STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	220071	A. BUILDING _____ B. WING _____	02/12/2010

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MASSACHUSETTS GENERAL HOSPITAL	55 FRUIT STREET BOSTON, MA 02114

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A 000	INITIAL COMMENTS A Validation Survey was conducted on 2/2/10 - 2/12/10. The Director of Compliance for the hospital was notified on 2/11/10 at 5:55 p.m. that Immediate Jeopardy (IJ) conditions existed. The determination was made related to the failure of the facility to provide care in a safe setting and for failure of nursing staff to respond to alarm indicators for Patient #77 who required continuous cardiac rhythum and rate monitoring. At 9:56 a.m., the patient was asystole (without a heart beat) and the staff did not respond until 10:16 a.m. The facility provided corrective measures that abated the immediacy of the situation. This was done by stationing qualified staff at every central monitoring display on each general care unit to ensure timely response to alarms at 10:58 p.m. on 2/11/10.	A 000		
A 021	482.11(a) COMPLIANCE WITH LAWS The hospital must be in compliance with applicable Federal laws related to the health and safety of patients. This STANDARD is not met as evidenced by: Based on interview with the facility's staff and record reviews, it was determined that the hospital did not ensure compliance with all applicable Federal, State and local law requirements regarding conducting criminal background checks of security/police after rehire. The findings include: Review of the personnel file of Security Officer (SO) #2 provided by the Police and Security Department's Night Manager, revealed SO #2 was originally hired in 2/03. He left service for three years, but returned and was rehired in 5/05.	A 021	The MGH acknowledges that the personnel file of security officer #2 was missing a CORI from 05/05, which was when this officer was rehired. According to the hospital's policy, employees who return for employment greater than six months from the date of their separation from the institution must have a new criminal background check upon rehire. In fact, the security officer in question was originally hired in 2003, left the hospital in 01/05 and returned to employment in 05/05. He was gone for a period of only 4 months, and therefore, a CORI would not have been required upon his rehire. A CORI, however, in fact, had been completed in 05/05. A redacted copy of that CORI is attached to this report (Attachment 1), and it has been recorded in the employee's personnel file.	02/12/10

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

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A 021	Continued From page 1 The personnel file also confirmed only one criminal background check dated 2/03. This was acknowledged by the Night Manager during the interview on 2/10/10 at 12:00 p.m. Additionally, he stated that upon rehire all security and police staff should have a new criminal background check. During an interview with the Human Resource Director (HRD) #1 on 2/10/10 at 2:45 p.m., she verified this information. She stated that the facility's policy indicated that employees, who return for employment six months from the date of their separation from services, must have a new criminal background check done upon rehire.	A 021		
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 observations, review of medical records, review of the General Hospital Corporation Bylaws of the Corporation and the Bylaws of the Professional Staff of the General Hospital, review of other facility documentation and staff interviews, it was determined that the hospital failed to meet the Conditions of Participation for Governing Body as evidenced by: The Governing Body did not ensure that all services offered and provided met the Medicare Conditions of Participation. Areas of noncompliance identified included: Nursing Services, Medical Staff, Medical Record	A 043	The MGH Board of Trustees is responsible for the operations of the Hospital, including its compliance with the CMS Conditions of Participation. Please see the specific plans of correction for each deficiency under the appropriate tag below. The President and Chief Executive Officer of Massachusetts General Hospital is responsible for ensuring the implementation of this plan of correction. Specific to the Governing Body Condition of Participation, please see the plans of correction below for A046, A047, A049 and A050.	04/28/10

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A 043	Continued From page 2 Services, Physical Environment, Infection Control, Surgical Services, and Rehabilitation Services. The hospital failed to protect and promote the rights of each patient. (See A 115, A122, A123, A143, A144, A147, A164, A166, A168, A169, A185, A186, A188, A206, and A214). The hospital failed to ensure that nursing services meet the needs of each patient. (See A385, A395, and A405). The Medical Staff failed to operate under the Bylaws approved by the Governing Body. (See A338, A341, A357, A358, A359 and A363). The hospital failed to ensure that medical record services were accountable for confidentiality and maintenance of medical records. (See A431, A438, A441, A449, and A450). The hospital failed to ensure that the hospital's buildings and equipment were arranged and maintained to ensure the safety and well being of patients. (See A700, A701, and A724). The hospital failed to have a hospital wide infection control program to control the transmission of infections and communicable diseases. (See A747, A749 and A750). The hospital failed to ensure that surgical services were provided according to acceptable standards to achieve and maintain high standards of patient care. (See A940 and A951). The hospital failed to ensure that rehabilitation services meet the needs of each patient. (See A1124 and A1132).	A 043		

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A 043	Continued From page 3 The findings include: Review of the General Hospital Corporation Bylaws of the Corporation revealed that the hospital acting through its Board of Trustees "shall oversee the affairs" of the General Hospital Corporation. The "committees of the Trustees shall consist of the Patient Care Assessment Committee and such other committees as the Trustees may establish and charge." In addition, the bylaws indicated that the "Patient Care Assessment Committee shall be responsible for patient care assessment and shall be constituted, shall have, and may exercise and discharge such powers and duties as described in the Patient Care Assessment Plan." This written plan describes the various programs of the hospital which are designed to assure the effective assessment of patient care in the hospital. During an interview on 2/11/10 at 7:00 a.m., with the hospital's Chief Executive Officer (CEO), he stated that the General Hospital Corporation is the governing body of the hospital which includes a minimum of twelve members of the Board of Trustees. The CEO confirmed that the governing body is responsible for the operation of the hospital.	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 review of the General Hospital	A 046	The MGH will establish a process to obtain Board of Trustees approval prior to any member of the Professional Staff beginning his/her clinical activities. At its April 16, 2010	04/28/10

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A 046	Continued From page 4 Corporation Bylaws of the Corporation and the Bylaws of the Professional Staff of the General Hospital, Governing Body Board Minutes, and staff interviews, it was determined that the Governing Body did not appoint members of the medical staff according to Medicare Conditions of Participation requirements. The findings include: Review of the General Hospital Corporation Bylaws of the Corporation revealed that the "Trustees may adopt, amend or repeal bylaws and similar instruments of governance for the organization and conduct of the affairs of the professional staff and any other functional entity of the Corporation. The bylaws of the professional staff shall provide for a general executive committee of the professional staff, which shall be constituted, shall have, and may exercise and discharge such powers and duties as provided in those bylaws or other instrument, including the power to consider and on behalf of the Trustees adopt policies and procedures relating to patient care and medical education and, at the request of the Trustees, other matters affecting the optimal operation of the General Hospital." In addition, the General Hospital Corporation Bylaws of the Corporation indicated that the "bylaws of the professional staff shall establish procedures for processing and evaluating applications for appointment and reappointment to the staff, and for the granting of clinical privileges, which shall be consistent with these Bylaws; and every appointment to the staff shall be in accordance with such procedures." During an interview on 2/11/10 at 7:00 a.m., with	A 046	meeting the MGH Board of Trustees will establish a Committee on Appointments and Privileges and will grant to this Committee the authority to approve all appointments and privileges. The Committee on Appointments and Privileges will consist of the following three members of the MGH Board of Trustees; the President of the Hospital, the Chief Executive Officer of the Physicians Organization and the representative Chief of Service on the Board of Trustees. The Committee on Appointments and Privileges will begin meeting on April 28, 2010. The MGH will amend the Professional Staff bylaws to set forth the process for granting privileges to the clinical staff, including the criteria for determining the privileges to be granted and a procedure for applying the criteria to individuals requesting privileges. The Professional Staff bylaws will also be amended to explicitly include judgment as a criterion for determining membership on the professional staff. Allied health professionals/nurses in the expanded role, and physician assistants complete the authorization to practice application done in collaboration with their collaborating/supervising physician. This application is signed by the candidate, their collaborating physician and the chief of service. If the candidate requires privileges to the operating room those privilege requests will be reviewed by the Surgical Coordinating Committee with recommendation for approval	

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A 046	Continued From page 5 the hospital's CEO, he stated that the Chief of Services proposes medical staff appointments and the Chiefs' Council approves the medical staff appointments and then forwards the information to the Board of Trustees. Review of the Board of Trustees Meeting Minutes indicated that the Trustees consider the recommendations of the Chiefs' Council for certain appointments and other actions related to the Professional Staff set forth in the lists made available at the meeting. The Board of Trustees then vote to adopt each recommendation of the Chiefs' Council concerning appointments to and changes in the professional staff as set forth in the lists presented at the meeting. In order to appoint members to the medical staff, the Trustees review information provided by the Chiefs' Council. However, review of the 12/18/09 Trustees of the General Hospital Corporation Summary of First Time Clinical/Non-Clinical Staff Appointments, revealed that privileging information was not consistently included with the information about each candidate. Examples include: 1. Doctor will work per diem in the main operating room (OR). 2. Doctor will be working as an assistant in Neurosurgery after having completed his residency training. 3. Doctor will see patients in the Structural Heart Disease Clinic. Review of 13 of 23 credentials files indicated that the governing body's approval date occurred after	A 046	to the Health Profession Staff Committee, to the Senior Vice President for Patient Care and Chief Nurse or designee who will forward the application to the committee on Appointments and Privileges for approval. Applicants will not practice in the expanded role or as physician assistants until they have been approved by the Committee on Appointments and Privileges. The existing policies, *Credentialing and Authorization of Nurses in the Expanded Roles who are MGH and MGPO Employees* and *Credentialing and Authorization of Physician Assistants who are MGH and MGPO Employees,* were revised on 3/9/10. These revised policies will be reviewed and approved by the Patient Care Services Executive Committee and the Board of Trustees by 4/16/10. These changes to the policies reflect the approval process for nurses in the expanded role and physician assistants that are approved by the Committee on Appointment and Privileges. The policy will change to reflect the improved process. The candidate will receive a final action letter listing privileges granted or refusal that will originate from the Patient Care Services Credentialing Coordinator once approved by the Committee on Appointments and Privileges. The letter will include the type of appointment and individual specific clinical privileges approved by the Committee. Updates on our performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality	

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A 046	Continued From page 6 the date that privileges were granted, resulting in physicians beginning clinical activities before Board approval. (See A341). Clinical privileges are granted by individual clinical departments, resulting in clinical practice in the facility without Medical Staff recommendations for Board approval. (See A341). Review of 1 of 1 RN/NP First Assistant's credential file revealed, "temporary Operating Room privileges" were granted by the Executive Medical Director of ORs and the Chief of Surgical Services, and the "temporary privileges" were extended until the next scheduled Surgical Committee meeting, resulting in clinical practice in the facility for a prolonged period of time without completing the facility's own approval process and without Medical Staff recommendation for Board approval. (See A341). The Professional Staff Bylaws are missing candidate qualifications and description of the hospital's privileging process. (A357). The Professional Staff Bylaws do not include the criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges. (A363).	A 046	Oversight Committee (QOC). The QOC, which reports up through our General Executive Committee and through the Boards of Trustees Quality Subcommittee to the Boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that we are making progress as planned, and communicate our progress and concerns to the Boards through the mechanism above on a quarterly basis until the issue is resolved to prevent the likelihood of the deficient practice from reoccurring. Subsequent compliance will be reviewed through our quality and safety dashboards which will now include an explicit area to monitor our CoP compliance. In addition to these periodic reviews we will be flagging all safety event reports related to CoP issues so that ad hoc compliance issues can be addressed in a robust and timely fashion. The appointment and privileging process for physicians is monitored by the Director of the Medical Staff Office. The credentialing process for nurses in the expanded role and physician assistants will be monitored by the Patient Care Services Credentialing Coordinator. All applicants will complete the process and provide the appropriate documentation necessary to meet the requirements for approval by the Committee on Appointments and Privileges.	
A 047	482.12(a)(3) MEDICAL STAFF - BYLAWS [The governing body must] assure that the medical staff has bylaws. This STANDARD is not met as evidenced by: Based on review of the General Hospital Corporation Bylaws of the Corporation and the Bylaws of the Professional Staff of the General	A 047		

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A 046	Continued From page 6 the date that privileges were granted, resulting in physicians beginning clinical activities before Board approval. (See A341). Clinical privileges are granted by individual clinical departments, resulting in clinical practice in the facility without Medical Staff recommendations for Board approval. (See A341). Review of 1 of 1 RN/NP First Assistant's credential file revealed, "temporary Operating Room privileges" were granted by the Executive Medical Director of ORs and the Chief of Surgical Services, and the "temporary privileges" were extended until the next scheduled Surgical Committee meeting, resulting in clinical practice in the facility for a prolonged period of time without completing the facility's own approval process and without Medical Staff recommendation for Board approval. (See A341). The Professional Staff Bylaws are missing candidate qualifications and description of the hospital's privileging process. (A357). The Professional Staff Bylaws do not include the criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges. (A363).	A 046	If issues arise relating to an applicant, those issues will be forwarded to the MGH Chief Medical Officer or the Executive Director for The Institute for Patient Care and the Senior Vice President for Patient Care and Chief Nurse. The MGH Chief Medical Officer is responsible for ensuring the implementation of this plan of correction.	
A 047	482.12(a)(3) MEDICAL STAFF - BYLAWS [The governing body must] assure that the medical staff has bylaws. This STANDARD is not met as evidenced by: Based on review of the General Hospital Corporation Bylaws of the Corporation and the Bylaws of the Professional Staff of the General	A 047	The MGH will amend the Professional Staff bylaws to explicitly include judgment as a criterion for determining membership on the professional staff and privileges. In addition the Professional Staff bylaws will be amended to set forth the process for granting privileges to the clinical staff, including the criteria for determining the privileges to be granted and a procedure for applying the criteria to individuals requesting privileges.	05/21/10

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A 047	Continued From page 7 Hospital, and interviews with staff, it was determined that the Governing Body has approved Medical Staff Bylaws that do not meet the Medicare Hospital Conditions of Participation. The findings include: The General Hospital Corporation Bylaws of the Corporation indicated that the "Bylaws of the professional staff shall establish procedures for processing and evaluating applications for appointment and reappointment to the staff, and for the granting of clinical privileges, which shall be consistent with these Bylaws; and every appointment to the staff shall be in accordance with such procedures." During an interview on 2/11/10 at 7:00 a.m. with the hospital's CEO, he stated that the governing body of the hospital approves the bylaws of the medical staff. Review of the Professional Staff Bylaws revealed the following information: The Professional Staff Bylaws are missing candidate qualifications and description of the hospital's privileging process. (See A357). The Professional Staff Bylaws do not include a requirement that a medical history and physical examination be completed and documented for each patient no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. (See A358). The Professional Staff Bylaws do not include a requirement that an updated examination of the	A 047	The Professional Staff bylaws will be amended to add the requirement regarding updated patient examinations when the medical history and physical examination are completed within 30 days before admission or registration. Lastly, an amendment will be made to the Professional Staff bylaws to add requirements regarding the taking of medical histories and physicals, including the timeframe for taking such actions. Revisions to the Professional Staff Bylaws will be approved by the MGH General Executive Committee on 4/28/10 and the Physicians Organization Executive Committee on 4/23/10. The MGH will establish a new process to obtain Board of Trustee approval prior to any member of the Professional Staff beginning their clinical activities. All applications for Professional Staff appointments and privileges will be presented to a Committee on Appointments and Privileges (consisting of members of the Board of Trustees) and such applicants will be allowed to begin their clinical activities after receiving approval. Privileging information will be included in the summary provided to the Chiefs Council and the Committee on Appointments and Privileges for consideration prior to the appointment of the Professional Staff. Allied health professional/nurses in the	

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A 047	Continued From page 8 patient, including any changes in the patient's condition, be completed and documented within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, when the medical history and physical examination are completed within 30 days before admission or registration. (See A359). The Professional Staff Bylaws do not include the criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges. (See A363). Review of 13 of 23 credentials files revealed that the governing body's approval date occurred after the date that privileges were granted, resulting in physicians beginning clinical activities before Board approval. (See A341). Clinical privileges are granted by individual clinical departments, resulting in clinical practice in the facility without Medical Staff recommendations for Board approval. (See A341). Review of 1 of 1 RN/NP First Assistant's credential file revealed, "temporary Operating Room privileges" were granted by the Executive Medical Director of ORs and the Chief of Surgical Services, and the "temporary privileges" were extended until the next scheduled Surgical Committee meeting, resulting in clinical practice in the facility for a prolonged period of time without completing the facility's own approval process and without Medical Staff recommendation for Board approval. (See A341)	A 047	expanded role and physician assistants complete the authorization to practice application done in collaboration with their collaborating/supervising physician. This application is signed by the candidate, their collaborating physician and the chief of service. If the candidate requires privileges to the operating room those privilege requests will be reviewed by the Surgical Coordinating Committee with recommendation for approval to the Health Profession Staff Committee, to the Senior Vice President for Patient Care and Chief Nurse or designee who will forward the application to the Committee on Appointments and Privileges for approval. Applicants will not practice in the expanded role or as physician assistants until they have been approved by the Committee on Appointments and Privileges. The existing policies, *Credentialing and Authorization of Nurses in the Expanded Roles who are MGH and MGPO Employees* and *Credentialing and Authorization of Physician Assistants who are MGH and MGPO Employees* were revised on 3/09/10. These revised policies will be reviewed and approved by the Patient Care Services Executive Committee and the Board of Trustees by 4/16/10. These changes to the policies reflect the approval process for nurses in the expanded role and physician assistants that are approved by the Committee on Appointments and Privileges. The policy will change to reflect the improved process. The candidate will receive a final action letter listing privileges granted or	
A 049	482.12(a)(5) MEDICAL STAFF - ACCOUNTABILITY	A 049		

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A 047	Continued From page 8 patient, including any changes in the patient's condition, be completed and documented within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, when the medical history and physical examination are completed within 30 days before admission or registration. (See A359). The Professional Staff Bylaws do not include the criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges. (See A363). Review of 13 of 23 credentials files revealed that the governing body's approval date occurred after the date that privileges were granted, resulting in physicians beginning clinical activities before Board approval. (See A341). Clinical privileges are granted by individual clinical departments, resulting in clinical practice in the facility without Medical Staff recommendations for Board approval. (See A341). Review of 1 of 1 RN/NP First Assistant's credential file revealed, "temporary Operating Room privileges" were granted by the Executive Medical Director of ORs and the Chief of Surgical Services, and the "temporary privileges" were extended until the next scheduled Surgical Committee meeting, resulting in clinical practice in the facility for a prolonged period of time without completing the facility's own approval process and without Medical Staff recommendation for Board approval. (See A341)	A 047	refusal that will originate from the Patient Care Services Credentialing Coordinator once approved by the Committee on Appointments and Privileges. The letter will include the type of appointment and individual specific clinical privileges approved by the Committee. Updates on our performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through our General Executive Committee and through the Boards of Trustees Quality Subcommittee to the Boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that we are making progress as planned, and communicate our progress and concerns to the Boards through the mechanism above on a quarterly basis until the issue is resolved to prevent the likelihood of the deficient practice from reoccurring. Subsequent compliance will be reviewed through our quality and safety dashboards which will now include an explicit area to monitor our CoP compliance. In addition to these periodic reviews we will be flagging all safety event reports related to CoP issues so that ad hoc compliance issues can be addressed in a robust and timely fashion. The appointment and privileging process for physicians is monitored by the Director of the Medical Staff Office. The credentialing process for nurses in the expanded role and physician assistants will be monitored by the Patient Care Services Credentialing Coordinator. All applicants will complete the	
A 049	482.12(a)(5) MEDICAL STAFF - ACCOUNTABILITY	A 049		

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A 047	Continued From page 8 patient, including any changes in the patient's condition, be completed and documented within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, when the medical history and physical examination are completed within 30 days before admission or registration. (See A359). The Professional Staff Bylaws do not include the criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges. (See A363). Review of 13 of 23 credentials files revealed that the governing body's approval date occurred after the date that privileges were granted, resulting in physicians beginning clinical activities before Board approval. (See A341). Clinical privileges are granted by individual clinical departments, resulting in clinical practice in the facility without Medical Staff recommendations for Board approval. (See A341). Review of 1 of 1 RN/NP First Assistant's credential file revealed, "temporary Operating Room privileges" were granted by the Executive Medical Director of ORs and the Chief of Surgical Services, and the "temporary privileges" were extended until the next scheduled Surgical Committee meeting, resulting in clinical practice in the facility for a prolonged period of time without completing the facility's own approval process and without Medical Staff recommendation for Board approval. (See A341)	A 047	process and provide the appropriate documentation necessary to meet the requirements for approval by the Committee on Appointment and Privileges. If issues arise relating to an applicant, those issues will be forwarded to the MGH Chief Medical Officer or the Executive Director for The Institute for Patient Care and the Senior Vice President for Patient Care and Chief Nurse. The MGH Chief Medical Officer is responsible for ensuring the implementation of this plan of correction.	
A 049	482.12(a)(5) MEDICAL STAFF - ACCOUNTABILITY	A 049	The MGH plan of correction for the deficiencies related to the process of privileging physicians and allied health	04/16/10

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A 049	Continued From page 9 [The governing body must] ensure that the medical staff is accountable to the governing body for the quality of care provided to patients. This STANDARD is not met as evidenced by: Based on review of the General Hospital Corporation Bylaws of the Corporation and the Bylaws of the Professional Staff of the General Hospital, and interviews with staff, it was determined that the Governing Body did not ensure that Allied Health Professionals were privileged according to the Medicare Hospital Conditions of Participation. The findings include: The General Hospital Corporation Bylaws of the Corporation indicated that the "Bylaws of the professional staff shall establish procedures for processing and evaluating applications for appointment and reappointment to the staff, and for the granting of clinical privileges, which shall be consistent with these Bylaws; and every appointment to the staff shall be in accordance with such procedures." Review of clinical privileges revealed that privileges are granted by individual clinical departments, resulting in clinical practice in the facility without Medical Staff recommendations for Board approval. (See A341). Review of 1 of 1 RN/NP First Assistant's credential file revealed that, "temporary Operating Room privileges" were granted by the Executive Medical Director of ORs and the Chief of Surgical Services, and the "temporary privileges" were extended until the next scheduled Surgical Committee meeting, resulting in clinical practice	A 049	professionals is discussed in detail in A046 above.	

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A 049	Continued From page 10 in the facility for a prolonged period of time without completing the facility's own approval process and without Medical Staff recommendation for Board approval. (See A341). Review of the the Professional Staff Bylaws revealed the following information: The Professional Staff Bylaws are missing candidate qualifications and description of the hospital's privileging process. (See A357). The Professional Staff Bylaws do not include the criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges. (See A363). During an interview on 2/11/10 at 7:00 a.m. with the hospital's CEO, he stated that the Allied Health Professionals are not members of the medical staff and are not privileged.	A 049		
A 050	482.12(a)(6) MEDICAL STAFF - SELECTION CRITERIA [The governing body must] ensure that criteria for selection are individual character, competence, training, experience, and judgement. This STANDARD is not met as evidenced by: Based on review of the General Hospital Corporation Bylaws of the Corporation and the Bylaws of the Professional Staff of the General Hospital, and interviews with the facility's staff, it was determined that the Governing Body did not ensure that the primary source of verification of training is done according to the Medicare Hospital Conditions of Participation. The findings include:	A 050	The MGH believes that the current process for verifying evidence of training and professional education is in full compliance with the Medicare Hospital Conditions of Participation. MGH uses the Massachusetts Board of Registration in Medicine for completion of primary source verification of graduation from an accredited medical school. The use of the Massachusetts Board of Registration in Medicine for this purpose has been explicitly approved by national accrediting organizations. During on-site investigations the Massachusetts Department of Public Health has accepted the current process of providing evidence of training and professional education as meeting the Medicare Hospital Conditions of Participation.	02/12/10

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A 050	Continued From page 11 The General Hospital Corporation Bylaws of the Corporation indicated that the "Bylaws of the professional staff shall establish procedures for processing and evaluating applications for appointment and reappointment to the staff, and for the granting of clinical privileges, which shall be consistent with these Bylaws; and every appointment to the staff shall be in accordance with such procedures." The hospital failed to include evidence of training and professional education through primary source verifications for all members of the medical staff. On 2/4/2010, review of a letter "To Whom It May Concern" dated 1/16/09, from the Commonwealth of Massachusetts Board of Registration in Medicine, Regarding Primary Source Verification, indicated the following information, "Please be advised that the on-line verification information is maintained by the Massachusetts Board of Registration in Medicine and is updated every evening, in compliance with JCAHO (Joint Commission on Accreditation of Healthcare Organizations) and the National Committee on Quality Assurance (NCQA) standards for primary source verification of physician information." During interview with the Director, MGH/GPO Medical Staff Office on 2/4/10 at 8:40 a.m., she stated that medical education is the only thing not done by primary source verification - done by the Board of Medicine "in compliance with the Joint Commission and the INCA." During an interview on 2/11/10 at 7:00 a.m. with the hospital's CEO, he stated that the Medical	A 050	The process for verifying training and professional education developed by the Massachusetts Board of Registration in Medicine is intended to remove redundancy and duplication of efforts, and thereby significant costs, from the health care system. Therefore, the MGH respectfully requests that CMS accept this process as meeting the Medicare Hospital Conditions of Participation.	

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A 050	Continued From page 12 Staff Office ensures that primary verification is utilized when performing credentialing of medical staff.	A 050		
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, record review, staff interviews and review of the facility's internal investigation reports, it was determined that the facility failed to protect and promote patients rights. The facility failed to ensure that one of 84 patients (Patient #77) received care and services in a safe and timely manner to prevent lethal arrhythmias (any disturbance or irregularity of the heart beat.) The facility failed to ensure that grievances were investigated and/or provided a written response in a timely manner for five of five grievances reviewed (Patients # 79, 80, 81, 82 & 83). The facility to failed to ensure that the right to patient privacy was protected by the use of video cameras and personal and health information was accessible to unauthorized individuals. The facility failed to ensure that the use of physical restraints as an intervention for seven of 84 patients were in accordance with the Medicare Requirements (Patients # 11, 38, 41, 61, 68, 75 & 76). (See A122, A123, A143, A144, A147, A164, A166, A168, A169, A185, A186, A188, A206 &A214)	A 115	Please see the responses below to A122, A123, A143, A144, A147, A164, A166, A168, A169, A185, A186, A188, A206 and A214.	
A 122	482.13(a)(2)(ii) PATIENT RIGHTS: GRIEVANCE REVIEW TIME FRAMES	A 122	The hospital acknowledges that at the time of survey the MGH's patient educational materials did not state specific time frames	04/30/10

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A 122	Continued From page 13 At a minimum: The grievance process must specify time frames for review of the grievance and the provision of a response. This STANDARD is not met as evidenced by: Based on staff interview, and review of facility's policies, grievance files and other facility documents, it was determined that the facility failed to include specific time frames in their grievance procedures for review and resolution of grievances, and provision of a written response to the complainant. In addition, the facility failed to provide a written response in a timely manner for three of the five sampled grievances reviewed for Patients #81, #82 and #83. The findings include: Review of the facility's Patient Information Guide, provided to patients at the time of their admission, revealed patients are given the following information regarding registering a grievance (the term "complaint" is used by the facility): Page 8: You, your family, or your guardian have the right to tell us when something is seriously wrong. This is called presenting a complaint. If you present a complaint, your care will not be affected in any way. Also, if you have a problem that you cannot solve with your doctor, nurse, or other caregiver, please call the Office of Patient Advocacy at (telephone number.) Page 26: The Office of Patient Advocacy serves as the liaison between patients and the organization in their expressions of praise or concern so that moral, ethical, operational and care standards are upheld on behalf of MGH	A 122	for the review and resolution of patient grievances. To address this deficiency, specific time frames for review and resolution of grievances will be established. A time frame will be established for a written response to the complainant. A time frame also will be established for update communications to complainants. These time frames will be added to the *Patient Information Guide*, *Patient Rights & Responsibilities* posters, *Patient Rights & Responsibilities* pamphlets and the *Patient Rights & Responsibilities* section posted on the Office of Patient Advocacy website. To improve the process of review and resolution times for grievances, CMS Conditions of Participation guidelines were reviewed and a draft policy was written. Staff in the Office of Patient Advocacy held a meeting to review the draft, discuss changes, brainstorm and formulate methods for compliance. In addition, input was received from the Center for Quality and Safety staff. Input also was sought from the MGH chief nurse and MGH chief medical officer. (Attachment 2) Current Massachusetts General Hospital documents related to patient grievances were reviewed. After the review, it was decided to eliminate the categories of “ordinary” and “difficult” complaints. The Office of Patient Advocacy will use the terms “complaint” and “grievance.” Time frames will be established for review and resolution of grievances. A time frame and method for communication to the complainant, if grievance is not resolved within the established time frame, will be established. Software changes to accommodate new event classification of grievances will be made. Software changes to accommodate all types of complainant	

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A 122	Continued From page 14 patients. Patient Advocates have the authority to communicate your complaints or to look into your complaint. If you have a complaint, we will work to resolve your problem in a neutral and non-threatening way.(The final sentence included the location of the Office of Patient Advocacy, telephone number, hours of operation and website address.) The Patient Information Guide did not include specific time frames for review of the submitted complaint or for the provision of a written response. During an interview on 2/9/10 at 9:00 a.m., the Director of the Office of Patient Advocacy, RN FF, provided a booklet labeled with "Office of Patient Advocacy,"on the front cover. The booklet included the following information: Our investigation will include: - Asking your permission to start the investigation; - Talking with you and/or your family so that we know your concerns; - Contacting and talking with the person(s) named in your complaint; - Reviewing all appropriate documents, including your medical record, if necessary - Collaborating with you on a possible resolution. The MGH booklet contained the following information; MGH and outside regulatory agencies have set standards that we must follow when we manage patient or family complaints. These standards ensure that: -Patients and families are told that they have a right to file a complaint and they are told how to do so;	A 122	follow-up communication also will be made. Education about these changes will be provided for staff in the Office of Patient Advocacy, in the Center for Quality and Safety and in Patient Financial Services. Communication about the changes will also include hospital staff members involved in this process (e.g., departmental quality chairpersons, practice managers). The correction for this deficiency will be completed by 4/30/10. Updates on performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through the MGH General Executive Committee and through the Boards of Trustees Quality Subcommittee to the boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that the hospital is making progress as planned, and communicate progress and concerns to the boards through the mechanism above on a quarterly basis until the issue is resolved to prevent the deficient practice from recurring. Subsequent compliance will be reviewed through quality and safety dashboards, which will now include an explicit area to monitor the hospital's Condition of Participation compliance. In addition to these periodic reviews, the hospital will flag all safety event reports related to the Conditions of Participation so that ad hoc compliance issues can be addressed in a robust and timely fashion. Reports will be produced in the Office of Patient Advocacy online system. These reports will be able to track grievances, time taken to send acknowledgement letters, time	

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A 122	Continued From page 15 - We look into the complaint and, when indicated, make efforts to correct the problem; - Each patient or family that makes a complaint receives a response from us, and - If you present a complaint, your care will not be affected in any way. A section in the booklet for frequently asked questions included the question, "If I have a complaint, how will it be handled?" The response indicated: A Patient Advocate will be assigned to look into your complaint and work with you to resolve the issue. Your complaint is entered into our database and reports are sent to hospital leadership several times a year. This information is used to improve the care we deliver. The Office of Patient Advocacy booklet did not include specific time frames for review of the submitted complaint or for the provision of a written response. During the 2/9/10 interview, RN FF stated 90% (percent) of complaints received by the facility can be resolved within a day. RN FF stated 20% of the complaints received are in writing, 25% are received verbally, 50% are received via telephone call, and 5% are received by e-mail. RN FF stated their office tries to resolve grievances within one month. She stated, the Patient Advocate assigned to investigate the complaint sends an initial letter and also makes a telephone call to the complainant. RN FF stated they try to keep the complainant updated weekly or every other week of the progress of the investigation. At the conclusion of the investigation, a letter is sent and a telephone call is placed to the complainant to inform them of the outcome. Additionally, RN FF stated staff responds in writing to the individual making the complaint, but can't guarantee this	A 122	taken to send written responses with resolutions, and time lapse when sending update communications. Reports will be produced weekly for two months at the start of the changes, monthly for three months, and then quarterly thereafter to monitor compliance. These reports will be sent to the Patient Care Assessment Committee, Center for Quality and Safety, department heads and senior vice presidents. Random audits of patient care areas will be conducted for one month to ensure updated posters, updated pamphlets and updated *Patient Information Guides* are being distributed. Periodic audits to ensure ongoing compliance will also be conducted. Office of Patient Advocacy staff will obtain usage reports from Standard Register (printing company) to monitor usage throughout the hospital. The director of the Office of Patient Advocacy is responsible for ensuring implementation of this plan of correction.	

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A 122	Continued From page 16 happens 100% of the time. Review of documents provided by RN FF on 2/2/10 indicated that the facility's complaint process involves three categories of complaints: Serious (defined by the facility as a report which alleges care that may have resulted in death, permanent or disabling injury, abuse or abandonment); ordinary (no definition provided); and difficult (no definition provided). The procedure for investigating serious complaints indicated notification of appropriate staff and investigation would occur within 24 hours of receipt of the complaint. The complainant would be informed during and after review of the complaint, as significant findings are determined, but at the very least within a week, and at completion of the investigation. The final communication with the complainant would be in writing. The facility's procedure did not include time frames for the resolution of serious, ordinary or difficult complaints. Additionally, the procedures did not include provision of a written response to the complainant for ordinary or difficult complaints. Review of a complaint letter received from Patient #81 on 12/4/09, indicated the patient complained of contracting a surgical site infection post-operatively secondary to an error in the surgery or in the surgical technique. The facility did not provide a written response to the patient's complaint until 1/26/10-53 days later. Review of a complaint letter received from Patient #82 on 11/9/09, indicated the patient complained of being prescribed an antibiotic on two different	A 122		

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A 122	Continued From page 17 occasions to treat a . The patient noted was allergic to both medications. A response to the patient's complaint was not sent until 12/15/09-36 days later. Review of a complaint letter received from Patient #83 on 12/15/08, indicated that the patient complained about the management and dosage of prescribed Coumadin (blood thinner) medication. A written response to the patient's complaint was not sent until 1/12/09-28 days later.	A 122		
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 interview, policy review and review of patients' grievance files from 10/1/09 through 12/31/09, it was determined that the facility failed to provide a written response to the complainant for two of five patient grievances reviewed. (Patients #79 and #80) The findings include: 1. A grievance received by telephone from Patient #79 on 10/30/09 indicated that a complaint relative to the patient's personal health information had been leaked to the press. The	A 123	The hospital acknowledges that at the time of survey not all patient grievances were responded to in writing. To correct this deficiency the hospital will ensure that all grievance decisions will be sent in writing to complainants following the time frames for the specific method of review. Written responses to grievances will include steps taken to investigate the grievance, results of the investigation, and name and contact information for the hospital contact person. To address this issue and improve the MGH's record of sending written responses within expected time frames, CMS Conditions of Participation guidelines were reviewed. Staff in the Office of Patient Advocacy held a meeting to discuss the issue and brainstorm possible actions. This discussion led to agreement about process change. Input was obtained from the Center for Quality and Safety staff. In addition, advice was sought from the MGH chief nurse and MGH chief medical officer. The procedure for implementing this plan of correction includes a process update within	04/30/10

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A 123	Continued From page 18 complaint file revealed that the patient was referred to the HIPAA (Health Insurance Portability and Accountability Act) compliance office. (HIPAA is a law designed to provide privacy standards to protect patients' medical records and other health information provided to health plans, doctors, hospitals and other health care providers.) The complaint file contained an address for the patient to forward written correspondences. There was no evidence in the complaint file indicating the facility's staff provided a written response to the patient of the results of the investigation. 2. A grievance received in person from Patient #80 on 11/9/09 revealed a report by the patient indicating that a volunteer in the had stolen a plastic bag from the basket on the patient's walker. The bag contained the patient's wallet, red folding card and emergency information. The patient identified the volunteer by name. The grievance file contained an address for the patient to forward written correspondences. The file lacked evidence indicating that the facility's staff provided a written response to the patient with the results of the investigation. During an interview on 2/9/10 at 9:00 a.m., RN FF, Director of the Office of Patient Advocacy, stated their office tries to resolve grievances within one month. She stated the Patient Advocate assigned to investigate the complaint, forwards an initial letter, and also makes a telephone call to the complainant. RN FF stated they try to keep the complainant updated weekly or every other week relative to the progress of the investigation. At the conclusion of the investigation, another letter is sent and a	A 123	the Office of Patient Advocacy, and education of the staff in the Office of Patient Advocacy, in the Center of Quality and Safety, and in Patient Financial Services. Communication also will include other hospital staff members involved in this process, (e.g., departmental quality chairpersons and practice managers). The correction for this deficiency will be completed by 4/30/10. Updates on performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through the MGH General Executive Committee and through the Boards of Trustees Quality Subcommittee to the boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that the hospital is making progress as planned, and communicate progress and concerns to the boards through the mechanism above on a quarterly basis until the issue is resolved to prevent the deficient practice from recurring. Subsequent compliance will be reviewed through the hospital's quality and safety dashboards, which will now include an explicit area to monitor Conditions of Participation compliance. In addition to these periodic reviews the MGH will flag all safety event reports related to Conditions of Participation issues so that ad hoc compliance issues can be addressed in a robust and timely fashion. A report will be produced from the Office of Patient Advocacy system that will provide completed grievances, confirmation that a written response was sent and when it was sent, time period from the date the grievance was received in the Office of Patient Advocacy to the date of written response.	

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A 123	Continued From page 19 telephone call is placed to the complainant to inform them of the outcome. RN FF stated staff respond in writing to the individual making the complaint but can't guarantee this happens 100% of the time. Review of documents provided by RN FF on 2/2/10 indicated the facility's complaint process involves three categories of complaints: Serious (defined by the facility as a report which alleges care that may have resulted in death, permanent or disabling injury, abuse or abandonment); ordinary (no definition provided); and difficult (no definition provided). The procedure for investigating serious complaints indicated notification of appropriate staff and investigation would occur within 24 hours of receipt of the complaint. The procedure also indicated that the complainant would be informed during and after review of the complaint, as significant findings are determined, but at the very least within a week and at completion of the investigation. The final communication with the complainant would be in writing. The facility's procedure did not include timeframes for the resolution of serious complaints. The procedures for investigating ordinary and difficult complaints did not include specific time frames for review and resolution of the grievance, and provision of a written response to the complainant.	A 123	In addition, the Office of Patient Advocacy staff will conduct random audits of 10 percent of the monthly grievances to verify that the written responses included steps taken to investigate the grievance, results of the investigation, and the name and contact information for the specific hospital contact person. The director of the Office of Patient Advocacy is responsible for the implementation of this plan of correction.	
A 143	482.13(c)(1) PATIENT RIGHTS: PERSONAL PRIVACY The patient has the right to personal privacy. This STANDARD is not met as evidenced by: Based on observations and staff interviews it was determined that the facility failed to protect the patients' rights to personal privacy as well as	A 143	The MGH has identified two mechanisms to ensure patient privacy for closed circuit surveillance monitors based on the specific type of monitor used. Some monitors will be covered with a film, allowing a singular view by staff positioned directly in front of the monitor. Monitor hoods will be placed on the other monitors, ensuring a singular view by staff positioned directly in front of the monitor.	04/30/10

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A 143	Continued From page 20 having closed circuit surveillance monitoring cameras in the patients' rooms. Additionally, the facility had personal information visible to anyone in the hallway. This permitted the potential for observations of patients in various stages of undress, treatments, and care such as perineal, bed baths, bathing and catheter insertions. The findings include: Observations on all days of the survey revealed that had a white board hanging behind the nurses' stations facing toward the hallway visible to patients, staff and visitors. Information on these board included patients' names and their room numbers. On 02/09/10 between 9:15 a.m. and 10:00 a.m. the was toured in the presence of the assigned Clinical Nurse Specialist (CNS) F and the Unit Nursing Director B. Surveillance cameras were noted in the following rooms: . Three closed circuit TV (televisions) monitors were strategically located at the nurses' station, two of which were on. The monitor located at the nurses' station in front of Rooms designated "the high side" of the unit was visible to family, visitors, all staff alike from the corridor/hallway near stairway #3. During the tour of , a surveillance camera was noted in . In the room, a gentleman was seated in a chair. The gentleman identified himself as the of the patient in the bed. During an interview with this	A 143	MGH has completed an assessment of all applicable rooms with closed circuit surveillance monitor cameras. Modifications will be made to the camera location and/or the cubicle curtain track to provide adequate privacy for the patient. This work was completed . The MGH Privacy Office will create a patient consent form consistent with privacy and confidentiality regulations and aligning with patient rights. This form will be available on floors that have surveillance cameras and will be available on the intranet for staff to print copies. Efforts to address improving the processes that led to this deficiency involve a complete assessment of patients' rights to personal privacy before any future modifications to the physical environment requiring the placement of in-room cameras and associated monitors. This assessment will be executed by incorporating a personal privacy risk assessment into the unit checklist for renovations. To implement this plan of correction, the MGH has begun - and will continue - to make changes to the physical environment as detailed above. The hospital will educate clinical staff to routinely use the cubicle curtain to help ensure patient privacy while in the room caring for the patient. The consent form will emphasize quality of care needs for surveillance, and this form will be scanned into the medical record. The completion date for correction of this deficiency is 4/30/10. Updates on the hospital's performance related	

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A 143	Continued From page 21 gentleman stated that he had not been approached by any staff members regarding the use of the camera and had not consented to its use. Interviews with the CNS, and the Unit Nursing Director on the afternoon of 2/9/10 revealed it was not the practice of the floor staff to obtain consents for the use of the surveillance cameras. They also stated the facility does not have a policy regarding obtaining consents for the use of the surveillance cameras. During the tour of on 2/9/10, an observation revealed that the privacy curtain when pulled did not obstruct the camera's view. The two staff members who acknowledged that the privacy curtains did not provide privacy from the cameras. Interview with staff Nurse L during the mid-morning on 02/09/10 revealed that there is no policy in place to guide nursing staff regarding obtaining consent related to the use of the camera, or for informing patients and/or family members about its use. Observation on 2/10/10 at 11:50 AM showed two monitors at the rear desk of . The monitors were at the north-west end of the desk. The monitors were clearly visible when anyone approached to ask a question or stand close to the desk. One of the monitors was off. The second monitor showed a patient in bed with staff around performing a bronchoscopy (procedure in which a physician inserts a tube into the airways to examine the lungs for abnormalities). Interview on 2/10/10 at the time of the	A 143	to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through the MGH General Executive Committee and through the Boards of Trustees Quality Subcommittee to the boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that the hospital is making progress as planned, and communicate progress and concerns to the boards through the mechanism above on a quarterly basis until the issue is resolved to prevent the deficient practice from recurring. Subsequent compliance will be reviewed through the MGH quality and safety dashboards, which will include an explicit area to monitor Conditions of Participation compliance. In addition to these periodic reviews, the hospital will flag all safety event reports related to Conditions of Participation so that ad hoc compliance issues can be addressed in a robust and timely fashion. Procedures for monitoring and tracking to ensure this plan of correction is effective and the specific deficiencies cited remain corrected and/or in compliance with the regulatory requirements include Biomedical Engineering and Nursing undertaking a thorough review of the identified locations following the implementation of physical modifications to ensure that patient privacy has been achieved. When changes are made to the physical environment - either at the nurses' station, where closed circuit surveillance cameras and monitors are located, or within patient rooms on these units - an assessment will be conducted to ensure patient privacy is maintained using the unit checklist for renovations.	

