The following reflects the findings of the California Department of Public Health during a complaint investigation visit:

Complaint # CA00196406

Representing the California Department of Public Health: HFN, and HFEN.

This Department was able to substantiate a violation of the regulations.

The CNO was notified Immediate Jeopardy was identified on August 12, 2009, at 4 p.m. The Immediate Jeopardy was due to the facility’s failure to implement their policy and procedure regarding:

a. assessment and identification of newborns at risk for developing hyperbilirubinemia (high bilirubin levels in the blood);

b. conducting TcB and TSB testing on newborns at-risk for developing hyperbilirubinemia; and, 

c. conducting Coombs testing (test to detect destruction of red blood cells in the newborn) when the mother’s blood type was O positive, to identify hemolytic disease of the newborn and provide treatment as necessary.

Upon receipt of an acceptable plan of correction, the CNO was notified the Immediate Jeopardy was abated on August 12, 2009, at 6:47 p.m.

Preparation and submission of this Plan of Correction does not constitute an admission or agreement by Southwest Healthcare System ("Southwest" or "the Hospital") of the truth of the facts alleged or conclusions set forth in the Statement of Deficiencies. The Hospital is submitting this Plan of Correction as required by state regulations. This Plan of Correction documents the actions taken by the Hospital to address the alleged deficiencies.

A. The CNO reviewed the situation and identified that all of the cited infants had been discharged and were no longer newborns in the hospital. Therefore, any corrective actions put in place would not affect those infants.

The CNO also reviewed the cited medical records and confirmed that none of the cited newborns suffered any harm.

B. Administration identified that not following the policies on assessing newborns for risk factors for hyperbilirubinemia could affect any newborn with risk factors born at the Hospital. Therefore, the Hospital took the actions outlined below in sections C. and D. to protect infants born at the Hospital.
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Abbreviations used in this document:

- less than
- AAP - American Association of Pediatrics
- ABO - antibodies blood group
- AB+ - blood type
- CNO - Chief Nursing Officer
- GACH - General Acute Care Hospital
- NICU - Neonatal intensive care unit
- O+ - blood type
- PCP - Primary Care Practitioner (or Physician)
- RH Rh - Rhesus factor
- RN - Registered Nurse
- SB - serum bilirubin
- \( TcB/TCB \) - transcutaneous bilirubin (a test conducted to obtain bilirubin level using a device applied on the forehead)
- TSB - total serum bilirubin (a blood test to determine the bilirubin levels)

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For the purpose 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.

T22 DIV5 CH1 ART3 - 70213(a) Nursing Service Policies and Procedures.

(a) Written policies and procedures for patient care shall be developed, maintained and implemented by the nursing service

C. The Hospital took the following actions to improve assessment and care for newborns:

- The CNO reviewed and confirmed that the process changes as described in the Hospital's immediate plan of correction and put in place on 08/12/09 were in effect.

- The CNO and the Director of Women's Services revised the Hospital's policy and procedure for assessing and treating newborns at risk for hyperbilirubinemia consistent with American Academy of Pediatrics guidelines and recommendations of the Department of Pediatrics.

- The CNO oversaw the review of the policies and forms pertaining to assessment, testing, and treatment if indicated for newborns, and assured that pertinent revisions were made. It is the responsibility of the physician to determine each patient's plan of care based upon both clinical and diagnostic information. The physician progress note for discharge of newborns was initiated to include risk assessment for hyperbilirubinemia. The newborn orders were revised to include Q12 hour serum bilirubin levels for infants with serum bilirubin results > 75th percentile. Specifically, revisions were made to the Cord
Continued From page 2

Based on interview and record review, the facility failed to ensure the facility's policy and procedure was implemented to meet the needs of three newborns (Patients 11, 12, and 13) at risk for developing hyperbilirubinemia (high bilirubin levels in the blood), by failing to:

1. Assess and identify risk factors for hyperbilirubinemia for three newborns (Patient 11, 12, and 13), resulting in the delay of testing and the potential for brain damage, developmental disabilities, and death;

2. Perform TcB testing (a non-invasive method of checking bilirubin levels) when risk factors were identified for three newborns (Patients 11, 12, and 13), resulting in the delay of the test and the potential for brain damage, developmental disabilities, and death;

3. Obtain an order for phototherapy when the TSB (bilirubin level in the blood) was in the high intermediate risk zone or high risk zone on the Bhuta curve for one newborn (Patient 11), resulting in exposure of the babies to elevated bilirubin levels and the potential for brain damage, developmental disabilities, and death;

