STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	280119	A. BUILDING ______ B. WING ______	10/14/2011

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A 000	INITIAL COMMENTS An unannounced recertification survey was conducted at this hospital with on-site survey activity occurring August 22, 2011 through September 1, 2011 and with additional staff interviews occurring off-site through October 14, 2011. This survey resulted in Condition level non-compliance at 42CR 482.12 Governing Body; 42CFR 482.13 Patient Rights; 42CFR 482.21 Quality Assurance Performance Improvement; 42CFR 482.22 Medical Staff; 42CFR 482.23 Nursing Services; 42CFR 482.26 Radiologic Services; 42CFR 482.42 Infection Control; 42CFR 482.45 Organ, Tissue, Eye Procurement; 42CFR 482.55 Emergency Services. Refer to the CMS-2567 for regulatory citations.	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 Governing Body Bylaws, Governing Body meeting minutes, document review, credential file review, Medical Staff Bylaws, Rules, and Regulations review, QIO (Quality Improvement Organization) document review, medical record review, and staff interview, the facility failed to have a governing body that that effectively took responsibility for the institution. The facility identified a census of 2. Findings included:	A 043		

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

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 043	Continued From page 1	A 043		

-The governing body failed to be organized as one governing body for the facility. The Governing Body Bylaws states in part, "The Director, Aberdeen Area IHS [Indian Health Service] delegates authority and assigns responsibility for day-to-day governance, management, and operations to the Chief Executive Officer [CEO] and the Service Unit Governing Body." "Section 3.02 Authority Authority for governance is assumed variously by the Aberdeen Area Director, the Service Unit Executive Committee and the CEO of the Omaha/Winnebago P.H.S. [Public Health Service] Hospital as follows..." "Article IV. Meetings Section 4.01 Membership: The Area Director, Area Executive Officer, and Area Chief Medical Officer, or designees, will attend at least one Governing Body meeting per year and the Area Director will retain chairmanship for the meeting." Review of Governing Body meeting minutes from 6/8/10 through 8/15/11 lacked evidence of attendance by the Area Director, Area Executive Officer, or Area Chief Medical Officer. The Director of the Aberdeen office retains responsibility for the operation of the facility and show how this function is accomplished.

-The governing body failed to appoint members to the medical staff based on recommendations from the existing members of the medical staff prior to the individual providing patient care in the facility for 7 of 7 practitioners reviewed. (See A-46)

-The governing body failed to hold the medical staff accountable for the quality of care provided to patients in the facility. (See A-49)

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A 043	Continued From page 2 -The governing body failed to meet the emergency needs of it's patients in accordance with acceptable standards of practice. (See A-92) The cumulative effect of the systemic failure of the governing body to lead the hospital as a single governing body led to the failure in ensuring medical staff are appointed and held accountable to the governing body for the quality of care provided in the facility including the emergency department where this failure is exhibited as failure to meet the needs of emergent patients with qualified medical staff this led to the system failure of the governing body to effectively manage the facility to provide quality health care to the patients.	A 043		
A 046	482.12(a)(2) MEDICAL STAFF - APPOINTMENTS [The governing body must] appoint members of the medical staff after considering the recommendations of the existing members of the medical staff. This STANDARD is not met as evidenced by: Based on Governing Body Bylaws review, Governing Body meeting minutes review, document review, credential file review, and staff interview, the governing body failed to appoint members to the medical staff based on recommendations from the existing members of the medical staff prior to the individual providing patient care in the facility for 7 (Practitioner S,T, U, V, W, X, and the Clinical Director) of 7 practitioners reviewed. The facility identified a census of 2. Findings included:	A 046		

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A 046	Continued From page 3	A 046		

Review of Governing Body Bylaws with an effective date of 6/23/11 states in part, "Article III. Responsibility and Authority Section 3.01 Responsibilities ...G. Act on Medical Staff appointment and reappointment, granting of delineated clinical privileges recommended by the Clinical Director and the Medical Staff, (with the exception of temporary Clinical Privileges, which can be granted for a limited period of consecutive days by the Chief Executive Officer)." The Governing Body Bylaws fail to recognize they must be responsible for the appointment providers to the medical staff.

Review of Governing Body meeting minutes from June 8, 2010 through August 15, 2011 lack evidence of a review of recommendations for appointment to the medical staff.

Review of a credential flowchart provided by the facility fails to indicate the point in the process where medical staff reviews and approves the practitioner or where governing body reviews recommendations from the medical staff. The process indicates the Clinical Director will review and sign the credential file then the CEO (Chief Executive Officer) will review and sign the credential file then the CMO (Chief Medical Officer - housed at the area office) will review and sign, then the Area Director will review and sign only then is the credentialing process complete and the Provider notified.

Review of credential file for Physician S reveales a form titled Medical Privileges Request and Approval signed by the former Clinical Director (Physician W) on 3/7/11, the CEO on 3/11/11, the CMO on 8/1/11, and the Area Director on 8/1/11.

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A 046	Continued From page 4	A 046		

There were 146 days between when the former Clinical Director signed the form and when the Area Director signed the form. A letter sent to Physician S on 3/7/11 indicates the Medical Staff Executive Committee granted temporary privileges for 120 days. There is no evidence that there is a letter notifying Physician S he received full privileges or the category of those privileges.

Review of Medical Staff meeting minutes showed Physician S received their recommendation for privileges on 5/25/11.

Review of the Governing Body meeting minutes lacked evidence of consideration or approval of the Medical Staff recommendation for privileges for Physician S.

Review of credential file for Physician T revealed a form titled Medical Privileges Request and Approval signed by the Acting Clinical Director (Physician Z) on 4/7/11 and the CEO on 4/11/11. The form lacks the signature of the CMO or the Area Director. A letter sent to Physician T on 4/12/11 indicates the Medical Staff Executive Committee granted temporary privileges for 120 days. Information provided by the facility indicates Physician T began practicing at the facility on 4/11/11. There is no evidence that there is a letter notifying Physician S he received full privileges or the category of those privileges.

Review of Medical Staff meeting minutes shows Physician T received their recommendation for privileges on 5/25/11.

Review of the Governing Body meeting minutes lacks evidence of consideration or approval of the Medical Staff recommendation for privileges for

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A 046	Continued From page 5	A 046		

Physician T.

Review of credential file for Practitioner U reveals a form titled Medical Privileges Request and Approval signed by the former Clinical Director (Physician W) on 8/31/10, the CEO on 10/13/10, the CMO on 10/20/10, and the Area Director on 10/20/10.

Review of Medical Staff Executive meeting minutes shows Provider U received their recommendation for privileges on 9/8/10.

Review of the Governing Body meeting minutes lacks evidence of consideration or approval of the Medical Staff recommendation for privileges for Practitioner U.

Review of credential file for Practitioner V reveals a form titled Medical Privileges Request and Approval signed by the former Clinical Director (Physician W) on 11/19/10, the CEO on 11/29/10, the CMO on 12/6/10, and the Area Director on 12/7/10.

Review of Medical Staff Executive meeting minutes shows Provider V received their recommendation for privileges 12/10. There is no day specified on the Medical Staff meeting minutes.

Review of the Governing Body meeting minutes lacks evidence of consideration or approval of the Medical Staff recommendation for privileges for Practitioner V.

Review of credential file for Physician W reveals a form titled Medical Privileges Request and

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A 046	Continued From page 6 Approval signed by the Acting Clinical Director (Physician Z) on 12/21/10, the CEO on 1/12/11, the CMO on 1/26/11, and the Area Director on 1/27/11. Review of Medical Staff Executive meeting minutes shows Physician W received their recommendation for privileges on 1/5/11. Review of the Governing Body meeting minutes lacks evidence of consideration or approval of the Medical Staff recommendation for privileges for Physician W. Review of the credential file for Physician X reveals a form titled Temporary Privilege Request and Approval signed by the Clinical Director and the CEO on 6/6/11. The form lacks the signature of the CMO or the Area Director. Information provided by the facility indicates Physician X began practicing at the facility on 5/29/11. Review of Medical Staff meeting minutes lacks evidence of review and recommendation of privileges for Physician X. Review of the Governing Body meeting minutes lacks evidence of consideration or approval of the Medical Staff recommendation for privileges for Physician X. Review of the credential file for the Clinical Director reveals a form titled Temporary Privilege Request and Approval signed by the previous Clinical Director (Physician W) and the CEO on 6/10/11. The form lacks the signature of the CMO or the Area Director. Information provided by the facility indicates the Clinical Director began practicing at the facility on 5/16/11.	A 046		

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A 046	Continued From page 7 Review of Medical Staff meeting minutes lacks evidence of review and recommendation of privileges for the current Clinical Director. Review of the Governing Body meeting minutes lacks evidence of consideration or approval of the Medical Staff recommendation for privileges for the Clinical Director. Interview with the Office of Medical Care Evaluation Director on 9/20/11 at 12:50 PM reveals that the expectation for hospitals within the Aberdeen Area Office is to have credential files reviewed through the Medical Staff and Governing Body prior to appointment.	A 046		
A 048	482.12(a)(4) MEDICAL STAFF - BYLAWS AND RULES [The governing body must] approve medical staff bylaws and other medical staff rules and regulations. This STANDARD is not met as evidenced by: Based on Medical Staff Bylaws, Rules, and Regulations review, Governing Body meeting minutes review, and staff interviews, the facility failed to ensure the Governing Body approved the Medical Staff Bylaws, Rules, and Regulations for the facility. The facility identified a census of 2. Findings included: Review of the Medical Staff Bylaws, Rules, and Regulations reveals a cover sheet indicating an effective date of FY (fiscal year) 2009 - 2011. The bottom of the page has the date 1/13/10 page 1 of 49. The second page of the Medical	A 048		

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A 048	Continued From page 8 Staff Bylaws, Rules and Regulations revealed a signature page with signatures of various providers and the former CEO (chief executive officer) with dates of 11/09 and 12/09. The bottom of this page is dated 11/21/09 with a page number of 2 of 47. The remainder of the document contains pages consecutively number from 3 to 49 with a date of 1/13/10 on each page. The signature page contains the following statement at the top, "These Bylaws and Rules and Regulations are hereby recommended by the active Medical Staff of the United States Public Health Service, Winnebago Indian Health Service Facility and shall become effective upon the approval of the Aberdeen Area Governing Body". No member of the Aberdeen Area Governing Body has signed the page. Review of Governing Body meeting minutes dated 7/8/10 states in part, Agenda item #8 "Medical Staff By-laws [Staff B] will bring back with final changes". There is no evidence the Governing Body approved the Medical Staff Bylaws, Rules, and Regulations. Interview with the Improving Operation Performance/Risk Manager (IOP/RM) on 9/16/11 at 2:17 PM revealed there is no documentation in the Medical Staff meeting minutes or the Governing Body meeting minutes approving the Medical Staff Bylaws, Rules, and Regulation.	A 048		
A 049	482.12(a)(5) MEDICAL STAFF - ACCOUNTABILITY [The governing body must] ensure that the medical staff is accountable to the governing body for the quality of care provided to patients.	A 049		

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A 049	Continued From page 9	A 049		

This STANDARD is not met as evidenced by:
Based on Governing Body Bylaws review, Governing Body minutes review, and staff interview, the governing body failed to hold the medical staff accountable for the quality of care provided to patients in the facility. The facility identified a census of 2.

Findings included:

Review of the Governing Body Bylaws revised 6/23/11 and not signed by the Area Director who is the Chairman of the governing body lacks evidence of holding the medical staff accountable for the quality of care in the hospital as a function of the governing body.

Review of Governing Body meeting minutes from 6/8/10 through 8/15/11 lacks evidence that the medical staff informs the governing body about the quality of care provided to patients, any issues with that care, or any interventions to improve the quality of care provided to patients.

Interview with the current Clinical Director on 9/19/11 at 4:40 PM reveals the medical staff evaluation of provider quality of care was vague in the past. The Clinical Director identified a need for a more analytical review of the quality of care provided to patients and worked on a new form and process. There is not a written protocol for the process and forms have only been developed for outpatient clinic and emergency service review at the present time.

Interview with the former Clinical Director on 10/3/11 at 1:07 PM reveals there is not a process to bring medical records to the attention of the medical staff if there is a concern regarding the

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A 049 — Continued From page 10

quality of care.

A 057 — 482.12(b) CHIEF EXECUTIVE OFFICER

The governing body must appoint a chief executive officer who is responsible for managing the hospital.

This STANDARD is not met as evidenced by:
Based on Governing Body Bylaws review, Governing Body meeting minutes review, and staff interview, the governing body failed to appoint a single chief executive officer to assume responsibility for managing the facility. The facility identified a census of 2.

Findings included:

Review of Governing Body Bylaws states in part, The Director, Aberdeen Area IHS [Indian Health Service] delegates authority and assigns responsibility for day-to-day governance, management, and operations to the Chief Executive Officer and the Service Unit Governing Body." This statement does not denote that there is a single Chief Executive Officer (CEO) responsible for the operation of the hospital but implies that the Service Unit Governing Body shares in the responsibility.

Review of Governing Body meeting minutes from 6/8/10 through 8/15/11 lacks evidence of the current CEO receiving appointment to the position.