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A 143	Continued From page 21 gentleman/spouse, he stated that he had not been approached by any staff members regarding the use of the camera and had not consented to its use. Interviews with the CNS, and the Unit Nursing Director on the afternoon of 2/9/10 revealed it was not the practice of the floor staff to obtain consents for the use of the surveillance cameras. They also stated the facility does not have a policy regarding obtaining consents for the use of the surveillance cameras. During the tour of on 2/9/10, an observation revealed that the privacy curtain when pulled did not obstruct the camera's view. The two staff members who acknowledged that the privacy curtains did not provide privacy from the cameras. Interview with staff Nurse L during the mid-morning on 02/09/10 revealed that there is no policy in place to guide nursing staff regarding obtaining consent related to the use of the camera, or for informing patients and/or family members about its use. Observation on 2/10/10 at 11:50 AM showed two monitors at the rear desk of . The monitors were at the north-west end of the desk. The monitors were clearly visible when anyone approached to ask a question or stand close to the desk. One of the monitors was off. The second monitor showed a patient in bed with staff around performing a bronchoscopy (procedure in which a physician inserts a tube into the airways to examine the lungs for abnormalities). Interview on 2/10/10 at the time of the	A 143	mechanism above on a quarterly basis until the issue is resolved to prevent the deficient practice from recurring. Subsequent compliance will be reviewed through the MGH's quality and safety dashboards, which will include an explicit area to monitor our Conditions of Participation compliance. In addition to these periodic reviews the hospital will flag all safety event reports related to Conditions of Participation so that ad hoc compliance issues can be addressed in a robust and timely fashion. Procedures for monitoring and tracking to ensure that the plan of correction is effective and the specific deficiencies cited remain corrected and/or in compliance with the regulatory requirements will involve monthly and annual surveillance rounds conducted by senior department representatives from Patient Care Services, the Center for Quality and Safety and other key support departments. This survey tool, which is used to thoroughly and regularly assess the patient care environment, will formally incorporate a section dedicated to review of the physical environment for compliance with patient privacy. Surveillance round reports will indicate the level of compliance and identify any area where patient personal privacy rights are not being maintained. The person responsible for implementing the plan of correction is the senior vice president for Patient Care Services and chief nurse.	

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A 143	Continued From page 22 observation with the Nurse Director of Staff CH revealed that the expectation would be that curtain would be drawn by the staff or the staff can turn the monitor off, at the monitor. Observation on 2/10/10 at 12:09 p.m. revealed that two staff members were repositioning the patient on the monitor in bed. Interview on 2/10/10 at 12:14 p.m. with the Nurse Director of Staff CH revealed that the hospital installed ceiling tracks about a year ago for lifts in some rooms. The curtain can be drawn in these rooms and would not block the camera's view. Staff could turn the camera but the camera is really high. Staff could shut the monitors off at the respiratory acute care unit but the monitors on the medical side of the unit are on a separate circuit.	A 143		
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 observation, record review, staff interviews and review of facility internal investigation reports, it was determined that the facility failed to ensure one patient (Patient #77) who required continuous cardiac rate and rhythm monitoring, from a sample of 84 patients, received the necessary nursing assessment, supervision and timely life-saving interventions when the patient developed lethal arrhythmias (any disturbance or irregularity of the heart beat) for approximately 22 minutes and asystole (absence of a heart beat) for approximately 17 minutes before staff found the patient	A 144	The MGH has developed a comprehensive, multifaceted plan of correction, and the majority of it has already been completed. The plan addresses the following three issues: 1) alarm broadcast settings and the ability to turn alarms off; 2) audibility of alarms; and, 3) timeliness of response to alarms. To address the concern about alarm broadcast settings and the ability to turn alarms or alarm volume off on bedside physiological and central monitors, Biomedical Engineering disabled the minimum arrhythmia alarm level “off” option (ability to turn off all arrhythmia alarms) on all bedside monitors with this option (initiated 1/25/10 and completed by 1/28/10) and disabled alarm volume “off” settings at both central and bedside monitors with this option (completed 2/12/10 and 3/5/10 respectively).	03/26/10

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A 144	Continued From page 23 unresponsive. Resuscitative measures were initiated, however, the patient died. Additionally, the facility failed to ensure that patients' access to rooms and Emergency Department restrooms were not blocked to prevent possible injury. The findings include: 1. Patient #77 On 2/10/10 review of Patient #77's closed medical record revealed a (Note, dated 1/20/10, that documented the following:	A 144	To address the audibility of alarms, alarm volume defaults for bedside physiological monitors (alarm volume default and alarm minimum volume) and central monitors (default volume and minimum volume) were standardized on all inpatient care units. This included minimum lockouts, where available. A process for review and approval of requests for variation from institutional standard was developed and implemented. Lastly, an accelerated schedule to complete installation of distributed speaker systems on all inpatient care units with central monitoring was initiated on 3/8/10. To address timely response to alarms, a two-part education program was initiated on 2/12/10 for all RN staff on general care units to ensure physiologic monitoring competency, alarm responsiveness, and related safety measures. In addition, a temporary corrective action step was taken on 2/12/10, to station an RN 24/7 at every central monitor station on every general care unit at the hospital. Please note that this step is a short-term practice change until the sustainable changes noted above are fully implemented. Several efforts were employed to improve the processes that led to the cited deficiency. One manufacturer's physiologic monitors at the hospital includes an alarm setting in which one of the scrolling options enables the user to turn off all arrhythmia alarms for an individual patient. When set in the off position, the bedside monitor (and therefore the central monitor as well) is unable to emit an alert for any arrhythmia including lethal arrhythmias. Immediately following an incident associated with this arrhythmia alarm-off option, the hospital's Biomedical Engineering Department inspected all bedside monitors with this setting	

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A 144	Continued From page 24 of the surgical procedure. Progress Notes, dated 1/20/10 at 9:00 p.m. showed the . The temporary pacemaker wire was removed on 1/21/10 at 12:30 a.m. Nursing documentation showed the patient's heart rhythm in the was atrial fibrillation with heart rates in the 50's and 60's (normal adult heart rate is 60-80 beats per minute). Physician Progress Notes indicated that the patient was transferred from the to the on 1/21/10. On 1/22/10 Cardiology Progress Notes indicated the patient to be in atrial fibrillation with heart rates was dropping into the 40's when asleep. Documentation indicated that the patient was scheduled for a permanent pacemaker on 1/25/10. The patient was approved for transfer from with telemetry monitoring. Review of Nursing Flow Sheets and Progress Notes indicated that the patient was transferred to a surgical patient care floor at 6:00 p.m. on 1/22/10 with physician's orders for centralized cardiac telemetry (monitoring a patient's heart activity from a distance) and was a full code (wished resuscitation if the heart and/or breathing stopped). Nursing documentation on 1/22/10 at 5:55 p.m. 7:30 p.m. 8:30 p.m. and 10:00 p.m. revealed that the patient's vital signs after transfer to the surgical floor indicated heart rates from 59 to 74 bpm and a heart rhythm of atrial fibrillation. Review of Surgical Progress Notes, dated 1/23/10	A 144	and disabled the arrhythmia alarm "off" feature. An additional corrective action was taken on 2/12/10 to station an RN 24/7 at every central monitor station on every general care unit at the hospital. This step is a temporary practice change until the investigation is completed and sustainable practice changes are implemented. With the creation of volume standards, default and minimum alarm volumes on central monitors with user-adjustable settings were set at 80 percent of maximum. A full inventory of alarm broadcast settings was conducted for cardiac monitoring devices by Biomedical Engineering. Recommendations for alarm standards were evaluated for safety and efficacy. The recommendations were approved on 2/25/10 by Nursing Executive Operations, and bedside monitors were reviewed and set based on the new standards by 3/5/10. Additionally, a centralized authorization plan was instituted for reviewing requests for future adjustments to monitor settings. To ensure staff competency relative to physiologic monitors and the related safety measures, a two-part educational program was conducted with all general care unit nursing staff. The program reviewed monitoring principles and critical elements, RN responsibilities relative to responsiveness, and related safety measures. In addition, the program provided a review of monitor technology that included skills checklists and scenario evaluation. A target of 95 percent compliance with the education program (completion of both parts of the program) was established for the nurses working in general care units. This target factored in those staff	

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A 144	Continued From page 25 indicated: The patient's heart rhythm was atrial fibrillation/SSS (sick sinus syndrome is a malfunction of the normal pacemaker of the heart in which the heart rate slows below normal limits); -Monitor heart rate closely; Interviews on 2/10/10 and 2/11/10 with hospital nursing administrative staff responsible for conducting the hospital's investigation into Patient #77's death - RN AA (Patient Staff Specialist), RN BB (Associate Chief Nurse), RN CC (Nurse Director), and RN DD (Clinical Nurse Specialist) - revealed the following: -On 1/23/10 the patient's heart rate was 56-62 beats per minute (bpm) and the blood pressure was stable; -During the night shift from 7:00 p.m. on 1/23/10 to 7:00 a.m. on 1/24/10 the patient's heart rate was 55-77 bpm, blood pressure stable, no nausea or vomiting, tolerating a liquid diet and bowel sounds present; -Staff RN E assumed the care of the patient as well as two additional patients at 7:00 a.m. on 1/24/10; -There were 32 inpatients including Patient 77-receiving care on this surgical floor the morning of 1/24/10 and 10 RN's on duty; -Nursing staff did not continuously monitor the cardiac rates/rhythms at the central nurses' station monitors. This responsibility falls on all nursing staff on the unit. When an alarm sounds or a message appears on the alarm display unit, any available nurses are to evaluate the reason the alarms are sounding and respond as necessary;	A 144	that may be out of work on a leave of absence. Upon returning to work, these individuals will be required to complete this two-part monitoring education program. Installation of distributed speakers on all remaining inpatient care units with only local speakers was initiated on 3/8/10, to ensure alarms are audible throughout the care units. As of Monday, 3/15/10, distributed speakers have been installed on 17 additional care units and by 3/26/10 installation to a total of 23 general care units with central monitors will be complete. Audibility of alarms is confirmed with nursing leadership on each unit prior to sign-off that the installation is complete. The hospital has used a number of methods and procedures to implement this corrective action plan. Biomedical Engineering conducted an assessment of monitors at the bedsides and at central stations. During these assessments, monitor settings were reset as indicated to ensure minimum arrhythmia alarm level off and alarm volume off options are disabled and minimum volume settings are in place. The two-part education plan is being rolled out via on-line training with oversight by the Patient Care Services Knight Nursing Center educators, unit-based clinical nurse specialists and selected staff who have participated in a train-the-trainer program for the checklist demonstration portion of the educational program. Lastly, all patient care units with central monitors were assessed for speaker coverage to determine strategic placement of distributed speakers to ensure alarm audibility throughout the unit. Any new care units opened in the future will follow physiologic monitoring standards implemented in this plan of correction.	

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A 144	Continued From page 26 -The patient's heart rate at 7:30 a.m. on 1/24/10 was 77 bpm and heart rhythm showed atrial fibrillation; -The patient ate breakfast, ambulated in the hallway, family visited, morning bath taken and a pain medication was administered at 9:28 a.m.; -Central nurses station cardiac monitor logs revealed: · At 9:40 a.m. was 82 bpm, · At 9:53 a.m. heart rate at 53 bpm, · At 9:54 am heart rate at 44 bpm, · From 9:56-9:58 a.m. heart rate at 0 bpm, · From 9:59-10:01 a.m. heart rate at 0-29 bpm, · From 10:02-10:16 a.m. heart rate at 0 bpm, · A high-low audible warning alarm (alarm set to sound when the patient's heart rate exceeded 120 bpm or fell below 50 bpm) sounded for the patient from 9:53-10:01 a.m. and from 10:06-10:16 a.m. by repeatedly broadcasting two "beeps" at the central nurses station cardiac monitors. · The three (3) ceiling mounted digital alarm display units that were located at the end of the two patient care hallways and near the central nurses station showed "HR LO" (heart rate low) and the patients room number during the time of the audible alarms; - -The volume to the alarms on the patient's bedside cardiac monitor had been turned off at an unknown date and time and by an unknown person; -No one was at the patient's bedside while the central nurses' station cardiac monitors were alarming and no staff responded to the alarms	A 144	Completion dates for each element of the correction plan are as follows. Alarm settings and ability to turn “off” function: disable minimum arrhythmia alarm level “off” option - 1/28/10; and disable alarm volume “off” at both central and bedside monitors - 2/12/10 and 3/5/10 respectively. Audibility of alarms: standardize alarm volume defaults for bedside monitors and central monitor - 2/26/10; implement a review and approval process for any requests for variation to monitor default settings - 2/26/10; and, installation of distributed speaker systems on general care units with central monitoring - 3/26/10. Response to alarms: 95 percent compliance with the two-part education program - 3/15/10. The deficiency will be corrected by 3/26/10 at which time the temporary corrective action of stationing an RN 24/7 at central monitor stations will no longer be required. Updates on performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through the hospital's General Executive Committee and through the Board of Trustees Quality Subcommittee to the boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that the MGH is making progress as planned, and communicate progress and concerns to the boards through the mechanism above on a quarterly basis until the issue is resolved to prevent the deficient practice from recurring. Subsequent compliance will be reviewed through quality and safety dashboards, which will now include an explicit area to monitor Conditions of Participation compliance. In addition to these periodic reviews, the hospital	

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A 144	Continued From page 27 until 10:16 a.m. when RN E entered the patient's room to assess the patient's urinary output, a time span of 20 minutes after the alarms initially sounded. The patient was found unresponsive Cardio-pulmonary resuscitation was initiated and a Code Blue was called. Efforts to resuscitate the patient were unsuccessful and the patient expired; -Administrative nursing staff interviews with the RN's on duty the morning of 1/24/10 revealed that no one could recall hearing the alarms that sounded from the central nurses' station cardiac monitors and no one recalled seeing the "HR LO" displayed on the alarm display units. The 10 RNs interviewed said the alarm notifications that morning were no more than usual. If in a patient room with the door closed, staff could not hear the alarms coming from the central nurses' station; -Nursing staff interviewed on the patient care unit said they were experiencing alarm fatigue and a desensitization to alarms after hearing them constantly throughout the workday. Interviews on 2/10/10 and 2/11/10 with Biomedical Engineering Staff M and N and review of a Biomedical Engineering Findings Report, dated 2/4/10, revealed: -In addition to the two "beep" high-low audible alarms on the central nurse's station cardiac monitors and bedside cardiac monitors, there is also an arrhythmia alarm that is supposed to be set to "Full," which means the alarms are on. This alarm triggers the broadcast of a three "beep"	A 144	will flag all safety event reports related to Condition of Participation issues so that ad hoc compliance issues can be addressed in a robust and timely fashion. To ensure that the plan of correction is effective and the specific deficiencies cited remain corrected and/or in compliance with the regulatory requirements, biweekly audits will be conducted by nursing leadership on all general care units to evaluate the timely response to physiologic monitor alarms. Immediate correction steps will be taken at the local level to address any issues. In addition, data are submitted to, and analyzed by, the Patient Care Services Office of Quality & Safety. To ensure that monitor default settings are configured to the hospital's standards, Biomedical Engineering will implement a multi-step verification process when installing and configuring new and replacement bedside and central monitors as well as during periodic scheduled maintenance and inspection of these devices. Safety reports of any physiologic monitor-related issues will be reviewed by the MGH Center for Quality & Safety and PCS Office of Quality & Safety and shared with the appropriate associate chief nurse to coordinate development, implementation and completion of a correction plan. The senior vice president for Patient Care and chief nurse is responsible for implementing this plan.	

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A 144	Continued From page 28 audible alarm when a patient develops a crisis or lethal arrhythmia-such as asystole. An investigation conducted by Biomedical Engineering after Patient #77's death found the arrhythmia alarm on the patient's bedside cardiac monitor had been set to "Off" on 1/22/10 at approximately 6:15 p.m. As a result, on 1/24/10 between 9:54 a.m. and 10:16 a.m. the arrhythmia alarm did not broadcast the three "beep" audible alarm from the central nurses' station that would have signified to nursing staff that Patient #77 was experiencing a lethal arrhythmia. The Biomedical Engineering Findings Report showed recommendations to install a distributed speaker system on the surgical patient care unit where Patient #77 had resided, which would make monitoring alarms more audible throughout the unit rather than only at the central monitors located at the nurse's station. The report also showed recommendations for the surgical patient care unit to make the necessary changes so that staff could not turn the arrhythmia alarms to "Off" and could not turn the alarm volume to "OFF" on patients' bedside cardiac monitors. Observation on 2/10/10 at 1:00 p.m. of the surgical patient care unit where Patient #77 had resided showed two patient care hallways with the floor plan in the shape of the letter "V." The central nurse's station cardiac monitors with audible alarms were located near the point of the "V." Ceiling mounted digital alarm display units were located at the far end of the two hallways and at the point of the "V."	A 144	In an effort to ensure that care is provided in the safest possible setting, the Massachusetts General Hospital has focused attention on making sure that patient access to rooms and restrooms is not blocked and has taken various steps to improve such access. Emergency Department staff continue to monitor the equipment alcove in the Urgent A treatment area to ensure that excess equipment does not accumulate and impede patient access tot the restrooms. The equipment that was present 2/4/10 at 8:45AM during the CMS survey was immediately removed, and the employee who was building the wall holder was relocated to another area that didn't impact patient flow. While the CMS report states on page 31, A 144 3, that "During a tour of the . . . ," the hospital would like to clarify that this tour and the related finding actually occurred in the . As a result of this finding, the linen cart on has been relocated to an area interior to the unit, out of the flow of patient traffic. The housekeeping cart and supply cart containing paper towels and toilet paper are now being stored, when not in use, in a janitor closet exterior to the front entrance of the unit. The vital signs monitoring stand and dirty linen hamper have been relocated so as not to impede egress or create a fall risk to patients. Minor renovation involving the removal of an obsolete x-ray viewing box was completed to better accommodate the relocated linen cart. MGH also will be purchasing a new linen cart that will better fit the new storage area. In addition the hospital will adjust storage locations and renovate space to ensure unobstructed patient flow while providing efficient access to key supplies and linen on .	04/30/10

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A 144	Continued From page 29 In addition, a wall-mounted flat screen cardiac monitor without audible alarms was located part way down each hallway. Six patient's heart rates/rhythms were being continuously monitored. However, no staff were observed at the central nurse's station monitoring these six patients' cardiac rates/rhythms continually. The room where Patient #77 had resided from 1/22/10 until 1/24/10 was across the hallway and slightly diagonal from the location of the central nurses' station cardiac monitors. At approximately 2:15 p.m., Biomedical Engineering staff programmed an unused cardiac monitor at the central nurses' station to broadcast an alarm identical to the alarm that sounded on Patient #77's cardiac monitor on 1/24/10. The alarm volume was audible from the central nurses' station but was barely audible to inaudible when standing at the farthest ends of the hallways. Staff caring for patients in the rooms at the farthest end of the hallways would not be able to hear the alarms. During an interview at 2:30 p.m., Biomedical Engineering Staff N said the Biomedical Engineering department had identified a need one to two years ago for the installation of additional speakers on all patient care units and was currently a work in progress. Installation of a distributed speaker system on this unit and all other patient care units would make the alarm volumes more audible throughout the unit rather than only at the central monitor's at the nurses' station. Speakers had been installed on some other patients' care units of the hospital, but had not been installed on this floor yet. Review of documentation dated 2/2/10 by Medical	A 144	Most of the identified issues have already been corrected. The correction of this entire deficiency will be completed 4/30/10. Updates on performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through the MGH General Executive Committee and through the Boards of Trustees Quality Subcommittee to the boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that the hospital is making progress as planned, and communicate progress and concerns to the boards through the mechanism above on a quarterly basis until the issue is resolved to prevent the deficient practice from recurring. Subsequent compliance will be reviewed through the hospital's quality and safety dashboards, which will include an explicit area to monitor Conditions of Participation compliance. In addition to these periodic reviews, the MGH will flag all safety event reports related to the Conditions of Participation so that ad hoc compliance issues can be addressed in a robust and timely fashion. To monitor and track compliance, the hospital will conduct unit-based environmental tracer rounds and annual, central surveillance rounds to audit this issue on an ongoing basis and any findings will be reported to the MGH senior vice president for Administration. The senior vice president for Administration is responsible for implementing the plan of correction.	

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Doctor (MD) AAA in a report that was prepared for medical peer review activities at the hospital revealed the preliminary autopsy report for Patient #77 revealed no pulmonary emboli (a sudden blockage in a lung artery - usually caused by a blood clot) and no aspiration. The patient's death appears due to unrecognized severe bradycardia from faulty alarm settings.

2. During an observation of the Urgent A care area on 2/4/10 at 8:45 a.m., FW#1 was observed crafting a wooden crutch/walker holder on a work cart that blocked the entrance to two restrooms. Directly adjacent to the work cart were two fans, two large surgical lamps, three rolling blood pressure monitors, one oxygen tank, one scale and two pieces of respiratory equipment. Approximately three patients were observed on stretchers to the right of this area. RN EE acknowledged the observation, and confirmed that the restrooms can be used by patients awaiting treatment. Staff Member Q also acknowledged the observation, and stated that they would identify an area for placement of the equipment. A subsequent observation on 2/5/10 at approximately 10:00 a.m., revealed, the work cart had been removed, and the equipment was positioned close to the wall allowing accessibility into the restrooms.

3. During a tour of the on 2/3/10 at 10:40 a.m., the entrance to were blocked by a housekeeping cart, a linen cart, a supply cart that contained paper towels and toilet paper, a dirty linen hamper, and a vital signs monitoring stand. Affixed to the windows outside of Rooms were signs that indicated "fall

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A 144	Continued From page 31 precaution." According to the facility's Policy and Procedure Document: FALL RISK ASSESSMENT STANDARD FOR THE ADULT IN PATIENT CARE UNITS approved by the Nursing Practice Committee 12/08: Universal Interventions for Fall Prevention. The following interventions apply to all patients: -Keep floors clutter/obstacle free... -Remove excess equipment/supplies/furniture from rooms and hallways... It was stated during an interview on 2/12/10 at 9:57 a.m. with Staff Member S that the patient care areas should be "maintained in a manner to minimize the potential for falls and should not impact patient flow."	A 144		
A 147	482.13(d)(1) PATIENT RIGHTS: CONFIDENTIALITY OF RECORDS The patient has the right to the confidentiality of his or her clinical records. This STANDARD is not met as evidenced by: Based on observations, review of the facility's policies and reports, and interviews with staff, it was determined that the facility failed to ensure patients' right to personal privacy by posting notebooks containing patients' personal health information in areas accessible to unauthorized individuals. Additionally, the facility failed to ensure confidentiality of patients' clinical records when Nursing Directors and Clinical Nurse Specialists were able to access patients' health information from their non-secured personal home computers. The findings include:	A 147	MGH stopped sending the email communications described in this report on 3/11/10. An on-going plan of correction is under development and is detailed below. MGH will undertake multiple efforts to enhance securing access to hospital systems from remote desktop computers. After conducting a risk assessment, MGH decided to focus its initial information security efforts on portable devices, particularly laptops, as the loss or theft of these devices poses the greatest security risk to patient confidentiality. The risk assessment determined that remote desktop computers used by the hospital workforce posed less risk as these are physically secured, and workforce members are required to follow existing privacy and security policies when working remotely. As part of ongoing privacy and security training, MGH educates its workforce about the necessity of complying	03/11/10

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A 147	Continued From page 32 A. Patients' Health Information Accessible from Non-secured Home Computers. On 2/10/10, the hospital policy was reviewed, "Patient Record, 7.16- The information or data contained in the record belongs to the patient and is protected against loss, unauthorized disclosure and destruction." The policy failed to contain any directions or safeguards to ensure that all information regarding patients is kept secure and inaccessible to people not involved in the care of patients. During an interview on 2/5/10 at 9:45 a.m. with RN GG and CNS HH, they were asked for a list of restrained patients on the unit. CNS HH stated, every morning a list of restrained patients is sent out hospital-wide via e-mail to leadership staff, including the Nursing Director and CNS on each patient care unit. RN HH then accessed the hospital e-mail account and printed a document sent on 2/5/10 at 6:39 a.m. with the subject line showing, "Daily Patient Quality Needs E-Mail Report." Documentation on the report indicated, "Patient List - Vaccination and Restraint Orders, Tracheotomy, Warfarin Teaching and Heart Failure Instructions." RN HH stated, staff receiving the report on their e-mail at work can also access the report from their personal e-mail account on their home computer. RN GG acknowledged this information. Both RN GG and CNS HH stated their e-mail accounts from their home computers were password protected only, and were not encrypted. The report contained the following information for 7 patients: name, room number, admission date, primary diagnosis and information on pneumovax, fluvax, heart failure,	A 147	with organizational data privacy and security policies and procedures. MGH will develop an additional component to its ongoing privacy and security training that is focused on the security of remote computing, including the requirement that attachments can be opened only on encrypted computers. The MGH will also develop a plan to test technologies that enhance the security of email attachments retrieved through Outlook Web Access on remote computers and a plan to evaluate second factor authentication technologies. (See Tag 441.) Finally, MGH will continue to look at other organizations, including the National Institute of Standards of Technology (NIST), for industry best practices and standards for securing remote computing. To implement the plan of correction, the MGH will develop a process for upgrading to Microsoft Exchange 2010 and testing its security functionality to reduce the risk associated with email attachments accessed from remote computers. MGH will also develop a plan for reviewing second factor authentication technologies. The MGH will review best practices for remote worker security defined by NIST (User's Guide to Securing External Devices for Telework and Remote Access - NIST SP800-114.pdf; Guide to Enterprise Telework and Remote Access Security - NIST SP800-46r1.pdf). The MGH Information Security Office will work the MGH Privacy Office and other stakeholders to enhance training related to the security of remote computing, including the requirement that attachments can be opened only on encrypted computers. As part of this effort, National Institute of Standards and Technology guidance will be reviewed for best practices for security training (NIST SP 800-50 Building an Information Technology Security Awareness and Training Program).	

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A 147	Continued From page 33 tracheostomies, and restraints. Interviews on 2/8/10 at 10:55 a.m., with the Nursing Director RN CC and CNS DD revealed identical information that had been provided by RN GG and RN HH relative to their ability to access the "Daily Patient Quality Needs E-Mail Report" from e-mail accounts on their home computers. Both RN CC and RN DD also stated their e-mail accounts from their home computers were password protected only, and were not encrypted. Review of a "Daily Patient Quality Needs E-Mail Report," sent on 2/8/10 at 6:39 a.m. to RN CC and RN DD, revealed a list of six patients from the two patient care units that RN CC and RN DD were responsible for. Documentation on the report indicated, "Patient List - Vaccination and Restraint Orders, Tracheotomy, Warfarin Teaching and Heart failure Instructions." The report contained the same information for these 6 patients that was indicated for the aforementioned 7 patients. Review of a facility's policy and procedure titled, "Patient Record," approved by the Medical Policy Committee in 7/09, indicated the following: 1.2: This policy defines the MGH patient's health record and the documentation, access, security and audit requirements for all patients record-keeping across the MGH continuum of care. 1.3: This policy is guided by the following principles: · Records shall be easily accessible at any time and place where patient care information is needed, and available to persons with a legitimate reason for access.	A 147	The completion date for correction of this deficiency is 4/30/10. MGH will develop the plan for deploying Exchange 2010 by 4/30/10. MGH will develop the plan for testing second factor authentication technology by 4/30/10. MGH will review NIST guidance related to information security training by 4/15/10. MGH will review the NIST standards related to remote access security by 4/30/10. MGH will develop a plan for enhancing MGH's information security training program by 4/30/10. Updates on performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through the MGH General Executive Committee and through the Boards of Trustees Quality Subcommittee to the boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that the hospital is making progress as planned, and communicate progress and concerns to the boards through the mechanism above on a quarterly basis until the issue is resolved to prevent the deficient practice from recurring. Subsequent compliance will be reviewed through the hospital's quality and safety dashboards, which will include an explicit area to monitor Conditions of Participation compliance. In addition to these periodic reviews, the hospital will flag all safety event reports related to Conditions of Participation so that ad hoc compliance issues can be addressed in a robust and timely fashion. To monitor and track the correction plan, the MGH will conduct thorough internal testing of software functionality prior to implementation. Regular status meetings involving the senior vice president for Strategic Planning and	

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A 147	Continued From page 34 ·All users of the MGH electronic health record shall adhere to prevailing standards of confidentiality, quality and accountability, as defined by the MGH Clinical Policy and Records Committee. The policy contained no further information or procedures for ensuring patients' health information is properly protected. During an interview on 2/11/10 at 10:32 a.m., the Information Security Officer stated the following: -The hospital utilizes several different methods to allow staff members to remotely access confidential patient information. -the hospital utilizes several different methods to allow staff members to remotely access confidential patient information. These include remote access to the Longitudinal Medical Record (LMR); remote access to the MGH network (LAN) in which word documents, spreadsheets, databases and reports used for administrative and research purposes and containing protected information can be accessed and downloaded; and the ability to access hospital e-mail in which some e-mails or attachments may contain protected information. The hospital utilizes several technical strategies to facilitate remote access, including two types of virtual private networks (VPN clients such as gotomypc, which are used on laptops and home desktops; and SSL VPN which is loaded on MGH-issued laptops) to access the LAN and LMR; and Internet browsers to access webmail and a web version of their LMR from any computer with Internet access. -Staff access information on their hospital desktop computer over the Internet via	A 147	Information Management, the MGH chief information officer, the MGH information security officer and other management personnel will be conducted. The person responsible for implementing the plan of correction is the MGH chief information officer. On 3/1/10 the MGH implemented a secure email service called Send Secure, which provides users the ability to encrypt email messages sent over the Internet. MGH is currently training users to use the service. MGH implemented the Cisco IronPort platform for securing email. Users are able to send encrypted messages by typing the phrase “Send Secure” in the subject line of a message. Messages sent via the Send Secure service are encrypted with transaction layer security encryption as they travel over the Internet. Send Secure can be used when sending email from computers on the MGH network, and by users sending email on remote computers using Outlook Web access. As part of ongoing privacy and security training, MGH educates its workforce about the necessity of complying with organizational data privacy and security policies and procedures. As an enhancement to this training, MGH has added a component related to the use of the Send Secure service. The training includes email announcements about the service, presentations at a range of key meetings, and the development of frequently asked questions (FAQs), which are accessible via the MGH intranet. On 3/1/10, the MGH deployed Send Secure at the institution. To date, MGH has completed additional tasks, including distributing broadcast email messages to the hospital	03/01/10

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A 147	Continued From page 35 "gotomypc.com" from any computer using a user identifier and password to log-on to the "gotomypc.com" website and another user identifier and password to access their hospital computer, neither password is a randomly generated one-time synchronized password. Once the staff member accesses the hospital computer, it forms a secure tunnel of information that leaves no residual information on the computer used to access the information. Staff cannot download or print the information from the website; -Staff access VPN Client from any computer to form a secure tunnel to access patient information. This information would not leave residual information nor could it be printed; however the information can be downloaded to an unencrypted (encrypt means to scramble access codes to computerized information so as to prevent unauthorized access) computer and printed once staff exits VPN client. This would leave residual information even if the staff member deleted the downloaded information. -Staff access webmail from any computer;-patient information may be embedded in an e-mail or sent as an attachment. Information embedded into the e-mail could be downloaded to an unencrypted computer or portable storage device as a screen print or printed from the computer; however, the information security officer was not sure if the embedded e-mail would leave residual information on an unencrypted computer. Information accessed from the e-mail attachment would leave a temporary file on an unencrypted computer. The information can be downloaded to an unencrypted computer or portable storage device or printed from the	A 147	community about Send Secure, training of Help Desk staff, and posting intranet Help Desk training pages and FAQs The completion date for correction of this deficiency is 3/1/10. Updates on performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through the MGH General Executive Committee and through the Boards of Trustees Quality Subcommittee to the boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that the hospital is making progress as planned, and communicate progress and concerns to the boards through the mechanism above on a quarterly basis until the issue is resolved to prevent the deficient practice from recurring. Subsequent compliance will be reviewed through the MGH quality and safety dashboards, which will include an explicit area to monitor Conditions of Participation compliance. In addition to these periodic reviews the hospital will flag all safety event reports related to Conditions of Participation so that ad hoc compliance issues can be addressed in a robust and timely fashion. To monitor and track the plan of correction the MGH conducted thorough internal testing of software functionality prior to implementation. The MGH information security officer will ensure ongoing training about Send Secure for all new and existing employees. The person responsible for implementing this correction plan is the MGH chief information officer.	

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A 147	Continued From page 36 computer; and both e-mails and attachments containing confidential information could be forwarded to another e-mail address outside the MGH system. - Any documented that is downloaded to unencrypted computers or any residual information left on unencrypted computers via web browsers or any other software using temporary files is potentially accessible by unauthorized persons. The hospital has no definitive plans to restrict access to confidential patient information contained in e-mail, LAN or LMR to hospital-authorized and encrypted computers. The hospital is in the process of encrypting hospital issued laptop computers. The process is estimated to be 75-80% complete; however, staff is still locating computers that are issued to departments not an individual. The hospital has begun to encrypt staffs' personal laptops on a voluntary basis; however the information security officer was not sure to what extent, as there is not an inventory available of staffs' personal computers. The hospital has no definitive plans to encrypt staffs personal desktop home computers. B. Notebooks Containing Patients' Personal Health Information 1. During an initial morning tour of the hospital on 2/2/10, the following was observed. In :, books containing confidential patient information including treatment flow sheets and a pulse volume results form were located in a wooden holder outside patients' rooms that were accessible to unauthorized staff, family members and/or visitors	A 147	MGH has assessed the GoToMyPC service as a means of providing a remote access to information in a way that is consistent with information security regulations and industry best practices. The service is configured to provide remote access over an encrypted channel with data remaining in the secured data center, so it cannot be downloaded to remote computers. MGH will enhance user training related to using GoToMyPC in a secure manner, consistent with MGH's data privacy and security policies. As part of ongoing privacy and security training, MGH educates its workforce about the necessity of complying with organizational data privacy and security policies and procedures. MGH will develop an additional component in its ongoing privacy and security training that is focused on the secure use of GoToMyPC, including access from remote computers. In addition, MGH will develop a plan for evaluating second factor authentication technologies within 90 days. To implement this plan of correction the MGH Information Security Office will work with the MGH Privacy Office and other stakeholders to enhance training related to the secure usage of GoToMyPC, including user access of GoToMyPC from remote computers. As part of this effort, MGH will review National Institute of Standards and Technology guidance for best practices for security training (NIST-SP 800-50 Building an Information Technology Security Awareness and Training Program). MGH also will develop a formal plan for enhancing security training as it relates to GoToMyPC usage. The hospital's information security team will	04/30/10

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A 147	Continued From page 37 passing in the area. The Unit's Nursing Director acknowledged that the books were not secured from personal view. 2. During morning observations on 2/10/10 of it was observed that books containing confidential patient information were in unsecured common areas where unauthorized staff, visitors, and/or other patients could have access. The Staff Specialist in at the time of the observations acknowledged that the books containing the confidential information was located in these unsecured locations. 3. Observation at 3:00 p.m. on 2/2/10 in the revealed large, green, three-ring binder notebooks in wooden holders outside each patient's occupied room. Each notebook maintained documents that contained the individual patient's name, birthdate, date of admission, advance directives and diagnoses. The notebooks included the nursing care flow sheet for 2/2/10, which indicated the following: -patient's vital signs (temperature, blood pressure, pulse, respirations); -patient's oxygen use, if applicable, and oxygen saturation percentage (a measure of the amount of oxygen that is carried in the bloodstream); -pain assessment and pain management information; -neurological assessment; -oral, intravenous or tube feeding intake; -urinary output and whether the patient urinates voluntarily, involuntarily or through an indwelling catheter; -bowel movement information.	A 147	develop a plan for evaluating second factor authentication technologies. The completion date for correction of the deficiency is 4/30/10. MGH will develop a plan for evaluating second factor authentication technologies within 90 days. MGH will review NIST SP 800-50 Building an Information Technology Security Awareness and Training Program by 4/15/10. MGH will develop a plan for enhancing its information security training program by 4/30/10. Updates on performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through the MGH General Executive Committee and through the Boards of Trustees Quality Subcommittee to the boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that the hospital is making progress as planned, and communicate progress and concerns to the boards through the mechanism above on a quarterly basis until the issue is resolved to prevent the deficient practice from recurring. Subsequent compliance will be reviewed through the hospital's quality and safety dashboards, which will now include an explicit area to monitor Conditions of Participation compliance. In addition to these periodic reviews, the hospital will flag all safety event reports related to Conditions of Participation so that ad hoc compliance issues can be addressed in a robust and timely fashion. To monitor and track the plan of correction the MGH will conduct thorough internal testing of any enhanced or modified functionality prior to implementation. The MGH information security officer will receive regular updates from the	

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A 147	Continued From page 38 4. Observations on 2/3/10 at 3:00 p.m. of , on 2/5/10 at 8:00 a.m. of a , and on 2/5/10 at 1:45 p.m. revealed large, green, three-ring binder notebooks in wooden holders outside each patient's occupied room. The documents in the notebooks revealed the individual patient's name, date of birth, admission date, marital status, advance directives, and religion. The notebooks also included the nursing care flow sheet for 2/3/10 and the treatment flow sheet. 5. Observations on 2/8/10 at 8:35 a.m. of revealed large, green, three-ring binder notebooks in wooden holders outside each patient's occupied room. Review of one patient's notebook revealed documents that contained the patient's name, date of birth, admission date, advance directives and a nursing care flow sheet. Additionally, a notebook on had information attached to the front cover of one patient's notebook, a large, red sticker labeled, "Allergy," and documented the patient's full name and allergies to bee stings, acetaminophen, penicillin and amoxicillin. Review of another patient's notebook revealed documents that contained the patient's name, date of birth, payment source, nursing care flow sheet for 2/8/10 and a treatment flow sheet. The nursing care flow sheet included vital signs and documentation revealing that the patient had edema (excessive amount of watery fluid in the tissues) in the .	A 147	Information Security technical team. The person responsible for implementing the plan of correction is the MGH chief information officer. The MGH believes the Longitudinal Medical Record over the Internet (LOTI) system is secure in conformance with information security regulations and industry best practices. To correct the specific deficiency cited, the MGH will enhance user training related to using the system in a secure manner, consistent with MGH's data privacy and security policies. To address improving the processes that led to the deficiency, the MGH will continue to be strongly committed to ensuring that LOTI secures patient data, both as it travels over the Internet, and as it is accessed on remote PCs and laptops. LOTI was designed to not cache data on remote devices used to access the system. When LOTI generates an html page, an http header is inserted that instructs the browser to not cache the page on the remote device accessing the system. LOTI follows the W3C HTML specification regarding caching. Additionally, LOTI traffic over the Internet is secured through transaction layer security encryption, protecting data from unauthorized access. All access to LOTI is protected through authenticated user sessions that terminate after a pre-defined period of inactivity. Finally, as part of continual efforts to ensure that LOTI is secure, MGH is hiring a Web application security specialist who will work with the LOTI development team to ensure that application development remains consistent with industry standards.	04/30/10

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A 147	Continued From page 39 6. Observation on 2/10/10 at 9:30 a.m. of an revealed large, green, three-ring binder notebooks in wooden holders outside each patient's occupied room. Review of one patient's notebook revealed documents containing the patient's name, date of birth, age, and physician's orders for the total parenteral nutrition (TPN) nursing care flow sheet for 2/10/10, and a treatment sheet. (TPN is an intravenous feeding that provides a patient with all of the fluid and essential nutrients they need when they are unable to feed themselves by mouth.) The treatment sheet revealed the patient required anti-embolism stockings and incentive spirometry. 7. Observation on 2/10/10 at 2:30 p.m. on revealed fourteen of fifteen medical records , hanging outside patients' doors without securing personally identifiable patient information. 8. On 2/10/10 at 3:54 p.m., there were 33 patients admitted to the . Observations of the revealed that a green binder for each patient was located in a bin in the hallway outside each patient's room. Inside this green binder were the patient's flow sheets, nurses' progress notes, and other resource material. An interview with Nurse CC on 2/10/10 at 3:55 p.m., revealed that the green binders were kept in the hallway and were accessible to any staff member, patient or visitor, and that the information in the green binders is considered part of the patients' medical record.	A 147	As part of ongoing privacy and security training, MGH educates its workforce about the necessity of complying with organizational data privacy and security policies and procedures. The MGH will develop an additional component to its ongoing privacy and security training that is focused on the secure use of LOTI, including access from remote computers. To implement this plan of correction, the MGH Information Security Office will work with the MGH Privacy Office and other stakeholders to enhance training related to the secure usage of LOTI, including user access of LOTI from remote computers. As part of this effort, MGH will review National Institute of Standards and Technology (NIST) guidance for best practices for security training (NIST-SP 800-50 Building an Information Technology Security Awareness and Training Program). Also, MGH will develop a formal plan for enhancing security training as it relates to LOTI usage. The completion date for correction of this deficiency is 4/30/10. The MGH will review NIST SP 800-50 Building an Information Technology Security Awareness and Training Program by 4/15/10. MGH will hire a Web application security specialist by 4/30/10. MGH will develop a plan for enhancing the hospital's information security training program by 4/30/10. Updates on performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through the MGH General Executive Committee and through the Boards of Trustees Quality Subcommittee to the	

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A 147	Continued From page 39 6. Observation on 2/10/10 at 9:30 a.m. of an revealed large, green, three-ring binder notebooks in wooden holders outside each patient's occupied room. Review of one patient's notebook revealed documents containing the patient's name, date of birth, age, and physician's orders for the total parenteral nutrition (TPN) nursing care flow sheet for 2/10/10, and a treatment sheet. (TPN is an intravenous feeding that provides a patient with all of the fluid and essential nutrients they need when they are unable to feed themselves by mouth.) The treatment sheet revealed the patient required anti-embolism stockings and incentive spirometry. 7. Observation on 2/10/10 at 2:30 p.m. on revealed fourteen of fifteen medical records hanging outside patients' doors without securing personally identifiable patient information. 8. On 2/10/10 at 3:54 p.m., there were 33 patients admitted to the . Observations of the l revealed that a green binder for each patient was located in a bin in the hallway outside each patient's room. Inside this green binder were the patient's flow sheets, nurses' progress notes, and other resource material. An interview with Nurse CC on 2/10/10 at 3:55 p.m., revealed that the green binders were kept in the hallway and were accessible to any staff member, patient or visitor, and that the information in the green binders is considered part of the patients' medical record.	A 147	To implement this plan of correction, the MGH will replace its procedure of sending emails containing PHI to specific clinical staff with an alternative solution involving a secure, password protected access to stored quality information to minimize risk of inappropriate disclosure. The hospital also will re-educate staff members to ensure that they are knowledgeable and in compliance with policies related to safeguarding PHI. The completion date for correction of this deficiency is 4/30/10. Updates on performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through the General Executive Committee and through the Boards of Trustees Quality Subcommittee to the boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that the hospital is making progress as planned, and communicate progress and concerns to the boards through the mechanism above on a quarterly basis until the issue is resolved to prevent the deficient practice from recurring. Subsequent compliance will be reviewed through the hospital's quality and safety dashboards, which will include an explicit area to monitor our Conditions of Participation compliance. In addition to these periodic reviews the hospital will flag all safety event reports related to Conditions of Participation so that ad hoc compliance issues can be addressed in a robust and timely fashion.	

