

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

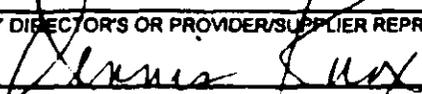
PRINTED: 11/27/2009
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050701	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED C 09/17/2009
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NAME OF PROVIDER OR SUPPLIER SOUTHWEST HEALTHCARE SYSTEM	STREET ADDRESS, CITY, STATE, ZIP CODE 25500 MEDICAL CENTER DRIVE MURRIETA, CA 92562
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A 000	<p>INITIAL COMMENTS</p> <p>The following reflects the findings of the California Department of Public Health during a Complaint Validation survey (Complaint # CA00196406, CA00199586, and CA00200713) conducted August 6 through September 17, 2009. An initial visit was made August 6, 2009, with subsequent visits on August 12, 25, 26, 27, 28, and September 3 and 4, 2009.</p> <p>Representing the California Department of Public Health: Omar Fausto, HFEN; Tina Buchanan, HFEN; Jan Brink, MD, Medical Consultant; Janne Powell, HFEN; Nancy Neil, HFEN.</p> <p>The average daily census was 165.</p> <p>The sample size was 142.</p> <p>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:</p> <p>a. assessment and identification of newborns at risk for developing hyperbilirubinemia (high bilirubin levels in the blood);</p> <p>b. conducting TcB and TSB testing on newborns at-risk for developing hyperbilirubinemia; and,</p> <p>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</p>	A 000	<p>The submission of a plan of correction does not constitute agreement that all citations are correct or that the hospital violated the rules.</p>	<p>09 DEC 16 AM 10:59</p> <p>CA DEPT OF PUBLIC HEALTH</p>
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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE 	TITLE CEO	(X6) DATE 12.14.09
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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.

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A 000	<p>Continued From page 1 provide treatment as necessary.</p> <p>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.</p> <p>The CEO was notified Immediate Jeopardy was identified on September 4, 2009, at 11:40 a.m. The Immediate Jeopardy was identified due to the facility's failure to provide appropriate discharge planning and follow up care for Infants who were at risk for developing hyperbilirubinemia, resulting in the potential for development of brain damage and death for at-risk newborn infants discharged from SWHCS.</p> <p>Upon receipt of an acceptable plan of correction, the CNO was notified the Immediate Jeopardy was abated on September 4, 2009, at 4:15 p.m.</p> <p>Abbreviations used in this document:</p> <ul style="list-style-type: none"> < - less than > - more than AAP - American Association of Pediatrics ABO - antibodies blood group AB+ - blood type ASAP - as soon as possible BMP - basic metabolic panel BP - blood pressure CBC - complete blood count CDPH - California Department of Public Health CEO - Chief Executive Officer CLS - Clinical Laboratory Services CM - Case Manager CN - Charge Nurse CNE/O - Chief Nursing Executive/ Officer COPD - Chronic Obstructive Pulmonary Disease CPAP - Continuous Positive Airway Pressure 	A 000		<p style="writing-mode: vertical-rl; transform: rotate(180deg);">09 DEC 16 AM 10:59</p>
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A 000	Continued From page 2 CPS - Child Protective Services CT - Computerized Tomography DC - Discharge DCM - Director of Case Management DOB - date of birth DWS - Director of Women's Services ED - Emergency Department GACH - General Acute Care Hospital H&P - History and Physical HMO - Health Maintenance Organization ICC - Infection Control Coordinator ICU - Intensive Care Unit IVMC - Inland Valley Medical Center kg - Kilogram L&D - labor and delivery LS - Laboratory Supervisor mcg - Micrograms mg/dl - milligram(s) per deciliter(s) min - minute MRSA - Methicillin Resistant Staphylococcus Aureus MS or M/S - Medical Surgical MST - Medical Surgical Telemetry MSW - Masters in Social Work NICU - Neonatal intensive care unit OB - Obstetrics O+ - blood type PCP - Primary Care Practitioner (or Physician) PCU - Progressive Care Unit PDR - Physician's Desk Reference PI - Performance Improvement PCP - patient care plan PMD - Primary Medical Doctor PPE - Personal Protective Equipment PT - Physical Therapist P&P - policy and procedure RH/Rh - Rhesus factor RN - Registered Nurse RSMC - Rancho Springs Medical Center	A 000		

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A 000	Continued From page 3 SB - serum bilirubin STAT - immediately SWHCS - Southwest Healthcare System 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) VA - Veterans Affairs	A 000		
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 observation, interview, and record review, the governing body failed to effectively lead the organization by failing to ensure: 1. effective operation of the grievance process, resulting in failure to ensure safe discharge planning and follow up care for newborns at risk for developing hyperbilirubinemia (jaundice caused by high bilirubin levels in the blood), improvement in systems, and patient satisfaction (A119); 2. appropriate less restrictive interventions were attempted prior to placing one patient in wrist restraints (Patient 201), resulting in unnecessary restraint for 21 days (A164); 3. modification of the plan of care for one patient (Patient 201) when the patient was placed in	A 043	To provide increased oversight to hospital operations, just before this complaint survey, the Board of Governors had elected to increase the frequency of its regularly-scheduled meetings from quarterly to monthly and hold additional meetings if needed. This change was made on 07/28/09. During the survey, the Board of Governors (BOG) met on 08/26/09. The CEO presented the initial findings from the survey activity to the BOG, with focus on the concerns related to the discharge of newborns and process for identifying newborns at high risk for hyperbilirubinemia; the status of the case review; and plans for policy and procedure revisions. The BOG provided feedback and made arrangements to be available to the survey team. After the survey, the hospital and BOG took the following actions: The CEO advised the BOG of the exit conference findings, particularly those related to the Conditions of Participation for Governing Body, Patient Rights, QA/PI, Medical Staff, Nursing Services and Discharge Planning. The BOG was advised that CDPH had accepted the plan of correction to address the issue identified as an immediate jeopardy on 9/3/09.	08/26/09 09/15/09

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A 043	<p>Continued From page 4 restraints, resulting in failure to assess for, and identify, the effectiveness of less restrictive measures (A166);</p> <p>4. measurement, analysis, and tracking of information obtained through the grievance process, resulting in the failure to ensure safe discharge planning and follow up care of newborns at risk for developing severe hyperbilirubinemia (jaundice caused by high bilirubin levels in the blood), improvement in systems, and patient satisfaction (A119)(A267);</p> <p>5. measurement of improvement actions taken to ensure safe discharge of newborns at risk of developing hyperbilirubinemia (high bilirubin level in the blood) after Immediate Jeopardy was identified, resulting in continued discharge of at-risk newborns, and the potential for brain damage and death in newborns discharged from SWHCS (A290)(A800);</p> <p>6. assessment of the effectiveness of the discharge planning process, resulting in the potential for unsafe discharge, injury, and death (A263)(A843);</p> <p>7. adequate quality assurance was done on contracted services for discharge planning done by outside CMs, and infection control done by a consultant, resulting in the potential for unsafe discharges and the spread of infection between patients, staff, and visitors (A263)(A084);</p> <p>8. monitoring of the effectiveness of education provided to nurses administering continuous sedation in the ICU, resulting in the potential for under sedation or over sedation of patients receiving propofol (a hypnotic used for sedation in</p>	A 043	<p>The BOG approved the implementation plan for the revised PSC structure.</p> <p>The BOG reviewed and approved the revised Grievance policy.</p> <p>The BOG was presented the revised forms for discharge planning risk screening and needs assessment.</p> <p>The BOG met and was advised by the CEO of the outcome of a meeting with CMS and acknowledged the hospital's improvement in a number of areas.</p> <p>The BOG accepted the Grievance Committee report regarding the number of concerns reported and the timeliness of responding to the patient was presented.</p> <p>The BOG received a favorable evaluation from an IC specialist of the contracted Interim IC Director.</p> <p>The Medical Executive Committee (MEC) recommended that the BOG approve the following revised or new policies/procedures: Restraints, Hyperbilirubinemia, Newborn Discharge, and Cord Blood Collection. The MEC also recommended approval of the following forms: Restraint Order forms, Newborn Nursery Orders, Hours Specific Bilirubin Nomogram, and Physician's Record of Newborn. The BOG approved these policies and forms.</p> <p>The BOG reviewed the Women's Services Bilirubin and Coombs audit from 8/14/09 to 9/27/09 in the PI/RM Committee report. No major issues were identified.</p> <p>The BOG reviewed a copy of the minutes of the first meeting of the PSC. The BOG recommended that the Medical Staff Bylaws be revised to update the wording of the PI/RM</p>	<p>09/15/09</p> <p>09/15/09</p> <p>09/15/09</p> <p>10/19/09</p> <p>10/19/09</p> <p>10/19/09</p> <p>10/19/09</p> <p>10/19/09</p> <p>10/19/09</p>
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A 043	<p>Continued From page 5 mechanically ventilated patients) (A263)(A395);</p> <p>9. the needs of 15 newborns (Patients 11, 12, 13, 17, 20, 21, 29, 30, 204, 205, 207, 217, 228, 267, and 268) at risk for developing hyperbilirubinemia (high bilirubin levels in the blood), two of two patients receiving sedation in the ICU, and one patient with pain, were met, by failing to:</p> <p>a. assess and identify risk factors for hyperbilirubinemia for eight newborns (Patient 11, 12, 13, 204, 205, 207, 267, and 268), resulting in the delay of testing and the potential for brain damage, developmental disabilities, and death (A395);</p> <p>b. 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 (A395);</p> <p>c. 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 Bhutani curve for three newborns (Patients 11, 20, and 207), resulting in exposure of the babies to elevated bilirubin levels and the potential for brain damage, developmental disabilities, and death (A395);</p> <p>d. conduct TSB testing when the TcB was in the high intermediate risk zone or high risk zone on the Bhutani curve for three newborns (Patients 12, 13, and 228), resulting in the potential for lack of treatment, brain damage, developmental disabilities, and death (A395);</p>	A 043	<p>Committee and expanding the membership to include a Board member and the Pharmacy Director.</p> <p>The CEO reports ongoing progress to the Chair of the Board of Governors weekly. Senior Management reports ongoing progress to the BOG at the monthly meetings.</p> <p>A combined MEC and BOG retreat was held and included an educational presentation entitled, "A Culture of Compliance". The CEO reported that the Infection Control Department has been expanded by adding a second IC Practitioner; there is a coordinator for each hospital; and there is a Director with overall program responsibility. The CEO also reported to the BOG that the hospital's PI program is supported with a consultant 3 to 4 days/week.</p> <p>The CEO advised the BOG that the preliminary deficiency report for the August survey had been received.</p> <p>The Administrative Director of Quality Outcomes (ADQO) advised the BOG that one health plan had elected to continue to provide discharging planning for its clients and would comply with all associated hospital policies. In addition, the external Infection Control Consultant had increased support with an on-site presence five days/week.</p> <p>The BOG reviewed the Grievance report and requested additional analysis of the data, with a follow-up report at the next BOG meeting.</p> <p>The Chair of the BOG presented a report on the Patient Safety Council.</p> <p>The BOG approved the revised Utilization Review Plan and referred it to the MEC.</p>	<p>08/26/09</p> <p>11/06/09</p> <p>11/16/09</p> <p>11/16/09</p> <p>11/16/09</p> <p>11/16/09</p> <p>11/16/09</p>
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A 043	<p>Continued From page 6</p> <p>e. conduct Coombs testing (test to detect destruction of red blood cells in the newborn) when the mother's blood type was O+ for three newborns (Patients 12, 13, and 17) to identify and treat hemolytic disease of the newborn, resulting in the potential for brain damage, developmental disabilities, and death (A395);</p> <p>f. conduct TSB testing STAT when the TcB was in the high intermediate risk zone or high risk zone on the Bhutani curve for five newborns (Patients 17, 21, 29, 30, and 228), resulting in the potential for delayed treatment, brain damage, developmental disabilities, and death (A395);</p> <p>g. provide evidence the physician was notified of the TSB results for two newborns (Patients 20 and 205), resulting in the potential for delayed treatment, brain damage, developmental disabilities, and death (A395);</p> <p>h. notify the physician STAT when the TSB was in the high intermediate risk zone on the Bhutani curve for one newborn (Patient 30), resulting in the delay of treatment and the potential for brain damage, developmental disabilities, and death (A395);</p> <p>i. accurately document the bilirubin result on the Hour Specific Bilirubin Nomogram (documented in the low intermediate risk zone instead of the high intermediate risk zone) for one newborn (Patient 20), resulting in the lack of intervention from the staff and the potential for brain damage, developmental disabilities, and death (A395);</p> <p>j. monitor sedation levels for two of two patients receiving propofol for sedation in the ICU (Patients 201 and 215), resulting in potential for</p>	A 043	<p>The BOG continues actively to oversee improvements throughout the hospital, including:</p> <ul style="list-style-type: none"> -Improvements to the grievance process, including measuring, analyzing, and tracking information obtained through the grievance process to identify opportunities for improvement (see specific responses to A 119, A 267); -Revision to the restraint policy and practice (see specific responses to A 201 and A 164); -Reminders about formulating and updating the plans of care for patients (see responses to A 166 and A 396); -Revamping the processes for communicating and evaluating services furnished in the hospital, including measurement of improvements taken with respect to the discharge of newborns, and the appropriateness and effectiveness of the discharge planning process (see responses to A 263, A 290, A 800, A 811, A 843); -Confirming outside contracted services meet minimum criteria, and performing quality assurance on contracted services, including discharge planning by case managers from HMOs and consultation by an infection control specialist (see responses to A 084, A 263, and A 394); -Monitoring the effectiveness of education provided to nurses administering continuous sedation in the ICU, and the process of evaluating and treating patients' pain (see responses to A 263 and A 395); -Compliance with the hospital's policy on assessing, screening, testing, and treating newborns at risk for hyperbilirubinemia (see response to A 395); 	08/26/09
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A 043	<p>Continued From page 7</p> <p>under sedation or over sedation (A395); and,</p> <p>k. to ensure one patient's pain (Patient 302) was evaluated and treated in accordance with accepted nursing standards and hospital policy and procedure. This failed practice placed the patient at risk for untreated pain (A395);</p> <p>(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);</p> <p>10. nurses providing outside case management for HMO patients had current licensure, resulting in the potential for nursing care to be provided by unlicensed nurses (A394);</p> <p>11. the formulation of a care plan to meet identified needs for one patient (Patient 306), resulting in the risk for a poor health outcome (A396);</p> <p>12. appropriate discharge planning and follow-up care for 11 newborn infants (Patients 11, 12, 13, 205, 265, 218, 227, 228, 247, 276, and 285) with risk factors for developing hyperbilirubinemia and/or a TcB and/or TSB in the High Intermediate Risk Zone on the Bhutani Curve (A800);</p> <p>13. discharge planning for one patient (Patient</p>	A 043	<p>—Oversight of the medical staff and its oversight of medical care furnished to patients, including care by physicians to newborns at risk for hyperbilirubinemia and completion of appraisal by proctoring of a physician (see responses to A 338 and A 340).</p>	
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A 043	<p>Continued From page 8</p> <p>304) who had concerns about her living situation, resulting in the potential for an unsafe discharge (A800);</p> <p>14. documentation of the discharge planning process for three of three HMO patients (Patients 22, 211, and 213), by failing to require outside CMs to document in the permanent record, resulting in the potential for an inappropriate discharge, discharge needs not being met, and injury and death for patients belonging to a HMO (A811);</p> <p>15. the effectiveness of the discharge planning process was reassessed on an ongoing basis, resulting in the inability to determine if discharged patients had their post hospital needs met, and the potential for inappropriate discharges, injury and/or death of discharged patients (A843);</p> <p>16. the facility's medical staff ensured quality medical care was provided, by failing to;</p> <p>a. provide timely follow-up of the newborns discharged with risk factors for the development of hyperbilirubinemia (Patients 11, 12, 205, 265, 218, 227, 228, 247, 276, and 285), resulting in the delay of a follow-up after discharge and the potential exposure of the newborns to increased bilirubin levels, which may cause brain damage, developmental disabilities, and death (A338);</p> <p>b. ensure physicians provided the same level of care to newborns at risk for developing hyperbilirubinemia, in ordering follow up care (A338):</p> <p>b1. the day after discharge for nine of 13 babies discharged Saturday through Thursday (Patients</p>	A 043		
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A 043	<p>Continued From page 9 221, 225, 232, 233, 234, 237, 238, 239, and 240) (A338);</p> <p>b2. two days after discharge for four of 13 babies discharged Saturday through Thursday (Patients 222, 228, 247, and 285) (A338);</p> <p>b3. three to five days after discharge for seven of seven babies discharged on Fridays (Patients 11, 13, 205, 265, 218, 227, and 276) (A338), resulting in severe hyperbilirubinemia and admission to a NICU in one newborn discharged on a Friday, and greater potential for developing severe hyperbilirubinemia in the babies discharged on Fridays;</p> <p>c. implement phototherapy according to facility policy and AAP Guidelines, resulting to the exposure of the newborns to increased bilirubin levels, which may cause brain damage, developmental disabilities, and death (Patients 11 and 247) (A338);</p> <p>d. ensure the facility policy, "Hyperbilirubinemia, Assessment, Identification, and Intervention Protocol" outlined a response consistent with the AAP Guidelines, used by facility staff, which had the potential to result in inaccurate assessment and intervention to the newborns with hyperbilirubinemia (A338); and,</p> <p>e. ensure appraisal via proctoring was completed for one physician, which created the potential for substandard care (A338)(A340).</p> <p>The cumulative effects of these systemic problems resulted in the facility's failure to provide quality health care in a safe environment.</p>	A 043		
A 084	482.12(e)(1) CONTRACTED SERVICES	A 084		

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PRINTED: 11/27/2009
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OMB NO. 0938-0391

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A 084	<p>Continued From page 10</p> <p>The governing body must ensure that the services performed under a contract are provided in a safe and effective manner.</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the governing body failed to ensure adequate quality assurance was done on contracted services for discharge planning done by outside CMs and infection control done by a consultant, resulting in the potential for unsafe discharges and the spread of infection between patients, staff, and visitors.</p> <p>Findings:</p> <p>1. The facility failed to ensure appropriate precautions were taken in three of three rooms (ICU four, 165, and 161) where patients had MRSA (a bacteria resistant to multiple antibiotics) and were in contact isolation, resulting in the potential for spread of infection to patients in the ICU and on the MST floor, visitors, and staff (Cross-refer A748).</p> <p>The PI Director was interviewed on August 27, 2009, at 9 a.m. Quality Assurance data for the contracted infection control practitioner was requested. She stated a corporate infection control consultant had visited the facility in May (when the SWHCS infection control consultant started), but had produced no written report, and had not returned since to monitor the work of the consultant. She was unable to provide evidence of quality assurance related to the effectiveness of the infection control practitioner.</p> <p>2. The facility failed to ensure documentation of</p>	A 084	<p>INFECTION CONTROL CONSULTANT</p> <p>The Administrative Director of Quality Outcomes (ADQO) contacted a corporate-level Infection Control Specialist, who evaluated and reported positively on the quality of services provided by the Infection Control Consultant through on-site observations and through record review.</p> <p>The ADQO presented the Infection Control Specialist's evaluation of the contracted Infection Control Consultant to the BOG, which accepted the reviewer's findings.</p> <p>On an annual basis, the Infection Control Specialist will evaluate the Infection Control Consultant to assure ongoing competency.</p> <p>EXTERNAL CASE MANAGERS</p> <p>The Director of Case Management (DCM), the ADQO, and the Chief Financial Officer met with the leadership of the two health plans that provided on-site nursing staff for discharge planning to present requirements those organizations must meet to continue providing discharge planning to their clients when hospitalized at Southwest Healthcare System (SWHCS). Meanwhile, SWHCS employees provided all discharge planning for enrollees in those health plans.</p> <p>One health plan continued to provide discharge planning to its hospitalized clients. The DCM provided education to the health plan employees on:</p> <ul style="list-style-type: none"> • Required documentation for initial discharge screening, completion of a needs assessment when indicated, and discharge planning notes. • The External Reviewer policy and the external reviewer's log. • Community resource information <p>The DCM finalized the external reviewer's files to confirm that all required documentation was present, including licensure verifications.</p> <p>External reviewers for the one health plan resumed discharge planning for their clients and documented their activities in the patient's medical record.</p> <p>The DCM or CM Supervisors review the charts. During the review of the discharge planning process,</p>	<p>09/18/09</p> <p>10/19/09</p> <p>10/19/09</p> <p>09/24/09</p> <p>11/12/09</p> <p>11/24/09</p> <p>11/30/09</p> <p>12/01/09</p>
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A 084	Continued From page 11 the discharge planning process for three of three HMO patients (Patients 22, 211, and 213), by failing to require outside CMs to document in the permanent record, resulting in the potential for an inappropriate discharge, discharge needs not being met, and injury and death for patients belonging to HMOs (Cross-refer A811). During an interview with the Director of CM on August 27, 2009, at 10 a.m., she stated the quality of the discharge planning process had not been evaluated in, "quite a while," and, "we need to do it again." She stated problems with the quality of the HMO discharge planning (done by outside CMs) were noticed one year prior, but had not been corrected. She stated the outside CMs did not document in the permanent medical record, and it had been a problem for, "a long time," but was unable to further quantify the duration. When asked about reviewing the performance or qualifications of the HMO personnel working in the facility, she stated, "We are not evaluating each of their people."	A 084	the DCM/designee will include cases that were reviewed by the health plan's external case managers to ensure that the contracted staff comply with hospital policy for performing the initial risk screen and complete a needs assessment if risk factors are identified. The outcome of the monitoring will be reported to the Quality pillar of the PSC for analysis and action as indicated. After three consecutive months of achieving target, the Quality pillar will determine what, if any further action is warranted. CONTRACTS: The Senior Team members reviewed and developed a contract tracking matrix, working with all Directors to develop the criteria for review of different contractors based on the level of involvement they have with patients. The CNO and ADQO expanded the quality assurance/performance improvement (QAPI) program so that it covered contracted services based on the level of involvement they have with patients.	11/30/09 12/09/09
A 115	482.13 PATIENT RIGHTS A hospital must protect and promote each patient's rights. This CONDITION is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure: 1. effective operation of the grievance process, resulting in failure to ensure safe discharge planning and follow up care for newborns at risk for developing hyperbilirubinemia (jaundice caused by high bilirubin levels in the blood), improvement in systems, and patient satisfaction (A119);	A 115	The CNO and ADQO reported the tracking matrix to the Board of Governors, and report aggregated data from evaluations when they are completed. A 115: Please see the specific responses to A 119, A 164, and A 166 for actions the hospital has taken to improve the grievance process, use of restraints, and documentation on patients' plans of care.	12/14/09 12/14/09

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A 115	Continued From page 12 2. appropriate less restrictive interventions were attempted prior to placing one patient in wrist restraints (Patient 201), resulting in unnecessary restraint for 28 days (A164); and, 3. modification of the plan of care of one patient (Patient 201) when the patient was placed in restraints, resulting in the failure to assess for and identify the effectiveness of less restrictive measures (A166). The cumulative effect of these failed practices resulted in failure to ensure protection and promotion of patients' rights.	A 115		
A 119	482.13(a)(2) PATIENT RIGHTS: REVIEW OF GRIEVANCES [The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance.] The hospital's governing body must approve and be responsible for the effective operation of the grievance process, and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee. This STANDARD is not met as evidenced by: Based on interview and record review, the governing body failed to ensure effective operation of the grievance process by failing to: a. effectively investigate nine of nine grievances; b. inform patients of the resolution of their grievances; and, c. use the grievance process to identify opportunities for improvement.	A 119	The ADQO had a review done of the cited grievances and confirmed that they had been or were being investigated even though the grievance documentation did not reflect the detail of those investigations. The ADQO further confirmed that Grievance 1 was still under investigation; Grievance 4 involved an outside vendor that was neither operated nor under contract with the hospital, and the vendor resolved the situation on the day the complaint was received; and Grievance 7 was a complaint about a billing issue not covered by this rule. After the exit conference at the hospital on August 28, 2009, the hospital took the following comprehensive actions to improve its grievance process: The ADQO and the Service Excellence Coordinator confirmed that in the current policy, the Board of Governors had delegated the responsibility for investigating and resolving grievances to a Grievance Committee.	11/06/09 09/01/09 09/01/09

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A 119	Continued From page 13 This failed practice resulted in the failure to ensure safe discharge planning and follow up care of newborns at risk for developing severe hyperbilirubinemia (jaundice caused by high bilirubin levels in the blood), improvement in systems, and patient satisfaction. Findings: 1. Grievance 1 was reviewed during a complaint investigation on August 6, 2009. The grievance was date stamped as received by the facility on July 28, 2009. The grievance included the following: a. a newborn baby was discharged from IVMC with a high bilirubin level, without being treated with phototherapy (using lights to decrease bilirubin levels in the blood); b. follow up for the baby (with a pediatrician) was not until four days after discharge; c. at the follow up visit, the baby was admitted to a NICU for, "immediate," treatment of hyperbilirubinemia (high bilirubin levels in the blood) and the, "possibility of brain damage;" and, d. necessary supplies were not available in the L&D room during labor. The investigation conducted August 6 and 12, 2009 (nine and 15 days after the facility received the grievance), revealed the following: a. the perinatal nurses failed to follow the facility policy to assess and identify risk factors for	A 119	The ADQO and the Service Excellence Coordinator reviewed and revised the hospital's grievance policy to comply more clearly with the rule. At the direction of the Board of Governors, the CEO formed a Grievance Committee, with the ADQO as the Chair. The standing members of the Grievance Committee are the ADQO, the Service Excellence Coordinator, the CNO and the Director of Risk Management; the Grievance Committee is scheduled to meet monthly. The ADQO and the Service Excellence Coordinator revised the grievance form that staff use to report a grievance. Staff completes the initial part of the form and forwards it to the Service Excellence Coordinator, who is responsible for overseeing and tracking the investigation of the grievance, resolution, and notification to the complainant. The form contains sections for documenting the steps of the investigation, any opportunities for improvement that have been identified, any actions taken, notification of the complainant, and report to the Grievance Committee. The ADQO and the Service Excellence Coordinator developed a tracking mechanism and form to use to be sure the hospital complies with timeframes in the rule and its policy. The Board of Governors confirmed delegation of the responsibility for dealing with grievances to the Grievance Committee and approved the revised policy and the new grievance form.	09/12/09 09/15/09 09/15/09 09/15/09 09/15/09

