represented a failure of the medical staff to be well organized and accountable to the governing body for the quality of medical care provided to the patients when Physician A's non-compliance was not addressed by the Medical Staff and governing body.	A 057		

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A 057	Continued From page 17 On 10/24/07 at 9:15 a.m., during an interview, Staff K acknowledged being the responsible individual within the administration who should have known about Physician A's non-compliance with the high risk rounds guideline. Staff K also acknowledged being the responsible individual within the administration who should have conveyed directly to Administrator G that Physician A was non-compliant with the high risk rounds guideline. Staff K stated that there was no excuse for not conveying the information regarding Physician A's non-compliance with the high risk rounds guideline to Administrator G.	A 057		
A 263	482.21 QAPI The hospital must develop, implement and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program. The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.	A 263	**A263: Quality & PI** The Hospital has, and has always had, an effective, ongoing, hospital-wide, data driven, legally compliant Quality Assessment and Performance Improvement (QAPI) Program since it began operations on February 28, 1995. The twelve alleged events or problems identified in Tag A263 in the Statement of Deficiencies do not indicate that the Hospital has an ineffective QAPI Program. As part of its' ongoing QAPI Program, the Hospital monitors for opportunities for improvement to enhance patient safety and quality of care. Because of the processes in place for monitoring in the QAPI Program, the Hospital identifies, investigates, and implements appropriate corrective actions and process improvements to enhance patient care and safety. The response to the noted allegations in the Statement of Deficiencies are as follows:	Leads: AAQS, Quality Chief

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A 263	Continued From page 18 This CONDITION is not met as evidenced by: Based on staff interview and clinical and administrative document review, the hospital failed to develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven Quality Assessment Performance Improvement (QAPI) program. In addition, the hospital failed to verify its governing body made sure that the QAPI program reflected the complexity of the hospital's organization and services: involved all hospital departments and services, focused on indicators related to improved health outcomes, and prevented and reduced medical errors as evidenced by: 1. Refer to A48. The hospital failed to ensure the medical staff enforced bylaws to carry out its responsibilities when: a. Three out of 35 credentialing files reviewed were inadequate and/or incomplete. b. The current proctoring was not done as set forth in the Bylaws. 2. Refer to A49. The hospital failed to ensure that the medical staff was accountable to the governing body for the quality of care provided to two of 23 patients (Patient 1 and 2). 3. Refer to A50. The hospital failed to ensure the governing board used competence as one of the criteria for selection to the medical staff when there was no objective evidence of current and timely proctoring in three out of 35 credentialing files reviewed. 4. Refer to A57. The hospital failed to ensure the governing body appointed a chief executive officer who was responsible for managing the hospital when Physician A was not held accountable for not following the administrative	A 263	**A263-1:** The CMS CoP for Hospitals do not require the performance of proctoring. The CoP require the Medical Staff to have a process to assess the competence of medical staff members. The Medical Staff is accountable to the hospital governing body for assuring that there is a process for assessment of medical staff members' competencies. The KFH Fresno Professional Staff Bylaws, which were approved by the Hospital Governing Body, delineate such processes including the requirement for proctoring in Section H-2. The Hospital has an active medical staff that is competent in specialty and subspecialty services provided to its patients. **Please refer to "A043(1) Proctoring Process" as outlined above.** **A263 – 2:** **Please refer to "A043(2) Patients 1 and 2" as outlined above.** **A263-3:** **Please refer to "A043(1) Proctoring Process" as outlined above.** **A263 – 4:** **Please refer to "A043(4) Chief Executive Officer as outlined above.**	Leads: AAQS, Quality Chief, AAPCS Leads: AAQS, Quality Chief Leads: AAQS, Quality Chief

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A 263	Continued From page 19 guideline titled "High Risk Rounds with Perinatologist." 5. The hospital failed to ensure that specific program requirements were met when a Quality Assessment and Performance Improvement (QAPI) Program was not established to show: a. Once the QA program had identified there was a concern with Physician A's competency, they failed to provide evidence the concern was resolved in two of 23 patients (Patient 1 and 2). b. The QA program failed to ensure the staff implemented their quality of care policies and procedures. (A264) 6. The hospital failed to have a QAPI program which showed measurable improvement indicators for which there was evidence that it would improve health outcomes when the hospital failed to look at the care given to two out of 23 patients (Patient 1 and 2) with a quality view. (A265) 7. The hospital failed to have a QAPI program which showed measurable improvement indicators for which there was evidence that it would improve health outcomes and identify and reduce medical errors when an effective process of notification of negative outcomes was not put in place to ensure patient safety. (A266) 8. The hospital failed to ensure its governing body (or organized group or individual who assumed full legal authority and responsibility for operation of the hospital), medical staff, and administrative officials were responsible and accountable for ensuring that an on-going program for quality improvement was defined, implemented, and maintained when Physician A	A 263	**Refer to attached page 263(5) a** **Refer to attached page 263(6) a** **Refer to attached page 263(7) a** **Refer to attached page 263(8) a**	

ID Prefix TAG	Providers' Plan of Correction	Lead and Completion Date
A263 (5)	A263-5: The Hospital has, and has always had, an effective, ongoing, hospital-wide, data driven, legally compliant Quality Assessment and Performance Improvement (QAPI) Program since it began operations on February 28, 1995. As part of its' ongoing QAPI Program, the Hospital monitors for opportunities for improvement to enhance patient safety and quality of care. Because of the processes in place for monitoring in the QAPI Program, the Hospital identifies, investigates and implements appropriate corrective actions and process improvements to enhance patient care and safety. In 2005, the Hospital QAPI Program identified and addressed the alleged concerns. The cases identified occurred in 2004 and 2005. Physician A's privileges were restricted by MEC and the restriction was approved by the Board 4/24/2007. Reports of restriction were made to the Medical Board of California and the National Practitioner Data Bank as required by Professional Staff Bylaws and legal requirements. **Please refer to "A043(2) Patients 1 and 2" as outlined above for further details related to the Hospital's response.**	Leads: AAQS, Quality Chief, Quality Director 05/19/05 04/24/07

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A263 (6)	A263 – 6: The Hospital has an effective, ongoing, hospital-wide, data driven, legally compliant Quality Assessment and Performance Improvement (QAPI) Program since it began operations on February 28, 1995. The alleged events or problems identified in the Statement of Deficiencies do not indicate that the Hospital has an ineffective QAPI Program. As part of its ongoing QAPI Program, the Hospital monitors for opportunities for improvement to enhance patient safety and quality of care. Because of the processes in place for monitoring in the QAPI Program, the Hospital identifies, investigates, and implements appropriate corrective actions and process improvements to enhance patient care and safety. The Hospital's QAPI process enables the root cause analysis and response to ensure improvements in patient quality of care and patient safety. **Please refer to "A043(2) Patients 1 and 2" as outlined above for further details related to the Hospital's response.**	Leads: AAQS, Quality Chief, Quality Director

ID Prefix TAG	Providers' Plan of Correction	Lead and Completion Date
A263 (7)	**A263 – 7:** The Hospital has, and has always had, an effective, ongoing, hospital-wide, data driven, legally compliant Quality Assessment and Performance Improvement (QAPI) Program that identifies and reduces medical errors and includes an effective process of notification of negative outcomes. **See "A266: Risk Management Process" as outlined below.**	Leads: AAQS, Quality Chief, Risk Director

ID Prefix TAG	Providers' Plan of Correction	Lead and Completion Date
A263 (8)	**A263 – 8:** The Hospital disputes this finding. The "High Risk Rounds with the Perinatologist" memo is neither a hospital or medical staff policy nor guideline as identified by the surveyor in the Statement of Deficiencies. The memo did not describe, nor was related to, the practitioner's privileges. This physician-to-physician memo was not a policy or guideline. The memo from the chief of the department to the practitioner explained the process that the nursing staff should use to contact the practitioner for orders or consultative services. The physician did not fail to make rounds as alleged in the Statement of Deficiencies because no such rounds with the Clinical Nurse Specialist were required as a condition of the exercise of the practitioner's clinical privileges.	Leads: AAQS, Quality Chief

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A 263	Continued From page 20 did not follow the administrative guideline titled "High Risk Rounds with Perinatologist." (A310) 9. The hospital failed to ensure its governing body (or organized group or individual who assumed full legal authority and responsibility for operation of the hospital), medical staff, and administrative officials were responsible and accountable for verifying that an on-going program for patient safety included: the reduction of medical errors, was defined, and was implemented and maintained when Physician A did not follow the High Risk Rounds with Perinatologist guideline. (A311) 10. Refer to A340. The hospital failed to ensure the medical staff conducted appraisals of its members when 45 of 50 provisional physicians were not proctored according to the Bylaws. 11. Refer to A347. The hospital failed to ensure the medical staff was well organized and accountable to the governing body for the quality of the medical care provided to the patients when 45 of 50 provisional physicians were not proctored according to the Bylaws. 12. Refer to A951. The hospital failed to provide surgical services consistent with needs and resources. The hospital failed to have policies governing surgical care which were designed to ensure the achievement and maintenance of high standards of medical practice and patient care when the Chain of Command (Conflict Resolution), Labor Delivery Recovery Postpartum (LDRP), and Vacuum Assisted Delivery policies were not followed by Physician A. The cumulative effect of these systemic problems	A 263	**Refer to attached page 263(9) a** **A263 - 10:** **Please refer to "A043(1) Proctoring Process" as outlined above.** **A263 - 11:** Although proctoring is a part of the process to assure that quality physicians serve on its medical staff, an entire host of activities act as a check and balance to ensure that a competent and experienced medical staff provides care to patients. **Please refer to "A043(1) Proctoring Process" as outlined above.** **A263 – 12** **See response to "A951: Surgical Services" as outlined below.**	Leads: AAQS, Quality Chief Leads: AAQS, Quality Chief Leads: AAQS, Quality Chief, AAPCS

ID Prefix TAG	Providers' Plan of Correction	Lead and Completion Date
A263 (9)	**A263 –9:** The Hospital has, and has always had, an effective, ongoing, hospital-wide, data driven, legally compliant Quality Assessment and Performance Improvement (QAPI) Program that identifies and reduces medical errors and includes an effective patient safety processes. The Hospital disputes this finding and the allegation that the Hospital fails to maintain an ongoing program for patient safety that includes processes for the reduction of medical errors. The "High Risk Rounds with the Perinatologist" memo is neither a hospital or medical staff policy nor guideline as identified by the surveyor in the Statement of Deficiencies. The memo did not describe, nor was related to, the practitioner's privileges. The memo from the Interim Chief of the department to the practitioner explained the process that the nursing staff should use to contact the practitioner for orders or consultative services. The physician did not fail to make rounds as alleged in the Statement of Deficiencies because no such rounds with the Clinical Nurse Specialist were required as a condition of his practice **Please refer to "A043(2) Patients 1 and 2" and A266: Risk Management Process as outlined above for further details related to the Hospital's response.**	Leads: AAQS, Quality Chief