4. Conduct TSB testing when the TcB was in the high intermediate risk zone or high risk zone on the Bhuta curve for two newborns (Patients 12 and 13), resulting in the potential for lack of treatment, brain damage, developmental disabilities, and

Blood Collection policy, Newborn Nursery Orders form, Hours Specific Bilirubin Nomogram form, and Physician's Record of Newborn form. The revised policies and processes included:

- Newborn nursery admission orders initially called for the testing of cord blood for type, RH, and Coombs on infants of Type O or RH negative mothers within one hour of birth, and were revised in October to require the testing within two hours of birth;

- Nurses conduct an initial assessment within the first 2 hours after a baby comes to the nursery to determine whether the baby is jaundiced and whether any of six risk factors are present. If the nurse identifies jaundice or risk factors, a TcB is performed;

  - If the TcB result is greater than or equal to the 75th percentile, the nurse must notify the physician and obtain further orders, which may include orders for phototherapy; and

  - If a newborn does not have risk factors and does not need treatment, the nurse must notify the physician and obtain further orders, which may include orders for phototherapy; and

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the facility may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. Except for nursing homes, the findings above are traceable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plan of correction are traceable 14 days to 6 months following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is required to continued program participation.

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5. conduct Coombs testing (test to detect destruction of red blood cells in the newborn) when the mother's blood type was O+ for two newborns (Patients 12 and 13) to identify and treat hemolytic disease of the newborn resulting in the potential for brain damage, developmental disabilities, and death.

(The Bhutani Curve contains hour specific curves of normal bilirubin values within the first 5 days of life. High, intermediate, and low risk zones are designated along the curves according to the risk of developing hyperbilirubinemia that will need follow-up. A TcB or TSB in the Low Risk Zone or Low Intermediate Zone (40%) does not require intervention. A TcB or TSB in the High Risk Zone (95%) or High Intermediate Zone (75%) requires further investigation and possible intervention. Bilirubin levels are charted on the curve using the Hour Specific Bilirubin Nomogram document.)

Findings:

1. The record for Patient 11 was reviewed on August 9, 2009. Patient 11 was born on June 4, 2009, at 4:28 a.m., at 37-67 weeks gestation (time developing in the womb - normal 40 weeks).

The Newborn Admit Flowsheet dated June 4, 2009, at 6:45 a.m., indicated:

a. the mother was Rh negative and the baby was factors, then the nursing staff must obtain a TcB or TSB (as indicated by policy) on the day of discharge. If the test result at that point is greater than or equal to the 75th percentile, the nursing staff notifies the physician for further orders. The parents/guardians of any newborn at risk of developing severe hyperbilirubinemia are instructed to keep their early follow-up appointment with their physician or clinic after discharge as ordered.

* The Department of Pediatrics, the Medical Executive Committee, and the Board of Governors approved the revised policies and forms.

* The Women's Services Leadership Team provided education to nursing staff on the process for assessing and documenting risk factors for hyperbilirubinemia at the beginning of each shift prior to nurses taking responsibility for patient care.

* The Women's Services Director directs and provides ongoing followup education on this process through various means, including educational modules, memoranda, and a weekly communication newsletter called "Baby Steps."
Continued From page 4

b. the baby's general appearance included Caput Succedaneum (scalp swelling that extends across the midline and over the suture lines and is associated with head moulding); and,

c. the baby had bruises on the right forearm.

The Well Newborn Care Flowsheet dated June 4, 2009, at 6:30 p.m., indicated the baby was breast fed for the first time at 11 hours and 45 minutes of age.

The Hour Specific Bilirubin Nomogram indicated the nurses did not assess for risk factors for developing hyperbilirubinemia. The nurses did not identify the Rh incompatibility, bruising, delay in feeding, caput, or gestational age of <38 weeks as risk factors. On June 5, 2009, at 10:15 a.m. (30 hours of age), the TcB was 9.5 mg/dl and the TSB was 8.9 mg/dl, both in the high intermediate risk zone on the Bhutani curve.

Patient 11 was discharged home on June 5, 2009, at 12:50 p.m., with multiple risk factors for developing hyperbilirubinemia. The TSB in the high intermediate risk zone, to follow up with the physician three to four days after discharge.