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A 119	<p>Continued From page 14</p> <p>developing hyperbilirubinemia in three of three newborns found to be at risk;</p> <p>b. the perinatal nurses failed to follow the facility policy and perform TcB testing on three of three newborns when risk factors were identified;</p> <p>c. the perinatal nurses failed to follow the facility policy and obtain an order for phototherapy (placing the baby under lights) for two of two newborns with bilirubin levels in the high intermediate risk zone or high risk zone on the Bhutani curve;</p> <p>(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 hyperbillrubinemia 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).</p> <p>d. the perinatal nurses failed to follow the facility policy and conduct Coombs testing (to detect destruction of red blood cells in the newborn) on two of two newborns whose mothers had O+ blood; and,</p> <p>e. the facility had not yet conducted interviews of staff or physicians regarding the grievance.</p> <p>During an interview with the CEO on August 25, 2009, at 2:05 p.m., the CEO stated he received the grievance on July 28, 2009. The CEO stated after he read the grievance, he, "immediately," sent copies of it to the PI Director and the CNE.</p>	A 119	<p>The ADQO and the Service Excellence Coordinator educated all staff leaders on the new policy, process, and grievance reporting form. Staff leaders then educated their staff members on completion of the new grievance reporting form and that it is to be forwarded to the Service Excellence Coordinator immediately upon completion.</p> <p>The Grievance Committee meets monthly to handle grievances. The Grievance Committee may refer particular concerns through the Quality Pillar to the new Patient Safety Council for further evaluation and action. The Grievance Committee reports to the Patient Safety Council and to the Board of Governors.</p> <p>Person responsible: ADQO</p> <p>Monitoring: The Grievance Committee is auditing 100% of grievances for six months to be sure the process is being followed, the forms are complete, reports are going to the Patient Safety Council and the Board of Governors, and opportunities for improvement are being identified and forwarded to the Quality Pillar and the Patient Safety Council for evaluation and action through the hospital-wide QAPI system. At the end of six months, the ADQO and Service Excellence Coordinator will determine whether to reduce the audit to a lower percentage of cases.</p>	<p>10/07/09</p> <p>10/19/09</p> <p>09/16/09</p>
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A 119	<p>Continued From page 15</p> <p>The CEO stated the investigation should have started, "immediately."</p> <p>During an interview with the PI Director on August 25, 2009, at 2:30 p.m., the director stated she received the grievance on August 4, 2009 (seven days after it was received by the CEO), and notified the department managers of the grievance on August 6, 2009. The director stated there was no, "formal," grievance committee. She stated there was no form used to track the progress and findings of the investigation. She stated there was no tracking or trending of grievances to look for patterns and identify opportunities for improvement. She further stated she was not aware of any assessment that had been done of the department managers' capabilities for resolving quality issues that had been reported to them. The director stated a meeting to discover the root cause of the findings was scheduled to take place September 9, 2009 (43 days after the facility received the grievance). She stated the investigation for Grievance 1 was not yet complete.</p> <p>During an interview with the PI Director on August 25, 2009, at 4:40 p.m., the director stated the newborn's record went to the Department of Pediatrics (medical staff committee) for review on August 12, 2009. According to the PI Director, the committee determined, because the baby was discharged with a TSB in the high intermediate risk zone, she should have had her bilirubin checked and/or been seen by her PCP the following day. The PI Director stated the committee determined there was a deviation with the standard of medical care to treat hyperbilirubinemia.</p>	A 119		
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A 119	<p>Continued From page 16</p> <p>During an interview with the CNE on August 25, 2009, at 3:05 p.m., the CNE stated she left for vacation on July 29, 2009, and she did not see the grievance before she left. The CNE stated she returned August 10, 2009, and was informed of the grievance by the Director of OB, who had initiated an investigation. The CNE explained her role in the grievance process; when she received a grievance, she sent it to the, "appropriate," director and convened the, "appropriate people," for conducting an investigation, making corrections if needed, and conducting follow up as needed. The CNE stated there was not any one person responsible for coordinating the grievance investigation. She stated, "we all own it, and we all wear different hats." The CNE stated during the facility investigation, they did not realize their findings could have affected other babies. She stated the findings from the CDPH investigation made her realize, "this was a global issue."</p> <p>2. Grievance 2, dated March 13, 2009, was reviewed on August 27, 2009. The grievance, written by a nurse on behalf of a patient's wife, was filed due to a delay in administering pain medication to a post operative patient. The nurse documented problems getting the patient into the computer system, resulting in the inability to obtain pain medication for him for, "over an hour."</p> <p>The nurse manager of the department documented on March 16, 2009 (three days later), he called the patient's wife twice, and she was, "satisfied with all except medication error."</p> <p>There was no evidence the reason for the delay in medicating the patient was investigated. There was no evidence a committee reviewed the</p>	A 119		<p>09 DEC 16 AM 10:59</p> <p>2405 CERT MURRIETA COUNTY</p> <p>DEPT OF PUBLIC HEALTH</p>
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A 119	<p>Continued From page 17</p> <p>grievance. There was no evidence corrective action was taken to ensure the event would not reoccur. There was no evidence the patient's wife was informed of a resolution to her grievance.</p> <p>3. Grievance 3, dated April 7, 2009, was reviewed on August 27, 2009. The grievance was filed by the sister of a patient who presented to the ED with severe abdominal pain, was subsequently diagnosed with ischemic (dead) bowel, and underwent surgery. The grievance alleged delays in care and being treated poorly by the ED staff, like a "drug seeker."</p> <p>The ED physician reviewed the case and sent the ED director a letter stating there were delays in getting the patient into an ED bed, delays in receiving test results, and, "some staff did ascribe behavioral attributes to the patient's symptoms," (staff thought the patient was not having real pain), which may have caused a delay.</p> <p>There was no evidence the ED director investigated the delays in getting the patient into an ED bed, the delays in receiving test results, or the treatment of the patient by the ED staff. There was no evidence a committee reviewed the grievance. There was no evidence corrective action was taken to ensure the events would not happen again. There was no evidence the patient's sister was informed of a resolution to her grievance.</p> <p>4. Grievance 4, dated February 10, 2009, was reviewed on August 27, 2009. The grievance was filed by the patient's husband, and alleged the patient's rights were violated when she was discharged home to hospice care before equipment and medications were delivered to the</p>	A 119		
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A 119	<p>Continued From page 18</p> <p>home, resulting in pain and discomfort for the patient.</p> <p>According to the grievance documents, the Director of CM referred the grievance to the hospice provider, the hospice provider called the patient's husband, and the issues were resolved.</p> <p>There was no evidence the facility investigated the discharge for appropriateness. There was no evidence a committee reviewed the grievance. There was no evidence corrective action was taken to ensure the events would not reoccur. There was no evidence the patient's husband was informed of a resolution to his grievance.</p> <p>5. Grievance 5, not dated, was reviewed on August 27, 2009. The grievance, filed by the patient, alleged a prolonged stay in the ED, lack of nurses in the ED, being placed in a broken hospital bed, a dirty hospital room, inability to shower due to the shower being used for storage, and being served the wrong food after a visit from the dietitian.</p> <p>The ED physician reviewed the case and documented appropriate medical care while in the ED, but noted a five and one half hour delay in getting CT results. The MS Manager reviewed the case, and documented investigating and correcting the broken bed issues.</p> <p>There was no evidence the delay in CT results, the ED nurse staffing concerns, the cleanliness of the room, the inability of the patient to take a shower, or the appropriateness of the food served were investigated. There was no evidence a committee reviewed the grievance. There was no evidence corrective action was taken (outside of</p>	A 119		
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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050701	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED C 09/17/2009
NAME OF PROVIDER OR SUPPLIER SOUTHWEST HEALTHCARE SYSTEM		STREET ADDRESS, CITY, STATE, ZIP CODE 25600 MEDICAL CENTER DRIVE MURRIETA, CA 92562		
(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 119	<p>Continued From page 19</p> <p>the broken bed issue) to ensure the events were corrected and would not recur. There was no evidence the patient was informed of a resolution to her grievance.</p> <p>6. Grievance 6, dated July 20, 2009, was reviewed on August 27, 2009. The grievance, filed by the patient, alleged she was discharged home with unresolved hypertension because she did not have insurance.</p> <p>According to the grievance documents, the facility attempted to contact the patient by phone, but the telephone number they had on file was incorrect.</p> <p>There was no evidence the facility attempted to contact the patient through other means. There was no evidence the allegations made by the patient were investigated. There was no evidence a committee reviewed the grievance. There was no evidence corrective action was taken to ensure the event would not reoccur. There was no evidence the patient was informed of a resolution to her grievance.</p> <p>7. Grievance 7, dated April 5, 2009, was reviewed on August 27, 2009. The grievance, filed by the patient, alleged the patient had VA insurance, and repeatedly told hospital staff he needed to be transferred or he would incur a bill. According to the grievance, the hospital staff assured the patient multiple times the VA coverage would pay for his stay.</p> <p>According to the grievance documents, the patient received a phone call from the facility and was told of his appeal rights with the VA.</p> <p>There was no evidence an investigation was done</p>	A 119		

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A 119	<p>Continued From page 20</p> <p>to determine if the hospital staff acted appropriately. There was no evidence a committee reviewed the grievance. There was no evidence corrective action was taken to ensure the event would not reoccur. There was no evidence the patient was informed of a resolution to his grievance.</p> <p>8. Grievance 8, dated July 15, 2009, was reviewed on August 27, 2009. The grievance, filed by the patient's daughter, alleged necessary tests were not done during her mother's hospital stay, and her mother was discharged home before she was ready.</p> <p>According to the grievance documents, the patient's daughter was contacted by the facility and they answered the questions that they "could." She was referred to her mother's PMD for further questions.</p> <p>There was no evidence an investigation was conducted to determine appropriateness of tests performed. There was no evidence an investigation was performed to determine the appropriateness of discharge. There was no evidence a committee reviewed the grievance. There was no evidence corrective action was taken to ensure the event would not reoccur. There was no evidence the patient's daughter was informed of a resolution to her grievance.</p> <p>9. Grievance 9, dated April 11, 2009, was reviewed on August 27, 2009. The grievance, filed by the patient's sister, alleged neglect that led to her sister's death as follows:</p> <p>a. the patient had severe abdominal pain with a history of gastric bypass surgery, which the facility</p>	A 119		
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A 119	<p>Continued From page 21 staff ignored;</p> <p>b. the patient lay in the ED for 12 hours in, "excruciating," pain while her vital signs deteriorated;</p> <p>c. the patient had a bowel obstruction, and the surgeon who was called to come in was a, "no show;"</p> <p>d. nursing staff was not responsive to multiple requests to check on the patient. When they did check, her BP, respirations, and body temperature had dropped, "considerably;" and,</p> <p>e. the patient was taken to ICU, and her sister was left in a waiting room for over an hour. When the staff came to get the patient's sister, they told her the patient had coded, and offered to allow her to be in the room when they, "called her time of death."</p> <p>The grievance was in the form of an e-mail sent to the facility's corporate office. There was no evidence the facility attempted to locate the complainant. There was no evidence an attempt was made to investigate the allegations. There was no evidence a committee reviewed the grievance. There was no evidence corrective action was taken to ensure the events would not happen again. There was no evidence the patient's sister was informed of a resolution to her grievance.</p> <p>During an interview with the service excellence employee on August 27, 2009, at 11:40 a.m., the employee stated there was no grievance committee. She stated letters were not sent to complainants on a regular basis. She stated no</p>	A 119		
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A 119	<p>Continued From page 22</p> <p>letters were sent to the persons who filed grievances one through nine. The employee stated there was no system in place to ensure a thorough investigation of the allegations was conducted, there was no information being gathered to determine patterns or trends, and there was no reporting of grievances to PI committees.</p> <p>During an interview with three members of the Governing Board on August 27, 2009, at 12:15 p.m., the members stated they were aware of grievances presented to the hospital when the CEO or members of the public brought them to their individual attention, or when a particular grievance was discussed in a governing body meeting. They stated they believed most grievances concerning patient care were brought to their attention, but they did not review all grievances and were not aware of details of the grievance resolutions in all cases. The CEO stated he considered the senior management team the grievance committee, but he did not know if all grievances were reviewed by the team.</p> <p>The facility policy titled, "Customer Grievances," was reviewed on August 25, 2009. The policy indicated the following:</p> <ul style="list-style-type: none"> a. the governing body delegated the responsibility of reviewing and resolving grievances to a grievance committee; b. upon receipt of a grievance, the original grievance would be filed in administration for record keeping purposes; c. a copy of the grievance would be forwarded to the senior manager responsible for the area of 	A 119		
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A 119	<p>Continued From page 23 concern;</p> <p>d. the senior manager would designate a committee to review and investigate the grievance;</p> <p>e. the committee would consist of hospital and/or medical staff members directly related to the allegations cited in the grievance;</p> <p>f. the senior manager would use the, "Grievance Form," to track and document the actions taken by the committee; and,</p> <p>g. the senior manager would provide a written response to the patient within 15 working days from the date the grievance was received.</p> <p>The facility policy titled, "Patient's Rights and Responsibilities " was reviewed on August 25, 2009. The policy indicated a grievance committee would review every grievance and provide a written response to the complainant within 15 business days. The policy indicated the written response would include the name of a contact person at the hospital, the steps taken to investigate the grievance, the results of the grievance investigation, and the date of completion of the grievance process.</p> <p>The facility policy titled, "Customer Concerns and Complaints," was reviewed on August 25, 2009. The policy indicated the service excellence department was responsible for tracking significant customer complaints, reporting them to department managers at least quarterly, and initiating action where necessary to reverse trends in complaints.</p>	A 119		
A 164	482.13(e)(2) PATIENT RIGHTS: RESTRAINT	A 164		

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A 164	Continued From page 24 OR SECLUSION Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient, a staff member, or others from harm. This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure appropriate less restrictive interventions were attempted prior to placing one of three patients in wrist restraints (Patient 201). Patient 201 was restrained in the ICU for 21 days, then transferred to the PCU where a sitter was provided so the restraints were no longer needed. These failed practices resulted in unnecessary restraint for 21 days. Findings: The record for Patient 201 was reviewed on August 25 and 26, 2009. Patient 201, a 35 year old male with Down's Syndrome (with the mental capacity of a six year old) was admitted to the facility on July 17, 2009, with diagnoses that included respiratory failure. 1. The record indicated Patient 201 was intubated (a tube in the trachea to assist with breathing) on July 18, 2009, and was attempting to pull at tubes and lines being used for treatment. Patient 201 was placed in restraints at 11 a.m. The physician ordered, and the nurse applied, bilateral (both) wrist restraints. The ICU flow sheet indicated the bilateral restraints remained on for the remainder of the day shift and the entire night shift (20 hours). There was no evidence the staff attempted to provide companionship to prevent restraint use.	A 164	The CNO reviewed the citation and patient 201's medical record and confirmed that the patient was intubated and on a ventilator while in the ICU; he often attempted to pull out the tubing on the ventilator even while family members and nurses were at the bedside; he was transferred to the PCU once his condition had improved and the tubing and ventilator had been removed; and because he had improved and was no longer intubated, he was responsive to a sitter and further restraints were not necessary. After the survey exit conference on August 28, 2009, the hospital took the following actions with regard to use of restraints: The Director of Nurses (DON) reviewed and revised the restraint policy and procedure to comply more clearly with the recently updated regulations. Revisions include assessment requirements, alternatives attempted, use of least restrictive measures; that staff must document the clinical justification and rationale for a restraint; that restraint orders must include the type of restraint to be used and the criteria for discontinuing restraints; and that nursing staff should assess a patient in restraints every two hours (Non-violent/non-self destructive patient) or every 15 minutes (Violent/self-destructive) to determine whether the continuation of restraint is necessary. The DON revised the restraint forms to reflect the updated policy. The Forms Committee, the Policy and Procedure Committee, and Medical Executive Committee, and the Board of Governors reviewed and approved the changes to the policy.	11/12/09 10/27/09 10/19/09

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A 164	<p>Continued From page 25</p> <p>2. On July 19, 2009, the physician ordered, and the nurse continued the use of, bilateral wrist restraints. The ICU flow sheet indicated the bilateral restraints remained on for the entire day and night shifts (24 hours). There was no evidence the staff attempted to provide companionship to prevent restraint use.</p> <p>3. On July 29, 2009, the restraint assessment and order form revealed the following:</p> <ul style="list-style-type: none"> a. the nurse observed agitated and combative behavior, and the inability to follow instructions; b. an order for a right arm and right leg restraint (there was no evidence of rationale for restraining the leg); c. no clinical justification for the use of restraints; and, d. no criteria for discontinuing the use of restraints. <p>The ICU flow sheet dated July 29, 2009, indicated the following:</p> <ul style="list-style-type: none"> a. at 8 a.m., Patient 201 was sedated and unresponsive to stimulus; b. at 10 a.m., Patient 201 was, "unresponsive." A CPAP trial was started, so the patient was placed in wrist restraints (even though he was unresponsive); c. at 11:15 a.m., sedation was discontinued, and the wrist restraints remained on; 	A 164	<p>The Department of Education provided education fairs throughout the month of October to educated nursing staff on the revised restraint policy and procedure. Education emphasized trying less restrictive alternatives before using restraints, documentation requirements, and conducting an assessment of the patient each hour to determine whether the patient meets the criteria for release from restraints.</p> <p>The CNO and designees from the Department of Education provided education to physicians on the revisions to the policy and the requirements for documenting orders. They emphasized the need for documenting assessment and clinical justification for restraint, the components of a complete restraint order including the type of restraint to be used, and guidance in identifying ways to help the patient gain control so that restraints may be discontinued. The CNO provided education to the physicians at the General Medical Staff meeting on 9/23/09, and through a blast fax of educational information to all medical staff offices also on 9/23/09. In addition the CNO provided a presentation at each medical staff department meeting during October and November.</p> <p>Person Responsible for implementation and monitoring: CNO</p> <p>The Nursing Directors are auditing 100% of the charts of patients on whom restraints are used for compliance with the revised policy. The appropriate Nursing Director addresses deficiencies directly with the responsible nursing staff member; The Medical Staff Department Chair addresses deficiencies with the responsible physician. The CNO reports aggregated data, trends, and variances to the Quality Pillar. Reports are forwarded to the MEC, Patient Safety Council and the Board of Governors monthly, as indicated.</p>	<p>10/27/09</p> <p>11/30/09</p> <p>11/01/09</p>
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NAME OF PROVIDER OR SUPPLIER SOUTHWEST HEALTHCARE SYSTEM			STREET ADDRESS, CITY, STATE, ZIP CODE 25600 MEDICAL CENTER DRIVE MURRIETA, CA 92582		
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A 164	<p>Continued From page 26</p> <p>d. at 4 p.m., the patient was making no attempts to pull at his tubes or lines;</p> <p>e. at 6 p.m., the patient remained sedated with no attempts to pull at tubes or lines; and,</p> <p>f. Patient 201 had no movement of his extremities for the entire shift, there was no evidence the restraints were needed, and there was no evidence the restraints were removed until 7 p.m. (nine hours after they were applied).</p> <p>4. The restraint assessment and order form dated August 8, 2009, revealed the following:</p> <p>a. no clinical justification for the use of restraints;</p> <p>b. no indication of the type of restraint to be used; and,</p> <p>c. no criteria for discontinuing the use of restraints.</p> <p>The ICU flow sheet dated August 8, 2009, indicated the nurse put a mitt on Patient 201's right hand at 9 p.m., to prevent him from pulling at his tubes and lines. There was no evidence the staff attempted to provide companionship to prevent restraint use.</p> <p>5. The restraint assessment and order form dated August 9, 2009, revealed the following:</p> <p>a. no clinical justification for the use of restraints; and,</p> <p>b. a left arm restraint was ordered.</p> <p>The ICU flow sheet dated August 9, 2009,</p>	A 164			

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A 164	<p>Continued From page 27</p> <p>indicated Patient 201 had a mitt on his left hand until 9:30 p.m., when the nurse applied a restraint to the left wrist. There was no evidence the staff attempted to provide companionship to prevent restraint use.</p> <p>6. The restraint assessment and order form dated August 10, 2009, revealed the following:</p> <ul style="list-style-type: none"> a. no clinical justification for the use of restraints; b. a left arm restraint was ordered; and, c. no criteria for discontinuing the use of restraints. <p>The ICU flow sheet dated August 10, 2009, indicated Patient 201 had both a mitt on the left hand and a restraint on the left wrist. There was no evidence the staff attempted to provide companionship to prevent restraint use.</p> <p>7. The restraint assessment and order form dated August 11, 2009, revealed the following:</p> <ul style="list-style-type: none"> a. no clinical justification for the use of restraints; b. a left arm restraint was ordered; and, c. no criteria for discontinuing the use of restraints. <p>The ICU flow sheet dated August 11, 2009, indicated Patient 201 had a restraint on his left wrist for the entire 24 hours. There was no evidence the staff attempted to provide companionship to prevent restraint use.</p> <p>8. The restraint assessment and order form dated</p>	A 164		
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A 164	<p>Continued From page 28</p> <p>August 12, 2009, indicated a left arm restraint was ordered, with no criteria for discontinuing the restraint.</p> <p>The ICU flow sheet dated August 12, 2009, indicated Patient 201 had a restraint on his left wrist the entire 24 hours. There was no evidence the staff attempted to provide companionship to prevent restraint use.</p> <p>9. The restraint assessment and order form dated August 13, 2009, indicated a left arm restraint was ordered, with no criteria for discontinuing the restraint.</p> <p>The ICU flow sheet dated August 13, 2009, indicated Patient 201 had a restraint on his left wrist the entire 24 hours. There was no evidence the staff attempted to provide companionship to prevent restraint use.</p> <p>10. The restraint assessment and order form dated August 14, 2009, indicated a left arm restraint was ordered, with no criteria for discontinuing the restraint.</p> <p>The ICU flow sheet dated August 14, 2009, indicated Patient 201 had a restraint on his left wrist the entire 24 hours. There was no evidence the staff attempted to provide companionship to prevent restraint use.</p> <p>11. The restraint assessment and order form dated August 15, 2009, indicated a left arm restraint was ordered, with no criteria for discontinuing the restraint.</p> <p>The ICU flow sheet dated August 15, 2009, indicated Patient 201 had a restraint on his left</p>	A 164		
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A 164	<p>Continued From page 29</p> <p>wrist the entire 24 hours. There was no evidence the staff attempted to provide companionship to prevent restraint use.</p> <p>12. The restraint assessment and order form dated August 16, 2009, revealed the following:</p> <ul style="list-style-type: none"> a. no clinical justification for the use of restraints; b. a left arm restraint was ordered; and, c. no criteria for discontinuing the restraint. <p>The ICU flow sheet dated August 16, 2009, indicated Patient 201 had a restraint on his left wrist the entire 24 hours. There was no evidence the staff attempted to provide companionship to prevent restraint use.</p> <p>13. The restraint assessment and order form dated August 17, 2009, revealed the following:</p> <ul style="list-style-type: none"> a. no clinical justification for the use of restraints; b. a left arm restraint was ordered; and, c. no criteria for discontinuing the restraint. <p>The ICU flow sheet dated August 17, 2009, indicated Patient 201 had a restraint on his left wrist the entire 24 hours. There was no evidence the staff attempted to provide companionship to prevent restraint use.</p> <p>14. The ICU flow sheet dated August 18, 2009, indicated Patient 201 had a restraint on his left wrist the entire 24 hours. There was no evidence the staff attempted to provide companionship to prevent restraint use.</p>	A 164		
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A 164	<p>Continued From page 30</p> <p>15. The ICU flow sheet dated August 19, 2009, indicated Patient 201 had a restraint on his left wrist the entire 24 hours. There was no evidence the staff attempted to provide companionship to prevent restraint use.</p> <p>16. The restraint assessment and order form dated August 20, 2009, revealed the following:</p> <ul style="list-style-type: none"> a. no clinical justification for the use of restraints; b. no indication of the type of restraint to be used; and, c. no criteria for discontinuing the restraint. <p>The ICU flow sheet dated August 20, 2009, indicated Patient 201 had a restraint on his left wrist the entire 24 hours. There was no evidence the staff attempted to provide companionship to prevent restraint use.</p> <p>17. The restraint assessment and order form dated August 21, 2009, revealed the following:</p> <ul style="list-style-type: none"> a. no behaviors observed by the nurse that required the use of restraints; b. no alternative interventions were attempted to prevent the use of restraints; c. no clinical justification for the use of restraints; d. a left arm restraint was ordered; and, e. no criteria for discontinuing the restraint. <p>The ICU flow sheet dated August 21, 2009,</p>	A 164		
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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050701	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED C 09/17/2009
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NAME OF PROVIDER OR SUPPLIER SOUTHWEST HEALTHCARE SYSTEM	STREET ADDRESS, CITY, STATE, ZIP CODE 25500 MEDICAL CENTER DRIVE MURRIETA, CA 92562
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A 164 Continued From page 31 indicated Patient 201 had a restraint on his left wrist the entire 24 hours. There was no evidence the staff attempted to provide companionship to prevent restraint use.

18. The restraint assessment and order form dated August 22, 2009, indicated four side rails were to be used to restrain the patient, with no criteria for the discontinuation of the side rails.

The ICU flow sheet dated August 22, 2009, indicated Patient 201 had a restraint on his left wrist the entire 24 hours. There was no evidence the staff attempted to provide companionship to prevent restraint use.

19. The restraint assessment and order form dated August 23, 2009, indicated a left arm restraint was ordered, with no clinical justification for the use of restraints.

The ICU flow sheet dated August 23, 2009, indicated Patient 201 had a restraint on his left wrist the entire 24 hours. There was no evidence the staff attempted to provide companionship to prevent restraint use.

20. The restraint assessment and order form dated August 24, 2009, revealed the following:

- a. no clinical justification for the use of restraints;
- b. a left arm restraint was ordered; and,
- c. no criteria for discontinuing the restraint.

The ICU flow sheet dated August 24, 2009, indicated Patient 201 was not restrained until 6 p.m., when he became restless and was pulling at

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NAME OF PROVIDER OR SUPPLIER SOUTHWEST HEALTHCARE SYSTEM	STREET ADDRESS, CITY, STATE, ZIP CODE 25800 MEDICAL CENTER DRIVE MURRIETA, CA 92582
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A 164	<p>Continued From page 32</p> <p>his tracheostomy oxygen tubing. There was no evidence the staff attempted to provide companionship to prevent restraint use. Patient 201 remained restrained for the remainder of the night.</p> <p>21. The restraint assessment and order form dated August 25, 2009, revealed the following:</p> <ul style="list-style-type: none"> a. no clinical justification for the use of restraints; b. right and left arm restraints were ordered (even though the right side was paralyzed); and, c. no criteria for discontinuing the restraint. <p>During a tour of the ICU on August 25, 2009, at 9:20 a.m., Patient 201 was observed lying calmly in bed with his left arm and left leg restrained.</p> <p>During an interview with RN 21 on August 25, 2009, at 9:46 a.m., the RN stated he did not know why the patient's leg was restrained. He stated his arm was restrained to prevent him from pulling off his oxygen tubing.</p> <p>22. During a tour of the PCU on August 26, 2009, at 8:58 a.m., Patient 201 was observed sitting up in bed with a smile on his face, watching a movie and coloring. There were no restraints on either wrist or ankle. A staff member was sitting at the patient's bedside, also coloring.</p> <p>During an interview with RN 22 (Patient 201's nurse) on August 26, 2009, at 9:38 a.m., the RN stated when Patient 201 was admitted to PCU the night before, they put a sitter with him. She stated he was, "doing well," with a sitter, so he did not need to be restrained. She stated before they</p>	A 164		
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A 164	<p>Continued From page 33</p> <p>restrained a patient in PCU, they tried alternatives such as visiting the patient often and providing a sitter for the patient.</p> <p>The ICU/PCU flow sheet dated August 25, 2009, indicated Patient 201 was transferred from ICU to PCU that day. According to the flow sheet, the restraints were removed upon arrival to PCU and a sitter was assigned to stay with the patient. Patient 201 became agitated on August 26, 2009, at 1 a.m. His agitation was treated without the use of restraints.</p> <p>During a concurrent interview with the MS Director and the ICU Director on August 26, 2009, at 9:15 a.m., the MS Director stated the facility had taken actions to reduce the use of restraints. The MS Director stated one of the actions they took was to assign sitters in an attempt to prevent restraining the patient. The ICU Director stated they did not use sitters in the ICU, because the staff had constant visualization of the patients. She stated the ICU nurses had two patients each, and because they had to go into both rooms, sometimes patients had to be restrained.</p> <p>The facility policy titled, "Restraint Management," was reviewed on August 26, 2009. The policy indicated the following:</p> <p>a. all members of the health care team would attempt to obtain the patient's cooperation and compliance through less restrictive measures, including staff supervision;</p> <p>b. restraints could only be used when less restrictive measures had been tried and proven to be ineffective;</p>	A 164			

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NAME OF PROVIDER OR SUPPLIER SOUTHWEST HEALTHCARE SYSTEM	STREET ADDRESS, CITY, STATE, ZIP CODE 25600 MEDICAL CENTER DRIVE MURRIETA, CA 92582
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A 166	<p>Continued From page 35</p> <p>a.m., and restraints were applied due to attempts to pull the tube out.</p> <p>The ICU flowsheets indicated Patient 201 had restraints on as follows:</p> <ul style="list-style-type: none"> a. July 18, 2009 - bilateral (both sides) wrist restraints; b. July 19, 2009 - bilateral wrist restraints; c. no restraints July 20 through July 29, 2009, due to the use of sedation; d. July 29, 2009, bilateral wrist restraints during a CPAP trial (an attempt to get him off the ventilator); e. no restraints July 30 through August 7, 2009, due to the use of sedation; f. August 8, 2009, a mitt on the left hand; g. August 9 and 10, 2009, a mitt on the left hand and a restraint on the left wrist; and, h. August 11 through August 25, 2009 (15 days), a restraint on the left wrist. <p>On August 25, 2009, at 4:45 p.m., Patient 201 was moved to PCU. A sitter was assigned to stay at the bedside of the patient, and the restraints were removed.</p> <p>During a tour of the PCU on August 26, 2009, at 8:58 a.m., Patient 201 was observed sitting up in his bed, with no restraints on, coloring, watching a movie, and smiling. A sitter was at the bedside coloring with him.</p>	A 166		
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A 166	Continued From page 36 During an interview with RN 32 on August 26, 2009, at 9 a.m., the RN stated Patient 201 was, "doing well," with the sitter at the bedside, and he no longer needed restraints. The Interdisciplinary Plan of Care was reviewed on August 26, 2009. The plan, initiated July 18, 2009, indicated the patient had impaired physical mobility, the restraint protocol was checked as a standard of care, and, "wrist restraints," was checked as a planned intervention. The desired outcomes were to prevent falls and prevent injury to self. There was no evidence the plan of care was modified as the restraints were placed, removed, or changed. There was no evidence the staff planned interventions to prevent the use of restraints or use less restrictive means to protect the patient.	A 166			
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	Please see plan of correction starting next page.	09 DEC 16 AM 10:59 SAN GABRIEL COUNTY CALIFORNIA LA DEPT OF HEALTH & HUMAN SERVICES	