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A 264	Continued From page 22 These failures placed patients at risk for medical errors and unsafe patient care practices. Findings: 1. On 10/23/07 at 9:30 a.m., Physician B was interviewed. Physician B worked with Physician A for ten years. Quality issues regarding poor judgment were identified in 2004 and Physician A was asked to improve. Physician B stated that Physician A only got upset and accused others. Physician B stated that Physician A continued to have problems, but "the governing body choose to reorganize the whole quality department instead of dealing with the deficiencies." Physician B stated that the quality department reviewed the delivery of Patient 1's baby in 2004 when the baby died months later, and found there was a "significant deviation" in Physician A's "competency". Physician B stated the quality department reviewed the delivery of Patient 2's twin babies in 2005 when the second twin was pronounced dead 22 minutes after birth, and found it to be a "Sentinel Event" (an indicator that should only occur on a rare basis in a hospital) with "adverse action" (caused harm). Physician B stated that the quality of care delivered by Physician A for Patient 1 in 2004 was unacceptable. Physician B stated that Physician A's general Obstetrical skills were poor. Physician B stated the quality of care delivered by Physician A for Patient 2 in 2005 was also unacceptable. Physician B stated he was alarmed because of Physician A's poor judgement and poor obstetrical skills, but management refused to listen. Physician B had no knowledge that the governing body did anything between 2004 and 2005 about the	A 264		

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A 264	Continued From page 23 quality of care provided by Physician A. On 10/23/07 at 3:10 p.m., an interview was conducted with Staff 1. Staff 1 worked with Physician A for ten years. There were letters of complaints from the staff regarding Physician A as early as 1998 to the present time. Staff 1 stated that these letters were sent to the Nurse Executive (NE) at the time. The NE's job was to refer issues to administration and the medical staff. Staff 1 was a supervisor during the time Physician A delivered care to Patient 1 in 2004 and Patient 2 in 2005. Staff 1 was aware that there were quality of care issue regarding the care Physician A provided to both patients. Staff 1 stated that the policy titled "Chain of Command (Conflict Resolution)" in effect in 2004 and 2005 was not followed when quality of care issues with Physician A were not addressed and resolved. Staff 1 stated that as a supervisor, she was told by staff that Physician A lashed out at the nursery nurse after Patient 2's baby was born dead. Physician A told the nurse that he "Only gave a gentle pull." Staff in the room during the vacuum extraction delivery of Patient 2 in 2005 told Staff 1 that Physician A "pulled with a jerk motion at the end. " Staff 1 stated that Physician A violated the vacuum extraction policy and procedure by continuing to use the vacuum extractor on Patient 2's second twin beyond what any other Obstetrical doctor would have. After the delivery of Patient 2's twins in 2004, the quality of care issue was brought to the attention of the NE immediately. Staff 1 stated Physician A was back on call two days after the incident. Staff 1 stated there was a Labor Delivery Recovery Postpartum (LDRP) Escalation Algorithm (set rules) in place in 2005 when Patient 2's twins were delivered. Staff 1 stated that staff present during Patient 2's	A 264		

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A 264	Continued From page 24 Twin B delivery "did not escalate the event" as set for the in the Algorithm when "it was taking too long" and the "vacuum pulls" were inappropriate. After the incidents during delivery with Patient 1 and 2, Staff 1 stated there was no feedback given about any effort that "Quality" addressed Physician A. 2. The QA program failed to ensure the following quality of care policies and procedures were implemented: a. On 10/23/07, the Chain of Command (Conflict Resolution) effective in 2004 and 2005 was reviewed. The policy contained documentation under Procedure: 1. When a problem was identified on the unit, the staff involved along with the physicians and other care providers would work towards resolution. 2. If the staff were unable to resolve the issue, the unit management team would be contacted to assist. 3. The unit management staff would then assess the situation and assist in solving the problem. 4. If the unit management staff was unable to resolve the problem, the nursing supervisor would be contacted. 5. The nursing supervisor would then assess the situation and assist in solving the problem. 6. If the nursing supervisor was not able to resolve the problem, the service director or nurse executive would be contacted for assistance. If the problem continued to be unresolved, the hospital administrator would be contacted. A medical staff call resource was available for assistance but was to only be called by the nursing supervisor or On-Call administrator.	A 264		

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A 264	Continued From page 25 The procedure was not followed when administration and the medical staff failed to address and resolve problems regarding Physician A's behavior and competency during the deliveries of Patient 1 and 2's babies when they were identified. b. On 10/2307, the "LDRP (Labor Delivery Recovery Postpartum) Escalation Algorithm" guideline effective in 2005 was reviewed. The guideline contained documentation as follows: 1. For clinical practice issues, the Licensed Vocational Nurse/ Registered Nurse (LVN/RN) was to confer with peers and or the Clinical Nurse Specialist (CNS). 2. Then the Medical Doctor (MD) on-call was to be contacted. 3. Then then the consult with back-up MD was to be contacted. 4. Then Obstetrical (OB) Nursing Manager was to be contacted. 5. Then if the nursing manager was unavailable, the RN was to go upward to the OB Chief and to the Assistant Physician In Chief (APIC) or MD Administrator on-call, 6. Before the OB Chief was notified, the Service Director could be notified and the Perinatologist could be consulted as needed. The Algorithm was not followed during the delivery of Patient 2's twins when staff present during Patient 2's delivery "did not escalate the event" as set forth in the Algorithm when too much time elapsed between vacuum pulls and delivery, and the vacuum pulls were inappropriate. c. On 10/23/07, The Vacuum Assisted Delivery	A 264		

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A 264	Continued From page 26 policy dated March of 2004 was reviewed. The purpose was to clarify indications of use, procedure and contraindications of vacuum assisted deliveries. When to discontinue the use of the vacuum was as follows: 1. If progress was not being made with each contraction. 2. If the extractor becomes disengaged (disconnected) 3 times. 3. If 20 to 30 minutes elapsed without success. 4. If trauma (injury) of fetal scalp was observed. The policy was not being followed when progress was not made with each contraction, over two hours elapsed between the start of the use of the vacuum until delivery, and when injury was noted to the fetal scalp at birth. On 10/25/07 at 8:50 a.m., an interview was conducted with Administrator G and Physician C. Administrator G and Physician C stated they were aware of the incident in 2004 with Patient 1 where there was complete disorder in the operating room, prolonged labor with an untimely progression to a cesarean section, and no guidance for an escalation of concerns. They were also aware of the incident in 2005 with Patient 2's twin deliveries where there was complete disorder in the operating room, a prolonged vacuum extraction delivery of a non-viable twin , and quality of care policies and procedures that were not followed when concerns about Physician A were not communicated appropriately and/or addressed and resolved effectively.	A 264		
A 265	482.21(a)(1) QAPI HEALTH OUTCOMES The program must include, but not be limited to,	A 265		

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A 265	Continued From page 27 an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes. This STANDARD is not met as evidenced by: Based on staff interview and clinical and administrative document review, the hospital failed to have an ongoing Quality Assessment Performance Improvement (QAPI) Program that showed measurable improvement in indicators in areas for which there were evidence that a program would improve health outcomes when the hospital failed to look at the care given to two of 23 patients (Patient 1 and 2) with a quality view. These failures resulted in negative health care outcomes for two patients (Patient 1 and 2). Findings: On 10/23/07 at 9:30 a.m., Physician B who was part of the Quality Assurance (QA) team was interviewed. Physician B worked with Physician A for ten years. Quality issues regarding poor judgment were identified in 2004 and Physician A was asked to improve. Physician B stated that Physician A only got upset and accused others. Physician B stated that Physician A continued to have problems, but "the governing body choose to reorganize the whole quality department instead of dealing with the deficiencies." Physician B stated that the quality department reviewed the delivery of Patient 1's baby in 2004 because the baby died months later, and found	A 265	**A265: Quality and PI** The Hospital has, and has always had, an effective, ongoing, hospital-wide, data driven, legally compliant Quality Assessment and Performance Improvement (QAPI) Program since it began operations on February 28, 1995. None of the alleged events or problems identified in the Statement of Deficiencies indicates an inability of the Hospital to sustain an effective QAPI Program. As part of its' ongoing QAPI Program, the Hospital monitors for opportunities for improvement to enhance patient safety and quality of care. Because of the processes in place for monitoring in the QAPI Program, the Hospital identifies, investigates and implements appropriate corrective actions and process improvements to enhance patient care and safety. The Hospital's QAPI process enables the root cause analysis and response to ensure improvements in patient quality of care and patient safety. **Please refer to "A043(2) Patients 1 and 2" as outlined above for further details related to the Hospital's response.**	Leads: AAQS, Quality Chief, Quality Director, Risk Director

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A 265	Continued From page 28 there was a "significant deviation" in Physician A's "competency" from the standard of practice. Physician B stated the quality department reviewed the delivery of Patient 2's twin babies in 2005 because the second twin was pronounced dead 22 minutes after birth, and found it to be a "Sentinel Event" (an indicator that should only occur on a rare basis in a hospital) with "adverse action" (caused harm). Physician B stated that the quality of care delivered by Physician A for Patient 1 in 2004 was unacceptable. Physician B stated that Physician A's general Obstetrical skills were poor. Physician B stated the quality of care delivered by Physician A for Patient 2 in 2005 was also unacceptable. Physician B was alarmed because of Physician A's poor judgement and poor obstetrical skills, but management refused to listen. Physician B had no knowledge that the governing body did anything between 2004 and 2005 about the quality of care provided by Physician A. On 10/23/07 at 9:35 a.m., Physician D who was responsible for the oversight of the QA committee was interviewed. Physician D was not working during the delivery of Patient 1's baby, but reviewed it. Physician D stated that "if a general Obstetrical Gynecological (OBGYN) physician looked at Patient 1's fetal monitoring strip, it would have been unacceptable." Physician D stated that the quality of care delivered by Physician A was unacceptable and that the physician's OBGYN skills were not acceptable. Physician D stated that there was nothing that he was aware of that was done about Physician A's poor judgment and poor Obstetrical (OB) skills between Patient 1's delivery in 2004 and Patient 2's delivery in 2005.	A 265		

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A 265	Continued From page 29 On 10/23/07 at 3:10 p.m., an interview was conducted with Staff 1. Staff 1 worked with Physician A for ten years. There were letters of complaints from the staff regarding Physician A as early as 1998 to the present time. Staff 1 stated that these letters were sent to the Nurse Executive (NE) at the time. The NE's job was to refer issues to administration and the medical staff. Staff 1 was a supervisor during the time Physician A delivered care to Patient 1 in 2004 and Patient 2 in 2005. Staff 1 was aware that there were quality of care issue regarding the care Physician A provided to both patients. Staff 1 stated that the policy titled "Chain of Command (Conflict Resolution)" in effect in 2004 and 2005 was not followed when quality of care issues were not addressed and resolved. Staff 1 stated that as a supervisor, she was told by staff that Physician A lashed out at the nursery nurse after Patient 2's baby was born dead. Physician A told the nurse that he "Only gave a gentle pull." Staff in the room during the vacuum extraction delivery of Patient 2 in 2005 told Staff 1 that Physician A "pulled with a jerk motion at the end. " Staff 1 stated that Physician A violated the vacuum extraction policy and procedure by continuing to use the vacuum extractor on Patient 2's baby beyond what any other Obstetrical doctor would have. After the delivery of Patient 2's twins in 2005, the quality of care issue was brought to the attention of the NE immediately. Physician A was back on call two days after the incident. Staff 1 stated there was a Labor Delivery Recovery Postpartum (LDRP) Escalation Algorithm (set rules) in place in 2005 when Patient 2's twin baby was delivered. Staff 1 stated that staff present during Patient 2's delivery "did not escalate the event" as set for the in the Algorithm when "it was taking too long" and the "vacuum pulls" were	A 265		