According to the AAP Guidelines:

- An infant with no risk factors who is discharged home at 30 hours of age should be seen by the age of 96 hours, but earlier follow up should be provided

D. The Hospital monitors the corrective actions as follows:

- The Women's Services Director 08/12/09 ensures review of 100% of charts of newborns to confirm they are being assessed timely for jaundice and risk factors, and tested timely and in compliance with the policies and procedures. The indicators being reviewed include the following for high risk cases:
  - TcB/TSB done each shift
  - STAT TSB results received in 1 hr
  - Cord Blood testing within 1 hr initially, then within 2 hrs as of 10/19/09
  - Admit Risk on Nomogram
  - Narrative re Abnormal Findings
  - STAT TSB if TcB elevated
  - TSB q 12 hours
  - MD notification of TSB

- The Women's Services Director 08/12/09 Leadership Team provides re-education and counseling to nurses whose audits fall out of compliance. Audit results reflect substantial compliance with the process.

- The Women's Services Director 10/19/09 reports audit results to staff members, the Department of Pediatrics, High Reliability Unit (HRU) Multidisciplinary
Continued From page 5

for those babies who have risk factors for developing hyperbilirubinemia:

b. the risk factors most frequently associated with hyperbilirubinemia are breastfeeding, gestation below 38 weeks, jaundice in a previous sibling (brother or sister), and jaundice noted before discharge (Patient 11 had three of these four risk factors).

c. phototherapy is recommended for an infant at 30 hours of age, with risk factors for developing hyperbilirubinemia, and a TSB of 8.9.

On August 6, 2009, at 2:26 p.m., Patient 11’s records were reviewed with the Nursery Manager. The Manager stated Patient 11 had risk factors for increased bilirubin levels: 37.6/7 weeks gestation, bruises on the forearm, mother and baby’s Rh incompatibility, not feeding until approximately 12 hours after delivery, and caput succedaneum. The Manager stated the risk factors should have been identified on the Hour Specific Bilirubin Nomogram.

During a concurrent interview with the Manager, she stated the TCB testing should have been performed as soon as the risk factors were present, not just on discharge. She stated the TCB testing should have been performed within two hours of birth, not 30 hours of age. The Manager stated Patient 11 should have received an order for phototherapy because the TSB was in the high intermediate risk zone on the Bhutani curve.

The Hospital hereby also requests an informal conference with the district administrator/district manager to discuss the citations because the Hospital submits there was no immediate jeopardy to patients. Immediate jeopardy is defined as “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.” None of the cited patients suffered actual harm, nor were they likely to suffer serious injury or death because all of the patients were under the care of a pediatrician and were discharged with instructions to follow up with the pediatrician in accordance with orders from the pediatrician.
On August 6, 2009, at 4:35 p.m., RN 1 was interviewed. RN 1 stated TcB testing was conducted when a baby was jaundiced within 24 hours of life and if positive for Coombs test. RN 1 stated TcB should also be conducted before discharging the newborn from the facility.

On August 6, 2009, at 4:40 p.m., RN 2 was interviewed. RN 2 stated TcB testing should be done on all babies before discharging them. RN 2 stated if risk factors for increased bilirubin were identified, TcB and/or TSB testing would be conducted only if the physician ordered it. RN 2 stated if a baby had increased bilirubin levels in the high intermediate risk zone or high-risk zone, she would discharge the baby from the facility if the physician ordered it.

On August 12, 2009, at 11:18 a.m., RN 3 was interviewed. RN 3 stated she was the nurse who discharged Patient 11 from the facility. RN 3 stated she would only conduct TcB testing if the baby was jaundiced, and only before discharging the baby from the facility. RN 3 stated she would not conduct TcB testing even if risk factors were identified, unless the baby was jaundiced or being discharged. RN 3 stated she informed Patient 11's physician of the increased bilirubin level (high-intermediate risk zone), and the physician ordered to discharge Patient 11 from the facility.

On August 11, 2009, Patient 11's record at GACH 2 was reviewed. Patient 11 was admitted to GACH 2 on June 9, 2009, at 7:15 p.m. (four days after discharge from the facility).
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The Admission H&P dated June 9, 2009, indicated the baby was taken to her PCP on the day of admission (June 9, 2009) for a scheduled visit. The PCP did a TcB and the level was 15. A TSB was done and the result was 25. The parents were instructed to go to [GACH 2] NICU for further evaluation and treatment of hyperbilirubinemia.

On June 9, 2009, at 7:40 p.m., the Total Bilirubin level was 28.2 mg/dl (reference range was 0-12.4 mg/dl) and the Direct Bilirubin was 0.6 mg/dl (reference range was 0-0.4 mg/dl).

The Discharge Summary dated June 15, 2009, at 9:35 a.m., was reviewed. The record indicated, "...Discharge diagnoses: indirect hyperbilirubinemia - treated and resolved; dehydration - resolved; and, feeding dyscoordination - improved..."