Interview with the Improving Operation Performance/Risk Manager (IOP/RM) on 8/30/11 at 12:25 PM confirms there is no documentation of the Governing Body approving the current CEO

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A 057	Continued From page 11 to manage the facility.	A 057		
A 092	482.12(f)(1) EMERGENCY SERVICES If emergency services are provided at the hospital, the hospital must comply with the requirements of §482.55. This STANDARD is not met as evidenced by: Based on Medical Staff Bylaws, Rules, and Regulations review, QIO (Quality Improvement Organization) document review, medical record review, credential file review, and staff interview, the facility failed to meet the emergency needs of it's patients in accordance with acceptable standards of practice. The facility identified a census of 2. Findings included: -The facility failed to ensure there was a qualified director of the emergency department by experience or training. (See A-1102) -The facility failed to ensure that medical staff providing care in the emergency department were knowledgeable to meet the needs of the community for emergent situations. (See A-1112)	A 092		
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 Governing Body Bylaws review, Medical Staff Bylaws, Rules, and Regulations review, policy review, medical record review, incident report review, and staff interview, the facility failed to protect patient rights by having an	A 115		

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A 115	Continued From page 12 effective system to review and resolve grievances, provide care in a safe setting, and report abusive situations and protect the patient while the incident is investigated. The facility identified a census of 2. Findings included: - The facility failed to have a system in place that reviewed and resolved patient grievances or a system to ensure staff informed patients of the steps taken to resolve their grievances and the outcome of the process. (See A-118, A-119, and A-123) - The facility failed to assess patients and provide patient care in a safe setting in the inpatient unit or the emergency department. (See A-144) - The facility failed to identify potential abuse, notify appropriate authorities, and protect the patient from the potential for further abuse. (See A-145) The cumulative effect of the systemic failure of the facility to provide an effective grievance process, provide a safe environment for patient care in the inpatient area and emergency department, and to report and protect patients from abuse during the ensuing investigation led to the system failure of the facility to protect and promote patients' rights within the facility.	A 115		
A 118	482.13(a)(2) PATIENT RIGHTS: 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.	A 118		

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A 118	Continued From page 13	A 118		

This STANDARD is not met as evidenced by:
Based on policy review, submitted patient grievances review, and staff interview, the facility failed to ensure there was a process for the prompt resolution of patient grievance defined by policy. The facility further failed to ensure the phone number to contact CMS (Centers for Medicaid and Medicare) was correct on patient brochures. The facility identified a census of 2.

Findings included:

Review of policy titled, "Patient Grievance Policy" with a signature by the CEO (Chief Executive Officer) as the Chairman of the Governing Body as the final approval of the policy on 6/23/11, states in part, "Resolving, Withdrawing and Terminating a grievance A. The patient and/or family member may withdraw a complaint at any time. B. The Winnebago Hospital personnel may terminate the complaint as follows: 1. When the complaint or concern has been totally and successfully resolved. 2. When all reasonable efforts for resolution have failed and the patient and/or family member have been appropriately notified. 3. When the patient and /or family member does not wish to pursue the complaint. 4. When reasonable efforts have been made to contact the patient and/or family member, without success (i.e., three telephone calls to the individual, a letter sent to the individual with no response, etc.). 5. When the complaint is not justified." The policy failed to clearly demonstrate that resolution of a grievance ends when the patient is satisfied with the actions taken on their behalf.

Review of submitted patient grievances reveals the utilization of two forms. The first form titled,

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A 118	Continued From page 14 Formal Investigation Form, has a place for the supervisor and the grievance committee to document if the complaint was valid or not. There was not a place on the form to document steps taken to resolve the patients complaint. Review of 4 of 4 (#6, #8, #41, and #42) of these formal investigations lacked documentation of a resolution to the incident. The second form titled, Winnebago Verbal Complaint Form Patient Care Issues", contained an area for resolution. Review of 6 of 6 (#35, #36, #37, #38, #39, and #40) of these verbal complaints lacks an actual resolution to the patient's concern. Three of the 6 indicate a written complaint would be filed. Interview with the Improving Operation Performance/Risk Manager on 8/30/11 at 12:30 PM reveals the nursing supervisors as well as some providers insist on having a written complaint from the patient before they will investigate a complaint.	A 118		
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 Governing Body Bylaws review, policy review, patient grievances review, and staff interview, the governing body failed to delegate the responsibility to resolve patient grievances to	A 119		

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the grievance committee and ensure staff resolved grievances to patient satisfaction. The facility identified a census of 2.

Findings included:

Review of the Governing Body Bylaws with a revision date of 6/23/11 states in part, "3.02 Authority D. Grievance committee: Will review all written grievance and make decision on validation of each grievance. The committee members are IOP [Improving Operation Performance] Director, Risk Manger/IOP assistant, Compliance officer, and Human Resources. This committee will report all findings to the CEO [Chief Executive Officer]." This statement does not delegate the authority for the responsibility of the effective operation of the grievance process or the responsibility to resolve grievances.

Review of policy titled, "Patient Grievance Policy" with a signature by the CEO as the Chairman of the Governing Body as the final approval of the policy on 6/23/11, states in part, "V. Responsibilities A. Grievance committee will review all grievance investigations, verbal complaints and patient issues, they will then validate the grievances and submit findings to the CEO, department head and supervisor."

Interview with the IOP/Risk Manager (RM) on 10/14/11 at 11:46 AM confirms the Grievance Committee reviews the investigation done by the department head and validates their findings as to where the complaint is valid or not. The Grievance Committee does not discuss how to prevent the issue from happening again or how to resolve the complaint for the patient.

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A 123	482.13(a)(2)(iii) PATIENT RIGHTS: NOTICE OF GRIEVANCE DECISION At a minimum: In its resolution of the grievance, the hospital must provide the patient with written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion. This STANDARD is not met as evidenced by: Based on policy review, patient grievances review, and staff interview, the facility failed to inform patients in writing of the steps taken to investigate the grievance, the results of the grievance process, and the date of completion of the investigation. The facility identified a census of 2. Findings included: Review of policy titled, "Patient Grievance Policy" with a signature by the CEO [Chief Executive Officer] as the Chairman of the Governing Body as the final approval of the policy on 6/23/11, states in part, "Grievance Investigation: ...F. The CEO will develop the final conclusion letter to the patient." The policy failed to outline the specific information to be contained in the notice to the patient. Review of 6 of 6 (#35, #36, #37, #38, #39, and #40) Winnebago Verbal complaint Forms lacks evidence a letter has been sent to the patient acknowledging the complaint or any attempts to resolve the complaint.. Interview on 8/30/11 at 3:00 PM with the	A 123		

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A 123	Continued From page 17 Improving Operation Performance/Risk Manager (IOP/RM) confirmed no preliminary letter has been sent to any of the 6 patients with verbal complaints. Two of the 6 (#35 and #36) fell outside the 30 day completion time frame and had no letter regarding the resolution. Review of 2 of 2 (#42 and #43) complaint investigations lacks evidence the facility sent a letter to the complainant regarding the steps taken to investigate the grievance, the results of the grievance process, or the completion date of the investigation. Interview on 8/30/11 at 3:00 PM with the IOP/RM confirmed no letter had been sent to patients #42 and #43 regarding the steps taken to investigate a grievance, the results of the grievance process, or the completion date of the investigation because the investigation had not been completed within the 30 day timeframe. Review of 4 of 4 (#6, #8, #41, and #44) letters written to patients following a grievance investigation lacks evidence of the patient being informed of the steps taken to investigate the grievance, the results of the grievance process, or the completion date of the investigation.	A 123		
A 144	482.13(c)(2) PATIENT RIGHTS: CARE IN SAFE SETTING The patient has the right to receive care in a safe setting. This STANDARD is not met as evidenced by: Based on medical record review, policy review, incident report review, Medical Staff Bylaws, Rules, and Regulations review, and staff	A 144		

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A 144	Continued From page 18 interview, the facility failed to ensure nursing staff provided care in a safe setting for 6 of 32 (#1, #7, #22, #32, #33, and #45) patients reviewed due to the failure to assess and provide appropriate interventions. The facility identified a census of 2. Findings included: See A-395 See A-1100	A 144		
A 145	482.13(c)(3) PATIENT RIGHTS: FREE FROM ABUSE/HARASSMENT The patient has the right to be free from all forms of abuse or harassment. This STANDARD is not met as evidenced by: Based on medical record review, policy review, and staff interview, the facility failed to ensure nursing staff evaluated 1 of 32 (#45) patient reviewed for abuse by her mother and took action to separate the patient from the potential abuser to protect her. The facility identified a census of 2. Findings included: Review of medical record for Patient #45, 15 years old, admitted to the medical surgical unit with a diagnosis of suicidal ideations and superficial skin lacerations on 9/28/11. Further review of the medical record shows Patient #45 presented to the emergency room with police with complaints she would hurt herself if she had to go back to her mom's house tonight. ...Relates that she has been thinking about suicide lately but that today is the first time she has said anything out loud. Denies having a plan to commit suicide."	A 145		

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A 145	Continued From page 19 The medical record indicates Patient #45 reports that her mother hit her with a toilet brush and scratched her left arm and leg. Patient #45's mother acknowledged throwing a toilet brush at Patient #45. Physical examination shows Patient #45 had 2 superficial scratches approximately 3 cm to the left upper arm and 1 superficial scratch to left lower arm approximately 3 cm. There are also 2 moon shaped superficial scratches to lateral aspect left arm below the elbow. The medical record indicates staff transferred Patient #45 to the medical surgical unit on 9/28/11 at 10:00 PM. Review of the medical record reveals a nursing pediatric admission form completed 9/29/11 at 3:11 AM. Patient #45 answered 'yes' to the question "Has your partner or someone important to you ever hurt you?". Patient #45 answered 'yes' to the question "Are you concerned about your safety or the safety of anyone in your family?". The medical record lacks any probes related to these questions to determine potential abuse especially in light of reports of being struck by her mother. The nursing pediatric admission form questions if the patient has any safety needs which is answered 'yes' with only a statement "suicide precautions". The nurse failed to assess the patient's need for safety from her mother. The mother is present with patient in room unsupervised throughout the night. The patient had reported earlier that her mother had struck her with a toilet brush and did not want to return home with her. This was the precipitating cause of wishing to harm self. The medical record states, "Pt is placed in room 309, which is directly across [from] the nurses' station. Mother plans to stay with pt throughout the night; hourly checks to be performed." Documentation in the medical record reveals hourly checks on 9/28/11 at 10:00 PM and 11:00 PM, on 9/29/11 at	A 145		

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12:10 AM, 2:15 AM, 3:20 AM, 4:20 AM, 5:35 AM, and 6:38 AM. There is no documentation of an hourly check at 1:00 AM; nursing staff failed to monitor Patient #45 for over 2 hours. Documentation on 9/29/11 at 7:45 AM states, "Pt mother present in the room, sleeping in the bed window. Pt has no concerns at this time other than the room being cold. Nurse leaves pt door open as it was closed when arriving to floor at 7:00 AM." Placing Patient #45 in a room across from the nurses' station is ineffective if the door is closed. The nursing staff failed to assess Patient #45 for abuse by her mother and to protect the patient by allowing the mother to remain in the room with the patient.

Review of policy titled, "Abuse and Neglect Policy" signed as being approved 6/23/11 states in part, "IV. Procedures The following criteria may be used to assist in the identification of abuse: A. Physical Abuse - Willful infliction of injury, unreasonable confinement or cruel punishment: a. Scratches, cuts, bruises, or burns..."
The policy further states, "IV. Procedures E. Management of Suspected Abuse/Neglect:
-c. As all staff are Mandatory Reporters in the Omaha/Winnebago PHS [Public Health Service] Hospital, all cases of suspected abuse/neglect must be reported to direct supervisor, security, and local/state/federal authorities.
-d. Any person (including an employee, volunteer or other person) associated with the Omaha/Winnebago PHS Hospital, who reasonably believes or who know of information that would reasonably cause a person to believe that the physical or mental health or welfare of a patient of the hospital, who is receiving medical services, has been, is or will be adversely

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affected by abuse or neglect by any person shall, as soon as possible, report the information supporting the belief to local/tribal/state department of Protective Services, or the Centers for Medicare and Medicaid Services (CMS) and/or Joint Commission, by telephone or in writing.
e. When domestic violence has occurred, always notify law enforcement officials, even if the patient does not want to press charges.
f. A healthcare provider who fails to report suspected abuse and/or neglect shall be referred to the individual's licensing board for appropriate disciplinary action."

Interview with the DON on 10/14/11 at 11:54 AM revealed when abuse is suspected nurses should report to social services and child protective services and not leave the suspected abuser in the room with the patient.

A 214 482.13(g) PATIENT RIGHTS: SECLUSION OR RESTRAINT A 214

Death Reporting Requirements: Hospitals must report deaths associated with the use of seclusion or restraint.

(1) The hospital must report the following information to CMS:

Each death that occurs while a patient is in restraint or seclusion.

Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion.

Each death known to the hospital that occurs

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within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death. "Reasonable to assume" in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing or asphyxiation.

(2) Each death referenced in this paragraph must be reported to CMS by telephone no later than the close of business the next business day following knowledge of the patient ' s death.

(3) Staff must document in the patient's medical record the date and time the death was reported to CMS.

This STANDARD is not met as evidenced by:
Based on policy review and staff interview, the facility failed to ensure the restraint policy included a system to notify the Centers for Medicare and Medicaid (CMS) Regional Office of any patient death that is associated with the use of restraint or seclusion. The facility census was 2.

Findings included:

Review of the hospital policy titled, "Restraint Policy - Nursing Procedure", revised 12/10 and 4/11, failed to show the hospital had a system in place to report the following information to the CMS Regional Office:
-Each patient death that occurs while the patient is in restraint or seclusion;
-Each patient death that occurs within 24 hours after the patient has been removed from restraint

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A 214	Continued From page 23 or seclusion; -Each patient death known to the hospital that occurs within one week after restraint or seclusion where it is reasonable to assume that the use of restraint or seclusion contributed directly or indirectly to the patient's death. During an interview on 8/24/11 at 1:15 PM, the Improving Operations Performance/Risk Management Director said the restraint policy is all they have related to restraints. She said if there is nothing in the policy related to restraint death reporting to CMS then there is no other policy.	A 214		
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. This CONDITION is not met as evidenced by: Based on Performance Improvement/Quality Assurance Plan review, quality assurance monitors review, Improving Operations Performance (IOP) meeting minutes review, and	A 263		

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staff interviews, the facility failed to develop and maintain a data driven quality assurance program that collected and analyzed data then implemented interventions, and monitored and maintained the success of those interventions with oversight by the Governing Body, Medical Staff, and administrative officials. The facility identified a census of 2.

