

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA35000081	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 08/15/2008
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NAME OF PROVIDER OR SUPPLIER THOUSAND OAKS SURGICAL HOSPITAL	STREET ADDRESS, CITY, STATE, ZIP CODE 401 ROLLING OAKS DR THOUSAND OAKS, CA 91361
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E 000	Initial Comments The following reflects the findings of the Department of Public Health-Licensing and Certification during the investigation of an Entity reported incident #CA00151772. The inspection was limited to the specific entity reported incident and does not reflect the findings of a full inspection of the facility. Representing the Department of Public Health: [REDACTED]	E 000	[REDACTED]	[REDACTED]
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E 242	T22 DIV5 CH1 ART3-70203(a)(2) Medical Service General Requirements (2) Developing, maintaining and implementing written policies and procedures in consultation with other appropriate health professionals and administration. Policies shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate. This RULE: is not met as evidenced by: Based on record review, facility policy and procedure review, and staff interview the facility failed to consistently implement their policy and procedure related to Adverse Events, including disclosure of the adverse event to the patient or patient's representative, with documentation of the disclosure in the patient's record. Findings: Clinical record review on 5/30/08 revealed Patient A was admitted to the facility and underwent a vaginal hysterectomy on 2/22/08. A	E 242	1. E242 The Manager of Regulatory Compliance provided education to the Hospital Administration team regarding reporting of adverse events including documentation requirements and time frame for reporting HSC Section 1279.1 (a)(b)(1)(D) [Date of Completion: 5/20/08] 5/1/2008 letter to the Hospital CEO is not part of patient A's clinical record. The Manager of Regulatory Compliance voluntarily shared a copy with the CDPH surveyors. During the conversation with the CDPH surveyors, the Manager of Regulatory Compliance realized that the written documentation of the conversation she had with patient A on 5/08/2008 was not written in the patient's chart. On 6/04/2008 a late	008 OCT 29 AM 10:53 VENTURA DISTRICT OFFICE
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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE <i>Michael Khan</i>	TITLE CEO	(X8) DATE 10/27/08
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E 242	<p>Continued From Page 1</p> <p>review of the facility documentation and interview with the Manager of Regulatory Compliance on 5/30/08 revealed the facility had received a phone call from Patient A's physician and surgeon on 4/18/08, informing them that Patient A had returned to surgery on 4/17/08, for the removal of a foreign object, retained during surgery performed at the facility on 2/22/08. The pathology report confirmed a surgical lap sponge.</p> <p>Patient A's clinical record contained a letter, dated 5/1/08, addressed to the facility's CEO (chief executive officer) from Patient A's physician/surgeon. Contained in the letter was the statement that Patient A was "upset" that no-one from the facility had contacted the patient "regarding the incorrect sponge and needle count."</p> <p>A review of the facility's policy and procedure entitled "Adverse Events, Reporting to CDPH" on 6/4/08 revealed the following, " Disclosure of Adverse Event to Patient or Patient's Representative".." The patient, or the party responsible for the patient, will be notified by the manager of regulatory compliance of the nature of the adverse event by the time the report to the DHS is made. Such disclosure shall be reflected in the patient's record."</p> <p>During an interview with the facility's Manager of Regulatory Compliance on 6/4/08 at 3:00 p.m., she confirmed that Patient A's medical record contained no documentation that the patient was notified by the facility of the adverse event. "I just documented it here" she stated pointing to her hand written notes on the back of a questionnaire, completed by Patient A, and mailed to the manager. The Manager of Regulatory Compliance added that the notes on</p>	E 242	<p>addendum was made in the patient's chart "1700 late entry on 5/8/08 I [Manager of Regulatory Compliance] had a conversation with the patient regarding her experience over the last few months and informed her that a report would be made to the appropriate department of P.H. [Public Health]".</p> <p>[Date of Completion: 6/4/2008]</p> <p>As part of the ongoing Performance Improvement program the Manger of Regulatory Compliance tracks and trends surgical cases through confidential occurrence reports for possible reportable events.</p>	<p>2008 OCT 29 AM 10:53 LICENSING & CERTIFICATION VENTURA DISTRICT OFFICE PUBLIC HEALTH</p>
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E 242	Continued From Page 2 the questionnaire were not a part of Patient A's record.	E 242		
E 273	<p>T22 DIV5 CH1 ART3-70214(a) Nursing Staff Development</p> <p>(a) There shall be a written, organized in-service education program for all patient care personnel, including temporary staff as described in subsection 70217(m). The program shall include, but shall not be limited to, orientation and the process of competency validation as described in subsection 70213(c).</p> <p>This RULE: is not met as evidenced by: Based on clinical record and personnel file review, staff interview and facility policy and procedure review, the facility failed to ensure Surgical Technician 1 (scrub technician) was only assigned duties and responsibilities for which competency had been validated.</p> <p>Findings:</p> <p>Clinical record review on 5/30/08 revealed Patient A was admitted to the facility and underwent a vaginal hysterectomy on 2/22/08. A review of the facility documentation and interview with the Manager of Regulatory Compliance on 5/30/08 revealed the facility had received a phone call from Patient A's physician and surgeon on 4/18/08, informing them that Patient A had returned to surgery on 4/17/08, for the removal of a foreign object retained during surgery performed at the facility on 2/22/08. The pathology report confirmed a surgical lap sponge.</p> <p>According to Patient A's medical record Surgical</p>	E 273	<p>2. E273</p> <p>April 15, 2008, a competency grid and notebook were created to be used as a reference when making patient care assignments in the O.R. It contains all core competency and current annual competency validations, as well as skills checklists for all O.R. personnel. The O.R. charge nurse refers to this book before making the daily assignments for all O.R. RNs and OR Techs. [CONTINUOUSLY UPDATED]</p> <p>OR Manager or qualified designee assesses and evaluates new hires for Core OR standard competencies prior to giving individual assignments.</p> <p>High risk skill competencies are reviewed and revalidated not less than annually. Examples include, but not limited to, electrosurgical safety, fires in the OR, malignant hyperthermia, laser safety, positioning, new service lines/procedures and new equipment.</p> <p>New employees are oriented only by qualified staff member who have been validated on competencies for which they are assessing. When orientation is completed, the evaluator will discuss and review the competency evaluations with the orientee. Each evaluation is reviewed by the OR Manager and only then are independent assignments given after final review and approval by the OR Manager.</p>	