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A 265	Continued From page 30 inappropriate. After the incidents during delivery with Patient 1 and 2, Staff 1 stated there was no feedback given about any effort that "Quality" addressed Physician A. On 10/25/07 at 8:50 a.m., an interview was conducted with Administrator G and Physician C . They were aware of the incident regarding Patient 1's delivery in 2004 where there was complete disorder in the operating room, prolonged labor with an untimely progression to a cesarean section, and no guidance for an escalation of concerns. They were aware of the incident during the delivery of Patient 2's twins where there was complete disorder in the operating room, prolonged vacuum extraction delivery of a non-viable second twin , and a Labor Delivery Recovery Postpartum (LDRP) Escalation Algorithm guideline was not followed. Physician C stated that there was a Department Quality Review and a Facility Quality Review that identified Sentinel Events (Sentinel Events with scores of 1, 2, or 3) would have been reviewed based on criteria. To Physician C's knowledge, Physician A was adhering to the restrictions put upon him. When asked about the high risk rounds guidelines, Physician C said he had seen them. When asked if Physician C knew Physician A was not there half of the time, was making it difficult for the nurses, and was in violation of the guidelines, he said he was not aware. Physician A was given guidelines to follow regarding making rounds (reviews) on high risk patients to ensure the plan of care was communicated to the staff, the patients and other physicians. Medical staff represented by Physician C and Governing Body represented by Administrator G were not aware Physician A was not adhering to the High Risk Rounds with	A 265		

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A 265	Continued From page 31 Perinatologist guideline. There was no documented evidence the QA program was monitoring measurable improvements and indicators in areas for which there was evidence that a program would improve health outcomes.	A 265		
A 266	482.21(a)(1) QAPI MEDICAL ERRORS The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will identify and reduce medical errors. This STANDARD is not met as evidenced by: Based on staff interview, clinical record review, and administrative document review; the hospital failed to ensure there was an ongoing Quality Assessment Performance Improvement (QAPI) Program that showed measurable improvement indicators in areas for which there were evidence that a program would identify and reduce medical errors when an effective process of notification of negative outcomes was not put in place to ensure patient safety for 2 of 23 patients reviewed (Patient 1 and 2). These failures resulted in the death of 2 patients. Findings: 1. On 10/23/07 at 1:00 p.m., Patient 1's clinical record was reviewed. Patient 1 was admitted with	A 266	**A266: Quality and PI** The cases cited in the Statement of Deficiencies occurred in 2004 and 2005. The Hospital has, and has always had, an effective, ongoing, hospital-wide, data driven, legally compliant Quality Assessment and Performance Improvement (QAPI) Program that identifies and reduces medical errors and includes an effective process of notification of negative outcomes. The Quality Program is accountable to the MEC for the oversight of quality reviews and actions to remedy issues, either systemic or specific to a department or individual, and reporting its findings to OPIC and MEC on an ongoing basis. The Hospital respectfully disagrees with the surveyors' statement that the hospital did not have quality mechanisms in place at the time these events occurred and that the lack of this process directly resulted in the death of these two patients. During the survey, the surveyors had access to review the peer reviews conducted in 2004 and 2005. The actions taken as a result of the peer review substantiates the effectiveness of the Hospital's QAPI Program. The surveyors were aware that Physician A's privileges were restricted by the MEC and the restriction was approved by the Board on 4/24/2007. Reports of the restriction	Leads: AAQS, Quality Chief, Risk Director, Quality Director

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A 266	Continued From page 32 preterm (about three weeks early) labor and polyhydramnios (an excess of fluid surrounding the fetus in pregnancy) for observation to the hospital's labor and delivery department on 1/28/04 at 4:15 p.m. with complaints of uterine contractions (uterus squeezes) since 1:30 p.m.. Her contractions were 2 to 4 minutes apart lasting 60 to 70 seconds, her babies' fetal heart tones were 154, and her membranes (bag encasing fluid surrounding the fetus) were intact. Patient 1 was started on a drug that inhibited preterm uterine contractions at 4:25 p.m. In spite of the drug, Patient 1 continued to have contractions. The stored fetal strip dated 1/28/04 at 6:09 p.m. contained documentation of contractions five minutes apart lasting 50 seconds, fetal heart tones with a baseline of 150 to 180 with late decelerations (a slowing of the heart rate in relation to contractions) and variability (changes in heart rate which reflect the status of the nervous system). At 7:00 p.m., contractions were two to four minutes apart lasting 50 to 60 seconds, and fetal heart tones with a baseline of 170 with late decelerations and poor variability. At 8:04 p.m., contractions were three to four minutes apart lasting for 50 seconds, and fetal heart tones with a baseline of 150 to 170 with late decelerations and poor variability. Physician A arrived at Patient 1's bedside to evaluate her at 8:00 p.m.. Patient 1 was dilated 1 to 2 centimeters (a measurement that is similar to inches), and "late decelerations were noted with uterine contractions" by Physician A. At 8:05 p.m., the drug to stop preterm labor was discontinued. At 8:20 p.m., contractions were 5 minutes apart lasting 50 seconds, and fetal heart tones with a baseline of 170 with late decelerations occurring consistently, and poor variability. At 10:18 p.m., contractions were two	A 266	were made to the Medical Board of California and the National Practitioner Data Bank as required by Professional Staff Bylaws and legal requirements. **Refer to "A043(2) Patients 1 and 2" as outlined above for further details related to the Hospital's response.** Re-education has occurred with the staff regarding the Chain of Command and Escalation policies and the accountability of all staff and physicians to report timely any concerns for patient safety. **A266: Risk Management Process** The Risk Management Department manages the risk identification for the hospital. A key element involves the responsible reporting form process (RRF). All staff and physicians are encouraged to report all unusual events and near misses as timely as possible. All reports are documented and reviewed by the Risk Management Department. Reports or concerns related to quality of care are investigated and evaluated of applicability for peer review. Events may be reported to the Risk Hotline where there is a daily review and triage of calls that merit immediate investigation. Additionally, the staff is encouraged to call the Quality, Compliance, AR&L and/or Risk Departments with concerns or when in need of assistance. The Risk Management Department reviews the events within a short time after the occurrence. All "significant events", as indicated in the significant event policy, are investigated through department review, peer review or both. Reviews determine if system issues are present which are referred by to Risk Management for additional investigation.	

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A 266	Continued From page 33 minutes apart lasting 60 seconds, and fetal heart tone baseline was 150 with late decelerations after each contraction and poor variability. Patient 1's membranes were artificially ruptured at 11:00 p.m., and at 11:08 p.m. contractions were two minutes apart lasting 60 seconds and the fetal heart tone baseline was 150 with late decelerations after each contraction and poor variability. At 11:40 p.m., Staff 2 took over the nursing care of Patient 1. Staff 2 voiced concerns regarding the fetal monitoring strip and the late decelerations to Physician A. The fetal monitoring strip indicated consistent late decelerations and poor variability until Patient 1 was taken to the operating room for a cesarean section at 1:03 a.m. on 1/29/04. Patient 1's labor progress was from one to two centimeters at 10:00 p.m. to four centimeters before the cesarean section at 1:03 a.m. (per the Operative Report). The fetal monitor strip indicated poor blood flow to the placenta (mothers' organ that nourished the fetus) by late decelerations and poor neurological (nervous system) status as indicated by poor variability for three hours. Patient 1 delivered her baby by cesarean section and the reasons for it were documented as "fetal" distress according to the Anesthesia Pre-Op Evaluation and a "non- reassuring tracing" according to Physician A's Discharge Summary report. On 10/23/07 1:30 p.m., an interview was conducted with Staff 2 who took over nursing care for Patient 1 at 11:40 p.m.. Staff 2 did not feel comfortable with the "lates (decelerations) and not good variability and the way labor was progressing", and voiced these concerns to Physician A at that time. Staff 2 stated that	A 266	System issues may also be identified during the peer review process. Any system issues determined to have a high potential for serious injury to patients are referred to Risk Management for additional investigation and reporting. Department Managers and Supervisors are enlisted to assist in the investigation and formulation and implementation of the action plan. The review of significant events is the accountability of the Risk Management Committee, a multi-disciplinary group of directors, physicians, hospital senior leaders. The committee reviews the findings after the investigation and reach consensus on necessary corrective activities, including any reporting requirements. This committee reports monthly to the MEC. The MEC is accountable for reporting risk management data to the Board through existing reporting mechanisms.	

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A 266	Continued From page 34 Patient 1 had a non-reassuring monitor strip and a slow progression of labor for over two hours. Staff who were in the operating room during the cesarean section told Staff 2 conditions were "stressed". Staff 2 stated Physician A was hounding nurses after delivery, telling them how to chart. On 10/24/07 at 2:00 p.m., an interview was conducted with Staff 3. Staff 3 stated that a fetal monitor strip with late decelerations indicated that the placenta was not getting enough oxygen and the baby needed to be delivered. On the fetal monitor strip nurses would also look at the variability which was a reflection of the autonomic nervous system of the baby and indicated the baby was compensating (making up for a deficiency). Staff 3 stated that the incident with the birth of Patient 1's baby in 2004 "should have been escalated" and that there was a policy in place for Chain of Command/Conflict Resolution that was not followed. Staff 3 stated that there was a "violation of common sense and standard of practice" in the care delivered by Physician C to Patient 1 during her babies' delivery in 2004. Patient 1's baby died months later after going home. On 10/24/07, the Chain of Command (Conflict Resolution) effective in 2004 and 2005 was reviewed. The policy contained documentation under Procedure: 1. When a problem was identified on the unit, the staff involved along with the physicians and other care providers would work towards resolution. 2. If the staff were unable to resolve the issue, the unit management team would be contacted to	A 266		