Findings included:

-The facility failed to identify the scope of the program through measurable improvement that will improve health outcomes or prevent medical errors by measuring, analyzing, and tracking quality indicators. (See A-264)

-The facility failed to structure data collected in a method to monitor safety and quality of services or use the data to identify opportunities for change. The Governing Body failed to identify the frequency and detail of data collection. (See A-273)

-The facility failed to utilize data in the identified manner by the Plan to develop a system to analyze the data and enact preventive actions. This prevents the facility from being able to monitor any successful implementation of interventions and ensure that the success is maintained. (See A-283)

-The governing body, medical staff, and administrative officials failed to ensure the facility had a system in place for an ongoing, defined, implemented, and maintained program of quality improvement. (See A-309)

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A 263	Continued From page 25 The cumulative effect of the facility, Governing Body, Medical Staff, and administrative officials failure to develop and maintain a data driven quality assurance program that collected and analyzed data then implemented interventions, and monitor and maintain the success of those interventions to improve patient outcomes resulted a systemic failure of the Quality Improvement program for the facility.	A 263		
A 264	482.21(a) QAPI PROGRAM SCOPE Standard: Program Scope This STANDARD is not met as evidenced by: Based on Performance Improvement/Quality Assurance Plan review, quality assurance monitors review, Improving Operations Performance (IOP) meeting minutes review, and staff interviews, the facility failed to identify the scope of the program through measurable improvement that will improve health outcomes or prevent medical errors by measuring, analyzing, and tracking quality indicators. The facility identified a census of 2. Findings included: Review of the 2011 Performance Improvement/Quality Assurance Plan dated 5/9/11 states in part, "IV> Scope: As part of the Performance Improvement/Quality Assurance Program, the Omaha/Winnebago P.H.S. [Public Health Service] Hospital has identified its scope of care to include all services that may have a direct or indirect impact on patient care. ....The dimensions of performance of patient care and and quality control activities in the following service are monitored, assessed and evaluated.	A 264		

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All data and reports are provided by staffs that are in the departments and as needed chart or data reviews will be done by Performance Improvement/Quality Assurance Staff." The Performance Improvement/Quality Assurance Plan further states in part, "5. Performance Improvement Methodology (duties performed by IOP Team) The Omaha/Winnebago P.H.S. Hospital uses the PDCA (Plan-Do-Check-Act) format to facilitate performance improvement activities provided by performance improvement/quality assurance team. ...Plan: a) Identify current processes, outputs, customers, expectations b) Identify root causes c) Focus on improvement opportunity d) Identify what data is needed, how you will measure and analyze e) Generate improvement list and choose solutions.

Review of monitors provided by the facility including but not limited to inpatient nursing unit, outpatient nursing unit, emergency department, radiology, laboratory, and pharmacy were essentially data collection tools. The format did not identify the root cause of the identified concern nor did it identify how the concern will be measured and analyzed. The monitor did not contain solutions specific to a root cause identified for the concern.

Review of the IOP meeting minutes provided by the facility from 6/30/10 through 7/28/11 lacks evidence of staff reporting quality data and analysis related to quality improvement projects to the committee.

Interview with the IOP/Risk Manager (RM) on 9/28/11 at 12:25 PM shows that none of the monitors will have a root cause analysis. Staff have not delved into the root cause of the

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A 264	Continued From page 27 identified concerns. Staff identified concerns with the quality improvement program in January and have been working to fix it.	A 264		
A 273	482.21(b) QAPI PROGRAM DATA Standard: Program Data This STANDARD is not met as evidenced by: Based on Performance Improvement/Quality Assurance Plan review, quality assurance monitors review, Improving Operations Performance (IOP) meeting minutes review, Governing Body meeting minutes review, medical record review, root cause analysis review, and staff interviews, the facility failed to structure data collected in a method to monitor safety and quality of services or use the data to identify opportunities for change. The Governing Body failed to identify the frequency and detail of data collection. The facility identified a census of 2. Findings included: Review of the 2011 Performance Improvement/Quality Assurance Plan dated 5/9/11 states in part, "3. Periodic Assessment and Improvement The PDCA [Plan-Do-Check-Act] process for systematic collection of data needed to design and assess new process, or redesign existing processes is outlined below in the Organization Performance Improvement/Quality Assurance Plan." ..."5. Performance Improvement Methodology (duties performed by IOP Team) The Omaha/Winnebago P.H.S. [Public Health Service] Hospital uses the PDCA (Plan-Do-Check-Act) format to facilitate performance improvement activities provided by	A 273		

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performance improvement/quality assurance team. ...Plan: a) Identify current processes, outputs, customers, expectations b) Identify root causes c) Focus on improvement opportunity d) Identify what data is needed, how you will measure and analyze e) Generate improvement list and choose solutions.

Review of monitors provided by the facility including but not limited to inpatient nursing unit, outpatient nursing unit, emergency department, radiology, laboratory, and pharmacy were essentially data collection tools. The format did not identify the root cause of the identified concern nor did it identify how the concern will be measured and analyzed. The monitor did not contain solutions specific to a root cause identified for the concern. Without enacting the steps set forth in the 2011 Performance Improvement/Quality Assurance Plan for developing a plan, the facility failed to provide the structure needed to monitor services and identify opportunities for improvement.

Review of the IOP meeting minutes provided by the facility from 6/30/10 through 7/28/11 lacks evidence of staff reporting quality data and analysis related to quality improvement projects to the committee.

Review of Governing Body meeting minutes provided by the facility from 6/8/10 to 8/15/11 lacks evidence of specifying the frequency or detail of data collection for the quality program.

Further review of the 2011 Performance Improvement/Quality Assurance Plan lacks evidence of the frequency or detail of data collection for the quality program, however; the

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Plan states in part, "The Improving Organization Performance Director will keep a list of the current indications being measured throughout the facility."

Interview with the IOP/Risk Manager (RM) on 9/28/11 at 12:25 PM shows that none of the monitors will have a root cause analysis. Staff have not delved into the root cause of the identified concerns. There is confusion as to who does the analysis of the monitors. The nursing staff believe they collect the data and it is the physician's responsibility to analyze it. There won't be any analysis of the data in the monitors. Area sent out the templates to structure data collection but there is no plan for reporting. Governing Body has not specified the frequency and detail of data collection. Staff identified concerns with the quality improvement program in January and have been working to fix it.

Review of medical record for Patient #1 identified concerns with documentation, patient assessment, and communication between nursing staff and providers regarding patient condition. See A-395.

The facility requested a root cause analysis of Patient #1's medical record by the Area Chief Medical Officer (CMO). This request was initiated on 6/2/11. Patient #1 died on 4/9/11. The CMO completed the root cause analysis and returned it to the facility on 8/2/11 with recommendations. Interview with the Director of Nursing (DON) on 8/31/11 at 1:30 PM reveals she was unaware that the CMO returned the root cause analysis to the facility. There is no documentation of any of the risk reduction strategies that have been implemented.

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Interview with the IOP/RM on 8/31/11 at 2:10 PM reveals the Day and Evening Nursing Supervisors for the Medical Surgical unit were working on training for the nursing staff, but have not gotten back to the IOP/RM regarding the training.

A 283 — 482.21(c) QAPI PROGRAM ACTIVITIES — A 283

Standard: Program Activities

This STANDARD is not met as evidenced by:
Based on Performance Improvement/Quality Assurance Plan review, quality assurance monitors review, Improving Operations Performance (IOP) meeting minutes review, and staff interviews, the facility failed to utilize data in the identified manner by the Plan to develop a system to analyze the data and enact preventive actions. This prevents the facility from being able to monitor any successful implementation of interventions and ensure that the success is maintained. The facility identified a census of 2.

Findings included:

Review of the 2011 Performance Improvement/Quality Assurance Plan dated 5/9/11 states in part, "3. Periodic Assessment and Improvement The PDCA [Plan-Do-Check-Act] process for systematic collection of data needed to design and assess new process, or redesign existing processes is outlined below in the Organization Performance Improvement/Quality Assurance Plan." ..."5. Performance Improvement Methodology (duties performed by IOP Team) The Omaha/Winnebago P.H.S. [Public Health Service] Hospital uses the PDCA

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(Plan-Do-Check-Act) format to facilitate performance improvement activities provided by performance improvement/quality assurance team. ...Plan: a) Identify current processes, outputs, customers, expectations b) Identify root causes c) Focus on improvement opportunity d) Identify what data is needed, how you will measure and analyze e) Generate improvement list and choose solutions.

Review of monitors provided by the facility including but not limited to inpatient nursing unit, outpatient nursing unit, emergency department, radiology, laboratory, and pharmacy were essentially data collection tools. The format did not identify the root cause of the identified concern nor did it identify how the concern will be measured and analyzed. The monitor did not contain solutions specific to a root cause identified for the concern. Without enacting the steps set forth in the 2011 Performance Improvement/Quality Assurance Plan for developing a plan, the facility failed to provide the structure needed to monitor services and identify opportunities for improvement. The failure to identify opportunities for improvement prevents the facility from implementing the next steps in the PDCA model of Do-Check-Act.

Review of the IOP meeting minutes provided by the facility from 6/30/10 through 7/28/11 lacks evidence of staff reporting quality data and analysis related to quality improvement projects to the committee.

Interview with the IOP/Risk Manager (RM) on 9/28/11 at 12:25 PM shows there won't be any analysis of the data in the monitors. Staff at the facility don't know how to analyze and trend data.

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A 283	Continued From page 32 Staff identified concerns with the quality improvement program in January and have been working to fix it.	A 283		
A 309	482.21(e) EXECUTIVE RESPONSIBILITIES The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following: This STANDARD is not met as evidenced by: Based on Performance Improvement/Quality Assurance Plan review, quality assurance monitors review, Medical Staff meeting minutes review, Governing Body meeting minutes review, and staff interviews, the governing body, medical staff, and administrative officials failed to ensure the facility had a system in place for an ongoing, defined, implemented, and maintained program of quality improvement. The facility identified a census of 2. Findings included: Review of the 2011 Performance Improvement/Quality Assurance Plan dated 5/9/11 states in part, "III. Authority ...The organization's leaders include members of the Governing Body, Chief Executive Officer, Administrative Officer, Clinical Director, Director of Nursing, Performance Improvement Coordinator, and all Department Heads. ...The organization leaders are responsible for overseeing the design of the organization's approach to improving quality and ensuring that this approach is carried out."	A 309		

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Review of monitors provided by the facility including but not limited to inpatient nursing unit, outpatient nursing unit, emergency department, radiology, laboratory, and pharmacy were essentially data collection tools. The format did not identify the root cause of the identified concern nor did it identify how the concern will be measured and analyzed. The monitor did not contain solutions specific to a root cause identified for the concern. Without enacting the steps set forth in the 2011 Performance Improvement/Quality Assurance Plan for developing a plan, the facility failed to provide the structure needed to monitor services and identify opportunities for improvement.

Review of Medical Staff meeting minutes, including the Medical Staff Executive Committee meeting minutes, provided by the facility from 10/13/10 to 5/25/11 lacks evidence of involvement in the quality assurance process through out the facility other than Morbidity/Mortality, Utilization, code Blue Reviews, Pathology Reporting, and Webcident/Complaints. This does not demonstrate responsibility for the ongoing quality program of the facility.

Review of Governing Body meeting minutes provided by the facility from 6/8/10 to 8/15/11 lacks evidence of responsibility for the ongoing quality program of the facility.

Further review of the 2011 Performance Improvement/Quality Assurance Plan lacks evidence of the frequency or detail of data collection for the quality program; however, the Plan states in part, "The Improving Organization

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A 309	Continued From page 34 Performance Director will keep a list of the current indications being measured throughout the facility." Interview with the IOP/Risk Manager (RM) on 9/28/11 at 12:25 PM shows no quality monitors or results have been reported to the Medical Staff or Governing Body because no monitors have been analyzed so there is nothing to offer. Staff identified concerns with the quality improvement program in January and have been working to fix it.	A 309		
A 338	482.22 MEDICAL STAFF 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 Medical Staff Bylaws, Rules, and Regulations review, Medical Staff meeting minutes review, Governing Body meeting minutes review, credential file review, and staff interviews, the facility failed to ensure the Medical Staff operated as described by the bylaws to ensure the quality of care provided to the patients in the facility. The facility identified a census of 2. Findings included: -The facility failed to ensure the Medical Staff conducted periodic objective reviews in a systematic manner to ensure the quality of care in the facility. (See A-340) -The facility failed to ensure the Medical Staff	A 338		

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A 338	Continued From page 35 reviewed the qualifications and competence of practitioners and made recommendations to the Governing Body for membership in the Medical Staff. (See A-341) -The facility failed to ensure that practitioners exercised only those privileges they were given by the Medical Staff following a review of their qualifications and competence. (See A-363) The cumulative effect of the facility's failure to ensure Medical Staff made recommendations to the Governing Body regarding the qualifications and competence of practitioners prior to their providing care in the facility, failure to review practitioners for ongoing quality of care, and failure to ensure practitioners did not perform procedures outside of their scope of practice within the facility resulted in a systemic failure of the Medical Staff to ensure the quality of care provided to patients in the facility.	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 Medical Staff Bylaws, Rules, and Regulations review, Medical Staff credential files review, document review, and staff interview, the facility failed to ensure the medical staff conducted periodic objective appraisals of its members. The facility identified a census of 2. Findings included:	A 340		

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Review of Medical Staff Bylaws, Rules, and Regulations lacks evidence of delineation of an objective process to evaluate the performance of medical staff members.