2. On August 12, 2009, Patient 12's record was reviewed. Patient 12 was born on July 26, 2009, at 9:06 a.m., at 37 2/7 weeks gestation (time developing in the womb - normal 40 weeks).

The Newborn Admit Flowsheet dated July 26, 2009, at 9:06 a.m., indicated the baby had a slight Caput Succedaneum (scalp swelling that extends across the midline and over suture lines and is associated with head moulding), was large for gestational age, and the mother's blood type was O+. There was no Coombs test performed on the cord blood.

The Hour Specific Bilirubin Nomogram indicated the nurses did not assess for risk factors for developing
Continued From page 8

hyperbilirubinemia. The nurses did not identify the gestational age of <38 weeks as a risk factor. On July 27, 2009, at 5 a.m. (20 hours of age), the TcB was 6.1, in the high intermediate risk zone on the Bhutani curve. There was no TSB drawn.

Patient 12 was discharged home on July 27, 2009, at 12 p.m., with risk factors for developing hyperbilirubinemia, the TcB in the high intermediate risk zone, and no order for follow-up with the physician.

There was no evidence a case manager identified the baby was at risk for hyperbilirubinemia during their screening process. There was no evidence a case manager was involved in the discharge planning of the baby to determine post hospital needs. There was no evidence the nursing staff identified the need for a discharge plan that included close follow up for prevention of severe hyperbilirubinemia.

On August 12, 2009, at 3:25 p.m., Patient 12's record was reviewed with the Nursery Manager. The Manager stated Patient 12's <38 weeks gestation was a risk factor for hyperbilirubinemia. The Manager stated the TSB Nomogram should have indicated the risk factor for increased bilirubin levels.

The Manager stated the TCB testing should have been conducted within two hours of the baby's age, sooner than 20 hours of age. The Manager was unable to explain why TSB testing was not completed when the TCB resulted in the high risk zone.

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LABORATORY DIRECTOR’S OR PROVIDER SUPPLIER REPRESENTATIVE’S SIGNATURE TITLE (AS) DATE

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intermediate risk zone. The Manager stated TSB testing should have been completed to determine the need for phototherapy.

During a concurrent interview, the Manager was unable to find evidence Coombs testing was performed on Patient 12. The Manager stated Coombs testing should have been done.

3. On August 12, 2009, Patient 13's record was reviewed. Patient 13 was born on June 11, 2009, at 12:40 p.m., at 36 6/7 weeks gestation (time developing in the womb - normal 40 weeks), and the mother's blood type was O+. There was no Coombs test done on the cord blood.

The Hour Specific Bilirubin Nomogram indicated the nurses did not assess for risk factors for developing hyperbilirubinemia. The nurses did not identify the gestational age of <38 weeks as a risk factor. On June 12, 2009, at 3:40 p.m. (27 hours of age), the TcB was 6.8, on the line of the high intermediate risk zone of the Bhutani curve.

Patient 13 was discharged home on Friday, June 12, 2009, at 6:30 p.m., with a risk factor for developing hyperbilirubinemia, the TcB on the line of the high intermediate risk zone, to follow up with the physician in two to three days (Sunday, a non office day, or Monday), with no specific appointment.

On August 12, 2009 at 3:25 p.m. Patient 13's record was reviewed with the Nursery Manager. The Manager stated the nurses should have assessed

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Continued from page 10

and identified the gestational age of <38 weeks as a risk factor. The Manager stated the TCB testing should have been done sooner than 27 hours of age. She stated the testing should have been done within two hours of birth.

During a concurrent interview, the Manager was unable to find evidence Coombs testing was performed on Patient 13. The Manager stated Coombs testing should have been done due to the mother's blood type.

The facility policy titled, "Hyperbilirubinemia, Assessment, Identification, and Intervention Protocol," last revised April 2008, was reviewed on August 6, 2009. The policy indicated the purpose was to identify newborns at risk for hyperbilirubinemia, promote timely assessment of hyperbilirubinemia, and initiate appropriate follow-up to aid in the prevention of kernicterus (damage to the brain centers of infants caused by increased levels of bilirubin).