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A 263	<p>Continued From page 37</p> <p>This CONDITION is not met as evidenced by: Based on interview and record review, the facility failed to ensure an effective, ongoing, hospital-wide quality assessment and performance improvement program by failing to:</p> <ol style="list-style-type: none"> measure, analyze, track information obtained through the grievance process, and use the information to assess the quality and the performance provided by the facility. The failed practice resulted in the failure to ensure: <ol style="list-style-type: none"> safe discharge planning and follow up care of newborns at risk for developing severe hyperbilirubinemia (jaundice caused by high bilirubin levels in the blood) (A119) (A267); improvement in the facility's systems were identified using the information obtained from the grievances (A119) (A267); and, patient satisfaction (A119)(A267). measure improvement actions taken to ensure safe discharge of newborns at risk of developing hyperbilirubinemia (high bilirubin level in the blood) after Immediate Jeopardy was identified, resulting in continued discharge of at-risk newborns, and the potential for brain damage and death in newborns discharged from SWHCS (A290)(A800); assess the effectiveness of the discharge planning process, resulting in the potential for unsafe discharge, injury, and death (A800); ensure adequate quality assurance was done on contracted services for discharge planning 	A 263	<ol style="list-style-type: none"> Please see the responses to A 119 and A 267 regarding actions the hospital has taken to document the investigation of grievances better, to identify opportunities for improvement from grievances, and to refer those issues to the Quality pillar, the Patient Safety Council and the Board of Governors. and 3. Please see the responses to A 290 and A 800 for actions the hospital has taken to improve assessment of and discharge planning for newborns, as well as actions to improve the QAPI system and include evaluation of the discharge planning process. In addition to the response to A 084, please see the responses to A 394, A748, and A 811 regarding actions the hospital has taken to be sure contracted services, including the infection control consultant, receive adequate review through the QAPI system. Please see the response to A 395 for actions the hospital has taken to monitor the effectiveness of education provided to nurses administering continuous sedation in the ICU. 	
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A 263	<p>Continued From page 38</p> <p>done by outside CMs, and infection control done by a consultant, resulting in the potential for unsafe discharges and the spread of infection between patients, staff, and visitors (A394)(A748)(A811); and,</p> <p>5. monitor the effectiveness of education provided to nurses administering continuous sedation in the ICU, resulting in the potential for under sedation or over sedation of patients receiving propofol (a hypnotic used for sedation in mechanically ventilated patients) (A395).</p> <p>The cumulative effect of these systemic problems resulted in the failure of the facility to assure the quality of the healthcare provided.</p> <p>Findings:</p> <p>1. During an interview with the DCM on August 28, 2009, at 10:50 a.m., the DCM stated the facility did not have a process in place to assess the effectiveness of the discharge planning process. She stated there was no process in place to assess the effectiveness of the discharge planning being done by the outside CMs. She stated she had not assessed the competency of the outside CMs, therefore she did not know if the discharge planning that was conducted by the outside CMs was appropriate.</p> <p>2. The PI Director was interviewed on August 27, 2009, at 9 a.m. Quality Assurance data for the contracted infection control practitioner was requested. She stated a corporate infection control consultant had visited the facility in May (when the SWHCS infection control consultant started), but had produced no written report, and had not returned since to monitor the work of the</p>	A 263			

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A 263	Continued From page 39 consultant. She was unable to provide evidence of quality assurance related to the effectiveness of the infection control practitioner. During an interview with the Director of CM on August 27, 2009, at 10 a.m., she stated the quality of the discharge planning process had not been evaluated in, "quite a while," and, "we need to do it again". She stated problems with the quality of the HMO discharge planning (done by outside CMs) were noticed one year prior, but had not been corrected. She stated the outside CMs did not document in the permanent medical, and it had been a problem for, "a long time," but was unable to further quantify the duration. When asked about reviewing the performance or qualifications of the HMO personnel working in the facility, she stated, "We are not evaluating each of their people."	A 263		
A 267	482.21(a)(2) QAPI QUALITY INDICATORS The hospital must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital services and operations. This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to measure, analyze, track information obtained through the grievance process, and use the information to assess the quality and the performance provided by the facility. The failed practice resulted in the failure to ensure: 1. safe discharge planning and follow up care of newborns at risk for developing severe hyperbilirubinemia (jaundice caused by high bilirubin levels in the blood);	A 267	See plan of correction starting next page.	

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A 267	Continued From page 40 2. improvement in the facility's systems were identified using the information obtained from the grievances; and, 3. patient satisfaction. Findings: 1. Grievance 1 was reviewed during a complaint investigation on August 6, 2009. The grievance was date stamped as received by the facility on July 28, 2009. The grievance included the following: a. a newborn baby was discharged from IVMC with a high bilirubin level, without being treated with phototherapy (using lights to decrease bilirubin levels in the blood); b. follow up for the baby (with a pediatrician) was not until four days after discharge; c. at the follow up visit, the baby was admitted to a NICU of another GACH for, "immediate," treatment of hyperbilirubinemia (high bilirubin levels in the blood) and the, "possibility of brain damage;" and, d. necessary supplies were not available in the L&D room during labor. The investigation conducted August 6 and 12, 2009 (nine and 15 days after the facility received the grievance), revealed the following: a. the perinatal nurses failed to follow the facility policy to assess and identify risk factors for developing hyperbilirubinemia in three of three	A 267	The ADQO had a review done of the cited grievances and confirmed that they had been or were being investigated even though the grievance documentation did not reflect the detail of those investigations. The ADQO further confirmed that Grievance 1 was still under investigation; Grievance 4 involved an outside vendor that was neither operated nor under contract with the hospital, and the vendor resolved the situation on the day the complaint was received; and Grievance 7 was a complaint about a billing issue not covered by this rule. At the direction of the Board of Governors, the CEO formed a Grievance Committee, with the ADQO as the Chair. The standing members of the Grievance Committee are the ADQO, the Service Excellence Coordinator, the CNO and the Director of Risk Management; the Grievance Committee is scheduled to meet monthly. The ADQO and the Service Excellence Coordinator revised the grievance form that staff use to report a grievance. Staff completes the initial part of the form and forwards it to the Service Excellence Coordinator, who is responsible for overseeing and tracking the investigation of the grievance, resolution, and notification to the complainant. The form contains sections for documenting the steps of the investigation, any opportunities for improvement that have been identified, any actions taken, notification of the complainant, and report to the Grievance Committee. The Board of Governors confirmed delegation of the responsibility for dealing with grievances to the Grievance Committee and approved the revised policy and the new grievance form. Person responsible: ADQO	11/06/09 09/15/09 09/15/09 09/15/09

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A 267	<p>Continued From page 41 newborns found to be at risk;</p> <p>b. the perinatal nurses failed to follow the facility policy and perform TcB testing on three of three newborns when risk factors were identified;</p> <p>c. the perinatal nurses failed to follow the facility policy and obtain an order for phototherapy (placing the baby under lights) for two of two newborns with bilirubin levels in the high intermediate risk zone or high risk zone on the Bhutani curve;</p> <p>(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).</p> <p>d. the perinatal nurses failed to follow the facility policy and conduct Coombs testing (to detect destruction of red blood cells in the newborn) on two of two newborns whose mothers had O+ blood; and,</p> <p>e. the facility had not yet conducted interviews of staff or physicians regarding the grievance.</p> <p>During an interview with the CEO on August 25, 2009, at 2:05 p.m., the CEO stated he received the grievance on July 28, 2009. The CEO stated after he read the grievance, he, "immediately," sent copies of it to the PI Director and the CNE. The CEO stated the investigation should have</p>	A 267	<p>The ADQO developed a grid reflecting all departments and the items each department is measuring and monitoring to facilitate the tracking of indicators, improvements, and evaluation of the improvements.</p> <p>The ADQO reviewed the department indicators with the Clinical Directors. The indicators were updated during the November Quality Pillar meeting and forwarded to the PI/RM Committee, the MEC, the Patient Safety Council and the BOG.</p> <p>Monitoring: The Grievance Committee is auditing 100% of grievances for six months to be sure the process is being followed, the forms are complete, reports are going to the Patient Safety Council and the Board of Governors, and opportunities for improvement are being identified and forwarded to the Quality Pillar and the Patient Safety Council for evaluation and action through the hospital-wide QAPI system. At the end of six months, the ADQO and Service Excellence Coordinator will determine whether to reduce the audit to a lower percentage of cases.</p>	09/22/09 12/14/09 09/01/09

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A 267	<p>Continued From page 42 started, "immediately."</p> <p>During an interview with the PI Director on August 25, 2009, at 2:30 p.m., the director stated she received the grievance on August 4, 2009 (seven days after it was received by the CEO), and notified the department managers of the grievance on August 6, 2009. The director stated there was no, "formal," grievance committee. She stated there was no form used to track the progress and findings of the investigation. She stated there was no tracking or trending of grievances to look for patterns and identify opportunities for improvement. She further stated she was not aware of any assessment that had been done of the department managers' capabilities for resolving quality issues that had been reported to them. The director stated a meeting to discover the root cause of the findings was scheduled to take place September 9, 2009 (43 days after the facility received the grievance). She stated the investigation for Grievance 1 was not yet complete.</p> <p>During the same interview, the PI Director stated the newborn's record went to the Department of Pediatrics (medical staff committee) for review on August 12, 2009. According to the PI Director, the committee determined because the baby was discharged with a TSB in the high intermediate risk zone, she should have had her bilirubin checked and/or been seen by her PCP the following day.</p> <p>During an interview with the CNE on August 25, 2009, at 3:05 p.m., the CNE stated she left for vacation on July 29, 2009, and she did not see the grievance before she left. The CNE stated she returned August 10, 2009, and was informed</p>	A 267		
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NAME OF PROVIDER OR SUPPLIER SOUTHWEST HEALTHCARE SYSTEM	STREET ADDRESS, CITY, STATE, ZIP CODE 25500 MEDICAL CENTER DRIVE MURRIETA, CA 92562
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A 267	<p>Continued From page 43</p> <p>of the grievance by the Director of OB, who had initiated an investigation. The CNE explained her role in the grievance process; when she received a grievance, she sent it to the, "appropriate," director and convened the, "appropriate people," for conducting an investigation, making corrections if needed, and conducting follow up as needed. The CNE stated there was no specific person responsible for coordinating the grievance investigation. She stated, "we all own it, and we all wear different hats." The CNE stated during the facility investigation, they did not realize their findings could have affected other babies. She stated the findings from the CDPH investigation made her realize, "this was a global issue."</p> <p>2. Grievance 2, dated March 13, 2009, was reviewed on August 27, 2009. The grievance, written by a nurse on behalf of a patient's wife, was filed due to a delay in administering pain medication to a post operative patient. The nurse documented problems getting the patient into the computer system, resulting in the inability to obtain pain medication for him for, "over an hour."</p> <p>The nurse manager of the department documented on March 16, 2009 (three days later), he called the patient's wife twice, and she was, "satisfied with all except medication error."</p> <p>There was no evidence the reason for the delay in medicating the patient was investigated. There was no evidence a committee reviewed the grievance. There was no evidence corrective action was taken to ensure the event would not reoccur. There was no evidence the patient's wife was informed of a resolution to her grievance.</p> <p>3. Grievance 3, dated April 7, 2009, was reviewed</p>	A 267		
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A 267	<p>Continued From page 44</p> <p>on August 27, 2009. The grievance was filed by the sister of a patient who presented to the ED with severe abdominal pain, was subsequently diagnosed with ischemic (dead) bowel, and underwent surgery. The grievance alleged delays in care and being treated poorly by the ED staff, like a "drug seeker."</p> <p>The ED physician reviewed the case and sent the ED director a letter stating there were delays in getting the patient into an ED bed, delays in receiving test results, and, "some staff did ascribe behavioral attributes to the patient's symptoms," (staff thought the patient was not having real pain), which may have caused a delay.</p> <p>There was no evidence the ED director investigated the delays in getting the patient into an ED bed, the delays in receiving test results, or the treatment of the patient by the ED staff. There was no evidence a committee reviewed the grievance. There was no evidence corrective action was taken to ensure the events would not reoccur. There was no evidence the patient's sister was informed of a resolution to her grievance.</p> <p>4. Grievance 4, dated February 10, 2009, was reviewed on August 27, 2009. The grievance was filed by the patient's husband, and alleged the patient's rights were violated when she was discharged home to hospice care before equipment and medications were delivered to the home, resulting in pain and discomfort for the patient.</p> <p>According to the grievance documents, the Director of CM referred the grievance to the hospice provider, the hospice provider called the</p>	A 267		
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A 267	<p>Continued From page 45 patient's husband, and the issues were resolved.</p> <p>There was no evidence the facility investigated the discharge for appropriateness. There was no evidence a committee reviewed the grievance. There was no evidence corrective action was taken to ensure the events would not reoccur. There was no evidence the patient's husband was informed of a resolution to his grievance.</p> <p>5. Grievance 5, not dated, was reviewed on August 27, 2009. The grievance, filed by the patient, alleged a prolonged stay in the ED, lack of nurses in the ED, being placed in a broken hospital bed, a dirty hospital room, inability to shower due to the shower being used for storage, and being served the wrong food after a visit from the dietitian.</p> <p>The ED physician reviewed the case and documented appropriate medical care while in the ED, but noted a five and one half hour delay in getting CT results. The MS Manager reviewed the case, and documented investigating and correcting the broken bed issues.</p> <p>There was no evidence the delay in CT results, the ED nurse staffing concerns, the cleanliness of the room, the inability of the patient to take a shower, or the appropriateness of the food served were investigated. There was no evidence a committee reviewed the grievance. There was no evidence corrective action was taken (outside of the broken bed issue) to ensure the events would not reoccur. There was no evidence the patient was informed of a resolution to her grievance.</p> <p>6. Grievance 6, dated July 20, 2009, was reviewed on August 27, 2009. The grievance,</p>	A 267		

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A 267	<p>Continued From page 46</p> <p>filed by the patient, alleged she was discharged home with unresolved hypertension because she did not have insurance.</p> <p>According to the grievance documents, the facility attempted to contact the patient by phone, but the telephone number they had on file was incorrect.</p> <p>There was no evidence the facility attempted to contact the patient through other means. There was no evidence the allegations made by the patient were investigated. There was no evidence a committee reviewed the grievance. There was no evidence corrective action was taken to ensure the event would not reoccur. There was no evidence the patient was informed of a resolution to her grievance.</p> <p>7. Grievance 7, dated April 5, 2009, was reviewed on August 27, 2009. The grievance, filed by the patient, alleged the patient had VA insurance, and repeatedly told hospital staff he needed to be transferred or he would incur a bill. According to the grievance, the hospital staff assured the patient multiple times the VA coverage would pay for his stay.</p> <p>According to the grievance documents, the patient received a phone call from the facility and was told of his appeal rights with the VA.</p> <p>There was no evidence an investigation was done to determine if the hospital staff acted appropriately. There was no evidence a committee reviewed the grievance. There was no evidence any corrective action was taken to ensure the event would not happen again. There was no evidence the patient was informed of any resolution to his grievance.</p>	A 267		

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A 267	<p>Continued From page 47</p> <p>8. Grievance 8, dated July 15, 2009, was reviewed on August 27, 2009. The grievance, filed by the patient's daughter, alleged necessary tests were not done during her mother's hospital stay, and her mother was discharged home before she was ready.</p> <p>According to the grievance documents, the patient's daughter was contacted by the facility and they answered the questions that they "could." She was referred to her mother's PMD for further questions.</p> <p>There was no evidence an investigation was conducted to determine appropriateness of tests performed. There was no evidence an investigation was performed to determine the appropriateness of discharge. There was no evidence a committee reviewed the grievance. There was no evidence corrective action was taken to ensure the event would not happen again. There was no evidence the patient's daughter was informed of a resolution to her grievance.</p> <p>9. Grievance 9, dated April 11, 2009, was reviewed on August 27, 2009. The grievance, filed by the patient's sister, alleged neglect that led to her sister's death as follows:</p> <p>a. the patient had severe abdominal pain with a history of gastric bypass surgery, which the facility staff ignored;</p> <p>b. the patient lay in the ED for 12 hours in, "excruciating," pain while her vital signs deteriorated;</p>	A 267		

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A 267	<p>Continued From page 48</p> <p>c. the patient had a bowel obstruction, and the surgeon who was called to come in was a, "no show;"</p> <p>d. nursing staff was not responsive to multiple requests to check on the patient. When they did check, her BP, respirations, and body temperature had dropped, "considerably;" and,</p> <p>e. the patient was taken to ICU, and her sister was left in a waiting room for over an hour. When the staff came to get the patient's sister, they told her the patient had coded, and offered to allow her to be in the room when they, "called her time of death."</p> <p>The grievance was in the form of an e-mail sent to the facility's corporate office. There was no evidence the facility attempted to locate the complainant. There was no evidence an attempt was made to investigate any of the allegations. There was no evidence a committee reviewed the grievance. There was no evidence corrective action was taken to ensure the events would not reoccur. There was no evidence the patient's sister was informed of a resolution to her grievance.</p> <p>During an interview with the service excellence employee on August 27, 2009, at 11:40 a.m., the employee stated there was no grievance committee. She stated letters were not sent to complainants on a regular basis. She stated no letters were sent to the persons who filed grievances one through nine. The employee stated there was no system in place to ensure a thorough investigation of the allegations was conducted, there was no information being gathered to determine patterns or trends, and</p>	A 267		

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A 267	<p>Continued From page 49</p> <p>there was no reporting of grievances to any PI committees.</p> <p>During an interview with three members of the Governing Board on August 27, 2009, at 12:15 p.m., the members stated they were aware of grievances presented to the hospital when the CEO or members of the public brought them to their individual attention, or when a particular grievance was discussed in a governing body meeting. They stated they believed most grievances concerning patient care were brought to their attention, but they did not review all grievances and were not aware of details of the grievance resolutions in all cases. The CEO stated he considered the senior management team the grievance committee, but he did not know if all grievances were reviewed by the team.</p> <p>The facility policy titled, "Customer Grievances," was reviewed on August 25, 2009. The policy indicated the following:</p> <ul style="list-style-type: none"> a. the governing body delegated the responsibility of reviewing and resolving grievances to a grievance committee; b. upon receipt of a grievance, the original grievance would be filed in administration for record keeping purposes; c. a copy of the grievance would be forwarded to the senior manager responsible for the area of concern; d. the senior manager would designate a committee to review and investigate the grievance; 	A 267			

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A 267	Continued From page 50 e. the committee would consist of hospital and/or medical staff members directly related to the allegations cited in the grievance; f. the senior manager would use the, "Grievance Form," to track and document the actions taken by the committee; and, g. the senior manager would provide a written response to the patient within 15 working days from the date the grievance was received. The facility policy titled, "Patient's Rights and Responsibilities " was reviewed on August 25, 2009. The policy indicated a grievance committee would review every grievance and provide a written response to the complainant within 15 business days. The policy indicated the written response would include the name of a contact person at the hospital, the steps taken to investigate the grievance, the results of the grievance investigation, and the date of completion of the grievance process. The facility policy titled, "Customer Concerns and Complaints," was reviewed on August 25, 2009. The policy indicated the service excellence department was responsible for tracking significant customer complaints, reporting them to department managers at least quarterly, and initiating action where necessary to reverse trends in complaints.	A 267			
A 290	482.21(c)(3) QAPI IMPROVEMENT MEASUREMENTS [The hospital must take actions aimed at performance improvement and,] after implementing those actions, the hospital must measure its success, and ...	A 290	See plan of correction starting next page.		

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A 290	<p>Continued From page 51</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to measure improvement actions taken to ensure safe discharge of newborns at risk of developing hyperbilirubinemia (high bilirubin level in the blood) after Immediate Jeopardy was identified, resulting in continued discharge of at-risk newborns, and the potential for brain damage and death in newborns discharged from SWHCS.</p> <p>Findings:</p> <p>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 hyperbillrubinemia 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.</p> <p>An Hour Specific Bilirubin Nomogram indicates the risk zones for hyperbilirubinemia which is determined by the age in hours of the newborn and the bilirubin level.</p> <p>A Coombs test is a test to detect hemolytic (breaking down of red blood cells) disease of the newborn.</p> <p>1. The record for Patient 11 was reviewed on August 6, 2009. Patient 11 was born on June 4, 2009, at 4:28 a.m., at 37 6/7 weeks gestation</p>	A 290	<p>In addition to the actions described in A 119, the hospital has taken the following comprehensive actions:</p> <p>The ADQO created the new position of Compliance Coordinator and hired a person for the job. The Compliance Coordinator is responsible for coordinating all auditing processes and monitoring improvements and changes for effectiveness. The Compliance Coordinator conducts weekly rounds and provides ongoing oversight with a focus on quality, documentation, and "just in time" education by providing immediate feedback to staff members during unit rounds.</p> <p>The ADQO developed a grid reflecting all departments and the items each department is measuring and monitoring to facilitate the tracking of indicators, improvements, and evaluation of the improvements.</p> <p>Senior management revamped the hospital's QAPI structure and implemented a new Patient Safety Council (PSC) structure that oversees services furnished in the hospital in five identified areas: Service, Quality, People, Growth, and Finance. These areas are identified as the pillars. In the previous structure, the Operational Performance Improvement Committee (OPIC) was a large group that did not lend itself to the analysis of data and effective action planning. In addition, a review of the hospital activities identified gaps in the flow of information. Under the revised PSC, each clinical department and task group was assigned to a pillar, and in this way, a defined reporting mechanism was established. The membership of each pillar consists of 6-10 members. This size is more conducive to effective analysis and action planning. Each pillar is chaired by a Senior Team Member. Other members of the Joint Leadership team</p>	<p>09/16/09</p> <p>09/22/09</p> <p>09/15 AM 10:59</p>

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A 290	<p>Continued From page 52 (time developing in the womb - normal 40 weeks).</p> <p>The Newborn Admit Flowsheet dated June 4, 2009, at 8:45 a.m., indicated:</p> <p>a. the mother was Rh negative and the baby was AB+ (Rh incompatible);</p> <p>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,</p> <p>c. the baby had bruises on the right forearm.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>According to the AAP Guidelines:</p> <p>a. an infant with no risk factors who is discharged</p>	A 290	<p>were assigned to the five pillars for multidisciplinary representation. The Associate Administrator was assigned to both the Service and Quality pillars. This was done to enhance the communication between these two key groups by having a designated liaison who is a member of both pillars. Senior management reorganized the hospital functions into these five areas, delineated the work of each council, identified Chairs, established goals for each council, and implemented tools for each council to use to receive information and to report to the Patient Safety Council. The BOG approved the implementation plan for the revised PSC structure.</p> <p>The current BOG Chair serves as Chair for the PSC. The PSC council members are all the pillar chairs, the Director of Pharmacy and representatives from the Medical Staff. The first PSC meeting was held on 10/12/09 to review the role of the Council. The BOG was advised of the initiation of the PSC at their regular meeting.</p> <p>The ADQO conducted an educational presentation to the Joint Leadership team to review the PSC structure, the implementation plan, roles and responsibilities, and reporting tools.</p> <p>Senior management transitioned the work of the Operational Performance Improvement Committee to the revised PSC structure. (The last meeting of OPIC was 10/13/09.) The five pillars began meeting and reporting to the PSC. Each pillar has authority to initiate QAPI activities and to determine if an activity has achieved and maintained the identified goal. The pillar Chair is responsible for ensuring that appropriate departments are involved in a PI</p>	<p>10/19/09</p> <p>10/22/09</p> <p>11/09/09</p>
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A 290	<p>Continued From page 53</p> <p>home at 30 hours of age should be seen by the age of 96 hours, but earlier follow up should be provided for those babies who have risk factors for developing hyperbilirubinemia;</p> <p>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); and,</p> <p>c. phototherapy is recommended for an infant at 30 hours of age, with risk factors for developing hyperbilirubinemia, and a TSB of 8.9.</p> <p>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.</p> <p>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.</p> <p>On August 6, 2009, at 4:35 p.m., RN 1 was</p>	A 290	<p>activity. The PSC meets monthly, has the authority to over-ride a decision made by a pillar and provides a report to the BOG. During this transition, the PI/RM Committee continues to meet and quality reports are forwarded from PI/RM to MEC.</p>	
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CENTERS FOR MEDICARE & MEDICAID SERVICES

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NAME OF PROVIDER OR SUPPLIER SOUTHWEST HEALTHCARE SYSTEM	STREET ADDRESS, CITY, STATE, ZIP CODE 25500 MEDICAL CENTER DRIVE MURRIETA, CA 92562
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A 290	<p>Continued From page 54</p> <p>interviewed. RN 1 stated TcB testing was conducted when the baby was jaundiced within 24 hours of life and if positive for Coombs test. RN 1 stated TcB was also conducted before discharging the newborn from the facility.</p> <p>On August 6, 2009, at 4:40 p.m., RN 2 was interviewed. RN 2 stated TcB testing was 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.</p> <p>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.</p> <p>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. (4 days after discharge from the facility).</p> <p>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</p>	A 290		
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A 290	<p>Continued From page 55</p> <p>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.</p> <p>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).</p> <p>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..."</p> <p>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).</p> <p>The Newborn Admit Flowsheet dated July 26, 2009, at 9:06 a.m., indicated the baby had a slight Caput Sucedaneum (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.</p> <p>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 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.</p>	A 290		

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A 290	<p>Continued From page 58</p> <p>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.</p> <p>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 hyperbillirubinemia.</p> <p>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.</p> <p>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 intermediate risk zone. The Manager stated TSB testing should have been completed to determine the need for phototherapy (the application of light for therapeutic purposes - to decrease the bilirubin level).</p> <p>During a concurrent interview, the Manager was unable to find evidence Coombs testing was performed on Patient 12. The Manager stated</p>	A 290		
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A 290	<p>Continued From page 57</p> <p>Coombs testing should have been done.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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 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.</p> <p>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.</p>	A 290		
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A 290	<p>Continued From page 58</p> <p>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).</p> <p>The policy indicated the risk factors for hyperbilirubinemia included but were not limited to the following;</p> <ul style="list-style-type: none"> 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 suboptimal breastfeeding; d. jaundice appearing in the first 24 hours after birth (dark skin pigments may obscure visualization); e. macrosomic (large for gestational age) infant of a diabetic mother; f. near-term newborns at 35, 36, and 37 weeks of gestation, particularly if they were breastfed; g. significant weight loss (defined as > (greater than) 10 % by discharge; 	A 290		
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A 290	<p>Continued From page 59</p> <p>h. temperature instability or treatment of sepsis; and,</p> <p>i. unrecognized hemolysis, such as ABO blood type incompatibility.</p> <p>The policy further indicated:</p> <p>a. a TcB and/or TSB would be done when visible jaundice and/or risk factors were present, and prior to discharge;</p> <p>b. bilirubin levels were to be plotted on the Hour-specific Billirubin Nomogram;</p> <p>c. if the TcB value was greater than 75% (high intermediate risk zone) on the nomogram (Bhutani Curve) a TSB was to be drawn stat;</p> <p>d. the physician was to be notified stat for values in the high intermediate or high-risk zone, or values greater than 12; and,</p> <p>e. an order for phototherapy was to be obtained if the TSB was in the high intermediate or high-risk zone.</p> <p>The Newborn Nursery Preprinted Orders were reviewed on August 6, 2009. The orders directed the staff to do the following:</p> <p>a. obtain a TcB as indicated per protocol;</p> <p>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;</p>	A 290		
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A 290	<p>Continued From page 60</p> <p>c. follow the protocol for recommended interventions; and,</p> <p>d. obtain an order for phototherapy if indicated per protocol.</p> <p>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.</p> <p>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:</p> <p>a. assessing and identifying risk factors for increased bilirubin levels;</p> <p>b. performing TCB testing as soon as risk factors were identified;</p> <p>c. obtaining an order for phototherapy when the SB levels were in the high intermediate risk or high risk zone; and,</p> <p>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.</p> <p>Upon receipt of an acceptable written plan of correction on August 12, 2009, at 6:47 p.m., the Immediate Jeopardy was abated.</p>	A 290			