Interview with the Improving Operations Performance (IOP)/Risk Manager (RM) on 9/16/11 at 3:16 PM acknowledges the Medical Staff Bylaws fail to delineate a process to objectively review the performance of Medical Staff members. She further states that the Clinical Director has begun an appraisal process but indicates this process is not defined in writing at this time. The IOP/RM indicates the Clinical Director has a number of performance appraisals completed and that part of the process entails each provider reviewing a number of records for a peer.

Review of credential files for 4 (Z, W, V, and U) of 8 providers contains a document titled, "Re-Appointment Worksheet Medical Staff of Winnebago IHS (Indian Health Service) Hospital." This form documents reviews of the providers performance in several departments of the facility but lacks an objective review by a physician of the providers diagnosis and treatment of patients in the facility.

Interview with Physician W on 9/19/11 at 12:30 PM shows in the past the physicians had not done a good job of peer review. Physician W and Physician Z knew the providers and the quality of care they provided and would discuss this.
An e-mail provided by the Improving Operations Performance (IOP)/Risk Manager (RM) reveals the following information from the Clinical Director "the PEER Review process through 12/10 was a bit confusing and the PEER Review forms vague,

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so they were revised in 06/11 and distributed for first use in June 2011...".
The facility failed to provide documentation of the process now followed for a reappraisal of each providers qualifications and competency.

Interview with the Clinical Director and previous Clinical Director on 9/19/11 reveals that the peer review process is to review 5 random records per provider each month but that is probably too many and will be changed to each quarter. The physician assistants (PA) from the emergency department are reviewing all 72 hour returns as a quality improvement project. The Clinical Director believed that both chart reviews could be utilized in the peer review process. The Clinical Director acknowledges that a PA does not have the expertise to evaluate the competence of a physician. And that physician cases reviewed by the PA would either have to be reviewed by a physician or thrown out for peer review. The Clinical Director further acknowledged that the review forms provided were for outpatient and emergency services. At this time there is not a form to review the quality of treatment providers provide to inpatients.

Review of medical record for patient #32 shows the patient presented to the emergency department on 12/30/10 at 9:15 AM complaining of hives and SOB (shortness of breath). Further review of the medical record shows Practitioner V ordered Epinephrine 1:1000 0.3 mg (milligrams) IV (intravenous) push once.

Review of a QIO (Quality Improvement Organization) review of the medical record for patient #32 on 6/16/11 shows there were concerns regarding the quality of care provided to

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the individual specifically the route of epinephrine was inappropriate. The appropriate route for 0.3 mg of epinephrine would be IM (intramuscular).

Review of the medical record for Patient #33 reveals she presented to the Outpatient Clinic for an appointment on 7/29/11 at 10:42 AM. During the course of the visit a Depression Screen was performed with Patient #33 answering yes to every question. The ambulatory care note for Patient #33 written by Physician W states in part, "Subjective: c/o [complained of] severely depressed, thoughts about hurting herself or her spouse, having crying spells, recently had interaction between cymbalta (antidepressant) and her zomig (for treatment of migraine headaches) (seretonegic syndrome and cymbalta dose was 60 mg [milligrams], we give her cymbalta 30 mg for one week, then discontinued, having some issues with her husband, told she is suicidal, can be placeed at [Hospital G] or [Hospital H] (close to her home), she needs to be evaluated by mental health and psychiatrist too. I will follow their recommendations, her blood sugar is ok, within normal range, needs refill of her hydrocodone (pain medication) and rest of her regular meds, told she needs placement first then will refill her pills, depression screen done by nurse showing she is severely depressed." The outpatient clinic record further states in part, "Plan Contacted tribal mental health supervisor who agreed with transfer plan, they will follow up her care as outpatient, and a referral is made to mental health, spoken to ER [emergency room] provider to transfer the patient to ER for placement, patient and her spouse taken to ER in stable condition."

Review of the ER medical record for Patient #33

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revealed Practitioner V documented a clinical course of contacting several police departments to obtain emergency protective custody. The medical record documents that Patient #33 is willing to be admitted for inpatient treatment. The medical record lacks documentation that Provider V contacted any hospital in an effort to place Patient #33 in a psychiatric unit for her severe depression and suicidal ideations.

Interview on 10/3/11 at 1:07 PM with Physician W reveals he did recall reviewing the medical record for Patient #32 and was aware there was an issue with the dosage of epinephrine given the patient on 12/30/10. Physician W confirms that Patient #33 was suicidal during the clinic visit with him on 7/29/11. He transferred Patient #33 to the emergency room per protocol so the patient could be transferred to the appropriate level of care. Physician W states he was unaware that Practitioner V had Patient #33 sign out Against Medical Advice (AMA) so she could go to another hospital. Physician W indicates that Practitioner V should not have done that and that he was available to help with the transfer but Practitioner V did not call.

Review of a complaint filed by Patient #33 on 8/5/11 indicates she felt she was forced to sign out AMA from the emergency department on 7/29/11

Further interview with Physician W on 10/3/11 at 1:07 PM reveals the concern regarding the care provided for Patient #32 and Patient #33 by Practitioner V was not reviewed and discussed in either the Medical Staff meeting or the Medical Staff Executive meeting to date. There is not a process developed yet to get medical records

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A 340	Continued From page 40 with concerns regarding the quality of care provided by a Provider to the medical staff for review in a timely manner.	A 340		
A 341	482.22(a)(2) MEDICAL STAFF CREDENTIALING The medical staff must examine credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidates. This STANDARD is not met as evidenced by: Based on Medical Staff Bylaws, Rules, and Regulations review, Medical Staff credential file review, Medical Staff meeting minutes review, and staff interview, the facility failed to ensure medical staff examined the credentials of candidates for medical staff membership and made recommendation for appointment to the Governing Body prior to the individual providing patient care in the facility for 3 (Practitioner T, X, and the Clinical Director) of 8 practitioners reviewed. The facility identified a census of 2. Findings included: Review of the Medical Staff Bylaws states in part, "Section 5.08 Temporary appointment and Privilege 1. May not exceed 120 days 2. May be granted by (The CEO [Chief Executive Officer] or designee) in the following circumstances: - a. To fulfill an important patient care need. The following must be obtained and primary source verified: - i. Current, valid, non-limited license from any state or territory of the United States, - ii. Relevant training and experience, - iii. Current competency as determined, - iv. Current NPDB/HIPDB [National Practitioner	A 341		

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Data Base/Healthcare Integrity and Protection Data Base] obtained and evaluated,
- v. Malpractice coverage for physicians who are not federal employees,
- vi. AMA[American Medical Association] Profile
b. When a complete application is awaiting review and approval by the medical executive committee and/or the governing body. 3. May only be granted if the applicant:
- a. has submitted a complete application,
- b. has no current or previously successful challenges to licensure or registration,
- c. has not been subject to involuntary termination of medical staff membership at another organization,
- d. has not been subject to involuntary limitation, reduction, denial or loss of clinical privileges,
- e. has no current federal sanctions.

Review of a credential flowchart provided by the facility fails to indicate the point in the process where medical staff reviews and approves the practitioner or where governing body reviews recommendations from the medical staff. The process indicates the Clinical Director will review and sign the credential file, then the CEO will review and sign the credential file, then the CMO (Chief Medical Officer - housed at the area office) will review and approve, then the Area Director will review and sign, only then is the credentialing process complete and the Provider notified.

Review of the credential file for the Clinical Director reveals a form titled Temporary Privilege Request and Approval signed by the previous Clinical Director (Physician W) and the CEO on 6/10/11. The form lacks the signature of the CMO or the Area Director. Information provided by the facility indicates the Clinical Director began

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practicing at the facility on 5/16/11. Review of Medical Staff meeting minutes lacks evidence of review and approval of the current Clinical Director.

Review of the credential file for Physician X reveals a form titled Temporary Privilege Request and Approval signed by the Clinical Director (see above) and the CEO on 6/6/11. The form lacks the signature of the CMO or the Area Director. Information provided by the facility indicates Physician X began practicing at the facility on 5/29/11. Review of Medical Staff meeting minutes lacks evidence of review and approval of Physician X.

Review of credential file for Physician T reveals a form titled Medical Privileges Request and Approval signed by the Acting Clinical Director (Physician Z) on 4/7/11 and the CEO on 4/11/11. The form lacks the signature of the CMO or the Area Director. A letter sent to Physician T on 4/12/11 indicates the Medical Staff Executive Committee granted temporary privileges for 120 days. Information provided by the facility indicates Physician T began practicing at the facility on 4/11/11. Interview on 9/19/11 at 12:30 PM with the Clinical Director and Physician W reveals both attested repeatedly that Medical Staff never reviewed and approved Physician T for full privileges at the facility. Review of Medical Staff meeting minutes dated 5/25/11 shows the Medical Staff approved full privileges for Physician T with Physician W making the motion to approve and the Clinical Director seconding. Further review of the credential file for Physician T reveals documentation of legal action in the states of Georgia and New Mexico enacting the revocation of licensure. New Mexico revoked

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Physician T's license on 1/10/85. Physician T voluntarily surrendered which the document further indicates has the same effect as revocation of the license on 9/11/84 in Georgia. The facility indicates the online search that obtained the legal documentation was conducted 5/31/11 following the 5/25/11 Medical Staff meeting. Interview on 9/19/11 at 12:30 PM with the Clinical Director and Physician W indicates that they would not have recommended Physician T for privileges had they known about the revocation of licensure in New Mexico and Georgia.

Interview with the Office of Medical Care Evaluation Director on 9/20/11 at 12:50 PM reveals that the expectation for hospitals within the Aberdeen Area Office is to have credential files reviewed through the Medical Staff and Governing Body prior to appointment.

A 354 482.22(c)(1) APPROVAL OF MEDICAL STAFF BYLAWS A 354

[The bylaws must:]

(1) Be approved by the governing body.

This STANDARD is not met as evidenced by:
Review of Medical Staff Bylaws, Rules, and Regulations review, Governing Body meeting minutes review, and staff interviews, the facility failed to ensure the Governing Body approved the Medical Staff Bylaws, Rules, and Regulations for the facility. The facility identified a census of 2.

Findings included:

Review of the Medical Staff Bylaws, Rules, and

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A 354	Continued From page 44 Regulations reveals a cover sheet indicating an effective date of FY (fiscal year) 2009 - 2011. The bottom of the page has the date 1/13/10 page 1 of 49. The second page of the Medical Staff Bylaws, Rules and Regulations reveals a signature page with signatures of various providers and the former CEO (chief executive officer) with dates of 11/09 and 12/09. The bottom of this page is dated 11/21/09 with a page number of 2 of 47. The remainder of the document contains pages consecutively numbered from 3 to 49 with a date of 1/13/10 on each page. The signature page contained the following statement at the top, "These Bylaws and Rules and Regulations are hereby recommended by the active Medical Staff of the United States Public Health Service, Winnebago Indian Health Service Facility and shall become effective upon the approval of the Aberdeen Area Governing Body". No member of the Aberdeen Area Governing Body has signed the page. Review of Governing Body meeting minutes dated 7/8/10 states in part, Agenda item #8 "Medical Staff By-laws [Staff B] will bring back with final changes". There is no evidence the Governing Body approved the Medical Staff Bylaws, Rules, and Regulations. Interview with the Improving Operation Performance/Risk Manager (IOP/RM) on 9/16/11 at 2:17 PM reveals there is no documentation in the Medical Staff meeting minutes or the Governing Body meeting minutes approving the Medical Staff Bylaws, Rules, and Regulation.	A 354		
A 363	482.22(c)(6) CRITERIA FOR MEDICAL STAFF PRIVILEGING	A 363		

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[The bylaws must:]

Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges. For distant-site physicians and practitioners requesting privileges to furnish telemedicine services under an agreement with the hospital, the criteria for determining privileges and the procedure for applying the criteria are also subject to the requirements in §482.12(a)(8) and (a)(9), and §482.22(a)(3) and (a)(4).

This STANDARD is not met as evidenced by:
Based on medical record review, credential file review, Medical Staff Bylaws, Rules, and Regulations review, and staff interview, the facility failed to ensure to 2 of 8 practitioners (Practitioner S and Practitioner T) exercised only the privileges granted by the Governing Body in accordance with meeting criteria established through the Medical Staff. The facility identified a census of 2.

Findings included:

Review of Medical Staff Bylaws, Rules, and Regulations dated FY (fiscal year) 2009-2011, states for all categories of Medical Staff membership including Active, Courtesy, and Provisional that the practitioner will exercise approved clinical privileges.

Review of medical record for Patient #22, dated 8/18/11 at 10:30 PM, Practitioner T completed the suture process for reattaching the tip of the

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second finger of the right hand.

Review of the medical record for Patient #22 dated 8/21/11 at 8:39 PM reveals Practitioner T states in the History of Present Illness, "70 yr [year] male here for 3rd recheck of right index finger. Patient had a traumatic amputation of half of the distal phalanx at home on the 17 th, and I reattached it here in the ED [emergency department] within an hour. (I advised him that most orthopedic physicians would not "bother" with a distal phalanx but I have had success with 4 out of 5 of my previous attempts in local EDs.) He has been coming by the ED nightly for unofficial rechecks....He came back tonight for the recheck and the reattached part is black and has some odiferous debris>>> after confirming he has BC/BS [Blue Cross/Blue Shield] insurance which can be used as a primary, I advised him we would make a referral for him to be seen in the morning but that I needed to remove the distal fragment tonight."

Review of the credential file for Practitioner T reveals Medical Privileges form signed by the Acting Clinical Director (Physician Z) on 4/7/11 and by the CEO (Chief Executive Officer) on 4/11/11. The Medical Privileges form had a check-mark beside full privileges 'requested and recommended' for "repair and closure of simple lacerations (not involving tendons, nerves, or major vessels)." There was a 'not requested or recommended' check-mark beside "repair and closure of complicated lacerations." The Medical Privileges form does not have reattachment or amputation listed as a privilege for Practitioner T.

