STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	050058	A BUILDING B VvlNG	C 05/31/2007

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
GLENDALE MEM HOSPITAL & HLTH CENTER	1420 S CENTRAL AVE GLENDALE, CA 91204

(X4) 10 PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	10 PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
E 0001	Initial Comments	EOOO		

Surveyor: 10587
Representing the Department of Public Health
was [redacted]

1280.1(a) HSC Section 1280
If a licensee of a health facility licensed under subdivision (a), (b), or (f) of Section 1250 receives a notice of deficiency constituting an immediate jeopardy to the health or safety of a patient and is required to submit a plan of correction, the department may assess the licensee an administrative penalty in an amount not to exceed twenty-five thousand dollars ($25,000) per violation.

1280.1(c) HSC Section 1280
For purposes of this section, "immediate jeopardy" means a situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient.

DEFICIENCY CONSTITUTING IMMEDIATE JEOPARDY

ALPHABETICAL LIST OF ABBREVIATIONS:

cc - cubic centimeter	RE - regarding
gM or GM - gram	VL - vial
IJ - immediate jeopardy	X 1 - one time
IV - intravenous	# - number
NS - normal saline	
PC - percent	
PCXR - patient chest x-ray	
RCA - root cause analysis	

E 4851 T22 DIV5 CH1 ART3-70263(g)(2)
Pharmaceutical Service General Requirements

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X 1) PROVI DERISUPPLIERICLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION A.	(X3) DATE SURVEY COMPLETED
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(2) Medications and treatments shall be administered as ordered.

This Statute is not met as evidenced by:
Surveyor [redacted]
Based on review of facility & clinical records. and interviews with staff, the facility failed to ensure that drugs were administered as ordered by the practitioner in accordance with the facility approved protocol for one of fifteen (Patient A) sampled patients. For Patient A, the facility failed to clarify an incomplete medication order, and failed to follow facility approved policies, procedures and protocol for the safe administration of talc slurry for pleurodesis.

This deficient practice involving nursing services in tandem with corresponding pharmacy department failure to follow policies and procedures for the safe administration of drugs, and physician's use of abbreviations & handwriting resulted in a fatal medication error involving the talc slurry that was administered by the wrong route, intravenously to Patient A.

On May 31.2007 at4:10 p.m., an immediate jeopardy (IJ) was called due to a fatal medication error affecting (Patient A) involving multiple hospital departments & deficient practices including the intravenous administration of a talc slurry contrary to facility approved policies, procedures, and protocols. In addition. as of May 31. 2007, after three facility meetings regarding this medication error. facility analysis of the precipitating {root cause} continued to be incomplete, insufficient and failed to address key operational aspects pertaining to this medication error. The findings relating to the IJ had a potential to harm all hospital patients who may be

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affected by these unsafe systems. The facility began to immediately address and initiate corrections to the deficient systemic processes. The IJ was lifted approximately 24 hours later on June 01,2007, at 5:45 p.m., after onsite confirmation of implementation of the facility's corrective action.

Findings:

A clinical record review on May 14 & 30, 2007 for Patient A and interviews with Physician Two, Administrator Two & Three on May 14, 2007 at 8:30 a.m. and May 30, 2007 at 1 :40 p,m. revealed a 71-year-old female admitted into the facility on April 30, 2007 with a primary diagnosis of shortness of breath, tachycardia, palpitations, diaphoresis, and pleural effusion secondary to metastatic breast cancer.

On May 06,2007 at approximately 2:00 p.m., Physician One wrote an order as follows: "TALC SLURRY (STERILE TALC) 5gM IN SOcc NS FOR PLEURODESIS 2 CHEST TUBE CLAMPS UPRIGHT PCXR IN AM *Sfil07* RE= EFFUSION." The accompanying physician's progress note for Physician One dated May 06, 2007, stated, "Malignancy Pleural Effusion with decreased output. Will order Talc Powder. Physician Three to do {sic)Sclero treatment tomorrow. PCXR in morning prior to (sic)sdero treatment."