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A 290	<p>Continued From page 61</p> <p>The plan of correction included the following immediate actions:</p> <ul style="list-style-type: none"> 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 assignment; and, g. the facility would monitor for compliance. <p>4. Patient 17's record was reviewed on August 26, 2009. Patient 17 was born on July 14, 2009, at 3:33 a.m.</p> <p>The Newborn Admit Flowsheet dated July 14, 2009, indicated the mother's blood type was O+.</p>	A 290		

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A 290	<p>Continued From page 62</p> <p>There was no Coombs testing performed on the cord blood.</p> <p>The Hour Specific Nomogram indicated on July 15, 2009, at 4:30 a.m. (25 hours of age), the TCB was 7, in the high intermediate risk zone. At 4:35 a.m., the TSB was 5.3.</p> <p>The laboratory report for the TSB test, dated July 15, 2009, was reviewed. The report indicated the blood specimen was collected on July 15, 2009, at 6:30 a.m. (2 hours after the TCB test).</p> <p>On August 26, 2009, at 9:45 a.m., the CLS Director and the LS were interviewed. The LS reviewed the TSB test order in the computer. The LS stated the laboratory department received the order in the computer on July 15, 2009, at 4:45 a.m., and was placed as "routine" laboratory and not as "Stat." The LS stated the blood was collected for the test at 6:30 a.m. The LS stated the laboratory department received the blood specimen for the test at 6:44 a.m., and entered results at 7:12 a.m.</p> <p>On August 26, 2009, at 9:45 a.m., in an interview with the CLS Director, she stated for "Stat" laboratory tests, the specimen needed to be collected immediately. The CLS Director stated "Stat" laboratory test results were expected within an hour of the order. The CLS Director stated if the TSB was ordered "Stat," the results were expected within an hour.</p> <p>On August 26, 2009, at 10:10 a.m., RN 4 was interviewed. RN 4 worked in the nursery department. RN 4 stated when TCB results were in the high intermediate or high risk zone in the Hour Specific Bilirubin Nomogram, a TSB testing</p>	A 290		

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A 290	<p>Continued From page 63</p> <p>needed to be done. RN 4 stated the blood was drawn either by the nurses or the laboratory. RN 4 stated she entered the order for the TSB test in the computer as ASAP according to facility instructions. RN 4 stated the TSB testing was not done "Stat" at all times.</p> <p>On August 26, 2009, at 10:25 a.m., RN 6 was interviewed. RN 6 stated she did couplet care (mother and baby). She stated when TCB results were in the high intermediate or high risk zone in the TSB Nomogram, a TSB testing needed to be done. She stated she would enter the TSB test as "ASAP" and not as "Stat."</p> <p>On August 26, 2009, at 9:30 a.m., the Nursery and OB Managers were interviewed. The Managers stated when a TCB test resulted in the high intermediate risk zone or high risk zone, the TSB test needed to be done "Stat." The Managers stated the blood specimen for the "Stat" tests needed to be drawn immediately after the TCB test. The Managers were unable to explain why it took two hours for the blood to be drawn for the TSB. The Manager stated tests done as ASAP would not require the results to be back within one hour. She stated "Stat" tests required the results to be back within one hour.</p> <p>5. Patient 20's record was reviewed on August 26, 2009. Patient 20 was born on August 22, 2009, at 5:08 p.m.</p> <p>The Well Newborn Care Flowsheet dated August 23, 2009, at 7:55 p.m., indicated the baby was taken to the nursery for an assessment, risk factors for hyperbilirubinemia were reviewed, the baby was jaundiced in color, and the TCB was 9.7.</p>	A 290			<p>CA DEPT OF HEALTH & HUMAN SERVICES MURRIETA COUNTY 09 DEC 16 AM 11:00</p>

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A 290	<p>Continued From page 64</p> <p>The Hour Specific Bilirubin Nomogram indicated on August 23, 2009, at 7:55 p.m. (27 hours of age), the TcB was 9.7, in the high risk zone on the Bhutani curve. At 8 p.m. (27 hours of age), the TSB result was 6.6, in the high intermediate risk zone, but plotted by the nurse in low intermediate risk zone.</p> <p>Patient 20's record did not have evidence an order for phototherapy was obtained for the 6.6 TSB level, or documented evidence the staff attempted to obtain an order for phototherapy from the physician.</p> <p>On August 26, 2009, at 11:50 a.m., Patient 20's record was reviewed with the Nursery Manager and the DWS. The Manager stated the TSB result of 6.6 was plotted incorrectly, and should have been plotted in the high intermediate risk zone.</p> <p>During a concurrent interview with the manager, she stated she could not find evidence the physician was notified of the 6.6 TSB level, in the high intermediate risk zone.</p> <p>6. Patient 21's record was reviewed on August 27, 2009. Patient 21 was born on August 24, 2009, at 10:39 p.m.</p> <p>The Hour Specific Bilirubin Nomogram indicated on August 26, 2009, at 8 p.m. (45 hours of age), the TCB was 10.7, in the high intermediate risk zone, and the TSB was 7.9, in low risk zone.</p> <p>The laboratory report for the TSB test, dated August 26, 2009, was reviewed. The report indicated the blood specimen was collected on August 26, 2009, at 9:30 p.m. (1 1/2 hours after</p>	A 290		
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A 290	<p>Continued From page 65</p> <p>the TCB test), and not at 8 p.m. as indicated in the Hour Specific Bilirubin Nomogram.</p> <p>On August 27, 2009, RN 5 was interviewed. RN 5 was assigned to couplet care (mother and baby). RN 5 stated when a patient's TCB results were in the high intermediate or high risk zone, the TSB test was done "Stat." RN 5 stated "Stat" TSB test results were expected within 45 minutes of the TCB test.</p> <p>On August 26, 2009, at 9:45 a.m., in an interview with the CLS Director, she stated for "Stat" laboratory test, the specimen needed to be collected immediately. The CLS Director stated "Stat" laboratory tests results were expected within an hour of the order. The CLS Director stated if the TSB was ordered "Stat," the results were expected within an hour.</p> <p>7. The record for Patient 204 was reviewed on August 25, 2009. Patient 204, a newborn female of Asian descent, was born on July 10, 2009, at 8:58 a.m.</p> <p>The Well Newborn Care Flowsheet indicated the baby was not feeding well, so a lactation (breastfeeding) consult was done on July 11, 2009, at 10:30 a.m.</p> <p>The Hour Specific Bilirubin Nomogram indicated the nursing staff did not assess for risk factors for developing hyperbilirubinemia. The nurses did not identify the Asian descent or poor feeding as risk factors. The nurses did not do a TcB until July 11, 2009, at 5:45 p.m. (32 hours of age). The value was 10.1, in the high risk zone on the Bhutani curve. A TSB was drawn at 6:10 p.m. (33 hours of age) with a result of 6.2, in the low intermediate</p>	A 290		
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A 290	<p>Continued From page 66 risk zone of the curve.</p> <p>On July 12, 2009, at 5 a.m. (44 hours of age), the TcB was 10.0, in the high intermediate risk zone. The nurse's notes indicated the physician was not notified, and no TSB was drawn.</p> <p>On July 12, 2009, at 8:20 a.m., the nurse's notes indicated the baby had, "sl(ight) jaundice."</p> <p>The baby was discharged home on July 12, 2009, at 11:05 a.m., with risk factors for developing hyperbilirubinemia, the previous TcB in the high intermediate risk zone, no TSB done, jaundice in color, and no physician notification.</p> <p>8. The record for Patient 205 was reviewed on August 25, 2009. Patient 205, a newborn male of Asian descent, was born on June 2, 2009, at 11:55 p.m., at 37 4/7 weeks gestation (time developing in the womb - normal 40 weeks).</p> <p>The Hour Specific Bilirubin Nomogram indicated the nursing staff did not assess for risk factors for developing hyperbilirubinemia. The nurses did not identify the Asian descent or the gestational age of <38 weeks as risk factors. The nurses did not do a TcB until June 4, 2009, at 3 p.m. (39 hours of age), after discharge orders were written. The value was 11.9, on the line of the high risk zone on the Bhutani curve. A TSB was drawn at 3:11 p.m. (39 hours of age) with a result of 9.5, on the line of the high intermediate risk zone of the curve. There was no evidence the physician was notified.</p> <p>The baby was discharged home on June 4, 2009, at 6 p.m., with risk factors for developing hyperbilirubinemia, a TSB on the line of the high</p>	A 290		
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A 290	<p>Continued From page 67</p> <p>intermediate risk zone, no notification of the physician, and follow up with the pediatrician's office in five days.</p> <p>9. The record for Patient 207 was reviewed on August 26, 2009. Patient 207, a newborn male of Hispanic descent, was born May 4, 2009, at 2 a.m.</p> <p>The Physician's Record indicated the baby had a cephalhematoma (bruising on the head), and was being monitored for a possible infection.</p> <p>The Well Newborn Care Flowsheet indicated the baby was jaundiced on May 6, 2009, at 2:40 a.m., 6:30 a.m., 8 a.m., and 12 noon.</p> <p>The Hour Specific Bilirubin Nomogram indicated the nursing staff did not assess for risk factors for developing hyperbilirubinemia. The nurses did not identify the dark skin pigmentation, the cephalhematoma, or the possible infection as risk factors. The nurses did not do a TcB until May 6, 2009, at 2:40 a.m. (48.5 hours of age), when the baby appeared jaundiced. The result was 12.1, in the high intermediate risk zone on the Bhutani curve. A TSB was drawn, with a result of 11.3, still in the high intermediate risk zone on the curve. There was no order obtained for phototherapy.</p> <p>10. Patient 29's record was reviewed on September 3, 2009. Patient 29 was born on August 31, 2009, at 12:40 p.m.</p> <p>The Hour Specific Bilirubin Nomogram indicated on September 1, 2009, at 9:30 p.m. (32 hours of age), the TCB was 8.7, in the high intermediate risk zone on the Bhutani curve. At 10:45 p.m.,</p>	A 290		
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A 290	<p>Continued From page 68</p> <p>the TSB was 8.9, in the high intermediate risk zone.</p> <p>On September 3, 2009, at 12:40 p.m., a facility document, which indicated the laboratory test order entry, collecting, and processing, was reviewed with the CLS Director. According to the document, the CLS Director stated:</p> <p>a. The order for the TSB testing was entered in the computer on September 1, 2009, at 10:33 p.m. (one hour after the TCB testing);</p> <p>b. The blood specimen for the TSB test was collected on September 1, 2009, at 10:45 p.m. (one and 1/4 hours after the TCB testing); and,</p> <p>c. The TSB result of 8.9 was relayed to the licensed nurse at 11:40 p.m. (two hours and 10 minutes after the TCB testing).</p> <p>On September 3, 2009, at 3:55 p.m., the Nursery Manager was interviewed. The Manager stated the "Stat" TSB test should have been completed immediately and the results should have been available within an hour of the TcB results.</p> <p>On August 26, 2009, at 9:45 a.m., in an interview with the CLS Director, she stated for "Stat" laboratory test, the specimen needed to be collected immediately. The CLS Director stated "Stat" laboratory test results were expected within an hour of the order. The CLS Director stated if the TSB was ordered "Stat," the results were expected within an hour.</p> <p>The facility policy titled, "Hyperbilirubinemia, Assessment, Identification, and Intervention Protocol," last revised April 2008, was reviewed</p>	A 290		
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A 290	<p>Continued From page 69 on August 6, 2009. The policy indicated if the TcB value was in the greater than 75% on TSB Nomogram (Bhutani curve), the TSB test should be done "Stat."</p> <p>11. Patient 30's record was reviewed on September 3, 2009. The patient was born on August 28, 2009, at 10:38 a.m.</p> <p>The Hour Specific Bilirubin Nomogram indicated on August 29, 2009, at 5 a.m. (18 1/2 hours of age), the TCB was 8.1, in the high risk zone on the Bhutani curve. At 7:10 a.m., the TSB was 7, in the high intermediate risk zone.</p> <p>The laboratory report for the TSB test, dated August 29, 2009, was reviewed. The report indicated the blood specimen was collected on August 29, 2009, at 7:10 a.m. (2 hours after the TCB test).</p> <p>On September 3, 2009, at 3:55 p.m., the Nursery Manager was interviewed. The Manager stated the "Stat" TSB test should have been completed immediately and the results should have been available within an hour of the TcB results.</p> <p>On August 26, 2009, at 9:45 a.m., in an interview with the CLS Director, she stated for "Stat" laboratory tests, the specimen needed to be collected immediately. The CLS Director stated "Stat" laboratory test results were expected within an hour of the order. The CLS Director stated if the TSB was ordered "Stat," the results were expected within an hour.</p> <p>The facility policy titled, "Hyperbilirubinemia, Assessment, Identification, and Intervention Protocol," last revised April 2008, was reviewed</p>	A 290		
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A 290	<p>Continued From page 70 on August 6, 2009. The policy indicated if the TcB value was in the greater than 75% on TSB Nomogram (Bhutani curve), the TSB test should be done "Stat"</p> <p>12. The record for Patient 228 was reviewed on September 4, 2009. Patient 228, a newborn male, was born on August 31, 2009, at 4:22 a.m. The Newborn Admit Flowsheet indicated the baby ingested maternal blood at the time of delivery. The admission physical assessment was not complete. There were no evidence physical risk factors for developing hyperbilirubinemia was assessed.</p> <p>The Hour Specific Bilirubin Nomogram indicated the nurses identified dark skin pigmentation and ingestion of maternal blood as risk factors, and TcB levels were obtained each shift. The TcB result on September 1, 2009, at 8:40 a.m., was 7.0, on the line of the high intermediate risk zone on the Bhutani curve. There was no TSB drawn.</p> <p>The baby was discharged home on September 1, 2009, at 10:40 a.m., with risk factors for developing hyperbilirubinemia, a TcB on the line of the high intermediate risk zone of the curve, no TSB level, and instructions to follow up with the pediatrician in two days.</p> <p>13. The record for Patient 217 was reviewed on September 4, 2009. Patient 217, a newborn male, was born on September 3, 2009, at 37 3/7 weeks gestation (time developing in the womb - normal 40 weeks).</p> <p>The Hour Specific Bilirubin Nomogram indicated the nursing staff did not identify gestational age of <38 weeks as a risk for developing</p>	A 290		
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A 290	<p>Continued From page 71 hyperbilirubinemia.</p> <p>14. The record for Patient 267 was reviewed on September 3, 2009. Patient 267 was born on August 27, 2009, at 1:29 p.m., at 37 6/7 weeks gestation (time developing in the womb - normal 40 weeks), and was being breastfed.</p> <p>The Well Newborn Care Flowsheet indicated the nurses did not identify the gestational age of <38 weeks as a risk factor for developing hyperbilirubinemia.</p> <p>The Hour Specific Bilirubin Nomogram indicated the nurses did not identify gestational age of <38 weeks as a risk factor for developing hyperbilirubinemia.</p> <p>15. The record for Patient 268 was reviewed on September 3, 2009. Patient 268 was born on August 27, 2009, at 1:31 p.m., at 37 6/7 weeks gestation (time developing in the womb - normal 40 weeks), and was being breastfed.</p> <p>The Physician's Record of Newborn Infant indicated the physician identified the gestational age of 37 weeks as, "pertinent," history.</p> <p>The Well Newborn Care Flowsheet indicated the nurses did not identify the gestational age of <38 weeks as a risk factor for developing hyperbilirubinemia.</p> <p>The Hour Specific Bilirubin Nomogram indicated the nurses did not identify the gestational age of <38 weeks as a risk factor for developing hyperbilirubinemia.</p>	A 290		
A 338	482.22 MEDICAL STAFF	A 338	See plan of correction starting next page.	

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A 338	Continued From page 72 The hospital must have an organized medical staff that operates under bylaws approved by the governing body and is responsible for the quality of medical care provided to patients by the hospital. This CONDITION is not met as evidenced by: Based on interview, record review, and facility document review, the facility's medical staff failed to ensure quality medical care was provided, by failing to: 1. provide timely follow-up of the newborns discharged with risk factors for the development of hyperbilirubinemia (Patients 11, 12, 205, 265, 218, 227, 228, 247, 276, and 285), resulting in the delay of a follow-up after discharge and the potential exposure of the newborns to increased bilirubin levels, which may cause brain damage, developmental disabilities, and death; 2. ensure physicians provided the same level of care to newborns at risk for developing hyperbilirubinemia, by ordering follow up care: a. the day after discharge for nine of 13 babies discharged Saturday through Thursday (Patients 221, 225, 232, 233, 234, 237, 238, 239, and 240); b. two days after discharge for four of 13 babies discharged Saturday through Thursday (Patients 222, 228, 247, and 285); and, c. three to five days after discharge for seven of seven babies discharged on Fridays (Patients 11, 13, 205, 265, 218, 227, and 276), resulting in severe hyperbilirubinemia and admission to a NICU in one newborn discharged on a Friday, and greater potential for developing severe	A 338	Beginning 8/12/09, the Chair of the Department of Pediatrics reviewed and initiated revisions to the policies and procedures that guide the care of the newborns to ensure early detection and treatment of hyperbilirubinemia. At Department of Pediatrics meetings on 9/9/09 and 10/14/09, the Department reviewed the procedures and monitoring to make additional changes in procedures and forms in accordance with the American Academy of Pediatrics guidelines. These changes included discharge guidelines to ensure timely follow-up for babies deemed to be at risk for hyperbilirubinemia, including discharge orders for post-hospitalization follow up and related forms. 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 babies with serum bilirubin results > 75th percentile. The revised policies, Hyperbilirubinemia, Newborn Discharge, Cord Blood Collection and the following forms: Newborn Nursery Orders, Hours Specific Bilirubin Nomogram and Physician's Record of Newborn were approved by the Department of Pediatrics, the MEC and the BOG. Person Responsible: Director of Women's Services The Director of Women's Services is auditing 100% of charts where jaundice or risk factors were identified to confirm completeness of physician documentation. The Director of Women's Services reports trends and variances to the Department of Pediatrics, and data up through the Quality Pillar.	08/12/09 10/14/09 10/19/09 08/14/09 & ongoing

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A 338	<p>Continued From page 73</p> <p>hyperbilirubinemia in the babies discharged on Fridays;</p> <p>3. implement phototherapy according to facility policy and AAP Guidelines, resulting in the exposure of two newborns to increased bilirubin levels, which may cause brain damage, developmental disabilities, and death (Patients 11 and 247);</p> <p>4. ensure the facility policy, "Hyperbilirubinemia, Assessment, Identification, and Intervention Protocol" outlined a response consistent with the AAP Guidelines, used by facility staff, which had the potential to result in inaccurate assessment and intervention in all newborns with hyperbilirubinemia; and,</p> <p>5. ensure appraisal via proctoring was completed for one physician (Physician 1), which created the potential for substandard care (Refer to A340).</p> <p>The cumulative effects of these systemic problems resulted in the failure of the medical staff to ensure the quality of medical care was provided by the hospital to the patients.</p> <p>Findings:</p> <p>(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</p>	A 338		
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A 338	<p>Continued From page 74 further investigation and possible intervention)</p> <p>(A TcB is a non invasive method of screening to determine the probable level of bilirubin in the blood)</p> <p>(A TSB is the actual level of bilirubin in the blood, determined by drawing blood and sending it to the lab)</p> <p>1a. The record for Patient 11 was reviewed on August 6, 2009. Patient 11 was born on June 4, 2009, at 4:28 a.m., at 37 6/7 weeks gestation (time developing in the womb - normal 40 weeks).</p> <p>The Newborn Admit Flowsheet dated June 4, 2009, at 6:45 a.m., indicated:</p> <p>a. the mother was Rh negative and the baby was AB+ (Rh incompatible);</p> <p>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);</p> <p>c. the baby had bruises on the right forearm;</p> <p>d. the baby was large for gestational age; and,</p> <p>e. the baby was breastfed.</p> <p>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.</p> <p>The Hour Specific Bilirubin Nomogram indicated the nurses did not assess for risk factors for</p>	A 338		

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A 338	<p>Continued From page 75</p> <p>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.</p> <p>The Physician's Order Sheet dated June 5, 2009, at 11:20 a.m., indicated, "Ok to DC home. F/U (Follow up) Mon(day) on Tue(sday) (three to four days after discharge)..."</p> <p>The Well Newborn Care Flowsheet indicated ~ Patient 11 was discharged home on Friday, June 5, 2009, at 12:50 p.m. (with multiple risk factors for developing hyperbilirubinemia, the TSB in the high intermediate risk zone).</p> <p>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 Billirubin Nomogram.</p> <p>On August 6, 2009, at 4:40 p.m., RN 2 was interviewed. RN 2 stated TcB testing was 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</p>	A 338		
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A 338	<p>Continued From page 76 physician ordered it.</p> <p>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.</p> <p>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 being discharged from the facility).</p> <p>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.</p> <p>The Laboratory Test result dated 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).</p> <p>The Discharge Summary from GACH 2, dated June 15, 2009, at 9:35 a.m., was reviewed. The record indicated, "...Discharge diagnoses: indirect hyperbilirubinemia - treated and resolved;</p>	A 338		
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A 338	<p>Continued From page 77 dehydration - resolved; and, feeding dyscoordination - improved..."</p> <p>According to the AAP Guidelines:</p> <p>a. an infant with no risk factors who was discharged home at 30 hours of age should be seen by the age of 96 hours, but earlier follow up should be provided for those babies who have risk factors for developing hyperbilirubinemia;</p> <p>b. the risk factors most frequently associated with hyperbilirubinemia were 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); and,</p> <p>c. phototherapy was recommended for an infant at 30 hours of age, with risk factors for developing hyperbilirubinemia, and a TSB of 8.9.</p> <p>During an interview with the PI Director on August 25, 2009, at 4:40 p.m., the director stated the newborn's record went to the Department of Pediatrics (medical staff committee) for review on August 12, 2009. According to the PI Director, the committee determined, because the baby was discharged with a TSB in the high intermediate risk zone, she should have had her bilirubin checked and/or been seen by her PCP the following day (24 hours later). The PI Director stated the committee determined there was a deviation with the standard of medical care to treat hyperbilirubinemia.</p> <p>1b. On August 12, 2009, Patient 12's record was reviewed. Patient 12 was born on July 26, 2009, at 9:08 a.m., at 37 2/7 weeks gestation (time</p>	A 338		
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A 338	<p>Continued From page 78 developing in the womb - normal 40 weeks).</p> <p>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, was breastfed, and the mother's blood type was O+. There was no Coombs test performed on the cord blood.</p> <p>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 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.</p> <p>Patient 12 was discharged home on July 27, 2009, at 12 p.m., (27 hours of age) with risk factors for developing hyperbilirubinemia, the TcB in the high intermediate risk zone, and no order for follow-up with the physician.</p> <p>On August 12, 2009, at 3:25 p.m., Patient 12's record was reviewed with the Nursery Manager. The Manager stated Patient 12 being at <38 weeks gestation was a risk factor for hyperbilirubinemia and the TSB Nomogram would have indicated the risk factor for increased bilirubin levels.</p> <p>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</p>	A 338		
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A 338	<p>Continued From page 79</p> <p>intermediate risk zone. The Manager stated TSB testing should have been completed to determine the need for phototherapy.</p> <p>During a concurrent interview, the Manager was unable to find evidence Coombs testing was performed on Patient 12 and stated Coombs testing should have been done.</p> <p>According to the AAP Guidelines:</p> <p>a. an infant with no risk factors who was discharged home at 27 hours of age should be seen by the age of 96 hours, but earlier follow up should be provided for those babies who have risk factors for developing hyperbilirubinemia; and,</p> <p>b. the risk factors most frequently associated with hyperbilirubinemia were breastfeeding, gestation below 38 weeks, jaundice in a previous sibling (brother or sister), and jaundice noted before discharge (Patient 12 had three of these four risk factors).</p> <p>1c. The record for Patient 205 was reviewed on August 25, 2009. Patient 205, a newborn male of Asian descent, was born on June 2, 2009, at 11:55 p.m., at 37 4/7 weeks gestation (time developing in the womb - normal 40 weeks), and was breastfed.</p> <p>The Hour Specific Bilirubin Nomogram indicated the baby was at risk for developing hyperbilirubinemia due to his Asian descent and gestational age of <38 weeks. The first TcB was done June 4, 2009, at 3 p.m. (39 hours of age), after discharge orders were written. The value</p>	A 338		

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Continued From page 81

During an interview with the governing body on August 27, 2009, at 12:20 p.m., the physician members stated they expected a baby at risk for developing hyperbilirubinemia would be followed up, by a physician after discharge from the facility, sooner than those not at risk.

1d. The record for Patient 265 was reviewed on September 3, 2009. Patient 265 was born on August 27, 2009, at 3:11 p.m., and was breastfed.

The Hour Specific Bilirubin Nomogram indicated the baby was at risk for developing hyperbilirubinemia due to an identified risk factor of poor feeding. On Friday, August 28, 2009, at 4:10 p.m. (25 hours of age), the TcB was 7.0, in the high intermediate risk zone on the Bhutani curve. At 5 p.m. (26 hours of age), the TSB was 6.2, in the high intermediate risk zone on the curve.

The nurse notified the physician of the bilirubin results at 6:05 p.m., and the physician ordered the baby to be discharged home with follow up on, "Monday."

The baby was discharged home on August 28, 2009, at 7 p.m. (28 hours of age), with risk factors for developing hyperbilirubinemia, a TSB in the high intermediate risk zone on the Bhutani curve, and follow up with a pediatrician three days later.