Review of medical record for Patient #34 dated 7/2/11 at 8:44 AM reveals Patient #34 presented

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to the emergency room with a deep tissue wound to the right antecubital fossa (bend of the elbow) and bicep (muscle in the upper arm) area and was bleeding profusely. A note written by Practitioner R indicates Practitioner S took the case and achieved hemostasis of venous bleeds with tie offs (surgically tied the bleeding veins in the patient's arm to stop the bleeding), stabilized the patient. There is no documentation by Practitioner S as to exact procedure he performed.

Review of the credential file for Practitioner S revealed a Medical Privileges form signed by the Clinical Director and CEO on 3/7/11 and by the Chief Medical Officer and Area Director on 8/1/11. The Medical Privileges form had a check-mark for full privileges 'requested and recommended' next to "repair and closure for simple lacerations (not involving tendons, nerves, or major vessels)." There was a 'not requested or recommended' check-mark beside "repair and closure of complicated lacerations." The Medical Privileges form listed "vascular" with the only privileges 'requested and recommended' being "arterial puncture, cutdown for insertion of catheters, central venous line insertion, emergency care, and referral to outside facility." Emergency care was not specific to performing vascular surgery to stop bleeding.

Interview with the Clinical Director on 8/25/11 at 1:35 PM reveals that Practitioner T deviated from the standard of practice regarding Patient #22. The Clinical Director said, "We do not sew fingers back on at IHS hospitals". The Clinical Director said that Practitioner S was not privileged to perform vascular surgery.

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A 363	Continued From page 48 Further interview with the Clinical Director on 9/19/11 at 3:56 PM reveals it was acceptable for Practitioner S to tie off the artery in Patient #34's arm as it was life or limb saving and he had the expertise even though he was not privileged to perform the task at the hospital.	A 363		
A 385	482.23 NURSING SERVICES The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse. This CONDITION is not met as evidenced by: Based on Medical Staff Bylaws, Rules, and Regulations review, policy review, medical record review, incident report review, and staff interview, the nursing service failed to be appropriately organized to ensure nursing staff assesses patients and provides safe and appropriate care based on that assessment. The facility identified a census of 2. Findings included: - The nursing staff failed to appropriately assess patients and develop and institute care interventions that promoted the health and well being of patients in their care. The cumulative effect of the systemic failure of the nursing service and Director of Nursing to ensure nursing staff were organized to assess and provide care to patients appropriately led to the system failure of the nursing service to care for patients safely.	A 385		
A 395	482.23(b)(3) RN SUPERVISION OF NURSING CARE	A 395		

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A registered nurse must supervise and evaluate the nursing care for each patient.

This STANDARD is not met as evidenced by:
Based on medical record review, policy review, incident report review, Medical Staff Bylaws, Rules and Regulations review, and staff interview, the facility failed to ensure nursing staff evaluated and assessed the care provided to each patient on an ongoing basis for 3 of 32 (#1, #7, and #45) medical records reviewed. The facility identified a census of 2.

Findings included:

Review of medical record for Patient #1 revealed she was 45 years old and admitted to the facility on 4/5/11 with diagnosis to include: post operative transmetatarsal amputation of both feet (removal of the toes from both feet), diabetes, chronic kidney disease with hemodialysis (removal of waste and water from the bloodstream by filtering blood through an artifical membrane), peripheral vascular disease, neuropathy (numbness and pain frequently in the hands and feet often associated with diabetes due to damage to the nerves), hypertension (high blood pressure), and hyperlipidemia (high fat content in the blood). The medical record further indicated Patient #1 was admitted for pain management and diabetes control.

Review of medical record for Patient #1 revealed documentation inconsistent with interviews obtained from staff. Interview with the Improving Operation Performance/Risk Manager (IOP/RM) on 8/31/11 at 2:10 PM revealed the contract podiatrist saw Patient #1 on 4/8/11 and told the

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A 395	Continued From page 50 nursing staff he thought Patient #1 was oversedated. The medical record lacked documentation of the contract podiatrist visit or observations. There is an order documented on 4/8/11 at 6:25 PM to discontinue Morphine (pain medication) 30 mg (milligrams) by mouth twice daily from the contract podiatrist. The medical record revealed an order to discontinue Fentanyl (a pain medication that provides continuous, around-the-clock delivery of the drug) 25 mcg (microgram) patch 1 patch every 72 hours from Physician W on 4/8/11 at 6:43 PM. The medical record lacked evidence nursing staff assessed and reported any significant findings to Physician W regarding Patient #1's status at the time the Fentanyl patch was discontinued. The medical record does not indicate that nursing staff monitored Patient #1 closely following the reported concerns from the podiatrist, nor is there documentation nursing staff removed the discontinued Fentanyl patch. Interview with the Day Nursing Supervisor on the Medical Surgical unit on 8/31/11 at 3:00 PM revealed during review of this medical record she spoke with Registered Nurse E, the nurse taking the order to remove the Fentanyl patch. Registered Nurse E indicated to the Day Nursing Supervisor that she did not remove the Fentanyl patch because she thought she could leave it on until it expired in 72 hours. The medical record indicates that Patient #1 called out to the nurses' station at 8:20 PM stating that she went down. The documentation indicates that Patient #1 was alert and oriented to person, place, and time. There is no documentation regarding how the fall took place to indicate if the patient had impaired safety awareness and/or judgement that could indicate further concerns regarding sedation. The medical record indicates Registered Nurse D	A 395		

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A 395	Continued From page 51 notified Physician Z, who was on call, regarding the fall. The medical record lacks documentation Registered Nurse D informed Physician Z of the contract podiatrists concerns regarding oversedation and the discontinuation of pain medications. The medical record does document that Patient #1 had a pain level of 5 on a scale of 1 to 10 and was given a prn (as needed) pain medication. Review of the MAR (medication administration record) revealed Patient #1 received a Temazepam (sleeping pill) 30 mg at 8:05 PM and an acetaminophen/oxycodone (pain pill) pill at 8:20 PM. There is no evidence in the medical record Patient #1 requested the sleeping pill or the pain pill. The is no evidence in the medical record Registered Nurse D assessed Patient 1's level of sedation prior to administering these medications. There are vital signs documented on 4/8/11 at 8:30 PM temperature 100 degrees Fahrenheit, pulse 91 beats per minute (bpm), respirations 20 per minute, blood pressure 98/67 and oxygen saturation 92 %. The assessment documented 4/8/11 at 9:16 PM indicates Patient #1 was alert and oriented. There is no in depth assessment of Patient #1's response to the pain medication and sleeping pill in light of the prior concerns regarding the patient's oversedation. Documentation in the MAR indicates Patient #1 was asleep at 10:00 PM and had a pain level of 0 at 10:05 PM. Documentation in the medical record indicates Registered Nursed D gave Patient #1 medication on 4/8/11 at 10:17 PM but there is no assessment of the patient's level of sedation. Documentation in the medical record on 4/9/11 at 12:12 AM indicates Patient #1 spit on floor. Even though it is documented earlier at 8:30 PM that Patient #1 had an oxygen saturation of 92%, Registered Nurse D does not assess breath sounds,	A 395		

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A 395	Continued From page 52 respiratory effort, or level of sedation. Registered Nurse D did note on 4/9/11 at 12:12 AM that the head of Patient #1's bed was elevated 35 degrees. It is not noted if this is normal for Patient #1 or if there is a reason, such as shortness of breath, for the head of the bed to be elevated. Documentation on 4/9/11 at 3:32 AM indicates Registered Nurse D found Patient #1 low in the bed and attempted to reposition Patient #1 in the bed, but Patient #1 appeared sleepy. Registered Nurse D called a second nurse to assist in repositioning Patient #1. Further documentation at the time indicates that Patient #1 looks at the nurse but returns to sleep when her name is called and is coughing up phlegm. Registered Nurse D provided oral care. The medical record lacked an in depth assessment of Patient #1's sedation or lung or breath sounds. The assessment on 4/8/11 at 9:16 PM indicates Patient #1 provides mouth care independently and there is no documentation Patient #1 had phlegm at that time. There is no documentation in the medical record Registered Nurse D assessed Patient #1 for this change of condition or notified the physician on call of the change in condition. Documentation on 4/9/11 at 3:56 AM showed Register Nurse D found Patient #1 hard to arouse and unable to obtain a blood pressure. Documentation by the emergency room physician (Physician K) on 4/9/11 at 4:22 AM indicates nursing found Patient #1 pulseless and apneic (no respirations). Staff attempted to resuscitate Patient #1; however, efforts failed and Patient #1 died. Review of product information for Fentanyl indicates that serum concentration continues to rise for the first two system applications, however, by the end of the second 72 hour application a	A 395		

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A 395	Continued From page 53 steady state is achieved. The product information further indicates that a fever can increase the absorption of Fentanyl and patients with fever should be monitored for opoid (a prescription narcotic pain-reliever) side effects. Review of the MAR for Patient #1 indicated the first Fentanyl patch was applied 4/5/11 at 11:00 PM and the second Fentanyl patch was applied 4/8/11 at 10:00 AM. Patient #1's serum concentration would have been continuing to rise. Further review of the medical record revealed Patient #1 had a fever. Patient #1's temperatures for 4/8/11 given in degrees Fahrenheit were 6:10 AM - 100.4; 10:05 AM - 100.8; 3:55 PM - 101; 5:00 PM - 101.6; 7:17 PM - 101.4; 8:30 PM - 100; 9:10 PM - 99.8; 10:05 PM - 99.1; and for 4/9/11 at 3:15 AM 99.9. Interview with the DON (Director of Nursing) on 8/31/11 at 1:30 PM revealed she had reviewed the medical record for Patient #1 and confirmed the lack of documentation and the failure to assess Patient #1's respiratory status. Interview with Physician W on 10/3/11 at 1:07 PM revealed nursing staff notified him between 6:00 PM and 7:00 PM on 4/8/11 regarding the contracted podiatrist concerns that Patient #1 was oversedated. Physician W told nursing staff to stop the pain medication. Physician W expressed concern that Patient #1 fell and was frothing at the mouth during the night of 4/8/11 into the morning of 4/9/11 and nursing staff did not make the physician on call aware this was a change of condition for Patient #1. Physician W stated that nursing staff should pay closer attention and notify the provider of any change in condition.	A 395		

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A 395	Continued From page 54 Review of the medical record showed hospital staff admitted Patient #7 on 8/9/11 at 2:17 AM with diagnosis of alcohol encephalopathy (a severe syndrome characterized by ataxia (gross lack of coordination of muscle movements), ophthalmoplegia, confusion, and short-term memory loss), diabetes, hypertension, and mass in the left kidney. Admission data indicates Patient #7 had a fall score of 70 (anything above 50 is considered high risk). Staff documented Patient #7's level of consciousness as oriented to place, oriented person, but confused. Staff identifies that Patient #7 is ambulatory but will require stand by assistance due to unsteady gait and confusion. Staff further identify that Patient #7 has no religious, traditional, ethnic, or cultural practices that should be part of hospital care. Review of incident reports for the month of August revealed Patient #7 sustained three falls. The first report on 8/9/11 at 2:10 PM revealed that Patient #7 heard a loud noise and found Patient #7 sitting on his buttocks approximately 3 feet from his bed. Patient #7 stated his legs just gave out. Review of the medical record for Patient #7 revealed the only nursing documentation on 8/9/11 were alcohol withdrawal assessment flow sheets. Review of the medical record revealed a History & Physical (H&P) dated 8/9/11 at 9:09 AM. Review of the H&P showed Patient #7 was alert and oriented to person, place, and time with normal memory and judgment. The H&P showed that Patient #7 complained of stumbling around. Review of the withdrawal assessment flow sheet dated 8/9/11 at 2:20 PM revealed Patient #7 was hallucinating and agitated, Valium (anti-anxiety medication) 5 mg was given intramuscularly. There is no documentation in the medical record regarding Patient #7's fall or any nursing assessment following the fall. There is no	A 395		

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A 395	Continued From page 55 evidence in the medical record that nursing staff notified the physician of the fall. The next withdrawal assessment flow sheet dated 8/9/11 at 5:20 PM indicates Patient #7 was hallucinating, agitated, and had a change in sensorium. Review of the incident reports revealed Patient #7 had a fall on 8/9/11 at 4:40 PM. There is no documentation in the medical record regarding Patient #7's fall or any nursing assessment following. There was no change to Patient #7's care plan interventions following the first fall. There is no documentation in the medical record indicating nursing staff notified the physician of the fall. Review of the medical record showed a note by the Clinical Social Worker dated 8/10/11 at 10:24 AM stating "Patient is also requesting an evaluation for a power chair as he feels his legs are not strong enough to carry him without him falling." Review of a hospital inpatient physician daily progress note dated 8/10/11 at 12:27 PM stated, "the patient still having withdrawal, fell down yesterday twice but he is ok today, alert, awake, answers questions appropriately, still have unsteady gait..." Review of incident reports revealed Patient #7 fell a third time on 8/10/11 at 6:05 PM. The incident report indicates an unidentified CNA (certified nurse aide) assisted Patient #7 to the shower with a shower bench and left the patient unattended to shower. Patient #7 sustained a 1 cm (centimeter) x 1 cm abrasion to the right elbow and a large ecchymosis (bruise) to the back. Patient #7 report pain 8 of 10 (scale of 1 to 10 with 1 being mild pain and 10 the worst pain imaginable) in his back and legs following the fall. Review of the medical record revealed nursing documentation that states"At 1805 [6:05 PM] the CNA took pt [patient] to the toilet for shower, the pt fell while taking shower, pt (patient) has an abrasion to right elbow. a 50	A 395		