A review of the facility Medication Management Manual policy and procedure 10-02 pertaining to medication orders & administration indicated that a complete medication order would include directions for use including route of administration. The policy also stated that when there was a question about the physician's order, it must be discussed with the physician writing the

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order.

The Talc Slurry order that was written by Physician One was then noted on May 06, 2007 at 4:30 p.m. by Unit Clerk One, noted by RN 1 at 5:00 p.m. and the order was clarified with Physician One by Registered Nurse (RN) 1 to add, "X 1." Contrary to the facility policy and procedure 10-02 for complete medication orders, the directions for use and route of administration were not further clarified by RN 1 regarding the route and directions for use.

A review of facility documents dated May 24, 2007, review of declarations from RN 1 & Pharmacist One, and clinical record review for Patient A revealed that the Talc slurry order was scanned to the pharmacy department on May 06, 2007 at approximately 4:30 p.m.

A review of the facility Medication Management Manual policy "10-02" for medication order processing and interview with Pharmacist two on May 14, 2007 at 8:30 a.m. disclosed a procedure whereby the pharmacist would review medication orders for completeness and clarify as necessary. In addition, a complete order included an appropriate route. Contrary to the facility policy and procedure "10-02" for complete medication orders, the route of administration was not clarified by Pharmacist One.

A continued review of the facility documents, dated May 24,2007, and clinical record for Patient One indicated that the pharmacy order system generated a label for medication preparation on May 06, 2007 and the pharmacy label included information such as:

Patient Name (Last, First), Account #, Volume of

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preparation = Oml, Rate = Oml/hour, 5/06/07, 16:26:00, Sodium Chloride 0.9PC - 50ml, Talc Sterile 5GM - 1VL,
IV Admixture Service.

Pharmacy technician One then retrieved the label, gathered the medication components. and mixed the components in a 60ml Luer Lok syringe under the pharmacy hood. Pharmacist One then checked the finished Talc Slurry product against the label and verified the product as ordered by initialing the label on May 06, 2007 at approximately 5:00 p.m.

A review of the facility Medication Management Manual policy "10-02" policy for medication order processing and interview with Pharmacist two on May 14, 2007 at 8:30 a.m. revealed a procedure whereby the pharmacist would review labels for completeness and correct as necessary.
Contrary to the facility policy and procedure 10-02 for complete medication labels, the label was not corrected by Pharmacist One to include the route of administration.

A continued review of the facility documents dated May 24,2007, declarations from RN 1 & Pharmacist One, and clinical record for Patient A disclosed that at approximately 5:30 p.m. on May 06, 2007, RN 1 double checked the medication as prepared and delivered by the pharmacy as well as patient identification at the bedside and then proceeded to administer the Talc Slurry that was prepared by the pharmacy department within a Luer-Lok syringe into the connecting peripheral, intravenous access port for the Luer-Lok that was located in Patient One's right hand.

The Talc Slurry administration was initiated by RN 1 as a slow intravenous bolus on May 06,

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2007 at approximately 5:30 p.m. Patient A immediately complained of localized pain and Licensed Nurse One stopped the infusion, repositioned the hand and resumed infusion. After about 30 seconds to one minute, Patient A exh bited "adverse reaction of a seizure to the drug and became bluish in color of her face" as documented by RN 1. A Code Blue was called by RN 1 at approximately 5:35 p.m. that was attended by Physician Four but Patient A expired on May 06, 2007 at 6:05p.m. despite attempts with resuscitation.

A review of the declaration dated May 24, 2007 from RN 1 and interview with RN 1 on June 5, 2007 at 1:45 p.m. disclosed that he mistook the "IN" that was handwritten by Physician One on the May 6, 2007 order as IV.