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A 147	Continued From page 39 6. Observation on 2/10/10 at 9:30 a.m. of an revealed large, green, three-ring binder notebooks in wooden holders outside each patient's occupied room. Review of one patient's notebook revealed documents containing the patient's name, date of birth, age, and physician's orders for the total parenteral nutrition (TPN) nursing care flow sheet for 2/10/10, and a treatment sheet. (TPN is an intravenous feeding that provides a patient with all of the fluid and essential nutrients they need when they are unable to feed themselves by mouth.) The treatment sheet revealed the patient required anti-embolism stockings and incentive spirometry. 7. Observation on 2/10/10 at 2:30 p.m. on revealed fourteen of fifteen medical records hanging outside patients' doors without securing personally identifiable patient information. 8. On 2/10/10 at 3:54 p.m., there were 33 patients admitted to the Observations of the revealed that a green binder for each patient was located in a bin in the hallway outside each patient's room. Inside this green binder were the patient's flow sheets, nurses' progress notes, and other resource material. An interview with Nurse CC on 2/10/10 at 3:55 p.m., revealed that the green binders were kept in the hallway and were accessible to any staff member, patient or visitor, and that the information in the green binders is considered part of the patients' medical record.	A 147	To monitor and track this plan of correction, the hospital will provide authorized access to only those staff with a specific need to know. The MGH will conduct surveillance rounds to assess for proper destruction of PHI if material is printed. The person responsible for implementing this plan of correction is the senior vice president for Strategic Planning and Information Management.	

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A 147	Continued From page 40 C. On 2/8/10 at 2:17 p.m., CNS CI provided a patient list for vaccination and restraint orders, tracheotomy (incision directly into the airway to help the patient breath), Warfarin (medication to thin the blood) teaching and heart failure instructions for for 2/8/10. There were five patient names and medical record numbers on the sheet. The sheet indicated that four of the five patients had a pneumovax vaccine and that one of the five patients had a tracheotomy. During the interview with CNS CI, she revealed that this information is generated to Nursing Directors and Clinical Nurse Specialists daily via e-mail at 7:00 a.m. Nursing Directors and Clinical Nurse Specialists can retrieve information from other units via e-mail. This is continued non-compliance as evidenced by citations written by the Department of Public Health during the surveys of 3/26/09 and 8/13/09.	A 147		
A 164	482.13(e)(2) PATIENT RIGHTS: RESTRAINT OR SECLUSION Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient, a staff member, or others from harm. This STANDARD is not met as evidenced by: Based on review of medical records and facility's policy, and interview with staff, it was determined that the facility failed to conduct an individualized, comprehensive assessment for two of 84 patients in the sample to ensure physical restraints were used only after lesser restrictive methods were determined to be ineffective to protect the patient from harm. (Patients #41 & #38)	A 164	The plan of correction involves convening a multidisciplinary team to address the overall care and management of patients requiring restraint. As part of the improvement initiative, the team will review issues including, assessment of patients to determine if least restrictive methods would be effective or ineffective in protecting the patient, and ensure that this assessment is documented in the medical record; documentation of the type of restraint device and extremities restrained; and documentation of the attempts to discontinue restraints when patient becomes less agitated. The team will identify the root cause of noncompliance (e.g., lack of knowledge verses noncompliance with documentation). The team also will develop a plan for improvement based on root cause analysis. The plan will include improvement	04/01/10

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A 164	Continued From page 41 The findings include: 1. Patient #41 Review of the facility's policy and procedure titled, "Restraint and Seclusion," approved by the Medical Policy Committee on 6/3/09, indicated the following: 3.1 - The decision to use a restraint or seclusion is driven not by diagnosis, but by a comprehensive individual assessment; 3.3 - Restraints shall not be used when less restrictive interventions would be effective. Restraint or seclusion should be considered only as a temporary means of intervention when the patient is in immediate danger of harming self or others; 3.4 - When a restraint or seclusion is required, the least restrictive method should be utilized; 5.1 - Non-behavioral medical restraint may be used for the following indications when less restrictive means would not be effective in protecting the patient: a) the patient is pulling at tubes, lines or dressings, b) the patient's actions are endangering themselves; for example the patient is thrashing around in bed or attempting to get out of bed in a way or under conditions where it might cause harm; 5.3 - Type and location of the restraining device(s) shall be documented at least once per shift and when changed; alternatives to and less restrictive forms of restraint considered by the care giver shall be documented at least once per shift. Review of Patient #41's medical record on 2/4/10 at 2:00 p.m. revealed a nursing progress note on 2/1/10 at 4:15 a.m., that indicated the following:	A 164	strategies, communication and education and monitoring compliance. To improve the processes that led to the deficiency, short-term, intermediate and longer-range plans have been developed. Short-term plan: effective 3/15/10, unit-based nurse leaders (i.e., nursing directors, clinical nurse specialists) will review documentation of all restrained patients in their respective practice area. They will provide immediate feedback to the care provider. Intermediate plan: The team will convene a focus group of nurses as a strategy to identify root causes of noncompliance. Knowledge related to the goal of least restrictive measures will be assessed, barriers to documentation will be discussed, and ideas for improvement will be generated. Based upon findings, next steps will be identified, which may include but not be limited to, education and modification of documentation format. Long term: Successful documentation strategies will be incorporated into the Acute Care Documentation Project planning; (project focus is converting from paper to electronic documentation). To implement a plan of correction, the MGH will undertake various documentation strategies and educational strategies. Documentation strategies: If the improvement process results in revisions or enhancements to current documentation processes, these will be implemented through the educational strategies listed below. Educational strategies: Nursing leadership will review documentation and provide real time feedback; the multidisciplinary team will develop teaching sheets for discussion at the unit level; and a mandatory education plan will be electronically available to all nursing staff through Healthstream, which has the	

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A 164	Continued From page 42 -the patient was at risk for injury related to dementia; -early in the shift, patient was extremely agitated-yelling and using oxygen cable to hit out at people; -refused to take medications and spit them out when offered; -physician notified and Haldol (antipsychotic) injection given as prescribed; -took approximately one hour to quiet the patient; -bed in low locked position with bed alarm on. Review of the physician's orders indicated siderails were prescribed on 2/1/10 at 9:22 a.m. The orders indicated the reasons for the siderails were to limit the patient from pulling at/out equipment (such as intravenous lines, feeding tube, airway management tubes, urinary drains, to prevent injury), and to limit the patient's mobility to prevent injury. At 10:10 a.m., a physician ordered soft 2 point restraints (restraint device used on 2 extremities-usually the wrists) and the reason for the restraints was to limit mobility to prevent injury. Review of a nursing progress note, dated 2/1/10 at 6:00 p.m. indicated the following: -alert and oriented to self, agitated much of the a.m.; -continues with 2 point soft restraint order although has not required restraints since daughter in to visit; -patient has hallucinations, agitation and multiple attempts to get out of bed; -per report patient is spitting out medications-daughter administered oral medications successfully this shift;	A 164	functionality to allow the nursing directors to monitor compliance with required education. The completion date for the correction of this deficiency, for the short-term and intermediate plans is 4/1/10. Updates on performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through the MGH General Executive Committee and through the Boards of Trustees Quality Subcommittee to the boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that the hospital is making progress as planned, and communicate progress and concerns to the Boards through the mechanism above on a quarterly basis until the issue is resolved to prevent the deficient practice from recurring. Subsequent compliance will be reviewed through the hospital's quality and safety dashboards, which will include an explicit area to monitor Conditions of Participation. In addition to these periodic reviews the MGH will flag all safety event reports related to Conditions of Participation issues so that ad hoc compliance issues can be addressed in a robust and timely fashion. To monitor and track the plan of correction, each week, staff from Patient Care Services Office of Quality and Safety will review the documentation of a statistically significant sample of restrained patients. Nursing directors will receive unit-specific data. When ongoing compliance is achieved, the frequency of monitoring will be reduced to monthly to ensure sustained compliance. Data will be summarized quarterly and sent	

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A 164	Continued From page 43 -patient much less agitated in afternoon. Review of a document in the medical record titled, "Restraint Documentation Flow Sheet For Non-Behavioral Medical Restraint," dated 2/1/10, revealed nurses' initials indicating restraints were on at 9:00 a.m., 11:00 a.m., 1:00 p.m., 3:00 p.m., 5:00 p.m., 7:00 p.m., 8:00 p.m. and 10:00 p.m. There was no evidence documented in the patient's medical record indicating staff had conducted an assessment of the patient to determine if least restrictive methods than 2 point soft restraints would be effective or ineffective in protecting the patient. In addition, the restraint flow sheet did not include the type of restraint device ordered or used, and did not reveal the extremities that were restrained. There was no documentation in the progress note indicating staff attempted to discontinue the patient's restraints during the time the Patient #41 was described as being much less agitated. Review of the next nursing progress note, dated 2/2/10 at 4:40 a.m., indicated the following: -patient extremely agitated, yelling out, swearing, kicking and hitting out; -patient now has 4 point soft restraints on; -patient attempted to bite staff, refused to take any medications and spit them out when offered; -patient was medicated with intravenous Haldol with some calming effect after 1½ hours. Review of the physician's orders, dated 2/2/10 at	A 164	to QA/PI as described above. The person responsible for this plan of correction is the MGH senior vice president for Patient Care and chief nurse.	

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A 164	Continued From page 44	A 164		

9:59 a.m. indicated, in addition to the soft 2 point restraints the physician added another order for staff to use soft 4 point restraints (restraint device used on 4 extremities- usually the wrists and ankles) to limit the patient from pulling at/out equipment and to limit the patient's mobility to prevent injury. Review of the patient's Restraint Flow Sheet, dated 2/2/10, revealed nurses' initials indicating restraints were on at 12:00 a.m., 2:00 a.m., 4:00 a.m., 6:00 a.m., 8:00 a.m., 10:00 a.m. and 12:00 p.m.

There was no evidence documented in the patient's medical record indicating staff had conducted an assessment of the patient to determine if less restrictive methods, other than 2 and 4 point soft restraints, would be effective or ineffective in protecting the patient.

In addition, the Restraint Flow Sheet did not include the type of restraint device ordered or used and did not show the extremities that were restrained.

During an interview on 2/4/10 at 2:00 p.m., RN JJ stated she had been the patient's primary nurse on 2/1/10 and 2/4/10. RN JJ stated the restraints were used because the patient was receiving IV fluids and IV antibiotics, and the patient kept trying to pull out the IV. RN JJ stated the patient was swatting at staff and trying to get out of bed. RN JJ stated efforts were made to calm the patient prior to using restraints, including re-orientation to place and time, and touch therapy with a soft ball. RN JJ stated the patient calmed when the daughter came to visit. RN JJ

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A 164	Continued From page 45 could not find documentation in the patient's medical record revealing that staff had conducted an assessment of the patient to determine if less restrictive methods than 2 and 4 point soft restraints would be effective or ineffective in protecting the patient. 2. Patient #38 A patient with was ordered four point leather restraints and two point leather restraints were applied for 3 hours and forty-five minutes without a least restrictive intervention being tried first. On 2/10/10 at 1:35 a.m., the Nurse Practitioner ordered "Restraint Intervention-Non Behavioral (Medical/Surgical) Restraints: Leather 4-Point. Reasons: Limit pulling at/out equipment e.g. (that is), IVs, feeding tube, management tubes, urinary drains, to prevent injury. Expires: 2/11/10 at 11:59 p.m." On 2/10/10 at 3:29 a.m., the nursing staff documented that the patient knows her name, year, and month (sometimes), but aware of place, amnesic to accident when asked. Patient restless and at times agitated throughout night, very impulsive and trying to climb out of bed stating she has to go to the bathroom. Patient reminded she has a catheter and offered a bedpan for a bowel movement with no results. 1:1 sitter at bedside, bed low and locked, and bed alarm on. Patient placed in locked leathers x (times) 2 after pulling out Foley catheter and intravenous heparin lock. Foley reinserted this shift and urine currently pink-tinged.	A 164		

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A 164	Continued From page 46 Although four point leather restraints were ordered, two point leather restraints were applied. There was no documentation of a least restrictive intervention being implemented prior to the two point leather restraints being applied. On 2/10/10 at 5:24 a.m., the physician ordered to discontinue the 4-point leather restraints. During an interview with Nurse CC on 2/10/10 at 2:25 p.m., she stated that patients are not placed in 4 point leather restraints for pulling out their Foley catheters.	A 164		
A 166	482.13(e)(4)(i) PATIENT RIGHTS: RESTRAINT OR SECLUSION The use of restraint or seclusion must be-- (i) in accordance with a written modification to the patient's plan of care. This STANDARD is not met as evidenced by: Based on clinical record review and staff interviews, it was determined that the facility failed to ensure that patient care plans were modified whenever there was a use of restraints for two of 84 clinical records reviewed. (Patient #75 and Patient #76) The findings include: 1. Patient #75 was admitted to the hospital on 1/31/10 with diagnoses which included A clinical record review was conducted at approximately 10:30 a.m. on 2/10/10 on the . The review revealed that the patient had been placed in 2 point soft restraints in	A 166	A multidisciplinary team described in Tag A164 will be convened to address the overall care and management of patients requiring restraint. As part of the improvement initiative, the team will address modification of patient care plans when patients are restrained. This team will identify the root cause of noncompliance and develop a plan for improvement based on such root cause analysis. The plan will include improvement strategies, communication and education strategies, and monitoring compliance strategies. Short-term, intermediate and longer-range efforts have been identified to ensure compliance. Short term: Effective 3/15/10, unit-based nurse leaders, including nursing directors and clinical nurse specialists, will review care plans and modifications to care plans of all restrained patients in their respective practice areas. They will provide immediate feedback to the care provider. Intermediate: Team will convene a focus group of nurses as a strategy to identify root causes of noncompliance. Barriers to	04/01/10

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A 166	Continued From page 47 accordance with the physician's orders. The clinical record lacked documentation of an individualized patient assessment before the use of restraints. The patient had a pre-printed, unsigned care plan titled, "Patient in Non-Behavioral Medical Restraint." This care plan also lacked any written assessment, dates, times and/or behaviors that necessitated the use of restraints during the dates that the patient was in restraints. An interview with Clinical Nurse Specialist of the Neurologic Intensive Care Unit, Nurse CNS G was conducted at the time of the clinical record review. She acknowledged that the clinical record lacked documentation of any changes in the care plans of Patient #75 regarding the use of restraints. 2. Patient #76 was admitted to the hospital on 1/13/10 with diagnoses that included A clinical record review was conducted on the morning of 2/10/10. The clinical record revealed that there were no written individualized assessments and/or any alternatives or interventions documented in the clinical record or care plans for the use of restraints. Review of the care plan revealed a "Patient in Non-Behavioral Medical Restraint" care plan. The preprinted care plan had only an undated entry that indicated, "ET (Endotracheal) tube safety," that was hand printed. An interview with CNS G and Charge Nurse KK of	A 166	documentation will be discussed. Ideas for improvement will be generated. Based upon findings, next steps will be identified, and these may include, but are not limited to, education and modification of documentation format. Long term: Successful documentation strategies will be incorporated into Acute Care Documentation Project planning (project focus involves converting from paper to electronic documentation). To implement the plan of correction, the MGH will undertake various documentation strategies and educational strategies. Documentation strategies: If the improvement process results in revisions or enhancements to current documentation processes, these will be implemented through the educational strategies listed below. Educational strategies: Nursing leadership will review documentation and provide real time feedback; the multidisciplinary team will develop teaching sheets for discussion at the unit level; a mandatory education plan will be electronically available to all nursing staff through Healthstream, which has the functionality to enable the nursing director to monitor compliance with required education. The completion date for correction of deficiency for both the short-term and intermediate plans is 4/1/10. Updates on performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through the MGH General Executive Committee and through the Boards of Trustees Quality Subcommittee to the boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that the	

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A 166	Continued From page 48 the PICU was conducted at the time of the clinical record review. Both acknowledged that there were no documented care plan modifications to the care plans of Patient #76 regarding the use of restraints.	A 166		
A 168	482.13(e)(5) PATIENT RIGHTS: RESTRAINT OR SECLUSION The use of restraint or seclusion must be in accordance with the order of a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under §482.12(c) and authorized to order restraint or seclusion by hospital policy in accordance with State law. This STANDARD is not met as evidenced by: Based on review of clinical records and hospital policies, and staff interviews, it was determined that two of 84 patients (Patient #75 and Patient #76) had been placed into restraints without a physician's order after a surgical intervention. The findings include: 1. Patient #75 was admitted to the hospital on 1/31/10 with diagnoses which included a On 2/10/10 a clinical record review was conducted on . The review revealed that the Patient #75 had been placed in 2 point soft restraints by a physician's order on 2/3/10 at 10:09 a.m., and the order was to expire on 2/4/10 at 11:59 p.m. Documentation in the clinical record also revealed that the patient was removed from the unit to the and remained	A 168	A multidisciplinary team described in tag A164 will be convened to address various issues related to the use of restraints, including ensuring that a timely physician or other ordering clinician order is present for all patients who are in restraint or seclusion. This team will identify the root causes of noncompliance with a particular focus on timely renewal of restraint orders as well as re-initiation of restraint orders after major surgical intervention; develop a plan for improvement based on root cause analysis that will include strategies for process improvement, communication and education, and ongoing compliance monitoring; recommend changes to the hospital's provider order-entry system to change auto-notification for renewal of restraint or seclusion orders to include a reminder to reassess patients before renewing the order; and review the MGH Restraint and Seclusion Policy for compliance with CMS Conditions of Participation. To improve the processes that led to the deficiency, the hospital has developed a two-pronged approach. Short term: Effective 3/15/10, unit-based nurse leaders, including nursing directors and clinical nurse specialists, will review documentation of all restrained patients in their respective practice areas. Nursing will provide feedback to the responding ordering clinician of any patients who are identified as being in restraints without a timely order. Intermediate: Team will convene a focus group with physician, nursing,	04/30/10

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A 168	Continued From page 49 there from about 1:00 p.m. to 4:00 p.m. The clinical record lacked any documentation of a new physician's order to re-start the restraints upon return to the unit. The next physician's order for 2 point soft restraints was documented at 8:18 a.m. on 2/4/10, and expired at 11:59 p.m. on 2/5/10. The clinical record lacked a physician's order for restraints between approximately 4:00 p.m. on 2/3/10, and 8:18 a.m. on 2/4/10. However, the "Restraint Documentation Flow Sheet for Non-Behavioral Medical Restraint" contained documentation that the patient was in restraints on 2/3/10 from 2:00 p.m. to 3:00 p.m., 4:00 p.m. to 5:00 p.m., and 8:00 p.m. to 2/4/10 at 8:18 a.m. without a physician's order for restraints. On 2/9/10, the patient returned to the OR where she remained from approximately 9:00 a.m. to 9:00 p.m. Upon return to the unit, the patient was again placed into restraints without a new physician's order for restraints. The patient remained in restraints until 2/10/10 at 6:34 a.m., when a new physician's order for 2 point soft restraints was obtained. 2. Patient #76 was admitted to the hospital on 1/13/10 with diagnoses that included A clinical record review was conducted on the morning of 2/10/10 on . The clinical record revealed that there was a physician's order for 2 point soft restraint which expired on 1/29/10 at 11:59 p.m. The next physician's order for restraints was on 1/30/10 at 3:02 a.m. A review of the "Restraint Documentation Flow	A 168	and Health Information Technology representation to review the existing workflows associated with restraint initiation and renewal. Barriers to full compliance with the CMS Conditions of Participation and MGH policy will be discussed. Ideas for improvement will be generated and next steps will be identified. Such steps may include, but are not limited to, education of staff and technical modifications to the provider order-entry system. To implement the plan of correction, unit-based nurse leaders and physician staff will be notified of the immediate plans related to patients in restraint by 3/15/10. The focus group will convene on or before 4/1/10 with recommendations for next steps developed by 4/15/10. Implementation of subsequent steps is dependent on the nature of the recommendations of the focus group. The hospital's Health Information Systems team will work with the multidisciplinary team to identify the changes to the provider order entry system that are required for full compliance and will develop technical specifications for these changes by 4/30/10, including sample screen shots. Coding, testing and implementation will be completed by 5/25/10. Updates on performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through the MGH General Executive Committee and through the Boards of Trustees Quality Subcommittee to the boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that the hospital is making progress as planned, and communicate	

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A 168	Continued From page 49 there from about 1:00 p.m. to 4:00 p.m. The clinical record lacked any documentation of a new physician's order to re-start the restraints upon return to the unit. The next physician's order for 2 point soft restraints was documented at 8:18 a.m. on 2/4/10, and expired at 11:59 p.m. on 2/5/10. The clinical record lacked a physician's order for restraints between approximately 4:00 p.m. on 2/3/10, and 8:18 a.m. on 2/4/10. However, the "Restraint Documentation Flow Sheet for Non-Behavioral Medical Restraint" contained documentation that the patient was in restraints on 2/3/10 from 2:00 p.m. to 3:00 p.m., 4:00 p.m. to 5:00 p.m., and 8:00 p.m. to 2/4/10 at 8:18 a.m. without a physician's order for restraints. On 2/9/10, the patient returned to . where she remained from approximately 9:00 a.m. to 9:00 p.m. Upon return to the unit, the patient was again placed into restraints without a new physician's order for restraints. The patient remained in restraints until 2/10/10 at 6:34 a.m., when a new physician's order for 2 point soft restraints was obtained. 2. Patient #76 was admitted to the hospital on 1/13/10 with diagnoses that included A clinical record review was conducted on the morning of 2/10/10 on The clinical record revealed that there was a physician's order for 2 point soft restraint which expired on 1/29/10 at 11:59 p.m. The next physician's order for restraints was on 1/30/10 at 3:02 a.m. A review of the "Restraint Documentation Flow	A 168	progress and concerns to the boards through the mechanism above on a quarterly basis until the issue is resolved to prevent the deficient practice from recurring. Subsequent compliance will be reviewed through the hospital's quality and safety dashboards, which will include an explicit area to monitor Conditions of Participation. In addition to these periodic reviews, the MGH will flag all safety event reports related to Conditions of Participation so that ad hoc compliance issues can be addressed in a robust and timely fashion. To monitor and track the plan of correction, unit-based nurse leaders, including nursing directors and clinical nurse specialists, will review documentation of all restrained patients in their respective practice areas. Nursing will provide feedback to the responding ordering clinician of any patients who are identified as being in restraints without a timely order. Data from these daily audits will flow centrally to the appropriate QA/PI staff to ensure organizational learning around noncompliant cases. Staff from Patient Care Services Office of Quality and Safety will review the documentation and timeliness of orders of 20 percent of those patients in restraints each week. This review will complement ongoing monitoring by nursing leadership. The purpose will be to collect compliance data and validate unit-based findings. When ongoing compliance is achieved, the frequency of monitoring will be reduced to monthly to ensure sustained compliance. The person responsible for implementing the plan of correction is the senior vice president for Patient Care Services and chief nurse.	

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A 168	Continued From page 50 Sheet for Non-Behavioral Medical Restraint" contained documentation that Patient #76 remained in restraints without a physician's order for approximately three hours, from 12:00 a.m. until 3:00 a.m. on 1/30/10 when a new physician's order for restraints was obtained. On 2/11/10 at 9:00 a.m., during an interview with the Staff Specialist , she acknowledged that the clinical record lacked physician's restraint orders documented for Patient #75 on 2/3/10 from approximately 4:00 p.m. until 8:18 a.m. on 2/4/10, and again from 9:00 p.m. 2/9/10 until 6:34 a.m. 2/10/10. She also acknowledged that Patient #76 had been placed in restraints without a physician's orders between 12:00 a.m. through 3:00 a.m. on 1/30/10. On 2/11/10 a review of the facility's policy, "Patient Orders 2.14.2." indicated "Pre-operative orders which will continue post-operatively must be rewritten. 6.1 "Orders shall be rewritten, whenever the patient has been to	A 168		
A 169	482.13(e)(6) PATIENT RIGHTS: RESTRAINT OR SECLUSION Orders for the use of restraint or seclusion must never be written as a standing order or on an as needed basis (PRN). This STANDARD is not met as evidenced by: Based on clinical record reviews, observations and staff interview, it was determined that the hospital failed to ensure that physicians' orders for restraints were obtained for three of 84 patients based on individual assessments and behaviors indicating a need for restraint usage. (Patients #11, #68 and #76)	A 169	Ordering providers at the MGH are unable to enter standing orders for restraints through the hospital's provider order-entry system (POE). To address the PRN nature of the restraint orders, the MGH will implement a plan for enhancements to the POE system by 5/25/10 that will require ordering providers to select only one type of restraint, or to select a predetermined clinically appropriate combination of restraints. The hospital's Health Information Systems team will work with the multidisciplinary team to identify the changes to the provider order entry system that are required for full compliance and will develop technical specifications for these	05/25/10

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A 169	Continued From page 51 The findings include: 1. Review of medical record for Patient #68 revealed an untimed nurses' note between the hours of 8:55 a.m. and 9:30 a.m. on 2/1/10 that stated, Pt (patient) swung and hit RN (registered nurse) with mitted hand, soft restraints applied until mom arrives. The medical record does not specify the type of soft restraint or where staff applied the restraint. The Nursing Admission Note dated 2/1/10 at 11:00 p.m. indicated, 1:1 sitter, seizure pads, bed low, soft mitts as ordered. Review of Physician's Orders from 1/31/10 at 10:57 a.m. through 2/2/10 at 2:19 a.m., lacked evidence of a physician order for hand mitts or soft restraints. At 2:19 a.m. on 2/2/10, the physician wrote an order for Restraints: Mitts with Wrist Restraints Soft 2-point Start 2/2/10 at 2:19 a.m. Expires on 2/3/10 at 11:59 p.m. 2. Patient #76 was admitted to the hospital on 1/13/10 with diagnoses that included A clinical record review was conducted on the morning of 2/10/10 on The clinical record revealed that there was a physician's order for 2 point soft restraint on 1/15/10 at 5:12 a.m., that would have expired on 1/16/10 at 11:59 p.m. The clinical record lacked any documentation of an assessment or other interventions attempted prior to the restraint being ordered. The clinical record lacked a "Restraint Documentation Flow Sheet for Non-Behavioral Medical Restraint" for	A 169	changes by 4/30/10, including sample screen shots. Coding, testing and implementation will be completed by 5/25/10. A communication and education program will be developed and will be rolled out to all ordering providers. This program will be take advantage of the hospital's ongoing strategies for communicating changes to the POE system, including “Clinical Application Advisories” and internal mailings. To improve the processes that led to the deficiency, the changes made to the POE system will be developed and reviewed by the multidisciplinary team described in Tag A164 above before implementation. To implement the plan of correction, the multidisciplinary team described in Tag A164 will recommend changes to the POE system. The hospital's Health Information Systems team will develop technical specification by 4/30/10 and will complete coding, testing and implementation by 5/25/10. An ensuing communication and education plan will be rolled out using the hospital's various communication vehicles and methods. Updates on performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through the MGH General Executive Committee and through the Boards of Trustees Quality Subcommittee to the boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that the hospital is making progress as planned, and communicate progress and concerns to the boards through the mechanism above on a quarterly basis until the issue is resolved to prevent the deficient	

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A 169	Continued From page 52 this time period. The clinical record also contained documentation of a physician's order for 2 point soft restraints from 2/2/10 through 11:59 p.m. on 2/3/10. There was an additional physician's order for 2 point soft restraint on 2/3/10 until 11:59 p.m. on 2/4/10. A review of the "Restraint Documentation Flow Sheet for Non-Behavioral Medical Restraint" contained documentation that the restraints were, "d/c'd" (discontinued) on a (unknown date) after 2/2/10 at approximately 12:00 p.m. However, the physician's orders for restraints continued until 2/4/10 at 11:59 p.m. There was no documentation in the clinical record that a physician's order to discontinue the restraints was obtained for the period between 12:00 p.m. on 2/3/10 and 1:50 p.m. on 2/4/10. An interview of the CNS of the , CNS G was conducted at approximately 10:30 a.m. She acknowledged that the clinical record of Patient #76 lacked a "Restraint Documentation Flow Sheet for Non-Behavioral Medical Restraint" in the clinical record for the physician's order for restraints of 1/15/10 through 1/16/10. She also said that the clinical record lacked a "Restraint Documentation Flow Sheet for Non-Behavioral Medical Restraint" after the handwritten documentation that the restraints were "d/c'd" on what appeared to be 12:00 p.m. on 2/3/10. She also acknowledged that there were no physician's orders to discontinue the restraints after 2/3/10. 3. On 02/10/10 at approximately 2:05 p.m., Patient #11 was observed sitting in a chair in	A 169	practice from recurring. Subsequent compliance will be reviewed through the hospital's quality and safety dashboards, which will include an explicit area to monitor Conditions of Participation. In addition to these periodic reviews, the MGH will flag all safety event reports related to Conditions of Participation so that ad hoc compliance issues can be addressed in a robust and timely fashion. To monitor and track the plan of correction, unit-based nurse leaders, including nursing directors and clinical nurse specialists, will review documentation of all restrained patients in their respective practice areas. They will provide immediate feedback to the care providers. Staff from the Patient Care Services Office of Quality and Safety will review the documentation of 20 percent of patients in restraints each week. This review will complement monitoring by nursing leadership. The purpose will be to collect compliance data and validate unit-based findings. Nursing directors will receive unit-specific data. When compliance appears to be achieved, the frequency of monitoring will be reduced to monthly to ensure sustained compliance. Data will be summarized quarterly and sent to QA/PI as described above. The person responsible for implementing the plan of correction is the senior vice president for Quality and Safety.	

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A 169	Continued From page 53	A 169		

There was a Patient Care Aide (PCA) sitting in room with the patient, and a security guard posted outside the room. Patient #11's, clinical record was reviewed on 2/10/10 at approximately 2:15 p.m.

. Patient #11 also fell at home and sustained compression fractures of vertebrae T4 (Thoracic), T5 and T11. The

Included with medication, diet and treatment orders, were an order for restraints which read; Restraints Intervention-Non-Behavioral (Medical/Surgical)

Restraints:
- Side Rails
- Safety Net Bed
- Soft 2 Point
- Soft 4 Point

Reason:
- Limit Mobility to prevent injury

Start 2/10/10 at 9:18 a.m., expires 02/11/10 at 11:59 p.m.

There were no written specific reasons for the application of any of the restraint intervention orders.

At 02/10/10 at approximately 2:30 p.m., the ND #1 for the unit was interviewed. ND #1 stated that

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A 169	Continued From page 54 Patient #11 has displayed many episodes of agitation and has caused injuries to the staff. That is why we have PCA in the room to help with care and treatments. A security guard is outside the room to assist us when the patient gets extremely agitated. There has been an increase in the psychoactive medications which has decreased acting out behaviors. We haven't had to use any restraints for a couple of days. When asked about what type of restraint would be used, it was stated that the orders should have been more specific.	A 169		
A 185	482.13(e)(16)(ii) PATIENT RIGHTS: RESTRAINT OR SECLUSION [there must be documentation in the patient's medical record of the following:] A description of the patient's behavior and the intervention used. This STANDARD is not met as evidenced by: Based on clinical record review, staff interview, and facility policy review, it was determined that the hospital failed to ensure that patients' clinical records contained documentation of patient's behaviors and the interventions used in conjunction with restraints for two of 84 patients. (Patients #75 and #76) The findings include: 1. Patient #75 was admitted to the hospital on 1/31/10 with diagnoses which included A clinical record review was conducted on the morning of 2/10/10 on The clinical record revealed that the patient had been placed in physician ordered restraints periodically between	A 185	A multidisciplinary team described in Tag A164 will be convened to address the overall care and management of patients requiring restraint. As part of the improvement initiative, the team will address documentation of the patient's behavior and the intervention used. The team will identify the root cause of noncompliance and develop a plan for improvement based on root cause analysis that will include improvement strategies, communication and education strategies and compliance monitoring strategies. To improve the processes that led to the deficiency, short-term, intermediate and longer-range efforts have been identified. Short term: Effective 3/15/10, unit-based nurse leaders, including nursing directors and clinical nurse specialists, will review care plans including documentation of patient behaviors and interventions used on all restrained patients in their respective practice areas. They will provide immediate feedback to the care provider. Intermediate: Team will convene a focus group of nurses as a strategy to identify root causes of noncompliance. Barriers to documentation will be discussed. Ideas for improvement will be generated. Based upon findings, next steps will be	04/01/10

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A 185	Continued From page 55 1/31/10 through 2/10/10. The patient's care plans lacked any documentation of the patient's behaviors requiring restraints or any interventions attempted before the patient was placed in restraints. The clinical record contained a pre-printed, unsigned Care Plan titled, "Patient in Non-Behavioral Medical Restraint." The care plan lacked any written assessment, dates, times, behaviors and/or interventions attempted prior to the use of restraints. 2. Patient #76 was admitted to the hospital on 1/13/10 with diagnoses that included A clinical record review was conducted on the morning of 2/10/10. The clinical record revealed a lack of a written assessment, documentation of behaviors, or interventions attempted before the patient had been placed into restraints. An interview with the CNS of the , CNS G and the Charge Nurse KK of the was conducted at the time of the clinical record review. They acknowledged that there were no behaviors documented or alternatives attempted prior to the use of restraints for Patients #75 and #76. 3. Review of the facility's policy and procedure titled, "Restraint and Seclusion", approved by the Medical Policy Committee on 6/3/09, indicated the following: 3.1 - The decision to use a restraint or seclusion is driven not by diagnosis, but by a comprehensive individual assessment;	A 185	identified that may include, but are not limited to, education and modification of documentation format. Long term: Successful documentation strategies will be incorporated into Acute Care Documentation Project planning (project focus involves converting from paper to electronic documentation). To implement the plan of correction the MGH will undertake various documentation and educational strategies. Documentation strategies: If the improvement process results in revisions or enhancements to current documentation processes, these will be implemented through the educational strategies listed below. Educational strategies: Nursing leadership will review documentation and provide real time feedback; the multidisciplinary team will develop teaching sheets for discussion at the unit level; and a mandatory education plan will be electronically available to all nursing staff through Healthstream, which has the functionality to allow the nursing directors to monitor compliance with required education. The completion date for both the short-term and intermediate plans of correction of this deficiency is 4/1/10. Updates on performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through the MGH General Executive Committee and through the Boards of Trustees Quality Subcommittee to the boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that the hospital is making progress as planned, and communicate progress and concerns to the boards through the mechanism above on a quarterly basis until	

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A 185	Continued From page 55 1/31/10 through 2/10/10. The patient's care plans lacked any documentation of the patient's behaviors requiring restraints or any interventions attempted before the patient was placed in restraints. The clinical record contained a pre-printed, unsigned Care Plan titled, "Patient in Non-Behavioral Medical Restraint." The care plan lacked any written assessment, dates, times, behaviors and/or interventions attempted prior to the use of restraints. 2. Patient #76 was admitted to the hospital on 1/13/10 with diagnoses that included A clinical record review was conducted on the morning of 2/10/10. The clinical record revealed a lack of a written assessment, documentation of behaviors, or interventions attempted before the patient had been placed into restraints. An interview with the CNS of the , CNS G and the Charge Nurse KK of the , was conducted at the time of the clinical record review. They acknowledged that there were no behaviors documented or alternatives attempted prior to the use of restraints for Patients #75 and #76. 3. Review of the facility's policy and procedure titled, "Restraint and Seclusion", approved by the Medical Policy Committee on 6/3/09, indicated the following: 3.1 - The decision to use a restraint or seclusion is driven not by diagnosis, but by a comprehensive individual assessment;	A 185	the issue is resolved to prevent the deficient practice from recurring. Subsequent compliance will be reviewed through the hospital's quality and safety dashboards, which will include an explicit area to monitor Conditions of Participation. In addition to these periodic reviews, the MGH will flag all safety event reports related to Conditions of Participation so that ad hoc compliance issues can be addressed in a robust and timely fashion. To monitor and track compliance with the plan of correction, weekly, staff from PCS Office of Quality and Safety will review the documentation of a statistically significant sample of restrained patients. Nursing Directors will receive unit-specific data. When compliance is achieved, the frequency of monitoring will be reduced to monthly to ensure sustained compliance. Data will be summarized quarterly and sent to QA/PI as described above. The person responsible for implementing the plan of correction is the senior vice president for Patient Care Services and chief nurse.	

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MASSACHUSETTS GENERAL HOSPITAL	55 FRUIT STREET BOSTON, MA 02114

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A 185	Continued From page 56 3.3 - Restraints shall not be used when less restrictive interventions would be effective. Restraint or seclusion should be considered only as a temporary means of intervention when the patient is in immediate danger of harming self or others; 3.4 - When a restraint or seclusion is required, the least restrictive method should be utilized; 5.1 - Non-behavioral medical restraint may be used for the following indications when less restrictive means would not be effective in protecting the patient: a) the patient is pulling at tubes, lines or dressings, b) the patient's actions are endangering themselves; for example the patient is thrashing around in bed or attempting to get out of bed in a way or under conditions where it might cause harm; 5.3 - Type and location of the restraining device(s) shall be documented at least once per shift and when changed; alternatives to and less restrictive forms of restraint considered by the care giver shall be documented at least once per shift	A 185		
A 186	482.13(e)(16)(iii) PATIENT RIGHTS: RESTRAINT OR SECLUSION [there must be documentation in the patient's medical record of] Alternatives or other less restrictive interventions attempted (as applicable); This STANDARD is not met as evidenced by: Based on clinical record review and staff interviews, and facility policy review, it was determined that the hospital failed to ensure that alternatives or interventions were attempted prior to the use of restraints for two of 84 patients. (Patients #75 and #76).	A 186	A multidisciplinary team described in Tag A164 will be convened to address the overall care and management of patients requiring restraint. As part of the improvement initiative, the team will address documentation of the patient's behavior and the intervention used. The team will identify the root cause of noncompliance - including such potential issues as lack of knowledge about least restrictive alternatives verses noncompliance with documentation - and develop a plan for improvement based on root cause analysis that will include improvement strategies, communication and education strategies and compliance monitoring strategies.	04/01/10

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A 186	Continued From page 57 The findings include: 1. Patient #75 was admitted to the hospital on 1/31/10 with diagnoses which included A clinical record review was conducted on 2/10/10 at approximately 10:30 a.m. on the The clinical record revealed that the patient had been placed in restraints between 1/31/10 through 2/10/10. The clinical record lacked any documented interventions or alternatives attempted prior to the use of restraints. The clinical record contained a pre-printed, unsigned care plan titled "Patient in Non-Behavioral medical Restraint." The care plan lacked any documentation of behaviors, alternatives or interventions attempted prior to the use of 2 point soft restraints. 2. Patient #76 was admitted to the hospital on 1/13/10 with diagnoses that included A clinical record review was conducted on the morning of 2/10/10 on The clinical record revealed that there were no written assessment, alternatives, or interventions prior to or after the patient had been placed into restraints. The patient had been placed into 2 point soft restraints from 1/19/10 through 2/3/10. An interview of the CNS of the , CNS G and the Charge Nurse KK of the , was conducted at approximately 10:30 a.m. They acknowledged	A 186	To improve the processes that led to the deficiency, the hospital will undertake various short-term, intermediate and longer-term strategies. Short term: Effective immediately, unit-based nurse leaders, including nursing directors and clinical nurse specialists, will review care plans, including documentation of less restrictive interventions (as applicable) of all restrained patients in their respective practice areas. They will provide immediate feedback to the care provider. Intermediate: Team will convene a focus group of nurses as a strategy to identify root causes of noncompliance. Barriers to documentation will be discussed. Ideas for improvement will be generated. Based upon findings, next steps will be identified that may include, but are not limited to, education and modification of documentation format. Long term: Successful documentation strategies will be incorporated into Acute Care Documentation Project planning (project focused on converting from paper to electronic documentation). To implement the plan of correction, the hospital will rely on documentation and educational strategies. Documentation strategies: If the improvement process results in revisions or enhancements to current documentation processes, these will be implemented through the educational strategies listed below. Educational strategies: Nursing leadership will review documentation and provide real-time feedback; the multidisciplinary team will develop teaching sheets for discussion at the unit level; and a mandatory education plan will be electronically available to all nursing staff through Healthstream, which has the functionality to allow the nursing directors to monitor compliance with required education.	