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A 395	Continued From page 56 centimeter (cm) by 18 cm ecchymosis (bruising) to right dorsa [back] area and 8/10 pain to right lower extremities, [Clinical Director] was notified at 1810 [6:10 PM], evaluated the pt. Band-Aid applied to abrasion, set of vital sign taken and entered at 1825 [6:25 PM]" The medical record further showed a crisis note written by the Clinical Director that states, "..he is also to undergo back surgery for his leg weakness. Called [Clinical Director was called] by [Registered Nurse F] at 6:20 pm this evening and was told that pt. had fallen in the bathroom. Although he fell twice yesterday and is on fall precautions -- he was showering unattended and tried to stand in the shower -- per pt. and found the floor slippery and fell. He reports pain level 8-9/10 to his right posterior back and right lateral knee -- post impact with the wall and floor." The crisis note further indicates, "Admits he has been falling repeatedly lately -- even before admission to hospital. Admits to having tight caplike pressure around the top of his head -- at this time since his fall and pain-headache 8/10 in intensity. He states that he hit his head very hard on wall. Denies nausea or vomiting . Denies blurred vision. Admits that he feels very dizzy -- more so than before his fall." The neurological assessment of Patient #7 is alert and oriented to person, place and time but memory poor. The crisis note concludes with a plan to "transfer patient to [Hospital M] for acute eval [evaluation] of head trauma and tight headache and as he seems to be having repeated falls -- with difficulty preventing even on fall precautions here." Review of the medical record lacks evidence that nursing staff assessed the reasons for the patient falling and instituted appropriate interventions to protect the patient and ensure his safety.	A 395		

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Review of documentation by the Day Inpatient Supervisor on 8/29/11 regarding the falls experienced by Patient #7 showed the documentation validated the falls and formulated a plan of action. The review failed to identify the cause of the falls or document the trend of the falls prior to formulating a plan of action. The plan of action failed to address the lack of assessment and formulation of interventions to prevent further falls. There was no written documentation that the facility enacted the plan of action. Interview with the Day Inpatient Supervisor on 8/31/11 at 3:00 PM confirmed there was no written documentation of any training provided to staff.

Interview with the Clinical Director on 8/25/11 at 1:35 PM revealed she transferred Patient #7 from the facility because of concern related to the number of falls the patient experienced and the failure of the nursing staff to keep him safe. Patient #7 had alcohol withdrawal, was receiving Ativan (antianxiety medication), and was a high risk for falls. Patient #7 was allowed to shower alone and staff indicated it was because native men were very private.

Interview with the DON on 8/30/11 at 4:00 PM revealed that nursing staff should have assessed Patient #7 more frequently. The CNA could have rounded on Patient #7 more frequently or could have sat with the patient. The CNA is very traditional and was trying to be culturally sensitive to allow Patient #7 privacy while showering. Documentation in the medical record indicated that Patient #7 did not identify cultural issues that should be part of the hospital care during the admission process. Further interview with the DON on 10/14/11 at 11:54 AM confirmed there

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was no real assessment of this patient at high risk for falls in the medical record nor was there documentation of an assessment following the falls.

Review of medical record for Patient #45, 15 years old, admitted to the medical surgical unit with a diagnosis of suicidal ideations, superficial skin lacerations on 9/28/11. Further review of the medical record showed Patient #45 presented to the emergency room with police with complaints she would hurt herself if she had to go back to her mom's house tonight. ...Relates that she has been thinking about suicide lately but that today is the first time she has said anything out loud. Denies having a plan to commit suicide." The medical record indicates that Registered Nurse G informed the Clinical Director, who was the admitting physician, of nurse staffing, and that the patient will be admitted close to the nurses station with frequent supervision. The medical record further indicates Patient #45 reports that her mother hit her with a toilet brush and scratched her left arm and leg. Patient #45's mother acknowledged throwing a toilet brush at Patient #45. Physical examination showed Patient #45 had 2 superficial scratches approximately 3 cm to the left upper arm and 1 superficial scratch to left lower arm approximately 3 cm. There are also 2 moon shaped superficial scratches to lateral aspect left arm below the elbow. The medical record indicates staff transferred Patient #45 to the medical surgical unit on 9/28/11 at 10:00 PM. Review of the medical record revealed a nursing pediatric admission form completed 9/29/11 at 3:11 AM. Patient #45 answered 'yes' to the question, "Has your partner or someone important to you ever hurt you?". Patient #45 answered 'yes' to the question, "Are you

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A 395	Continued From page 59 concerned about your safety or the safety of anyone in your family?". The medical record lacks any probes related to these questions to determine potential abuse especially in light of reports of being struck by her mother. The nursing pediatric admission form questions if the patient has any safety needs which is answered 'yes' with only a statement "suicide precautions". The nurse failed to assess the patient's need for safety from her mother. The mother is present with patient in room unsupervised throughout the night. The patient had reported earlier that her mother had struck her with a toilet brush and did not want to return home with her. This was the precipitating cause of wishing to harm self. The medical record states, "Patient (pt.) is placed in room 309, which is directly across [from] the nurses' station. Mother plans to stay with pt throughout the night; hourly checks to be performed." Documentation in the medical record reveals hourly checks on 9/28/11 at 10:00 PM and 11:00 PM, on 9/29/11 at 12:10 AM, 2:15 AM, 3:20 AM, 4:20 AM, 5:35 AM, and 6:38 AM. There is no documentation of an hourly check at 1:00 AM; nursing staff failed to monitor Patient #45 for over 2 hours. Documentation on 9/29/11 at 7:45 AM stated, "Pt mother present in the room, sleeping in the bed window. Pt has no concerns at this time other than the room being cold. Nurse leaves pt door open as it was closed when arriving to floor at 7:00 AM." Placing Patient #45 in a room across from the nurses' station is ineffective if the door is closed. The expectation of close monitoring of a suicidal patient is at a minimum every 15 minutes. Further review of the medical record reveals a H&P by the Clinical Director indicating Patient #45 was not clearly suicidal the previous night and was admitted to allow the patient to dispel her	A 395		

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A 395	Continued From page 60 anger and anguish. However, the patient was admitted with suicidal ideations. Review of Medical Staff Bylaws, Rules, and Regulations dated FY (fiscal year) 2009 - 2011 stated in part, "Rules and Regulations - Principles of Medical Ethics: ...Admitting and Discharge of Patients ...7. Suicidal Patient For the protection of patients, the medical and nursing staff and the Hospital, the care of the potentially suicidal patient shall be as follows: 7.1.1 The patient shall be placed in the most secure area available within the facility. As soon as possible the patient shall be referred to another institution where suitable facilities are available. When transfer is not possible the patient may be admitted to a general area of the Hospital as a temporary measure. The patient will be afforded psychiatric consultation, and the Mental Health Services shall be consulted when necessary for assistance. Family members/relatives shall watch the patient (one on one), if not available nursing staff will do. Weekend admissions shall have on-call staff available from the Mental Health department." Review of policy titled, "Suicide Gestures, Ideations, and Attempts" revised 6/11 defines suicidal ideations as "a common medical term for thoughts about suicide, which may be as formulated as a formal plan, without the suicidal act itself. Although most people who undergo suicidal ideations do not commit suicide, some go on to make suicide attempts." The policy does not provide guidance to the inpatient nursing staff on how to manage a suicidal patient. An e-mail from the IOP/RM on 10/5/11 at 5:00 PM confirmed there was no inpatient policy related to dealing with suicidal patients. There is no indication in the medical record that nursing staff took steps to secure the environment of the room in which they place Patient #45. Nursing staff	A 395		

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A 395	Continued From page 61 failed to observe Patient #45 every hour. The medical record failed to assess Patient #45 for abuse by the patient's mother and allowed the mother to remain in the room with the patient. Interview with the DON on 10/14/11 at 11:54 AM revealed there is no policy for the management of suicidal patients on the inpatient unit. Any monitoring the nursing staff would do would be based on the orders of the provider and if there were no orders for monitoring it would be her expectation that patients be monitored every 15 to 30 minutes. Suicidal patients should be close to the nurses' station with the door open. When abuse is suspected nurses should report to social services and child protective services and not leave the suspected abuser in the room with the patient.	A 395		
A 528	482.26 RADIOLOGIC SERVICES The hospital must maintain, or have available, diagnostic radiological services. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications. This CONDITION is not met as evidenced by: Based on policy review, document review, Medical Staff Bylaws,Rules, and Regulations review, and facility staff interviews, the facility failed to ensure the safety of radiological services provided at the facility by not implementing systems to ensure the radiologic equipment was safe for patient use prior to placing it into service and that the Medical Staff appointed a qualified Radiologist to supervise the department in a manner to ensure the safety of patients and staff,	A 528		

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A 528	Continued From page 62 and/or delineate the radiologic tests that require specialized interpretation by a radiologist. The facility identified a census of 2 but all patients who received an x-ray at the facility could be affected. Findings included: -The failure to ensure a medical physicist evaluated new equipment for safety prior to placing it in service for patient use for both the only x-ray suite and the only portable x-ray machine available at the facility. (See details at A-537) -The failure to ensure that the the Medical Staff designated a qualified Designated Radiology Director to supervise the Radiology department or to designate which radiologic images should be interpreted by a radiologist. (See details at A-546) The cumulative effect of the facility's failure to ensure that a qualified medical physicist evaluated radiologic equipment prior to placing the equipment in use to assure it was functioning properly and not exposing patients and staff to unnecessary dosages of radiation and to ensure that the Medical Staff designated a qualified Radiology Director to supervise the Radiology department resulted in a systemic failure of the radiology service.	A 528		
A 537	482.26(b)(2) PERIODIC EQUIPMENT MAINTENANCE Periodic inspection of equipment must be made and hazards identified must be promptly corrected. This STANDARD is not met as evidenced by:	A 537		

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Based on standards of practice for radiology review, document review, and facility staff interview, the facility failed to ensure a medical physicist evaluated the safety of 2 of 2 radiology units prior to the units being placed into patient use. The facility identified a census of 2.

Findings included:

Review of standards of practice for the American College of Radiology (ACR) reveals, " The American College of Radiology, with more than 30,000 members, is the principal organization of radiologists, radiation oncologists, and clinical medical physicists in the United States. The College is a nonprofit professional society whose primary purposes are to advance the science of radiology, improve radiologic services to the patient, study the socioeconomic aspects of the practice of radiology, and encourage continuing education for radiologists, radiation oncologists, medical physicists, and persons practicing in allied professional fields.
The American College of Radiology will periodically define new practice guidelines and technical standards for radiologic practice to help advance the science of radiology and to improve the quality of service to patients throughout the United States. Existing practice guidelines and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.
Each practice guideline and technical standard, representing a policy statement by the College, has undergone a thorough consensus process in which it has been subjected to extensive review, requiring the approval of the Commission on Quality and Safety as well as the ACR Board of Chancellors, the ACR Council Steering

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Committee, and the ACR Council. The practice guidelines and technical standards recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques, as described in each document. A standard titled, ACR TECHNICAL STANDARD FOR DIAGNOSTIC MEDICAL PHYSICS PERFORMANCE MONITORING OF RADIOGRAPHIC AND FLUOROSCOPIC EQUIPMENT, states in part, This standard was revised by the American College of Radiology (ACR) with assistance from the American Association of Physicists in Medicine (AAPM). The performance of all radiographic and fluoroscopic equipment must be evaluated upon installation and monitored at least annually by a Qualified Medical Physicist to ensure that the equipment is functioning properly and that patients are not exposed to unnecessary doses of radiation. "

Review of documentation provided by the facility regarding the assembly and installation of the Shimadzu portable x-ray unit and the GE (General Electric) stationary general radiology unit revealed the following:

-A biomedical technician assembled the Shimadzu portable unit on 3/27/09.
-A biomedical technician assembled the GE stationary unit on 6/15/11.

Review of a fax forwarded by the facility on 9/9/11 at 3:27 PM reveals in part a statement from the Aberdeen Area Institutional Environmental Health Officer, "It should be clarified that VA (Veterans Affairs) conducts biomedical acceptance testing; not medical physics acceptance testing (the FDA [Food and Drug Administration] 2579 form

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A 537	Continued From page 65 documents testing and adjustments to certify compliance with federal x-ray equipment performance standards). " Review of documentation provided by the facility regarding periodic survey of the portable Shimadzu on 11/4/10 reveals "Available manuals neither provided manufacturer specific quality control testing procedures nor provided instruction for placing the unit in a non-imaging mode to protect the digital detector plate. Therefore, the unit could not be tested without risking damage to the detector. Upon returning to Aberdeen, the service contractor for the Shimadzu portable digital radiological unit was contacted and information was acquired for placing the unit in a manual/non-digital mode for future testing." Interview with the Radiology Supervisor on 8/23/11 at 2:40 PM reveals that the Aberdeen Area Institutional Environmental Health Officer did not return to evaluate the Shimadzu portable unit after 11//4/10 and has not evaluated the GE stationary unit. The Aberdeen Area Institutional Environmental Health Officer will evaluate both x-ray units when he returns in November of this year for his annual inspection. Interview with the Radiology Supervisor on 9/16/11 at 9:49 AM reveals the Shimaduz portable x-ray unit was put into service for patients on 9/10/10 and the GE stationary x-ray unit was put into service for patients on 7/22/ 11.	A 537		
A 546	482.26(c)(1) RADIOLOGIST RESPONSIBIITIES A qualified full-time, part-time, or consulting radiologist must supervise the ionizing radiology	A 546		

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services and must interpret only those radiological tests that are determined by the medical staff to require a radiologist's specialized knowledge. For purposes of this section, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.