A review of the American Hospital Formulary Service Drug Information Manual - 2006; ISBN 1-58528-142-5; Chapter 24:16; Page 1783 and Lexi-Comp 2007 Sclerosing Agents Online - http://online.lexi.com/crlsqllservletlcrlonline respectively indicated that talc was a sclerosing agent for intrapleural administration to treat pleural effusions. In addition, the manufacturer stated that the syringe of the talc slurry should be appropriately labeled with the statement, "For Pleurodesis Only - NOT FOR INTRAVENOUS ADMINISTRATION. "

A review of the facility approved sclerosing protocol for treatment of pleural effusion with sterile talc and interview with Physician Two, Pharmacist Two, and Nursing Administrator Four on May 14, 2007 at 8:30 a.m. revealed a procedure whereby the pharmacy was to prepare the drug in a catheter tip syringe and send to the unit for intrapleural administration by the

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physician only. It was stated by Physician Two and Pharmacist Two that the sderosing protocol with sterile talc was approved by the medical staff over a year ago in March 2006. Contrary to the facility approved protocol for sclerosing with talc, the drug was not administered by a physician but by RN 1 as prepared by the pharmacy department in a Luer Lok syringe and not in a catheter tip syringe as outlined in facility protocol.

A review of the facility policy for Intravenous Push Administration and interview with Nursing Administrator Four on May 14, 2007 at 8:30 a.m. also disclosed guidelines pertaining to medications that properly trained registered nurses could administer by intravenous Push. Sterile Talc slurry was not listed on this policy and procedure and was not approved as a
medication for administration by registered nurses by intravenous push.

A review of the facility approved manual for abbreviations indicated that" IN" was an approved abbreviations but the manual also stated that, "this is a dangerous abbreviation as it can be read as IV." In addition, the abbreviation manual that was used and approved by the facility as verified by interview with the Director of Medical Records on June 4, 2007 at 10:15 a.m. was entitled, "Medical Abbreviations: 26,000 Conveniences at the Expense of Communication and Safety. 12th Edition: ISBN 0-931431-12-3"

A review of the facility policy for Bedside Invasive Procedures policy "625" on May 30, 2007 disclosed a policy that identified invasive procedures that could be done safely at the bedside by a qualified physician. As of February 2005 when the policy was last reviewed,

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pleurodesis sclerosing with talc was not listed as an approved bedside procedure. In addition, the Bedside Invasive Procedures policy stipulated, " Invasive or surgical procedures that are considered 'elective' or non emergent are generally performed in an operating room setting."

A continued review of the facility documents dated May 24, 2007, and interviews with Physician Two, Nursing Administrator Four, and Pharmacist Two on May 30 & 31, 2007 disclosed that the facility had completed three full meetings to analyze this incident (Root Cause Analysis (RCA) meetings) involving Patient A. An interview with Physician Two on May 31, 2007 at 2:50 p.m. revealed that that he and the committee were unaware of the facility approved Bedside Invasive Procedures policy "625" and had not considered aspects of this policy and procedure during the RCA analysis and implementation of corrective actions.

On May 31,2007 at 4:10 p.m., an immediate jeopardy (IJ) was called due to a fatal medication error (Patient A) involving multiple hospital departments. In addition, as of May 31, 2007, after three facility meetings regarding this medication error, the facility analysis (RCA) and corrective actions continued to be incomplete, and failed to address key systemic, operational aspects pertaining to this medication error such as the facility approved Bedside Invasive Procedures policy "625."

The facility began to initiate immediate corrective actions and the IJ was lifted approximately 24 hours later on June 01, 2007, at 5:45 p.m., after meetings with the survey team to discuss key aspects of correction and onsite confirmation of

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implementation of the facility's corrective action. A voluntary facility ban on bedside procedures of pleurodesis was initiated. In addition, the facility mandated the use of existing pre-printed order forms for all future sclerosing pleurodesis in the operating room and the review of all future pleurodesis procedures in the operating room by a gatekeeper such as the chief of staff who will assess and approve procedures.

The violation involving the failure of the facility to administer medications on May 6, 2007 to Patient A as prescribed by Physician One and the failure to adhere to facility poliCies & protocolS to ensure safe medication administration such as proper clarification, labeling, and preparation procedures resulted in the fatal intravenous administration of a sterile talc slurry.