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E 273	<p>Continued From Page 3</p> <p>Technician (ST) 1 was a member of the surgical team for Patient A's surgery on 2/22/08. A review of ST 1's personnel file on 5/30/08 revealed a "SURGICAL TECH EMPLOYEE COMPETENCY ORIENTATION AND EVALUATION" form for the technician indicating the surgical technician had demonstrated the ability to "i. Ensure correct sponge, needle, and instrument (when applicable) counts ", however, the competency verification for this procedure was 4/1/08, almost two months after Patient A's surgery on 2/22/08. During an interview with the Operating Room Manager on 5/30/08 she stated that ST 1 was working independently on 2/22/08, the date of Patient A's surgery.</p> <p>Review of the facility's policy and procedure titled "Orientation and Annual Competencies" on 6/4/08 revealed.... "Licensed and non-licensed personnel will complete the department orientation program prior to independent assignments....The orientee and their manager will review the orientation form at the completion of the orientation program to ascertain that all objectives have been met..."</p> <p>During a subsequent interview with the Operating Room Manager, she stated that each item (skill/element of knowledge) on the competency and evaluation forms is not initialed until that function or skill is completed satisfactorily. She also stated that the "department orientation program" referred to in the "Orientation and Annual Competencies" policy is the competency orientation and evaluation check list for each employee, and that it is to be completed prior to working independently. She confirmed that ST 1 was working independently on 2/22/08 during Patient A's surgery, prior to completion of the department orientation program (competency orientation and evaluation). She also verified that</p>	E 273	<p>Monthly ongoing monitoring of competency notebook is done by the OR Manager.</p> <p>On a continuous basis the OR Manager, Director of Nursing, Manager of Regulatory Compliance and Manager of Materials Management regularly monitor medical device alerts; the OR Manager, Director of Nursing, and Manager of Regulatory Compliance monitor confidential occurrence reporting and Performance Improvement indicators to determine new and or changes in high risk skills or behaviors.</p>	