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A 186	Continued From page 57 The findings include: 1. Patient #75 was admitted to the hospital on 1/31/10 with diagnoses which included _ A clinical record review was conducted on 2/10/10 at approximately 10:30 a.m. on the The clinical record revealed that the patient had been placed in restraints between 1/31/10 through 2/10/10. The clinical record lacked any documented interventions or alternatives attempted prior to the use of restraints. The clinical record contained a pre-printed, unsigned care plan titled "Patient in Non-Behavioral medical Restraint." The care plan lacked any documentation of behaviors, alternatives or interventions attempted prior to the use of 2 point soft restraints. 2. Patient #76 was admitted to the hospital on 1/13/10 with diagnoses that included . A clinical record review was conducted on the morning of 2/10/10 on The clinical record revealed that there were no written assessment, alternatives, or interventions prior to or after the patient had been placed into restraints. The patient had been placed into 2 point soft restraints from 1/19/10 through 2/3/10. An interview of the CNS of the CNS G and the Charge Nurse KK of the , was conducted at approximately 10:30 a.m. They acknowledged	A 186	The completion date for correction of this deficiency for both the short-term and intermediate plans is 4/1/10. Updates on performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through the MGH General Executive Committee and through the Boards of Trustees Quality Subcommittee to the boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that the hospital is making progress as planned, and communicate progress and concerns to the boards through the mechanism above on a quarterly basis until the issue is resolved to prevent the deficient practice from recurring. Subsequent compliance will be reviewed through the hospital's quality and safety dashboards, which will include an explicit area to monitor Conditions of Participation. In addition to these periodic reviews, the MGH will flag all safety event reports related to Conditions of Participation so that ad hoc compliance issues can be addressed in a robust and timely fashion. To monitor and track compliance with this plan of correction, staff from the Patient Care Services Office of Quality and Safety each week will review the documentation of a statistically significant sample of restrained patients. Nursing directors will receive unit-specific data. When compliance is achieved, the frequency of monitoring will be reduced to monthly to ensure sustained compliance. Data will be summarized quarterly and sent to QA/PI as described above.	

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A 186	Continued From page 58 that there were no changes in the clinical records of Patient #75 or Patient #76 concerning changes or interventions attempted for the use of restraints. 3. Review of the facility's policy and procedure titled, "Restraint and Seclusion", approved by the Medical Policy Committee on 6/3/09, indicated the following: 3.1 - The decision to use a restraint or seclusion is driven not by diagnosis, but by a comprehensive individual assessment; 3.3 - Restraints shall not be used when less restrictive interventions would be effective. Restraint or seclusion should be considered only as a temporary means of intervention when the patient is in immediate danger of harming self or others; 3.4 - When a restraint or seclusion is required, the least restrictive method should be utilized; 5.1 - Non-behavioral medical restraint may be used for the following indications when less restrictive means would not be effective in protecting the patient: a) the patient is pulling at tubes, lines or dressings, b) the patient's actions are endangering themselves; for example the patient is thrashing around in bed or attempting to get out of bed in a way or under conditions where it might cause harm; 5.3 - Type and location of the restraining device(s) shall be documented at least once per shift and when changed; alternatives to and less restrictive forms of restraint considered by the care giver shall be documented at least once per shift	A 186	The person responsible for implementing the plan of correction is the senior vice president for Patient Care Services and chief nurse.	
A 188	482.13(e)(16)(v) PATIENT RIGHTS: RESTRAINT OR SECLUSION [there must be documentation in the patient's	A 188	A multidisciplinary team as described in Tag A 164 will be convened to address the overall care and management of patients requiring restraint. As part of the	04/01/10

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A 188	Continued From page 59 medical record of the following:] The patient's response to the intervention(s) used, including the rationale for continued use of the intervention. This STANDARD is not met as evidenced by: Based on clinical record reviews and staff interviews, and review of facility policy, it was determined that the hospital failed to ensure that patients' clinical records contained documentation of patients' responses to attempted interventions and the staffs' rationale to continue the interventions used for two of 84 patients. (Patients #75 and #76) The findings include: 1. Patient #75 Patient #75 was admitted to the hospital on 1/31/10 with diagnoses which included A clinical record review was conducted on the morning of 2/10/10 on the . The clinical record revealed that the patient had been placed in restraints periodically. The clinical record lacked any documented interventions attempted prior to or after the use of restraints, thus there was not a rationale. The clinical record contained a pre-printed, unsigned care plan titled, "Patient in Non-Behavioral Medical Restraint." This care plan lacked any written interventions or a rationale for the use of restraints. 2. Patient #76	A 188	improvement initiative, the team will address documentation of the patient's response to the intervention, including rationale for its continued use. The team will identify the root cause of noncompliance and develop a plan for improvement based on root cause analysis. The plan will include improvement strategies, communication and education strategies and compliance monitoring strategies. To improve the processes that led to the deficiency, the MGH will undertake short-term, intermediate and longer-range efforts. Short term: Effective 3/15/10, unit-based nurse leaders, including nursing directors and clinical nurse specialists, will review care plans including documentation of the response to intervention and rational for continued use (as applicable) of all restrained patients in their respective practice areas. They will provide immediate feedback to the care provider. Intermediate: Team will convene a focus group of nurses as a strategy to identify root causes of noncompliance. Barriers to documentation will be discussed. Ideas for improvement will be generated. Based upon findings, next steps will be identified that may include, but are not limited to, education and modification of documentation format. Long term: Successful documentation strategies will be incorporated into Acute Care Documentation Project planning; (project focused on converting from paper to electronic documentation). To implement the plan of correction, the hospital will undertake various documentation and educational strategies. Documentation strategies: If the improvement process results in revisions or enhancements to current documentation processes, these will be	

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A 188	Continued From page 60 Patient #76 was admitted to the hospital on 1/13/10 with diagnoses that included A clinical record review was conducted on the morning of 2/10/10 on the The clinical record lacked documentation of any interventions attempted, patient response to those interventions or rationale for implementing an intervention. The clinical record contained documentation that Patient #76 had been periodically been in 2 point wrist restraints from 1/19/10 through 2/3/10. An interview with CNS G and Charge Nurse KK of the was conducted at approximately 10:30 a.m. They both acknowledged that the clinical records lacked documentation of interventions attempted, the patient's response to those interventions and any rationale for the interventions. 3. Review of the facility's policy and procedure titled, "Restraint and Seclusion", approved by the Medical Policy Committee on 6/3/09, indicated the following: 3.1 - The decision to use a restraint or seclusion is driven not by diagnosis, but by a comprehensive individual assessment; 3.3 - Restraints shall not be used when less restrictive interventions would be effective. Restraint or seclusion should be considered only as a temporary means of intervention when the patient is in immediate danger of harming self or others; 3.4 - When a restraint or seclusion is required, the least restrictive method should be utilized; 5.1 - Non-behavioral medical restraint may be	A 188	implemented through the educational strategies listed below. Educational strategies: Nursing leadership will review documentation and provide real-ime feedback; the multidisciplinary team will develop teaching sheets for discussion at the unit level; and a mandatory education plan will be electronically available to all nursing staff through Healthstream, which has the functionality to allow the nursing directors to monitor compliance with required education. The completion date for correction of the deficiency for both the short-term and intermediate plans is 4/1/10. Updates on performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through the MGH General Executive Committee and through the Boards of Trustees Quality Subcommittee to the boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that the hospital is making progress as planned, and communicate progress and concerns to the boards through the mechanism above on a quarterly basis until the issue is resolved to prevent the deficient practice from recurring. Subsequent compliance will be reviewed through the hospital's quality and safety dashboards, which will include an explicit area to monitor Conditions of Participation. In addition to these periodic reviews, the MGH will flag all safety event reports related to Conditions of Participation so that ad hoc compliance issues can be addressed in a robust and timely fashion. To monitor and track compliance with the	

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A 188	Continued From page 61 used for the following indications when less restrictive means would not be effective in protecting the patient: a) the patient is pulling at tubes, lines or dressings, b) the patient's actions are endangering themselves; for example the patient is thrashing around in bed or attempting to get out of bed in a way or under conditions where it might cause harm; 5.3 - Type and location of the restraining device(s) shall be documented at least once per shift and when changed; alternatives to and less restrictive forms of restraint considered by the care giver shall be documented at least once per shift	A 188	plan of correction, staff from the Patient Care Services Office of Quality and Safety each week will review the documentation of a statistically significant sample of restrained patients. Nursing directors will receive unit-specific data. When compliance is achieved, the frequency of monitoring will be reduced to monthly to ensure sustained compliance. Data will be summarized quarterly and sent to QA/PI as described above. The person responsible for implementing the plan of correction is the senior vice president for Patient Care Services and chief nurse.	
A 206	482.13(f)(2)(vii) PATIENT RIGHTS: RESTRAINT OR SECLUSION [The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:] (vii) The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification. This STANDARD is not met as evidenced by: Based on observation, record review and interview with the facility's staff, it was determined that the facility failed to ensure that security personnel received 1st. Responder training and are certified in first aide procedures, Cardio-Pulmonary Resuscitation (CPR) and use of the AED (Automated External Defibrillator.) The findings include:	A 206	Security Officer #1 has successfully completed CPR/first-responder training in accordance with department policy. Department policy at the time of survey required Police & Security officers to complete CPR/first-responder training within one year of employment. After discussion with surveyors during the review, the hospital has decided that, going forward, security supervisors will ensure that training related to patient care is prioritized, and new timelines for employee training will be designed. Patient care-related training will be offered monthly and prioritized within the first 90 days of employment. Quarterly audit reports are generated by the training manager to measure compliance. In this case the security officer had already been scheduled to receive the training the following week of the survey. He successfully completed the training 2/19/10. Updates on performance related to the deficiency cited will be reviewed on a	02/12/10

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A 206	Continued From page 62 During an observation in the hallway leading to the on 2/3/10 at approximately 7:45 a.m., Security Officer (SO) #1 was observed assisting in restraint of Patient #61 who exhibited aggressive behavior while waiting to be seen in . According to a statement documented in a follow-up report dated 2/4/10 by SO #1, he stated, "...This officer then went to the ground and attempted to hold his legs down and to try to get him to stop kicking anyone." Review of SO #1's personnel file revealed he was hired on 3/4/09. Further review of his personnel file revealed, that as of 2/10/10, SO #1 has not received training in CPR and has not been certified as a 1st. Responder. SM #1 stated during an interview on 2/10/10 at 12:00 p.m., that all security/police staff are required to be certified as a 1st Responder and trained in CPR, and use of the AED. He also stated the training is done monthly. SM #1 went on to state that secondary to difficulties in scheduling and staffing SO #1 had not attended the required training, but he was expected to attend the course scheduled for 3/15-18/10. Review of the personnel files for six other security/police/ambassadors revealed that there was a training class conducted in 5/09, but SO #1 had not attended the training on that date. This was acknowledged by SM #1.	A 206	quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through the MGH General Executive Committee and through the Boards of Trustees Quality Subcommittee to the boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that the hospital is making progress as planned, and communicate progress and concerns to the boards through the mechanism above on a quarterly basis until the issue is resolved to prevent the deficient practice from recurring. Subsequent compliance will be reviewed through the hospital's quality and safety dashboards, which will include an explicit area to monitor Conditions of Participation. In addition to these periodic reviews, the MGH will flag all safety event reports related to Conditions of Participation so that ad hoc compliance issues can be addressed in a robust and timely fashion. To monitor and track compliance with this plan, MGH Police and Security supervisors will review quarterly audit reports to provide appropriate documentation and correlate completed training information with new hire data. The MGH Police & Security training manager is responsible for ensuring this plan of correction is implemented.	
A 214	482.13(g) PATIENT RIGHTS: SECLUSION OR RESTRAINT Death Reporting Requirements: Hospitals must	A 214	The hospital acknowledges that although staff members had been reporting deaths associated with the use of seclusion or restraint by faxing a report to CMS, the MGH	02/15/10

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A 214	Continued From page 63 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 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 record review and interview, it was determined that the facility failed to report by telephone to the Centers for Medicare & Medicaid Services' (CMS) Regional Office each patient's death that occurred while the patient was in	A 214	had not been reporting these deaths by telephone, in accordance with CMS Conditions of Participation. The hospital has changed its process to include a telephone call to the appropriate CMS designee at the same time the Hospital Restraint Death Report Worksheet is faxed. The hospital immediately revised the process for reporting deaths associated with the use of seclusion or restraint upon verbal notification of this deficiency during the survey. All staff members involved in the reporting process were notified of the procedural change, and the Hospital Restraint Death Report fax cover sheet was amended to include the CMS telephone number for verbal reporting. As of the date of correction, the hospital has been documenting the specific time the telephone call was placed to CMS on the fax cover sheet. The completion date for this plan of correction was 2/15/10. Updates to the hospital restraint policies will be completed as discussed in A164 Updates on performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through the MGH General Executive Committee and through the Boards of Trustees Quality Subcommittee to the boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that the hospital is making progress as planned, and communicate progress and concerns to the boards through the mechanism above on a quarterly basis until the issue is resolved to prevent the deficient practice from recurring.	

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A 214	Continued From page 64 restraints or seclusion; each patient's death that occurred within 24 hours after the patient was removed from restraints or seclusion; or each patient's death known to the hospital that occurred within one week after restraints or seclusion where it would have been reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to the patient's death. The facility did not report to CMS Regional Office twenty-four patients' deaths that occurred between 8/19/09 and 2/4/10 that were associated with one of the afore mentioned categories. The findings include: During an interview on 2/4/10 at 11:35 a.m., the Director and Associate Director of Corporate Compliance, Staff O and Staff P, stated each morning their offices receive an electronic file that lists all patients that died in the past 24 hours. Staff O, Staff P or another member of their staff immediately review each deceased patient's electronic medical record to determine if the patient died while in restraints or seclusion, if the patient died within 24 hours after their restraints or seclusion were removed, or if the patient died within one week after being in restraints or seclusion and it's reasonable to assume the use of restraint or seclusion contributed directly or indirectly to the patient's death. If the deceased patient falls into one of these categories, a worksheet is completed with information required by CMS concerning the death, and faxed to the CMS Regional Office. The worksheet is faxed the same day the Corporate Compliance staff learns of the death. Staff O and Staff P stated their office does not	A 214	Subsequent compliance will be reviewed through the hospital's quality and safety dashboards, which will include an explicit area to monitor Conditions of Participation. In addition to these periodic reviews, the MGH will flag all safety event reports related to Conditions of Participation so that ad hoc compliance issues can be addressed in a robust and timely fashion. To monitor and track compliance with the plan of correction, the hospital maintains a log of Hospital Restraint Death Reports submitted to CMS with documentation of the date and time of the fax and telephone call. The director of Corporate Compliance is responsible for implementing this plan of correction.	

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A 214	Continued From page 65 report the deaths to the CMS Regional Office by telephone. On 2/4/10, Staff O provided a list of 24 patients' names who died in the facility between 8/18/09 and 2/4/10 and whose deaths fit one of the restraint death reporting categories. During an interview on 2/5/10 at 1:30 p.m., Staff P acknowledged that none of the deaths had been reported to the CMS Regional Office by telephone. Review of the facility's policy and procedure titled, "Restraint and Seclusion" approved by the Medical Policy Committee on June 3, 2009, indicated the following: 8.1 There are specific requirements to report any death associated with the use of restraint or seclusion. -These requirements can be located in the Patients Rights section of the Medicare Hospital Conditions of Participation. -The following must be reported within twenty four hours following knowledge of the patient's death: 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 within one week after restraint or seclusion where it is reasonable to assume that the use of restraint or placement in seclusion contributed directly or indirectly to the patient's death. 8.2 The Hospital will screen deaths to determine reportability. 8.3 Any staff member who has knowledge about the afore mentioned criteria should report this	A 214		

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A 214	Continued From page 66 immediately to the Office of Quality and Safety or by use of the safety reporting system. 8.4 The Compliance Officer will file a copy of the report to CMS in the patient record after reporting is complete. Review of the facility's policy and procedure for reporting patient deaths associated with the use of restraint or seclusion, did not follow the death reporting requirements by failing to include directions in submitting the reports to the CMS Regional Office by telephone.	A 214		
A 264	482.21(a) QAPI PROGRAM SCOPE Standard: Program Scope This STANDARD is not met as evidenced by: Based on the review of the Departmental Quality Assurance Measures and staff interviews, it was determined that the facility failed to integrate its departmental Quality Assessment and Performance Improvement (QAPI) programs into the hospital wide program. The findings include: 1. Ongoing routine Departmental Quality Assurance Measures are not being reported to the facility's centralized Quality Assurance Safety Committee. The following departments/services are not reporting: - During an interview with Director #1 of the Department on 02/02/10 at 9:30 a.m., the non-reporting QA measures were acknowledged. - During an interview	A 264	The plan for correcting the deficiency is as follows: The hospital will improve the integration of department-based Quality Assessment and Performance Improvement (QA/PI) activities into the hospital's QA/PI program by using the already existing Quality Oversight Committee to receive reports on departmentally-based QA/PI activities. The Quality Oversight Committee (QOC) reports to the General Executive Committee (GEC), and to the Board of Trustees Subcommittee on Quality of both the hospital and physicians organization. The QOC includes representatives from (or managers with oversight of) all departments and functions involved with quality and safety activities. The QOC's main functions are to coordinate QA/PI activities across the hospital, ensure clear communications and alignment across the entire institution's quality and safety agenda, and provide a forum for interaction among key quality and safety committees. The QOC will receive reports on QA/PI measures and initiatives from each area represented by the committee's membership once per year. As of 3/12/10, the hospital reviewed QOC membership to ensure that the areas cited in	04/13/10

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A 264	Continued From page 67 with of the 02/02/10 at 10:30 a.m.,. the non-reporting QA measures were confirmed. - During an interview with on 02/02/10 at 11:30 a.m., the non-reporting QA measures were confirmed. - During an interview with the on 02/05/10 at 10:00 a.m. the non-reporting QA measures were confirmed - During an interview with the on 02/08/10 at 09:30 a.m., .the non-reporting QA measures were confirmed. - During an interview with the in the department on 02/02/10 at 10:30 a.m.,. the non-reporting QA measures were confirmed. - During an interview with the of the Center on 02/09/10 at 10:30 a.m., the non-reporting QA measures was confirmed. - During an interview with on 02/09/10 at 1:30 p.m., the non-reporting QA measures were confirmed - During an interview with the service on 02/03/10 at 10:30	A 264	the report as insufficiently integrated into the hospital-wide program are adequately represented on the committee, and made any needed changes to membership or QA/PI reporting responsibilities. Additionally, the committee will continue to include the Chairperson of the hospital's Patient Care Assessment Committee (PCAC). The PCAC reports directly to the Board of Trustees Subcommittee on Quality for both the hospital and physicians organization, and includes representatives from each clinical service at the hospital. The PCAC reviews serious safety events reported from every department in the hospital and determines whether those events should be reported to external agencies. It also helps coordinate department-level quality improvement efforts. By having the chair of the PCAC as a permanent member of the QOC, the hospital ensures integration, alignment and sharing of relevant QA/PI activities and data between two key committees. The efforts to address improving the processes that led to the deficiency cited are as follows: The Quality Oversight Committee will develop a schedule of updates of quality measures and performance improvement activities from each area represented at the committee to ensure that QA/PI measures and activities are reported to the committee once per year. Additionally, clinical and administrative leaders from the departments identified in the report will be informed of this new process through a memo from the Senior Vice President for Quality and Safety by 4/1/10. The procedure for implementing the acceptable plan of correction will proceed as follows: First, updates to Quality Oversight Committee membership or reporting	

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A 264	Continued From page 67 with of the 02/02/10 at 10:30 a.m.,. the non-reporting QA measures were confirmed. - During an interview with on 02/02/10 at 11:30 a.m., the non-reporting QA measures were confirmed. - During an interview with the of the Pharmacy on 02/05/10 at 10:00 a.m. the non-reporting QA measures were confirmed During an interview with the on 02/08/10 at 09:30 a.m., .the non-reporting QA measures were confirmed. - During an interview with the in the department on 02/02/10 at 10:30 a.m.,. the non-reporting QA measures were confirmed. - During an interview with the of the Center on 02/09/10 at 10:30 a.m., the non-reporting QA measures was confirmed. - During an interview with on 02/09/10 at 1:30 p.m., the non-reporting QA measures were confirmed - During an interview with the on 02/03/10 at 10:30	A 264	responsibilities were completed by 3/12/10. Second, the clinical and administrative leaders from the departments identified in the report, as well as the senior leadership of the hospital (Senior Vice Presidents, Chiefs of Service and Department Heads) will be informed of this new process by 4/1/10. Finally, the first reports on QA/PI data from appropriate departments will be presented to the Quality Oversight Committee by 4/13/10. The QOC reports to the General Executive Committee, and Boards of Trustees Quality Subcommittee of both the hospital and physicians organization. The QOC will present updates and data relevant to this deficiency to both the GEC and the Board of Trustees Quality Subcommittee until the issue is resolved to prevent the likelihood of the deficient practice from reoccurring. The procedures for monitoring and tracking to ensure that the plan of correction is effective and the specific deficiencies cited remain corrected and/or in compliance with the regulatory requirements are as follows: Meeting minutes and attendance records at the Quality Oversight Committee will be reviewed by the committee chair on a quarterly basis, beginning on 4/13/10. The senior vice president for Quality and Safety, MGH/MGPO, is responsible for implementing this plan.	

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A 264	Continued From page 68 a.m., the non-reporting QA measures were confirmed. - During an interview with the Director on 2/2/10 at approximately 2:30 p.m., the stated that statistics are reported to the . During an interview with , at approximately 9:30 a.m., she stated that hand hygiene is a QAPI activity carried out by departments across the board and is integrated into the hospital wide QAPI program. On 2/8/10, at approximately 9:40 a.m., an interview with who is responsible for the was conducted. In response to questioning on integration into hospital wide QAPI it was stated that the hospital does not spend time to put it all together in one central repository. There was no indication that QAPI activities are integrated into the hospital wide QAPI program.	A 264		
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 record review and interview, it was determined that the Medical Staff failed to make recommendations to the Governing Body for privileges of Medical Staff as well as non-physicians, prior to clinical practice in the	A 338	Please see detailed plans of correction below for A341, A357, A358, A359, and A363.	05/21/10

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A 338	Continued From page 69	A 338		

facility. In addition, the Medical Staff failed to incorporate specific criteria for privileges and timeliness of history and physical examination documentation within Professional Staff Bylaws. (See A341, A357, A358, A359 & A363)

The findings include:

1. In 13 of 23 credentials files reviewed, the governing body approval date occurred after the date that privileges were granted, resulting in physicians beginning clinical activities before Board approval.

2. Clinical privileges are granted by individual clinical departments, resulting in clinical practice in the facility without Medical Staff recommendations for Board approval.

3. In 1 of 1 RN/NP First Assistant's credential files reviewed, "temporary Operating Room privileges" were granted by the Executive Medical Director of ORs and the Chief of Surgical Services, and the "temporary privileges" were extended until the next scheduled Surgical Committee meeting, resulting in clinical practice in the facility for a prolonged period of time without completing the facility's own approval process and without Medical Staff recommendation for Board approval.

4. In 1 of 23 credential files reviewed, "preliminary approval" was granted by the Chief Medical Officer for an Assistant in Neurosurgery two days prior to placement on the Surgical Committee's agenda, resulting in clinical practice in the facility without completing the facility's own approval process and without Medical Staff recommendation for Board approval.

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A 338	Continued From page 70 5. The hospital failed to include evidence of training and professional education through primary source verification for all members of the Medical Staff. 6. The Professional Staff Bylaws are missing candidate qualifications and description of the hospital's privileging process. 7. The Professional Staff Bylaws do not include a requirement that a medical history and physical examination be completed and documented for each patient no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. 8. The Professional Staff Bylaws do not include a requirement that an updated examination of the patient, including any changes in the patient's condition, be completed and documented within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, when the medical history and physical examination are completed within 30 days before admission or registration. 9. The Professional Staff Bylaws do not include the criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.	A 338		
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.	A 341	The MGH will establish a process to obtain Board of Trustees approval prior to any member of the Professional Staff beginning his/her clinical activities.	05/21/10

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A 341	Continued From page 71 This STANDARD is not met as evidenced by: Based on interviews and review of the "Bylaws of the Professional Staff of the General Hospital, Section 2.04-Allied Health Practitioners, and Massachusetts General Hospital, Department of Nursing, Credentialing and Authorization of Nurses in the Expanded Roles- Who are MGH and MGHO Employees," it was determined that the medical staff failed to make recommendations to the governing body for privileging of Allied Health Practitioners, and failed to make recommendations on the appointment of candidates that are specific to the type of appointment, and extent of the individual practitioner's specific clinical privileges. In 13 of 23 credential files reviewed, the facility also failed to make recommendations to the governing body prior to practice at the hospital for 1 of 1 RN/NP First Assistant, and failed to make recommendations for privileges for two of five surgeons prior to performing surgery in the facility, and one of five surgeons prior to scheduling surgery. In addition, the facility failed to include evidence of training and professional education as part of the credentials of candidates for Medical Staff membership. The findings include: A. The Governing Body approval date occurred after the date that privileges were granted resulting in physicians beginning clinical activities before Board approval. 1. The hospital notification letter to Physician MS 19, dated 11/14/08 indicated that "the Trustees of The General Hospital Corporation, at a meeting on 11/21/08, appointed you as Physician	A 341	At its April 16, 2010 meeting the MGH Board of Trustees will establish a Committee on Appointments and Privileges and will grant to this Committee the authority to approve all appointments and privileges. The Committee on Appointments and Privileges will consist of the following three members of the MGH Board of Trustees; the President of the Hospital, the Chief Executive Officer of the Physicians Organization and the representative Chief of Service on the Board of Trustees. The Committee on Appointments and Privileges will begin meeting on April 28, 2010. Privileging information will be included in the summary provided to the Chiefs Council, the Board Subcommittee on Appointments and Privileging and the Board of Trustees for consideration prior to the appointment of the Professional Staff. The Professional Staff bylaws will be amended to set forth the process for granting privileges to the clinical staff, including the criteria for determining the privileges to be granted and a procedure for applying the criteria to individuals requesting privileges. The Professional Staff bylaws will also be amended to explicitly include “judgment” as a criterion for determining membership on the Professional Staff. Allied health professional/nurses in the expanded role and physician assistants complete the authorization to practice application done in collaboration with their collaborating/supervising physician. This application is signed by the candidate, their	

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A 341	Continued From page 72 (Medicine Service) for the period from 11/10/08 to and including 11/9/10." This physician's appointment was effective 11 days prior to Governing Body approval. 2. The hospital notification letter to Physician MS 23 dated 4/21/08 indicated that "the Trustees of The General Hospital Corporation, at a meeting on 4/18/08, appointed you as Physician (Medicine Service) for the period from 4/14/08 to and including 4/13/10." This physician's appointment was effective 4 days prior to Governing Body approval. 3. The hospital notification letter to Physician MS 24 dated 7/20/09 indicated that "the Trustees of The General Hospital Corporation, at a meeting on 7/17/09, appointed you as Dermatologist (Dermatology Service) for the period from 7/16/09 to and including 7/15/11." This physician's appointment was effective 1 day prior to Governing Body approval. 4. The hospital notification letter to Physician MS 25 dated 12/22/08 indicated that "the Trustees of The General Hospital Corporation, at a meeting on 12/19/08, appointed you as Physician (Emergency Service) for the period from 12/4/08 to and including 12/3/10." This physician's appointment was effective 15 days prior to Governing Body approval. 5. The hospital notification letter to Physician MS 26 dated 11/23/09 indicated that, "the Trustees of The General Hospital Corporation, at a meeting on 11/20/09, appointed you as Visiting Surgeon (Surgery Service) for the period from 10/30/09 to and including 10/29/11." This physician's appointment was effective 22 days prior to	A 341	collaborating physician and the chief of service. If the candidate requires privileges to the operating room those privilege requests will be reviewed by the Surgical Coordinating Committee with recommendation for approval to the Health Profession Staff Committee, to the Senior Vice President for Patient Care and Chief Nurse or designee who will forward the application to the Board Subcommittee on Appointments and Privileging or Board of Trustees for approval. Applicants will not practice in the expanded role or as physician assistants until they have been approved by the Board Subcommittee on Appointments and Privileging or the Board of Trustees. The existing policies, *Credentialing and Authorization of Nurses in the Expanded Roles who are MGH and MGPO Employees* and *Credentialing and Authorization of Physician Assistants Who are MGH and MGPO Employees* were revised on 3/09/10. The revised policies will be reviewed and approved by the Patient Care Services Executive Committee and the Board of Trustees by 4/16/10. These changes to the policies reflect the approval process for nurses in the expanded role and physician assistants that are approved by the Board of Trustees. The policy will change to reflect the improved process. The candidate will receive a final action letter listing privileges granted or refusal that will originate from the Patient Care Services Credentialing Coordinator once approved by the Board Subcommittee on Appointments and Privileging or Board of Trustees. The letter will include the type of appointment and individual specific clinical privileges approved by the Board of Trustees.	

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A 341	Continued From page 73 Governing Body approval. 6. The hospital notification letter to Physician MS 27 dated 7/20/09 indicated that "the Trustees of The General Hospital Corporation, at a meeting on 7/17/09, appointed you as Assistant In Neurosurgery (Neurosurgery Service) for the period from June 15, 2009 to and including 12/21/09." This physician's appointment was effective 33 days prior to Governing Body approval. 7. The hospital notification letter to Physician MS 28 dated 2/22/10 indicated that "the Trustees of The General Hospital Corporation, at a meeting on 2/19/10, appointed you as Visiting Oral and Maxillofacial Surgeon (Oral and Maxillofacial Surgery) for the period from 2/14/10 to and including 2/13/12." This physician's appointment was effective 5 days prior to Governing Body approval. MS 28 was scheduled to perform a Bilateral Endoscopic Coronoidectomy on 2/16/10. The surgical procedure was scheduled three days prior to the governing body meeting and subsequent appointment on 2/19/10 as a Visiting Oral and Maxillofacial Surgeon. 8. The hospital notification letter to Physician MS 29 dated 9/21/09 indicated that "the Trustees of The General Hospital Corporation, at a meeting on 9/18/09, appointed you as Podiatrist (Orthopaedic Surgery) for the period from 8/14/09 to and including 8/13/11." This physician's appointment was effective 36 days prior to Governing Body approval. 9. The hospital notification letter to Physician MS 30 dated 9/21/09 indicated that, "the Trustees of The General Hospital Corporation, at a meeting	A 341	Updates on our performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through our General Executive Committee and through the Boards of Trustees Quality Subcommittee to the Boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that we are making progress as planned, and communicate our progress and concerns to the Boards through the mechanism above on a quarterly basis until the issue is resolved to prevent the likelihood of the deficient practice from reoccurring. Subsequent compliance will be reviewed through our quality and safety dashboards which will now include an explicit area to monitor our CoP compliance. In addition to these periodic reviews we will be flagging all safety event reports related to CoP issues so that ad hoc compliance issues can be addressed in a robust and timely fashion. The appointment and privileging process for physicians is monitored by the Director of the Medical Staff Office. The credentialing process for nurses in the expanded role and physician assistants will be monitored by the Patient Care Services Credentialing Coordinator. All applicants will complete the process and provide the appropriate documentation necessary to meet the requirements for approval by the Board of Trustees. If issues arise relating to an applicant, those issues will be forwarded to the MGH Chief Medical Officer or the Executive Director for The Institute for Patient Care and the Senior Vice President for Patient Care and Chief Nurse.	

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A 341	Continued From page 74 on 9/18/09, appointed you as Assistant Pathologist (Pathology Service) for the period from 9/3/09 to and including 5/31/11." This physician's appointment was effective 15 days prior to Governing Body approval. 10. The hospital notification letter to Physician MS 31 dated 7/21/08 indicated that, "the Trustees of The General Hospital Corporation, at a meeting on 9/18/08, appointed you as Psychologist (Psychiatry Service) for the period from 9/25/08 to and including 9/24/10." This physician's appointment was effective 69 days prior to Governing Body approval. 11. The hospital notification letter to Physician MS 32 dated 5/18/09 indicated that, "the Trustees of The General Hospital Corporation, at a meeting on 5/15/09, appointed you as Clinical Affiliate (Radiology Service) for the period from 5/7/09 to and including 1/2/11." This physician's appointment was effective 8 days prior to Governing Body approval. 12. The hospital notification letter to Physician MS 33 dated 4/20/09 indicated that, "the Trustees of The General Hospital Corporation, at a meeting on 4/17/09, appointed you as Associate Visiting Surgeon (Surgery Service) for the period from 4/12/09 to and including 4/11/11." This physician's appointment was effective 5 days prior to Governing Body approval. MS 33 performed one surgical procedure, a Laparoscopic Distal Pancreatectomy with Splenectomy on 4/16/09. This procedure was performed one day prior to the appointment by the governing body as an Associate Visiting Surgeon on 4/17/09. 13. An e-mail from the Program Manager,	A 341	The MGH Chief Medical Officer is responsible for ensuring the implementation of this plan of correction.	

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A 341	Continued From page 75 MGH/MGPO Medical Staff Office to the Chief Medical Officer dated 6/9/09 at 3:27 p.m., requesting "preliminary approval" for an Assistant in Neurosurgery beginning 6/15/09 for an application that, "will be on the 6/17/09 agenda" was approved via e-mail by the Chief Medical Officer on 6/9/09 at 3:41 p.m. The "preliminary approval" was not recommended by the Medical Staff for approval by the Governing Body. Physician MS 34 performed fifty-four neurosurgery procedures between the dates of 6/15/09 through 7/17/09. These procedures were performed with "preliminary approval" of privileges granted by the Chief Medical Officer on 6/9/09. Privileging cannot be delegated by the governing body. The governing body is required to take the final appropriate action for granting or refusing privileges. 14. Review of delineation of privileges for / and the indicated that there is insufficient documentation to confirm that clinical privileges were confirmed by the Governing Body. During an interview with Operations Director of the (on 02/02/10 at 11:30 a.m., it was determined that privileges to perform invasive procedures are only approved at the departmental level with no participation by the Governing Body. During an interview with the Executive Director of the 02/08/10 at 09:30 a.m., it was determined that	A 341		

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A 341	Continued From page 76 privileges for surgeons at t are only approved at the departmental level only with no participation by the Governing Body. During an interview with the Director, MGH/MGPO Medical Staff Office on 2/2/10 at 10:00 a.m., she stated that, "Physicians can begin clinical activities before Board approval." B. The hospital failed to make recommendations to the Governing Body for privileging of Allied Health Professionals. 1. The medical staff failed to make recommendations to the governing body for two Allied Health Practitioners CRNA #6 and RN/NP First Assistant #7, specifically the type of appointment and extent of the individual practitioner's specific clinical privileges. The privileging process for Allied Health Practitioners stops with authorization for practice with the Senior Vice President for Patient Care, Chief Nurse Executive. 2. During an interview with the Chief Medical Officer on 2/2/10 at 1:50 p.m., he stated that Physicians' Assistants and Nurse Practitioners are credentialed through the Health Professions Committee, not through Medical Staff recommendation to the Governing Body. 3. According to Massachusetts General Hospital Department of Nursing policy titled, " Credentialing and Authorization of Physician Assistants Who Are MGH and MGPO Employees", Initial Authorization and the re-approval process is facilitated by the patient care services credentialing program coordinator	A 341		

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A 341	Continued From page 77 within The Institute for Patient Care. Physician Assistants practice in accordance with guidelines mutually developed with their supervising physician. Candidates requesting authorization to practice cannot practice as physician assistants until they have submitted the credentialing application with accompanying forms to the credentialing program coordinator; their application is reviewed by the Health Professions Staff Committee (a committee with representation from each of the nurses in the expanded role groups and physician assistants) and receives final approval to practice by the Senior Vice President for Patient Care and Chief Nurse or designee." Medical Staff recommendation to practice is not made to the Governing Body. 4. Review of the facility's policy "Credentialing and Authorization of Nurses in the Expanded Roles Who Are MGH (Massachusetts General Hospital) and MGPO (Massachusetts General Physician's Organization) Employees", Page 9-10, under the heading "AUTHORIZATION PROCESS", "Initial Authorization for nurses in the expanded role" indicated, "Protocols should be described using the scope for practice and must be reviewed and approved by the Health Professions Staff Committee. The credentialing program coordinator will forward this recommendation to the Senior Vice President for Patient Care and Chief Nurse, or designee for approval." In the same document, Page 10-11, under "Nurses in the expanded role in the First or Second Assist Role", Section 2.6.1.1, indicated, "Nurses in the expanded role who want to practice in the Operating Room in the First or Second Assist role must have credentials authorized and approved by the Health Professions Staff Committee and then reviewed by the Surgical Coordinating	A 341		

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A 341	Continued From page 78 Committee for access to the Operating Room. The Associate Chief for Perioperative Services coordinates this process." There were no signatures or statements regarding approval of privileging for Allied Health Practitioners by the governing body. 5. Review of the facility's policy "Credentialing and Authorization of Nurses in the Expanded Roles Who Are MGH and MGPO Employees", Page 9-10, under the heading "AUTHORIZATION PROCESS", "Initial Authorization for nurses in the expanded role," "Initial Authorization and re-approval process is facilitated by the patient care services credentialing program coordinator within The Institute for Patient Care. Candidates requesting authorization to practice cannot practice in the expanded role until they have submitted the credentialing application with accompanying forms to the credentialing program coordinator; their application is reviewed by the Health Professions Staff Committee (a committee with representation from each of the nurses in the expanded role groups) and receives final approval to practice by the Senior Vice President for Patient Care and Chief Nurse or designee." There were no signatures or statements regarding approval of privileging for Allied Health Practitioners by the governing body. 6. Review of a document entitled "Process to credential and privilege CRNA's (Certified Registered Nurse Anesthetists)" provided by the Clinical Director of Anesthesia outlines the steps of privileging for CRNAs. The steps included: - Obtain Curriculum Vitae (CV) and written references. - Interview applicant.	A 341		

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A 341	Continued From page 79 - Review written references and follow-up via phone with references. The goal of these conversations is to understand the hospital setting where the CRNA has practiced and their scope of practice at that facility. - Applicant completes MGH CRNA scope of practice document. - Requested privileges approved, denied or given conditional approval depending on previous scope of practice, skills and knowledge. - Packet reviewed and approved by collaborating physician, Chief CRNA, Departmental Chair and then sent to PCS (Patient Care Services) Institute for Patient Care Credentialing Coordinator. 7. Review of the privileging file for CRNA #6 revealed a "Massachusetts General Hospital Nurses in Expanded Roles Authorization to Practice Form" that displayed on the "Certification Signatures" page, the following signatures: the requesting Advanced Practice Nurse, the Collaborating Physician, and the Chief of Service. Under the heading "Reviewing Signature" was indicated the signature of the Associate Chief for Nursing Practice. Under the heading, "Approval Signature" was the signature of the Health Professions Staff Committee Designee. Lastly, the "Authorization Signatures" included the signatures of the Senior Vice President for Patient Care, Chief Nurse Executive, and Chair of the PCS Executive Committee dated 12/16/09. There were no signatures or statements regarding approval of privileging for Allied Health Practitioners by the governing body. Review of the privileging file for CRNA #6 revealed a letter from the Health Professions Staff Committee dated 12/18/09, indicating that	A 341		

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A 341	Continued From page 80	A 341		

the practice guidelines submitted by CRNA #6 had been approved by the Senior Vice President and Chief Nurse.

8. Record review of re-privileging for RN/NP First Assistant #7 revealed a "Massachusetts General Hospital Nurses in Expanded Roles Authorization to Practice Form" that displayed on the "Certification Signatures" page the following signatures including: the requesting Advanced Practice Nurse, and the Collaborating Physician. The signature for the Chief of Service was blank. Under the heading "Reviewing Signature" was indicated the signature of the Associate Chief for Nursing Practice. Under the heading "Approval Signature" was the signature of the Health Professions Staff Committee Designee. Lastly, the "Authorization Signatures" included the signatures of the Senior Vice President for Patient Care, Chief Nurse Executive, and Chair of the PCS Executive Committee dated 12/16/09. There were no signatures or statements regarding approval of privileging for Allied Health Practitioners by the governing body.

In an interview on 2/3/10 at 11:25 a.m., the Executive Medical Director of the OR and Associate Chief Nurse of Perioperative Services were asked to explain the privileging process for CRNA #6. They stated the credentialing process was completed by the Health Professions Staff Committee and the privileging is completed by the Collaborating Physician, Chief CRNA, and the Department Chair. They were asked if anyone else participated in the privileging process. The Executive Medical Director of the OR stated there is no other committee that reviews this process.