The policy indicated the risk factors for hyperbilirubinemia included but were not limited to the following:

- a. bruising and cephalhematomas (which increase the production of bilirubin);
- b. genetic or ethnic risk factors include sibling with neonatal jaundice (yellowish skin discoloration), East-Asian or Mediterranean descent;
- c. inadequate nutrition/hydration through...
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- Suboptimal breastfeeding:
  - Jaundice appearing in the first 24 hours after birth (dark skin pigments may obscure visualization):
  - Macrosomic (large for gestational age) infant of a diabetic mother:
  - Near-term newborns at 35, 36, and 37 weeks of gestation, particularly if they were breastfed:
  - Significant weight loss (defined as greater than 10% by discharge):
  - Temperature instability or treatment of sepsis:
  - Unrecognized hemolysis, such as ABO blood type incompatibility.

The policy further indicated:

- A TcB and/or TSB would be done when visible jaundice and/or risk factors were present, and prior to discharge:
- Bilirubin levels were to be plotted on the Hour-specific Bilirubin Nomogram:
- If the TcB value was greater than 75% (high intermediate risk zone) on the nomogram (Bhutani Curve) a TSB was to be drawn stat:
- The physician was to be notified stat for values in the high intermediate or high-risk zone, or values
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greater than 12; and,

e. an order for phototherapy was to be obtained if
the TSB was in the high intermediate or high-risk
zone.

The Newborn Nursery Preprinted Orders were
reviewed on August 6, 2009. The orders directed
the staff to do the following:

a. obtain a TcB as indicated per protocol;

b. if a TcB was performed, and the value was
greater than or equal to 75% on the Bhutani Curve
(high intermediate risk zone), draw a TSB and
notify the physician with results;

c. follow the protocol for recommended
interventions; and,

d. obtain an order for phototherapy if indicated per
protocol.

The facility policy titled, “Cord Blood Collection &
Processing,” last revised November 2006, was
reviewed on August 12, 2009. The policy indicated
cord blood would be processed for Rh, type, and
coombs, on all infants of Rh negative and/or type O
mothers that delivered in this hospital.

On August 12, 2009, at 4 p.m., the CNO was
notified Immediate Jeopardy was identified. The
Immediate Jeopardy was identified due to the
facility’s failure to implement their policies and
procedures on:

Event ID: 11-06-11

1/14/2010 5:57.53PM
LABORATORY DIRECTOR’S OR PROVIDER/SUPPLIER REPRESENTATIVE’S SIGNATURE

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of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are reportable 14 days following
the date these documents are made available to the facility. If deficiencies are cured, an approved plan of correction is required to continued program
participation.
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a. assessing and identifying risk factors for increased bilirubin levels;

b. performing TCB testing as soon as risk factors were identified;

c. obtaining an order for phototherapy when the SB levels were in the high intermediate risk or high risk zone; and,

d. conducting Coombs testing when the baby's mother's blood type was O positive or Rh negative, to identify hemolytic disease of the newborn and provide treatment as necessary.

On August 12, 2009, at 4 p.m., the CNO was notified Immediate Jeopardy was identified. The Immediate Jeopardy was identified due to the facility's failure to implement their policies and procedures on:

a. assessing and identifying risk factors for increased bilirubin levels;

b. performing TCB testing as soon as risk factors were identified;

c. obtaining an order for phototherapy when the SB levels were in the high intermediate risk or high risk zone; and,

d. conducting Coombs testing when the baby's mother's blood type was O positive or Rh negative, to identify hemolytic disease of the newborn and provide treatment as necessary.
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provide treatment as necessary.

Upon receipt of an acceptable written plan of correction on August 12, 2009, at 6:47 p.m., the Immediate Jeopardy was abated.

The plan of correction included the following immediate actions:

a. newborn nursery admission orders to test cord blood for type, Rh, and Coombs on all infants of Type O or Rh negative mothers within one hour of birth would be followed;

b. hyperbilirubinemia risk factors would be assessed during the initial newborn assessment, every shift, and prior to discharge;

c. if risk factors were identified, a TcB would be performed at the time of identification;

d. if the TcB was in the high intermediate risk zone or above, a TSB would be drawn, and the results would be called to the physician;

e. if the TSB was in the high intermediate risk zone or above, the physician would be contacted for interventions, which may include an order for phototherapy;

f. all nursery and couplet care nurses would receive education on the cord blood collection policy, the hyperbilirubinemia policy, the newborn nursery admission orders, and the hour specific bilirubin nomogram, prior to assuming a patient care
Continued From page 15
assignment; and,

g. the facility would monitor for compliance.

The facility's failure to ensure their nursing policies and procedures were implemented to meet the needs of the newborns at risk for developing hyperbilirubinemia is a deficiency that has caused, or is likely to cause serious injury or death to the patient and therefore constitutes an immediate jeopardy within the meaning of Health and Safety Code section 1280.1.