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E 273	Continued From Page 4 ST 1's "COMPETENCY AND EVALUATION" was not completed until 4/1/08.	E 273		
E 278	<p>T22 DIV5 CH1 ART3-70214(a)(C) Nursing Staff Development</p> <p>(C) Registered nurses shall not be assigned total responsibility for patient care, including the duties and responsibilities described in subsections 70215(a) and 70217(h)(3), until all the standards of competency for that unit have been validated.</p> <p>This RULE: is not met as evidenced by: Based on clinical record and personal file review, staff interview and review of facility policy and procedures, the facility failed to ensure Licensed Nurse (LN) 1 was assigned only duties and responsibilities for which competency had been validated.</p> <p>Findings:</p> <p>Clinical record review on 5/30/08 revealed Patient A was admitted to the facility and underwent a vaginal hysterectomy on 2/22/08. A review of the facility documentation and interview with the Manager of Regulatory Compliance on 5/30/08 revealed the facility received a phone call from Patient A's physician and surgeon on 4/18/08, informing them that Patient A had returned to surgery on 4/17/08 at another hospital for the removal of a foreign object, retained during surgery performed at the facility on 2/22/08. The pathology report confirmed a surgical lap sponge.</p> <p>According to Patient A's clinical record LN 1 was a member of the surgical team for Patient A's surgery on 2/22/08. A review of LN 1's personnel</p>	E 278	<p>3. E278</p> <p>On March 27, 2008 the hospital Director of Nursing, Clinical Nursing Managers, Laboratory Manager, Manager of Regulatory Compliance and Human Resources Manager began the process of reviewing the orientation and competency assessment and validation procedures for the Hospital. A standardized/uniform format for Hospital wide competency assessment and validation was devised. This standardized/uniform format will also be used for department specific orientation and competency validation. This new format allows for employee self evaluation in addition to objective measurement by the evaluator.</p> <p>[Date of Completion: 9/9/08]</p> <p>The competency evaluation process now includes a written post test in addition to direct observation and self assessment of skills. Each component was reviewed for accuracy and alignment with the standards. The validation methodologies utilized within the standardized/uniform format reflect best practices according to established and recognized professional organizations (i.e., Title 22,CMS, AORN, APIC, ASPAN, The Joint Commission) and take into consideration specific licensing, job descriptions, and scope of practice for each job title. The competency</p>	

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Continued From Page 5

file on 6/4/08 revealed an "OPERATING ROOM RN EMPLOYEE COMPETENCY ORIENTATION AND EVALUATION" form dated 12/15/04. According to the form LN 1 had initialed the listed skills/elements of knowledge indicating that the employee verbally understood the skills/elements listed. One of the skills/elements of knowledge initialed by LN 1 was "Ensure correct sponge, needle, and instrument (when applicable) counts." Although the form indicated that the employee understood the skills listed, there was no documented evidence LN 1's competency to perform the skills/elements listed had been verified by the facility.

Review of the facility's policy and procedure "Orientation and Annual Competencies" on 6/4/08 reflects in part: "Licensed and non-licensed personnel will complete the department orientation program prior to independent assignments..."

During a subsequent interview with the Operating Room Manager, she stated that each item (skill/element of knowledge) on the competency and evaluation form is not initialed until that function or skill is completed satisfactorily. She also stated that the "department orientation program" referred to in the "Orientation and Annual Competencies" policy is the competency orientation and evaluation check list for each employee, and that it is completed prior to working independently. She confirmed that LN 1 should have demonstrated the ability to perform each of the skills/elements on the form and that the RN evaluating/observing this demonstration should have initialed each item as having been directly observed.