In an interview on 2/9/10 at 9:05 a.m., the Chief of

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A 341	Continued From page 81	A 341		

Anesthesia and the Clinical Director of Anesthesia were asked to explain the privileging process for nurses in the expanded role. The Executive Medical Director of the OR and Associate Chief Nurse of Perioperative Services were in attendance. The Clinical Director of Anesthesia stated, privileges are reviewed and recommended by the Clinical Director, the Chief of that Service, Associate Chief Nurse, and then approved by the Senior Vice President for Patient Care and Chief Nurse.

In an interview on 02/11/10 at 10:00 a.m. with the Senior Vice President for Patient Care and Chief Nurse, she stated, the final approval for practice of "Nurses in the Expanded Roles" is delegated to her by the General Executive Committee.

9. The hospital notification letter to NP 34 from the Executive Medical Director, Operating Rooms, dated 1/26/07 indicated that, "effective 1/26/07, (MS 35) and I grant you temporary Operating Room privileges as an MGH RN First Assistant in the Department of Orthopedics as requested in your application. The Surgical Coordinating Committee will meet on 2/13/07 and final approval will be granted at that time." Temporary privileges are not recommended by the Medical Staff for approval by the Governing Body.

C. The hospital failed to include evidence of training and professional education through primary source verifications for all members of the medical staff.

1. A letter, "To Whom It May Concern" dated 1/16/09, from the Commonwealth of Massachusetts Board of Registration in Medicine,

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A 341	Continued From page 82 RE: (regarding) Primary Source Verification, provided by the Director, MGH/MGPO Medical Staff Office on 2/4/10 indicated, "The Licensing Division of the Board of Registration in Medicine requires primary source verification of the following documents for M.D.'s (Medical Doctor) and D.O.'s (Doctor of Osteopathic Medicine) prior to issuing a medical license . . . Completion of two years of premedical school education; Completion of medical school training; Examination scores from United States Medical Licensing Examination (USMLE), National Boards and/or Federal Licensing Examination (FLEX); Postgraduate training from an Accreditation Council for Graduate Medical Education (A.C.G.M.E.) approved programs, one year of postgraduate training for U.S. graduates, (including Canadian and graduates of medical schools in Puerto Rico) and two years of postgraduate training for international medical graduates. All years of postgraduate training are collected and primary source verified . . . Please be advised that the on-line verification information is maintained by the Massachusetts Board of Registration in Medicine and is updated every evening, in compliance with JCAHO (Joint Commission on Accreditation of Healthcare Organizations) and the National Committee for Quality Assurance (NCQA) standards for primary source verification of physician information." During interview with the Director, MGH/MGPO Medical Staff Office on 2/4/10 at 8:40 a.m., she stated that medical education is the only thing not done by primary source verification - done by the Board of Medicine "in compliance with the Joint Commission and the INCA."	A 341		
A 357	482.22(c)(4) MEDICAL STAFF QUALIFICATIONS	A 357	The MGH Professional Staff bylaws will be amended to explicitly include judgment as a	05/21/10

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A 357	Continued From page 83 [The bylaws must:] (4) Describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body. This STANDARD is not met as evidenced by: Based on documentation review and interview, it was determined that the Bylaws of the Professional Staff of the General Hospital failed to detail the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body. The findings include: 1. During interview with Legal Counsel on 2/3/10 at 11:15 a.m., she stated that the qualifications of candidates for the Medical Staff could be found in Section 3.02.1 of the Bylaws of the Professional Staff of the General Hospital. 2. Section 3.02.1 of the Bylaws of the Professional Staff of the General Hospital state, "Every application for Membership on the Staff shall be in writing, submitted on forms prescribed by the Hospital, and signed by the applicant. The application shall include without limitation a specific request indicating the staff category or clinical privileges being applied for; verifiable information concerning the applicant's education, training and experience; the names of all health care facilities with which the applicant has been associated and the reasons for discontinuance of these associations; a listing and description of all malpractice claims pending or closed during the	A 357	criterion for determining membership on the professional staff and privileges. A meeting was held including the MGH Chief Medical Officer, Director of the Medical Staff Office, and legal counsel. This group reviewed the Medicare Hospital Conditions of Participation to ensure that we understood the requirements for the Professional Staff bylaws. As a result of this meeting, amendments to the Professional Staff bylaws were drafted as described above and the amendment approval process prescribed by the bylaws will be followed: (1) present amendments to MGH General Executive Committee on 4/28/10 and the Massachusetts General Physicians Organization Executive Committee on 4/23/10 for approval; (2) present amendments to voting members of the MGH Professional Staff for approval; and, (3) present amendments to MGH Board of Trustees/Governing Body for approval. Updates on our performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through our General Executive Committee and through the Boards of Trustees Quality Subcommittee to the Boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that we are making progress as planned, and communicate our progress and concerns to the Boards through the mechanism above on a quarterly basis until the issue is resolved to prevent the likelihood of the deficient practice from reoccurring. Subsequent compliance will be reviewed through our quality and safety dashboards which will now include an explicit area to monitor our CoP compliance. In addition to these periodic reviews we will be flagging all safety event reports related to	

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A 357	Continued From page 84 previous ten (10) years; a statement authorizing the applicant's insurance carrier to release specified information relating to claims or actions for damages; a statement authorizing any health care facility with which the applicant has been associated to release information which is relevant to the applicant's character and professional competence; a statement authorizing the Hospital to exchange information with any other health care facility or professional organization with which the applicant has been associated regarding any pending or final disciplinary action; and such other information as may be required from time to time by the Hospital or the applicable Service or Department. An applicant must submit a copy of his or her most recent Massachusetts licensure application form and must agree to undergo a mental or physical examination if requested. An application shall not be considered unless supplemented by written references attesting to the applicant's professional competence and ethical practice - at least three references in the case of Clinical Staff and at least two references in the case of Non-Clinical Staff." Section 3.02.1 does not include either a description of candidate qualifications or criteria for specific privileges that must be met for the Medical Staff to recommend the candidate to the governing body. This finding was verified with Legal Counsel on 2/3/10 at 11:15 a.m.	A 357	CoP issues so that ad hoc compliance issues can be addressed in a robust and timely fashion. Following approval of the amendments by the MGH Board of Trustees, the hospital will confirm that the amendments are incorporated into the final version of the Professional Staff bylaws and posted and disseminated as appropriate. The MGH Chief Medical Officer is responsible for ensuring the implementation of this plan of correction.	
A 358	482.22(c)(5) MEDICAL STAFF RESPONSIBILITIES [The bylaws must:] Include a requirement that--	A 358	The Professional Staff bylaws will be amended to add the requirements regarding the taking of medical histories and physicals, including the timeframe for taking such actions. A meeting was held including the MGH Chief Medical Officer, Director of the Medical Staff Office, and legal counsel. This group reviewed the	05/21/10

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A 358	Continued From page 85 (i) A medical history and physical examination be completed and documented for each patient no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. The medical history and physical examination must be completed and documented by a physician (as defined in section 1861(r) of the Act), an oromaxillofacial surgeon, or other qualified individual in accordance with State law and hospital policy. This STANDARD is not met as evidenced by: Based on interview and document review, it was determined that the Bylaws of the Professional Staff of the General Hospital do not include a requirement pertaining to the completion and documentation of a medical history and physical examination for each patient no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. The findings include: 1. Review of the Bylaws of the Professional Staff of the General Hospital revealed the absence of a requirement pertaining to the completion and documentation of a medical history and physical examination for each patient no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. 2. During an interview with Legal Counsel on 2/3/10 at 11:55 a.m., she stated that the Bylaws of the Professional Staff of the General Hospital do not have a statement regarding a requirement pertaining to the completion and documentation	A 358	Medicare Hospital Conditions of Participation to ensure that we understood the requirements for the Professional Staff bylaws. As a result of this meeting, amendments to the Professional Staff bylaws were drafted as described above and the amendment approval process prescribed by the bylaws will be followed: (1) present amendments to MGH General Executive Committee on 4/28/10, and the Massachusetts General Physicians Organization Executive Committee on 4/23/10 for approval; (2) present amendments to voting members of the MGH Professional Staff for approval; and, (3) present amendments to MGH Board of Trustees/Governing Body for approval on 5/21/10. Updates on our performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through our General Executive Committee and through the Boards of Trustees Quality Subcommittee to the Boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that we are making progress as planned, and communicate our progress and concerns to the Boards through the mechanism above on a quarterly basis until the issue is resolved to prevent the likelihood of the deficient practice from reoccurring. Subsequent compliance will be reviewed through our quality and safety dashboards which will now include an explicit area to monitor our CoP compliance. In addition to these periodic reviews we will be flagging all safety event reports related to CoP issues so that ad hoc compliance issues can be addressed in a robust and timely fashion.	

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A 358	Continued From page 86 of a medical history and physical examination for each patient no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. 3. During an interview with Legal Counsel on 2/5/10 at 9:40 a.m., she stated that physicians are bound by hospital policies through Articles 2.01 and 3.01 of the Bylaws of the Professional Staff of the General Hospital. 4. Review of Article 2.01 of the Bylaws of the Professional Staff of the General Hospital revealed that, "In discharging the duties and exercising the privileges of his or her appointment, each Staff Member shall be subject to these Bylaws and to all applicable rules and regulations and policies of the Hospital and shall be responsible to his or her Chief of Service or Department, the Hospital's President, and the Trustees." Article 2.01 does not include a requirement that a medical history and physical examination be completed and documented for each patient no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. 5. Review of Article 3.01 of the Bylaws of the Professional Staff of the General Hospital revealed that, "Each initial appointee to the Professional Staff shall be given a copy of the Bylaws of the Professional Staff and shall agree to be bound by the Bylaws and all applicable rules and regulations of the Hospital and the Professional Staff." Article 3.01 does not include a requirement that a medical history and physical examination be completed and documented for	A 358	Following approval of the amendments by the MGH Board of Trustees, the hospital will confirm that the amendments are incorporated into the final version of the Professional Staff bylaws and posted and disseminated as appropriate. The MGH Chief Medical Officer is responsible for ensuring the implementation of this plan of correction.	

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A 358	Continued From page 87 each patient no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. 6. Section 3.2.1, Admission Assessment, Patient Record Policy, Clinical Policy & Procedure Manual, provided by the Director of Compliance indicated, "The patient's history, physical examination, provisional diagnosis, and diagnostic or treatment plan shall be completed and entered into the record by either a physician, a nurse in the expanded role, a supervised medical student or a PA (Physician's Assistant) within the first twenty-four (24) hours of admission, and prior to any surgical procedure. The attending/responsible physician shall review the admission history, physical examination, provisional diagnosis and diagnostic or treatment plan and enter an appropriate note of his/her own." This policy does not meet the requirement that the bylaws include a requirement that a medical history and physical examination be completed and documented for each patient no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. 7. Section 3.5.5, Patient Record Policy, Clinical Policy and Procedure Manual, provided by the Director of Compliance indicated, "If any physician has three (3) or more delinquent records or any delinquent dictation older than thirty (30) days, he/she shall receive a Suspension Warning and have seven (7) calendar days to complete all available delinquent records." This policy does not meet the requirement that the bylaws include a requirement that a medical history and physical	A 358		

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A 358	Continued From page 88 examination be completed and documented for each patient no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.	A 358		
A 359	482.22(c)(5) MEDICAL STAFF RESPONSIBILITIES [The bylaws must:] [Include a requirement that --] (ii) An updated examination of the patient, including any changes in the patient's condition, be completed and documented within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, when the medical history and physical examination are completed within 30 days before admission or registration. The updated examination of the patient, including any changes in the patient's condition, must be completed and documented by a physician (as defined in section 1861(r) of the Act), an oromaxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy. This STANDARD is not met as evidenced by: Based on interview and document review, it was determined that the Bylaws of the Professional Staff of the General Hospital do not include a requirement pertaining to the completion and documentation of an updated examination of the patient, including any changes in the patient's condition, within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, when the medical history and physical examination are completed within 30 days before admission or registration.	A 359	The Professional Staff bylaws will be amended to add a requirement regarding updated patient examinations when the medical history and physical examination are completed within 30 days before admission or registration. A meeting was held including the MGH Chief Medical Officer, Director of the Medical Staff Office, and legal counsel. This group reviewed the Medicare Hospital Conditions of Participation to ensure that we understood the requirements for the Professional Staff bylaws. As a result of this meeting, amendments to the Professional Staff bylaws were drafted as described above and the amendment approval process prescribed by the bylaws will be followed: (1) present amendments to MGH General Executive Committee on 4/28/10, and the Massachusetts General Physicians Organization Executive Committee on 4/23/10 for approval; (2) present amendments to voting members of the MGH Professional Staff for approval; and, (3) present amendments to MGH Board of Trustees/Governing Body for approval on 5/21/10. Updates on our performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through our General Executive Committee and through the Boards of Trustees Quality Subcommittee to the Boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that we are making	05/21/10

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A 359	Continued From page 89 The findings include: 1. Review of the Bylaws of the Professional Staff of the General Hospital revealed the absence of a requirement pertaining to the completion and documentation of an updated examination of the patient, including any changes in the patient's condition, within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, when the medical history and physical examination are completed within 30 days before admission or registration. 2. During interview with Legal Counsel on 2/3/10 at 11:55 a.m., she stated that the Bylaws of the Professional Staff of the General Hospital do not have a statement regarding a requirement pertaining to the completion and documentation of an updated examination of the patient, including any changes in the patient's condition, within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, when the medical history and physical examination are completed within 30 days before admission or registration. 3. During an interview with Legal Counsel on 2/5/10 at 9:40 a.m., she stated that physicians are bound by hospital policies through Articles 2.01 and 3.01 of the Bylaws of the Professional Staff of the General Hospital. 4. Review of Article 2.01 of the Bylaws of the Professional Staff of the General Hospital revealed that, "In discharging the duties and exercising the privileges of his or her appointment, each Staff Member shall be subject to these Bylaws and to all applicable rules and	A 359	progress as planned, and communicate our progress and concerns to the Boards through mechanism above on a quarterly basis until the issue is resolved to prevent the likelihood of the deficient practice from reoccurring. Subsequent compliance will be reviewed through our quality and safety dashboards which will now include an explicit area to monitor our CoP compliance. In addition to these periodic reviews we will be flagging all safety event reports related to CoP issues so that ad hoc compliance issues can be addressed in a robust and timely fashion. Following approval of the amendments by the MGH Board of Trustees, the hospital will confirm that the amendments are incorporated into the final version of the Professional Staff bylaws and posted and disseminated as appropriate. The MGH Chief Medical Officer is responsible for ensuring the implementation of this plan of correction.	

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A 359	Continued From page 90	A 359		

regulations and policies of the Hospital and shall be responsible to his or her Chief of Service or Department, the Hospital's President, and the Trustees."

Article 2.01 does not include a requirement that an updated examination of the patient, including any changes in the patient's condition, be completed and documented within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, when the medical history and physical examination are completed within 30 days before admission or registration.

5. Review of Article 3.01 of the Bylaws of the Professional Staff of the General Hospital revealed that, "Each initial appointee to the Professional Staff shall be given a copy of the Bylaws of the Professional Staff and shall agree to be bound by the Bylaws and all applicable rules and regulations of the Hospital and the Professional Staff."

Article 3.01 does not include a requirement that an updated examination of the patient, including any changes in the patient's condition, be completed and documented within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, when the medical history and physical examination are completed within 30 days before admission or registration.

6. Section 3.2.1, Admission Assessment, Patient Record Policy, Clinical Policy and Procedure Manual, provided by the Director of Compliance indicated, "The patient's history, physical examination, provisional diagnosis, and

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A 359	Continued From page 91	A 359		

diagnostic or treatment plan shall be completed and entered into the record by either a physician, a nurse in the expanded role, a supervised medical student or a PA within the first twenty-four (24) hours of admission, and prior to any surgical procedure. The attending/responsible physician shall review the admission history, physical examination, provisional diagnosis and diagnostic or treatment plan and enter an appropriate note of his/her own."

This policy does not meet the requirement that the bylaws include a requirement that an updated examination of the patient, including any changes in the patient's condition, within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, when the medical history and physical examination are completed within 30 days before admission or registration.

7. Section 3.5.5, Patient Record Policy, Clinical Policy and Procedure Manual, provided by the Director of Compliance indicated, "If any physician has three (3) or more delinquent records or any delinquent dictation older than thirty (30) days, he/she shall receive a Suspension Warning and have seven (7) calendar days to complete all available delinquent records."

This policy does not meet the requirement that an updated examination of the patient, including any changes in the patient' s condition, within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, when the medical history and physical examination are completed within 30 days before

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A 359	Continued From page 92 admission or registration.	A 359		
A 363	482.22(c)(6) CRITERIA FOR MEDICAL STAFF PRIVILEGING [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. This STANDARD is not met as evidenced by: Based on interview and document review, it was determined the hospital failed to include specific criteria for determining privileges to be granted to individual practitioners, and a procedure for applying the criteria to individuals requesting privileges. The findings include: 1. During an interview with Legal Counsel on 2/3/10 at 11:55 a.m., she stated that granting of privileges is addressed in Article 4.01 Delineation of Privileges in General, of the Bylaws of the Professional Staff of the General Hospital. 2. Article 4.01 of the Bylaws of the Professional Staff of the General Hospital indicated, "Each appointment shall confer on the appointee only such privileges as have been granted in the written notice of appointment by the Trustees or by virtue of his or her staff category under these Bylaws. These privileges shall limit the appointee to activities in which he or she has demonstrated current competence and which are within the scope of his or her license to practice. The Chief of each Service and Department, following review and recommendation by the Quality Assessment	A 363	The Professional Staff bylaws will be amended to explicitly include judgment as a criterion for determining membership on the Professional Staff. A meeting was held including the MGH Chief Medical Officer, Director of the Medical Staff Office, and legal counsel. This group reviewed the Medicare Hospital Conditions of Participation to ensure that we understood the requirements for the professional staff bylaws. As a result of this meeting, amendments to the MGH Professional Staff bylaws will be drafted as described above and the bylaw amendment approval process prescribed by the bylaws will be followed: (1) present amendments to MGH General Executive Committee on 4/28/10, and the Massachusetts General Physicians Organization Executive Committee on 4/23/10 for approval; (2) present amendments to voting members of the MGH Professional Staff for approval; and, (3) present amendments to MGH Board of Trustees/Governing Body on 5/21/10 for approval. Updates on our performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through our General Executive Committee and through the Boards of Trustees Quality Subcommittee to the Boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that we are making progress as planned, and communicate our progress and concerns to the Boards through the mechanism above on a quarterly basis until the issue is resolved to	05/21/10

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A 359	Continued From page 92 admission or registration.	A 359		
A 363	482.22(c)(6) CRITERIA FOR MEDICAL STAFF PRIVILEGING [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. This STANDARD is not met as evidenced by: Based on interview and document review, it was determined the hospital failed to include specific criteria for determining privileges to be granted to individual practitioners, and a procedure for applying the criteria to individuals requesting privileges. The findings include: 1. During an interview with Legal Counsel on 2/3/10 at 11:55 a.m., she stated that granting of privileges is addressed in Article 4.01 Delineation of Privileges in General, of the Bylaws of the Professional Staff of the General Hospital. 2. Article 4.01 of the Bylaws of the Professional Staff of the General Hospital indicated, "Each appointment shall confer on the appointee only such privileges as have been granted in the written notice of appointment by the Trustees or by virtue of his or her staff category under these Bylaws. These privileges shall limit the appointee to activities in which he or she has demonstrated current competence and which are within the scope of his or her license to practice. The Chief of each Service and Department, following review and recommendation by the Quality Assessment	A 363	prevent the likelihood of the deficient practice from reoccurring. Subsequent compliance will be reviewed through our quality and safety dashboards which will now include an explicit area to monitor our CoP compliance. In addition to these periodic reviews we will be flagging all safety event reports related to CoP issues so that ad hoc compliance issues can be addressed in a robust and timely fashion. Following approval of amendments by the MGH Board of Trustees, the hospital will confirm that the amendments are incorporated into the final version of the Professional Staff bylaws and posted and disseminated as appropriate. The MGH Chief Medical Officer is responsible for ensuring the implementation of this plan of correction.	

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A 363	Continued From page 93 Committee, and subject to review and approval of the General Executive Committee (GEC), shall develop criteria for use in the granting of privileges in that Service or Department." 3. The Bylaws of the Professional Staff of the General Hospital do not include specific criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges. 4. These findings were verified with Legal Counsel on 2/3/10 at 11:55 a.m.	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 observations, review of clinical records, review of policies and procedures and facility internal investigation reports, and patient and staff interviews, it was determined that the hospital failed to meet the Condition of Participation for Nursing Services as evidenced by: 1. The facility failed to ensure that a Registered Nurse supervised and evaluated the nursing care for 14 of 84 patients. The nursing staff failed to respond to alarm indicators for Patient #77 who required continuous cardiac and rhythm rate monitoring and the heart rate decreased to asystole (without a heart beat.).	A 385	Please see the detailed plan of correction below under A395 and A405	

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A 385	Continued From page 94 The nursing staff failed to assess for pain and medicate as necessary Patient #38, Patient #21, Patient #24, Patient #28, Patient #56 and Patient #84. Patient #33 and Patient #36's pressure sores were not continually assessed. The facility did not have a Policy and Procedure for the steps staff were to take to assess and document a description of a pressure ulcer. Patient #22 and Patient #34's medications were not administered by the nurse in accordance with the physician's orders. The nurse left oral medications and eye drops in Patient #23 and Patient #78's rooms. Patient #12's care plan did not address pain or being on the transplant waiting list. (See A395) 2. The facility failed to follow standard blood product verification procedures for one of 84 patients, Patient #65. (See A405)	A 385		
A 395	482.23(b)(3) RN SUPERVISION OF NURSING CARE A registered nurse must supervise and evaluate the nursing care for each patient. This STANDARD is not met as evidenced by: Based on observations, review of the facility's policies and procedures, medical record reviews, and patient and staff interviews, it was determined that for 14 of 84 patients, the registered nurses did not evaluate the care for each of these patients and did not on an ongoing basis assess the patients' care needs related to	A 395	Please see A144 for detailed plan of correction for physiologic monitoring deficiency. The MGH will revise its current policy and procedures related to pain management, develop and disseminate appropriate educational tools, and devise an evaluation plan to ensure ongoing compliance with pain management policies and standards. Widespread education will be conducted following the revision of the pain assessment and management policy. These policy revisions will specify the following:	04/30/10

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A 395	Continued From page 95 cardiac monitoring, pain, pressure ulcers, and medication administration, and did not assess the patients' response to interventions. The nursing staff failed to respond to alarm indicators for Patient #77 who required continuous cardiac and rhythm rate monitoring and developed asystole (without a heart beat.).The nursing staff failed to assess for pain and medicate as necessary Patient #38, Patient #21, Patient #24, Patient #28, Patient #56 and Patient #84. Patient #33 and Patient #36's pressure sores were not continually assessed. The facility did not have a Policy and Procedure for the steps staff were to take to assess and document a description of a pressure ulcer. Patient #22 and Patient #34's medications were not administered by the nurse per physician orders. The nurse left oral medications and eye drops in Patient #23's room and an inhalation medication in Patient #78's rooms. In addition, Patient #12's care plan did not address pain or being on the transplant waiting list. The findings include: 1. Patient #77 On 2/10/10, review of Patient 77's closed medical record showed a	A 395	1) all inpatients will be screened for pain, 2) pain above the pain scale midpoint must be managed, or the responsible physician is notified, and 3) when pain is above the pain scale midpoint, it should be entered in the care plan. The hospital will include this information in the orientation of new nurses, and will initially target educational efforts to Clinical Nurse Specialists, Pain Relief Champions, and Excellence Everyday Champions so that they can serve as resources as the education rolls out to all nurses. The educational program for all nurses related to pain assessment will take several forms. A computer-based training module on pain management will be developed and launched in HealthStream. In addition, population-specific pain assessment tools will be distributed to each bedside on all clinical units. Finally, the hospital will establish an intranet site that provides access to current pain related policies, procedures and tools. Select topics include assessing pain in verbal, non-verbal and confused patients, proper use of Assume Pain is Present classification, and non-drug comfort measure for patients with medical contraindications to medicine commonly used to treat pain. The dissemination of pain assessment policies and assessment tools will be completed by 4/1/10. The education of CNSs, Pain Relief Champions, and Excellence Everyday Champions will be achieved by 4/30/10, and required education of RNs will be completed by 4/30/10. Updates on our performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight	

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A 395	Continued From page 96 -The patient was treated successfully with intravenous medications to increase the heart rate and a temporary pacemaker wire was placed intravenously into the heart; -The cause of the patient's complete heart block and bradycardia implies underlying conduction system disease; -The patient transferred to the post-anesthesia care unit ( ) on 1/20/10 following completion of the surgical procedure. Cardiology Progress Notes dated 1/20/10 at 9:00 p.m. showed the temporary pacemaker wire inserted during surgery failed to function properly while in the . The temporary pacemaker wire was removed on 1/21/10 at 12:30 a.m. Nursing documentation indicated that the patient's heart rhythm while in the indicated that the patient was in atrial fibrillation reflecting a heart rate with beats per minute in the 50's and 60's. (normal adult heart rate is 60-80 beats per minute). Physician Progress Notes indicated the patient was transferred from the to the Cardiac Care Unit (CCU) on 1/21/10. On 1/22/10 Cardiology Progress Notes showed the patient was in atrial fibrillation with heart rates dropping into the 40's when asleep. Documentation indicated the patient was scheduled for a permanent pacemaker on 1/25/10. The patient was approved for transfer	A 395	Committee (QOC). The QOC, which reports up through our General Executive Committee and through the Boards of Trustees Quality Subcommittee to the Boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that we are making progress as planned, and communicate our progress and concerns to the Boards through the mechanism above on a quarterly basis until the issue is resolved to prevent the likelihood of the deficient practice from reoccurring. Subsequent compliance will be reviewed through our quality and safety dashboards which will now include an explicit area to monitor our CoP compliance. In addition to these periodic reviews we will be flagging all safety event reports related to CoP issues so that ad hoc compliance issues can be addressed in a robust and timely fashion. To ensure the plan of correction is effective and the specific deficiencies cited remain corrected and in compliance with requirements, the hospital will track the completion rates of the computer-based pain assessment module in HealthStream. The MGH will also perform audits to ensure pain assessment tools are placed at the bedside. Policy compliance will be tracked by auditing a random sampling of patient charts for appropriate assessment and management of pain per policy. Finally, the hospital will continue to monitor H-CAHPS scores and patient comments regarding satisfaction with pain management. The title of the person responsible for implementing this plan of correction is the senior vice president for Patient Care and chief nurse.	

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A 395	Continued From page 97 Review of Nursing Flow Sheets and Progress Notes indicated that the patient was transferred to a surgical patient care floor at 6:00 p.m. on 1/22/10, with physician's orders for centralized cardiac telemetry (monitoring a patient's heart activity from a distance) and was a full code (wished resuscitation if the heart and/or breathing stopped). Nursing documentation on 1/22/10 at 5:55 p.m., 7:30 p.m., 8:30 p.m. and 10:00 p.m. relative to the patient's vital signs after transfer to the surgical floor indicated heart beats from 59 to 74 and a heart rhythm reflecting of atrial fibrillation. Review of Surgical Progress Notes, dated 1/23/10, showed: -The patient's heart rhythm was in atrial fibrillation/SSS (sick sinus syndrome is a malfunction of the normal pacemaker of the heart in which the heart rate slows below normal limits); -Monitor heart rate closely; -Surgical placement of permanent cardiac pacemaker scheduled on 1/25/10. Interviews on 2/10/10 and 2/11/10 with hospital nursing administrative staff responsible for conducting the hospital's investigation into Patient #77's death, RN AA (Patient Staff Specialist), RN BB (Associate Chief Nurse), RN CC (Nurse Director), and RN DD (Clinical Nurse Specialist) - revealed the following: -On 1/23/10 the patient's heart rate was 56-62 beats per minute (bpm) and the blood pressure was stable; -During the night shift from 7:00 p.m. on 1/23/10 through 7:00 a.m. on 1/24/10, the patient's heart rate was 55-77 bpm, blood pressure stable, no nausea or vomiting, tolerating a liquid diet and	A 395	The MGH's Nursing Practice Guideline for Risk for Impaired Skin Integrity will be revised to reflect necessary components for accurate documentation and assessment. Patients' skin will be assessed on admission and reassessed daily. Documentation will include measurements (Length x Width x Depth), location, a description of the wound bed, periwound area, and exudate. These revisions will be supported with a new wound care policy that directs nurses to refer to the guideline. To facilitate proper documentation, the Nursing Admission Dataset Form will be revised to include a pressure ulcer staging assessment, and the patient care flow sheet policy will be revised to refer the RN to the wound policy. Nursing staff will be educated on the changes in several ways. The current Skin Care Orientation module presented in RN orientation will be revised to reflect necessary components of Pressure Ulcer documentation. In addition, RN staff will be asked to complete the NDNQI online training module for Pressure Ulcer staging, and an updated skin care orientation module in HealthStream, the MGH's online training system. Educational efforts will also extend to all key nursing resources, including Clinical Nurse Specialists, Wound Care Task Force members, and Excellence Everyday Champions. The above plan will be presented to Nursing Leadership and the Nursing Practice Committee. Nursing leadership will distribute the new policy to their staff and NDNQI Pressure Ulcer Staging Guides will be distributed for all vital sign books. The Nursing Practice Guideline for Risk for Impaired Skin Integrity will be revised by	04/30/10

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A 395	Continued From page 98 bowel sounds present; -Staff RN E assumed the care of the patient as well as two additional patients at 7:00 a.m. on 1/24/10; -There were 32 inpatients-including Patient #77-receiving care on this surgical floor the morning of 1/24/10, and 10 RN's on duty; -Nursing staff did not continuously monitor the cardiac rates/rhythms at the central nurses' station monitors. This responsibility falls on all nursing staff on the unit. When an alarm sounds or a message appears on the alarm display unit, available nurses are to evaluate the reason the alarms are sounding, and respond as necessary; -The patient's heart rate at 7:30 a.m. on 1/24/10 was 77 bpm, and heart rhythm indicated the patient was in atrial fibrillation; -The patient ate breakfast, ambulated in the hallway, family visited, had his morning bath and was administered pain medication at 9:28 a.m.; -Central nurses' station cardiac monitor logs indicated that: · At 9:40 a.m. heart rate was 82 bpm, · At 9:53 a.m. heart rate at 53 bpm, · At 9:54 am heart rate at 44 bpm, · From 9:56-9:58 a.m. heart rate at 0 bpm, · From 9:59-10:01 a.m. heart rate at 0-29 bpm, · From 10:02-10:16 a.m. heart rate at 0 bpm, · A high-low audible warning alarm (alarm set to sound when the patient's heart rate exceeded 120 bpm or fell below 50 bpm) sounded for the patient from 9:53-10:01 a.m., and from 10:06-10:16 a.m. by repeatedly broadcasting two "beeps" at the central nurses' station cardiac monitors. · The three (3) ceiling mounted digital alarm display units that were located at the end of the two patient care hallways and near the central nurses' station indicated "HR LO" (Heart Rate Low) and the patients room number during the	A 395	3/31/10. The Nursing Admission Dataset Form will be revised with by 4/30/10. Both the NDNQI online training module for Pressure Ulcer staging, and the updated Skin Care Orientation in HealthStream will be completed by 95% of nurses by 4/30/10. Updates on our performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through our General Executive Committee and through the Boards of Trustees Quality Subcommittee to the Boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that we are making progress as planned, and communicate our progress and concerns to the Boards through the mechanism above on a quarterly basis until the issue is resolved to prevent the likelihood of the deficient practice from reoccurring. Subsequent compliance will be reviewed through our quality and safety dashboards which will now include an explicit area to monitor our CoP compliance. In addition to these periodic reviews we will be flagging all safety event reports related to CoP issues so that ad hoc compliance issues can be addressed in a robust and timely fashion. To ensure the plan of correction is effective and the specific deficiencies cited remain corrected and in compliance with requirements, the hospital will track the completion rates of the skin care orientation module in HealthStream and the NDNQI pressure ulcer staging module. In addition, nursing leadership will conduct 100 random chart audits per month to review skin and pressure ulcer documentation. These data will be centrally reported through the PCS Office of Quality and Safety and through the	

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A 395	Continued From page 99 time of the audible alarms; --The volume to the alarms on the patient's bedside cardiac monitor had been turned off at an unknown date and time and by an unknown person; -No one was at the patient's bedside while the central nurses' station cardiac monitors were alarming. No staff responded to the alarms until 10:16 a.m., when RN E entered the patient's room to assess the patient's urinary output. This reflected a time span of 20 minutes after the alarms initially sounded. The patient was found unresponsive, and with vomit on his/her mouth and gown. Cardio-pulmonary resuscitation was initiated and a Code Blue was called. Efforts to resuscitate the patient were unsuccessful and the patient expired; -Administrative nursing staff interviews with the RN's on duty the morning of 1/24/10 revealed that no one could recall hearing the alarms that sounded from the central nurses' station cardiac monitors, and no one recalled seeing the "HR LO" displayed on the alarm display units. All 10 RN's interviewed stated the alarm notifications that morning were no more than usual. If in a patient room with the door closed, staff could not hear the alarms coming from the central nurses' station; -Nursing staff interviewed on the patient care unit said they were experiencing alarm fatigue and a desensitization to alarms after hearing them constantly throughout the workday. Interviews on 2/10/10 and 2/11/10 with Biomedical Engineering Staff M and N, and review of a Biomedical Engineering Findings Report, dated 2/4/10, revealed:	A 395	hospital quality program through the mechanism outlined above. The senior vice president for Patient Care Services and chief nurse is accountable for implementing this plan of correction. The MGH respectfully disagrees with the surveyor's finding that nursing staff failed to assess for pain and medicate as necessary for patient #s 21, 24, 28, 38 and 56. A detailed record review of the patients below demonstrates that the hospital followed correct procedures for assessing and medicating for pain as necessary. Patient # 21 - The patient was undergoing evaluation to [illegible]. NSAIDs are contraindicated in patients being worked up for [illegible]. Opiates are used cautiously, especially in elderly patients. The patient's orders included immediate release oral morphine twice a day, as needed. The patient received morphine at 11:45 am for pain level of 6 (0-10 scale). At 12:57 pm the patient reported a pain level of 7 (0-10scale) post pain score. Since pain was an issue, the pain service was consulted, who ordered a Fentanyl patch and changed the morphine order to every 4 hours as needed. The patient received morphine 5mg at 5:15 pm along with Fentanyl patch. The RN proceeds with caution as the onset of Fentanyl is 6-12 hours with peak effect 16-24 hours, given the age of the patient. The patient was reassessed at 6:34 pm with a pain score of 8 (0-10). The patient was re-medicated at 9:18 pm, as soon as it is available to be given based on the frequency of the physician's order. Upon interview of nurse the next day, the RN reported patient was sleeping.	02/12/10

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A 395	Continued From page 100 -In addition to the two "beep" high-low audible alarms on the central nurses' station cardiac monitors and bedside cardiac monitors, there is also an arrhythmia alarm that is supposed to be set to "Full," which means the alarms are on. This alarm triggers the broadcast of a three "beep" audible alarm when a patient develops a crisis or lethal arrhythmia-such as asystole. An investigation conducted by Biomedical Engineering after Patient #77's death, found the arrhythmia alarm on the patient's bedside cardiac monitor had been set to "Off" on 1/22/10 at approximately 6:15 p.m. As a result, on 1/24/10 between 9:54 a.m. and 10:16 a.m., the arrhythmia alarm did not broadcast the three "beep" audible alarm from the central nurse's station that would have signified to nursing staff that Patient #77 was experiencing a lethal arrhythmia. -The Biomedical Engineering Findings Report showed recommendations to install a distributed speaker system on the surgical patient care unit where Patient #77 had resided, which would make monitoring alarms more audible throughout the unit rather than only at the central monitors located at the nurse's station. The report also showed recommendations for the surgical patient care unit to make the necessary changes so that staff could not turn the arrhythmia alarms to "Off" and could not turn the alarm volume to "OFF" on patients' bedside cardiac monitors. Observation on 2/10/10 at 1:00 p.m. of the surgical patient care unit where Patient #77 had resided revealed two patient care hallways with	A 395	This patient was also known to have short term memory loss, an affective component to pain and Remeron is taken for anxiety and sleep. This patient was treated with Remeron and appeared comfortable. Patient # 24- This patient had a ..fracture, and had Dilaudid ordered every 2 hours as needed for pain. The patient received 1mg at 12:10 am with a pain score of 9 (0-10). Patient received another dose at 2:42 am. The patient had documentation of post pain score of 9 at 3:07 am, which was too soon to know true effect of the 2:42 am dose. At 4:18am, the documented post pain scale is 7. Per the physician's order, it is too early to provide Dilaudid, last received at 2:42 am. At 6: 29 am, 8: 42 am and 10:32 am, the patient was medicated with Dilaudid. Review of the progress note indicates the use of ice with relief. The patient also received Ativan. The clinical record has documentation of the patient sleeping overnight. Oxycodone was also ordered for this patient but it not utilized as the pain was too severe and IV Dilaudid was being used. Patient #28 - This patient presented with behavior changes of confusion and agitation. These are classic signs of UTI and delirium, please see the attached reference, (Decker, SA (2009) Behavioral indicators of postoperative pain in older adults with delirium. Clinical Nursing Research 2009 Nov 18 (4): 336-47.) The FLACC scale has only been validated in patients 2 months -7 years, please see the attached ASPMN Position Paper. This was further revised to include older children with developmental delay or cognitive impairments, please see the attached reference (Herr, K, Coyne CJ, Key, T, Manworren, M, Merkel, S et al.	

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A 395	Continued From page 101 the floor plan in the shape of the letter "V." The central nurses' station cardiac monitors with audible alarms were located near the point of the "V." Ceiling mounted digital alarm display units were located at the far end of the two hallways and at the point of the "V." In addition, a wall-mounted flat screen cardiac monitor without audible alarms was located part way down each hallway. Six patients' heart rates/rhythms were being continuously monitored. However, no staff were observed at the central nurse's station monitoring these six patient's cardiac rates/rhythms continually. The room where Patient #77 had resided from 1/22/10 until 1/24/10 was across the hallway and slightly diagonal from the location of the central nurse's station cardiac monitors. At approximately 2:15 p.m., Biomedical Engineering staff programmed an unused cardiac monitor at the central nurse's station to broadcast an alarm identical to the alarm that sounded on Patient #77's cardiac monitor on 1/24/10. The alarm volume was audible from the central nurse's station but was barely audible to inaudible when standing at the farthest ends of the hallways. Staff caring for patients in the rooms at the farthest end of the hallways would not be able to hear the alarms. During an interview at 2:30 p.m., Biomedical Engineering Staff N said the Biomedical Engineering department had identified a need one to two years ago for the installation of additional speakers on all patient care units and was currently a work in progress. Installation of a distributed speaker system on this unit and all other patient care units would make the alarm volumes more audible throughout the unit rather	A 395	(2006) Pain Assessment in the Nonverbal Patient: Position Statement with Clinical Practice Recommendations, Pain Management Nursing Vol. 7, No 2, (June), 2006:p 44-52.) Haldol was given to this patient to ease delirium symptoms. Even with mild delirium, patients can use a numeric pain scale. The patient reported 0 on 0-10 scale. Patient #38 - The FLACC scale has only been validated in patient 2 months-7 years, please see the attached ASPMN Position Paper. This scale was further revised to include older children with developmental delay or cognitive impairments, please see the attached reference (Herr, K, Coyne CJ, Key, T, Man-Wren, M, Merkel, S et al. (2006) Pain Assessment in the Nonverbal Patient: Position Statement with Clinical Practice Recommendations, Pain Management Nursing Vol. 7, No 2, (June), 2006:p 44-52.) Further, Non Steroidal Anti-Inflammatory Drugs (NSAIDS), aspirin and opiates are contraindicated in patients being worked up for subdural hematomas. It is common, however, to provide Haldol for agitation during the diagnostic work up. The patient was also not a reliable report of pain. The clinical record indicates the patient was able to sleep and non- pharmacologic interventions provided (ice, elevation, warm packs) promoted relief. Lastly, the surveyor observed and noted “patient sat up” which did not support evidence of pain limiting functional status. Patient #56 - This patient was at MGH with ﴾ pain 8 out of 10 and was being evaluated . The patient's pain went from an 8 to a 6. Medication is not generally indicated while being evaluated for a potential surgical abdomen.	