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A 266	Continued From page 35 assist. 3. The unit management staff would then assess the situation and assist in solving the problem. 4. If the unit management staff was unable to resolve the problem, the nursing supervisor would be contacted. 5. The nursing supervisor would then assess the situation and assist in solving the problem. 6. If the nursing supervisor was not able to resolve the problem, the service director or nurse executive would be contacted for assistance. If the problem continued to be unresolved, the hospital administrator would be contacted. A medical staff call resource was available for assistance but was to only be called by the nursing supervisor or On-Call administrator. The procedure was not followed when administration and the medical staff failed to address and resolve problems regarding Physician A's behavior and competency during the delivery of Patient 1 baby when they were identified. On 10/25/07 at 8:50 a.m., an interview was conducted with Administrator G and Physician C. Administrator G and Physician C stated they were aware of the incident in 2004 with Patient 1 where there was complete disorder in the operating room, prolonged labor with an untimely progression to a cesarean section, and no guidance for an escalation of concerns. 2. On 10/18/07 at 2:00 p.m., Patient 2's clinical record was reviewed. According to documentation in the Discharge Summary written by Physician A, Patient 2 was admitted to the hospital on 4/21/05 at 11:50 a.m. with the diagnosis of twins at 37 weeks and uncontrolled	A 266		

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A 266	Continued From page 36 gestational diabetes for induction (causing labor). Patient 1 progressed to complete dilatation at 10:15 p.m. and 0 station (ready for delivery) and was taken to the operating room at 10:25 p.m. for double set up for twin vaginal delivery. Twin A was a normal vaginal delivery at 10:43 p.m. on 4/21/05 with Apgar scores of 9. After delivery of Twin A, Twin B was vertex (head down) with a "good" fetal heart rate. Active rupture of membranes (bag encasing fluid surrounding the fetus) was performed and clear fluid was noted. The head was at +1 station (the level of the fetal head in the cavity formed by the bones of the hip). Patient 1's labor was assisted by medication. After waiting for 40 minutes, vacuum extractions were tried at 10:58 p.m. to accelerate delivery. Two attempts with no pop-off (vacuum pops off when pressure exceeds the minimum) were made. The fetal head came down to +2 station. Two more vacuum attempts and the head came down to +3 station. The vacuum was applied one more time due to maternal exhaustion, and with one push and no pop-off, Twin B was delivered at 12:22 a.m.. Twin B was very pale, had Apgars of 0 and 0, was resuscitated for 20 minutes, and expired at 12:42 a.m. on 4/22/05. Vacuum extraction was attempted when the fetal head was high at +1 station. A total of five vacuum extractions were attempted. The Clinical Summary contained documentation that "Baby had a good fetal heart rate up to the time of delivery, but after delivery did not have a heart rate and did not respond to resuscitation ."The Patient Progress Record contained documentation that the first vacuum extraction was attempted 10:58 p.m. but did not engage (take hold), and the next vacuum extraction that engaged was at 11:24 p.m.. After four effective vacuum extractions were attempted, Patient 1	A 266		

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KAISER FOUNDATION HOSPITAL - FRESNO	7300 NORTH FRESNO ST FRESNO, CA 93720

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was prepared for a cesarean section at 12:09 a.m.. After preparation for at cesarean section at 12:18 a.m., one more vacuum extraction was attempted and Twin B was delivered at 12:22 a.m.. Twin B was pronounced dead at 12:42 a.m. An autopsy (exam to determine cause of death) was done on 4/22/07. The Autopsy report contained documentation that the external examination was of a normally formed male fetus at term with edema of the left eye region and scalp (skin on the head). The infant was pale with normal abdominal organs and a normal heart. The Autopsy report findings were "Large for gestational age, and sub-dural blood in posterior fossa and spinal cord and moderate disruption cervical spinal cord, consistent with occiput-C1 or cervical vertebral body separation."

On 10/18/07 at 4:30 p.m., an interview was conducted with Staff 6. Staff 6 took over nursing care of Patient 2 at 11:30 p.m. on 4/21/05. Staff 6 stated that the Patient 2's Twin B fetal heart tones were "good" until the last vacuum extraction. Staff 6 stated that on the last vacuum extraction that resulted in the delivery of Twin B, Physician A was on his hands and knees and pulled and was rough. Staff 6 stated that the baby was born dead, and Physician A was angry and yelled at everyone else saying it was their fault. Staff 6 stated that Physician A harassed others and told them what to chart. Staff 6 stated that Physician A was written up before this and after, and there was nothing done about it. Staff 6 stated it was hard to work with Physician A because he yelled at the nurses, harassed them, and would not listen to them. Staff 6 stated there was no control in the surgical room during the delivery.

On 10/22/07 at 8:40 a.m. an interview was

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A 266	Continued From page 38 conducted with Staff 4 regarding the hospitals' analysis of the incident with Patient 2. The Overview SE 05-004-SV contained documentation that there was a concern with "technique in extracting infant at delivery; lack of teamwork, communication." On 10/22/07 at 3:00 p. m., an interview was conducted with Staff 9. Staff 9 took over respiratory care in the operating room at 12:00 midnight on 4/22/05. Staff 9 was positioned behind Physician A near Patient 2's left leg. Staff 9 stated the fetal heart tones were within normal limits up to the last vacuum extraction. Staff 9 stated Physician A had to "reach high up" to place the vacuum extractor in the beginning. Staff 9 stated that the baby was born "white as a sheet." On 10/23/07 at 3:10 p.m., an interview was conducted with Staff 1. Staff 1 stated that as a supervisor, she was told by staff that Physician A lashed out at the nursery nurse after Patient 2's baby was born dead. Physician A told the nurse that he "Only gave a gentle pull." Staff in the room during the vacuum extraction delivery of Patient 2 in 2005 told Staff 1 that Physician A "pulled with a jerk motion at the end." Staff 1 stated that Physician A violated the vacuum extraction policy and procedure by continuing to use the vacuum extractor on Patient 2's baby beyond what any other Obstetrical doctor would have. After the delivery of Patient 2's twins in 2004, the quality of care issue was brought to the attention of the NE immediately. Physician A was back on call two days after the incident. Staff 1 stated there was a Labor Delivery Recovery Postpartum (LDRP) Escalation Algorithm (set rules) in place in 2005 when Patient 2's twin baby was delivered. Staff 1 stated that staff present	A 266		

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during Patient 2's delivery "did not escalate the event" as set for the in the Algorithm when "it was taking too long" and the "vacuum pulls" were inappropriate. After the incidents during delivery with Patient 1 and 2, Staff 1 stated there was no feedback given about any effort that "Quality" addressed Physician A.

On 10/24/07 at 1:45 p.m., an interview was conducted with Staff 5. Staff 5 took over nursing care in the operating room the night of 4/22/05 , when Patient 2's Twin B was delivered. Staff 5 stated that Physician A screamed and mumbled in the operating room. Staff 5 stated that the "technique method of the last one (vacuum extraction) was forceful, adamant, and rough and ultimately separated the spinal cord." Twin B had a "nuchal (neck) cord around the neck one time, and that was why the babies head would not come down". Staff 5 asked if Physician A was ready for a cesarean section, and he did not listen. Staff 5 stated Physician A had stated that he promised Patient 2 a vaginal delivery and stated "we are going to do this." Staff 5 stated Physician A harassed staff when charting and told staff what they should say. Physician A told Staff 5 to chart that there was gentle suction on Twin B.

On 10/24/07 at 2:30 p.m., an administrative record review was conducted. The hospital's policy for vaginal deliveries with vacuum extraction that transition into cesarean sections was requested. Staff 1 and Staff 3 stated that there were no policies regarding vaginal deliveries with vacuum extraction that transition into cesarean section.

On 10/24/07, the Chain of Command (Conflict

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Resolution) effective in 2004 and 2005 was reviewed. The policy contained documentation under Procedure:

1. When a problem was identified on the unit, the staff involved along with the physicians and other care providers would work towards resolution.
2. If the staff were unable to resolve the issue, the unit management team would be contacted to assist.
3. The unit management staff would then assess the situation and assist in solving the problem.
4. If the unit management staff was unable to resolve the problem, the nursing supervisor would be contacted.
5. The nursing supervisor would then assess the situation and assist in solving the problem.
6. If the nursing supervisor was not able to resolve the problem, the service director or nurse executive would be contacted for assistance. If the problem continued to be unresolved, the hospital administrator would be contacted. A medical staff call resource was available for assistance but was to only be called by the nursing supervisor or On-Call administrator.

The procedure was not followed when administration and the medical staff failed to address and resolve problems regarding Physician A's behavior and competency during the delivery of Patient 2's twins in 2005 when they were identified.

On 10/2407, the "LDRP (Labor Delivery Recovery Postpartum) Escalation Algorithm" guideline effective in 2005 was reviewed. The guideline contained documentation as follows:

1. For clinical practice issues, the Licensed

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A 266	Continued From page 41 Vocational Nurse/ Registered Nurse (LVN/RN) was to confer with peers and or the Clinical Nurse Specialist (CNS). 2. Then the Medical Doctor (MD) on-call was to be contacted. 3. Then then the consult with back-up MD was to be contacted. 4. Then Obstetrical (OB) Nursing Manager was to be contacted. 5. Then if the nursing manager was unavailable, the RN was to go upward to the OB Chief and to the Assistant Physician In Chief (APIC) or MD Administrator on-call, 6. Before the OB Chief was notified, the Service Director could be notified and the Perinatologist could be consulted as needed. The Algorithm was not followed during the delivery of Patient 2's twins when staff present during Patient 2's delivery "did not escalate the event" as set forth in the Algorithm when too much time elapsed between vacuum pulls and delivery, and the vacuum pulls were inappropriate. On 10/24/07, The Vacuum Assisted Delivery policy dated March of 2004 was reviewed. The purpose was to clarify indications of use, procedure and contraindications of vacuum assisted deliveries. The procedure as to when to discontinue the use of the vacuum was as follows: 1. If progress was not being made with each contraction. 2. If the extractor becomes disengaged (disconnected) 3 times. 3. If 20 to 30 minutes elapsed without success. 4. If trauma (injury) of fetal scalp was observed.	A 266		

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A 266	Continued From page 42 The policy was not being followed when progress was not made with each contraction, over two hours elapsed between the start of the use of the vacuum until delivery, and when injury was noted to the fetal scalp at birth. On 10/25/07 at 8:50 a.m., an interview was conducted with Administrator G and Physician C. Administrator G and Physician C stated they were aware of the incident in 2005 with Patient 2's twins where there was complete disorder in the operating room, a prolonged vacuum extraction delivery of a non-viable twin , and quality of care policies and procedures that were not followed when concerns about Physician A were not communicated appropriately and/or addressed and resolved effectively.	A 266		
A 310	482.21(e)(1) EXECUTIVE RESPONSIBILITIES The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring that an ongoing program for quality improvement is defined, implemented, and maintained. This STANDARD is not met as evidenced by: Based on staff interviews and administrative document review, the hospital failed to ensure the governing body, medical staff, and	A 310	**A310: Quality and PI** The Hospital disputes this finding. The "High Risk Rounds with the Perinatologist" memo is neither a hospital or medical staff policy nor guideline as identified by the surveyor in the Statement of Deficiencies. The memo did not describe, nor was related to, the practitioner's privileges. This physician-to-physician memo was not a guideline. The memo from the Interim Chief of the department to the practitioner explained the process that the nursing staff should use to contact the practitioner for orders or consultative services. The physician did not fail to make rounds as alleged in the Statement of Deficiencies because no such rounds with the Clinical Nurse Specialist were required as a condition of the exercise of the practitioner's clinical privileges.	Leads: AAQS, Quality Chief