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

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A 338	<p>Continued From page 82 identified the need for a discharge plan that included close follow up for prevention of severe hyperbilirubinemia.</p> <p>According to the AAP Guidelines, an infant with no risk factors who was discharged home at 28 hours of age should be seen by the age of 96 hours, but earlier follow up should be provided for those babies who have risk factors for developing hyperbilirubinemia.</p> <p>1e. The record for Patient 218 was reviewed on September 4, 2009. Patient 218, a newborn female, was born on September 2, 2009, at 10:09 a.m., and was breastfed.</p> <p>The Hour Specific Bilirubin Nomogram indicated the baby was at risk for developing hyperbilirubinemia due to dark skin pigmentation, family history of neonatal jaundice, and vacuum delivery, so bilirubin levels were checked every shift. On Friday, September 4, 2009, at 9:15 a.m. (47 hours of age), the TcB was 11.2, in the high intermediate risk zone on the Bhutani curve. The TSB was 10.4, on the line of the high intermediate risk zone on the curve.</p> <p>The physician was notified of the bilirubin levels, and ordered the baby to be discharged and followed up on, "Tuesday" (four days later [Friday started a holiday weekend, and offices were closed on Monday]).</p> <p>The nurse's notes indicated the physician was, "called and risk factors reviewed, no new orders received, Dr. does not want to order repeat bili or outpatient serum bili at this time."</p> <p>According to the AAP Guidelines:</p>	A 338		
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A 338	<p>Continued From page 83</p> <p>a. an infant with no risk factors who was discharged home at 47 hours of age should be seen by the age of 96 hours, but earlier follow up should be provided for those babies who have risk factors for developing hyperbilirubinemia; and,</p> <p>b. the risk factors most frequently associated with hyperbilirubinemia were breastfeeding, gestation below 38 weeks, jaundice in a previous sibling (brother or sister), and jaundice noted before discharge (Patient 218 had two of these four risk factors).</p> <p>1f. The record for Patient 227 was reviewed on September 4, 2009. Patient 227, a newborn male, was born on August 26, 2009, at 9:50 a.m., to a 19 year old first time mother.</p> <p>The Hour Specific Bilirubin Nomogram indicated the baby was at risk for developing hyperbilirubinemia due to bruising of the head, and TcB values were obtained every shift. Bilirubin results were as follows:</p> <p>a. August 27, 2009, at 8 a.m. (22 hours of age), the TcB was 7.5, on the line of the high risk zone on the Bhutani curve;</p> <p>b. August 27, 2009, at 9:45 a.m. (24 hours of age), the TSB was 7.1, in the high intermediate risk zone on the curve;</p> <p>c. August 27, 2009, at 9:45 p.m. (36 hours of age), the TSB was 9.4, in the high intermediate risk zone on the curve;</p> <p>d. August 28, 2009, at 4:30 a.m. (42.5 hours of</p>	A 338		
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A 338	<p>Continued From page 84</p> <p>age), the TSB was 10.1, in the high intermediate risk zone on the curve;</p> <p>e. August 28, 2009, at 10:40 a.m. (48.5 hours of age), the TcB was 14.4, in the high risk zone on the curve;</p> <p>f. August 28, 2009, at 11:10 a.m. (49 hours of age), the TSB was 12.3, in the high intermediate risk zone on the curve; and,</p> <p>g. August 28, 2009, at 4:05 p.m. (54 hours of age), the TSB was 13.0, in the high intermediate risk zone on the curve.</p> <p>The Well Newborn Care Flowsheet indicated the baby became jaundiced on August 27, 2009, at 7 p.m., and continued to be jaundiced in color until the time of discharge.</p> <p>The physician ordered the baby to be discharged home on Friday, August 28, 2009, and to follow up with the pediatrician's office on Monday, August 31, 2009 (three days later).</p> <p>The baby was discharged home to his 19 year old first time mother, with risk factors for developing hyperbilirubinemia, a TSB in the high intermediate risk zone on the Bhutani curve, jaundice in color, to be seen by the pediatrician in three days.</p> <p>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</p>	A 338			

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A 338	<p>Continued From page 85 hyperbilirubinemia.</p> <p>According to the AAP Guidelines, an infant with no risk factors who was discharged home at 54 hours of age should be seen by the age of 96 hours, but earlier follow up should be provided for those babies who have risk factors for developing hyperbilirubinemia.</p> <p>1g. The record for Patient 228 was reviewed on September 4, 2009. Patient 228, a newborn male, was born on August 31, 2009, at 4:22 a.m. The Newborn Admit Flowsheet indicated the baby ingested maternal blood at the time of delivery. The admission physical assessment was not completed, therefore, no physical risk factors for developing hyperbilirubinemia were assessed.</p> <p>The Hour Specific Bilirubin Nomogram indicated the baby was at risk for developing hyperbilirubinemia due to identified risk factors of dark skin pigmentation and ingestion of maternal blood, and TcB levels were obtained each shift. On September 1, 2009, at 8:40 a.m. (28 hours of age), the TcB was 7.0, on the line of the high intermediate risk zone on the Bhutani curve. There was no TSB drawn.</p> <p>The baby was discharged home on September 1, 2009, at 10:40 a.m. (30 hours of age), with risk factors for developing hyperbilirubinemia, a TcB in the high intermediate risk zone on the Bhutani curve, no TSB level, and follow up with the pediatrician in two days.</p> <p>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</p>	A 338		
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A 338	<p>Continued From page 86</p> <p>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.</p> <p>According to the AAP Guidelines, an infant with no risk factors who was discharged home at 30 hours of age should be seen by the age of 96 hours, but earlier follow up should be provided for those babies who have risk factors for developing hyperbilirubinemia.</p> <p>1h. The record for Patient 247 was reviewed on September 4, 2009. Patient 247, a newborn male, was born on August 30, 2009, at 10:02 a.m., at 36 1/7 weeks gestation (time developing in the womb - normal 40 weeks), and was breastfed.</p> <p>The Hour Specific Bilirubin Nomogram indicated the baby was at risk for developing hyperbilirubinemia due to identified risk factors of sibling (brother or sister) jaundice and gestational age <38 weeks, and bilirubin levels were obtained every shift. On September 1, 2009, at 8:30 a.m. (45 hours of age), the TcB was 11.2, in the high intermediate risk zone on the Bhutani curve. No TSB was drawn.</p> <p>The Well Newborn Care Flowsheet indicated the baby was jaundiced on September 1, 2009, at 8 a.m., 10 a.m., and 12 noon.</p> <p>The baby was discharged home on September 1, 2009, at 1:20 p.m. (50 hours of age), with risk factors for developing hyperbilirubinemia, a TcB in the high intermediate risk zone on the Bhutani curve, no TSB, and follow up with the pediatrician</p>	A 338		
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A 338	<p>Continued From page 87 in two days.</p> <p>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.</p> <p>1i. The Record for Patient 276 was reviewed on September 4, 2009. Patient 276 was born on August 26, 2009, at 5:38 p.m.</p> <p>The Hour Specific Bilirubin Nomogram indicated the baby was at risk for developing hyperbilirubinemia due to identified risk factors of bruising of the head and dark skin pigmentation, and bilirubin levels were obtained every shift. On August 27, 2009, at 8:30 p.m. (27 hours of age), the TcB was 8.4, in the high intermediate risk zone on the Bhutani Curve. At 10:20 p.m. (29 hours of age), the TSB was 7.4, in the high intermediate risk zone on the Bhutani Curve, and the physician was notified.</p> <p>On Friday, August 28, 2009, at 4:30 a.m. (35 hours of age), the TSB was 8.7, on the line of the high intermediate risk zone of the Bhutani curve. At 7:30 a.m., the nurse documented the value was, "at the base of 75% (high intermediate risk zone)," and the physician had been notified.</p> <p>On August 28, 2009, at 8:30 a.m. (39 hours of age), the TcB was 9.9, in the high intermediate risk zone on the Bhutani Curve. According to the</p>	A 338		
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A 338 Continued From page 88
nurse's notes, the physician was made, "aware of TcB results @ Base of 75th percentile."

At 8:50 a.m., the physician ordered to discharge the baby home with follow up in two days (which would have been Sunday, August 30, 2009, not an office day).

At 10:50 a.m., a "clarification," of the discharge order indicated the baby was to be seen by the pediatrician on Monday, August 31, 2009 (three days later)."

The baby was discharged home on August 28, 2009, at 2:10 p.m. (45 hours of age), with risk factors for developing hyperbilirubinemia, a TcB in the High Intermediate Risk Zone on the Bhutani curve, and follow up with the pediatrician three days later.

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.

According to the AAP Guidelines:

a. an infant with no risk factors who was discharged home at 45 hours of age should be seen by the age of 96 hours, but earlier follow up should be provided for those babies who have risk factors for developing hyperbilirubinemia.

1j. The record for Patient 285 was reviewed on

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A 338	<p>Continued From page 89</p> <p>September 4, 2009. Patient 285 was born on August 28, 2009, at 4:54 p.m.</p> <p>On Saturday, August 29, 2009, at 11:30 a.m. the physician ordered to discharge the baby with a follow up on Monday or Tuesday (two or three days later).</p> <p>At 2:20 p.m. (21.5 hours of age), the pre discharge TcB was 7.9, in the high risk zone on the Bhutani curve. At 2:25 p.m. (21.5 hours of age), the TSB was 6.1, in the high intermediate risk zone on the Bhutani curve. The physician was notified and ordered, "OK to DC, must follow up on Monday."</p> <p>The baby was discharged home on August 29, 2009, at 4:30 p.m. (23.5 hours of age), with a TSB in the high intermediate risk zone on the Bhutani curve (a risk factor for development of hyperbilirubinemia), and follow up with the pediatrician in two days.</p> <p>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.</p> <p>According to the AAP Guidelines:</p> <p>a. an infant with no risk factors who was discharged home at 23.5 hours of age should be seen by the age of 72 hours, but earlier follow up should be provided for those babies who have</p>	A 338		
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A 338	<p>Continued From page 90 risk factors for developing hyperbilirubinemia.</p> <p>In addition, the AAP recommends for all newborns, "if appropriate follow-up cannot be ensured in the presence of elevated risk for developing severe hyperbilirubinemia, it may be necessary to delay discharge either until appropriate follow-up can be ensured or the period of greatest risk has passed (72-96 hours)."</p> <p>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).</p> <p>The policy indicated the risk factors for hyperbilirubinemia included but were not limited to the following;</p> <ul style="list-style-type: none"> 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 suboptimal breastfeeding; d. jaundice appearing in the first 24 hours after birth (dark skin pigments may obscure visualization); 	A 338		
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A 338	<p>Continued From page 91</p> <p>e. macrosomic (large for gestational age) infant of a diabetic mother;</p> <p>f. near-term newborns at 35, 36, and 37 weeks of gestation, particularly if they were breastfed;</p> <p>g. significant weight loss (defined as > (greater than) 10 % by discharge);</p> <p>h. temperature instability or treatment of sepsis; and,</p> <p>i. unrecognized hemolysis, such as ABO blood type incompatibility.</p> <p>According to a document titled, "Severe Hyperbilirubinemia Prevention (SHP) Toolkit...on behalf of the Perinatal Quality Improvement Panel (PQIP) and California Perinatal Quality Care Collaborative (CPQCC)" dated October 19, 2005, was reviewed. The document indicated infants at risk for significant hyperbilirubinemia needed to have close follow up after discharge. The document indicated follow up visit should be performed within 24-48 hours post discharge.</p> <p>The document further indicated a follow up visit and/or bilirubin test within 24 hour post discharge to monitor for jaundice was recommended in babies whose serum bilirubin fell within the High Risk Zone in the Hour Specific Nomogram.</p> <p>The document further indicated a follow up visit and/or bilirubin test within 48 hour post discharge to monitor for jaundice was recommended in the following circumstances:</p> <p>a. a single bilirubin measurement in the High</p>	A 338		
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A 338	<p>Continued From page 92</p> <p>Intermediate Risk Zone in the Hour Specific Nomogram in the infant; and,</p> <p>b. a single bilirubin measurement in the Low Intermediate Risk Zone in infants who have any of the risk factors for development of hyperbilirubinemia.</p> <p>2. Records for discharged newborns were reviewed on August 6, 12, 25, 26, 27, 28, and September 4, 2009. The records indicated babies who were at risk for developing hyperbilirubinemia were discharged as follows:</p> <p>a. Patient 221, discharged Sunday, August 30, 2009, to follow up with the PCP in one day;</p> <p>b. Patient 222, discharged Sunday, August 30, 2009, to follow up in two days;</p> <p>c. Patient 225, discharged Thursday, September 3, 2009, to follow up in one day;</p> <p>d. Patient 232, discharged Monday, August 31, 2009, to follow up in one day;</p> <p>e. Patient 233, discharged Monday, August 31, 2009, to follow up in one day;</p> <p>f. Patient 234, discharged Monday, August 31, 2009, to follow up in one day;</p> <p>g. Patient 237, discharged Sunday, August 30, 2009, to follow up in one day;</p> <p>h. Patient 238, discharged Sunday, August 30, 2009, to follow up in one day;</p> <p>i. Patient 239, discharged Sunday, August 30,</p>	A 338		
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A 338	<p>Continued From page 93 2009, to follow up in one day;</p> <p>j. Patient 240, discharged Sunday, August 30, 2009, to follow up in one day;</p> <p>k. Patient 11, discharged Friday, June 5, 2009, to follow up in three to four days;</p> <p>l. Patient 13, discharged Friday, June 12, 2009, to follow up in two (Sunday [a non office day]) to three days (Monday);</p> <p>m. Patient 205, discharged Friday, June 5, 2009, to follow up in five days;</p> <p>n. Patient 265, discharged Friday, August 28, 2009, to follow up in three days;</p> <p>o. Patient 218, orders to discharge Friday, September 4, 2009, to follow up in four days (Monday was a holiday);</p> <p>p. Patient 227, discharged Friday, August 28, 2009, to follow up in three days; and,</p> <p>q. Patient 276, discharged Friday, August 28, 2009, to follow up in three days.</p> <p>3a. Patient 11 was born at the facility on June 4, 2009. The neonate had multiple risk factors for hyperbilirubinemia, including bruising, feeding delay, caput, and gestational age less than 38 weeks (Refer to A392). The TSB level at 30 hours was in the Bhutani high risk zone, and at the level requiring a physician order for phototherapy per facility policy and phototherapy per American Academy of Pediatrics guidelines.</p>	A 338		
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A 338	<p>Continued From page 94</p> <p>The Physician 1 did not supply an order for phototherapy, but instead discharged the patient. Patient 11 developed severe hyperbilirubinemia and was readmitted to the facility for treatment at a later date.</p> <p>3b. Patient 247 was born in the facility on August 30, 2009. The neonate had risk factors for hyperbilirubinemia, including gestational age less than 38 weeks and breastfeeding. The TcB level at 45 hours of age was 11.2, in the Bhutani high risk zone (Refer to A392). The physician failed to follow up on the screening test with additional testing or phototherapy, per facility policy and American Academy of Pediatrics guidelines.</p> <p>4. The facility policy titled, "Hyperbilirubinemia, Assessment, Identification, and Intervention Protocol", issued June 2006, and revised April 2008, approved by the MEC, was reviewed on August 6, 2009. The policy indicated an order for phototherapy should be obtained if the TSB fell in the high intermediate or high risk zone on the Hour Specific Bilirubin Nomogram.</p> <p>According to the AAP guidelines, the nomogram used to determine the need for phototherapy should be the, "Guidelines for Phototherapy in Hospitalized Infants of 35 or More Weeks Gestation," nomogram.</p> <p>If the facility policy was followed and phototherapy was implemented for newborns with bilirubin levels in the high risk zone or high intermediate risk zone on the Hour Specific Bilirubin Nomogram, the large majority of those neonates would, according to AAP guidelines, have been unnecessarily exposed to the risks of phototherapy.</p>	A 338		

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A 338	Continued From page 95 The policy further indicated the graph on page three provided two different sets of values for use in determining when to initiate phototherapy for a neonate with gestational age between 35 and 38 weeks, with no risk factors. Item 4d indicated, "Refer to nomogram below..." for follow-up of bilirubin level. The subsequent graph presented in the policy was that for determining the need for phototherapy, not for determining follow-up of bilirubin. The failure to ensure a policy for neonatal hyperbilirubinemia that provided staff with clear directions created a risk for incorrect assessment and response to neonatal elevated bilirubin in all the neonates.	A 338		
A 340	482.22(a)(1) MEDICAL STAFF PERIODIC APPRAISALS The medical staff must periodically conduct appraisals of its members. This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to ensure appraisal via proctoring as outlined in the bylaws and rules and regulations was carried out for one of seven medical staff members (Physician 1) whose credential files were reviewed. This placed patients at risk of substandard medical care. Findings: The credential file of Physician 1, reviewed on August 25, 2009, contained a letter appointing Physician 1 to the medical staff of the facility effective September 1, 2007. The proctoring (review, done by another physician, of the quality of a physician's services to patients) section of	A 340	The physician in question completed proctoring of cases. To facilitate the proctoring process and enforce the requirement that the initial 6 cases be proctored, the Departments are providing Provisional members a list of active staff members in their specialty whom they can use for proctoring, rather than being limited to only 2 assigned proctors. New Physicians have been reminded/educated at department meetings regarding the importance of completing proctoring timely. The Bylaws Committee also recommended a change that Provisional members have only six months from the time of initial appointment to complete their proctoring. This change was included in the recent ballot sent out for medical staff vote.	07/31/09 12/23/09

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A 340	<p>Continued From page 96</p> <p>the credential file indicated that, as of March 24, 2009, ten of 12 required proctored cases had been completed, including five pacemaker placements (a surgery in which a mechanism to regulate the heart rate is inserted under the skin with electrical wires in the heart). Of the ten cases reviewed, eight were proctored via chart review, including four of the five pacemaker placements. Two cases were proctored by concurrent review (review of the case while the patient was still in the facility). During an interview with the Director of Medical Staff Services on August 26, 2009, at 3 p.m., she stated Physician 1 had completed additional pacemaker placements at the facility which were not proctored.</p> <p>On August 25, 2009, the facility's Department of Medicine Rules and Regulations, revised April 2007, were reviewed. Page 2 stipulated, "Invasive medical procedures will be proctored by observation, unless the case is an emergency. The first six (6) cases require concurrent proctoring. Emergency cases also require concurrent proctoring by either the assigned proctor or by the specialty on-call physician." The facility failed to follow both the rules for proctoring invasive cases via observation and the rule for concurrent proctoring of the first six cases.</p> <p>During an interview with the Director of Medical Staff Services on August 27, 2009, at 11:50 a.m., she stated the bylaws required proctoring, and it was to be performed per department rules and regulations. She stated the rules on proctoring were not followed in the case of Physician 1.</p>	A 340	<p>The Hospital has an E-priv system that is available to all clinical staff to see what privileges have been granted to a physician. This information also includes demographic physician information including their staff status of "Provisional". This designation indicates to the staff that a physician is new and needs to have proctor.</p> <p>The Director of Medical Staff Services added a note to the E-priv record to identify physicians who are required to have a proctor.</p> <p>The OR, OB, Special Procedures, and Cath Lab staff (and all clinical staff) are required to check E-priv system when procedures are scheduled and note which physicians must have a proctor and the number of proctored cases still required.</p> <p>The Director of Medical Staff Services educated the OR, OB, Special Procedures and Cath Lab Managers regarding the initial proctoring requirements and the Epriv note regarding that status and requirement.</p> <p>Person Responsible: Director of Medical Staff Services</p> <p>Monitoring:</p> <p>The Medical Staff Office set up a system to track new appointees and identify their proctoring status. At each Department meeting, the Director of Medical Staff Services reports on the status of each provisional members proctoring status.</p>	<p>12/14/09</p> <p>12/15/09</p> <p>12/15/09</p> <p>12/23/09 & ongoing</p>
A 385	482.23 NURSING SERVICES	A 385		
	The hospital must have an organized nursing service that provides 24-hour nursing services.			

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A 385	<p>Continued From page 97</p> <p>The nursing services must be furnished or supervised by a registered nurse.</p> <p>This CONDITION is not met as evidenced by: Based on observation, interview, and record review, the facility failed to:</p> <ol style="list-style-type: none"> 1. meet the needs of 15 newborns (Patients 11, 12, 13, 17, 20, 21, 29, 30, 204, 205, 207, 217, 228, 267, and 268) at risk for developing hyperbilirubinemia (high bilirubin levels in the blood) and two of two patients receiving sedation in the ICU, by failing to: <ol style="list-style-type: none"> a. assess and identify risk factors for hyperbilirubinemia for eight newborns (Patient 11, 12, 13, 204, 205, 207, 267, and 268), resulting in the delay of testing and the potential for brain damage, developmental disabilities, and death (A395); b. 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 (A395); c. obtain an order for phototherapy when the TSB (billirubin level in the blood) was in the high intermediate risk zone or high risk zone on the Bhutani curve for three newborns (Patients 11, 20, and 207), resulting in exposure of the babies to elevated bilirubin levels and the potential for brain damage, developmental disabilities, and death (A395); d. conduct TSB testing when the TcB was in the high intermediate risk zone or high risk zone on 	A 385	<p>Please see response to A 395 for actions the hospital has taken to improve care of newborns and assessment of risks for hyperbilirubinemia, monitoring of sedation levels of patients in ICU, and evaluation and treatment of patients' pain.</p> <p>Please see response to A 394 for actions the hospital has taken with respect to outside case management for HMO patients.</p> <p>Please see response to A 396 for actions the hospital has taken with respect to care plans for patients.</p>	

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NAME OF PROVIDER OR SUPPLIER SOUTHWEST HEALTHCARE SYSTEM	STREET ADDRESS, CITY, STATE, ZIP CODE 25500 MEDICAL CENTER DRIVE MURRIETA, CA 92562
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A 385	<p>Continued From page 98</p> <p>the Bhutani curve for three newborns (Patients 12, 13, and 228), resulting in the potential for lack of treatment, brain damage, developmental disabilities, and death (A395);</p> <p>e. conduct Coombs testing (test to detect destruction of red blood cells in the newborn) when the mother's blood type was O+ for three newborns (Patients 12, 13, and 17) to identify and treat hemolytic disease of the newborn, resulting in the potential for brain damage, developmental disabilities, and death (A395);</p> <p>f. conduct TSB testing STAT when the TcB was in the high intermediate risk zone or high risk zone on the Bhutani curve for five newborns (Patients 17, 21, 29, 30, and 228), resulting in the potential for delayed treatment, brain damage, developmental disabilities, and death (A395);</p> <p>g. provide evidence the physician was notified of the TSB results for two newborns (Patients 20 and 205), resulting in the potential for delayed treatment, brain damage, developmental disabilities, and death (A395);</p> <p>h. notify the physician STAT when the TSB was in the high intermediate risk zone on the Bhutani curve for one newborn (Patient 30), resulting in the delay of treatment and the potential for brain damage, developmental disabilities, and death (A395);</p> <p>i. accurately document the bilirubin result on the Hour Specific Bilirubin Nomogram (documented in the low intermediate risk zone instead of the high intermediate risk zone) for one newborn (Patient 20), resulting in the lack of intervention from the staff and the potential for brain damage.</p>	A 385		
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A 385	<p>Continued From page 99 developmental disabilities, and death (A395);</p> <p>j. monitor sedation levels for two of two patients receiving propofol for sedation in the ICU (Patients 201 and 215), resulting in potential for under sedation or over sedation (A395); and,</p> <p>k. to ensure one patient's pain (Patient 302) was evaluated and treated in accordance with accepted nursing standards and hospital policy and procedure. This failed practice placed the patient at risk for untreated pain (A395);</p> <p>(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);</p> <p>2. ensure nurses providing outside case management for HMO patients had current licensure, resulting in the potential for nursing care to be provided by unlicensed nurses (A394); and,</p> <p>3. ensure the formulation of a care plan to meet identified needs for one patient (Patient 306), resulting in the risk for a poor health outcome (A396).</p> <p>The cumulative effect of these failed practices/system failures, resulted in the failure to</p>	A 385		
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A 385	Continued From page 100 ensure quality nursing care was provided in a safe and effective manner.	A 385		
A 394	<p>482.23(b)(2) LICENSURE OF NURSING STAFF</p> <p>The nursing service must have a procedure in place to ensure that hospital nursing personnel for whom current licensure is required have a valid and current licensure.</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to ensure nurses providing outside case management for HMO patients had current licensure, resulting in the potential for nursing care to be provided by unlicensed nurses.</p> <p>Findings:</p> <p>1. On August 27, 2009, Patient 22's record was reviewed. Patient 22 was admitted on August 24, 2009, with diagnoses that included decubitus ulcer (pressure sore) and cellulitis (infection of the skin tissue).</p> <p>On August 27, 2009, at 11:26 a.m., CM 3 was interviewed. CM 3 stated patients who belonged to HMOs were seen by an, "outside," case manager who worked for the medical group the patient belonged to. CM 3 stated an outside CM was assigned to Patient 22.</p> <p>On August 27, 2009, at 11:15 a.m., the outside CM (CM 4) was interviewed. CM 4 stated she had interviewed Patient 22, and was doing her discharge planning.</p> <p>2. During an interview with CM 5 on August 28, 2009, at 9:15 a.m., the CM stated the facility CMs saw every admitted patient, except the patients</p>	A 394	<p>As soon as the surveyors identified the requirement that external case managers/ reviewers must provide verification of their licenses, the DCM notified the managed care organizations (MCOs) that the MCOs must provide the hospital with verification of their case managers' current licensure and qualifications in order for the case managers to be able to come into the hospital to work with enrollees. License verification for the external reviewers/case managers was received the same day that this concern was identified and prior to the conclusion of the survey.</p> <p>The DCM created a file with the license verification for each external reviewers/case managers. Only after this verification is the external reviewer/case manager permitted to work with patients in the hospital. If the hospital is not provided with the nurse's license, that nurse is prohibited from performing case management/discharge planning activities.</p> <p>The CNO instructed the hospital case managers to develop and update discharge plans on all inpatients. Only in cases where an MCO has provided the required credentials information on a case manager to the hospital, that case manager may assist with discharge planning and documentation in the patient's hospital medical record.</p> <p>Person Responsible: Director of Case Management / Chief Nursing Officer</p> <p>The Director of Case Management reviews the files to confirm that the external case managers have current licensure.</p>	<p>08/28/09</p> <p>09/01/09</p> <p>09/01/09</p> <p>09/01/09 & ongoing</p>

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A 394	<p>Continued From page 101 who belonged to HMO's. The CM stated the HMO patients were seen by outside case managers.</p> <p>During an interview with the CM supervisor on August 28, 2009, at 9:30 a.m., the supervisor stated the facility CMs did not see the HMO patients for discharge planning.</p> <p>The record for Patient 211 (an HMO patient) was reviewed on August 28, 2009. Patient 211, a 92 year old male, was admitted to the facility on August 25, 2009, with diagnoses that included atrial fibrillation (an irregular heart rhythm) and COPD.</p> <p>The facility Discharge Planning document indicated, "(outside) case manager is responsible for all reviews and discharge planning. For questions or for a family request, contact the HMO at (phone number)."</p> <p>During an interview with the outside CM (CM 6) on August 28, 2009, at 10:30 a.m., the CM stated she did the discharge planning for patients belonging to the medical group she worked for.</p> <p>3. The record for Patient 213 (an HMO patient) was reviewed on August 28, 2009. Patient 213, an 88 year old female, was admitted to the facility on August 25, 2009, with diagnoses that included urosepsis (an overwhelming infection caused by an untreated urinary tract infection).</p> <p>The, "Outside Reviewer(s) Communication Sheet," indicated the patient was seen by an outside CM for discharge planning.</p>	A 394		

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A 394	<p>Continued From page 102</p> <p>The facility Discharge Planning document indicated, "(outside) case manager is responsible for all reviews and discharge planning. For questions or for a family request, contact the HMO at (phone number)."</p> <p>During an interview with the outside CM (CM 6) on August 28, 2009, at 10:30 a.m., the CM stated she did the discharge planning for patients belonging to the medical group she worked for.</p> <p>During an interview with the DCM on August 28, 2009, at 12:35 p.m., the DCM stated she was aware of the outside CMs coming in for the HMO patients. She stated the facility had an, "agreement," with the medical groups to maintain current licensure for their CMs. The DCM stated she did not keep records of the outside CMs licenses. She stated she did not have evidence of current licensure.</p>	A 394		
A 395	<p>482.23(b)(3) RN SUPERVISION OF NURSING CARE</p> <p>A registered nurse must supervise and evaluate the nursing care for each patient.</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to meet the needs of 15 newborns (Patients 11, 12, 13, 17, 20, 21, 29, 30, 204, 205, 207, 217, 228, 267, and 268) at risk for developing hyperbilirubinemia (high bilirubin levels in the blood); two of two patients (Patients 201 and 215) receiving sedation in the ICU; and, one patient (Patient 302) in pain; by failing to;</p> <p>1. assess and identify risk factors for hyperbilirubinemia for eight newborns (Patient 11, 12, 13, 204, 205, 207, 267, and 268), resulting in</p>	A 395	<p>A395</p> <p>The CNO reviewed and confirmed the process changes that were put in place on August 12, and then further revised the process for assessing and treating newborns at risk for hyperbilirubinemia consistent with American Academy of Pediatrics guidelines and recommendations of the Department of Pediatrics.</p> <p>The Department of Pediatrics developed discharge guidelines to ensure timely follow-up for babies deemed to be at risk for hyperbilirubinemia, including discharge orders for post-hospitalization follow up of infants at risk for hyperbilirubinemia. The discharge guidelines provide that the baby needs one of the following on the day after discharge: A: An appointment with the newborn's pediatrician with a specific appointment date/time within one day of discharge. B: Follow-up bilirubin testing at the hospital with results called to the pediatrician for further assessment and treatment, or C: Follow up in the hospital's ED.</p>	<p>10/19/09</p> <p>09/04/09</p>

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A 395	<p>Continued From page 103</p> <p>the delay of testing and the potential for brain damage, developmental disabilities, and death;</p> <p>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;</p> <p>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 Bhutani curve for three newborns (Patients 11, 20, and 207), resulting in exposure of the babies to elevated bilirubin levels and the potential for brain damage, developmental disabilities, and death;</p> <p>4. conduct TSB testing when the TcB was in the high intermediate risk zone or high risk zone on the Bhutani curve for three newborns (Patients 12, 13, and 228), resulting in the potential for lack of treatment, brain damage, developmental disabilities, and death;</p> <p>5. conduct Coombs testing (test to detect destruction of red blood cells in the newborn) when the mother's blood type was O+ for three newborns (Patients 12, 13, and 17) to identify and treat hemolytic disease of the newborn, resulting in the potential for brain damage, developmental disabilities, and death;</p> <p>6. conduct TSB testing STAT when the TcB was in the high intermediate risk zone or high risk zone on the Bhutani curve for five newborns (Patients 17, 21, 29, 30, and 228), resulting in the potential for delayed treatment, brain damage,</p>	A 395	<p>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 babies with serum bilirubin results > 75th percentile. The revised policies, Hyperbilirubinemia, Newborn Discharge, Cord Blood Collection and the following forms: Newborn Nursery Orders, Hours Specific Billirubin Nomogram and Physician's Record of Newborn were approved by the Department of Pediatrics, the MEC and the BOG.</p> <p>—Newborn nursery admission orders call 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; (this was revised to within two hours of birth in October).</p> <p>—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 6 risk factors are present. If the nurse identifies jaundice or risk factors, a TcB is performed;</p> <p>—If the TcB result is greater than or equal to the 75th percentile on the nomogram, a STAT TSB is performed within one hour;</p> <p>—If the TSB result is greater than or equal to 75th percentile, the nurse must notify the physician and obtain further orders, which may include orders for phototherapy.</p> <p>—If a newborn does not have risk factors, then the nursing staff must obtain a TcB or TSB (as indicated by policy) on the day of discharge. If the test results are greater than or equal to the 75th percentile, the nursing staff gives the newborn's family a set of discharge instructions to follow up within 24 hours after discharge.</p>	<p>10/19/09</p> <p>09/04/09; rev 10/19/09</p> <p>09/04/09</p> <p>09/04/09</p> <p>09/04/09</p> <p>09/04/09</p>