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A 395	Continued From page 102 than only at the central monitor's at the nurse's station. Speakers had been installed on some other patient care units of the hospital but had not been installed on this floor yet. Review of documentation dated 2/2/10, by Medical Doctor (MD) AAA in a report that was prepared for medical peer review activities at the hospital revealed the preliminary autopsy report for Patient #77 showed no pulmonary emboli (a sudden blockage in a lung artery - usually caused by a blood clot) and no aspiration. The patient's death appears due to unrecognized severe bradycardia from faulty alarm settings. 2. Patient #38 Although Patient #38 assessed for pain using a non-verbal pain assessment and the patient did not receive pain medication as ordered by the physician. Patient #38 was brought into the . The patient's pain assessment during the time in the from 9:15 a.m. until 4:15 p.m. was documented as "unable to be determined" or left blank. The FLACC Scale (FACE, Legs, Activity, Cry, Consolability) is a behavior pain assessment scale utilized by the hospital for use in non-verbal patients unable to provide reports of pain. The patient is rated a 0, 1, or 2 in each of the five measurement categories (face, legs, activity, cry and consolability), the scores are added together	A 395	This plan of correction will ensure that registered nurses supervise and evaluate the nursing care for each patient with regard to compliance with medication orders. As part of its ongoing work, the Medication Education Safe Administration Committee (MESAC) will address errors related to delayed medication orders and issues related to medication “hold” parameters. MESAC will review safety reports to identify specific concerns in the areas of prescribing, dispensing and administration of medications to identify system issues. As indicated, plans will be developed to improve reliability and efficiency relating to prescribing, dispensing and administration of medications. In the short term, The Institute for Patient Care and Pharmacy leadership will distribute information to in-patient nurses and pharmacists. In the long-term, for hospital-wide issues referenced above, the Medication Education Safe Administration Committee (MESAC) will identify systems improvements and target interventions. As needed, educational plans will be developed by a multi-disciplinary team based on the recommendations of the Medication Education Safe Administration Committee (MESAC). The completion date for the short-term measures is 4/1/10. A description demonstrating how the hospital has incorporated systemic improvement actions into its Quality Assessment and Performance Improvement (QAPI) program in order to prevent the likelihood of the deficient practice from reoccurring; Updates on our performance related to the deficiency	04/01/10

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A 395	Continued From page 103 for a total pain score. The scores of zero are given when the patient has no issues, a one is given for the following reasons: face (occasional grimace or frown, withdrawn, disinterested), legs (uneasy, restless, tense), activity (squirming, shifting back/forth, tense), cry (moans or whimpers, occasional complaint), and consolability (reassured by occasional touching, hugging, talking to, distractible). A score of two is given for the following reasons: face (frequent to constant frown, clenched jaw, quivering chin), legs (kicking or legs drawn up), activity (crying steadily, screams, sobs, frequent complaints), and consolability (difficult to console or comfort). Review of the a Flow Sheet and] Continuation Sheet revealed the following documentation: 9:10 a.m. Time of arrival. Ground transport. Immobilization with collar, headrolls and backboard. Responds to pain. Head hematoma. Comments: Positive loss of consciousness, "complains of neck pain? Dislocation of shoulder." 9:15 a.m. Two large bore intravenous (IVs) placed, one in the right arm and one in the left arm. Trauma team at bedside. Collar in place. 9:18 a.m. Labs sent. 9:20 a.m. Chest x-ray/pelvic at bedside. 9:23 a.m. Removed from back board. 9:28 a.m. To Cat Scan for stat CT of the head without IV contrast, cervical spine without IV contrast, thoracic spine without IV contrast, lumbar spine without IV contrast, chest with IV contrast; abdomen/pelvis with IV contrast. 9:37 a.m. Combative at CT. Haldol 5 mg IV (an antipsychotic medication) was given. 9:50 a.m. Haldol 5 mg IV given. 10:04 a.m. Calm. Head CT Scan done.	A 395	cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through our General Executive Committee and through the Boards of Trustees Quality Subcommittee to the Boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that we are making progress as planned, and communicate our progress and concerns to the Boards through the mechanism above on a quarterly basis until the issue is resolved to prevent the likelihood of the deficient practice from reoccurring. Subsequent compliance will be reviewed through our quality and safety dashboards which will now include an explicit area to monitor our CoP compliance. In addition to these periodic reviews we will be flagging all safety event reports related to CoP issues so that ad hoc compliance issues can be addressed in a robust and timely fashion. To ensure that the plan of correction is effective and the specific deficiencies cited remain corrected, reports will be generated from the safety reporting system to capture trends with medication orders. MESAC will review and analyze data to evaluate the effectiveness of the plan and MESAC will provide a quarterly summary to Quality Oversight Committee (QOC). The title of the person responsible for implementing the acceptable plan of correction is the senior vice president for Patient Care Services and chief nurse. To ensure that a Registered Nurse will supervise and evaluate the nursing care for each patient, the Medication Education Safety Approval Committee (MESAC) will establish that all medication policies are consistent	04/15/10

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A 395	Continued From page 104 10:20 a.m. Restless. Questionable infiltrate of contrast in left arm. CT stopped secondary to movement. 10:33 a.m. Repeat head CT without contrast. Haldol 2.5 mg IV given for restlessness. 10:40 a.m. Hot pack applied to left arm IV site. Physician ordered to keep left arm elevated as there is contrast extravasation. 10:45 a.m. Return from CT. 10:50 a.m. Calm on stretcher. 11:00 a.m. Foley placed #16. Return to CT with registered nurse. 11:15 a.m. Return to CT for CT of head. Moving all over patient will follow commands at times. 11:30 a.m. Back to the emergency department. 11:50 a.m. Stat Fosphenytoin 1000 milligrams (mg) Phenytoin Equivalents IV (antiepileptic medication) administered. 12:00 noon Vomited, medicated with Zofran 4 mg IV (used to prevent nausea and vomiting). 12:30 p.m. Calm, will arouse. 1:30 p.m. Family present. Foley draining clear fluid. 2:00 p.m. Family here. Restless. 2:45 p.m. Confused at times. Tries to get up. Reassure about Foley. 3:00 p.m. Report to ' nursing staff. Bed not ready. At times will follow commands, confused, sometimes understands. 4:15 p.m. To room on Review of the patient's 2/8/10 Patient Problem/Outcome/Intervention Sheet revealed that acute pain related to trauma injury was identified as a problem. Interventions included but were not limited to: monitor patient's pain level at least every shift, administer pain medication according to prescribed regimen and reassess after intervention provided.	A 395	related to the security of medications. Once this policy is finalized, the Knight Nursing Center educators and the PCS Office of Quality & Safety will educate nurses by 4/15/10 about the security of medications as outlined in the MGH current policy. Education will occur and be track via HealthStream. Updates on our performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through our General Executive Committee and through the Boards of Trustees Quality Subcommittee to the Boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that we are making progress as planned, and communicate our progress and concerns to the Boards through the mechanism above on a quarterly basis until the issue is resolved to prevent the likelihood of the deficient practice from reoccurring. Subsequent compliance will be reviewed through our quality and safety dashboards which will now include an explicit area to monitor our CoP compliance. In addition to these periodic reviews we will be flagging all safety event reports related to CoP issues so that ad hoc compliance issues can be addressed in a robust and timely fashion. Monitoring of medication security will be conducted biannually as part of the Department of Nursing unit based tracers and biannually as part of the Environment of Care Rounds. Episodes of identified breaks in medication security relating to the steps of medication administration will be reported to Unit Leadership and captured within the Safety Reporting system.	

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A 395	Continued From page 105 Review of the Physician's orders revealed the following information: Acetaminophen (Tylenol) 325-650 mg by mouth every four hours as needed for mild pain was ordered on 2/8/10 at 11:50 a.m. Side Rail Restraints was ordered on 2/8/10 at 5:24 p.m. On 2/8/10 at 6:00 p.m. upon admission to the the nursing staff completed the Nursing Dataset Form and initialed the completion of Section 2, Cognitive/Perceptual. The nurse indicated in Section 2 that the patient responded that the month was February and year 2010. Section 3 - Pain was checked no for pain, but was not dated, timed nor initialed by the nurse. The last page of the Nursing Dataset Form was dated as completed on 2/8/10 at 6:30 p.m. and the nurse documented that the information for the Nursing Dataset Form was obtained by the family· Review of the patient's Nursing Progress Notes revealed the following information: 2/8/10 at 10:06 p.m. Patient Patient was combative and confused at the scene. For CT scans the patient received 12.5 mg total of Haldol. Injuries: bilateral pulmonary contusions, subdural hematoma, frontal contusion, fracture of right temporomandibular joint, minimally displaced fracture of right parietal bone, right occipital fracture. Pain: Patient unable to use pain scale to rate pain due to confusion. When asked if patient has pain she will	A 395	The senior vice president for Patient Care Services and chief nurse is ensuring implementation of this plan of correction.	

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sometimes say yes, but when asked where she won't answer. Usually seems to be related to positional discomfort. Awake and oriented to self. Patient at times knows month and year, but not place or why she is here. Patient follows simple commands at times. Waxes and wanes. Patient took antibiotic by mouth for jaw fracture. Patient took pills ok with sips of water. Left arm is slightly edematous from IV that infiltrated. Ice packs applied and arm elevated. Patient impulsive at times, says she has to void, catheter does seem to be positional. Patient moves in bed at times impulsive. Bed alarm on for safety. Cervical collar remains intact. Side rail restraints up for safety.

2/9/10 at 4:01 a.m. CT scan done on 2/8/10 resulted in left arm swelling due to CT contrast infiltrated. Warm pack applied to left arm and elevated on a pillow. Patient states she does not have any pain. Did not require any pain medication was able to sleep for short periods of time during the night will continue to assess. Foley draining clear urine. Patient frequently attempting to get out of bed. States she has to void. Patient obeys some commands, good strength to arm and legs moves well. Continues to attempt to get up out of bed frequently and pulling at IV and catheter. Four side rails up in bed for safety, constant supervision to prevent injury.

Review of the Physician Progress Note reveal the following documentation:
2/9/10 at 6:00 a.m. Alert and responds appropriately to questions, but waxes and wanes, follows commands. Neuro exam stable-improved. Cervical collar. Clindamycin/sinus precautions.

Review of the patient's 2/8/10 flow sheet revealed

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that the patient was assessed as unable to quantify pain at 4:30 p.m., 5:30 p.m., 6:30 p.m., 8:00 p.m., 9:00 p.m., and 10:00 p.m. and no interventions for pain management were implemented.

Although the Nursing Progress Note on 2/9/10 at 4:01 a.m. indicated that the patient denied pain, review of the patient's 2/9/10 flow sheet revealed the patient was assessed as unable to quantify pain at 12:00 midnight, 1:00 a.m., 2:00 a.m., 3:00 a.m., 4:00 a.m., 5:00 a.m., 6:00 a.m., 7:00 a.m., 8:00 a.m., and at 9:00 a.m. and no interventions for pain management were implemented.

Review of the hospital's 1992 Guidelines for Pain Assessment and Management which was reviewed in 2000 revealed that the section entitled Method of Pain Assessment indicated that staff should assume, "pain is present for patients with conditions (e.g. broken bone) or procedures (e.g. dressing changes) known to be painful to other patients."

Although the patient had multiple fractures, bilateral pulmonary contusions and a left arm infiltrate, review of the patient's electronic Medication Administration Record on 2/9/10 at 10:21 a.m. revealed that the Acetaminophen (Tylenol) 325-650 mg ordered on 2/8/10 at 11:50 a.m. for mild pain had not been administered.

An interview was conducted on 2/9/10 at 10:30 a.m. with Nurse E who was caring for the patient for the 7:00 a.m. to 7:00 p.m. shift on 2/9/10. Nurse E stated that the patient was restless, tries to get out of the bed to go to the bathroom and has to be constantly reminded that the Foley is in place. The nurse stated that the patient's pain is

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A 395	Continued From page 108 assessed as unknown because the patient is confused at times. Nurse E confirmed that the patient has multiple fractures and that Tylenol could be given for pain, but the nurse stated she did not know if the patient had Tylenol ordered. Observation of the patient on 2/9/10 at 10:40 a.m., revealed that the patient was lying in bed on the left side with a cervical collar around her neck. The patient removed a probe from her finger and removed the blanket and sheet from her torso. The patient then laid her head back on the pillow, the nurse attempted to replace the probe and the patient sat up. The nurse asked her where she was going and the patient stated she had to go to the bathroom. The nurse reminded the patient that she had a Foley catheter. During an interview with the Clinical Nurse Specialist B on 2/9/10 at 11:00 a.m., she confirmed that the FLACC Scale for the assessment of pain was not in Patient #38's binder with the patient's flow sheets. Clinical Nurse Specialist B stated that staff could have obtained the FLACC Scale from the computer in order to assess the patient's pain. 3. Patient #21 There was a delay in implementing interventions to reduce the patient's pain resulting from Review of the hospital's 1992 Guidelines for Pain Assessment and Management which was	A 395		

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A 395	Continued From page 109 reviewed in 2000 revealed that the definition of pain is "whatever the experiencing person says it is, existing whenever he says it does." The section entitled Principles of Care of the Patient Experiencing Pain indicated that staff are to reassess "pain and response to treatment regularly." The desired outcomes included pain relief and the patient, "reports acute pain severity of 4 or less on a 0-10 scale or other acceptable point on a scale as defined by patient and provider." The numerical equivalents for the 0-10 pain scale are as follows: zero equals no pain, 5 equals quite a lot of pain, and 10 equals the worst pain imaginable. The section entitled Method of Pain Assessment included physical "assessment of the painful area and suspected sources of pain, when appropriate." "Assume pain is present for patients with conditions (e.g. broken bone) or procedures (e.g. dressing changes) known to be painful to other patients." Pain management indicated that regular assessment is needed to ensure that optimal control of pain and treatment-related side effects are achieved. Review of the patient's Progress Notes revealed the following information: Nursing Progress Note on 2/1/10 at 5:35 a.m., _ . Patient had been taking greater than 15 Tylenol per day. Multiple ecchymotic areas present on extremities. Aspen collar on at all times. Awake and oriented times three. Distinct short-term memory deficits apparent. Pleasant and cooperative, able to follow commands. Patient complained of pain being a four on a scale from 0-10 in neck, shoulder and back/rib	A 395		

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area. Refusing analgesia. Continue to assess level of pain. Offer and provide appropriate analgesia and comfort measures to maintain goal of less than 4 pain level or optimal level of comfort.

Surgical Attending Note on 2/1/10 at 9:20 a.m. Patient is doing very well. Observed sitting on the bed eating breakfast wearing a cervical collar. Complains of mild to moderate posterior rib pain but moves easily and take deep breaths without a problem. We discussed the importance of adequate respiratory effort and will continue pain control.

Review of the patient's Electronic Medication Administration Report Overview revealed that the patient had the following orders for pain medication: Morphine immediate release 5 milligrams (mg) by mouth twice a day as needed for pain. The patient received a dose at 11:45 a.m. The patient's pain level was rated a 6 prior to the pain medication being administered and at 12:57 p.m. the pain was assessed as having increased to a 7. Although a pain consult had been ordered, no other interventions were implemented to reduce the patient's pain level until four hours later at 5:15 p.m. after the patient was assessed by the physician from the Pain Service.

Review of the Acute Pain Service Note dated 2/1/10 at 5:38 p.m., revealed that the Patient had

Pain mostly along the right posterior chest and spine, minimal cervical spine pain. Plan: Fentanyl patch 12.5 mcg every 72 hours. Fentanyl patch will take 16

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hours to take full effect, recommend low dose Morphine immediate release 5-10 mg by mouth every four to six hours as needed for pain until patch is fully effective.

Review of the patient's Electronic Medication Administration Report Overview revealed that the patient had the following orders for pain medications: Fentanyl Patch 12.5 micrograms (mcg)/hour transdermal every 72 hours was ordered by the Pain Service physician. The Fentanyl patch was applied at 5:15 p.m. The patient's pain was assessed as a 6 on a 0-10 scale prior to the administration of the patch and as a 4 at 6:26 p.m.

Also ordered was Morphine immediate release 5 mg by mouth every six hours as needed for pain. The patient received a dose at 5:16 p.m. and was assessed as a 6 on a 0-10 scale prior to administration of the medication and an 8 at 6:34 p.m.

Review of the Nursing Progress Note dated 2/1/10 at 6:30 p.m., revealed the following: Patient alert and oriented times three, short term memory deficits at times. Pleasant and cooperative. Reports pain in right rib area and lower back. Ecchymosis noted throughout body. Morphine elixir given, states, "it didn't work that well." Pain service up to consult, Fentanyl patch placed to left shoulder and Morphine elixir now ordered every six hours. Reports pain is worse one hour after morphine given at 5:15 p.m. Physician notified at 6:30 p.m. about back pain, awaiting response. Plan: Assess comfort level, medicate as needed. Aspen collar in place at all times.

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In response to the patient's continued complaints of pain, at 6:58 p.m., the physician ordered the patient to receive Morphine immediate release 5-10 mg tablet by mouth every six hours as needed for pain. The nurse reviewed the order at 7:39 p.m.

Despite the patient's pain assessment being an 8 on a 0-10 scale at 6:34 p.m. and the physician increasing the Morphine dosage to 5-10 mg, the patient did not receive pain medication until 9:18 p.m. when the patient received all the evening medications and the dose administered was Morphine 5 mg. The reassessment of the patient's pain level did not occur until two and a half hours later at 11:50 p.m. and the patient's pain was a 6 on a 0-10 scale. However, there was no documentation that additional interventions to reduce the patient's pain were implemented.

Review of the Nursing Progress Note dated 2/2/10 at 4:44 a.m., revealed the following: The Patient is alert and oriented times three. Does have short term memory loss. Patient rates pain in back and all over an 8 on a 0-10 scale. Pain consult yesterday and Fentanyl patch applied. Also has Morphine elixir ordered 5-10 mg every six hours as needed; given 5 mg before bed. Requesting Remeron and Trazodone for sleep. Remeron given and patient found to be sleeping after medication - appears comfortable. Aspen collar at all times; ecchymosis noted on body.

During an interview with Patient #21 on 2/2/10 at 2:45 p.m., the patient confirmed that she continued to have pain after receiving pain medication yesterday, 2/1/10. The patient stated that if offered pain medication, the patient would

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A 395	Continued From page 113 not refuse it. During an interview with Unit Nursing Director A on 2/2/10 at 2:55 p.m., she stated that if something "is not documented, it is not done." During an interview with Nurse A on 2/2/10 at 3:30 p.m., she stated that the patient described the pain on 2/1/10 as "it was awful." The nurse also stated that Patient #21 had complained that the pain medication given at 5:15 p.m."didn't help." The nurse stated she paged the physician in response to the patient's complaint. During an interview with Nurse B on 2/3/10 at 7:28 a.m., she stated that on 2/1/10 she did not give the pain medication to the patient until 9:18 p.m. because the patient was sleeping. The nurse confirmed that she did not document that the patient was sleeping in the electronic medication administration record or in her progress notes. 4. Patient #24 There was a delay in implementing interventions to reduce the patient's pain resulting from a . The patient was alert and oriented on admission and rated the pain as an 8 on a scale from 1-10 with one being no pain and 10 being severe pain. The nursing staff initiated a Plan of Care that identified pain as a problem. Interventions included assess and document pain level using appropriate pain scale and medicate for pain/pre-medicate for painful interventions.	A 395		

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A 395	Continued From page 114 An orthopaedic consultation performed on 2/1/10 indicated that the patient had tenderness to palpation at mid-humerus, slight discomfort with palpation of right 5th metacarpal and mild discomfort with palpation of the left antero-superior shoulder. The patient continued to have pain over the superior aspect of the left shoulder. The physician indicated that these fractures are treated non-operatively and the patient was placed back into a coaptation splint. The left shoulder imagining studies showed no evidence of fracture or bone injury. The patient may have had a rotator cuff injury and if the patient remains symptomatic would consider an MRI of the left shoulder. Review of the Nursing Progress Note written on 2/3/10 at 5:30 a.m. for the shift that began on 2/2/2010 at 7:00 p.m., revealed the following information: Patient's pain located in the right arm and shoulder from recent fracture. The patient rates pain a 9/10. Ortho was consulted yesterday and right arm placed in fracture brace. Right arm elevated on a pillow for increased comfort. The patient can receive 1 mg Dilaudid as needed every 2 hours for pain. Administered Dilaudid x 3 this shift. Patient's pain decreased a 6-7/10 after receiving Dilaudid. Ice pack applied and patient reported good relief with ice pack. Patient received Ativan x 1 for complaints of anxiety and difficulty sleeping. Patient has been sleeping in naps overnight. Plan: continue to assess pain per protocol and administer pain medications as ordered. Although the Nursing Progress Note indicated that the patient's level of pain decreased during the night, review of the Electronic Medication	A 395		

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Administration Record (EMAR) revealed the following information: The patient was ordered to receive Hydromorphone (Dilaudid) 1 milligram (mg) intravenously (a narcotic analgesic) every 2 hours as needed for pain. On 2/3/10 at 12:10 a.m. the patient received Dilaudid 1 mg for pain that was assessed as a 9 on a scale from 0-10. At 3:07 a.m., the post medication pain scale indicated that the patient's pain remained a 9 on a scale from 0-10. At 2:42 a.m., two and a half hours after the 12:10 a.m. dose of Dilaudid, the patient received another dose of Dilaudid 1 mg for the continuation of pain at a level of 9 on a pain scale from 0-10. At 4:18 a.m., the post medication assessment indicated that the patient's pain was only reduced to a 7 on a pain scale from 0-10. There is no documentation that the patient was offered or received pain medication or other interventions were implemented at 4:18 a.m. to reduce the patient's pain level. At 6:29 a.m., two hours after the pain had been assessed as a 7, the patient's pain level had increased to an 8 on a scale from 0-10 and the patient received Dilaudid 1 mg IV.

At 8:47 a.m., the physician ordered the patient's Dilaudid to be increased to 2-4 mg IV every 2 hours as needed for pain. At 10:32 a.m., four hours after the last medication was administered, the patient's pain was assessed as a 10 on a scale from 0-10 and the patient received Dilaudid 2 mg.

During an interview with Patient #24 on 2/3/10 at 10:46 a.m., the patient was observed in bed with a sling around the right arm and shoulder. The patient stated that last night was a "tough night." The patient stated that the nurses had placed ice on the knee which helped, but the shoulder was

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painful most of the night as the pain medication helped only a little bit.

Review of the Electronic Medication Administration Record revealed that since admission on 2/1/10 the patient had an order for Oxycodone 10-15 mg by mouth (an opioid analgesic medication) every four hours for pain as needed. Review of the EMAR with Nurse #3 revealed that no Oxycodone medication had been administered to this patient.

During an interview with Patient #24's attending physician on 2/3/10 at 11:25 a.m., the physician stated that the goal was for the patient to have relief from pain.

5. Patient #28

There was no assessment of the patient's pain level immediately prior to the application of four point soft restraints.

The patient was admitted on 1/25/2010 with

The FLACC Scale (FACE, Legs, Activity, Cry, Consolability) is a behavior pain assessment scale utilized by the hospital for use in non-verbal patients unable to provide reports of pain. The patient is rated a 0, 1, or 2 in each of the five measurement categories (face, legs, activity, cry and consolability), the scores are added together for a total pain score. The scores of zero are given when the patient has no issues, a one is given for the following reasons: face (occasional grimace or frown, withdrawn, disinterested), legs

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(uneasy, restless, tense), activity (squirming, shifting back/forth, tense), cry (moans or whimpers, occasional complaint), and consolability (reassured by occasional touching, hugging, talking to, distractible). A score of two is given for the following reasons: face (frequent to constant frown, clenched jaw, quivering chin), legs (kicking or legs drawn up), activity (crying steadily, screams, sobs, frequent complaints), and consolability (difficult to console or comfort).

Review of the patient's Nursing Progress Note dated 1/26/10 at 6:00 p.m., revealed that the patient was alert and oriented to self and place and was pleasant and cooperative. Uses call bell appropriately. Urine culture sent. Started on Ciprofloxacin 500 milligrams (mg) (an antibiotic) by mouth every twelve hours for three days for assumed urinary tract infection. Patient was in a cardiac chair this morning. Was able to pivot between bed and chair. Side rails ups. Call bell within reach. Bed in locked position. No attempts to get out of bed. Bed alarm on for safety.

Review of Nurse D's Progress Note dated 1/27/10 at 4:00 a.m., revealed the following information: Patient is awake and oriented to self and place, some confusion noted. Agitated at times, wanting to go home. Reoriented patient, reminded patient of the repeat endoscopic retrograde cholangiopancreatography (ERCP) scheduled for today with attempt at biliary stent. Some confusion/agitation overnight. Incontinent of urine, using bed pan occasionally overnight. Attempted to get out of bed unassisted, reminded to call for help. Call bell within reach. Bed in low, locked position. Bed alarm on. Plan: Continue to monitor patient safety, maintain safety precautions. At 6:30 a.m., Nurse D added the

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following documentation: Patient's behavior escalated becoming more agitated and confused. Attempted to get out of bed, swinging and kicking at staff. Showed evidence of danger to self and others. Physician in to assess. Patient placed in four point soft restraints and given Haldol 1 mg IV. Patient's daughter called and informed of situation, voice understand, will be in to visit this morning.

Although the patient had a suspected urinary tract infection and the behavior demonstrated prior to being restrained could have been indicators of pain according to the FLACC scale, the patient was not assessed for pain prior to the restraints being applied. Review of the patient's 1/27/10 flow sheet indicated that at midnight the patient's pain level was assessed as a 0 on a scale from 0-10. No other pain assessment was documented on the flow sheet until nineteen and a half hours later at 7:35 p.m., when the patient was again assessed as a 0 on a pain scale from 0-10.

Review of the Physician's Progress Note dated 1/27/10 at 10:00 a.m., revealed that the patient was agitated this morning, given Haldol 1 mg (antipsychotic medication) and placed in four point soft restraints. The patient refused exam by the physician. The patient accused the physician of being the "fireman" and that the physician would try to kill her if the physician touched her. The physician indicated that the patient had a urinary tract infection and Ciprofloxacin was ordered for three days. Repeat ERCP today.

Review of the 1/27/10 Attending GI Note indicated that the ERCP findings were consistent with a distal common bile duct obstruction and a stent

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was placed. The 1/27/10 Endoscopy Report recommended to watch for pancreatitis, bleeding, perforation, and cholangitis.

Review of the Nursing Progress Note on 1/27/10 at 6:00 p.m., revealed that the patient was alert and oriented to self and place. The patient was in soft restraints at the beginning of the shift. Patient refused vital signs, labs, and medications, but when family came to visit the patient became more cooperative with care. Soft restraints have been off most of the shift. ERCP done today. The patient continues on Cipro for a urinary tract infection. The patient ambulates with two person assistance. Side rails up. Call bell within reach. Bed in locked position. No attempts to get out of bed. Bed alarm on for safety. Family is at bedside.

Although the patient continued to be treated for a urinary tract infection, underwent an ERCP which showed a distal common bile duct obstruction and had a stent placement, the patient was not assessed for pain prior to restraints being utilized again at 10:00 p.m.

Review of the Nursing Progress Note written by Nurse D on 1/28/10 at 4:00 a.m., revealed that at the beginning of the shift the patient was alert and oriented to self and place. The patient became increasingly confused and agitated. The patient wanted to go home and stated she thought we were trying to kill her. Attempted to reorient patient and remind her that she was safe here with little effect. Some confusion/agitation overnight. Incontinent of urine, brief on. Attempted to get out of bed unassisted. High fall risk. Attempting to hit, kick, and spit at staff. Became increasing agitated and aggressive.

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Showed evidence of danger to self and others. Physician into assess. Patient placed in four point soft restraints. Received 0.25 mg IV Ativan with little effect. Side rails up. Bed in low position. Bed alarm on. Frequent safety checks made. Family witness escalating behaviors, were informed that she may need to be put in restraints again overnight, voice understanding. Plan: Continue to monitor patient safety, maintain safety precautions.

At 8:00 a.m. on 1/28/10, Nurse F released the patient's restraints and at 9:00 a.m. the restraint was discontinued. Review of Nurse F's Progress Note dated 1/28/10 at 5:00 p.m., revealed that the patient was alert and inconsistently oriented this shift. The patient was disoriented to place in the morning and became more oriented throughout the morning. The patient follows commands 50% of the time. The patient denied nausea, vomiting or abdominal pain. The patient voided dark yellow urine in the bed pan when not incontinent and had two bowel movements in the bed pan this morning. Jaundice appearance is improving. At times attempts to get out of the bed without calling for assistance. Rolling walker with two person assistance to bathroom or chair. Bed pan used to void. Fall precautions initiated such as bed alarm, non-skid footwear, bed in low locked position, toileting schedule, and consistent reorientation. Plan: Frequent checks for safety.

Interview with Clinical Nurse Specialist A on 2/5/10 at 7:40 a.m. confirmed that restlessness and kicking could be indicators of pain as evaluated on the FLACC scale.

Review of the patient's Electronic Medication Administration Record with Nurse C on 2/5/10 at

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A 395	Continued From page 121 9:38 a.m., revealed that the patient had an order since admission on 1/25/10 for Acetaminophen 325-650 mg by mouth every four hours as needed for pain or fever. Nurse C confirmed that the patient had never received Acetaminophen during this admission. 6. Patient #33 A. There was no ongoing assessment of the patient's pressure ulcer. In addition, the facility did not have a Policy and Procedure for how staff were to assess and document a description of a pressure ulcer. The patient's pressure ulcer (PU) was assessed by Clinical Nurse Specialist D on 10/28/10 as measuring 1.5 x 1.5 centimeter (cm) oval shaped pressure injury on . Very small 1 x 1 cm area of slough in the center of the wound. Depth is unknown due to small slough, but I do not suspect any deep tissue involvement. Treatment: Cleanse with 30 cc syringe blunt tip and Normal Saline. This will remove necrotic tissue and not embed tissue into wound bed. Cover with Duoderm and change every three or four days. Monitor. Review of the Nursing Progress Notes revealed the following information: 1/20/10 at 10:45 p.m., with 2 ulcers present and Duoderm over sites. 1/21/10 at 6:45 p.m. Patient has a stage 2 pressure ulcer on covered with Duoderm dressing clean dry and intact. Changed yesterday, (Wednesday) next change Monday.	A 395		

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A 395	Continued From page 122 1/23/10 at 6:00 a.m. Patient has small Duoderm over . This is due to be removed and changed on Monday. 1/23/10 at 3:00 p.m. Patient has a pressure ulcer on (Duoderm intact. Stage 1 pressure ulcer to left hip identified by aide during morning care. Duoderm applied. 1/23/10 at 5:00 p.m. Duoderm on coccyx area in place for decubitus ulcer. 1/24/10 at 6:00 a.m. Patient has a small Duoderm over (. This is due to be removed and changed on Monday. 1/24/10 3:00 p.m. - 11:00 p.m. Patient has a pressure ulcer on (noted to be bleeding and leaking, Duoderm reinforced. Has a positive stage 1 decubitus on left hip. 1/25/10 at 6:00 a.m. Dressing to is intact, small amount of bloody drainage noted from under Duoderm. Plan: Monitor wound areas closely for healing and for signs and symptoms of infection. 1/25/10 at 4:45 p.m. Patient does not appear comfortable (moaning) with turning, any repositioning and cast/splint rotations. Medicated with Tylenol. Irregular shaped open area on (redressed by nurse clinician today. Also, has irregular shaped approximate 3 x 3 cm open blister on left hip covered by Tegaderm (or may use Duoderm per nurse clinician), some bloody drainage noted on old dressings, no signs or symptoms of infection. 1/26/10 at 6:30 a.m. Duoderm intact to sacral	A 395		

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A 395	Continued From page 123 area. 2/6/10 at 7:00 p.m. Patient has a Stage II decubitus ulcer on [redacted] per previous notes. Covered with new clean Duoderm. Soiled and changed on last shift. During an interview on 2/8/10 at 2:50 p.m. with Nurse H, she stated that she changed the patient's dressing yesterday, although note dated 2/6/2010, and she stated it was about a half dollar in size. Nurse H stated that they usually, "eye ball the wound" and do not usually measure the wound. Nurse H stated that her assignment changes daily and she last had the patient several weeks ago. During an interview with Clinical Nurse Specialist D on 2/8/10 at 3:00 p.m., she stated that there was a lack of documentation of the patient's pressure ulcers and that the Duoderm should have been removed to view the wound when it was described as bloody drainage. During an interview on 2/9/10 at 11:00 a.m. with Clinical Nurse Specialist A and Clinical Nurse Specialist E who are members of the hospital's Wound Care Task Force, they confirmed that there is not a Policy and Procedure that details the steps staff would take when performing an assessment including measurement of a wound or pressure ulcer and the information about the assessment that staff would be expected to document in the patient's record. They stated that nursing staff at a minimum should be assessing patients' pressure ulcers on a weekly basis. The assessment should include information about the location, size, shape, wound bed, and amount of drainage.	A 395		

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A 395	Continued From page 124 B. There was no assessment of Patient #33's which was identified as a result of wearing a Texas Catheter. Review of the Nursing Progress Notes revealed the following information: 1/23/2010 Texas catheter removed secondary to discoloring of area. 1/24/2010 Voiding via Texas catheter. 1/24/2010 3:00 p.m. - 11:00 p.m. Texas catheter remains off. During an interview with Clinical Nurse Specialist D on 2/8/10 at 3:00 p.m., she stated that staff should have continually assessed the patient's 7. Patient #36 There was a two day delay in nursing staff documenting a description of the patient's toe ulcers. Review of Patient #36's 2/5/10 Nursing Dataset Form which is completed during admission revealed that the section entitled Skin Integrity indicated that the patient had ulcers on the toes and legs. No further information about the ulcers was documented on the Nursing Dataset Form. Review of the patient's Nursing Progress Notes revealed the following information: 2/6/10 at 5:40 a.m. Legs both reddened, scaly with a few open ulcers. Left foot with 4 open	A 395		

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A 395	Continued From page 125 small ulcers. 2/6/10 at 5:55 p.m. Both legs very red, scaly with a few open ulcers left open to air. 2/7/10 at 7:47 a.m. Bilateral lower extremities extremely reddened. 2/7/10 at 5:04 p.m. Both legs very red, scaly with a few dried ulcers left open to air. 2/8/10 at 2:00 a.m. Right lower extremity redder and bigger than the left lower extremity, patient has some discomfort when right lower extremity moved. Patient able to move toes bilaterally. Applied Eucerin Cream to both legs. Feet are slightly cool and patient has a few old ulcers at right foot, one on the pinky toe, another on the 3rd toe which is black and at the lateral heel has an old ulcer scar, inside the wound is black. Observation of Patient #36 on 2/8/10 at 2:00 p.m., revealed that both legs were reddened and the left foot had small dark areas on the first, second, fourth and fifth toes. The right foot had a dark area on the first and third toes. During an interview with Clinical Nurse Specialist C on 2/8/10 at 2:05 p.m., she stated that she would have expected a more detailed description of the areas on Patient #36's feet including the number and the location of each ulcer area. 8. Patient #22 Medication that lowers blood pressure was administered to Patient #22 even though the patient's heart rate was below parameters set by the physician.	A 395		

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A 395	Continued From page 126 Review of the Electronic Medication Administration Record revealed that the patient had an order for Propranolol 80 milligrams (mg) to be taken by mouth twice a day. The order instructed the nurse to hold the medication if the patient's "systolic blood pressure was less than 100, heart rate less than 60." Propranolol is used to treat high blood pressure. Review of the patient's flow sheets revealed that on 2/1/10 and 2/2/10 at 8:00 a.m., the patient's heart rate was 56, yet the patient received Propranolol 80 mg on both days. During an interview with Nurse C on 2/3/10 at 8:30 a.m., she stated that Propranolol 80 mg was administered to Patient #22 on 2/1/10 and 2/2/10 and she confirmed that the patient's heart rate was below the physician ordered parameters at the time the Propranolol was administered. In addition, although the Propranolol medication was held on 1/29/10 and 1/30/10 at 8:00 p.m., and on 1/31/10 at 8:00 a.m. because the patient heart rate and/or blood pressure was below the parameters, there was no documentation in the medical record to indicate that nursing staff alerted the physician about the medication being held. 9. Patient #34 Patient #34's Metoprolol medication was not administered per physician orders. On 2/7/10 at 10:24 a.m., the Physician ordered Patient #34 to receive Metoprolol 25 mg by mouth three times a day. Start: Today. Metoprolol is	A 395		

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used to treat chest pain and high blood pressure.

Review of the Electronic Medication Administration Record (EMAR) revealed that the patient's medication was not given at 12:00 noon and at 2:50 p.m. Nurse G who documented that the medication was not given on 2/7/10 at 12:00 noon and 2:50 p.m., indicated on the EMAR that the medication was to start in the morning. However, further review of the EMAR revealed that at 7:46 p.m. on 2/7/10 the Metoprolol 25 mg was given.

During an interview with Nurse G on 2/8/10 at 10:55 a.m., she stated that the physician who ordered the Metoprolol 25 mg had stated to start the medication the next morning, on 2/8/10. However, Nurse G confirmed that the medication order did not indicate that the Metoprolol medication was to start on 2/8/10.

10. Patient #23

The nurse left oral medications and eye drops in Patient #23's room for fifteen minutes.

Observation of the medication pass for Patient #23 on 2/3/10 at 9:15 a.m., revealed that Nurse J had opened six oral medications in the patient's room at 8:57 a.m. The medications included: Atenolol (treats chest pain and high blood pressure), Citalopram (antidepressant), Clonazepam (anticonvulsant/muscle relaxant), Docusate Sodium (stool softener), Gabapentin (treats neuropathy), Omeprazole (treats dyspepsia).

Nurse J left these oral medications unsecured in the patient's room while she returned to the

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medication room to obtain an additional medication.

Review of the 11/10/09 Medication Management Policy and Procedure revealed that once "medications are removed from a secured storage location, the individual practitioner removing the medication is responsible for maintaining complete medication security until the medication is handed-off to another healthcare practitioner, or the medication is administered to the patient " Medications should not be stored at the bedside except in rare circumstances and medications not administered to a patient must be returned to secured storage.

During an interview with Nurse J on 2/3/10 at 9:50 a.m., she stated that she probably should not have left the medications in the room.

11. Patient #78

The nurse left Patient #78's Advair Diskus, an inhalation medication, in the patient's room for six hours.

Observation of the medication pass for Patient #78 on 2/3/10 at 2:20 p.m., revealed that Nurse K entered the patient's room and discovered that the patient's Advair Diskus was lying on the window shelf. Advair Diskus is used to treat asthma, bronchitis and chronic obstructive pulmonary disease.

The patient has a physician's order for Advair Diskus one puff twice a day. Review of the patient's Electronic Medical Administration Record revealed that the medication was last given on 2/3/10 at 7:57 a.m.

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During an interview with Nurse K on 2/3/10 at 2:35 p.m., she stated that she must have left the Advair Diskus in the patient's room earlier this morning. The nurse removed the Advair Diskus from Patient #78's room and secured it in the medication room.

12. Patient #56

Patient #56 was seen in the

. The form indicated the patient had a previous medical

. According to the Record dated 1/21/10 at 7:25 p.m., the patient was experiencing pain of "8" on a scale of 1-10 during admission to the
V/S (Vital Signs) B/P (blood pressure) 125/80, HR (heart rate) 107, RR (respiratory rate) 20, O2 (oxygen) saturation 99% on room air and a temperature 98.7.

Review of the Nursing Flow Sheet's Focused Assessment revealed documentation by the nurse as follows:
20:20 (8:20 p.m.)

positive - 1 negative. Has had pain since December. Over past few days pain has increased. 0 (no) bleeding. 0 (no)

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O (Objective) - AO (alert and oriented) x (times) 3. Response reliable. VSS (vital signs stable) Lungs cl. (clear) Abd. soft, tender rt. lower quadrant...

P (Plan)-
eval (evaluation)"

A continuation sheet indicated the following nursing documentation:
20:30 (8:30 p.m.)- B/P 125/80. HR 107, RR 20, O2 (oxygen) saturation 99% on ra (room air) and Temp 98.7. The section indicated as "Pain Assessment & Reassessment" was left blank. Pt. to Urgent A by (Initials). (Illegible documentation) Sent by MD (Medical Doctor) call.

21:45 (9:45 p.m.) B/P 111/63, HR 87, RR 18, O2 saturation 100% on ra and Temp 98.8 Pain Assessment & Reassessment was indicated as 6/10 on a scale of 1-10. To U/S (ultrasound)

22:15 (10:15 p.m.) B/P 123/76, HR 67, RR 18, O2 saturation 100% on ra and Temp 98.7 Pain Assessment & Reassessment 2/10. Pt. back from U/S.

Additionally, the nursing notes did not reveal a request for pain medication for the patient's pain of "8" at 19:25 or for the pain of "6" at 20:45. There was also no documentation that pain medication was administered by the nurse.

According to the physician's electronic orders provided by the Clinical Nurse Specialist that was dated 1/21/10 at 7:58 p.m. and reviewed by the nurse at 8:16 p.m., the physician ordered a U/S

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(ultrasound) of the pelvic- right focused, type and screen, an HCG (human chorionic gonadotropin), CBC (complete blood count) with differential, Basic Metabolic Panel 7 and a Urinalysis. There was no documentation of an order for pain medication. The physician indicated a final diagnosis of

13. Patient #84

Patient #84 was seen in) for a chief complaint of pain . According to the l Record dated 1/22/10 at 9:52 a.m., the patient was experiencing pain to the of "5" on a scale of 1-10. The triage form also indicated "Pt. c/o pain x (times) 1 week. No change in hearing. Pt. c/o pain to touch. Pt denies fever.
A.
P. EMS eval
Vital signs: B/P 104/68, HR 68, RR 20, O2 saturation 100% on room air, Temp 97.6
The ED Lab Documentation Sheet revealed a CT scan of the head was ordered by the physician.

The Nursing Notes indicated the following:
10:40 Pt. ambulated to Bay 33. MD (Physician's Name) at side
13:40 Pt. d/c'd (discharged) by MD.

The form did not have a section to indicate if Pain Assessment or Reassessment was done.

Additionally, the nursing notes did not reveal a request for pain medication for the patient's pain of "5" on admission to the There was also no documentation that a reassessment of the

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A 395	Continued From page 132	A 395		

patient's pain was conducted, and if pain medication was requested to relieve the patient's pain and/or administered by the nurse.

There were no additional test and/or medications ordered by the physician, who discharged the patient with a final diagnosis of head pain.

The was provided these findings during an interview on 2/10/10 at 10:30 a.m. During the interview she stated that the nursing staff should complete the pain assessment, attempt to get pain relief for the patient and document this information in the record.

14. Patient #12

Patient #12's clinical record was reviewed on 02/10/10 at approximately 1:45 p.m. The record indicated that the patient is a 57 year old who was admitted to the hospital on 02/07/10 with

and is listed as a candidate for a liver transplant.

Along with diet and treatment orders that were written for Patient #12, there was an order for pain which read: Oxycodone 5-10 mg. (milligrams), Q6H (every 6 Hours), PRN (whenever necessary) for pain.

