



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

IMPORTANT NOTICE --- PLEASE READ CAREFULLY

April 15, 2010

Dennis Knox, CEO/Managing Director
Southwest Healthcare System
25500 Medical Center Drive
Murrieta, CA 92562

CMS Certification Number: 05-0701

Dear Mr. Knox:

This is to inform you that based on a careful review of the findings of a revisit survey completed on January 19, 2010 by the California Department of Public Health (CDPH), the Centers for Medicare and Medicaid Services (CMS) has concluded that Southwest Healthcare System (Southwest) is not in compliance with the applicable Conditions of Participation for a provider of hospital services in the Medicare program, established by Title XVIII of the Social Security Act.

To participate in the Medicare program, a hospital must meet the statutory requirements in 42 U.S.C. § 1395x (e) and be in compliance with each of the applicable regulatory Conditions of Participation for hospitals at 42 C.F.R. Part 482. Indeed, when Southwest entered into a Medicare provider agreement it specifically undertook to comply with Federal statutes and regulations governing Medicare certified hospitals; see section 1861(e) of the Social Security Act, 42 U.S.C. § 1395x(e); 42 C.F.R. Parts 482 and 488.

As a result of the survey completed by CDPH on January 19, 2010, CMS concluded that Southwest continues to be out of compliance with the requirements for participation as a Medicare provider of hospital services. In particular, the survey showed that Southwest was not complying with the following Conditions of Participation:

42 C.F.R. 482.12	Governing Body
42 C.F.R. 482.13	Patient's Rights
42 C.F.R. 482.21	Quality Assurance/Performance Improvement (QAPI)
42 C.F.R. 482.22	Medical Staff
42 C.F.R. 482.23	Nursing Services
42 C.F.R. 482.25	Pharmaceutical Services
42 C.F.R. 482.41	Physical Environment
42 C.F.R. 482.42	Infection Control
42 C.F.R. 482.55	Emergency Services

The most recent survey that ended on January 19, 2010, identified numerous violations of federal requirements for quality of care in a hospital environment. The findings indicate that many previously identified systemic problems persist. The survey also documented the inability of the hospital's governing body to identify and take appropriate measures to eliminate clear threats to patient health and safety.

The following examples are representative of major and serious problems identified in the recent survey. In the area of **Nursing Services** (42 CFR 482.23), the hospital failed to ensure nursing staff administered blood pressure medications as ordered by the physician. The hospital failed to ensure the nursing staff administered the first dose of antibiotics to patients for the treatment and/or prevention of infection within the two hour timeframe specified by hospital policies and procedures. Additionally, hospital nursing staff also failed to ensure a patient with a low blood pressure was re-checked in a timely manner to verify the blood pressure was not continuing to fall. Also, hospital nursing staff failed to implement policies and procedures to prevent falls. In addition, the nursing staff failed to ensure a system for the safe assignment of Licensed Vocational Nurses (LVNs) to patient care duties within the Emergency Department to ensure that LVNs were providing care within their scope of practice.

In the area of **Medical Staff** (42 CFR 482.22), the medical staff failed to ensure six Physicians' Assistants performing medical screening examinations in the Emergency Department were competent to do medical screening examinations for determining if a condition was a medical/mental health emergency.

In the area of **Infection Control** (42 CFR 482.42), hospital staff assigned to the cardiac catheterization unit, a restricted area, acknowledged that surgical attire to be worn (including surgical head covering and face masks) was not always worn by physicians or staff. This restricted area is where cardiac catheterizations and cardiac pacemaker insertions took place (invasive procedures performed on the heart). This was in contradiction to hospital policy and procedure, and placed patients at risk for exposure to hospital acquired infections.

In the area of **Pharmacy** (42 CFR 482.25), the pharmacist did not demonstrate competency in medication management protocols. For example, the pharmacist failed to ensure the safe use of medications containing Black Box Warnings (medications with Black Box Warnings have the potential to cause significant injury or death). Additionally, the hospital pharmacy failed to ensure that the medication preparation area for chemotherapy medications/agents was properly decontaminated after use (or prior to the mixing of other non-chemotherapy medications/agents), thereby potentially exposing other patients to chemotherapeutic agents, and their side-effects.

In the area of **Physical Environment** (42CFR 482.41), the hospital failed to ensure the safety of newborns from abduction when an alarm system was removed, not replaced, and the security guards watching for infant abduction could not visualize the hallways leading to the newborn nursery and two exit doors from the hospital.

We have determined that these deficiencies, either individually or in combination, substantially limit the hospital's capacity to render adequate care to patients or are of such character as to

adversely affect patient health and safety, thus establishing a basis under 42 C.F.R. § 488.26(b) for concluding, that the above-referenced Condition(s) of Participation were not met. A description of the deficiencies is set forth on the enclosed Statement of Deficiencies, Form CMS-2567.

The date on which the agreement terminates is **June 1, 2010**. The Medicare program will not make payment for inpatient hospital services furnished to patients who are admitted on or after **June 1, 2010**. For patients admitted prior to **June 1, 2010**, payment may continue to be made for a maximum of 30 days of inpatient hospital services on or after **June 1, 2010**. You should submit as soon as possible, a list of names and Medicare claim numbers of beneficiaries in your hospital on **June 1, 2010** to the San Francisco regional office to facilitate payment for these individuals.

We will publish a public notice in the Riverside Press Enterprise. You will be advised of the publication date for the notice.

Application for Readmission Following Involuntary Termination

Once terminated, Southwest Healthcare System may apply for reinstatement. See 42 C.F.R. § 489.57. However, a new agreement will not be accepted unless CMS determines that the reason for termination of the previous agreement has been removed and that there is "reasonable assurance" that the hospital can maintain compliance with the applicable Conditions of Participation. 42 C.F.R. § 489.57(a). Compliance will be verified by on-site surveys conducted at the beginning and end of a reasonable assurance period determined by CMS. This period will be a minimum of 90 days. Prior to issuance of a new provider agreement the hospital also must fulfill, or make satisfactory arrangements to fulfill, all of the statutory and regulatory responsibilities of its previous agreement. 42 C.F.R. § 489.57(b).

Appeal Rights

If you do not agree with this determination, you may request a hearing before an administrative law judge of the Department of Health and Human Services, Departmental Appeals Board, in accordance with 42 C.F.R. Part 498. Such hearing request must be filed in writing no later than 60 days from receipt of this notice. The request should be sent to the following address:

Departmental Appeals Board
Civil Remedies Division
Attention: Oliver Potts
Cohen Building, Room G-644
330 Independence Avenue, SW
Washington, D.C. 20201

A copy of the hearing request should be sent to:

Rufus Arther, Branch Chief
Hospital and Community Care Operations
Division of Survey and Certification
90 7th Street, Suite 5-300 (5W)
San Francisco, CA 94103-6707

Your request must identify the specific issues as well as the findings of fact and conclusions of law with which you disagree and explain your basis for contending that the findings and conclusions are incorrect. You will have an opportunity to present evidence and further argument at an in-person hearing, where you may be represented by counsel. Completion of the administrative review process established by 42 C.F.R. Part 498 is a prerequisite to obtaining judicial review.

We are coordinating this action with the Medicaid State Agency, which will take similar action under Title XIX of the Social Security Act.

Should you have any questions concerning this matter, please contact me at (415) 744-3682.

Sincerely,



Steven D. Chickering
Western Consortium Survey and Certification Officer
Division of Survey and Certification

Attachments - Forms CMS-2567
cc: CDPH, Medicaid Agency