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A 395	<p>Continued From page 104 developmental disabilities, and death;</p> <p>7. provide evidence the physician was notified of the TSB results for two newborns (Patients 20 and 205), resulting in the potential for delayed treatment, brain damage, developmental disabilities, and death;</p> <p>8. notify the physician STAT when the TSB was in the high intermediate risk zone on the Bhutani curve for one newborn (Patient 30), resulting in the delay of treatment and the potential for brain damage, developmental disabilities, and death;</p> <p>9. accurately document the bilirubin result on the Hour Specific Billirubin Nomogram (documented in the low intermediate risk zone instead of the high intermediate risk zone) for one newborn (Patient 20), resulting in the lack of intervention from the staff and the potential for brain damage, developmental disabilities, and death;</p> <p>10. monitor sedation levels for two of two patients receiving propofol for sedation in the ICU (Patients 201 and 215), resulting in potential for under sedation or over sedation; and,</p> <p>11. to ensure one patient's pain (Patient 302) was evaluated and treated in accordance with accepted nursing standards and hospital policy and procedure. This failed practice placed the patient at risk for untreated pain.</p> <p>(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</p>	A 395	<p>The CNO and the Chair of Pediatrics Department developed a discharge instructions form specific to newborns at risk for hyperbilirubinemia. The instructions document the physician's order that directs the family to follow up with:</p> <p>A: the newborn's pediatrician with a specific appointment date/time within one day of discharge B: to obtain follow-up bilirubin testing at the hospital to be called to pediatrician for further assessment and treatment C: or to follow up through the hospital's ED.</p> <p>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.</p> <p>Women's Services Leadership Team provided education to nursing staff on the hyperbilirubinemia discharge guidelines and new forms at the beginning of each shift prior to nurses taking responsibility for patient care.</p> <p>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."</p>	<p>09/04/09</p> <p>08/12/09</p> <p>09/04/09</p> <p>08/12/09 & 09/04/09</p>

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A 395	<p>Continued From page 105</p> <p>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).</p> <p>Findings:</p> <p>1. The record for Patient 11 was reviewed on August 6, 2009. Patient 11 was born on June 4, 2009, at 4:28 a.m., at 37 6/7 weeks gestation (time developing in the womb - normal 40 weeks).</p> <p>The Newborn Admit Flowsheet dated June 4, 2009, at 6:45 a.m., indicated:</p> <p>a. the mother was Rh negative and the baby was AB+ (Rh incompatible);</p> <p>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,</p> <p>c. the baby had bruises on the right forearm.</p> <p>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.</p> <p>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</p>	A 395	<p>Women's Services Director ensures review of 100% of charts of newborns to confirm that they are being assessed timely for jaundice and risk factors, and tested timely and in compliance with the policy.</p> <p>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 Admit Risk on Nomogram Narrative re Abnormal Findings STAT TSB if TcB elevated TSB q 12 hours MD notification of TSB</p> <p>The Women's Services Leadership Team provides re-education and counseling to nurses whose audits fall out of compliance. Audit results reflect substantial compliance with the process.</p> <p>Women's Services Director reports audit results to staff members, Dept of Pediatrics, and High Reliability Unit (HRU) Multidisciplinary Team, and Quality Pillar to PSC.</p> <p>Sedation Scale/Pain Management</p> <p>The Director of Critical Care/designee provided re-education to ICU charge nurses on using the Ramsey scale when titrating sedatives in the ICU, and the ICU charge nurses in turn provided hands-on training to all ICU nurses, with the ICU nurses demonstrating competence.</p> <p>Med/Surg Telemetry Unit staff received Best of Southwest Meeting Minutes, which included a reminder that if patient has any pain it should be included in the IPOC along with notation of the patient's acceptable pain level.</p>	<p>08/12/09 & Ongoing</p> <p>08/12/09</p> <p>10/19/09</p> <p>12/18/09</p> <p>09/30/09</p>

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A 395	<p>Continued From page 107</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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</p>	A 395			

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A 395	<p>Continued From page 108 (high-intermediate risk zone), and the physician ordered to discharge Patient 11 from the facility.</p> <p>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).</p> <p>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.</p> <p>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).</p> <p>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..."</p> <p>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).</p> <p>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</p>	A 395		

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NAME OF PROVIDER OR SUPPLIER SOUTHWEST HEALTHCARE SYSTEM	STREET ADDRESS, CITY, STATE, ZIP CODE 25600 MEDICAL CENTER DRIVE MURRIETA, CA 92562
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A 395	<p>Continued From page 109</p> <p>gestational age, and the mother's blood type was O+. There was no Coombs test performed on the cord blood.</p> <p>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 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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>The Manager stated the TCB testing should have been conducted within two hours of the baby's</p>	A 395	<p style="text-align: right;">09 DEC 16 AM 11:00 COUNTY</p>	<p style="text-align: right;">SA DEPT OF HUMAN SERVICES</p>
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A 395	<p>Continued From page 110</p> <p>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 intermediate risk zone. The Manager stated TSB testing should have been completed to determine the need for phototherapy.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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 and identified the gestational age of</p>	A 395		

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A 395	<p>Continued From page 111</p> <p><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.</p> <p>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.</p> <p>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).</p> <p>The policy indicated the risk factors for hyperbilirubinemia included but were not limited to the following;</p> <ul style="list-style-type: none"> 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 suboptimal breastfeeding; d. jaundice appearing in the first 24 hours after birth (dark skin pigments may obscure 	A 395		

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A 395	<p>Continued From page 112 visualization);</p> <p>e. macrosomic (large for gestational age) infant of a diabetic mother;</p> <p>f. near-term newborns at 35, 36, and 37 weeks of gestation, particularly if they were breastfed;</p> <p>g. significant weight loss (defined as > (greater than) 10 % by discharge;</p> <p>h. temperature instability or treatment of sepsis; and,</p> <p>i. unrecognized hemolysis, such as ABO blood type incompatibility.</p> <p>The policy further indicated:</p> <p>a. a TcB and/ or TSB would be done when visible jaundice and/or risk factors were present, and prior to discharge;</p> <p>b. bilirubin levels were to be plotted on the Hour-specific Bilirubin Nomogram;</p> <p>c. if the TcB value was greater than 75% (high intermediate risk zone) on the nomogram (Bhutani Curve) a TSB was to be drawn stat;</p> <p>d. the physician was to be notified stat for values in the high intermediate or high-risk zone, or values greater than 12; and,</p> <p>e. an order for phototherapy was to be obtained if the TSB was in the high intermediate or high-risk zone.</p> <p>The Newborn Nursery Preprinted Orders were</p>	A 395		
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A 395	<p>Continued From page 113 reviewed on August 6, 2009. The orders directed the staff to do the following:</p> <ul style="list-style-type: none"> 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. <p>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.</p> <p>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:</p> <ul style="list-style-type: none"> 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, 	A 395	<p style="text-align: center;">09 DEC 16 AM 11:00 HOSPITAL COUNTY CA DEPT OF HUMAN SERVICES</p>	

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A 395	<p>Continued From page 114</p> <p>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.</p> <p>Upon receipt of an acceptable written plan of correction on August 12, 2009, at 6:47 p.m., the Immediate Jeopardy was abated.</p> <p>The plan of correction included the following immediate actions:</p> <p>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;</p> <p>b. hyperbilirubinemia risk factors would be assessed during the initial newborn assessment, every shift, and prior to discharge;</p> <p>c. if risk factors were identified, a TcB would be performed at the time of identification;</p> <p>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;</p> <p>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;</p> <p>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</p>	A 395		
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A 395	<p>Continued From page 115 care assignment; and,</p> <p>g. the facility would monitor for compliance.</p> <p>4. Patient 17's record was reviewed on August 26, 2009. Patient 17 was born on July 14, 2009, at 3:33 a.m.</p> <p>The Newborn Admit Flowsheet dated July 14, 2009, indicated the mother's blood type was O+. There was no Coombs testing performed on the cord blood.</p> <p>The Hour Specific Nomogram indicated on July 15, 2009, at 4:30 a.m. (25 hours of age), the TCB was 7, in the high intermediate risk zone. At 4:35 a.m., the TSB was 5.3.</p> <p>The laboratory report for the TSB test, dated July 15, 2009, was reviewed. The report indicated the blood specimen was collected on July 15, 2009, at 6:30 a.m. (2 hours after the TCB test).</p> <p>On August 26, 2009, at 9:45 a.m., the CLS Director and the LS were interviewed. The LS reviewed the TSB test order in the computer. The LS stated the laboratory department received the order in the computer on July 15, 2009, at 4:45 a.m., and was placed as "routine" laboratory and not as "Stat." The LS stated the blood was collected for the test at 6:30 a.m., the laboratory department received the blood specimen for the test at 6:44 a.m., and entered the results at 7:12 a.m.</p> <p>On August 26, 2009, at 9:45 a.m., in an interview with the CLS Director, she stated for "Stat" laboratory tests, the specimen needed to be collected immediately. The CLS Director stated</p>	A 395		

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A 395	<p>Continued From page 116</p> <p>"Stat" laboratory test results were expected within an hour of the order. The CLS Director stated if the TSB was ordered "Stat," the results were expected within an hour.</p> <p>On August 26, 2009, at 10:10 a.m., RN 4 was interviewed. RN 4 worked in the nursery department. RN 4 stated when TCB results were in the high intermediate or high risk zone in the Hour Specific Bilirubin Nomogram, a TSB testing needed to be done. RN 4 stated the blood was drawn either by the nurses or the laboratory. RN 4 stated she entered the order for the TSB test in the computer as ASAP according to facility instructions. RN 4 stated the TSB testing was not done "Stat" at all times.</p> <p>On August 26, 2009, at 10:25 a.m., RN 6 was interviewed. RN 6 stated she did couplet care (mother and baby). She stated when TCB results were in the high intermediate or high risk zone in the TSB Nomogram, a TSB testing needed to be done. She stated she would enter the TSB test as "ASAP" and not as "Stat."</p> <p>On August 26, 2009, at 9:30 a.m., the Nursery and OB Managers were interviewed. The Managers stated when a TCB test resulted in the high intermediate risk zone or high risk zone, the TSB test needed to be done "Stat." The Managers stated the blood specimen for the "Stat" tests needed to be drawn immediately after the TCB test. The Managers were unable to explain why it took two hours for the blood to be drawn for the TSB.</p> <p>The facility policy titled, "Hyperbilirubinemia, Assessment, Identification, and Intervention Protocol," last revised April 2008, was reviewed</p>	A 395		

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A 395	<p>Continued From page 117 on August 6, 2009. The policy indicated if the TcB value was in the greater than 75% on TSB Nomogram (Bhutani curve), the TSB test should be done "Stat."</p> <p>5. Patient 20's record was reviewed on August 26, 2009. Patient 20 was born on August 22, 2009, at 5:08 p.m.</p> <p>The Well Newborn Care Flowsheet dated August 23, 2009, at 7:55 p.m., indicated the baby was taken to the nursery for an assessment, risk factors for hyperbilirubinemia were reviewed, the baby was jaundiced in color, and the TCB was 9.7.</p> <p>The Hour Specific Billirubin Nomogram indicated on August 23, 2009, at 7:55 p.m. (27 hours of age), the TcB was 9.7, in the high risk zone on the Bhutani curve. At 8 p.m. (27 hours of age), the TSB result was 6.6, in the high intermediate risk zone, but plotted by the nurse in the low intermediate risk zone.</p> <p>Patient 20's record did not have evidence an order for phototherapy was obtained for the 6.6 TSB level, or documented evidence the staff attempted to obtain an order for phototherapy from the physician.</p> <p>On August 26, 2009, at 11:50 a.m., Patient 20's record was reviewed with the Nursery Manager and the DWS. The Manager stated the TSB result of 6.6 should have been plotted in the high intermediate risk zone.</p> <p>During a concurrent interview with the manager, she stated she could not find evidence the physician was notified of the 6.6 TSB level, in the</p>	A 395		
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A 395	<p>Continued From page 118 high intermediate risk zone.</p> <p>6. Patient 21's record was reviewed on August 27, 2009. Patient 21 was born on August 24, 2009, at 10:39 p.m.</p> <p>The Hour Specific Bilirubin Nomogram indicated on August 26, 2009, at 8 p.m. (45 hours of age), the TCB was 10.7, in the high intermediate risk zone. Also at 8 p.m., the TSB was 7.9, in the low risk zone.</p> <p>The laboratory report for the TSB test, dated August 26, 2009, was reviewed. The report indicated the blood specimen was collected on August 26, 2009, at 9:30 p.m. (1 1/2 hours after the TCB test).</p> <p>On August 27, 2009, RN 5 was interviewed. RN 5 was assigned to couplet care (mother and baby). RN 5 stated when a patient's TCB results were in the high intermediate or high risk zone, the TSB test should be done "Stat." RN 5 stated "Stat" TSB test results were expected within 45 minutes of the TCB test.</p> <p>On August 26, 2009, at 9:45 a.m., in an interview with the CLS Director, she stated for "Stat" laboratory tests, the specimen needed to be collected immediately. The CLS Director stated "Stat" laboratory test results were expected within an hour of the order. The CLS Director stated if the TSB was ordered "Stat," the results were expected within an hour.</p> <p>The facility policy titled, "Hyperbilirubinemia, Assessment, Identification, and Intervention Protocol," last revised April 2008, was reviewed on August 6, 2009. The policy indicated if the TcB</p>	A 395		
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A 395	<p>Continued From page 119</p> <p>value was in the greater than 75% on TSB Nomogram (Bhutani curve), the TSB test should be done "Stat."</p> <p>7. The record for Patient 204 was reviewed on August 25, 2009. Patient 204, a newborn female of Asian descent, was born on July 10, 2009, at 8:58 a.m.</p> <p>The Well Newborn Care Flowsheet indicated the baby was not feeding well, so a lactation (breastfeeding) consult was done on July 11, 2009, at 10:30 a.m.</p> <p>The Hour Specific Bilirubin Nomogram indicated the nursing staff did not assess for risk factors for developing hyperbilirubinemia. The nurses did not identify the Asian descent or poor feeding as risk factors. The nurses did not do a TcB until July 11, 2009, at 5:45 p.m. (32 hours of age). The value was 10.1, in the high risk zone on the Bhutani curve. A TSB was drawn at 6:10 p.m. (33 hours of age) with a result of 6.2, in the low intermediate risk zone of the curve.</p> <p>On July 12, 2009, at 5 a.m. (44 hours of age), the TcB was 10.0, in the high intermediate risk zone. The nurse's notes indicated the physician was not notified, and no TSB was drawn.</p> <p>On July 12, 2009, at 8:20 a.m., the nurse's notes indicated the baby had, "sl(ight) jaundice."</p> <p>The baby was discharged home on July 12, 2009, at 11:05 a.m., with risk factors for developing hyperbilirubinemia, the previous TcB in the high intermediate risk zone, no TSB done, jaundice in color, and no physician notification.</p>	A 395		
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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) COMPLETION DATE
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A 395	<p>Continued From page 120</p> <p>8. The record for Patient 205 was reviewed on August 25, 2009. Patient 205, a newborn male of Asian descent, was born on June 2, 2009, at 11:55 p.m., at 37 4/7 weeks gestation (time developing in the womb - normal 40 weeks).</p> <p>The Hour Specific Bilirubin Nomogram indicated the nursing staff did not assess for risk factors for developing hyperbilirubinemia. The nurses did not identify the Asian descent or the gestational age of <38 weeks as risk factors. The nurses did not do a TcB until June 4, 2009, at 3 p.m. (39 hours of age), after discharge orders were written. The value was 11.9, on the line of the high risk zone on the Bhutani curve. A TSB was drawn at 3:11 p.m. (39 hours of age) with a result of 9.5, on the line of the high intermediate risk zone of the curve. There was no evidence the physician was notified.</p> <p>The baby was discharged home on June 4, 2009, at 6 p.m., with risk factors for developing hyperbilirubinemia, a TSB on the line of the high intermediate risk zone, no notification of the physician, and follow up with the pediatrician's office in five days.</p> <p>9. The record for Patient 207 was reviewed on August 26, 2009. Patient 207, a newborn male of Hispanic descent, was born May 4, 2009, at 2 a.m.</p> <p>The Physician's Record indicated the baby had a cephalhematoma (bruising on the head), and was being monitored for a possible infection.</p> <p>The Well Newborn Care Flowsheet indicated the baby was jaundiced on May 6, 2009, at 2:40 a.m., 6:30 a.m., 8 a.m., and 12 noon.</p>	A 395		
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NAME OF PROVIDER OR SUPPLIER SOUTHWEST HEALTHCARE SYSTEM		STREET ADDRESS, CITY, STATE, ZIP CODE 25500 MEDICAL CENTER DRIVE MURRIETA, CA 92562		
(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 395	<p>Continued From page 121</p> <p>The Hour Specific Bilirubin Nomogram indicated the nursing staff did not assess for risk factors for developing hyperbilirubinemia. The nurses did not identify the dark skin pigmentation, the cephalhematoma, or the possible infection as risk factors. The nurses did not do a TcB until May 6, 2009, at 2:40 a.m. (48.5 hours of age), when the baby appeared jaundiced. The result was 12.1, in the high intermediate risk zone on the Bhutani curve. A TSB was drawn, with a result of 11.3, still in the high intermediate risk zone on the curve. There was no order obtained for phototherapy.</p> <p>10. Patient 29's record was reviewed on September 3, 2009. Patient 29 was born on August 31, 2009, at 12:40 p.m.</p> <p>The Hour Specific Bilirubin Nomogram indicated on September 1, 2009, at 9:30 p.m. (32 hours of age), the TCB was 8.7, in the high intermediate risk zone on the Bhutani curve. At 10:45 p.m., the TSB was 8.9, in the high intermediate risk zone.</p> <p>On September 3, 2009, at 12:40 p.m., a facility document, which indicated the laboratory test order entry, collecting, and processing was reviewed with the CLS Director. According to the document, the CLS Director stated:</p> <p>a. The order for the TSB testing was entered in the computer on September 1, 2009, at 10:33 p.m. (one hour after the TCB testing);</p> <p>b. The blood specimen for the TSB test was collected on September 1, 2009, at 10:45 p.m. (one and 1/4 hours after the TCB testing); and,</p>	A 395		

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A 395	<p>Continued From page 122</p> <p>c. The TSB result of 8.9 was relayed to the licensed nurse at 11:40 p.m. (two hours and 10 minutes after the TCB testing).</p> <p>On September 3, 2009, at 3:55 p.m., the Nursery Manager was interviewed. The Manager stated the "Stat" TSB test should have been completed immediately and the results should have been available within an hour of the TcB results.</p> <p>On August 26, 2009, at 9:45 a.m., in an interview with the CLS Director, she stated for "Stat" laboratory tests, the specimen needed to be collected immediately. The CLS Director stated "Stat" laboratory test results were expected within an hour of the order. The CLS Director stated if the TSB was ordered "Stat," the results were expected within an hour.</p> <p>The facility policy titled, "Hyperbilirubinemia, Assessment, Identification, and Intervention Protocol," last revised April 2008, was reviewed on August 6, 2009. The policy indicated if the TcB value was in the greater than 75% on TSB Nomogram (Bhutani curve), the TSB test should be done "Stat."</p> <p>11. Patient 30's record was reviewed on September 3, 2009. The patient was born on August 28, 2009, at 10:38 a.m.</p> <p>The Hour Specific Billirubin Nomogram indicated on August 29, 2009, at 5 a.m. (18 1/2 hours of age), the TCB was 8.1, in the high risk zone on the Bhutani curve. At 7:10 a.m., the TSB was 7, in the high intermediate risk zone.</p> <p>The laboratory report for the TSB test, dated</p>	A 395		
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A 395	<p>Continued From page 123</p> <p>August 29, 2009, was reviewed. The report indicated the blood specimen was collected on August 29, 2009, at 7:10 a.m. (2 hours after the TCB test).</p> <p>On September 3, 2009, at 3:55 p.m., the Nursery Manager was interviewed. The Manager stated the "Stat" TSB test should have been completed immediately and the results should have been available within an hour of the TcB results.</p> <p>On August 28, 2009, at 9:45 a.m., in an interview with the CLS Director, she stated for "Stat" laboratory tests, the specimen needed to be collected immediately. The CLS Director stated "Stat" laboratory test results were expected within an hour of the order. The CLS Director stated if the TSB was ordered "Stat," the results were expected within an hour.</p> <p>The facility policy titled, "Hyperbilirubinemia, Assessment, Identification, and Intervention Protocol," last revised April 2008, was reviewed on August 6, 2009. The policy indicated if the TcB value was in the greater than 75% on TSB Nomogram (Bhutani curve), the TSB test should be done "Stat."</p> <p>12. The record for Patient 228 was reviewed on September 4, 2009. Patient 228, a newborn male, was born on August 31, 2009, at 4:22 a.m. The Newborn Admit Flowsheet indicated the baby ingested maternal blood at the time of delivery. The admission physical assessment was not completed, therefore no physical risk factors for developing hyperbilirubinemia were assessed.</p> <p>The Hour Specific Billirubin Nomogram indicated the nurses identified dark skin pigmentation and</p>	A 395		

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A 395	<p>Continued From page 124</p> <p>ingestion of maternal blood as risk factors, and TcB levels were obtained each shift. The TcB result on September 1, 2009, at 8:40 a.m., was 7.0, on the line of the high intermediate risk zone on the Bhutani curve. There was no TSB drawn.</p> <p>The baby was discharged home on September 1, 2009, at 10:40 a.m., with risk factors for developing hyperbilirubinemia, a TcB on the line of the high intermediate risk zone of the curve, no TSB level, and instructions to follow up with the pediatrician in two days.</p> <p>13. The record for Patient 217 was reviewed on September 4, 2009. Patient 217, a newborn male, was born on September 3, 2009, at 37 3/7 weeks gestation (time developing in the womb - normal 40 weeks).</p> <p>The Hour Specific Bilirubin Nomogram indicated the nursing staff did not identify the gestational age of <38 weeks as a risk for developing hyperbilirubinemia.</p> <p>14. The record for Patient 267 was reviewed on September 3, 2009. Patient 267 was born on August 27, 2009, at 1:29 p.m., at 37 6/7 weeks gestation (time developing in the womb - normal 40 weeks), and was being breastfed.</p> <p>The Well Newborn Care Flowsheet indicated the nurses did not identify the gestational age of <38 weeks as a risk factor for developing hyperbilirubinemia.</p> <p>The Hour Specific Bilirubin Nomogram indicated the nurses did not identify gestational age of <38 weeks as a risk factor for developing hyperbilirubinemia.</p>	A 395		
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A 395	Continued From page 125 15. The record for Patient 268 was reviewed on September 3, 2009. Patient 268 was born on August 27, 2009, at 1:31 p.m., at 37 6/7 weeks gestation (time developing in the womb - normal 40 weeks), and was being breastfed. The Physician's Record of Newborn Infant indicated the physician identified the gestational age of 37 weeks as, "pertinent," history. The Well Newborn Care Flowsheet indicated the nurses did not identify the gestational age of <38 weeks as a risk factor for developing hyperbilirubinemia. The Hour Specific Bilirubin Nomogram indicated the nurses did not identify gestational age of <38 weeks as a risk factor for developing hyperbilirubinemia. After identification of Immediate Jeopardy on August 12, 2009, and submission of a plan of correction, the facility failed to monitor the effectiveness of the corrective action to ensure safe discharge of newborns at risk for developing hyperbilirubinemia. 16. The record for Patient 201 was reviewed on August 26, 2009. Patient 201, a 35 year old male, was admitted to the ICU on July 18, 2009, with diagnoses that included respiratory failure. The ICU flowsheet indicated the patient required intubation (a tube inserted into the trachea to assist with breathing), and sedation with propofol (a hypnotic medication used for sedation in	A 395		

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A 395	<p>Continued From page 126 patients on ventilators) at 11 a.m.</p> <p>A physician's order dated July 18, 2009, indicated the propofol was to be titrated (increased or decreased) to maintain a ramsay score of three (the ramsay scale scores the level of sedation according to how rousable the patient is. A score of three means the patient responds to commands).</p> <p>The ICU flowsheets indicated the propofol drip was managed as follows:</p> <p>On August 18, 2009:</p> <p>a1. 11 a.m., started at 20 mcg/kg/min, no ramsay score was documented;</p> <p>a2. 12 noon, decreased to 10 mcg/kg/min, no ramsay score was documented;</p> <p>a3. 1 p.m. and 2 p.m., decreased to 8.3 mcg/kg/min, no ramsay score was documented;</p> <p>a4. 3 p.m. and 4 p.m., increased to 20 mcg/kg/min, no ramsay score was documented;</p> <p>a5. 5 p.m., decreased to 18 mcg/kg/min, then to 16 mcg/kg/min, no ramsay score was documented;</p> <p>a6. 6 p.m. and 7 p.m., increased to 24.2 mcg/kg/min, no ramsay score was documented;</p> <p>a7. 8 p.m. through 2 a.m., increased to 36 mcg/kg/min, no ramsay score was documented;</p> <p>a8. 3 a.m. and 4 a.m., increased to 50 mcg/kg/min, no ramsay score was documented;</p>	A 395		
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A 395	<p>Continued From page 127 and,</p> <p>a9. 5 a.m. through 7 a.m., increased to 100 mcg/kg/min (doubled), no ramsay score was documented.</p> <p>On August 19, 2009:</p> <p>b1. 8 a.m., decreased to 30 mcg/kg/min, no ramsay score was documented;</p> <p>b2. 9 a.m., decreased to 25 mcg/kg/min, no ramsay score was documented;</p> <p>b3. 10 a.m., decreased to 20 mcg/kg/min, no ramsay score was documented;</p> <p>b4. 11 a.m., increased to 90 mcg/kg/min, then decreased to 80 mcg/kg/min, no ramsay score was documented;</p> <p>b5. 12 noon and 1 p.m., stayed at 80 mcg/kg/min, no ramsay score was documented;</p> <p>b6. 2 p.m., decreased to 70 mcg/kg/min, no ramsay score was documented;</p> <p>b7. 3 p.m., decreased to 60 mcg/kg/min, no ramsay score was documented;</p> <p>b8. 4 p.m. and 5 p.m., decreased to 50 mcg/kg/min, no ramsay score was documented;</p> <p>b9. 6 p.m. and 7 p.m., increased to 60 mcg/kg/min, no ramsay score was documented;</p> <p>b10. 8 p.m., increased to 60 mcg/kg/min, then to 80 mcg/kg/min, no ramsay score was documented;</p>	A 395		
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A 395	<p>Continued From page 128</p> <p>b11. 9 p.m. and 10 p.m., increased to 90 mcg/kg/min, no ramsay score was documented;</p> <p>b12. 11 p.m., decreased to 80 mcg/kg/min, no ramsay score was documented;</p> <p>b13. 12 midnight through 2 a.m., increased to 90 mcg/kg/min, no ramsay score was documented; and,</p> <p>b14. 3 a.m. through 7 a.m., increased to 100 mcg/kg/min, no ramsay score was documented.</p> <p>A physician's order dated August 20, 2009, indicated the propofol was to be titrated to maintain a ramsay score of 5 (the patient exhibits a sluggish response to a light tap between the eyebrows or a loud sound).</p> <p>The ICU flowsheet dated August 22, 2009, indicated the propofol was infusing at 100 mcg/kg/min from 7 p.m. to 7 a.m., and no ramsay score was documented.</p> <p>The ICU flowsheet dated July 29, 2009, indicated the propofol was infusing at 80 mcg/kg/min from 7 a.m. until 11 a.m., when it was turned off.</p> <p>17. The record for Patient 215 was reviewed on August 25, 2009. Patient 215, a 21 year old male, was admitted to the facility on August 15, 2009, with a stab wound.</p> <p>The ICU flowsheet indicated the patient required intubation (a tube inserted into the trachea to assist with breathing) and sedation with propofol (a hypnotic medication used for sedation in</p>	A 395		
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A 395	<p>Continued From page 129 patients on ventilators).</p> <p>A physician's order dated August 15, 2009, indicated the propofol was to be titrated (increased or decreased) to maintain a ramsay score of four (the ramsay scale scores the level of sedation according to how rousable the patient is. A score of four means the patient exhibits a brisk response to a light tap between the eyebrows or a loud sound).</p> <p>The ICU flowsheets indicated the propofol drip was managed as follows:</p> <p>On August 16, 2009:</p> <p>a1. 7 a.m. through 11 a.m., infusing at 60mcg/kg/min, no ramsay score was documented;</p> <p>a2. 12 noon and 1 p.m., decreased to 58 mcg/kg/min, no ramsay score was documented;</p> <p>a3. 2 p.m. and 3 p.m., decreased to 56 mcg/kg/min, no ramsay score was documented;</p> <p>a4. 4 p.m. and 5 p.m., decreased to 54 mcg/kg/min, no ramsay score was documented; and,</p> <p>a5. 7 p.m. through 7 a.m., increased to 60 mcg/kg/min, no ramsay score was documented.</p> <p>On August 17, 2009:</p> <p>b1. 7 a.m. through 7 p.m., infused at 60 mcg/kg/min, no ramsay score was documented;</p> <p>b2. 8 p.m., increased to 70 mcg/kg/min, no</p>	A 395		
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A 395	<p>Continued From page 130 ramsay score was documented; and,</p> <p>b3. 9 p.m. through 7 a.m., infused at 70 mcg/kg/min, no ramsay score was documented.</p> <p>On August 18, 2009:</p> <p>c1. 7 a.m. through 9 a.m., infusing at 70 mcg/kg/min, no ramsay score was documented;</p> <p>c2. 10 a.m., decreased to 60 mcg/kg/min, no ramsay score was documented;</p> <p>c3. 11 a.m., decreased to 50 mcg/kg/min, no ramsay score was documented;</p> <p>c4. 12 noon through 2 a.m., infusing at 50 mcg/kg/min, no ramsay score was documented;</p> <p>c5. 3 a.m., increased to 60 mcg/kg/min, no ramsay score was documented; and,</p> <p>c6. 4 a.m. through 7 a.m., infusing at 60 mcg/kg/min, no ramsay score was documented.</p> <p>A physician's order dated August 20, 2009, indicated the propofol was to continue, versed (a sedative) was to be added, and the combined drips were to be titrated to a ramsay score of three (the patient responds to commands).</p> <p>The ICU flowsheet dated August 20, 2009, indicated the propofol infused at 59 mcg/kg/min until 11 a.m., when it was turned off. The versed drip continued. No ramsay score was documented.</p> <p>The ICU flowsheet dated August 21, 2009, indicated the propofol was turned back on at 9:10</p>	A 395			