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A 310	Continued From page 43 administrative officials were responsible and accountable for ensuring that an ongoing program for quality improvement was defined, implemented and maintained when the guideline titled "High Risk Rounds with Perinatologist" was not followed. This failure placed patients at risk for negative health care outcomes. Findings: On 10/24/07 at 8:30 a.m., Administrator G (senior vice president/area manager) was shown a copy of the high risk rounds (reviews) guideline that had been put in place to ensure the perinatal clinical nurse specialist could make rounds with Physician A, and they were reviewed. Administrator G was aware of what it represented and acknowledged that the policy had been put in place. Administrator G did not know that Physician A had been non-compliant with the policy. Administrator G stated that Staff K (Director Quality Management) was the responsible individual within the administration who should have known directly that Physician A was non-compliant with the high risk rounds policy. Administrator G went on to state that Staff K should have been the responsible individual within the administration to convey that information directly to administration. Administrator G acknowledged that was no excuse for not being informed of Physician A's non-compliance with the high risk rounds guideline. During an interview with Physician C (physician in chief) and Administrator G (senior vice president/area manager) on 10/24/07 at 9:05 a.m., both stated that they were the responsible	A 310		

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A 310	Continued From page 44 individuals who represented Medical Staff and governing body, respectively. They both acknowledged that there was a high risk rounds guideline that had been put in place to ensure the perinatal clinical nurse specialist could make rounds with Physician A as he saw consult patients from 8:30 a.m. to 9:30 a.m., Monday through Friday. Both Physician C and Administrator G agreed that it was important to have such a policy and it was important that Physician A comply with the policy without exception. Both Physician C and Administrator G replied that they were unaware of the fact that Physician A was non-compliant with the High Risk rounds guidelines when it was brought to their attention. They both stated that Physician A's non-compliance represented a failure of the medical staff to be well organized and accountable to the governing body for the quality of medical care provided to the patients. On 10/24/07 at 9:10 a.m., Staff K (Director Quality Management) acknowledged that she was the responsible individual within the administration who should have known about Physician A's non-compliance with the high risk rounds guideline. Staff K also acknowledged that she was the responsible individual within the administration who should have conveyed directly to Administrator G (senior vice president/area manager) that Physician A was non-compliant with the high risk rounds guideline. Staff K acknowledged that there was no excuse for not conveying the information regarding Physician A's non-compliance with the high risk rounds guideline to Administrator G (senior vice president/area manager).	A 310		
A 311	482.21(e)(1) EXECUTIVE RESPONSIBILITIES	A 311		

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A 311	Continued From page 45 The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring that an ongoing program for patient safety, including the reduction of medical errors, is defined, implemented and maintained. This STANDARD is not met as evidenced by: Based on interview and administrative document review, the hospital failed to ensure the governing body, medical staff, and administrative officials were responsible and accountable for ensuring that an ongoing program for patient safety, including the reduction of medical errors was defined, implemented and maintained when the guideline titled "High Risk Rounds with Perinatologist" was not followed. This failure placed patients at risk of increased medical errors and placed the safety of patients at risk. Findings: On 10/23/07 at 3:30 p.m., during an interview with Staff 3 (perinatal nurse specialist) it was stated that Physician A was not fully compliant with all the policies within the birthing center of the facility. Staff 3 stated specifically that Physician A was non-compliant with a high risk rounds guideline that had been put in place to ensure the perinatal clinical nurse specialist could make rounds with Physician A as he saw consult	A 311	**A311: Quality and PI** The Hospital has, and has always had, an effective, ongoing, hospital-wide, data driven, legally compliant Quality Assessment and Performance Improvement (QAPI) Program that identifies and reduces medical errors and includes an effective patient safety processes. The Hospital disputes this finding and the allegation that the Hospital fails to maintain an ongoing program for patient safety that includes processes for the reduction of medical errors. The "High Risk Rounds with the Perinatologist" memo is neither a hospital or medical staff policy nor guideline as identified by the surveyor in the Statement of Deficiencies. The memo did not describe, nor was related to, the practitioner's privileges. The memo from the Interim Chief of the department to the practitioner explained the process that the nursing staff should use to contact the practitioner for orders or consultative services. The physician did not fail to make rounds as alleged in the Statement of Deficiencies because no such rounds with the Clinical Nurse Specialist were required as a condition of his practice **Please refer to "A043(2) Patients 1 and 2" and A266: Risk Management Process as outlined above for further details related to the Hospital's response.**	

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A 311	Continued From page 46 patients from 8:30 a.m. to 9:30 a.m. Monday through Friday. Staff stated that Physician A would not notify the birthing center when he was not rounding. In addition on days when he would be rounding, he would not contact the nursing team prior to beginning his rounds as directed in the high risk rounds guideline. Staff 3 stated that Physician A's non-compliance was a serious and significant problem with potential negative impact on the care of his consult patients. Staff 3 also specifically spoke to Physician A's non-compliance with his other assigned perinatology activities within the birthing center. Staff 3 stated that all policies and procedures for review, research, and approval were to be reviewed by Physician A with no more than a one week turn around time. Staff 3 went on to say that Physician A was compliant only intermittently with regard to his policy and procedure review responsibilities. On 10/23/07, the guideline titled "High Risk Rounds with Perinatologist" dated 4/12/06 were reviewed. Rounding (reviewing) time was to be from 8:30 a.m. to 9:30 a.m. Monday through Friday. Physician A was to notify the Birthing Center on the days he was not rounding. Upon arrival to the unit, Physician A was to contact Staff 1 or Staff 3 and contact the Medical Doctor (MD) on call. On 10/24/07 at 9:00 a.m., during an interview with Physician C (physician in chief) and Administrator G (senior vice president/area manager) both stated that they were the responsible individuals who represented Medical Staff and governing body, respectively. They both acknowledged that there was a high risk rounds guideline that had been put in place to ensure the perinatal clinical	A 311		

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A 311	Continued From page 47 nurse specialist could make rounds with Physician A as he saw consult patients from 8:30 a.m. to 9:30 a.m. Monday through Friday. Both Physician C and Administrator G agreed that it was important to have such a policy and it was important that Physician A comply with the policy without exception. Both Physician C and Administrator G replied that they were unaware of the fact that Physician A was non-compliant with the rounding policy when it was brought to their attention. Both Physician C and Administrator G replied that they were unaware of the fact that Physician A was non-compliant with his assigned reviews of policies and procedures when it was brought to their attention. They both stated that Physician A's non-compliance represented a failure of the medical staff to ensure that an ongoing program for patient safety, including the reduction of medical errors was defined, implemented and maintained.	A 311		
A 338	482.22 MEDICAL STAFF The hospital must have an organized medical staff that operates under bylaws approved by the governing body and is responsible for the quality of care provided to patients by the hospital.	A 338		
	This CONDITION is not met as evidenced by: Based on interview, record and document review, the hospital failed to have a organized medical staff that operates under bylaws approved by the governing body and the hospital failed to have an organized medical staff that is responsible for the quality of care provided to patients by the hospital:		**A338 (1-3) Organized Medical Staff** Since its opening in February 1995, the hospital has had a single organized medical staff that operates under its Bylaws which are approved by the Governing Body. The Medical Staff is in compliance with the Conditions of Participation as evidenced by: (1) it conducts periodic appraisals of	Leads: AAQS, Quality Chief, Quality Director, AAPCS

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A 338	Continued From page 48 Findings: 1. The failure of the hospital to ensure the medical staff conducted appraisals of its members when there was no documented evidence of proctoring in 45 of 50 credentialing files. (A 340) 2. The failure of the Hospital to ensure the medical staff was well organized and accountable to the governing body for the quality of the medical care provided to the patients when they failed to conduct appraisals of their members and 45 of 50 provisional physicians were not proctored per the hospital Bylaws. (A347) 3. The failure of the Hospital to ensure the medical staff enforced bylaws in order to carry out its responsibilities when 45 of 50 provisional physicians were not proctored per the hospital bylaws. (A353) The cumulative effect of these systemic practices resulted in the failure of the hospital to deliver statutorily mandated compliance with the Condition of Participation: Medical staff, CR § 482.22	A 338	its members as a condition of exercising clinical privileges in the Hospital; (2) it is accountable to the Governing body for physician- driven quality of care and (3) it enforces its Professional Staff Bylaws. The CMS Conditions of Participation (CoP) for Hospitals do not require the performance of proctoring. The CoP require that the Medical Staff has processes to assess the competence of medical staff members. The Medical Staff is accountable to the Hospital Governing Body for assuring that there is a process for assessment of medical staff members' competencies. The KFH Fresno Professional Staff Bylaws which were approved by the Hospital Governing Body delineate such processes including the requirement for proctoring in Section H-2. The Hospital has an active medical staff that is competent in specialty and subspecialty services provided to its patients. **Refer to attached pages 338 a through 338 c**	
A 340	482.22(a)(1) MEDICAL STAFF PERIODIC APPRAISALS The medical staff must periodically conduct appraisals of its members.	A 340	**A340: Medical Staff** **See "A338 Organized Medical Staff" as outlined above.** The surveyor reviewed a list of 90 physician files for evidence of proctoring, not 50 as stated in the report. The number of files without proctoring on file was 45 at the time of the survey. Therefore, the number should have been based on 45 of 90, not 45 of 50 as alleged in the Statement of Deficiencies.	Leads: AAQS, Quality Chief

ID Prefix TAG	Providers' Plan of Correction	Lead and Completion Date
A338	Although proctoring is a part of the process to assure that qualified physicians serve on its medical staff, an entire host of activities act as a check and balance to ensure that a competent and experienced medical staff provides care to patients. The Hospital assures that criteria for appointment of new medical staff members and reappointment of current medical staff members include an assessment of each individual's professional conduct, competence, character, training, experience and judgment. Proctoring is one of the mechanisms that the Medical Staff uses in conducting appraisals of its members. **Proctoring has been redesigned (see A043(1) Proctoring Process as outlined above).** Evidence of proctoring or plan for completion of proctoring/verification of initial competency will be present in every practitioner's Medical Staff file. **Process for New Staff Members:** The Hospital has an extensive process for verifying the competency and qualifications of initial applicants, as documented both in the Professional Staff Bylaws, Article B and in its credentialing policies and procedures. Each practitioner's file includes but is not limited to documentation and verification of education, training, licensure, past and current practice, and liability history. Practitioners are also required to submit evidence to substantiate their request for privileges specific to their practice; e.g. surgeons must provide evidence of cases performed in training or in recent practice at facilities where their affiliation is verified to be in good-standing. Residency Training Program Directors are asked to verify applicants' competence. Once a practitioner has been granted privileges, a member of the department is assigned to provide orientation to the medical staff and to observe his/her practice. To enhance the documentation of this process, a proctoring plan and related forms will be implemented and maintained in the practitioners' medical staff file. Actual proctoring and medical record review are conducted within the initial 12 month evaluation period as required in Bylaws Section H-2. No practitioner is advanced from provisional staff status until proctoring has been completed. Should the practitioner not have had a sufficient volume of cases to meet the proctoring	