This STANDARD is not met as evidenced by:
Based on Medical Staff Bylaws, Rules, and Regulations review, Medical Staff Committee meeting minutes, Governing Body meeting minutes review, policy review, and staff interview, the facility failed to ensure the Medical Staff appointed a Designated Radiology Director to supervise the Radiology department in a manner to ensure patient safety or designated which radiologic tests require interpretation by a radiologist. The facility identified a census of 2.

Findings included:

Review of Medical Staff Bylaws, Rules, and Regulations dated FY (fiscal year) 2009 - 2011 states in part, "Section 13.07 Designated Radiology Director - The courtesy Medical Staff Director/consultant is the designated overall consultant in regards to the Radiology Services provided. The clinical Director or designee will serve as the Service Unit's Radiology Director."

Interview with the Radiology Supervisor on 8/23/11 at 9:25 AM and 9/16/11 at 9:49 AM reveals that Radiologist Y was the supervising Radiologist for the Radiology Department.

Review of the signature sheet for the Radiology Department policies shows signatures by the Radiology Supervisor as the Chairperson for the

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A 546	Continued From page 67	A 546		

Initiating Committee/Department and Signature by the Chairperson of Concurring Committee Medical Staff, Physician Z, the area for the Director of Radiology to sign is again signed by the Radiology Supervisor.

Interview with the Radiology Supervisor on 9/16/11 at 11:01 AM revealed at the time staff signed the policies Radiology Supervisor on 3/18/11 and Physician Z on 3/29/11 respectively, that Physician Z was the Director of Radiology.

Review of the credential file for Physician Z reveals his speciality is Internal Medicine not Radiology.

Review of the contract with Radiology group A dated 4/13/10 lacks evidence of designating one radiologist as the Designated Radiology Director nor does it delineate the responsibilities of the Designated Radiology Director.

Review of Medical Staff meeting minutes dated 4/27/11, 5/3/11, 5/25/11, and 6/22/11 lacks evidence of the appointment of Radiologist Y as the Designated Radiology Director.

Review of Governing Body meeting minutes dated 6/23/11 and 8/15/11 lacks evidence of the appointment of Radiologist Y as the Designated Radiology Director.

Review of policies for the Radiology department lacks evidence of a policy defining which radiological tests require the specialized knowledge of a radiologist for interpretation. The Medical Staff approved the policies of the Radiology department on 3/29/11.

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A 546	Continued From page 68 Interview with the Radiology Supervisor on 9/16/11 at 9:49 AM confirms the facility lacks a policy defining which radiological tests required the specialized knowledge of a radiologist for interpretation. Review of the Medical Staff Bylaws, Rules, and Regulation lacks evidence of which radiologic tests require the specialized knowledge of a radiologist for interpretation. Interview of 9/16/11 at 2:17 PM with the Improving Operations Performance Director/Risk Manager confirms that there is no evidence that Medical Staff or Governing Body has appointed a Designated Radiology Director nor is there evidence of the Medical Staff defining which radiological tests require a radiologists interpretation. Interview on 9/19/11 at 12:30 PM with the Clinical Director and Physician W reveals the Clinical Director is the Director of Radiology. Physician W states the radiologists don't have anything to do with the internal direction of the hospital. The radiologists don't come to the hospital. The radiologists couldn't be the director of any department.	A 546		
A 710	482.41(b)(1)(2)(3) LIFE SAFETY FROM FIRE (1) Except as otherwise provided in this section- (i) The hospital must meet the applicable provisions of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and	A 710		

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A 710	Continued From page 69	A 710		

1 CFR Part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html
Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the Federal Register to announce the changes.
(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the LSC does not apply to hospitals.

(2) After consideration of State survey agency findings, CMS may waive specific provisions of the Life Safety Code which, if rigidly applied, would result in unreasonable hardship upon the facility, but only if the waiver does not adversely affect the health and safety of the patients.

(3) The provisions of the Life Safety Code do not apply in a State where CMS finds that a fire and safety code imposed by State law adequately protects patients in hospitals.

This STANDARD is not met as evidenced by:
Based on observation, record review and staff interview, this facility is not in compliance with the 2000 edition of the Life Safety Code. This affects all occupants in this facility with a capacity of 13 and a census of 2 at the time of the survey.
Findings include:

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A 710	Continued From page 70 1. See the results of the Life Safety Code survey - K12, K29, K37, K48, K52, K62, K154 and K155	A 710		
A 714	482.41(b)(7) FIRE CONTROL PLANS The hospital must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, personnel and guests; evacuation; and cooperation with fire fighting authorities. This STANDARD is not met as evidenced by: Based on observation, record review and staff interview, this facility does not have a plan in place to promptly report fires. Lack of written policies and procedures could result in staff failing to promptly report a fire preventing an investigation into the cause. This affects all occupants in this facility with a capacity of 13 and a census of 2 at the time of the survey. Findings include: 1. Record review on 8/24/11, between 8:00 a.m. and 6:00 p.m., of the facility ' s fire policy and procedure records showed that there was not a plan in place to report fires. This deficient practice was confirmed by Safety Manager A on 8/25/11.	A 714		
A 715	482.41(b)(8) REGULAR FIRE AND SAFETY INSPECTIONS The hospital must maintain written evidence of regular inspection and approval by State or local fire control agencies. This STANDARD is not met as evidenced by: Based on observation, record review and staff interview, this facility does not maintain regular inspections by local fire control agencies. Lack of written policies and procedures to coordinate with	A 715		

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A 715

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the local fire department could result in a failure of the fire department to be familiar with the structure and the hazards within. This affects all occupants in this facility with a capacity of 13 and a census of 2 at the time of the survey. Findings include:

1. Record review on 8/24/11, between 8:00 a.m. and 6:00 p.m., of the facility ' s fire policy and procedure records showed that there was not a plan in place to coordinate inspections with the local fire department. This deficient practice was confirmed by Safety Manager A on 8/25/11.

A 747

482.42 INFECTION CONTROL

The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.

This CONDITION is not met as evidenced by:
Based on Infection Prevention Plan review, Medical Staff meeting minutes review, Governing Body meeting minutes review, and staff interview, the facility failed to promote an active program to identify, report, and investigate infections. The facility identified a census of 2, but all inpatients and outpatients at the facility could be affected.

Findings included:

-The facility failed to have an effective system to identify, report, and investigate infections in the facility. (See A-747)

-The facility failed to maintain a log of all

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A 747	Continued From page 72 community and healthcare acquired infections and communicable diseases for both patients and staff members. (See A-749) -The chief executive officer (CEO), medical staff, and director of nursing (DON) failed to demonstrate responsibility for quality assurance activities and training of issues identified by the Infection Prevention Nurse. (See A-756) The cumulative effect of the facility's failure to ensure an effective system to identify, report, and investigate infections within the facility, failure to maintain a complete log of infections and communicable diseases, and the failure of the CEO, Medical Staff, and DON to demonstrate responsibility for the quality assurance and training of problems identified by the infection prevention program resulted in the systemic failure of the infection control program.	A 747		
A 749	482.42(a)(1) INFECTION CONTROL OFFICER RESPONSIBILITIES The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel. This STANDARD is not met as evidenced by: Based on Infection Prevention Plan review, document review, medical record review, and staff interview, the facility failed to ensure the Infection Prevention Nurse developed a system that identified, investigated, and controlled all infections and communicable diseases within the facility for patients and staff. The facility identified a census of 2.	A 749		

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A 749		A 749		

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Findings included:

Review of medical record for Patient # 29 reveals the patient had head lice at the time of admission.

Interview with the Infection Prevention Nurse on 8/30/11 at 11:30 AM identifies that the facility did not have a policy on the management of head lice but did have a number of patients present to the facility with head lice. The Infection Prevention Nurse further identifies that patients also frequently present with scabies and indicates that she does not track or trend either scabies or lice. The Infection Prevention Nurse indicates she was not aware that there was a need to track lice or scabies as neither is a reportable infection for the State of Nebraska.

Review of the Infection Prevention Plan approved 6/23/11 states in part, "Purpose: The executive committee directs that the Winnebago Comprehensive Health Care Facility has a functioning and coordinated process in place to reduce the risks of endemic, epidemic and health-care associated infections (HAI's) in patients, visitors, and healthcare workers."

Further review of the Infection Prevention Plan states in part, "Surveillance Methods include: 1. Total house surveillance--historically, healthcare associated infections have been very low at this institution. A low inpatient census and low number of superficial surgical wound makes it possible to investigate all potential healthcare associated infections."

The Infection Prevention Plan fails to discuss community acquired infections, tracking and

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A 749	Continued From page 74 trending infections and communicable diseases, or how noted trends will be investigated to determine the causative effect. Interview with the Infection Prevention Nurse on 8/31/11 at 2:00 PM acknowledges that there is no log for employee illnesses, the log for infection tracking contains only the reportable infections for the State of Nebraska, and there is no process in place for tracking and trending employee infections within the facility at this time. Further review of the Infection Prevention Plan lacks evidence of a system for reporting or investigating infections. Interview with the Infection Prevention Nurse on 9/28/11 at 1:48 PM confirms there was nothing in the Infection Prevention Plan regarding reporting or investigating infections and communicable diseases. The Infection Prevention Nurse identifies that reports on infections and communicable diseases are available but she has not been asked for them by the Improving Operations Performance/Risk Manager, Medical Staff or Governing Body. The Infection Prevention Nurse also identifies that she is not invited to the Medical Staff or Governing Body meetings to report findings for infections or communicable diseases.	A 749		
A 750	482.42(a)(2) INFECTION CONTROL LOG The infection control officer or officers must maintain a log of incidents related to infections and communicable diseases. This STANDARD is not met as evidenced by: Based on Infection Prevention Plan review and	A 750		

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A 750	Continued From page 75	A 750		

staff interview, the facility failed to ensure the Infection Prevention Nurse developed and maintained a log of all hospital acquired and community acquired infections and communicable diseases for patients and staff. The hospital identified a census of 2.

Findings included:

Review of the Infection Prevention Plan approved 6/23/11 states in part, "Purpose: The executive committee directs that the Winnebago Comprehensive Health Care Facility has a functioning and coordinated process in place to reduce the risks of endemic, epidemic and health-care associated infections (HAI's) in patients, visitors, and healthcare workers."

Further review of the Infection Prevention Plan states in part, "Surveillance Methods include: 1. Total house surveillance--historically, healthcare associated infections have been very low at this institution. A low inpatient census and low number of superficial surgical wound makes it possible to investigate all potential healthcare associated infections."

The Infection Prevention Plan failed to discuss community acquired infections, tracking and trending infections and communicable diseases, or how noted trends will be investigated to determine the causative effect.

Interview with the Infection Prevention Nurse on 8/31/11 at 2:00 PM acknowledges that there is no log for employee illnesses, the log for infection tracking contains only the reportable infections for the State of Nebraska, and there is no process in place for tracking and trending infections within

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A 750	Continued From page 76 the facility at this time.	A 750		
A 756	482.42(b) LEADERSHIP RESPONSIBILITIES Standard: Responsibilities of chief executive officer, medical staff and director of nursing services. The chief executive officer, the medical staff, and the director of nursing must-- (1) Ensure that the hospital-wide quality assurance program and training programs address problems identified by the infection control officer or officers; and (2) Be responsible for the implementation of successful corrective action plans in affected problem areas. This STANDARD is not met as evidenced by: Based on Infection Prevention Plan review, Medical Staff meeting minutes review, Governing Body meeting minutes review, and staff interview, the facility failed to ensure that the chief executive officer (CEO), medical staff, and/or director of nursing (DON) assured staff implemented quality assurance activities, including corrective action, and training programs to address issues identified by the Infection Prevention Nurse. The hospital identified a census of 2. Findings included: Review of the Infection Prevention Plan dated 6/23/11 states in part, "When problems or opportunities for improvement are identified, action taken/recommended will be documented in the WCHCF (Winnebago Comprehensive Health Care Facility) Infection Prevention Committee	A 756		

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A 756	Continued From page 77 minutes. Minutes are forwarded to the Medical Staff for review and assistance in resolution as necessary." The Infection Prevention Plan failed to address notification and involvement of the CEO and DON. Review of Medical Staff meeting minutes, including the Medical Staff Executive Committee meeting minutes for 10/13/10, provided by the facility from 10/13/10 to 5/25/11 lacks evidence of any report from the Infection Prevention Nurse or any discussion or action on Infection Prevention. Review of Governing Body meeting minutes provided by the facility from 6/8/10 to 8/15/11 lacks evidence of any report from the Infection Prevention Nurse or any discussion or action on Infection Prevention. Interview with the Infection Prevention Nurse on 9/28/11 at 1:48 PM reveals she identified problems with staff identifying the correct isolation procedure to follow and the implementation of the basic criteria for contact isolation and developed a monitor. The Infection Prevention Nurse further identified that she does not send reports to the Medical Staff or Governing Body and has not attended any Medical Staff or Governing Body meetings to inform them of infection prevention concerns. The Infection Prevention Nurse states that she communicates concerns to the DON through emails. She also notifies the DON and nursing supervisors of training sessions but there is not always a good showing. Nursing administration neither encourages attendance nor do they cover the nurses where they can attend.	A 756		
A 884	482.45 ORGAN, TISSUE, EYE PROCUREMENT	A 884		

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A 884	Continued From page 78 Organ, Tissue and Eye Procurement This CONDITION is not met as evidenced by: Based on document review and interview the hospital: - Failed to have a signed agreement with the Nebraska Organ Recovery System (NORS is the hospitals local organ procurement organization for organ donation) (see A886); -Failed to incorporate the agreement with the Lions Eye Bank into policy to ensure the opportunity to secure eye donors; also, there is no signed agreement for tissue procurement as NORS is responsible for this. (see A887). The cumulative effect of the hospitals failure to have a signed agreement with NORS and failure to incorporate the agreement with the Lions Eye Bank into policy resulted in a failure to meet the Condition of Participation for Organ, Tissue and Eye Procurement.	A 884		
A 886	482.45(a)(1) OPO AGREEMENT Incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the hospital. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the hospital, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the hospital for this purpose;	A 886		

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A 886	Continued From page 79	A 886		

This STANDARD is not met as evidenced by:
Based on document review and interview, the hospital failed to ensure they had a signed agreement with the Nebraska Organ Recovery System (NORS is the hospitals designated organ procurement organization [OPO] for organ and tissue donation) that included all the necessary components as identified in the regulation. The hospital census was 2.