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A 395	Continued From page 131 a.m. The ICU flowsheets indicated the propofol drip was managed as follows: On August 21, 2009: d1. 9:10 a.m., started at 20 mcg/kg/min, no ramsay score was documented; d2. 10 a.m., increased to 30 mcg/kg/min, no ramsay score was documented; d3. 11 a.m. and 12 noon, increased to 35.1 mcg/kg/min, no ramsay score was documented; d4. 1 p.m. through 3 p.m., increased to 38.7 mcg/kg/min, no ramsay score was documented; d5. 4 p.m. through 6 p.m., decreased to 37.2 mcg/kg/min, no ramsay score was documented; and, d6. 7 p.m. through 7 a.m., infusing at 37.2 mcg/kg/min. The nurse documented a ramsay score of four at 7 p.m., 8 p.m. and 9 p.m. (more sedate than ordered by the physician). No ramsay score was documented from 10 p.m. through 7 a.m. On August 22, 2009: e1. 7 a.m. through 7 p.m., infusing at 37.2 mcg/kg/min, no ramsay score was documented; e2. the nurse documented a ramsay score of three - four at 7 p.m. (more sedate than ordered by the physician), and increased the propofol to 39.3 mcg/kg/min;	A 395			

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A 395	<p>Continued From page 132</p> <p>e3. the nurse documented a ramsay score of three (the level ordered by the physician) at 10 p.m., but increased the propofol to 42.75 mcg/kg/min;</p> <p>e4. the nurse documented a ramsay score of four (more sedate than ordered by the physician), but increased the propofol to 44.5 mcg/kg/min. The infusion remained at 44.5 mcg/kg/min the rest of the night shift (until 7 a.m.). No additional ramsay scores were documented.</p> <p>On August 23, 2009:</p> <p>f1. 7 a.m., increased to 51.4 mcg/kg/min, no ramsay score was documented;</p> <p>f2. 8 a.m., increased to 63.8 mcg/kg/min, no ramsay score was documented;</p> <p>f3. 9 a.m., increased to 99 mcg/kg/min, no ramsay score was documented;</p> <p>f4. 10 a.m. and 11 a.m., decreased to 63.8 mcg/kg/min, no ramsay score was documented;</p> <p>f5. 12 noon, increased to 70.9 mcg/kg/min, no ramsay score was documented;</p> <p>f6. the propofol continued to infuse at 70.9 mcg/kg/min until 7 a.m. (19 hours). No ramsay score was documented.</p> <p>During an interview with the ICU CN on August 27, 2009, at 9:37 a.m., the CN stated they titrated propofol infusions according to the ramsay scale. She stated if the nurses needed a reference when they were assessing their patients, the scale was</p>	A 395		
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A 395	<p>Continued From page 133 on the physician order form.</p> <p>The Medication Drip Titration Order form was reviewed on August 27, 2009. The form indicated the ramsay scale was abbreviated as follows:</p> <p>a. SWHC score of four - asleep with brisk response to light stimulation. Ramsay score of four - exhibits brisk response to light glabellar (between the eyelids) tap or loud auditory stimulus.</p> <p>b. SWHC score of five - asleep without response to light stimulation. Ramsay score of five - exhibits a sluggish response to light glabellar tap or loud auditory stimulus.</p> <p>During an interview with the ICU Director on August 27, 2009, at 10:15 a.m., the director stated the facility did a "read and sign," to educate the nurses on the use of the ramsay scale. She stated all of the ICU nurses received a packet of information regarding the ramsay scale, and they had to read the information and sign a sign in sheet. The director stated the facility did not validate the nurses' understanding of the information. She stated, "if they have questions, they ask."</p> <p>The "read and sign" packet was reviewed on August 27, 2009. The packet had a cover page directing the nurses to document a ramsay score with every adjustment of propofol. The page included a sample ramsay scale (the same abbreviated scale that was on the physician's order form).</p> <p>According to Michael A. E. Ramsay, MD, How to use a Ramsay Score to assess the level of ICU</p>	A 395		
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A 395

Continued From page 134
sedation indicated:

a. the rousability stimulus (glabellar tap or loud auditory stimulus) was specifically designed not to be a painful test and not to startle the patient. It was planned that a sleeping patient would not be aroused to a fully awakened state, so the sleep pattern would not be disturbed.

b. the scoring system should be part of the regular assessment of the ICU patient;

c. under sedation can result in increased blood pressure, increased heart rate, self injury due to accidental removal of tubes and lines, and fear and pain leading to emotional problems; and,

d. over sedation can result in increased time on the ventilator and increased ICU stay.

According to the PDR, 2009, abrupt discontinuation of propofol should be avoided, as it may result in rapid awakening with associated anxiety, agitation, and resistance to mechanical ventilation.

Patients 201 and 215 were sedated with propofol drips without appropriate assessment of their sedation levels. Both patients were abruptly removed from the medication. Patient 215 was sedated more than ordered by the physician.

There was no evidence the nursing staff understood the use of the ramsay scale in managing the sedated patient on a propofol drip.

A 395

18. During a review of Patient 302's medical

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A 395

Continued From page 135
record on August 27, 2009, a note from the PT evaluator dated August 27, 2009, between 10:05 and 10:50 a.m., indicated the patient had, "extreme," pain and the PT had alerted the nurse to this fact.

A 395

During an interview with RN P on August 27, 2009, at 12:30 p.m., she stated the PT had informed her a couple of hours earlier that Patient 302 was in pain. When asked if she had subsequently re-evaluated the patient to assess his pain, RN P stated she had not. When asked if Patient 301 received the Norco (a pain medication) he had available under his doctor's orders, she stated Patient 302 received a dose at 4:30 a.m., but he had not been given the 10:30 a.m. dose of Norco.

During an interview with the MS Manager on August 27, 2009, at 12:35 p.m., she stated Patient 302's pain should have been reassessed and treated in accordance with the facility policy.

The facility policy titled, "Pain Management", revised 2/09, was reviewed on August 27, 2009. Page two of the policy indicated pain management should be aggressive as well as progressive, starting with the most effective immediate treatments. Page three indicated the staff was to, "Reassess patients at regular intervals such as:...With each new report of pain."

A 396

482.23(b)(4) NURSING CARE PLAN
The hospital must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient.

A 396

See plan of correction starting next page.

This STANDARD is not met as evidenced by:
Based on interview and record review, the facility

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A 396	<p>Continued From page 136</p> <p>failed, for one obstetric patient (Patient 306), to ensure the formulation of a care plan to meet identified needs. This failed practice placed the patient at risk for a poor health outcome.</p> <p>Findings:</p> <p>The record for Patient 306 was reviewed on August 26, 2009. The Obstetric Interdisciplinary Plan of Care indicated two care issues were identified, potential alteration in comfort and potential for infection, identified by the RN's initials and date. There were no expected goals or outcomes and no interventions were specified.</p> <p>The facility policy titled, "Care Planning, Patient", revised 3/06, was reviewed on August 26, 2009. Page 2 of the policy, indicate the care plan:</p> <ul style="list-style-type: none"> a. would be initiated by a registered nurse; b. would include a concise description of desired outcomes (short range goals); c. would include the standard of care (interventions/teaching plan); d. would include long-term goals (interventions/teaching plan, discharge planning); e. would be re-developed by a RN as needed; and, f. whenever possible, would include active participation of the patient/significant others and interdisciplinary health team. 	A 396	<p>Women's Services Director reeducated the Nursing staff concerning the requirements for completion of the IPOCs, including the need to identify desired outcomes and interventions for all identified care issues. 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."</p>	12/18/09
A 748	482.42(a) INFECTION CONTROL OFFICER(S) A person or persons must be designated as	A 748	See plan of correction starting next page.	

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A 748	<p>Continued From page 137</p> <p>infection control officer or officers to develop and implement policies governing control of infections and communicable diseases.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, and record review, the facility failed to ensure appropriate precautions were taken in three of three rooms (ICU four, 165, and 161) where patients had MRSA (a bacteria resistant to multiple antibiotics) and were in contact isolation, resulting in the potential for spread of infection to patients in the ICU and on the MST floor, visitors, and staff.</p> <p>Findings:</p> <p>1. During a tour of the ICU at RSMC on August 27, 2009, at 9:37 a.m., accompanied by the ICU CN, the CN stated bed four was an isolation room, as the patient had MRSA.</p> <p>Observation of the room revealed it was an open room, with three walls and no door. A sign indicating no blood draws on the right arm was on the right hand wall, covering a contact isolation sign. A cart containing PPE was part inside and part outside the room (overlapped into the room and the hallway).</p> <p>At 10:02 a.m., RN 30 was observed donning a gown, then drawing the privacy curtain with no gloves.</p> <p>During an observation in the ICU at RSMC on August 27, 2009, at 11 a.m., accompanied by the ICC, room four was observed with the soiled linen cart inside the room, facing out into the hall (the only way to get soiled linens into the cart would be to walk into the hall with the soiled linen and open</p>	A 748	<p>The ADQO reviewed and confirmed that the hospital hired an additional Infection Control Coordinator. This change provides an Infection Control Coordinator for each campus and an interim Director of Infection Control responsible for developing and implementing policies governing infection control.</p> <p>The Director of Infection Control reviewed and confirmed that the hospital policy on isolation precautions is consistent with CDC guidelines.</p> <p>The Director of Infection Control confirmed that training on isolation and cleaning procedures is part of new employee orientation and annual refresher training for all nursing staff.</p> <p>The Director of Infection Control reviewed and approved educational material for the nursing staff. The Department of Education provided reminder training for all nursing staff working on units where patients with infectious diseases may be in isolation. The training reviewed the placement of the isolation cart, the location of the barrier, the use of gloves, and the use of cavi-wipes. Training was provided on the units at shift change and in department meetings. Reminders were also circulated to nursing staff through newsletters. In addition to the above activities, Infection Control was a topic at the formal "What You Need to Know" educational sessions for the nursing staff.</p> <p>Nursing leadership teams on the units conduct periodic observation rounds on each shift to confirm compliance with infection control isolation procedures by physicians and staff working with patients in isolation.</p>	<p>11/09/09</p> <p>09/01/09'</p> <p>09/01/09</p> <p>10/31/09</p> <p>11/01/09 & ongoing</p>
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A 748	<p>Continued From page 138</p> <p>the cart). The privacy curtain was observed lying on the soiled linen cart. The ICC stated she could not define the line delineating clean and dirty. She stated it could be the privacy curtain, or it could be the wall where the room was entered. The ICC stated the soiled linen cart facing out to the hall, and the privacy curtain lying on the soiled linen cart were, "problems." The ICC stated the facility used, "cavi wipes," to clean surfaces in the room. She stated after wiping a surface with the cavi wipe, the surface needed to stay wet with solution (contact time) for three minutes.</p> <p>During an interview with RN 30, on August 27, 2009, at 11:10 a.m., the RN stated she considered the privacy curtain as the line delineating clean and dirty in the room. The RN stated she cleaned surfaces in the room with cavi wipes. She stated she wiped the surfaces for 20 to 30 seconds and waited for the surface to dry, "about 10 seconds."</p> <p>The manufacturer recommendations for cavi wipes were reviewed on August 27, 2009. The recommendations indicated the contact time for effective cleaning was three minutes.</p> <p>During an observation in the ICU at RSMC on August 27, 2009, at 11:17 a.m., accompanied by the ICC, room four was observed with the cart containing PPE inside the room, on the other side of the privacy curtain. The privacy curtain was lying on the top of the cart. RN 30 was observed entering the room, placing medications and papers from the medical record on the top of the cart, donning (putting on) PPE, then proceeding to the patient's bedside. The ICC stated, since the privacy curtain was dirty, and it was lying on the cart, the cart was contaminated (dirty).</p>	A 748	The Director of Infection Control and Infection Control Coordinators perform random rounds each week to observe nursing staff working with patients in contact isolation to confirm ongoing compliance with the procedures. They provide "just in time" feedback and reminder training directly for any observed deficiencies.	11/30/09 & ongoing	

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A 748	<p>Continued From page 139</p> <p>RN 30 was observed leaving room four at 11:32 a.m., with the papers from the medical record. She walked to the nurses' station, and placed the papers on the counter.</p> <p>2. During a tour of the MST unit on August 27, 2009, at 4:10 p.m., accompanied by the MS Director, room 165 was observed with a contact isolation sign on the door. Two blue bags with soiled linen were observed on the floor at the doorway. The MS Director stated the patient in the room had MRSA.</p> <p>At 4:14 p.m., RN 31 walked to the room, picked up the bags, and carried them down the hall. RN 31 was not wearing gloves. The RN stopped at a door, put the bags down, and with the same hand she carried the soiled linen, she pushed a keypad on the door, opened the door, and put the bags in the trash.</p> <p>During an interview with RN 31, on August 27, 2009, at 4:17 p.m., the RN stated she did not know room 165 was a contact isolation room. She stated she, "usually," wore gloves.</p> <p>3. During a tour of the MST unit on August 27, 2009, at 4:10 p.m., accompanied by the MS Director, room 161 was observed with two entrances. Both doors were closed. One of the doors led to the room the patient was in, and the other door led to an ante room (a small room adjoining the patient room where PPE is located, this is the room staff and visitors should enter when a patient is in isolation). A contact isolation sign was on the door leading to the patient room. There was no isolation sign on the door leading to the ante room. The MS Director stated the</p>	A 748		

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A 748 Continued From page 140 patient in the room had MRSA.

During an interview with the ICC on August 27, 2009, at 4:30 p.m., the ICC stated, since the staff and visitors entered through the ante room when a patient was in isolation, there should be a contact isolation sign on the ante room door.

The facility policy titled, "Isolation Precautions," was reviewed on August 27, 2009. The policy indicated the following:

- a. the goal of contact isolation was to provide a barrier between the infectious material and a person who could potentially spread the infection;
- b. the isolation cart is to be outside the room;
- c. an isolation sign should be visible on the door or door jam; and,
- d. gloves were to be worn if coming into contact with potentially infective material.

A 748

A 799 482.43 DISCHARGE PLANNING

The hospital must have in effect a discharge planning process that applies to all patients. The hospital's policies and procedures must be specified in writing.

This CONDITION is not met as evidenced by: Based on interview and record review, the facility failed to ensure:

A 799

See plan of correction next page.

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A 799 Continued From page 141

1. appropriate discharge planning and follow-up care for 11 newborn infants (Patients 11, 12, 13, 205, 265, 218, 227, 228, 247, 276, and 285) with risk factors for developing hyperbilirubinemia and/or a TcB and/or TSB in the High Intermediate Risk Zone on the Bhutani Curve (A800);
2. discharge planning for one patient (Patient 304) who had concerns about her living situation, resulting in the potential for an unsafe discharge (A800);
3. documentation of the discharge planning process for three of three HMO patients (Patients 22, 211, and 213), by failing to require outside CMs to document in the permanent record, resulting in the potential for an inappropriate discharge, discharge needs not being met, and injury and death for patients belonging to HMOs (A811); and,
4. the effectiveness of the discharge planning process was reassessed on an ongoing basis, resulting in the inability to determine if discharged patients had their post hospital needs met, and the potential for inappropriate discharges, injury and/or death of discharged patients (A843).

A 800 The cumulative effect of these failed practices resulted in the failure to ensure a safe and effective discharge planning process.

482.43(a) CRITERIA FOR DISCHARGE EVALUATIONS

The hospital must identify at an early stage of hospitalization all patients who are likely to suffer adverse health consequences upon discharge if there is no adequate discharge planning.

A 799

1. Please see the response to A 800 for actions the hospital has taken to improve discharge planning and follow-up care for newborns.
2. Please see the response to A 800 for actions the hospital has taken to improve discharge planning for other patients.
3. Please see the response to A 811 for actions the hospital has taken with regard to outside case managers.
4. Please see the response to A 843 for actions the hospital has taken to improve ongoing reassessment of the discharge planning process.

A 800 See next page for plan of correction.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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PRINTED: 11/27/2009
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OMB NO. 0938-0391

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NAME OF PROVIDER OR SUPPLIER SOUTHWEST HEALTHCARE SYSTEM	STREET ADDRESS, CITY, STATE, ZIP CODE 25800 MEDICAL CENTER DRIVE MURRIETA, CA 92562
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A 800	<p>Continued From page 142 This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to ensure:</p> <p>a. appropriate discharge planning and follow-up care for 11 newborn infants (Patients 11, 12, 13, 205, 285, 218, 227, 228, 247, 276, and 285) with risk factors for developing hyperbilirubinemia and/or a TcB and/or TSB in the High Intermediate Risk Zone on the Bhutani Curve; and,</p> <p>b. discharge planning for one patient (Patient 304) who had concerns about her living situation, resulting in the potential for an unsafe discharge.</p> <p>(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)</p> <p>(A TcB is a non invasive method of screening to determine the probable level of bilirubin in the blood)</p> <p>(A TSB is the actual level of bilirubin in the blood, determined by drawing blood and sending it to the lab)</p> <p>This failed practice resulted in Patient 11 being admitted to a NICU for treatment after discharge from the facility, and the potential for development of brain damage and death of the newborn infants.</p>	A 800	<p>The Department of Pediatrics developed discharge guidelines to ensure timely follow-up for babies deemed to be at risk for hyperbilirubinemia, including discharge orders for post-hospitalization follow up of infants at risk for hyperbilirubinemia. The discharge guidelines now advise that the baby needs the following on the day after discharge: A: An appointment with the newborn's pediatrician with a specific appointment date/time within one day of discharge, B: Follow-up bilirubin testing at the hospital with results called to the pediatrician for further assessment and treatment, or C: Follow up in the hospital's ED.</p> <p>The CNO and Chair of Pediatrics Department developed a discharge instructions form specific to newborns at risk for hyperbilirubinemia. The instructions document the physician's order that directs the family to follow up with: A: the newborn's pediatrician with a specific appointment date/time within one day of discharge B: to obtain follow-up bilirubin testing at the hospital to be called to pediatrician for further assessment and treatment C: or to follow up through the hospital's ED.</p> <p>Women's Services Leadership Team provided education to nursing staff on the process for assessing and documenting risk factors for hyperbilirubinemia and discharge guidelines/instructions.</p> <p>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."</p>	<p>10/19/09</p> <p>09/04/09</p> <p>08/12/09 & 09/04/09</p> <p>08/12/09 & 09/04/09</p>
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A 800	<p>Continued From page 143</p> <p>Findings:</p> <p>1. The record for Patient 11 was reviewed on August 6, 2009. Patient 11 was born on June 4, 2009, at 4:28 a.m., at 37 6/7 weeks gestation (time developing in the womb - normal 40 weeks).</p> <p>The Newborn Admit Flowsheet dated June 4, 2009, at 6:45 a.m., indicated:</p> <p>a. the mother was Rh negative and the baby was AB+ (Rh incompatible);</p> <p>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);</p> <p>c. the baby had bruises on the right forearm;</p> <p>d. the baby was large for gestational age; and,</p> <p>e. the baby was breastfed.</p> <p>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.</p> <p>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.</p>	A 800	<p>The Hospital has taken the following actions to improve the involvement of case managers in discharge planning, both for newborns and for adult patients:</p> <p>The DCM developed a pre-printed form for discharge planning. The form incorporates an initial screening for risk factors, a needs assessment that is to be completed if risk factors are identified, discharge planning notes and the final discharge plan. The key elements of the form were incorporated in the electronic documentation tool used by the Case Managers. Discharge planning risk factors include:</p> <ul style="list-style-type: none"> • A diagnosis that is likely to result in dependency • Age > 70 years • Inadequate support system • Readmit within 30 days • No insurance • Homeless, out of area, out of country • Mother/baby: Hospital stay exceeds 48hr (vaginal delivery) or 96hr (c-section delivery) • A referral for any reason. <p>The hard copy form is used as a "down time" form and for external case managers who have been appropriately trained by the CM staff. Input was received from the case managers for the final version.</p> <p>The DCM/designee conducted an educational Case Management staff meeting to review the discharge risk factors, needs assessment and the documentation tools - both the electronic version and the hard copy on 9/30/09. The revised process was implemented.</p> <p>The Interdisciplinary Plan of Care (IPOC) was revised to include a DC Planning section which is used to document discharge planning needs and interventions if applicable to the individual</p>	<p>10/01/09</p> <p>10/01/09</p> <p>12/07/09</p>
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A 800

Continued From page 144

Patient 11 was discharged home on Friday, 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, "Mon(day) or Tues(day)," three to four days after discharge.

There was no evidence a case manager identified the baby was at risk for severe 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 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.

A 800

patient. The Department of Education reviewed the IPOC, reinforced the discharge planning process including initial risk screen, needs assessment if indicated, Patient Right to Choose and community resources. The revised IPOC was implemented.

The Director of Case Management (DCM) reviewed the discharge planning process; the DC Screening & Assessment policy was revised. The policy improves the process for nursing to identify discharge planning needs and refer cases to the case managers.

Nursing leadership, in collaboration with the DCM, revised the Initial Nursing Database to ensure that the discharge planning risk factors used for screening were consistent with those identified in the DC Screening and Assessment policy. Nursing staff use the initial part of the form to screen patients and document any identified issues that need to be referred to the case managers for discharge planning. The revision was approved at Forms Committee.

The DCM provided education to nursing at the Joint Charge Nurse's Meeting on the revised Initial Nursing Database and the referral process should a risk factor be identified. The Charge Nurses communicated the change to the staff during morning unit meetings. This training included nurses in the newborn nursery so they know how to use the form to notify case managers of newborns at risk for hyperbilirubinemia and their need for prompt followup post discharge.

The revised form was implemented.