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A338	requirement that practitioner's provisional staff status can be extended only for an additional 12 month period. The practitioner must complete proctoring and other conditions of provisional staff status in that additional time frame to remain on the medical staff. During the initial evaluation period, the practitioner is also subject to the quality department's ongoing process. All Medical Staff members, regardless of length of service on the Medical Staff, are subject to this continuous quality appraisal process. Each department has quality indicators which set minimum thresholds for evaluation of competence. Practitioners who do not meet those minimums are subject to a focused peer review which could result in adverse action up to and including revocation of privileges. **Process for Continued Membership:** Continual evaluation is conducted on all practitioners in accordance with Policy P.15.00 "Provider Profiling and Peer Review and Evaluation of LIP Performance". A summary of performance is provided during bi-annual reappointment as required by the Professional Staff Bylaws, Article B-3 and its credentialing policies and procedures. This summary includes data on complaints, grievances, member satisfaction, mortality rates, admissions, length of stay, inpatient avoidable days, and other areas relating to utilization, medical record review and suspension history, infection rate, transfusion rate, and peer review. Information is again obtained for each practitioner relevant to licensure, practice during the previous two years at our own and other facilities, input from peers, and liability claims. Case volume is compared against requirements for privileges requested to ensure that there is a sufficient number performed to maintain competence. When there is not a sufficient number, the practitioner is not permitted to exercise those privileges until he or she can demonstrate the requisite competence in accordance with Medical Staff requirements. Information collected both for initial appointment and reappointment is reviewed and evaluated by the Chief of the appropriate department or specialty, who makes a recommendation to the C&P Committee, which consists of active staff members representing the various areas of practice. The committee's recommendation is then	

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A 340	Continued From page 49 This STANDARD is not met as evidenced by: Based on staff interview and administrative document review, the hospital failed to ensure the medical staff conducted appraisals of its members when there was no documented evidence of proctoring in 45 of 50 credentialing files. This failure resulted in physician practice not being reviewed for quality. Findings: On 10/18/07, the Bylaws of the Professional Staff for Kaiser Foundation Hospital states on page 6, C 4, " To qualify for and continue membership on the Professional Staff a practitioner must: Perform a sufficient number of cases, and have sufficient patient care contact within the Hospital or another community hospital or health care setting to permit the Professional Staff to assess the applicant's current competency for all clinical privileges, whether requested or already granted, including completion of initial evaluation and proctoring as specified in Section H-2." On 10/18/07, the Bylaws of the Professional Staff for Kaiser Foundation Hospital state on page 52, H-2 "Practitioners who are granted clinical privileges shall demonstrate current clinical competence by completing an initial period of monitoring consisting of observation of their practices and/or proctoring and compliance with the Professional Staff Bylaws, Rules and Regulations and hospital policies. Newly granted privileges shall be evaluated in a timely manner based on criteria established by the Department and approved by the Credentials and Privileges Committee. This requirement may be fulfilled by the collection and review of information from this	A 340		

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A 340	Continued From page 50 Hospital and/or other organizations. The Department Chief or designee shall be responsible for proctoring and shall submit proctoring reports and other evidence of compliance to the Credentials and Privileges Committee for it's approval. The initial evaluation shall be for a period of one (1) year, unless extended by the Credentials and Privileges Committee for an additional period of up to one year upon determination of a good cause. The initial evaluation shall not exceed two (2) years. Failure to successfully complete initial evaluation shall be grounds for termination of membership and/or clinical privileges. Such termination shall not be subject to review under Section B-5." 10/18/07 at 4:34 p.m., during an interview with staff I, she stated that the vast majority of the 50 provisional physicians on the medical staff roster had no objective evidence of proctoring in their credential files. On 10/18/07 at 4:45 p.m., during an interview with Physician D and Physician E, they both stated that the vast majority of the 50 provisional physicians on the medical staff roster had no objective evidence of proctoring in their credential files. They both also stated that the current proctoring process was not in accordance with the process set forth in the The Bylaws of the Professional Staff for Kaiser Foundation Hospital. They both stated that the current process did not allow for the assessment of competency in a timely manner as set forth in The Bylaws of the Professional Staff for Kaiser Foundation Hospital. On 10/22/07 at 8:00 a.m., during an interview with Staff I and Administrator H, Staff I produced	A 340		

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A 340	Continued From page 51 documentation which established the fact that 45 out of a total of 50 provisional physicians had no objective evidence of current and timely proctoring in their credential files. Both Staff I and Administrator H stated that the proctoring was not being done as set forth in the The Bylaws of the Professional Staff for Kaiser Foundation Hospital. They both conceded that the current proctoring process that was in use could not be found within the Bylaws. Both Staff I and Administrator H stated during the interview that physician in chief, the chief operating officer of the hospital, members of the Executive Committee, and members of the Credentials and Privileges Committee were aware of the fact that proctoring was not being done as set forth in the the Bylaws. They were also aware of the fact that the current proctoring process that was in use could not be found within the Bylaws. On 10/22/07 at 9:00 a.m., during an interview with Physician F, he stated that he was a member of the Credentials and Privileges Committee. He stated he was aware of the fact that the current proctoring was not being done as set forth in the The Bylaws of the Professional Staff for Kaiser Foundation Hospital. Physician F stated he was also aware of the fact that the current proctoring process that was in use could not be found within the Bylaws. He stated that the Department chiefs within the hospital who were responsible for the proctoring and reporting to the appropriate committees were not in compliance with the the Bylaws.	A 340		
A 347	482.22(b) MEDICAL STAFF ACCOUNTABILITY The medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to the patients.	A 347		

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A 347	Continued From page 52 The medical staff must be organized in a manner approved by the governing body. If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy. The responsibility for organization and conduct of the medical staff must be assigned only to an individual doctor of medicine or osteopathy or, when permitted by State law of the State in which the hospital is located, a doctor of dental surgery or dental medicine. This STANDARD is not met as evidenced by: Based on interview and document review, the hospital failed to ensure the medical staff was well organized and accountable to the governing body for the quality of the medical care provided to the patients. This failure placed patients at risk for not getting care that was driven by physician quality. Findings: During an interview with Staff I and Administrator H on 10/22/07 at 8:00 a.m., Staff I produced documentation which established the fact that 45 out of a total of 50 provisional physicians had no	A 347	**A347: Medical Staff** The Medical Staff is accountable to the Governing Body for physician-driven quality of care. The Conditions of Participation require that the Medical Staff have processes to assess the competence of medical staff members. The medical staff is accountable to the hospital governing body for assuring that there is a process for assessment of medical staff members' competencies. The KFH Fresno Professional Staff Bylaws, which were approved by the Hospital Governing Body, delineates such processes including the requirement for proctoring in Section	Leads: AAQS, Quality Chief

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A 347	Continued From page 53 objective evidence of current and timely proctoring in their credential files. Both Staff I and Administrator H stated that the proctoring was not being done as set forth in the The Bylaws of the Professional Staff for Kaiser Foundation Hospital. They both stated that the current proctoring process that was in use could not be found within the Bylaws. Both Staff I and Administrator H stated during the interview that the physician in chief, the chief operating officer of the hospital, members of the Executive Committee, and members of the Credentials and Privileges Committee were aware of the fact that proctoring was not being done as set forth in the Bylaws. They were also aware of the fact that the current proctoring process that was in use could not be found within the Bylaws. Staff I went on to state that notices were routinely sent to the appropriate individuals with regard to the deficient proctoring files. Staff I then produced objective documentation of the notification process that had taken place. The documentation clearly revealed attempts to relay information regarding late proctoring issues to members Credentials and Privileges Committee. Staff I conceded that in both documented cases there was breakdown in the chain of communication between the physician in chief, the Credentials and Privileges Committee, the Executive Committee and the chief executive officer of the hospital. During an interview with Physician F on 10/22/07 at 9:00 a.m., he stated that he was a member of the Credentials and Privileges Committee. He stated that the Department chiefs within the hospital who were responsible for the proctoring and reporting to the appropriate committees were	A 347	H-2. The CMS Conditions of Participation for Hospitals do not explicitly require the performance of proctoring. Although proctoring is a part of the process to assure that quality physicians serve on its medical staff, an entire host of activities act as a check and balance to ensure that a competent and experienced medical staff provides care to patients. The hospital assures that criteria for appointment of new medical staff members and reappointment of current medical staff members includes an assessment of each individual's professional conduct, competence, character, training, experience and judgment. Proctoring is one of the mechanisms that the Medical Staff uses in conducting appraisals of its members. The proctoring process has been redesigned to include monitoring reports related to each practitioner's proctoring status which are sent monthly from C&P Committee to the MEC as further evidence of the MEC's accountability for assuring that quality of care provided by physicians is evaluated in a systematic and consistent fashion. **See "A043(1) Proctoring Process" as outlined above for details related to the proctoring process.**	

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A 347	Continued From page 54 not in compliance with the "The Bylaws of the Professional Staff for Kaiser Foundation Hospital." He went on to state that the individual Department chiefs were overwhelmed with their proctoring and reporting responsibilities. He also stated there was an abdication of responsibilities at different levels among Department chiefs, key committee members and the members of the hospital administration. During an interview with Physician C (physician in chief) and Administrator G (senior vice president/area manager) on 10/24/07 at 9:00 a.m., both stated that they were the responsible individuals who represented Medical Staff and governing body, respectively. They both stated that the lack of proctoring for 45 out of a total of 50 provisional physicians represented a failure of the medical staff to be well organized and accountable to the governing body for the quality of medical care provided to the patients. Administrator G (senior vice president/area manager) stated in addition to being the responsible individual representing governing body within the facility she had also been a member of the Credentials & Privileges Committee for one year and the Executive Committee for two years. She acknowledged the fact that it was ultimately the responsibility of the Executive Committee members to address the proctoring issue. Further she stated that the full complexity of this issue had not been directly and appropriately escalated to her attention as the responsible individual representing governing body.	A 347		
A 353	482.22(c) MEDICAL STAFF BYLAWS The medical staff must adopt and enforce bylaws to carry out its responsibilities.	A 353		