Review of the care plan initiated on admission, revealed the plan failed to identify current needs of the patient. Specifically, the care plan did not address the patient's current status relative to being on the transplant waiting list. Additionally, the care plan did not document interventions to address management of the patient's pain. These

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A 395	Continued From page 133 findings were acknowledged by ND #1 during an interview on (date) at 2:30 p.m.	A 395		
A 405	482.23(c)(1) ADMINISTRATION OF DRUGS All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures. This STANDARD is not met as evidenced by: Based on review of clinical records, facility policies, and staff interview, it was determined that the facility failed to follow standard blood product verification procedures to ensure that 1 of 84 patients received compatible blood components to prevent transfusion error. The findings include: 1. Patient #65 Review of Nursing Progress Notes on 1/13/10 at 7:30 p.m. revealed "A second six-pack was started, fifteen minutes into the infusion the pt (patient) c/o (complained of) chills, became hypertensive (elevated blood pressure), tachycardic (rapid heart rate) and hypoxic (inadequate oxygen in the blood). Transfusion stopped, treated pt with IV (intravenous) Benadryl (medication used to suppress the body's reaction to allergic responses), IV steroids (medication used to treat inflammation), IV Zantac (medication used to suppress the release of stomach acid), IV Lopressor (medication used to decrease the workload of the heart and make it beat more regularly also lowers blood pressure),	A 405	To enhance compliance with blood product verification procedures, the hospital will convene a multidisciplinary improvement team including nurses, physicians and staff from Blood Transfusion Service. The team will focus on ensuring that blood verification procedures are followed and that documentation on the MGH Transfusion Record is complete. Patient Care Services (PCS) Office of Quality and Safety will collect baseline data by auditing Transfusion Records of all patients transfused during a specified time frame. The purpose will be to identify patterns of compliance and non-compliance; this information will help the team to identify the nature and scope of the problem and guide the development of effective improvement actions. Once this risk analysis is completed, mandatory reeducation for nurses will be electronically available for those who initiate transfusions. This mandatory reeducation will be completed by 4/15/10. Weekly, staff from PCS Office of Quality and Safety will review the documentation of a statistically significant sample of patients who received transfusions. Unit and department leadership will receive site-specific data. When compliance appears to be achieved, the frequency of monitoring will be reduced to monthly to ensure sustained compliance. . In addition, updates on our performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through our General	04/15/10

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A 405	Continued From page 134 and 100% non-rebreather mask (mask with one way valves so that patient breaths oxygen that is not mixed with room air)." Review of flowsheet for 1/13/10 revealed platelets started at 12:30 p.m., and stopped at 12:45 p.m. with a notation c/o feeling cold. Review of Patient #65's clinical record revealed the following information relative to the procedure of verification of blood products: -Fresh Frozen Plasma (blood product that contains clotting factors used when patients are actively bleeding to assist with clotting or if the patient received multiple units of red blood cells) on 1/11/10 at 7:20 p.m. lacked evidence that there was a mark beside Name and MR # (medical record number) on the slip that matches the patient's armband, bag # on this slip matches bag label, expiration date OK. -Fresh Frozen Plasma with a crossmatch date of 1/12/10 at 1:22 a.m. lacked evidence of a date and time when started. -Fresh Frozen Plasma with a crossmatch date of 1/12/10 at 5:28 a.m. lacked evidence of a date and time when started, and lacked evidence of the staff member starting the blood product. -Red Blood Cells (blood product that transports oxygen and carbon dioxide) with a crossmatch date of 1/12/10 at 2:42 p.m. lacked evidence of a date and time when started, and that there was no verification of the name and medical record noted on the blood verification administration slip. - Platelets (blood product containing cells that stick together to form clots) on 1/13/10 at 12:30 p.m. the box indicating "If reaction, check here" is not checked and there is no evidence that nursing staff notified the lab. -Platelets with a crossmatch date of 1/13/10 at	A 405	Executive Committee and through the Boards of Trustees Quality Subcommittee to the Boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that we are making progress as planned, and communicate our progress and concerns to the Boards through the mechanism above on a quarterly basis until the issue is resolved to prevent the likelihood of the deficient practice from reoccurring. Subsequent compliance will be reviewed through our quality and safety dashboards which will now include an explicit area to monitor our CoP compliance. In addition to these periodic reviews we will be flagging all safety event reports related to CoP issues so that ad hoc compliance issues can be addressed in a robust and timely fashion. The senior vice president for Patient Care Services and chief nurse is responsible for this corrective action plan.	

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A 405	Continued From page 135 8:24 a.m. lacked a time when started. -Platelets on 1/14/10 at 10:15 p.m. lacked evidence of the staff member starting the blood product. -Platelets with a crossmatch date of 1/15/10 at 11:08 p.m. lacked a time when started. Review of the facility's policy titled "Transfusion Therapy Overview" received on 2/4/10 at 8:10 a.m. indicated in part under the heading "Bedside Donor and Patient Verification Prior to Transfusion" that staff "Mark the checklist areas on the Transfusion Record as the bedside check is done. The two individuals checking the blood sign the Transfusion Record." Interview with Quality and Safety Staff CG on 2/3/10 at 3:00 p.m., acknowledged that the expectation would be for staff members to completely document the process, to verify that the correct patient received the correct blood product, that staff sign, date, and time the transfusion record.	A 405		
A 431	482.24 MEDICAL RECORD SERVICES The hospital must have a medical record service that has administrative responsibility for medical records. A medical record must be maintained for every individual evaluated or treated in the hospital. This CONDITION is not met as evidenced by: Based on record review and interview, it was determined that the hospital failed to meet the Conditions of Participation for Medical Records. (See A438, A441, A449 & A450) The findings include:	A 431	Please see detailed plans of correction below for A438, A441, A449, and A450	

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A 431	Continued From page 136 1. The facility failed to ensure that each patient's clinical record was properly filed. 2. The facility failed to have a procedure for ensuring the confidentiality of patients' records. 3. The facility failed to ensure that medical records contained information to describe patients' progress and responses. 4. The facility failed to ensure that medical record entries were legible and complete.	A 431		
A 438	482.24(b) FORM AND RETENTION OF RECORDS The hospital must maintain a medical record for each inpatient and outpatient. Medical records must be accurately written, promptly completed, properly filed and retained, and accessible. The hospital must use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries. This STANDARD is not met as evidenced by: Based on medical record reviews and staff interview, it was determined that the facility failed to ensure that medical records were accurately written and/or complete for 4 of 84 patients in the survey sample. (Patents #26, #27, #29 and #52). Patient #26, Patient #27 and Patient #29's flow sheets and the Electronic Medication Administration Record (EMAR) contained inconsistent or inaccurate pain documentation. Patient #52's Medical Record was incomplete.	A 438	The hospital is required to ensure that it maintains a medical record for each inpatient and outpatient. These medical records must be accurately written, promptly completed, properly filed and retained, and accessible, and the hospital must use a system of author identification and record maintenance to ensure the integrity of the authentication and protect the security of all record entries. To ensure compliance with the specific deficiencies identified, the MGH is revising its current policy and procedures to clarify the documentation requirement. Educational materials will be developed and an implementation/evaluation plan is being established. Information Systems will collaborate with caregivers and others to help facilitate the documentation of pain with the new electronic Acute Care Documentation (ACD) flow-sheet to reduce inconsistent entries. To improve the processes that led to this deficiency, in the short term, the hospital will	04/30/10

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A 438	Continued From page 137 The findings include: 1. Patient #26's Patient #26's Electronic Medication Administration Record (EMAR) contained inaccurate post medication documentation. Review of the patient's EMAR revealed that the 1/30/10 and 1/31/10 post medication assessments were documented on 2/1/10. Additionally, the record revealed that the patient's pain assessments were "0" (zero) on a scale from 0-10. During an interview with Nurse C on 2/4/10 at 12:15 p.m., she stated that the nurse should have indicated "unknown" for the post medication assessments instead of indicating a "0." 2. Patient #27 Patient #27's flow sheets and the EMAR contained inconsistent pain documentation. Review of the patient's flow sheet for 2/3/10 indicated that from 12:00 p.m. to 8:00 p.m., the patient's pain was assessed as "0." However, review of the patient's EMAR indicated that the patient received Dilaudid 0.35 mg. IV at 1:47 p.m. for pain assessed as a 10 on a scale from 0-10. The patient also received another dose of Dilaudid 0.35 mg IV at 5:23 p.m. for a pain level of "6" on a pain scale of 0-10. 3. Patient #29 Patient #29's flow sheets and the EMAR contained inconsistent pain documentation. Review of the patient's EMAR revealed that the patient had an order for Acetaminophen 650 mg by mouth every four hours for pain as needed. On	A 438	reinforce that pain reassessments may be documented in the electronic Medication Administration Record (eMAR), progress notes, or flow-sheets until the new electronic health record ACD flow-sheets are implemented. Once the ACD system has been implemented, this information will flow from one system to another via an interface. In the interim, the hospital will address the issue with widespread education about the documentation of pain reassessment using the eMAR system. This education will include documenting as soon after reassessment as is possible and documenting pain reassessments by the end of shift when analgesics are administered. An auditing system will be implemented to monitor the assessment and management of pain. To implement the plan of correction for this deficiency, the hospital will integrate the required education into the plan developed to improve pain assessment and reassessment. The completion dates for correction of this deficiency are, education to the clinical nurse specialists, pain relief / Excellence Everyday Champions by 04/30/10, and education to RNs by 04/30/10. Updates on performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through the MGH General Executive Committee and through the Boards of Trustees Quality Subcommittee to the boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that the hospital is making progress as planned, and communicate progress and concerns to the boards through the mechanism above on a quarterly basis until	

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A 438	Continued From page 138 1/29/10, the patient received the Acetaminophen 650 mg at 5:55 p.m. for pain assessed as a "2" on a scale of 0-10. Review of the patient's flow sheet on 1/29/10 at 9:00 p.m., indicated that the patient's pain level was "0." However, review of the patient's EMAR indicated that the Acetaminophen post medication pain scale was not documented until 1/30/10 at 8:33 a.m., and indicated that the patient's pain level was still "2" on a scale from 0-10. During an interview with Nurse C on 2/5/10 at 12:05 p.m., she stated that the EMAR system was in the process of evolving and post pain medication assessments will be part of the updates to the system. 4. Patient #52 Review of Patient #52's active inpatient record on the morning of 02/04/10, revealed an incomplete medical record. In the presence of the RN M, Unit Nursing Director C and Clinical Nurse Specialist H, it was noted that there were no notes in the patient's paper-based chart for 12/25/09 through 01/25/10. The missing documents included lab reports, and consultants, nursing, social work, and doctor's progress notes. The patient was admitted to the on 12/25/09 from the hospital's with a diagnosis of According to an interview with the Nursing Director on (date & time), there had not been any interim or departmental transfers for this patient. During the interview, the CNS and the Unit Nursing Director were unable to state where or	A 438	the issue is resolved to prevent the deficient practice from recurring. Subsequent compliance will be reviewed through the hospital's quality and safety dashboards, which will include an explicit area to monitor Conditions of Participation. In addition to these periodic reviews, the MGH will flag all safety event reports related to Conditions of Participation so that ad hoc compliance issues can be addressed in a robust and timely fashion. To monitor and track compliance of the plan of correction, the hospital will use Healthstream, a learning management system to track completion rates of online RN education on pain documentation of the reassessment of pain. In addition, the MGH will audit a random sample of patient charts for appropriate documentation of reassessment of pain in accordance with the policy. At least 100 charts will be audited each month. The person responsible for implementing this plan of correction is the senior vice president for Patient Care Services and chief nurse. The instructions for thinning of the patient record will be included in the Patient Record Policy. The procedure is included in the training of all operations associates on the units. Clinical nurse specialists, nursing directors, environmental operations managers, administrative operations managers and operations associates will be educated about the procedure for thinning charts and oriented to the location of thinned records on their respective units.	04/30/10

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A 438	Continued From page 138 1/29/10, the patient received the Acetaminophen 650 mg at 5:55 p.m. for pain assessed as a "2" on a scale of 0-10. Review of the patient's flow sheet on 1/29/10 at 9:00 p.m., indicated that the patient's pain level was "0." However, review of the patient's EMAR indicated that the Acetaminophen post medication pain scale was not documented until 1/30/10 at 8:33 a.m., and indicated that the patient's pain level was still "2" on a scale from 0-10. During an interview with Nurse C on 2/5/10 at 12:05 p.m., she stated that the EMAR system was in the process of evolving and post pain medication assessments will be part of the updates to the system. 4. Patient #52 Review of Patient #52's active inpatient record on the morning of 02/04/10, revealed an incomplete medical record. In the presence of the RN M, Unit Nursing Director C and Clinical Nurse Specialist H, it was noted that there were no notes in the patient's paper-based chart for 12/25/09 through 01/25/10. The missing documents included lab reports, and consultants, nursing, social work, and doctor's progress notes. The patient was admitted to the on 12/25/09 from the hospital's with a diagnosis of According to an interview with the Nursing Director on (date & time), there had not been any interim or departmental transfers for this patient. During the interview, the CNS and the Unit Nursing Director were unable to state where or	A 438	Efforts to address improving the processes that led to the deficiency include distributing a retraining bulletin about medical record thinning to the clinical nurse specialists, nursing directors, environmental operations managers, administrative operations managers and operations associates on each unit, reminding them that they should thin records on a regular basis. Each unit will have clearly identified locations for the thinned records. The procedure for implementing the plan of correction for each deficiency includes a revision of the Patient Record Policy to address the proper storage of thinned records while patients are in-house. The proposed policy change will state: “For prolonged inpatient hospitalizations, it may be necessary to thin a patient's medical record. The record should be thinned according to Medical Record Handling procedures. The procedures can be found in the HIS department policy and procedure manual or in the Operations Associate (OA) Handbook. Once the record is thinned, it should be stored in a designated location on each unit until the patient is discharged.” Policy revisions will be approved by the Clinical Policy and Records Committee and the Medical Policy Committee. Once the revisions have been approved, staff will be informed of them. The hospital policy will be integrated into the Health Information Services department policy and procedure manual. The completion date for correction of this deficiency is 04/30/10. Updates on performance related to the deficiency cited will be reviewed on a	

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A 438	Continued From page 139 what had happened to the information. After approximately 20 -30 minutes of investigating; the CNS revealed that the chart had been thinned and should have been labeled accordingly. The information was not available. On 02/04/10 during an interview with the Unit's Nursing Director at approximately 10:30 a.m., she acknowledged that the staff had failed to implement the facility's "Thinning Records" policy. Upon requesting the Thinning Record Policy, a memo on the topic, not policy was furnished. The staff member handed the Regional Surveyor the memo stating "this is the thinning policy that we use." The memo, dated 5/21/09, detailed which parts of the record should be removed when thinning and how they should be designated and notated.	A 438		
A 441	482.24(b)(3) CONFIDENTIALITY OF MEDICAL RECORDS The hospital must have a procedure for ensuring the confidentiality of patient records. Information from or copies of records may be released only to authorized individuals. This STANDARD is not met as evidenced by: Based on medical record review and interview with staff, it was determined that the hospital failed to provide safeguards to ensure the confidentiality of patients' records. On 2/8/10 at 2:17 p.m., CNS CI provided a patient list for vaccination and restraint orders, tracheotomy (incision directly into the airway to help the patient breath), Warfarin (medication to thin the blood) teaching and heart failure instructions for . There were five patient names and medical record numbers	A 441	MGH stopped sending the email communication described in this report on 3/11/10. An on-going plan of correction is under development. This corrective action plan will demonstrate the hospital's procedure for ensuring the confidentiality of patient records. Specifically, the information from or copies of records will be released only to authorized individuals. Effective immediately, emailing of the patient-level detail quality reports is discontinued. The MGH will next evaluate and assess the current process of providing quality reports to nursing directors and other clinical staff to determine appropriate level of need-to-know access and provide an alternative form of information. Included in this effort will be staff from the Quality, Information Systems and Patient Care Services to review/identify who needs to receive this information and why, how frequently, review minimum necessary information being provided and determine an alternative and secure approach to providing	03/11/10

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A 438	Continued From page 139 what had happened to the information. After approximately 20 -30 minutes of investigating; the CNS revealed that the chart had been thinned and should have been labeled accordingly. The information was not available. On 02/04/10 during an interview with the Unit's Nursing Director at approximately 10:30 a.m., she acknowledged that the staff had failed to implement the facility's "Thinning Records" policy. Upon requesting the Thinning Record Policy, a memo on the topic, not policy was furnished. The staff member handed the Regional Surveyor the memo stating "this is the thinning policy that we use." The memo, dated 5/21/09, detailed which parts of the record should be removed when thinning and how they should be designated and notated.	A 438		
A 441	482.24(b)(3) CONFIDENTIALITY OF MEDICAL RECORDS The hospital must have a procedure for ensuring the confidentiality of patient records. Information from or copies of records may be released only to authorized individuals. This STANDARD is not met as evidenced by: Based on medical record review and interview with staff, it was determined that the hospital failed to provide safeguards to ensure the confidentiality of patients' records. On 2/8/10 at 2:17 p.m., CNS CI provided a patient list for vaccination and restraint orders, tracheotomy (incision directly into the airway to help the patient breath), Warfarin (medication to thin the blood) teaching and heart failure instructions for . There were five patient names and medical record numbers	A 441	this information to those who need it to take better care of patients. To improve the processes that led to the deficiency, the MGH will assure that quality information is delivered to only those with a need to know. The hospital will review and re-educate on the use and access of the information, including how to properly dispose of PHI if it is printed as outlined in MGH Disposal of PHI policy. The MGH will ensure through education and compliance attestation that if the information is accessed remotely, that the device being used is encrypted. To implement this plan of correction, the MGH will replace its procedure of sending emails containing PHI to specific clinical staff with an alternative solution involving a secure, password protected access to stored quality information to minimize risk of inappropriate disclosure. The hospital also will re-educate	

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A 441	482.24(b)(3) CONFIDENTIALITY OF MEDICAL RECORDS The hospital must have a procedure for ensuring the confidentiality of patient records. Information from or copies of records may be released only to authorized individuals. This STANDARD is not met as evidenced by: Based on medical record review and interview with staff, it was determined that the hospital failed to provide safeguards to ensure the confidentiality of patients' records. On 2/8/10 at 2:17 p.m., CNS CI provided a patient list for vaccination and restraint orders, tracheotomy (incision directly into the airway to help the patient breath), Warfarin (medication to thin the blood) teaching and heart failure instructions for There were five patient names and medical record numbers	A 441	staff members to ensure that they are knowledgeable and in compliance with policies related to safeguarding PHI. The completion date for correction of this deficiency is 3/11/10. Updates on performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through the General Executive Committee and through the Boards of Trustees Quality Subcommittee to the boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that the hospital is making progress as planned, and communicate progress and concerns to the boards through the mechanism above on a quarterly basis until the issue is resolved to prevent the deficient practice from recurring. Subsequent compliance will be reviewed through the	

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A 441	482.24(b)(3) CONFIDENTIALITY OF MEDICAL RECORDS The hospital must have a procedure for ensuring the confidentiality of patient records. Information from or copies of records may be released only to authorized individuals. This STANDARD is not met as evidenced by: Based on medical record review and interview with staff, it was determined that the hospital failed to provide safeguards to ensure the confidentiality of patients' records. On 2/8/10 at 2:17 p.m., CNS CI provided a patient list for vaccination and restraint orders, tracheotomy (incision directly into the airway to help the patient breath), Warfarin (medication to thin the blood) teaching and heart failure instructions for . There were five patient names and medical record numbers	A 441	hospital's quality and safety dashboards, which will include an explicit area to monitor our Conditions of Participation compliance. In addition to these periodic reviews the hospital will flag all safety event reports related to Conditions of Participation so that ad hoc compliance issues can be addressed in a robust and timely fashion. To monitor and track this plan of correction, the hospital will provide authorized access to only those staff with a specific need to know. The MGH will conduct surveillance rounds to assess for proper destruction of PHI if material is printed. The person responsible for implementing this plan of correction is the senior vice president for Strategic Planning and Information Management.	

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A 441	Continued From page 140 on the sheet. The sheet indicated that four of the 5 patients had a pneumovax vaccine and that one of the five patients had a tracheotomy. During the interview with CNS CI, she revealed that this information is generated to Nursing Directors and Clinical Nurse Specialists daily via e-mail at 7:00 a.m. Nursing Directors and Clinical Nurse Specialists can retrieve information from other units via e-mail. (See A147) This is continued non-compliance as evidenced by citations written by the Department of Public Health during the surveys of 3/26/09 and 8/13/09.	A 441		
A 449	482.24(c) CONTENT OF RECORD The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services. This STANDARD is not met as evidenced by: Based on medical record review and staff interviews, it was determined that the hospital failed to ensure that the medical record contained all necessary information reflecting the progress of the patient and the patient's response to treatment for 2 of 84 patients in the survey sample. (Patients #37 and #12) The findings include: 1. Patient #37 Patient #37's medical record did not contain information describing the progress of the patient's l, and did not describe the wound's response to treatment.	A 449	The plan to ensure that medical records contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services involves convening a multidisciplinary team to perform focused documentation reviews. This team will track and trend the prevalence of the issue and coordinate hospitalwide strategic education. This education will include a guideline for appropriate documentation as well as instructions about on how to report these issues. To improve the processes that led to the deficiency, the MGH will strengthen its reporting of issues and trends to clinical leadership (physician and nursing). The hospital also will increase its monitoring of this issue and investigate technical solutions to better identify and track repetitive documentation and improve the ease of reporting paper documentation issues that are discovered by clinical staff.	04/30/10

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A 449	Continued From page 141 There was no consistent description of the patient's wound from 12/31/09 through 2/2/10 even though dressing changes have been done daily by the Physician's Assistant. Review of the patient's medical record revealed that the Physician's Assistant was changing the patient's dressing and documenting the findings in the Progress Notes . The notes revealed the following information: Progress Note on 12/31/09 at 9:12 a.m., indicated lesion on . Incision and drainage of area at bedside. Gram stain and culture sent. Packing placed. Plan first change in the morning. Progress Note on 1/01/10 at 6:53 p.m., indicated lesion on opened at bedside on 12/31/ 09. Culture no growth. Wound packing changed this morning; plan to change daily. Progress Note on 1/02/10 at 3:27 p.m. indicated lesion on opened at bedside on 12/31/09. Culture no growth. Wound packing changed this morning; plan to change daily. Progress Note on 1/03/10 at 1:21 p.m. indicated lesion on opened at bedside on 12/31/09. Culture no growth. Wound packing changed this morning; plan to change daily. Infectious Disease (ID) Attending Team A 1/3/10 at 1:45 p.m. indicated incision and drainage-clean small incision.	A 449	To implement the plan of correction, the hospital will create a multidisciplinary team to conduct focused reviews of clinical cases to ensure that the documentation accurately reflects the patient's progress. The team will include representatives from the clinical areas, case management and Health Information Services (HIS) staff. The reviewers will report their results up through HIS to the Clinical Policy and Records Committee. In addition, the data will be submitted to Clinical and Quality leadership for further review and possible action. The completion date for correction of this deficiency is 4/30/10. Updates on performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through the MGH General Executive Committee and through the Boards of Trustees Quality Subcommittee to the boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that the hospital is making progress as planned, and communicate progress and concerns to the boards through the mechanism above on a quarterly basis until the issue is resolved to prevent the deficient practice from recurring. Subsequent compliance will be reviewed through the hospital's quality and safety dashboards, which will include an explicit area to monitor Conditions of Participation. In addition to these periodic reviews, the MGH will flag all safety event reports related to Conditions of Participation so that ad hoc compliance issues can be addressed in a robust and timely fashion.	

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A 449	Continued From page 142 ID Attending 1/4/10 at 5:30 p.m. indicated site of incision and drainage with healed incision. Although the 1/4/10 ID Attending note indicated that the site had healed, review of the patient's medical record revealed the following documentation: Progress Note on 1/07/10 at 11:57 a.m. indicated lesion on opened at bedside on 12/31/09. Culture no growth to date. Wound packing changed this morning; change daily. Progress Note on 1/08/10 at 9:58 a.m. indicated lesion on opened at bedside on 12/31/09. Culture no growth to date. Wound packing changed this morning; change daily. Cardiac Surgery Progress Note on 1/11/10 at 2:22 p.m. and drainage remains with wick in place, changing daily. Although there was a change in the patient's wound status documented on 1/15/10, this same documentation is repeated on 1/16/10, 1/17/10 and 1/18/10. Progress Note on 1/15/10 at 3:21 p.m. indicated incision and drainage remains with wick in place, dressing changed twice on 1/15/10 for pus like discharge, now serous sanguineous, can do daily dressing changes. Progress Note on 1/16/10 at 5:40 p.m. indicated incision and	A 449	To monitor and track compliance with the plan of correction, the hospital will consider documentation deficiencies as a patient safety issue, and staff will be encouraged to report them as such through the MGH's patient safety event reporting process. This solution will enable better tracking and trending of instances of noncompliance. A multidisciplinary team will conduct documentation tracers to review records for evidence of accurate documentation. Review results will be reported to the Clinical Policy and Records Committee, QAPI and service chiefs on a monthly basis. Staff found to be noncompliant will be educated on improving their documentation procedures. The person responsible for implementing this plan of correction is the director of Health Information Services.	

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A 449	Continued From page 143 drainage remains with wick in place, dressing changed twice on 1/15/10 for pus like discharge, now serous sanguineous, can do daily dressing changes. Progress Note on 1/17/10 at 6:39 p.m. indicated incision and drainage remains with wick in place, dressing changed twice on 1/15/10 for pus like discharge, now serous sanguineous, can do daily dressing changes. Progress Note on 1/18/10 at 2:03 p.m. indicated incision and drainage remains with wick in place, can do daily dressing changes. On 2/9/10 at 9:05 a.m., review of the patient's medical record and interview with Nurse C revealed that from 1/18/10 until 2/3/10 the same information was documented, ' and drainage remains with wick in place, can do daily dressing changes." Nurse C acknowledged that the patient's wound documentation was the same from 1/18/10 until 2/3/10, and it did not describe the patient's progress and/or response to treatment. Interview with Physician's Assistant A on 2/9/10 at 9:16 a.m., revealed that there are eleven or twelve Physician's Assistants for the and they rotate duties. Physician's Assistant A stated that a wound assessment should be documented daily each time a dressing change is performed. The assessment should include what the wound looks like including shape and size, if it is painful, warm, and if it is getting any better.	A 449		

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A 449	Continued From page 144 2. Patient #12 Patient # 12's medical record was reviewed on 10/10/10 at approximately 1:45 p.m. Patient #12 is a 57 year old who was admitted to the hospital on 02/07/10 with . Included with medication, diet and treatment orders, there was an order for pain which reads; Oxycodone 5-10 mg, Q6H PRN for pain. The order did not stipulate the level of pain intensity for which the medication is to be given nor which amount of medication was to be given. The lack of specificity of the order was acknowledged at approximately 2:30 p.m., during an interview with the ND #1.	A 449		
A 450	482.24(c)(1) MEDICAL RECORD SERVICES All patient medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures. This STANDARD is not met as evidenced by: Based on review of clinical records, facility's policies, and staff interview, it was determined that for nine of 84 patients, the hospital failed to ensure that clinical records were complete, legible and/ or authenticated. (Patients #16, #39, #41, #45, #65, #77, #PP1, #PP9 and #80) The findings include: 1. Review of the facility's policy and procedure titled, "Patient Record," approved by the Medical Policy Committee 7/2009, indicated the following: 3.4.1 Each clinician shall enter dated and timed	A 450	A multidisciplinary team will be convened to review the processes related to physician orders being present in the record prior to nurse initiation of diagnostics and therapeutics not within the RN scope of practice. The team will identify the root cause of noncompliance - such as lack of knowledge that a procedure requires a doctor's order, or that verbal orders have been written. The team will develop a plan for improvement based on root cause analysis. The plan will include improvement strategies, communication and education strategies and monitoring compliance strategies. In the short term, the unit-based nursing leadership and department-based medical leadership will review with clinicians the need for written doctor's orders for procedures not within the RN scope of practice. Though MGH standard practice is that RNs accept only verbal orders in emergency situations, medical and nursing leadership will use	04/01/10

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A 450	Continued From page 145 notes documenting their visits. 7.1 All entries in the patient record, written or electronic, will be authenticated by the author. An authentication will include the author's signature and credential along with either a pager number (the pager number must be legible) or printed first and last name to assist in uniquely identifying the author. 7.2 When multi-authored documentation occurs on a single form, each author is responsible for their own individual entries regarding dating, timing and authentication as outlined in this policy. Each form shall provide a means to determine who completed the entry. 7.3 The entire contents of the record must be legible. 2. Patient #77 Review of Patient # 77's medical record on 2/10/10 revealed the following: ~ Post-op anesthesia note written on 1/22/10 did not include the time and credential(s) of the author; ~ progress notes written on 1/22/10 contained illegible signature; did not include the authors credentials; and did not include either a pager number or printed first and last name; ~ Progress notes written on 1/23/10 did not include the time; ~ Progress notes written on 1/20/10 did not include the time; the signature of the author was not legible; the credentials of the author were not included; the pager number was illegible; ~ Post-anesthesia care unit (PACA) overnight admission form did not include the date, time and signature of the author.	A 450	this opportunity to review this policy as well. The intermediate process includes the completion of organizational risk assessment to identify those sites most vulnerable to physician orders not being written prior to nurse initiation of diagnostics and therapeutics. Meetings will be convened within those practice areas to identify system issues affecting compliance. Ideas for improvement will be generated, and based upon findings, next steps will be identified. For system issues that are distinctive to a particular practice area, nursing and physician leadership of that area will identify and implement improvements. For issues that seem to be institutionwide, the multidisciplinary team referenced above will identify systems improvements and coordinate implementation and education plans. The completion date for correction of this deficiency is 4/1/10. Updates on performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through the MGH General Executive Committee and through the Boards of Trustees Quality Subcommittee to the boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that the hospital is making progress as planned, and communicate progress and concerns to the boards through the mechanism above on a quarterly basis until the issue is resolved to prevent the deficient practice from recurring. Subsequent compliance will be reviewed through the hospital's quality and safety dashboards,	

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A 450	Continued From page 146 3. Patient #41 Review of Patient #41's medical record on 2/4/10 indicated the following: ~medical progress notes dated 1/31/10 and 2/4/10 did not include the credentials of the authors and the time. 4. Patient #45 Review of Patient 45's medical record on 2/8/10 showed the following: ~operative report dated 2/5/10 contained an illegible signature and no credentials, pager number or printed first and last name of the author; ~progress notes dated 2/6/10 contained an illegible signature and pager number, and no printed first and last name; ~surgical progress note lacked the date, time, and author's credentials. 5. Patient #39 Review of Patient #39's medical record on 2/3/10 showed the following: ~clinician's progress note lacked the date, time and author's credentials. 6. Patient #65 Review of policy titled "Bladder Irrigation Adult Manual" indicated under the heading "Applicable Policy Statement" A physician's order is required.	A 450	which will include an explicit area to monitor Conditions of Participation. In addition to these periodic reviews, the MGH will flag all safety event reports related to Conditions of Participation so that ad hoc compliance issues can be addressed in a robust and timely fashion. Based upon the improvement strategies implemented, the Center for Quality and Safety and the Patient Care Services Office of Quality and Safety will identify monitoring methods to evaluate the effectiveness of the corrective action. Data will be summarized quarterly and sent to QOC as described above. The person responsible for implementing the acceptable plan of correction is the director of the Patient Care Services Office of Quality and Safety. The MGH has strengthened its plan to ensure that all patient medical record entries are legible, complete, dated, timed and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures. The completion of the implementation of an electronic health record will ensure that clinicians are fully compliant with this requirement. In the interim, additional resources will be added to ongoing record reviews to increase scrutiny of medical records. The current workflow will be revised to include increased feedback to clinicians who are deficient on this standard. Monthly compliance status will be sent to all service chiefs to inform them of the documentation status of clinicians in their departments, and the compliance status will be reported to the Clinical Policy and Records Committee.	04/30/10

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A 450	Continued From page 147 Review of the Physician's Orders for 1/13/10 through 1/15/10 revealed the following: -1/13/10 at 12:05 p.m. Irrigate bladder q 4 h. -1/13/10 at 10:03 p.m. D/C Irrigate bladder q 4 h. Murphy drip, titrate to clear urine. There was no physician's order to manually irrigate the Foley catheter after beginning the Murphy drip and no orders to change the Foley catheter. Review of flowsheets from 1/13/10 through 1/15/10 for Patient #65 revealed the following: -1/13/10 at 1:00 p.m. irrigated Foley changed to Murphy gtt (drip) (large volume continuous irrigation of the bladder) -1/13/10 at 9:00 p.m. Foley catheter irrigated manually for large amount clot -1/14/10 at 3:00 p.m. Manually irrigated for large amount of clot -1/14/10 at 4:30 a.m. Manual flush clots in Foley -1/14/10 at 10:00 a.m. Irrigated manually for clots -1/14/10 at 10:00 p.m. Manually flushed 50 cc (cubic centimeter) -1/14/10 at 11:00 p.m. Manually flushed 40 cc -1/15/10 at 11:00 p.m. Unable to flush Foley catheter changed blood clot -1/15/10 at 4:00 p.m. Foley changed flush but unable to aspirate from Foley Review of Nursing Progress Notes from 1/13/10 through 1/15/10 for Patient #65 revealed the following: -1/13/10 at 7:30 p.m. shift 7 a.m. 7 p.m.- Hematuria - symptoms as above starting at 9:00 a.m., flushed with 30 cc NS (normal saline) with no clot return. Foley changed to a 3-way Foley, small clot at end of original catheter, Murphy gtt started and multiple clots were flushed.	A 450	To improve the processes that led to this deficiency, an improved communication plan will be developed to provide a formal reporting structure and escalation of efforts to address chronic noncompliance. A documentation training module will be created and available for clinicians who have been identified as noncompliant. This training will be included as part of the new clinician orientation process. In the future, the completion of the MGH's implementation of an electronic health record will help ensure that clinicians are fully compliant with this deficiency. To implement this plan of correction, staff resources will be shifted to increase the number of records reviewed. The hospital's current reporting will include more specificity to facilitate clinician correction of deficiencies. Clinicians with deficient documentation will be reported to the chair of the Clinical Policy and Records Committee weekly, and to the MGH chiefs of service monthly. A documentation education module will be used as a re-training tool for clinicians who do not demonstrate adequate compliance for documentation issues. Efforts will be made to supply CME credits for pre-emptive completion of this education module. The completion date for correction of this deficiency is 4/30/10. Updates on performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through the MGH General Executive Committee and through the Boards of Trustees Quality Subcommittee to the boards of both the MGH and MGPO, will review data relevant to this deficiency,	

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A 450	Continued From page 148 -1/14/10 at 5:30 p.m. F/C (Foley catheter) manually irrigated (symbol for approximately) q 2 o (2 hours) for large amount of clot as well. -1/14/10 time 6 p.m. shift 7-7 p.m. Continues on Murphy gtt for hematuria. Foley manually flushed q 2-3 hrs (hours) for thick bloody clots however urine has cleared this afternoon to a "kool aide" color. -1/15/10 at 7:15 a.m. Hematuria: Murphy gtt (drop) going through 3 way Foley clotting frequently frequent manual flushing. Foley completely clotted at midnight. d/c and replaced since platelets up, hematuria has slowed oozing from Foley insert site. -1/15/10 at 7 p.m. Foley catheter changed and appeared to be draining. During an interview with CNS CG and Staff Nurse CH for the Surgical Intensive Care Unit on 2/4/10 at 9:15 a.m., they stated that there were no specific orders to manually flush the Foley catheter it was in the procedure for the Murphy drip. CNS CG reviewed the orders for Patient #65 and acknowledged that there was no physician's order to manually irrigate the Foley catheter after beginning the Murphy drip and no orders to change the Foley catheter. 7. Patient #PP1 During the medical record review at on 2/5/10, the Health Questionnaire dated 12/30/09 for Patient #PP1 was not signed by the Physical Therapist. This finding was verified with ADM17. 8. Patient #PP9	A 450	ensure that the hospital is making progress as planned, and communicate progress and concerns to the boards through the mechanism above on a quarterly basis until the issue is resolved to prevent the deficient practice from recurring. Subsequent compliance will be reviewed through the hospital's quality and safety dashboards, which will include an explicit area to monitor Conditions of Participation. In addition to these periodic reviews, the MGH will flag all safety event reports related to Conditions of Participation so that ad hoc compliance issues can be addressed in a robust and timely fashion. To monitor and track compliance with this plan of correction, the MGH will identify those clinicians with deficient documentation, and they will be reported to the chair of the Clinical Policy and Records Committee weekly, the MGH chiefs of service monthly and the Quality Oversight Committee quarterly. This information will be reviewed with clinical staff, and improvement efforts will be tracked on an ongoing basis. The person responsible for implementing this plan of correction is the director of Health Information Services.	

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A 450	Continued From page 149 During medical record review on on 2/10/10, the General Release Informed Consent for Admission, Procedures, and Treatment for Patient #PP9 was missing corresponding staff signatures for their initials on the referenced documents. This finding was acknowledged by OT2. Additionally, signatures for PP9 were missing from the "One Time Treatment Record" and "Non Ventilator Charting Record." 9. Patient #80 Review of the record for Patient #80 dated 1/22/10 at 9:00 a.m., revealed an Flow Sheet, that indicated that the nurse inserted an IV to the patient's right wrist with a 20 gauge needle, but there was not a physician's order noted for the IV. The Nursing Manager, and the CNS both acknowledged on 2/5/10 at approximately 8:00 a.m., that the physician's orders and notes are done in the electronic record. Upon request for the orders for this patient, they were provided by the CNS. Review of the electronic physician's order and notes for Patient #80 did not reveal an order for the IV insertion. During a subsequent interview with the Nurse Manager on 2/10/10 at 10:30 a.m., she stated the order should have been in the clinical record. 10. Patient #16 During clinical record review for Patient #16 on 2/9/10, the record contained documentation including an Flow Sheet	A 450		

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A 450	Continued From page 150 dated 2/4/10 that was illegible and difficult to read. The information was provided to the Nursing Manager on 2/10/10 at 10:30 a.m. She stated during the interview that all documentation by staff should be legible. The hospital staff provided a hospital wide "Policy and Procedure: Patient Record" reviewed, revised and approved 7/09 that revealed: DOCUMENTATION, ACCESS AND SECURITY 7.1 All entries in the patient record, written or electronic will be authenticated by the author. An authentication will include the author's signature and credentials along with either a pager number or printed first and last name to assist in uniquely identifying the author. 7.3 The entire contents of the record must be legible.	A 450		
A 491	482.25(a) PHARMACY ADMINISTRATION The pharmacy or drug storage area must be administered in accordance with accepted professional principles. This STANDARD is not met as evidenced by: Based on observations, record review and interview with the staff, it was determined that the facility failed to properly store medications including intravenous antibiotic refrigerated medication, and failed to maintain the ı Pharmacy and drug storage areas in accordance with their pharmacy policy and procedure, and acceptable standards of practice. The findings include:	A 491	The following plan of correction will ensure that pharmacy and drug storage areas are administered in accordance with the CMS Hospital Conditions of Participation and accepted professional principles. First, the hospital will include standards for warming medications and IV solutions in its Medication Management standards policy. Specific requirements will include labeling medications and solutions with the date and time warming began in order to ensure stability. The MGH will use a temperature monitor log to monitor compliance. Second, the MGH will also update its Omnicell manual so that it correctly reflects the roles of various staff groups in the distribution of medications on units. Specifically, the manual will reflect that an Operations Associate will	04/30/10

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A 491	Continued From page 151 1. On the morning of 2/9/10 during a tour of the medication room on l, 1 250 ml (milliliters) D5W (dextrose 5% water) bag was noted in a blue bin, identified as the "pharmacy in box" by CNS F and Unit Nursing Director B. The 250 ml D5W bag did not contain any patient information/identifiers. It had a pharmacy applied label that read the following: Total amount of Vancomycin 1000 mg D5W 250 ml bag For IV use only Refrigerate Review of the facility's policy and procedure for medication distribution as outlined in the CEN-005 Omnicell Manual (Rev. 06-21-07), Section #3.1 Omnicell Distribution, revealed the following work instructions: " .... Hand-delivered drugs are placed in the pharmacy in-box, the blue drop off bin. The OA (Operations Assistant) must monitor this box hourly and place medications in the appropriate location ... " " .... If a medication is refrigerated, it will be tubed to the floor and placed in the pharmacy in-box. The technician will check this bin daily and place them in the Omnicell under refrigerated medication." During an interview with the assigned CNS, and the Nursing Director, they acknowledged that the Vancomycin 1000 mg/250 ml D5W bag should have been refrigerated. The Unit's Pharmacist stated during an interview on 02/9/10 at 10:00 a.m., that the Vancomycin	A 491	notify a nurse when patient-specific medications requiring refrigeration arrive on a care unit via the pneumatic tube system. A nurse will then place the medications in the refrigerated Omnicell cabinet. To address the processes that led to the deficiency, an educational program will inform nurses and pharmacists on the updates to the Medication Management standards and Omnicell manual described above. The educational program will also reemphasize the MGH's existing standard prohibiting food or drink in medication refrigerators. The initial phase of education will be conducted by the MGH's clinical nurse specialists, Excellence Every Day Champions, and pharmacists. In the longer term, a mandatory computer-based training module will be developed for nurses and pharmacists. This plan of correction will be implemented as follows. First, the Medication Management standard and Omnicell manual will be updated, and then approved by the appropriate committees. The Medication Management standard will be approved by the MGH's Medication Education Safety Approval Committee (MESAC), and the Omnicell manual changes will be approved by the Pharmacy's Associate Chiefs. Following these revisions and approvals, the MGH will implement the educational program described above. Policy Updates and approvals will be completed by 4/30/10. The initial phase of education by CNSs and pharmacists will begin by 4/30/10. While this initial phase of education will ensure MGH is in compliance with the CMS Hospital Conditions of	

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A 491	Continued From page 152 1000 mg/250 ml D5W bag should have been refrigerated. She stated that it was impossible to know when it arrived to the unit and why it had not been placed in the Omnicell's refrigeration section. 2. During a tour of , on 2/4/10 at 10:35 a.m., an observation revealed a warming cabinet. The warming cabinet registered a temperature of 38 degrees Celsius (C) or 100.4 degrees Fahrenheit (F). The warming cabinet contained 43 bottles of Silver Nitrate Solution .5%, 13 - 500 ml bottles of normal saline, and 2 - 50 ml bottles of sterile water. Hospira manufactured the normal saline and sterile water. None of the bottles bore a label or date when staff placed them in the warmer or when to remove them. Review of the label on one of the bottles of Silver Nitrate Solution indicated in part, "Store at controlled room temperature 20 - 25 degrees C 68 - 77 degrees F." The Director of the unit Staff CC acknowledged that there was not any manner of identification to determine when staff placed the bottles in the warmer but stated that it was little more than a 24 hour supply. Review of policy titled, "Medication Management Standards" provided to the survey team on 2/3/10 at 3:20 p.m., lacked evidence in the heading titled "Storage," that staff should ensure medications are stored at appropriate temperature. Under the heading titled "Monitoring" point #1 indicates "Refrigerated storage areas are monitored for appropriate temperature control." This section failed to address the monitoring of warming	A 491	Participation, a second phase of computer-based training modules for nurses and pharmacists is under development and will be ongoing. Updates on our performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through the General Executive Committee and through the Boards of Trustees Quality Subcommittee to the Boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that we are making progress as planned, and communicate our progress and concerns to the Boards through the mechanism above on a quarterly basis until the issue is resolved to prevent the likelihood of the deficient practice from reoccurring. Subsequent compliance will be reviewed through our quality and safety dashboards which will now include an explicit area to monitor our CoP compliance. In addition to these periodic reviews we will be flagging all safety event reports related to CoP issues so that ad hoc compliance issues can be addressed in a robust and timely fashion. To monitor the effectiveness of the plan of correction and ensure the deficiencies cited remain in compliance, the areas cited will be audited monthly. The audit results will be sent to the Liaison pharmacist and nurse director of each area. In addition, aggregate results will be sent to the associate chiefs of Nursing and MESAC Executive Committee. Any variation from the standards will be addressed by the MESAC Executive Committee. The Chief Pharmacy Officer is responsible for implementing the plan of correction outlined above.	