Findings included:

On 8/24/11 the hospital provided two documents relating to their organ procurement responsibilities. The first document was titled, "Collaborative Agreement Between Aberdeen Area Indian Health Service, Winnebago Service Unit, and Nebraska Organ Recovery System. This two (2) page document contained date stamps on the cover letter page for 2/28/08 and 2/25/09 and was signed by a representative from NORS on 2/28/08 and the Acting Area Director of the Aberdeen Area Indian Health Service in Aberdeen, South Dakota on 2/22/08. The second document was titled, "Nebraska Organ Recovery System Donor Institution Agreement". The document included:
- definitions of organ procurement terms,
- responsibilities of NORS,
- responsibilities of the hospital,
- reimbursement,
- term and termination of the agreement,
- relationship of the parties, and
- miscellaneous.
The signature page of the document contained the handwritten signature for a NORS representative and dated 10/15/07. The signature page was not signed by the hospital.

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A 886	Continued From page 80 During an interview on 8/25/11 at 8:30 AM, the Improving Operations Performance/Risk Management Director said the first, signed document was a pre-collaborative agreement with NORS that the Aberdeen Area Health Service in Aberdeen, South Dakota required prior to the Winnebago Service Unit entering into a contractual agreement with NORS. The Improving Operations Performance/Risk Management Director said the second document was the contractual agreement between NORS and the Winnebago hospital and confirmed the agreement had not been signed by the hospital.	A 886		
A 887	482.45(a)(2) TISSUE AND EYE BANK AGREEMENTS Incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement; This STANDARD is not met as evidenced by: Based on policy and procedure review, contract review, and staff interview, the facility failed to ensure staff incorporated the contract for the Lions Eye Bank of Nebraska (LEBN) into the policy for organ and tissue donation for facility donations of eyes. The facility further failed to have a contract in place for tissue donation with the Nebraska Organ Recovery System (NORS). The hospital identified a census of 2. Findings included:	A 887		

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A 887	Continued From page 81 Review of contract with NORS lacks a signature from the Aberdeen Area Director to effectuate the terms of the contract. However the contract states in part, "Responsibility of NORS 2.1 Referral Source. NORS agrees to become the Hospital's sole referral source for all organ placement and tissue placement, excluding eye tissue, unless the Hospital has an existing agreement with Spirit of the North." Therefore, the hospital has no contract with a tissue bank. Review of the contract with LEBN states in part, "B. Responsibilities of Lions Eye Bank 1. Provide a twenty-four (24) hour answering service and available personnel qualified to evaluate patient deaths regarding medical suitability for potential eye donations. LEBN must determine the medical suitability for eye donation." Review of the policy and procedure titled, "Organ and Tissue Donation" revised/reviewed 7/06 lacks directive to contact LEBN to determine the medical suitability of eye donation. There is a form attached where either NORS or LEBN can be checked as having had a referral. It is not clear from the policy and procedure or the form that both entities must be notified.	A 887		
A1100	482.55 EMERGENCY SERVICES The hospital must meet the emergency needs of patients in accordance with acceptable standards of practice. This CONDITION is not met as evidenced by: Based on Medical Staff Bylaws, Rules, and Regulations review, QIO (Quality Improvement Organization) document review, medical record	A1100		

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review, credential file review, and staff interview, the facility failed to meet the emergency needs of it's patients in accordance with acceptable standards of practice. The facility identified a census of 2.

Findings included:

-The facility failed to ensure there was a qualified director of the emergency department by experience or training. (See A-1102)

-The facility failed to ensure that medical staff providing care in the emergency department were knowledgeable to meet the needs of the community for emergent situations. (See A-1112)

The cumulative effect of the systemic failure of the facility to provide competent emergent care with qualified leadership in the emergency department led to the system failure of the emergency services to provide quality emergency care to the community.

A1102 482.55(a)(1) ORGANIZATION OF EMERGENCY SERVICES

[If emergency services are provided at the hospital --]

(1) The services must be organized under the direction of a qualified member of the medical staff.

This STANDARD is not met as evidenced by:
Based on Medical Staff Bylaws, Rules, and Regulations review, credential file review, and staff interview, the facility failed to ensure there

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was a qualified director of the emergency department. The facility identified a census of 2.

Findings included:

Review of the Medical Staff Bylaws, Rules, and Regulations dated FY (fiscal year) 2009-2011 states in part, "Section 13.08 Designated Emergency Room Director The Emergency Room Director shall be a fully credentialed active staff physician provider with a documented record of providing proper Emergency Department Care according to IHS [Indian Health Service] rules & regulations, and according to the guidelines of specialty organizations (i.e. ACEP [American College of Emergency Physicians] AMA [American Medical Association]). If the ER [Emergency Room] Director is not Board Certified in Emergency Medicine he/she must maintain certification in BLS-C [Basic Life Support-Certified], ACLS [Advanced Cardiac Life Support], and ATLS [Advanced Trauma Life Support]. Certification in ALSO [Advanced Life Support in Obstetrics], PALS [Pediatric Advanced Life Support] and NRP [Neonatal Resuscitation Program] is considered beneficial but is not mandatory. The ER director shall demonstrate a proven knowledge and the ability to function as a manager and or supervisor with the Indian Health Service."

Review of the credential file for the Clinical Director reveals Medical Privileges signed by the Clinical Director and CEO (Chief Executive Officer) on 6/10/11. The Clinical Director requested and was recommended for limited emergency care in obstetrics, complicated asthma, and noted that neonatal resuscitation/emergency stabilization was

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A1102	Continued From page 84 requested and recommended with consultation. The clinical director failed to request and receive recommendation for acute and/or chronic heart failure, a tube thoracostomy (chest tube for drainage), cutdown for insertion of catheter, and many of the procedures listed under the emergency heading including cricothyroidotomy (emergrency airway puncture), pericardiocentesis (removal of fluid from the sac that surrounds the heart), peritoneal lavage (the technique of insertion of a tube into the abdomen to diagnose intra-abdominal bleeding),, use of manual and mechanical resuscitator, and use of rotating tourniquets. Further review of the credential file for the Clinical Director reveals a curriculum vitae (CV) that indicates the Clinical Director is board certified in family practice and holistic medicine but not emergency medicine. The CV further indicates that the Clinical Director lists no experience in emergency medicine. However the CV does document that the Clinical Director does have both BLS and ACLS. Interview with the Clinical Director and the former Clinical Director (Physician W) on 9/19/11 at 12:30 PM reveals that limited privileges as requested by providers meant they require consultation to perform the task/procedure. Further interview reveals that the Clinical Director is the Director of the Emergency Department but has no training at this time. There are plans for the Clinical Director to take ALSO this week and ATLS in November. The Clinical Director indicates she rarely covers ER.	A1102		
A1112	482.55(b)(2) QUALIFIED EMERGENCY SERVICES PERSONNEL There must be adequate medical and nursing	A1112		

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personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility.

This STANDARD is not met as evidenced by:
Based on Medical Staff Bylaws, Rules, and Regulations review, medical record review, QIO (Quality Improvement Organization) review, credential file review, and staff interview, the facility failed to ensure there was qualified medical staff available to meet the needs of the patients. The facility identified a census of 2.

Findings included:

Review of Medical Staff Bylaws, Rules, and Regulations fails to delineate the qualifications for emergency physicians, physician assistants, or nurse practitioners.

Interview with the Improving Operation Performance/Risk Manager (IOP/RM) on 10/5/11 at 10:42 AM confirms after checking with the Clinical Director the Medical Staff Bylaws, Rules, and Regulations did not delineate qualifications for emergency department practitioners. The IOP/RM further indicates there is no policy to delineate the qualifications of an emergency room provider.

Review of medical record for patient #32 shows the patient presented to the emergency department on 12/30/10 at 9:15 AM complaining of hives and SOB (shortness of breath). Further review of the medical record shows Practitioner V ordered Epinephrine 1:1000 0.3 mg (milligrams) IV (intravenous) push once.

Review of a QIO (Quality Improvement

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Organization) review of the medical record for patient #32 on 6/16/11 shows there were concerns regarding the quality of care provided to the individual specifically the route of epinephrine was inappropriate. The appropriate route for 0.3 mg of epinephrine would be IM (intramuscular).

Review of the medical record for Patient #33 revealed she presented to the Outpatient Clinic for an appointment on 7/29/11 at 10:42 AM. During the course of the visit a Depression Screen was performed with Patient #33 answering yes to every question. The ambulatory care note for Patient #33 written by Physician W states in part, "Subjective: c/o [complained of] severely depressed, thoughts about hurting herself or her spouse, having crying spells, recently had interaction between cymbalta (anti-depressant) and her zomig (for treatment of migraine attacks), (seretonegic syndrome and cymbalta dose was 60 mg [milligrams], we give her cymbalta 30 mg for one week, then discontinued, having some issues with her husband, told she is suicidal can, be placed at [Hospital G] or [Hospital H] (close to her home) she needs to be evaluated by mental health and psychiatrist too I will follow their recommendations, her blood sugar is ok, within normal range, needs refill of her hydrocodone (pain medication) and rest of her regular meds, told she needs placement first then will refill her pills, depression screen done by nurse showing she is severely depressed." The outpatient clinic record further states in part, "Plan Contacted tribal mental health supervisor who agreed with transfer plan, they will follow up her care as outpatient, and a referral is made to mental health spoke to ER [emergency room] provider to transfer the patient to ER for placement patient

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and her spouse taken to ER in stable condition"

Review of the ER medical record for Patient #33 reveals Practitioner V documented a clinical course of contacting several police departments to obtain emergency protective custody. The medical record documents that Patient #33 is willing to be admitted for inpatient treatment. The medical record lacked documentation that Provider V contacted any hospital in an effort to place Patient #33 in a psychiatric unit for her severe depression and suicidal ideations. The medical record indicated that Provider V encouraged Patient #33 to sign out against medical advice (AMA) so that she could seek care at another facility.

Interview on 10/3/11 at 1:07 PM with Physician W revealed he did recall reviewing the medical record for Patient #32 and was aware there was an issue with the dosage of epinephrine given the patient on 12/30/10. Physician W confirms that Patient #33 was suicidal during the clinic visit with him on 7/29/11. He transferred Patient #33 to the emergency room per protocol so the patient could be transferred to the appropriate level of care. Physician W states he was unaware that Practitioner V had Patient #33 sign out AMA so she could go to another hospital. Physician W indicates that Practitioner V should not have done that and that he was available to help with the transfer but Practitioner V did not call.

Review of Medical Staff Bylaws, Rules, and Regulations dated FY (fiscal year) 2009-2011, states for all categories of Medical Staff membership including Active, Courtesy, and Provisional that the practitioner will exercise approved clinical privileges.

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Review of medical record for Patient #22 dated 8/18/11 at 10:30 PM Practitioner T completed the suture process for reattaching the tip of the second finger of the right hand.

Review of the medical record for Patient #22 dated 8/21/11 at 8:39 PM reveals Practitioner T states in the History of Present Illness, "70 yr [year]old male here for 3rd recheck of right index finger. Patient had a traumatic amputation of half of the distal phalanx at home on the 17 th, and I reattached it here in the ED [emergency department] within an hour. (I advised him that most orthopedic physicians would not "bother" with a distal phalanx but I have had success with 4 out of 5 of my previous attempts in local EDs.) He has been coming by the ED nightly for unofficial rechecks....He came back tonight for the recheck and the reattached part is black and has some odiferous debris>>> after confirming he has BC/BS [Blue Cross/Blue Shield] insurance which can be used as a primary, I advised him we would make a referral for him to be seen in the morning but that I needed to remove the distal fragment tonight."

Review of the credential file for Practitioner T reveals Medical Privileges signed by the Acting Clinical Director (Physician Z) on 4/7/11 and by the CEO (Chief Executive Officer) on 4/11/11. The Medical Privileges had a check for full privileges 'requested and recommended' by repair and closure for simple lacerations (not involving tendons, nerves, or major vessels. There was a 'not requested or recommended' beside repair and closure of complicated lacerations. The Medical Privileges do not have reattachment or amputation listed as a privilege

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for Practitioner T.

Interview with the Clinical Director on 8/25/11 at 1:35 PM reveals that Practitioner T deviated from the standard of practice regarding Patient #22. "We do not sew fingers back on at IHS hospitals".

Interview with the Clinical Director on 9/19/11 at 4:40 PM reveals that Practitioner T had poor judgement. The Clinical Director indicates the vessels in a finger are so small that they seal off in a couple of hours and revascularization is impossible. Given the fact that Patient #22 had poor perfusion and was on dialysis the poor outcome should have been predicted. It was a significant risk to the patient to reattach the finger due to the probability of failure and infection.

Interview with the Clinical Director on 9/19/11 at 4:40 PM reveals that the facility had a vague process for peer review when she became Clinical Director. The Clinical Director indicates that new forms and a new process for peer review started in June. There is no written procedure for the process to perform the peer review at this time.

Interview with the former Clinical Director (Physician W) on 10/3/11 at 1:07 PM reveals there is no formal process to bring medical records that have concerns related to patient care to the Medical Staff for review.

Without a delineation of qualifications and an effective review system for the quality of diagnosis and treatment within the facility there is no effective manner to determine the medical staff of the emergency department is qualified to meet the needs of the patients it serves.

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