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assessment tool will be used for initial hire evaluation as well as for annual evaluations.

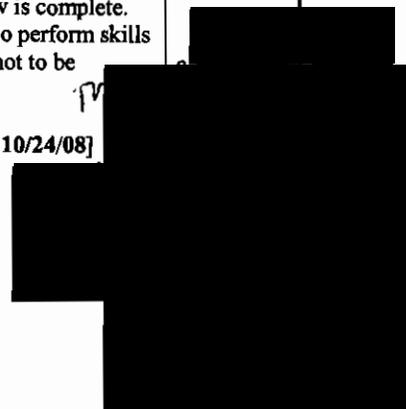
The format was changed so that it is consistent throughout each department. All new hires receive an orientation to the hospital policies and procedures and each department has specific skills that are evaluated based on the requirements of the department but the format of the tool is uniform.

[Date of Completion: 12/2008]

The O.R. Manager, with the assistance of the Human Resources Manager, reviewed the existing orientation checklists and competency assessments for all OR staff for completeness and accuracy. [10/16-24/08] Any current employees found to have missing, incomplete or inaccurate documentation is reassessed by a qualified staff member who has been validated on competencies for which they are assessing and updated documentation placed in their HR files and competency notebook.

Assignments are based on completed competency evaluation and assignments are not given until the department Manager signs off that the evaluation and competency review is complete. Staff are not assigned to perform skills not assessed or found not to be competent.

[Date of Completion: 10/24/08]



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E 347	Continued From Page 6	E 347		
E 347	<p>T22 DIV5 CH1 ART3-70223(b)(2) Surgical Service General Requirements</p> <p>(b) A committee of the medical staff shall be assigned responsibility for:</p> <p>(2) Development, maintenance and implementation of written policies and procedures in consultation with other appropriate health professionals and administration. Policies shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate.</p> <p>This RULE: is not met as evidenced by: Based on staff interview, clinical record review, and facility policy and procedure review, the facility failed to ensure their policy and procedure for the safe handling and labeling of specimens was consistently implemented by staff. According to Patient A's clinical record and the subsequent pathology reports the specimens submitted for review were incorrectly identified and mislabeled by the facility, placing the patient at risk for misdiagnosis and treatment.</p> <p>Findings:</p> <p>Clinical record review on 5/30/08 revealed Patient A was admitted to the facility and underwent a vaginal hysterectomy on 2/22/08, and two specimens were sent to pathology lab for analysis. Per the cytology request completed by the facility staff the specimens sent for analysis included the uterus, cervix, left fallopian tube and the right fallopian tube. However a review of the surgical pathology report of the specimens submitted from Patient A on 2/22/08, revealed no left fallopian tube specimen was received, as was indicated on the patient's</p>	E 347	<p>4. E347</p> <p>The OR Manager was notified by the Pathologist regarding the tissue specimen discrepancy from Patient A. The OR Manager called the surgeon and clarified the specimens with the surgeon. The pathology report was written by the pathologist according to the actual tissue specimens.</p> <p>[Date of Completion: 02/25/08]</p> <p>The O.R. Manager, in collaboration with the Medical Director of the Laboratory/Pathology, made changes to the Specimen Handling Policy/Procedure. Procedural changes made provide a way of following up on appropriate specimen labeling in a timely manner as well as ensuring physician accountability during read back of specimen collection, and ensuring proper documentation of compliance with the policy. The revised procedure includes the following elements:</p> <ol style="list-style-type: none"> The circulating RN will read back the specimens and get verbal confirmation from the surgeon and document same in patient profile. All procedures, except for those involving a needle puncture only, will have a pathology specimen form completed, even in the absence of a specimen. The RN circulator will enter the actual procedure performed as well as the 	

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cytology request, and a specimen of vaginal mucosa was received even though this specimen was not identified as sent by the facility.