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A 353	Continued From page 55 This STANDARD is not met as evidenced by: Based on staff interview and administrative document review, the hospital failed to ensure the medical staff enforced bylaws to carry out its responsibilities when 45 of 50 provisional physicians were not proctored per the hospital Bylaws. This failure placed patients at risk of not receiving quality patient care. Findings: On 10/22/07 at 8:00 a.m., Staff I produced a Summary of Progress on Proctoring dated 10/25/07 that directly related to the flow of information regarding non-compliance with the proctoring and credentialing process. Staff I stated that as medical staff services supervisor she presented reports on proctoring progress and non-compliance on a monthly basis to the Credentials & Privileges Committee. Staff I stated that after the Credentials & Privileges Committee was notified, the appropriate Department chairs were notified regarding the deficient proctoring of provisional physicians. Staff I went on to say that it was the responsibility of the Credentials & Privileges Committee as well as the Executive committee to work with the department chairs as a means of ensuring their cooperation regarding progress on proctoring. Staff I produced objective documentation which substantiated the appropriate individuals had been notified in a timely manner however had not cooperated as requested. The Bylaws contained documentation under Section H-2 that "the initial evaluation shall be for a period of one (1) year, unless extended by the Credentials and Privileges	A 353	**A353: Medical Staff** **Refer to A043(1) Proctoring Process as outlined above.** Proctoring has been redesigned to assure the Medical Staff's compliance with its Professional Staff Bylaws, and in particular in those provisions of the Bylaws related to assessing the competence of provisional staff members. The surveyor reviewed a list of 90 physician files for evidence of proctoring, not 50 as stated in the report. The number of files without proctoring on file was 45 at the time of the survey. Therefore, the number should have been based on 45 of 90, not 45 of 50 as alleged in the Statement of Deficiencies.	Leads: AAQS, Quality Chief

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A 353	Continued From page 56 Committee for an additional period of up to one year upon a determination of good cause. The initial evaluation period shall not exceed two (2) years." On 10/22/07 at 9:00 a.m., Physician F stated that he was a member of the Credentials and Privileges Committee. Physician F stated that the Department chiefs within the hospital who were responsible for the proctoring and reporting to the appropriate committees were not in compliance with the The Bylaws of the Professional Staff for Kaiser Foundation Hospital. Physician F went on to state that the individual Department chiefs were overwhelmed with their proctoring and reporting responsibilities. Physician F also stated there was an abdication of responsibilities at different levels among Department chiefs, key committee members, and the members of the hospital administration which in turn led to widespread non-compliance with the the Bylaws as they relate to assessing provisional physicians for competence.	A 353		
A 951	482.51(b) OPERATING ROOM POLICIES Surgical services must be consistent with needs and resources. Policies governing surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care. This STANDARD is not met as evidenced by: Based on staff interview, clinical record review, and administrative document review; the hospital failed to ensure surgical services were consistent	A 951	**A951: Surgical Services** The Hospital reviewed its Operating Room policies related to (1) Chain of Command policy, (2) Labor Delivery Recovery Post Partum Algorithm, and (3) Vacuum Assisted Delivery policy to assure the achievement and maintenance of high standards of medical practice and patient care. Consistent with that review is a summary of follow-up actions that occurred immediately after the event involving Patient 2 to re-educate the clinical staff and medical staff of the policies and their respective accountability to comply with the policies. Ongoing education continues through nursing forums, patient care team meetings and staff huddles.	Leads: AAQS Quality Chief Quality Director, AAPCS

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A 951	Continued From page 57 with needs and resources in two of 23 patients (Patient 1 & 2). Policies governing surgical care were not designed to assure the achievement and maintenance of high standards of medical practice when there was no policy and procedure for the transition from a vaginal delivery to surgical intervention. This placed the patients at risk for delayed surgical interventions. Findings: 1. On 10/23/07 at 1:00 p.m., Patient 1's clinical record was reviewed. Patient 1 was admitted with preterm (about three weeks early) labor and polyhydramnios (an excess of fluid surrounding the fetus in pregnancy) for observation to the hospital's labor and delivery department on 1/28/04 at 4:15 p.m. with complaints of uterine contractions (uterus squeezes) since 1:30 p.m.. Her contractions were 2 to 4 minutes apart lasting 60 to 70 seconds, her babies' fetal heart tones were 154, and her membranes (bag encasing fluid surrounding the fetus) were intact. Patient 1 was started on a drug that inhibited preterm uterine contractions at 4:25 p.m. In spite of the drug, Patient 1 continued to have contractions. The stored fetal strip dated 1/28/04 at 6:09 p.m. contained documentation of contractions five minutes apart lasting 50 seconds, fetal heart tones with a baseline of 150 to 180 with late decelerations (a slowing of the heart rate in relation to contractions) and variability (changes in heart rate which reflect the status of the nervous system). At 7:00 p.m., contractions were two to four minutes apart lasting 50 to 60 seconds, and fetal heart tones with a baseline of 170 with late decelerations and poor variability. At 8:04 p.m., contractions were three to four minutes apart lasting for 50 seconds, and fetal	A 951	**1.** A Root Cause Analysis (RCA) was performed after the event on 05/19/2005. During that RCA, review of Chain of Command policy, the LDRP Escalation Log Algorithm, and Vacuum Assisted Delivery policy were all reviewed with the staff. **2.** Perinatal Patient Safety Project Committee (PPSC) implemented in 03/01/2005. Multidisciplinary group consisting of staff, physicians and departmental managers. During meetings held from 03/05 through 10/05, issues addressed included but were not limited to: Chain of Command policy reviewed and revised, LDRP and Neonatal escalation algorithms developed and implemented SBAR communication and Human Factor training completed. **3.** Critical Events Training for staff completed in 10/05 (focus communications, team effectiveness). **4.** Vacuum Assisted Delivery Policy revised and education completed by 11/05. **5.** The current OB inpatient chief was designated by the Interim Department Chief to lead performance improvement activities with departmental manager in 2005 (Also serves as one of the co-chairs of Perinatal Service Performance Improvement Committee). **6.** Perinatology Algorithm for consultation requests amended and distributed to physicians and staff. **7.** Departmental Structure Standards updated 12/06. Section 2(F) – Consultation of Medical Staff outlines responsibilities of consulting and on-call physicians. **8.** Vacuum Assisted Delivery Perinatal Services Policy revised, effective 03/07. Staff educated on revisions. Revisions do include recommendations when to proceed to C-Section. **9.** Education initiated in 03/07 for staff and physicians on new Vacuum Assisted Delivery Device implemented in 05/07. Device is handled	05/19/05 03/01/05 a ongoing 10/05 11/05 11/05 07/06 12/06 03/07 and ongoing 03/07 and ongoing

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A 951	Continued From page 58 heart tones with a baseline of 150 to 170 with late decelerations and poor variability. Physician A arrived at Patient 1's bedside to evaluate her at 8:00 p.m.. Patient 1 was dilated 1 to 2 centimeters (a measurement that is similar to inches), and "late decelerations were noted with uterine contractions" by Physician A. At 8:05 p.m., the drug to stop preterm labor was discontinued. At 8:20 p.m., contractions were 5 minutes apart lasting 50 seconds, and fetal heart tones with a baseline of 170 with late decelerations occurring consistently, and poor variability. At 10:18 p.m., contractions were two minutes apart lasting 60 seconds, and fetal heart tone baseline was 150 with late decelerations after each contraction and poor variability. Patient 1's membranes were artificially ruptured at 11:00 p.m., and at 11:08 p.m. contractions were two minutes apart lasting 60 seconds and the fetal heart tone baseline was 150 with late decelerations after each contraction and poor variability. At 11:40 p.m., Staff 2 took over the nursing care of Patient 1. Staff 2 voiced concerns regarding the fetal monitoring strip and the late decelerations to Physician A. The fetal monitoring strip indicated consistent late decelerations and poor variability until Patient 1 was taken to the operating room for a cesarean section at 1:03 a.m. on 1/29/04. Patient 1's labor progress was from one to two centimeters at 10:00 p.m. to four centimeters before the cesarean section at 1:03 a.m. (per the Operative Report). The fetal monitor strip indicated poor blood flow to the placenta (mothers' organ that nourished the fetus) by late decelerations and poor neurological (nervous system) status as indicated by poor variability for three hours. Patient 2's baby was delivered by cesarean section and the reasons for the cesarean section	A 951	only by physician. **10.** Nurse Executive continues to discuss Chain of Command and escalation process at Patient Care Team meetings. In 2007, the following activities have occurred for staff and physicians regarding responsibilities for reporting and escalating quality of care issues: **1.** Critical Events Training – 10/23/07 through 10/25/07(was scheduled prior to the Validation Survey occurring). Perinatal staff and physicians participated with primary goal of improving communication and team effectiveness. Had exercises which involved emergency delivery during training. **2.** Highly Reliable Surgical Team (HRST) program implemented in 08/07 – Perinatal Services physicans and staff participating. Primary goals: Implement standardized communication techniques in every OR, Every procedure, Every day. **3.** Responsible Reporting Forms (RRF) Training and reporting of quality concerns and/or medical errors. Staff are continually re-educated on the importance of reporting medical errors and/or quality of care concerns via RRF reporting tools or utilizing the Oops line for a verbal message. Data indicators, such as shift, care provider, outcomes, human factors, etc., are entered and tracked in the Risk database. Trends are reviewed, analyzed and presented to OPIC and MEC for review and action minimally 4 times a year. **4.** Significant Event education and reporting (including SB 1301, 1312). Education to physicians occurred 5/24/07 and 8/2/097 for SB 1301/1312 reporting guidelines. Additional education to staff at leadership, departmental and staff huddles to increase awareness for reporting requirements. Staff expected to follow Significant Event Reporting policy. Significant Event report presented at MEC each month by Chief of Risk	06/01/07 10/25/07 08/07 and ongoing ongoing 05/24//07 and ongoing

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A 951	Continued From page 59 were documented as "fetal" distress according to the Anesthesia Pre-Op Evaluation and a "non-reassuring tracing" according to Physician A's Discharge Summary report. On 10/23/07 1:30 p.m., an interview was conducted with Staff 2 who took over nursing care for Patient 1 at 11:40 p.m.. Staff 2 did not feel comfortable with the "lates (decelerations) and not good variability and the way labor was progressing", and voiced these concerns to Physician A at that time. Staff 2 stated that Patient 1 had a non-reassuring monitor strip and a slow progression of labor for over two hours. Staff who were in the operating room during the cesarean section told Staff 2 conditions were "stressed". Staff 2 stated Physician A was hounding nurses, telling them how to chart. On 10/24/07 at 2:00 p.m., an interview was conducted with Staff 3. Staff 3 stated that a fetal monitor strip with late decelerations indicated that the placenta (organ that nurished the fetus) was not getting enough oxygen and the baby needed to be delivered. On the fetal monitor strip nurses would also look at the variability which was a reflection of the autonomic nervous system of the baby and indicated the baby was compensating (making up for a deficiency). Staff 3 stated that the incident with the birth of Patient 1's baby in 2004 "should have been escalated" and that there was a policy in place for Chain of Command/Conflict Resolution that was not followed. Staff 3 stated that there was a "violation of common sense and standard of practice" in the care delivered by Physician C to Patient 1 during her babies' delivery in 2004. Patient 1's baby died	A 951	Management. 5. CME presentations – sample topics: Peer Review Training (6/26/07, 6/29/07, 7/31/07, 9/12/07, 10/17/07, 11/28/07) Patient Provider Interaction (3/15/07, 10/11/07, 10/18/07), Language Services to Support Quality Care (4/20/07), Safety Training (5/18/07, 5/25/07, 6/8/07), EMTALA annual review (8/10/07), Hospital Reporting Requirements (5/24/07, 8/2/07).	Ongoing