Responsible person: DCM

11/30/09

11/20/09

11/20/09

12/07/09

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A 800	<p>Continued From page 145</p> <p>On August 6, 2009, at 4:35 p.m., RN 1 was interviewed. RN 1 stated TcB testing should be conducted when the 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.</p> <p>On August 6, 2009, at 4:40 p.m., RN 2 was interviewed. RN 2 stated TcB testing was 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.</p> <p>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.</p> <p>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 being discharged from the facility).</p> <p>The Admission H&P dated June 9, 2009, indicated the baby was taken to her PCP on the</p>	A 800	<p>Monitoring:</p> <p>The DCM or CM Supervisors reviews a random sampling of charts each month to ensure that the patient has been screened for discharge planning risk factors and if risk factors were present, was a needs assessment completed. The outcome of the review will forward through the Quality pillar and to the Patient Safety Council for action planning as indicated.</p> <p>Following the implementation of the revised Initial Nursing Database, the Case Management review of the charts will confirm that nursing staff are completing the initial screens timely and making appropriate referrals to the case managers, and that case managers conduct the needs assessment timely and document updates as indicated through the patient's stay.</p> <p>The DCM addresses deficiencies in case manager performance with the specific case manager(s) and should a concern be identified with an external case manager, the DCM will refer the issue to the MCO leadership. The DCM reports nursing deficiencies to the CNO/designee, who addresses them with the nurse(s) involved.</p> <p>The DCM reports trends and variances to the Quality pillar for analysis and action planning as appropriate. Reports forward to the PSC, which reports to the Board of Governors.</p>	<p>11/01/09</p> <p>12/7/09</p> <p>12/7/09</p> <p>12/7/09</p>
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CA DEPT OF HEALTH & HUMAN SERVICES
 COUNTY OF SAN DIEGO
 DEC 16 AM 11:00

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NAME OF PROVIDER OR SUPPLIER SOUTHWEST HEALTHCARE SYSTEM		STREET ADDRESS, CITY, STATE, ZIP CODE 25600 MEDICAL CENTER DRIVE MURRIETA, CA 92562		
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A 800	<p>Continued From page 146</p> <p>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.</p> <p>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).</p> <p>The Discharge Summary for GACH 2 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..."</p> <p>According to the AAP Guidelines:</p> <p>a. 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 for those babies who have risk factors for developing hyperbilirubinemia;</p> <p>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); and,</p> <p>c. phototherapy is recommended for an infant at 30 hours of age, with risk factors for developing hyperbilirubinemia, and a TSB of 8.9.</p> <p>During an interview with the PI Director on August</p>	A 800		

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A 800	<p>Continued From page 147</p> <p>25, 2009, at 4:40 p.m., the director stated the newborn's record went to the Department of Pediatrics (medical staff committee) for review on August 12, 2009. According to the PI Director, the committee determined, because the baby was discharged with a TSB in the high intermediate risk zone, she should have had her bilirubin checked and/or been seen by her PCP the following day. The PI Director stated the committee determined there was a deviation with the standard of medical care to treat hyperbilirubinemia.</p> <p>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).</p> <p>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, was breastfed, and the mother's blood type was O+. There was no Coombs test performed on the cord blood.</p> <p>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 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.</p> <p>Patient 12 was discharged home on July 27, 2009, at 12 p.m., (27 hours of age) with risk factors for developing hyperbilirubinemia, the TcB</p>	A 800		

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A 800	<p>Continued From page 148</p> <p>in the high intermediate risk zone, and no order for follow-up with the physician.</p> <p>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.</p> <p>On August 12, 2009, at 3:25 p.m., Patient 12's record was reviewed with the Nursery Manager. The Manager stated Patient 12 being at <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.</p> <p>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 intermediate risk zone. The Manager stated TSB testing should have been completed to determine the need for phototherapy.</p> <p>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.</p> <p>According to the AAP Guidelines:</p> <p>a. an infant with no risk factors who is discharged home at 27 hours of age should be seen by the</p>	A 800		
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A 800	<p>Continued From page 149</p> <p>age of 96 hours, but earlier follow up should be provided for those babies who have risk factors for developing hyperbilirubinemia; and,</p> <p>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 12 had three of these four risk factors).</p> <p>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), was breastfed, and the mother's blood type was O+. There was no Coombs test done on the cord blood.</p> <p>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.</p> <p>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.</p> <p>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</p>	A 800		
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A 800	<p>Continued From page 150</p> <p>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.</p> <p>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 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 and the testing should have been done within two hours of birth.</p> <p>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.</p> <p>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 and identified the gestational age of <38 weeks as a risk factor and 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</p> <p>4. The record for Patient 205 was reviewed on August 25, 2009. Patient 205, a newborn male of Asian descent, was born on June 2, 2009, at 11:55 p.m., at 37 4/7 weeks gestation (time developing in the womb - normal 40 weeks), and was breastfed.</p> <p>The Hour Specific Billirubin Nomogram indicated the baby was at risk for developing</p>	A 800		
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A 800	<p>Continued From page 151</p> <p>hyperbilirubinemia due to his Asian descent and gestational age of <38 weeks. The first TcB was done June 4, 2009, at 3 p.m. (39 hours of age), after discharge orders were written. The value was 11.9, on the line of the high risk zone on the Bhutani curve. A TSB was drawn at 3:11 p.m. (39 hours of age) with a result of 9.5, on the line of the high intermediate risk zone of the curve. There was no evidence the physician was notified.</p> <p>The baby was discharged home on June 4, 2009, at 6 p.m. (42 hours of age), with risk factors for developing hyperbilirubinemia, a TSB on the line of the high intermediate risk zone, no notification of the physician, and follow up with the pediatrician's office in five days.</p> <p>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.</p> <p>According to the AAP Guidelines:</p> <p>a. an infant with no risk factors who is discharged home at 42 hours of age should be seen by the age of 96 hours, but earlier follow up should be provided for those babies who have risk factors for developing hyperbilirubinemia; and,</p> <p>b. the risk factors most frequently associated with hyperbilirubinemia are breastfeeding, gestation below 38 weeks, jaundice in a previous sibling</p>	A 800		
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A 800	<p>Continued From page 152 (brother or sister), and jaundice noted before discharge (Patient 205 had two of these four risk factors).</p> <p>During an interview with the governing body on August 27, 2009, at 12:20 p.m., the physician members stated they expected a baby at risk for developing hyperbilirubinemia would be followed up sooner than those not at risk. The members stated they expected all patients to be seen by case management to determine their discharge planning needs. The CEO stated he was not aware they were not seeing all of the patients.</p> <p>5. The record for Patient 265 was reviewed on September 3, 2009. Patient 265 was born on August 27, 2009, at 3:11 p.m., and was breastfed.</p> <p>The Hour Specific Bilirubin Nomogram indicated the baby was at risk for developing hyperbilirubinemia due to an identified risk factor of poor feeding. On Friday, August 28, 2009, at 4:10 p.m. (25 hours of age), the TcB was 7.0, in the high intermediate risk zone on the Bhutani curve. At 5 p.m. (26 hours of age), the TSB was 6.2, in the high intermediate risk zone on the curve.</p> <p>The nurse notified the physician of the bilirubin results at 6:05 p.m., and the physician ordered the baby to be discharged home with follow up on, "Monday."</p> <p>The baby was discharged home on August 28, 2009, at 7 p.m. (28 hours of age), with risk factors for developing hyperbilirubinemia, a TSB in the high intermediate risk zone on the Bhutani curve, and follow up with a pediatrician three days later.</p>	A 800		

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A 800	<p>Continued From page 153</p> <p>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.</p> <p>According to the AAP Guidelines, an infant with no risk factors who is discharged home at 28 hours of age should be seen by the age of 96 hours, but earlier follow up should be provided for those babies who have risk factors for developing hyperbilirubinemia.</p> <p>6. The record for Patient 218 was reviewed on September 4, 2009. Patient 218, a newborn female, was born on September 2, 2009, at 10:09 a.m., and was breastfed.</p> <p>The Hour Specific Bilirubin Nomogram indicated the baby was at risk for developing hyperbilirubinemia due to dark skin pigmentation, family history of neonatal jaundice, and vacuum delivery, so bilirubin levels were checked every shift. On Friday, September 4, 2009, at 9:15 a.m. (47 hours of age), the TcB was 11.2, in the high intermediate risk zone on the Bhutani curve. The TSB was 10.4, on the line of the high intermediate risk zone on the curve.</p> <p>The physician was notified of the bilirubin levels, and ordered the baby to be discharged and followed up on, "Tuesday," (four days later [Friday started a holiday weekend, and offices were closed on Monday]).</p>	A 800		

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A 800	<p>Continued From page 154</p> <p>The nurse's notes indicated the physician was, "called and risk factors reviewed, no new orders received, Dr. does not want to order repeat bill or outpatient serum bill at this time."</p> <p>According to the AAP Guidelines:</p> <p>a. an infant with no risk factors who is discharged home at 47 hours of age should be seen by the age of 96 hours, but earlier follow up should be provided for those babies who have risk factors for developing hyperbilirubinemia; and,</p> <p>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 218 had two of these four risk factors).</p> <p>As a result of the findings for Patients 265 and 218, the CEO was notified Immediate Jeopardy was identified on September 4, 2009, at 11:40 a.m. The Immediate Jeopardy was identified due to the facility's failure to provide appropriate discharge planning and follow up care for infants who were at risk for developing hyperbilirubinemia, resulting in the potential for development of brain damage and death for at risk newborn infants discharged from SWHCS. When the findings were shared with the CEO, he stated, "It's black and white, even I know the baby should be seen the next day."</p> <p>After implementation of an acceptable plan of correction, the CNE was notified the Immediate Jeopardy was abated on September 4, 2009, at 4:15 p.m.</p>	A 800		
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A 800	<p>Continued From page 155</p> <p>The plan of correction included the following actions for newborns discharged with bilirubin levels in the high intermediate risk zone or high risk zone on the Bhutani curve to have follow up the day after discharge:</p> <p>a. at time of discharge, the pediatrician would be contacted to determine the level of follow up care required;</p> <p>b. the level of follow up care would be documented on a newly developed form (Hyperbilirubinemia Follow Up Instructions), and explained to the parents of the newborn as part of the discharge process;</p> <p>c. for patients who were able to obtain follow up in the pediatrician's office, the date and time of the visit would be documented on the form, and explained to the parents of the baby;</p> <p>d. for patients who were unable to obtain follow up in the pediatrician's office, they would receive instructions to return for outpatient bilirubin levels to be drawn, or to be seen by the ED physician, whichever the pediatrician preferred;</p> <p>e. for patients having outpatient bilirubin levels drawn, the pediatrician would be notified of the STAT results;</p> <p>f. for patients being seen by the ED physician, the ED physician would determine further follow up with the pediatrician;</p> <p>g. the managers would provide education to the nursing staff, and staff would sign an acknowledgement of the education;</p>	A 800		
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A 800	<p>Continued From page 156</p> <p>h. a manager from Women's Services would be notified of any newborn discharged with bilirubin levels in the high intermediate risk zone or high risk zone to ensure consistent application of the process;</p> <p>i. the chair of the Department of Pediatrics and the medical staff office would communicate the plan to the pediatricians;</p> <p>j. 100% of records would be reviewed for compliance until all staff were educated; and,</p> <p>k. the Department of Pediatrics would review and revise protocols to reflect AAP guidelines.</p> <p>7. The record for Patient 227 was reviewed on September 4, 2009. Patient 227, a newborn male, was born on August 26, 2009, at 9:50 a.m., to a 19 year old first time mother.</p> <p>The Hour Specific Billirubin Nomogram indicated the baby was at risk for developing hyperbilirubinemia due to bruising of the head, and TcB values were obtained every shift. Billirubin results were as follows:</p> <p>a. August 27, 2009, at 8 a.m. (22 hours of age), the TcB was 7.5, on the line of the high risk zone on the Bhutani curve;</p> <p>b. August 27, 2009, at 9:45 a.m. (24 hours of age), the TSB was 7.1, in the high intermediate risk zone on the curve;</p> <p>c. August 27, 2009, at 9:45 p.m. (36 hours of age), the TSB was 9.4, in the high intermediate risk zone on the curve;</p>	A 800		
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A 800	<p>Continued From page 157</p> <p>d. August 28, 2009, at 4:30 a.m. (42.5 hours of age), the TSB was 10.1, in the high intermediate risk zone on the curve;</p> <p>e. August 28, 2009, at 10:40 a.m. (48.5 hours of age), the TcB was 14.4, in the high risk zone on the curve;</p> <p>f. August 28, 2009, at 11:10 a.m. (49 hours of age), the TSB was 12.3, in the high intermediate risk zone on the curve; and,</p> <p>g. August 28, 2009, at 4:05 p.m. (54 hours of age), the TSB was 13.0, in the high intermediate risk zone on the curve.</p> <p>The Well Newborn Care Flowsheet indicated the baby became jaundiced on August 27, 2009, at 7 p.m., and continued to be jaundiced in color until the time of discharge.</p> <p>The physician ordered the baby to be discharged home on Friday, August 28, 2009, and to follow up with the pediatrician's office on Monday, August 31, 2009 (three days later).</p> <p>The baby was discharged home to his 19 year old first time mother, with risk factors for developing hyperbilirubinemia, a TSB in the high intermediate risk zone on the Bhutani curve, jaundice in color, to be seen by the pediatrician in three days.</p> <p>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</p>	A 800		
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A 800	<p>Continued From page 158 included close follow up for prevention of severe hyperbilirubinemia.</p> <p>According to the AAP Guidelines, an infant with no risk factors who is discharged home at 54 hours of age should be seen by the age of 96 hours, but earlier follow up should be provided for those babies who have risk factors for developing hyperbilirubinemia.</p> <p>8. The record for Patient 228 was reviewed on September 4, 2009. Patient 228, a newborn male, was born on August 31, 2009, at 4:22 a.m. The Newborn Admit Flowsheet indicated the baby ingested maternal blood at the time of delivery. The admission physical assessment was not completed, therefore, no physical risk factors for developing hyperbilirubinemia were assessed.</p> <p>The Hour Specific Bilirubin Nomogram indicated the baby was at risk for developing hyperbilirubinemia due to identified risk factors of dark skin pigmentation and ingestion of maternal blood, and TcB levels were obtained each shift. On September 1, 2009, at 8:40 a.m. (28 hours of age), the TcB was 7.0, on the line of the high intermediate risk zone on the Bhutani curve. There was no TSB drawn.</p> <p>The baby was discharged home on September 1, 2009, at 10:40 a.m. (30 hours of age), with risk factors for developing hyperbilirubinemia, a TcB in the high intermediate risk zone on the Bhutani curve, no TSB level, and follow up with the pediatrician in two days.</p> <p>There was no evidence a case manager identified the baby was at risk for hyperbilirubinemia during their screening process. There was no evidence</p>	A 800		

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A 800	<p>Continued From page 159</p> <p>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.</p> <p>9. The record for Patient 247 was reviewed on September 4, 2009. Patient 247, a newborn male, was born on August 30, 2009, at 10:02 a.m., at 38 1/7 weeks gestation (time developing in the womb - normal 40 weeks), and was breastfed.</p> <p>The Hour Specific Bilirubin Nomogram indicated the baby was at risk for developing hyperbilirubinemia due to identified risk factors of sibling (brother or sister) jaundice and gestational age <38 weeks, and bilirubin levels were obtained every shift. On September 1, 2009, at 8:30 a.m. (45 hours of age), the TcB was 11.2, in the high intermediate risk zone on the Bhutani curve. No TSB was drawn.</p> <p>The Well Newborn Care Flowsheet indicated the baby was jaundiced on September 1, 2009, at 8 a.m., 10 a.m., and 12 noon.</p> <p>The baby was discharged home on September 1, 2009, at 1:20 p.m. (50 hours of age), with risk factors for developing hyperbilirubinemia, a TcB in the high intermediate risk zone on the Bhutani curve, no TSB, and follow up with the pediatrician in two days.</p> <p>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</p>	A 800		

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A 800	<p>Continued From page 160</p> <p>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.</p> <p>10. The Record for Patient 276 was reviewed on September 4, 2009. Patient 276 was born on August 26, 2009, at 5:38 p.m.</p> <p>The Hour Specific Bilirubin Nomogram indicated the baby was at risk for developing hyperbilirubinemia due to identified risk factors of bruising of the head and dark skin pigmentation, and bilirubin levels were obtained every shift. On August 27, 2009, at 8:30 p.m. (27 hours of age), the TcB was 8.4, in the high intermediate risk zone on the Bhutani Curve. At 10:20 p.m. (29 hours of age), the TSB was 7.4, in the high intermediate risk zone on the Bhutani Curve, and the physician was notified.</p> <p>On Friday, August 28, 2009, at 4:30 a.m. (35 hours of age), the TSB was 8.7, on the line of the high intermediate risk zone of the Bhutani curve. At 7:30 a.m., the nurse documented the value was, "at the base of 75% (high intermediate risk zone)," and the physician had been notified.</p> <p>On August 28, 2009, at 8:30 a.m. (39 hours of age), the TcB was 9.9, in the high intermediate risk zone on the Bhutani Curve. According to the nurse's notes, the physician was made, "aware of TcB results @ Base of 75th percentile."</p> <p>At 8:50 a.m., the physician ordered to discharge the baby home with follow up in two days (which would have been Sunday, August 30, 2009, not</p>	A 800		

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A 800	<p>Continued From page 161 an office day).</p> <p>At 10:50 a.m., a "clarification," of the discharge order indicated the baby was to be seen by the pediatrician on Monday, August 31, 2009 (three days later)."</p> <p>The baby was discharged home on August 28, 2009, at 2:10 p.m. (45 hours of age), with risk factors for developing hyperbilirubinemia, a TcB in the High Intermediate Risk Zone on the Bhutani curve, and follow up with the pediatrician three days later.</p> <p>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.</p> <p>According to the AAP Guidelines:</p> <p>a. an infant with no risk factors who is discharged home at 45 hours of age should be seen by the age of 96 hours, but earlier follow up should be provided for those babies who have risk factors for developing hyperbilirubinemia.</p> <p>11. The record for Patient 285 was reviewed on September 4, 2009. Patient 285 was born on August 28, 2009, at 4:54 p.m.</p> <p>On Saturday, August 29, 2009, at 11:30 a.m. the physician ordered to discharge the baby with a follow up on Monday or Tuesday (two or three</p>	A 800		
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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 050701	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED C 09/17/2009
NAME OF PROVIDER OR SUPPLIER SOUTHWEST HEALTHCARE SYSTEM		STREET ADDRESS, CITY, STATE, ZIP CODE 25600 MEDICAL CENTER DRIVE MURRIETA, CA 92562		
(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 800	<p>Continued From page 162 days later).</p> <p>At 2:20 p.m. (21.5 hours of age), the pre discharge TcB was 7.9, in the high risk zone on the Bhutani curve. At 2:25 p.m. (21.5 hours of age), the TSB was 6.1, in the high intermediate risk zone on the Bhutani curve (putting the baby at risk for developing hyperbilirubinemia). The physician was notified and ordered, "OK to DC, must follow up on Monday."</p> <p>The baby was discharged home on August 29, 2009, at 4:30 p.m. (23.5 hours of age), with a TSB in the high intermediate risk zone on the Bhutani curve (a risk factor for development of hyperbilirubinemia), and follow up with the pediatrician in two days.</p> <p>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.</p> <p>According to the AAP Guidelines:</p> <p>a. an infant with no risk factors who is discharged home at 23.5 hours of age should be seen by the age of 72 hours, but earlier follow up should be provided for those babies who have risk factors for developing hyperbilirubinemia.</p> <p>In addition, the AAP recommends for all newborns, "if appropriate follow-up cannot be ensured in the presence of elevated risk for</p>	A 800		

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NAME OF PROVIDER OR SUPPLIER SOUTHWEST HEALTHCARE SYSTEM	STREET ADDRESS, CITY, STATE, ZIP CODE 28600 MEDICAL CENTER DRIVE MURRIETA, CA 92562
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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) COMPLETION DATE
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A 800	<p>Continued From page 163</p> <p>developing severe hyperbilirubinemia, it may be necessary to delay discharge either until appropriate follow-up can be ensured or the period of greatest risk has passed (72-96 hours)."</p> <p>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).</p> <p>The policy indicated the risk factors for hyperbilirubinemia included but were not limited to the following;</p> <ul style="list-style-type: none"> 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 suboptimal breastfeeding; d. jaundice appearing in the first 24 hours after birth (dark skin pigments may obscure visualization); e. macrosomic (large for gestational age) infant of a diabetic mother; f. near-term newborns at 35, 36, and 37 weeks of 	A 800		
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NAME OF PROVIDER OR SUPPLIER SOUTHWEST HEALTHCARE SYSTEM		STREET ADDRESS, CITY, STATE, ZIP CODE 25800 MEDICAL CENTER DRIVE MURRIETA, CA 92562		
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A 800	<p>Continued From page 164</p> <p>gestation, particularly if they were breastfed;</p> <p>g. significant weight loss (defined as > (greater than) 10 % by discharge;</p> <p>h. temperature instability or treatment of sepsis; and,</p> <p>i. unrecognized hemolysis, such as ABO blood type incompatibility.</p> <p>The facility policy titled, "Case Management: Discharge Planning - Screening and Assessment For," was reviewed on August 28, 2009. The policy indicated the following:</p> <p>a. the purpose was to identify discharge planning needs;</p> <p>b. each patient admitted to the hospital was screened for discharge planning needs;</p> <p>c. the screening included high risk indicators; and,</p> <p>d. continuity of care was a primary concern.</p> <p>The high risk indicators in the policy did not include babies at risk for developing severe hyperbillrubinemia.</p> <p>On August 26, 2009, at 3:57 p.m., CM 1 was interviewed. CM 1 stated she was the CM assigned to the OB department that day. She stated she did not see patients in the OB department unless a referral was made. She stated the patients and their babies could be discharged from the facility without being seen by the CM.</p>	A 800		

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A 800	<p>Continued From page 165</p> <p>On August 26, 2009, CM 2 was interviewed. CM 2 stated OB patients were only seen by the CMs for discharge planning if there was a referral. CM 2 stated the CM assigned to the OB department used a "screening tool," to determine which OB patient needed to be seen. CM 2 stated OB patients and their babies may be discharged without being seen by the CM. CM 2 stated it was, "physically impossible to see each and every patient."</p> <p>On August 28, 2009, at 10 a.m., the MSW was interviewed. The MSW stated she was assigned to see OB patients. She stated she would only see OB patients if there was a referral made.</p> <p>On August 28, 2009, at 10:15 a.m., CM 5 was interviewed. CM 5 stated she was the CM assigned to the Perinatal unit that day. CM 5 stated the CMs saw newborns and their mothers only when there was a referral made. She stated referrals were made for adoption, CPS, and teenage pregnancies. The CM stated she used a "screening tool," to determine if a visit was needed in the Perinatal unit. The CM stated the "screening tool," was the hospital's census and the facility's, "High Risk Criteria," list.</p> <p>A concurrent review of the facility census revealed the following information on a patient: Patient's name, diagnosis, age, and room #. The CM was unable to tell, through the census sheet, if there were any patients with any change in condition, which may indicate the need for a follow-up. The CM was unable to indicate in the census sheet whether a baby was being discharged at risk for developing hyperbilirubinemia.</p>	A 800		
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A 800	<p>Continued From page 166</p> <p>According to a document titled, "Severe Hyperbilirubinemia Prevention (SHP) Toolkit...on behalf of the Perinatal Quality Improvement Panel (PQIP) and California Perinatal Quality Care Collaborative (CPQCC)" dated October 19, 2005, was reviewed. The document indicated infants at risk for significant hyperbilirubinemia needed to have close follow up after discharge. The document indicated follow up visit should be performed within 24-48 hours post discharge.</p> <p>The document further indicated a follow up visit and/or bilirubin test within 24 hour post discharge to monitor for jaundice was recommended in babies whose serum bilirubin fell within the High Risk Zone in the Hour Specific Nomogram.</p> <p>The document further indicated a follow up visit and/or bilirubin test within 48 hour post discharge to monitor for jaundice was recommended in the following circumstances:</p> <p>a. a single bilirubin measurement in the High Intermediate Risk Zone in the Hour Specific Nomogram in the infant; and,</p> <p>b. a single bilirubin measurement in the Low Intermediate Risk Zone in infants who have any of the risk factors for development of hyperbilirubinemia.</p> <p>12. On August 26, 2009, the medical record of Patient 304 was reviewed. The form, "CRMC Case Management Notes," indicated the patient was discharged before the discharge planner arrived at her room. The Admission Data Base indicated, in the social services section, the</p>	A 800		

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A 800	Continued From page 167 patient had concerns regarding her living situation and her safety at home. There was no evidence in the chart those concerns were addressed prior to her discharge from the facility. During an interview with the Director of Case Management on August 27, 2009, at 10:30 a.m., she stated the concerns present on the admission assessment should have triggered intervention by social services or case management/discharge planning. She stated there was no evidence the concerns indicated on the admission assessment were addressed by the facility.	A 800			
A 811	482.43(b)(6) DOCUMENTATION OF EVALUATIONS The hospital must include the discharge planning evaluation in the patient's medical record for use in establishing an appropriate discharge plan and must discuss the results of the evaluation with the patient or individual acting on his or her behalf. This STANDARD is not met as evidenced by: Based on interview and record review, the facility failed to ensure documentation of the discharge planning process for three of three HMO patients (Patients 22, 211, and 213), by failing to require outside CMs to document in the permanent record, resulting in the potential for an inappropriate discharge, discharge needs not being met, and injury and death for patients belonging to HMOs. Findings: 1. On August 27, 2009, Patient 22's record was reviewed. Patient 22 was admitted to the facility on August 24, 2009, with diagnoses that included decubitus ulcer (pressure sore) and cellulitis	A 811	The Director of Case Management (DCM), the ADQO and the Chief Financial Officer met with the leadership of the two health plans who provided on-site nursing staff for discharge planning to determine if those organizations planned to continue providing discharge planning to their clients when hospitalized at Southwest Healthcare System (SWHCS). In order for the health plan staff to provide discharge planning at SWHCS, the health plan would have to agree to meet the hospital's expectation for complying with the policies of SWHCS, including documentation in the patient's medical record. The health plans were provided copies of pertinent hospital policies and documentation forms during this process. During the time of the health plan's evaluation, discharge planning was provided by SWHCS employees.	09/24/09	

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A 811	<p>Continued From page 169</p> <p>On August 27, 2009, at 11:35 a.m., the M/S unit charge nurse was interviewed. The charge nurse did not know what the discharge plan was for Patient 22. The charge nurse was unable to find evidence in Patient 22's record of any discharge planning, CM follow up, or social service follow up.</p> <p>On August 27, 2009, at 11:40 a.m., RN 6 was interviewed. RN 6 stated she was Patient 22's floor nurse. RN 6 did not know what the discharge plan was for Patient 22. RN 6 was unable to find evidence in Patient 22's record of discharge planning, CM follow up, or social service follow up. RN 6 was unable to find a care plan identifying Patient 22's social needs.</p> <p>2. During an interview with CM 5 on August 28, 2009, at 9:15 a.m., CM 5 stated the CMs saw every admitted patient, except the patients who belonged to HMOs. The CM stated the HMO patients were seen by outside case managers. She stated if an issue came up in the afternoon and her assistance was requested for an HMO patient, she would assist the staff, but otherwise she did not conduct discharge planning for HMO patients.</p> <p>During an interview with the CM supervisor on August 28, 2009, at 9:30 a.m., the supervisor stated the facility CMs did not assess the HMO patients for discharge planning.</p> <p>The record for Patient 211 (an HMO patient) was reviewed on August 28, 2009. Patient 211, a 92 year old male, was admitted to the facility on August 25, 2009, with diagnoses that included atrial fibrillation (an irregular heart rhythm) and COPD.</p>	A 811		
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A 811	<p>Continued From page 170</p> <p>The record indicated Patient 211 was on a BiPAP (positive pressure) machine to assist with breathing, was confused, had difficulty swallowing, and was on a pureed diet.</p> <p>There was no evidence in the record of any discharge planning.</p> <p>The Interdisciplinary Plan of Care failed to show a plan for meeting the patient's discharge needs.</p> <p>The facility Discharge Planning document indicated, "(outside) case manager is responsible for all reviews and discharge planning. For questions or for a family request, contact the HMO at (phone number)."</p> <p>During an interview with the outside CM (CM 6) on August 28, 2009, at 10:30 a.m., the CM stated she did the discharge planning for patients belonging to the medical group she worked for. The CM stated she documented the plan on the outside CM notes. She stated she had seen and evaluated Patient 211, and she, "thought," she put her notes in the record. CM 6 was unable to provide documented evidence of an evaluation for discharge planning for Patient 211.</p> <p>3. The record for Patient 213 (an HMO patient) was reviewed on August 28, 2009. Patient 213, an 86 year old female, was admitted to the facility on August 25, 2009, with diagnoses that included urosepsis (an overwhelming infection caused by an untreated urinary tract infection).</p> <p>The record indicated Patient 213 was blind and hard of hearing, and used a walker to assist with mobility.</p>	A 811			

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A 811	<p>Continued From page 171</p> <p>The, "Outside Reviewer(s) Communication Sheet," indicated the patient was seen by an outside CM for discharge planning. There was no date on the document. At the top of the document was the statement, "not a permanent part of the chart, discard at time of discharge!"</p> <p>The facility Discharge Planning document indicated, "(outside) case manager is responsible for all reviews and discharge planning. For questions or for a family request, contact the HMO at (phone number)."</p> <p>During an interview with the outside CM (CM 6) on August 28, 2009, at 10:30 a.m., the CM stated she did the discharge planning for patients belonging to the medical group she worked for. The CM stated she documented the plan on the outside CM notes. She stated she was aware the document was discarded after the patient was discharged. The CM stated she did not document on the facility records, and she did not document a discharge plan on the care plan.</p> <p>During an interview with the CM supervisor on August 28, 2009, at 10 a.m., the supervisor stated when patients were discharged, the nurses took information from the outside CM sheet and put it on the discharge instructions. The supervisor stated after a patient was discharged, and the chart was completed by medical records, there would be no evidence of the discharge planning that was done by the outside CMs because the outside CM document was discarded.</p> <p>During an interview with the DCM on August 28, 2009, at 10:50 a.m., the DCM stated she was aware the outside CM document was not</p>	A 811		
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A 811	Continued From page 172 part of the permanent medical record. She stated she had been trying to get the outside CMs to document on facility chart forms, but, "they won't"	A 811		
A 843	<p>482.43(e) REASSESSMENT OF DISCHARGE PLANNING PROCESS</p> <p>The hospital must reassess its discharge planning process on an on-going basis. The reassessment must include a review of discharge plans to ensure that they are responsive to discharge needs.</p> <p>This STANDARD is not met as evidenced by: Based on interview, the facility failed to ensure the effectiveness of the discharge planning process was reassessed on an ongoing basis, resulting in the inability to determine if discharged patients had their post hospital needs met, and the potential for inappropriate discharges, injury and/or death of discharged patients.</p> <p>Findings:</p> <p>During an interview with the DCM on August 28, 2009, at 10:50 a.m., the DCM stated the facility did not have a process in place to assess the effectiveness of the discharge planning process. She stated she did not have a process in place to assess the effectiveness of the discharge planning being done by the outside CMs. She stated she had not assessed the competency of the outside CMs, therefore she did not know if the discharge planning that was conducted by the outside CMs was appropriate.</p>	A 843	<p>In addition to the actions discussed above in Tag A811, the following actions have been taken to provide a reassessment of the effectiveness of the discharge planning process.</p> <p>The DCM established a process with the assistance of IS to identify a listing of 30-day readmissions. Beginning 12/1/09, the DCM or the CM Supervisors will audit a random sample of readmissions of patients who were discharged home, to assess the prior admission's discharge plan for effectiveness to determine if the plan was responsive to the patient's discharge needs. The outcome of this review will be reported to the Quality pillar for analysis and action planning as indicated. The goal will be to identify opportunities to improve the patient's transition from the hospital to their home.</p>	12/1/09

CA DEPT OF
PUBLIC HEALTH
09 DEC 16 AM 11:00
SAN DIEGO COUNTY