According to the physician's discharge summary the patient underwent a "total vaginal hysterectomy, right salpingo-oophorectomy and left salpingectomy." "During the operative procedure a piece of vaginal mucosa was given to the scrub tech to discard, however the scrub tech mistakenly got the left fallopian tube which was submitted separately confused with the vaginal mucosa, submitted the vaginal mucosa labeled as left fallopian tube to pathology and therefore the left fallopian tube was actually discarded by the scrub tech thinking that this was the vaginal mucosa."

A review of the facility's policy and procedure titled "Handling of Pathology Specimens" revealed the purpose is "To correctly identify the process tissue and non-tissue specimens requiring pathology examination"... "The surgeon has the responsibility for identifying the specimen properly to the scrub and circulating nurses. At the end of the case all specimens are read back by the circulating nurse and confirmed by the surgeon." The procedure states "Specimens will be transferred from the surgical field to the specimen container as soon as feasible, to avoid being misplaced or mislabeled... The circulating nurse asks the surgeon the name of the specimen and writes it on the specimen label and places the label on an appropriate container. The scrub nurse hands off the specimen from the sterile field into the appropriately labeled container and repeats the name of the specimen to the circulator during this process-all subsequent specimens are handled in the same manner... The circulating nurse uses two

E 347

preoperative diagnosis on the pathology form.

d. The pathology department will review all specimen slips and check the actual procedure for appropriateness on the day of surgery. Any discrepancies will be brought to the attention of the OR Manager immediately.

Compliance with the procedural change will be monitored monthly by the OR Manager and the Pathology department.

The OR Manager in-serviced staff on revised procedures 10/17/08.

[Date of Completion: 10/24/08]

August 2008 the Manager of Regulatory Compliance compiles weekly pathology reports from the Director of Pathology into a quarterly report to the Quality Committee

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E 347	<p>Continued From Page 8</p> <p>identifiers to check the patient labels with the patient chart and armband to ensure correctness..."</p> <p>During an interview with the Operating Room Manager on 5/30/08 she stated that there was "miscommunication" in the operating room during Patient A's surgery on 2/22/08. She stated a specimen was sent to pathology labeled as right fallopian tube. She verified that the pathology lab phoned the facility a few days later to inform them that the specimen labeled as "right fallopian tube" was actually vaginal mucosa. The staff failed to consistently implement the facility's policy and procedures to ensure collected tissue specimens are correctly identified and labeled.</p>	E 347		<p>CA DEPT OF PUBLIC HEALTH PUBLISHED BY 2008 OCT 29 AM 10:53 LICENSING & REGULATION VENTURA DISTRICT OFFICE</p>
E2048	<p>T22 DIV5 CH1 ART7-70707.5(a) Hysterectomy</p> <p>(a) Except for a previously sterile woman, a hysterectomy may be performed or arranged for by a physician only if:</p> <p>This RULE: is not met as evidenced by: Based on staff interview and review of a clinical record and facility policy and procedures, the facility failed to ensure Patient A, who had a hysterectomy performed on 2/22/08, was informed orally and in writing, by the person who secured the authorization to perform the hysterectomy, that the surgery would render the patient permanently sterile. There was no documented evidence that a written acknowledgement of this information, a copy of the signed statement, was retained by the hospital in the patient's medical record, as per the facility's policy and as required by regulation.</p>	E2048	<p>5. E2048</p> <p>10/3/08 Education was provided by the Manager of Regulatory Compliance for all pre-assessment, pre-op and OR nursing staff involved in admitting a patient for a hysterectomy including Department Managers. Information included HSC Sections 1690-1691; Title 22, California Code of Regulations, Sections 51305.6 and 70707.5</p> <ul style="list-style-type: none"> • Documentation of written and verbal informed consent for a hysterectomy • Unless a woman is already sterile, either because she is post menopausal, or other biological reasons she does not need the consent and this must be well documented in the H&P; 	

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Findings:

Clinical record review on 5/30/08 and on 6/4/08 revealed Patient A was admitted to the facility and underwent a vaginal hysterectomy on 2/22/08. The record contained no documented evidence that Patient A was informed orally and in writing that the surgery would render her permanently sterile.