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A 951	Continued From page 60 months later after going home. On 10/24/07, the Chain of Command (Conflict Resolution) effective in 2004 and 2005 was reviewed. The policy contained documentation under Procedure: 1. When a problem was identified on the unit, the staff involved along with the physicians and other care providers would work towards resolution. 2. If the staff were unable to resolve the issue, the unit management team would be contacted to assist. 3. The unit management staff would then assess the situation and assist in solving the problem. 4. If the unit management staff was unable to resolve the problem, the nursing supervisor would be contacted. 5. The nursing supervisor would then assess the situation and assist in solving the problem. 6. If the nursing supervisor was not able to resolve the problem, the service director or nurse executive would be contacted for assistance. If the problem continued to be unresolved, the hospital administrator would be contacted. A medical staff call resource was available for assistance but was to only be called by the nursing supervisor or On-Call administrator. The procedure was not followed when administration and the medical staff failed to address and resolve problems regarding Physician A's behavior and competency during the delivery of Patient 1 baby when they were identified. On 10/25/07 at 8:50 a.m., an interview was conducted with Administrator G and Physician C. Administrator G and Physician C stated they were	A 951		

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A 951	Continued From page 61 aware of the incident in 2004 with Patient 1 where there was complete disorder in the operating room, prolonged labor with an untimely progression to a cesarean section, and no guidance for an escalation of concerns. 2. On 10/18/07 at 2:00 p.m., Patient 2's clinical record was reviewed. According to documentation in the Discharge Summary written by Physician A, Patient 2 was admitted to the hospital on 4/21/05 at 11:50 a.m. with the diagnosis of twins at 37 weeks and uncontrolled gestational diabetes for induction (causing labor). Patient 1 progressed to complete dilatation at 10:15 p.m. and 0 station (ready for delivery) and was taken to the operating room at 10:25 p.m. for double set up for twin vaginal delivery. Twin A was a normal vaginal delivery at 10:43 p.m. on 4/21/05 with Apgar scores of 9. After delivery of Twin A, Twin B was vertex (head down) with a "good" fetal heart rate. Active rupture of membranes (bag encasing fluid surrounding the fetus) was performed and clear fluid was noted. The head was at +1 station (the level of the fetal head in the cavity formed by the bones of the hip). Patient 1's labor was assisted by medication. After waiting for 40 minutes, vacuum extractions were tried at 10:58 p.m. to accelerate delivery. Two attempts with no pop-off (vacuum pops off when pressure exceeds the minimum) were made. The fetal head came down to +2 station. Two more vacuum attempts and the head came down to +3 station. The vacuum was applied one more time due to maternal exhaustion, and with one push and no pop-off, Twin B was delivered at 12:22 a.m.. Twin B was very pale, had Apgars of 0 and 0, and was resuscitated for 20 minutes and expired at 12:42 a.m. on 4/22/05. Vacuum extraction was attempted when the fetal head	A 951		

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A 951	Continued From page 62 was high at +1 station. A total of five vacuum extractions were attempted. The Clinical Summary contained documentation that "Baby had a good fetal heart up to the time of delivery, but after delivery did not have heart rate and did not respond to resuscitation." The Patient Progress Record contained documentation that the first vacuum extraction was attempted 10:58 p.m. but did not engage (take hold) and the next vacuum extraction that engaged was at 11:24 p.m.. After four effective vacuum extractions were attempted, Patient 1 was prepared for a cesarean section at 12:09 a.m.. After preparation for at cesarean section at 12:18 a.m., one more vacuum extraction was attempted and Twin B was delivered at 12:22 a.m, and pronounced dead at 12:42 a.m. An autopsy (exam to determine cause of death) was done on 4/22/07. The Autopsy report contained documentation that the external examination was of a normally formed male fetus at term with edema of the left eye region and scalp (skin on the head). The infant was pale with normal abdominal organs and a normal heart. The Autopsy report findings were "Large for gestational age, and sub-dural blood in posterior fossa and spinal cord and moderate disruption cervical spinal cord, consistent with occiput-C1 or cervical vertebral body separation." On 10/18/07 at 4:30 p.m., an interview was conducted with Staff 6. Staff 6 took over nursing care of Patient 2 at 11:30 p.m. on 4/21/05. Staff 6 stated that the Patient 2's Twin B fetal heart tones were "good" until the last vacuum extraction. Staff 6 stated that on the last vacuum extraction that resulted in the delivery of Twin B, Physician A was on his hands and knees and pulled and was rough. Staff 6 stated that the baby was born	A 951		

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A 951	Continued From page 63 dead, and Physician A was angry and yelled at everyone else saying it was their fault. Staff 6 stated that Physician A harassed others and told them what to chart. Staff 6 stated that Physician A was written up before this and after, and there was nothing done about it. Staff 6 stated it was hard to work with Physician A because he yelled at the nurses, harassed them, and would not listen to them. Staff 6 stated there was no control in the surgical room during the delivery. On 10/22/07 at 8:40 a.m. an interview was conducted with Staff 4 regarding the hospitals' analysis of the incident with Patient 2. The Overview SE 05-004-SV contained documentation that there was a concern with "technique in extracting infant at delivery; lack of teamwork, communication" in the operating room. On 10/23/07 at 3:10 p.m., an interview was conducted with Staff 1. Staff 1 stated that as a supervisor, she was told by staff that Physician A lashed out at the nursery nurse after Patient 2's baby was born dead. Physician A told the nurse that he "Only gave a gentle pull." Staff in the room during the vacuum extraction delivery of Patient 2 in 2005 told Staff 1 that Physician A "pulled with a jerk motion at the end. " Staff 1 stated that Physician A violated the vacuum extraction policy and procedure by continuing to use the vacuum extractor on Patient 2's baby beyond what any other Obstetrical doctor would have. After the delivery of Patient 2's twins in 2004, the quality of care issue was brought to the attention of the NE immediately. Physician A was back on call two days after the incident. Staff 1 stated there was a Labor Delivery Recovery Postpartum (LDRP) Escalation Algorithm (set rules) in place in 2005 when Patient 2's twin baby	A 951		

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A 951	Continued From page 64 was delivered. Staff 1 stated that staff present during Patient 2's delivery "did not escalate the event" as set for the in the Algorithm when "it was taking too long" and the "vacuum pulls" were inappropriate. After the incidents during delivery in the operating room of Patient 2's twins, Staff 1 stated there was no feedback given about any effort that "Quality" addressed Physician A's behavior. On 10/24/07 at 1:45 p.m., an interview was conducted with Staff 5. Staff 5 took over nursing care in the operating room the night of 4/22/05 when Patient 2's Twin B was delivered. Staff 5 stated that Physician A screamed and mumbled in the operating room. Staff 5 stated that the "technique method of the last one (vacuum extraction) was forceful, adamant, and rough and ultimately separated the spinal cord." Twin B had a "nuchal (neck) cord around the neck one time, and that was why the babies head would not come down". Staff 5 asked if Physician A was ready for a cesarean section, and he did not listen. Staff 5 stated Physician A had stated that he promised Patient 2 a vaginal delivery and stated "we are going to do this." Staff 5 stated Physician A harassed staff when charting and told staff what they should say. Physician A told Staff 5 to chart that there was gentle suction on Twin B. On 10/24/07 at 2:30 p.m., an interview was conducted with Staff 1 and Staff 3. The hospital's policy for vaginal deliveries with vacuum extraction that transition into cesarean sections was requested. Staff 1 and Staff 3 stated that there were no policies regarding vaginal deliveries with vacuum extraction that transition into	A 951		

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A 951	Continued From page 65 cesarean section. On 10/24/07, the policy titled "Chain of Command (Conflict Resolution)" effective in 2004 and 2005 was reviewed. The policy contained documentation under Procedure: 1. When a problem was identified on the unit, the staff involved along with the physicians and other care providers would work towards resolution. 2. If the staff were unable to resolve the issue, the unit management team would be contacted to assist. 3. The unit management staff would then assess the situation and assist in solving the problem. 4. If the unit management staff was unable to resolve the problem, the nursing supervisor would be contacted. 5. The nursing supervisor would then assess the situation and assist in solving the problem. 6. If the nursing supervisor was not able to resolve the problem, the service director or nurse executive would be contacted for assistance. If the problem continued to be unresolved, the hospital administrator would be contacted. A medical staff call resource was available for assistance but was to only be called by the nursing supervisor or On-Call administrator. The procedure was not followed when administration and the medical staff failed to address and resolve problems regarding Physician A's behavior and competency during the delivery in the operating room of Patient 2's twins in 2005 when they were identified. On 10/2407, the "LDRP (Labor Delivery Recovery Postpartum) Escalation Algorithm" guideline effective in 2005 was reviewed. The guideline	A 951		

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A 951	Continued From page 66 contained documentation as follows: 1. For clinical practice issues, the Licensed Vocational Nurse/ Registered Nurse (LVN/RN) was to confer with peers and or the Clinical Nurse Specialist (CNS). 2. Then the Medical Doctor (MD) on-call was to be contacted. 3. Then then the consult with back-up MD was to be contacted. 4. Then Obstetrical (OB) Nursing Manager was to be contacted. 5. Then if the nursing manager was unavailable, the RN was to go upward to the OB Chief and to the Assistant Physician In Chief (APIC) or MD Administrator on-call, 6. Before the OB Chief was notified, the Service Director could be notified and the Perinatologist could be consulted as needed. The Algorithm was not followed during the delivery of Patient 2's twins when staff present during Patient 2's delivery "did not escalate the event" as set forth in the Algorithm when too much time elapsed between vacuum pulls and delivery, the vacuum pulls were inappropriate, and there was complete disorder in the delivery/operating room. On 10/24/07, The Vacuum Assisted Delivery policy dated March of 2004 was reviewed. The purpose was to clarify indications of use, procedure and contraindications of vacuum assisted deliveries. The procedure as to when to discontinue the use of the vacuum was as follows: 1. If progress was not being made with each contraction.	A 951		

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A 951	Continued From page 67 2. If the extractor becomes disengaged (disconnected) 3 times. 3. If 20 to 30 minutes elapsed without success. 4. If trauma (injury) of fetal scalp was observed. The policy was not being followed when progress was not made with each contraction, over two hours elapsed between the start of the use of the vacuum until delivery, vacuum pulls were inappropriate, and when injury was noted to the fetal scalp at birth. On 10/25/07 at 8:50 a.m., an interview was conducted with Administrator G and Physician C. Administrator G and Physician C stated they were aware of the incident in 2005 with Patient 2's twins where there was complete disorder in the operating room, a prolonged vacuum extraction delivery of a non-viable twin , and quality of care policies and procedures that were not followed when concerns about Physician A were not communicated appropriately and/or addressed and resolved effectively.	A 951		