In an interview with the facility's Operating Room Manager and Manager of Regulatory Compliance on 6/4/08 at 3:00 p.m., they confirmed that there was no documentation in Patient A's record that this required information was provided to the patient before her surgery on 2/22/08. The Operating Room Manager stated that the facility uses the "state form", and the pre-op area staff are to have the form signed by the patient. The presence of the form is to be re-checked by the circulating nurse. The Operating Room Manager and the Manager of Regulatory Compliance both confirmed again that there was no evidence of the required information in Patient A's record.

Review of the facility's policy and procedure titled "Consent for surgery, procedure and treatment" revealed in part:..."Sterilization Procedures...A copy of the sterilization consent will be on the patient chart at the time of surgery. The RN will review the patient record for the consent prior to the procedure...The sterilization procedure is delayed until a copy of the consent for sterilization is on the chart..."

Facility staff failed to consistently implement the facility's policies and procedures.

- The hysterectomy is irreversible and will leave the woman permanently sterile and unable to have children.
- Free to withhold or withdraw consent
- Ability of ask questions

The hospital staff was reminded that without a complete informed consent for hysterectomy and documentation that the patient received verbal and written informed consent for hysterectomy the physician who secured the authorization to perform the hysterectomy would be called to the pre-op area to complete the informed consent process with his/her patient before the patient will be brought to the OR. The nurses have the complete support and backing of the Administration, Department Managers and the Medical Director to call for support if a physician is in disagreement.

[Date of Completion: 10/3/08]

The Manager of Regulatory Compliance sent a fax with CC to the Medical Director to all gynecologists/physicians on the Hospital Medical Staff with privileges to perform a hysterectomy a detailed summary of the requirements for informed consent for a hysterectomy. The cover letter stated "California HSC Sections 1690-1691; Title 22, California Code of Regulations, Sections 51305.6 and 70707.5 contains physicians requirements regarding informed consent for hysterectomies. The law requires that the information included in this attachment be given by the

California Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: CA350000081	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 08/15/2008
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NAME OF PROVIDER OR SUPPLIER THOUSAND OAKS SURGICAL HOSPITAL	STREET ADDRESS, CITY, STATE, ZIP CODE 401 ROLLING OAKS DR THOUSAND OAKS, CA 91361
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(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) COMPLETE DATE
E 242	<p style="text-align: center;">CA DEPT OF PUBLIC HEALTH 2008 OCT 29 AM 10: 53 LICENSING & CERTIFICATION VENTURA DISTRICT OFFICE</p>	E 242	<p>physician to the patient verbally and in writing:</p> <ul style="list-style-type: none"> • Is irreversible • Possible benefits • Second opinion • Additional procedures that may be required because of unforeseen conditions • General risks and complications • Specific risks, complications and discomforts • No guarantees • Length of hospitalization • Length of recovery • Anesthesia • Consequences of no treatment • Alternative methods of treatment • Fees • Free to withhold or withdraw consent • Ability to ask questions <p>Revision were made to policy IM 103 "Consent for Surgery, Procedure and Treatment" to include listed (as above) required statements in an informed consent for hysterectomy and informed consent for sterilization as outlined in HSC Sections 1690-1691; Title 22, California Code of Regulations, Sections 51305.6 and 70707.5.</p> <p>[Date of Completion: 10/15/08]</p>	

California Department of Public Health

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E 242		E 242	<ul style="list-style-type: none"> • Additional approval of policy at the next scheduled meeting of: Quality Committee (11/19/08), • Additional approval of policy at the next scheduled meeting of Medical Executive Committee (11/19/08) • Additional approval of policy at the next scheduled meetings of Joint Operating Committee (11/13/08). <p>[Date of Completion: 12/15/08]</p> <p>As part of the Hospital Performance Improvement program informed consents for hysterectomy will be tracked and trended monthly for discrepancies by Hospital confidential communication occurrence reports. Report will be given to the Quality Committee not less than Quarterly.</p>	

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2008 OCT 29 AM 10:53
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VENTURA DISTRICT OFFICE