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A 491	Continued From page 153	A 491		

cabinets for appropriate temperature control.

Review of a letter dated 8/10/09 and provided to the survey team on 2/8/10 at 10:55 a.m. indicated in part, "Solutions for irrigation 1 Hospira's Aqualite plastic pour bottles, with their plastic screw cap intact and unopened, may be warmed up to 40 degrees C (104 degrees F) (unless specified otherwise on the product label), and for a period no longer than two weeks (14 days)."

Review of an e-mail from Teva Pharmaceuticals, manufacturer of the Silver Nitrate Solution, no date as to when the hospital received the e-mail and provided to the survey team on 2/9/10 indicated in part, "Regulatory Affairs Department has documentation that the Teva Pharmaceuticals Silver Nitrate Solution 0.5% is stable for 24 hours at 104 F and those conditions will not adversely effect the product. Please note the Silver Nitrate Solution labeling does not support these storage temperatures."

3. On 2/8/10 at 10:35 a.m., a quart of Golden Vanilla flavored Hood New England Ice Cream was observed in the freezer of the refrigerator. This refrigerator was located in the pharmacy of the . The refrigerator and freezer each had a bold green tag on the outside indicating, "Medication only, No Food or Drink."

During an interview on 2/8/10 at 10:35 a.m. with Pharmacist #1, it was stated this was not standard practice. Pharmacist #1 then took the ice cream out of the freezer and put it in the trash can.

During an interview on 2/11/10 at 9:45 a.m. with Pharmacist #2 and Pharmacist #3, both stated

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A 491	Continued From page 154 the expectation is there will be no food items in a medication refrigerator. They went on to say, if it were to happen again disciplinary action would be taken immediately.	A 491		
A 502	482.25(b)(2)(i) SECURE STORAGE All drugs and biologicals must be kept in a secure area, and locked when appropriate. This STANDARD is not met as evidenced by: Based on observations, interviews and review of facility's documents, it was determined that the hospital failed to ensure that drugs or biologicals were kept in a secure and in a locked area when appropriate. The findings include: On 2/5/10 during the morning hours during a tour of the located on , a Lidocaine 1% Ampoule 10 mg was found in an unlocked insertion cart. The PACU Nurse Manager and Senior Vice President Management of Care acknowledged the aforementioned observation. On 2/9/10 a review of the hospitals policy, "Medication Security," documented, Storage #5. "Medications not administered to a patient must be returned to secured storage or placed in the Pharmacy return bin as soon as possible. Placing medications on counter-tops, top of medicine carts, or any other location is not allowed." During tour of , on 2/3/10 at 1:55 p.m., an observation revealed an open three shelf cart with two bins on the top shelf and 3 bins on the second shelf. The cart sat outside the medication room for the unit in a busy hallway with visitors and staff walking by it. No	A 502	The following plan of correction will ensure that medications are kept in secure and locked areas as appropriate. The specific medication room cited in the report will be reconfigured so that it better facilitates access for medication carts. Additionally, the MGH will reeducate pharmacy and nursing staff on its Medication Management Standards and the responsibility each staff member has to comply with each of the standards. To address the processes that led to this specific deficiency, that education program will emphasize the security of medications. Initially, clinical nurse specialists and Excellence Every Day Champions will educate the nursing staff, while the Pharmacy Office of Quality, Safety and Compliance will teach the pharmacy staff. In the longer term, the MGH will develop a computer-based training module for mandatory nursing and pharmacy education. To implement the plan of correction outlined above, pharmacy and nursing service will work collaboratively to reconfigure the medication room cited in the report. The Policy and Compliance Sub-Committee of the Medication Education, Safety and Approval Committee (MESAC) will develop the multidisciplinary educational plan and the required content for nursing and pharmacy staffs. The medication rooms cited in the report will be reconfigured by 3/10/10. The initial	04/30/10

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A 502	Continued From page 155 staff member was close to the cart or monitoring the cart. Pharmacy Technician Staff CD was in the medication room stocking the medication dispensing unit with the door closed and locked. During an interview with the Chief of Pharmacy Operations (CPO) on 02/05/10 at approximately 10:30 a.m., she was asked, when medications are sent via the tub system to the nursing units is there any system to verify that the medications that were sent arrived on the unit. The CPO responded that there was no system of accountability to determine what was received on the units. Interview with Pharmacy Technician Staff CD at the time of the observation revealed that she leaves the cart in the hallway because it is too large to fit into the medication room. If nursing staff come in to get medications while she is filling the medication dispensing unit the drawers of the unit bump into the cart. Pharmacy Technician Staff CD further stated that she delivers medications to are the only units that he/she cannot bring the medication delivery cart into the medication room while filling the medication dispensing unit. Review of the medications on the cart included: -Omeprazole DR (delayed release) 20 mg capsule (32) - medication to treat too much acid in the stomach -Potassium Chloride 20 mEq (milliequivalent) tablet (15) - medication to replace potassium excreted by the body -Furosemide 20 mg tablet (33) - medication to	A 502	educational program for pharmacy and nursing staff will begin by 4/30/10. While this initial phase of education will ensure MGH is in compliance with the CMS Hospital Conditions of Participation, a second phase of computer-based training modules for nurses and pharmacists will be completed at a later date. Updates on our performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through our General Executive Committee and through the Boards of Trustees Quality Subcommittee to the Boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that we are making progress as planned, and communicate our progress and concerns to the Boards through the mechanism above on a quarterly basis until the issue is resolved to prevent the likelihood of the deficient practice from reoccurring. Subsequent compliance will be reviewed through our quality and safety dashboards which will now include an explicit area to monitor our CoP compliance. In addition to these periodic reviews we will be flagging all safety event reports related to CoP issues so that ad hoc compliance issues can be addressed in a robust and timely fashion. To monitor the effectiveness of the plan of correction and ensure ongoing compliance, the routine medication management audits performed by the Pharmacy will incorporate visual spot audits of the pharmacy technicians refilling Omnicell machines. These spot checks will verify that medication carts are not left unattended, and that medications in the medication room are not left on counters or in bins outside of the medication room. These reports will be reviewed monthly by the	

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A 502	Continued From page 156 increase urine production -Senna tablets (10) - medication used to relieve constipation -Thiamine 100 mg tablet (13) - medication used to replace the B vitamin Thiamine -Levothyroxine 75 mcg (micrograms) (12) - medication used to treat a thyroid deficiency -Mupirocin Nasal 2% ointment (3) - an antibiotic that can be used to treat skin infections -Ketorolac 15 mg/ml vial (5) - a non-steroidal anti-inflammatory medication used to treat pain -Hydrochlorothiazide 25 mg tablet (13) - medication to increase urine production -Simethicone 80 mg tablet (30) - medication used to relief stomach pain from excessive gas -Labetalol 300 mg tablet (11) - medication used to reduce the workload of the heart and help the heart beat more regularly, also reduces blood pressure -Benadryl 25 mg tablet (11) - medication used to treat allergic reactions -Trazodone 50 mg tablet (5) - medication used to treat depression -Buspirone 5 mg tablet (12) - medication used to treat anxiety disorders -Fragmin 5000 u (units) syringe (9) - medication used to thin the blood -Albuterol 0.83% vial (13) - medication to open the airways and make breathing easier -Ipratropium 0.02% vial (8) - medication to open the airways and make breathing easier -Lactulose 20 Gm (gram)/20 ml syrup cup (6) - medication to relieve constipation -Neutra-Phos packages (5) - medication used to replace phosphorus or to acidify the urine -Metoprolol 50 mg tablet (16) - medication used to reduce the workload of the heart and help the heart beat more regularly, also reduces blood pressure	A 502	Associate Chief of Pharmacy and the MESAC Executive Committee to ensure compliance. The Chief Pharmacy Officer is responsible for implementing the plan of correction outlined above.	

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A 502	Continued From page 157 -Metoprolol 25 mg tablet (10) -Simvastatin 20 mg tablet (12) - medication to lower cholesterol and fat in the bloodstream -NPH Insulin bottle (1) - a hormone used to control blood sugar levels -Colace 100 mg soft gel tablet (22) - medication to soften stool -Lipitor 80 mg tablet (10) - medication to lower cholesterol and fat in the bloodstream -Calcium 1250 mg tablet (15) - dietary supplement to replace calcium in the body -Tylenol 325 mg tablet (50) - medication to relieve pain -Warfarin 5 mg tablet (20) - anticoagulant medication -Prednisone 20 mg tablet (11) - medication used to treat inflammation -Metformin 500 mg tablet (1) - medication used to help control blood sugar in diabetics -Betamethasone 6 mg/ml 5 ml vial (1) - medication used to treat inflammation -Erythromycin ointment 1 Gm (1) - antibiotic used to treat bacterial infections -Ferrous gluconate 325 mg tablet (1) - supplement used to replace iron in the body Further interview with Pharmacy Technician Staff CD on 2/3/10 at 2:23 p.m., revealed that she has been working in this position since 2001 and has never been able to get the medication delivery carts into the medication rooms on During an interview with Pharmacy Staff CE and Pharmacy Staff CF on 2/3/10 at 2:40 p.m., she stated that medications should be secured at all times. Review of policy titled, "Medication Management	A 502		

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A 502	Continued From page 158 Standards" provided to the survey team on 2/3/10 at 3:20 p.m. under the heading of "Security" indicated in part, "...Only authorized persons, in accordance with the hospital's policy, law or regulations, can access medications."	A 502		
A 700	482.41 PHYSICAL ENVIRONMENT The hospital must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community. This CONDITION is not met as evidenced by: Based on observations, staff interviews, and review of the facility's policy and procedures, it was determined that the facility failed to be constructed, arranged, and maintained to ensure the safety of the patients. There are Hospital Regulation Standard level deficiencies as well as Life Safety Code Standard level deficiencies for all certified buildings. The accumulative effect that the facility does not meet the NFPA Life Safety Code Standard, therefore, the Condition of Participation: Physical Environment is not met and is a system wide failure. See Hospital Regulation and Life Safety Code Statements of Deficiencies for specific findings. (See A701 and A724)	A 700	Please see detailed plans of correction below for A701 and A724.	
A 701	482.41(a) MAINTENANCE OF PHYSICAL PLANT The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured. This STANDARD is not met as evidenced by:	A 701	The identified issues fall into three broad categories and one specific issue. The broad categories are: 1) Cleaning: dirty floor sinks, dusty ice machine air vents, dusty ceiling air vents, microwave ovens containing food crumbs, sticky refrigerator shelves, trash on closet floors, dusty stairwells and dirty linen in shower room; 2) Storage: items stored under sinks inappropriately, and closet storage of items above 18 inches from ceilings;	04/30/10

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A 701	Continued From page 159 Based on observations, staff interviews, and review of the facility's policies and procedures, it was determined that the facility failed to ensure that the hospital environment was maintained in a manner to assure the safety and well-being of all patients as evidenced by; dirty floor sinks, ice machines lacking air-gaps or backflow preventers, dusty ice machine air vents, items stored under sinks inappropriately, dusty ceiling air vents, microwave ovens containing food crumbs, sticky refrigerator shelves, closet storage of items above 18 inches of ceilings, stained ceiling tiles, trash on closet floors, dusty stairwells, inoperative out light bulbs, dirty linen in shower room, peeling paint in environmental services closet and shower room, standing water in ice machine trough, missing ceiling tiles, protruding escutcheon partially blocking a sprinkler head, and a black substance on a stained ceiling tile. The findings include: On 2/2/10 during a tour of the physical environment, the following was observed: Room - Environmental Services closet, floor sink with heavy accumulation of dirt, grime on the floor of the closet. -Dirty patient bath-tub with dust and dirt boxes of specimen containers stored under the sink inappropriately · f Environmental Services closet, floor sink with a heavy accumulation of dirt. I-ice machine without an air-gap or backflow preventer. Dust in ice machine air	A 701	and 3) Repairs: stained ceiling tiles, inoperative out light bulbs, peeling paint in environmental services closet and shower room, standing water in ice machine trough, missing ceiling tiles, protruding escutcheon partially blocking a sprinkler head, hole in wall, broken ice machine and broken floor tiles. The specific issue involves ice machines, including drain concerns and lack of air-gap and backflow preventers. All of the issues, concerns and locations identified in these categories have either already been fixed or are in the process of being addressed. Specific completion dates are listed in the body of this plan with a final completion date of 4/30/10. The efforts to address improving the processes that led to the deficiencies cited are as follows. Cleaning: All of the specific issues identified in the report will be addressed by a centralized cleaning team according to the dates outlined below. Following this initial central response, all of these areas will be cleaned on an ongoing basis in accordance with hospital policy. To ensure compliance, Environmental Services and Patient Care Services cleaning staff will receive refresher training, and involved staff must demonstrate proficiency with the specific cleaning issues and locations identified in A701. The goal is to have 95 percent of the approximately 800 staff members trained and assessed by 4/30/10. The final step in this improvement process is to implement ongoing quality assurance with staff on a quarterly basis. Nutrition and Food Services has added a process step that involves assessing and addressing galley cleanliness before tray assembly. Storage: All noncompliant items have been removed or reorganized as required. Staff re-education related to these	

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A 701	Continued From page 160 vents. Room · Environmental Services closet, dirty floor sink Room · Environmental Services closet, dirty floor sink -Box of laundry bags stored underneath sink Room 2131 Area under ice machine had heavy accumulation of dust and dirt. Room - Environmental Services closet, dirty floor sink. Room - Environmental Services closet, dirty floor sink. Room -Patient tub room- Oxygen canister stored in bathtub, dirt and dead spider in bathtub. Room Environmental Services closet, dirty floor sink. Galley Area · dust and dirt under ice machine. Room · Environmental Services closet, dirty floor sink. Room · Environmental Services closet, dirty floor sink. Room Environmental Services closet, dirty floor sink. dusty air vents on ice machine, no air-gap or backflow preventer on ice machine, microwave oven contained dried food and crumbs. Room -Environmental Services closet, floor sink contained dirty socks.	A 701	issues will be conducted in areas as needed. Repairs: All specific issues identified in the report will be addressed by a centralized team by the dates specified below. Key inpatient and ambulatory managers will receive refresher training on work order process to ensure that repair issues are identified and communicated for correction in a timely and effective manner. Regarding ice machine modifications, the MGH has undertaken a process to modify all ice machine drains to ensure that they have either air-gaps or backflow preventers. The specific responsibility for each of the 210 items identified has been assigned to individual staff members. Each issue will be worked on and overseen until that particular concern has been sufficiently addressed, recorded and verified as complete. Responsible department directors will ensure compliance and report to MGH Safety Committee on ongoing basis. The final completion date for correction of all deficiencies is 4/30/10. The completion dates for each type of issue identified are as follows: dirty floor sinks, complete by 4/10/10; ice machines lacking air-gaps or backflow preventers, complete by 4/30/10; dusty ice machine air vents, complete by 3/30/10; items stored under sinks inappropriately, completed 2/12/10; dusty ceiling air vents, complete by 3/20/10; microwave ovens containing food crumbs, completed 2/04/10; sticky refrigerator shelves, completed 2/04/10; closet storage of items above 18 inches of ceilings, completed 3/12/10; stained ceiling tiles, complete by 3/20/10; trash on closet floors, completed 2/04/10; dusty stairwells, completed 3/10/10; inoperative out light bulbs, completed 3/11/10; dirty linen in shower room, completed 2/12/10; peeling paint in environmental services closet and shower room, completed 3/11/10; standing	

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A 701	Continued From page 161 · ice machine lacked an air-gap or backflow preventer. Room boxes stored above 18 inches from the ceiling. Room · Environmental Services closet, dirty floor sink. - ice machine lacked air-gap or back flow preventer, ice machine air vents dusty. -Environmental Services closet dirty floor sink. Room - Environmental Services closet, dirty floor sink. Room - Environmental Services closet, dirty floor sink. Room Environmental Services closet, dirty floor sink. Room · Environmental Services closet, dirty floor sink. -ice machine air vents dirty. Room - Environmental Services closet, dirty floor sink. ·ice machine lacked air-gap or backflow preventer. Room · Environmental Services closet, dirty floor sink. Room · Environmental Services closet, dirty floor sink.	A 701	water in ice machine trough, completed 3/11/10; missing ceiling tiles, complete by 3/20/10; protruding escutcheon partially blocking a sprinkler head, completed 3/10/10; hole in wall, completed 3/11/10; ice machine broken, complete by 3/31/10; broken floor tiles, complete by 3/31/10. Comprehensive and thorough inpatient, ambulatory and support services surveillance rounds are conducted on an annual basis. Results from these surveillance rounds, including issues, trends and plans for improvement, are presented to the MGH Safety Committee, along with a description demonstrating how the hospital has incorporated systemic improvement actions into its Quality Assessment and Performance Improvement (QAPI) program to prevent the likelihood of the deficient practice from recurring. Updates on the hospital's performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/ MGPO Quality Oversight Committee (QOC). The QOC, which reports up through the MGH General Executive Committee and through the Board of Trustees Quality Subcommittee to the boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that the hospital is making progress as planned and communicate our progress and concerns to the boards through the mechanism above on a quarterly basis until the issue is resolved to prevent the deficient practice from recurring. Subsequent compliance will be reviewed through the institution's quality and safety dashboards, which will include an explicit area to monitor compliance with the Conditions of Participation. In addition to these periodic reviews, the MGH will flag all safety event reports related to Condition of Participation issues so that ad hoc compliance issues can	

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A 701	Continued From page 162 Environmental Services closet, dirty floor sink. Room Environmental Services closet, dirty floor sink. ı-ice machine lacked air-gap or backflow preventer, ice machine air vents dirty. On 2/3/10 the following observations were made during a tour of the physical environment. Room Environmental Services closet, dirty floor sink. -ice machine lacked air-gap or backflow preventer. Room Pantry-Environmental Services floor drain dirty. Room Environmental Services closet, 2 stained ceiling tiles. ı-ice machine lacked air-gap or backflow preventer, ice machine had dusty air vents. ı-ice machine with dusty air vents. ı- unused red bags stored under sink. Room - paper towels and cleaning materials stored under sink. Room - Environmental Services closet, dusty air vent.	A 701	be addressed in a robust and timely fashion. The MGH will follow specific procedures for monitoring and tracking to ensure that these plans of correction are effective and that the specific deficiencies cited remain corrected and/or in compliance with the regulatory requirements. Each of the 210 specific items listed in A701 is being tracked carefully, and its completion date is being recorded to ensure all items are addressed in a timely manner according to the plan. The surveillance rounds process will serve as the primary method for overseeing compliance. This process will enable the hospital to identify trends and prioritize further improvement opportunities. Additionally a handheld computerized cleaning quality assurance system will be used to monitor cleaning compliance and provide performance feedback. The person responsible for implementing these plans of correction is the senior vice president for Administration.	

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A 701	Continued From page 163 Room Environmental Services closet, dirty floor sink. Room J Supply Closet-dust and trash on floor. Room -boxes stored against ceiling, 2 stained ceiling tiles, ceiling air vent dusty. Area-ice machine had dusty air vents, lacked an air-gap or backflow preventer and had a sign " broken since 1/28/2010. " Area-ice machine lacked air-gap or backflow preventer, sink bottom contained rust stains and small black pellet type objects. Area-ice machine lacked air-gap or backflow preventer. Room Environmental Services closet, dirty floor sink. Room - Environmental Services closet, dirty floor sink. Area- ice machine lacked air-gap or backflow preventer. Room - Environmental Services closet, dirty floor sink. Room Environmental Services closet, dirty floor sink. Area-ice machine lacked air-gap or backflow preventer, ice machine air vents dusty. Room Environmental Services closet, dirty floor sink. - dusty	A 701		

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A 701	Continued From page 164 -2 stained ceiling tiles. Kitchen Area-ice machine lacked air-gap or backflow preventer, under sink shelf dirty with granules of a gray substance. Room Environmental Services closet, dirty floor sink. Hall Closet- medical records stored from floor to ceiling in locked hall closet. -dust and dirt on landing. Area-ice machine lacked air-gap or backflow preventer. Room 800J02-Environmental Services closet, dusty air vent. Area-ice machine lacked air-gap or backflow preventer. Room Environmental Services closet, dirty floor sink, stained ceiling tile. Area-ice machine lacked air-gap or backflow preventer, sink contained storage of 4 boxes of tea bags inappropriately. Room Environmental Services closet, stained ceiling tile. Room -dusty ceiling vent Area-ice machine lacked air-gap or backflow preventer, ice machine air vents dusty. Room Environmental Services closet, dusty ceiling air vent. -microwave oven contained an unknown spilled liquid and food particles.	A 701		

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A 701	Continued From page 165 Area-ice machine tube drainage tube approximately 2 inches into sink and lacked a backflow preventer. Room Environmental Services closet, overhead light inoperable, floor mop stored in sink. On 2/4/2010 the following observations were made on a tour of the physical environment. Area-ice machine lacked an air-gap or backflow preventer, refrigerator had sticky shelves with food crumbs, shower room contained dirty linen lying on floor and shower chair. Room -Environmental Services closet had a dirty floor drain and dusty ceiling air vent. Room -ice machine drain pipe lacked an air-gap or backflow preventer. -dusty ceiling air vent. Area-trash including plastic ware, cups, dust and dirt under refrigerator, ice machine had dusty air vents. Room opposite dusty ceiling air vent Room -contained unlabeled bar of soap and body powder in shower stall. ice machine lacked air-gap or backflow preventer, ice machine air vents dusty.	A 701		

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A 701	Continued From page 166 Galley-ice machine lacked air-gap or backflow preventer Room - Environmental Services closet had a dirty floor drain and a hole in the wall above the floor sink approximately 3 inches high by 8 inches wide. Room 900T1-restroom, dusty air vent Room -wall paint peeling above floor sink. Room dusty ceiling air vent in bathroom. Room broken tile on floor of bathroom. Room dusty ceiling air vent in bathroom. Medical side-ice machine lacked an air gap or backflow preventer. Room boxes were stored not greater than 18 inches of ceiling. Room 800T1-dusty vent in bathroom. Room opposite supply room-dusty vent, dusty floor. Room -stained ceiling tile, personal care items stored not greater that 18 inches of ceiling. Room dusty vent in bathroom. Room dusty ceiling air vent in bathroom. Area-ice machine lacked an air-gap or backflow preventer. paint peeling around floor sink. Area -ice machine lacked an air-gap or backflow preventer. -2 stained ceiling tiles	A 701		

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A 701	Continued From page 167 Roon Environmental Services closet had a dirty floor drain and dusty air vent Room)-dusty air vent in tub room Room -dusty air vent in bathroom. Room -overhead light inoperable in tub room. Room -2 stained ceiling tiles in the clean utility room. Room 1 Environmental Services closet had a cracked wall approximately 3 inches by 10 inches and paint peeling above the floor sink. Room Environmental Services closet had a dirty floor drain. Room Environmental Services closet had a dirty floor drain. Area-ice machine lacked an air-gap or backflow preventer. Room Environmental Services closet had a dirty floor drain. Room ceiling paint peeling in shower room. Room -a live insect in ceiling light of environmental services closet. Room -dusty ceiling air vent in patient shower room. Area -ice machine lacked air-gap or backflow preventer. Room -closet of Physical Therapy Department had dirty floor with dust and dirt. Room Environmental Services closet had	A 701		

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A 701	Continued From page 168 a dirty floor drain. Room Respiratory Services closet had an inoperable ceiling light. Area -ice machine lacked an air-gap or backflow preventer Room Environmental Services closet had a dirty floor drain. On 2/5/2010 the following observations took place during a tour of the hospital's physical environment. Room -closet with inoperable ceiling light, items stored above 18 inches from the ceiling. Room - Environmental Services closet had a dirty floor drain. Area -ice machine lacked air-gap or backflow preventer, standing water in trough of ice machine, ice machine air vents dusty, stained ceiling tile. Sterile operating room equipment packaging area-dusty ceiling air vents. Room Environmental Services closet had a dirty floor drain. Room -floor sink wall were dirty with paint and lathe peeling in an area of approximately 2 feet by 3 feet in diameter. Environmental Services closet had a dirty floor sink.	A 701		

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A 701	Continued From page 169 Room 800J1- Environmental Services closet had a dirty floor sink, dusty air vent. Room 2 dusty air vents in ladies bathroom Environmental Services closet had a dusty ceiling air vent. Endocrine/Reproductive Room - Environmental Services closet had a dirty floor drain and dusty ceiling air vent. Room -stained ceiling tile. Room -dusty ceiling air vent. Room - Environmental Services closet had a dirty floor sink. Room - Environmental Services closet had a dusty ceiling air vent. Room Environmental Services closet had a dirty floor sink, dusty ceiling air vent and stained ceiling tile. Room -2 missing ceiling tiles, ceiling air vent dusty. On 2/8/2010, the following observations were made during a tour of the hospital's Room -ceiling air vent in bathroom dusty. Room Environmental Services closet had	A 701		

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A 701	Continued From page 170 a dirty floor sink, missing ceiling tile. Room -dusty ceiling vent in bathroom. 1st floor-Medical Walk-in Room -ceiling vent dusty in bathroom. Room - Environmental Services closet had a dirty floor sink and 2 stained ceiling tiles. Area ice machine lacked an air-gap or backflow preventer. Area -ice machine lacked air-gap or backflow preventer. Area -ice machine lacked air-gap or backflow preventer. Room -ceiling air vent dusty in supply closet. Room -dusty ceiling air vent in environmental services closet. Room -ceiling air vent dusty in bathroom 2nd floor hallway Room - Environmental Services closet had a dirty floor sink. Room -paper towels stored within 18 inches of ceiling. Room ice machine lacked air-gap or backflow preventer; sink had plastic bags stored underneath inappropriately. Room -dusty ceiling air vent dusty, trash can overflowing. Room items stored above 18 inches from ceiling.	A 701		

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A 701	Continued From page 171 Hallway- Environmental Services closet had a dirty sink. Center Room -dusty ceiling air vent in the clean storage room. Room -storage of boxes of dry ice above 18 inches of ceiling Room · Environmental Services closet had a dirty sink. Area -ice machine lacked an air-gap or backflow preventer On 2/10/2010, the following observations were made during a tour of the physical environment for the following Room under sink storage of chemicals ' , dirt and debris on shelf. Room stained ceiling tile in clean utility room, dust in ceiling air vent, boxes stored above 18 inches of ceiling. Area · stained ceiling tile with a black substance. Room -dusty ceiling air vent in bathroom. Room -ceiling light inoperable in storage closet. area-stained ceiling tile, 11 chairs with dirty upholstery. Room stained ceiling tile in reception area, escutcheon partially blocking sprinkler head. Room stained ceiling tile in	A 701		

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A 701	Continued From page 172	A 701		

Rear entrance-stained ceiling tile.
Elevator light bulbs inoperative.

Outside Room -ice machine lacked an air-gap or backflow preventer.

The observations of the Physical Environment tour were confirmed by the following staff that was present at various times during the tours:
Staff Specialist,
Senior Construction Manager Buildings and Grounds
Patient Safety Staff Specialist
Quality and Safety Nurse
Senior Vice President Management of Care
Plumbing Shop Supervisor

Review of the 2006 International Plumbing Code section 802.2.1- Air-gap. "The air-gap between the indirect waste pipe and the flood level rim of the waste receptor shall be a minimum of twice the effective opening of the indirect waste pipe."

On 2/10/10 review of policy CS968, Cleaning, revealed the following:
Section 7.22 "The following guidelines must be adhered to: Supplies stored 6-8 inches off the floor to facilitate cleaning of floors ... Supplies should be stored at least 3 feet away from a water source ...Supplies must be at least 18 inches from the sprinkler ... "

Section 7.24 Soiled Linen, "Soiled linen should be placed in designated linen bags."
Section 8.8 Guidelines for the Use of Sterilizing

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A 701	Continued From page 173 Processes, Storage of Sterile items, "Sterilized items should be stored in an area that is well ventilated, and promotes protection against dust, moisture, insects, and temperature and humidity extremes." A review of the cleaning specifications for revealed the following; Night Cleaning, Bathrooms, Monthly, "Dust all ceiling vents." Cleaning Specific for Medical Space, "Dust all ventilating, air conditioning covers and grills." On 2/12/10 a review of a facility policy titled, "Care of Non-Critical patient care Equipment Storage of Clean/Sterile Supplies was reviewed. The review revealed the following; Section C "This equipment does not make direct contact with the patient or makes contact only with the patient's skin ...The major requirement for non critical equipment is cleaning to remove dirt and soil and destruction of the ordinary vegetative bacteria. Non-critical equipment requires intermediate-or low level disinfection as can be achieved by cleaning with hospital-approved disinfectant." Procedures, A. Cleaning, "Equipment must be free of gross soil for surface disinfection to be accomplished. Heavy soiled items must be cleaned first with a detergent or combination detergent disinfectant to remove soil. Disinfectant is then applied to clean surface."	A 701		
A 724	482.41(c)(2) FACILITIES, SUPPLIES, EQUIPMENT MAINTENANCE Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality. This STANDARD is not met as evidenced by:	A 724	The MGH will take appropriate steps to address and correct the deficiencies identified in Facilities, Supplies, Equipment Maintenance section. Enzymatic solution: The Sterile Processing Department's (SPD) procedure for collecting reusable instruments for centralized reprocessing will change. The current process involves SPD staff filling the collection bin with an	03/31/10

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A 724	Continued From page 174 Based on observations, staff interviews, and review of the facility's policies and procedures, it was determined that the facility failed to ensure that hospital's equipment was maintained in a manner to assure the safety and well-being of all patients as evidenced by, failure to check emergency equipment, dirty code cart, failure to inspect eye-wash station, and no changing enzymatic solution containers in a timely manner. The findings include: On 2/3/10 the following observations were made during a physical environment tour: : Galley-ice machine had a sign posted, "broken since 1/28/2010." Dirty instrument container No documentation of date when Enzymatic Cleaner changed. -emergency eye wash station not cleaned according to policy The eyewash station lacked documentation of weekly inspection for the following periods, 4/13/09 to 4/27/09, 6/29/09 to 7/17/09, 11/2/09 to 2/3/10. Soiled Utility Room-container of Enzymatic cleaner had a date of 1/26. There were instruments in the container. The date of the observation was 2/3/10. On 2/4/10 the following observations were made on a tour of the physical environment.	A 724	place instruments in the solution to soak until the SPD staff pick up the instruments. The bin is filled with fresh solution each time the instruments are collected. After collection, the instruments are returned to SPD, where they undergo a full reprocessing procedure, including washing and decontamination in an automated washer/decontamination unit before sterilization. Under the new process, collection bins will no longer be filled with enzymatic solution. Rather, instruments will be placed in a dry bin for pick up by SPD staff. Eye wash stations: According to policy, eye wash stations must be checked and documented and any issues identified must be addressed on a weekly basis. Staff in the (/ will be educated about the policies and proper procedures for maintaining eye wash stations by 3/25/10. Code carts: According to policy, code carts must be checked and documented and any issues must be identified and addressed on a daily basis if the site of the code cart is a open to patients dail. Staff in the / will be educated on the policies and proper procedures for maintaining code carts by 3/25/10. Repair issues: a broken ice machine will be corrected by 3/31/10, and the inoperative light bulb issue was corrected 3/11/10. Additional plan details for addressing these two issues are included in the A701 plan. The MGH is focused on improving the processes that led to the deficiency identified by the surveyors. Leadership from Infection Control and from Sterile Processing Department have consulted, and they determined that given the low volume and type of instruments involved, the minimal level of bioburden on the instruments	

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A 724	Continued From page 175 Room - container of enzymatic solution dated 2/2. The container contained instruments. Room -Soiled Holding room-container of Enzymatic cleaner dated 1/26 On 2/8/10, the following observations were made of the Emergency Code Cart-#111 dusty Gomco machine and tubing, top shelf of cart dusty and had a brown stain. Emergency Code cart lacked documentation of being inspected on 2/1/10 and 2/2/10 2nd floor Eye Wash Station-no container of eye wash solution in holder. Enzymatic container-no date when cleaning solution changed. On 2/10/10, the following observations were made during a tour of the physical environment; Elevator light bulbs inoperative.	A 724	collected and the fact that a full enzymatic wash and high temperature decontamination process is completed within SPD before sterilization, it is not necessary to pre-soak instruments in enzymatic detergent before pick up from SPD. In addition, it was determined that this soak had not been intended to be the primary part of the instrument cleaning process and was identified as an unnecessary step. Implementing this plan of correction involves the SPD management team revising the current procedures for instrument pick-up. All locations participating in the SPD instrument pick-up program will be notified that the bins will no longer be filled with enzymatic solution by SPD staff and that pre-soaking will not be required. SPD staff will be retrained in this new process. The completion date for correction of this deficiency is 3/31/10. The hospital will incorporated systemic improvement actions into its Quality Assessment and Performance Improvement (QA/PI) program to prevent the deficient practice from recurring. Updates on performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through the MGH General Executive Committee and through the Board of Trustees Quality Subcommittee to the boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that the MGH is making progress as planned, and communicate the progress and any concerns to the boards through the mechanism above on a quarterly basis until the issue is resolved to prevent the	

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A 724	Continued From page 176 The observations of the Physical Environment tour were confirmed by the following staff that was present at various times during the tour. Staff Specialist Senior Construction Manager Buildings and Grounds Patient Safety Staff Specialist Quality and Safety Nurse Senior Vice President Management of Care Technical Director Technical Manager Manager On 2/10/10 a review of facility policy and procedure titled Code Cart/Emergency Equipment in Ambulatory Settings documented the following; Policy, 6. "Defibrillators and Suction devices are checked daily on days of unit/department operation. A Code Cart/Emergency Equipment record will be maintained for all code carts and emergency equipment. Staff who have checked the lock and emergency equipment will record date, time, and signature. The current record will be located at the code cart." On 2/9/10, the following Safety Manual section 1.4.2 was reviewed, "Supervisors need to assure the weekly activation of any plumbed eyewash and/or equipment installed in their unit to flush the lines and verify equipment operation. This check is also to be documented and the record maintained on the unit." On 2/10/10 a review of the facility policy, Cleaning Sterilization and Disinfection page 25 Guidelines for Use of Cleaners indicated,. #12. "Enzymatic solution may be used as a soak for multiple instruments. Solution should be mixed fresh at least daily and changed as often when visibly	A 724	likelihood of the deficient practice from recurring. Subsequent compliance will be reviewed through the hospital's quality and safety dashboards, which will include an explicit area to monitor Conditions of Participation compliance. In addition to these periodic reviews, the MGH will flag all safety event reports related to Condition of Participation issues so that ad hoc compliance issues can be addressed in a robust and timely fashion. The procedure for monitoring and tracking to ensure this plan of correction is effective and that the specific deficiencies cited remain corrected and/or in compliance with the regulatory requirements will involve daily review of pick-up sheets to check that the instrument pick-up schedule has been completed. The person responsible for implementing this plan of correction is the director of the MGH Sterile Processing Department.	

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A 724	Continued From page 177 soiled." #13. Soaking container must be labeled and dated." 14. Discard Enzymatic-cleaning solution after each use. Solution may be poured down sanitary waste system."	A 724		
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 upon observations, staff interviews and review of infection control policies, it was determined that the hospital failed to provide a sanitary environment in order to avoid the transmission of infections, communicable diseases. The hospital failed to develop, implement and maintain an active, hospital -wide program for the prevention, control and investigation of infections and communicable diseases. (See A749 & A750) The findings include: 1. The Infection Control Officer (ICO) failed to have an active hospital wide infection control program and ensure infection control policies were being followed to control the spread of infections and communicable diseases. 2. The Infection Control Officer (ICO) failed to control infections throughout the hospital when the ICO failed to monitor sanitary conditions	A 747	See responses to A749 and A750 below.	

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A 747	Continued From page 178 throughout the hospital. 3. The Infection Control Officer (ICO) failed to maintain an accurate and up to date log of infections and communicable diseases.	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 observation, document review, and staff interview, it was determined that the facility failed to ensure the provision of a sanitary environment and to have processes in place that identified and investigated the potential infectious disease processes present in 1 of 83 patients on admission. (Patient #66) The findings include: Review of the Infection Control Program 2010 received 2/9/10, revealed that one of the infection control priorities is - Daily cleaning and disinfection of high touch surfaces and bathrooms in patient rooms. The evaluation for this priority is - Monitor new HAI (Healthcare Associated Infection) cases in real time for clusters and review rates quarterly. Observations on 2/8/10 at 10:25 a.m., revealed Staff CJ, Unit Service Associate (USA) mop room 910 on with a solution of Virex 256.	A 749	1. The plan for correcting the deficiency cited is as follows. The competency of all USAs will be assessed with regard to their ability to perform patient room cleaning, including procedures specific to rooms housing patients on precautions. The managers will observe unit staff performing room cleaning, and record observations using Walsh Integrated handheld devices programmed with current hospital approved policies around cleaning. Deficiencies will be noted and immediate re-training will be provided as needed. The verification of competence of all 300 USAs within our department to perform cleaning of patient rooms following prescribed hospital procedures will be completed by 4/30/10. MGH Patient Care Services purchased the Walsh Integrated Handheld System in December 2009. The system contains a database of hospital real estate and employees, structured to support systematic, regularly scheduled quality assurance auditing of patient room cleaning by each employee. Upon performing the compliance rounds, management will use the database to generate QA reports, target specific areas for re-training, and provide performance feedback. Updates on our performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality	04/30/10

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A 749	Continued From page 179 Staff CJ, USA exited the room removed the mop head from the mop, removed gloves sanitized hands, replaced gloves. The floor remained wet for 6 minutes. At 10:30 a.m. Staff CJ, USA entered room 910 with a bottle containing Virex 256. Staff CJ, USA sprayed the top of a footstool with the Virex 256 and wiped the solution off. Staff CJ, USA then sprayed the cloth with Virex 256 and wiped a shelf on the far side of the room next to the window that held a radio and wiped around the radio sitting on the shelf. Staff CJ, USA then used the Virex 256 and sprayed the counter to the right of the sink and wiped it off and then sprayed the counter to the left of the sink and wiped it off. Staff CJ finished by spraying the cloth with Virex 256 and wiping the inside of the sink. Observations on 2/8/10 at 10:37 a.m. revealed, Staff CK, Registered Nurse (RN) enter room and remove a large blue recliner. Staff CK, RN sprayed Virex 256 on the chair and wipe the cushion, back, and along the sides of the chair. Observations on 2/10/10 at 10:59 a.m. revealed, Staff CL, USA spray the sink outside of room on with Virex 256. Staff CL, USA walked approximately 7 feet to the cart containing cleaning supplies and retrieved a dry cloth. Staff CL, USA wiped the Virex off of the sink with the dry cloth. Staff CL, USA wet the cloth in the sink and used it to wipe the metal covered corner of the wall adjacent to the sink. Staff CL, USA sprayed Virex 256 on the metal covered corner while wiping it with the wet cloth. Staff CL, USA used the same wet cloth to wipe the door frame of room 710. Staff CL, USA then removed gloves sanitized hands and replaced gloves. Staff CL, USA placed a clean dry cloth into a solution of	A 749	Oversight Committee (QOC). The QOC, which reports up through our General Executive Committee and through the Boards of Trustees Quality Subcommittee to the Boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that we are making progress as planned, and communicate our progress and concerns to the Boards through the mechanism above on a quarterly basis until the issue is resolved to prevent the likelihood of the deficient practice from reoccurring. Subsequent compliance will be reviewed through our quality and safety dashboards which will now include an explicit area to monitor our CoP compliance. In addition to these periodic reviews we will be flagging all safety event reports related to CoP issues so that ad hoc compliance issues can be addressed in a robust and timely fashion. Results of routine surveillance rounds including issues, trends and plans for improvement will be presented to the MGH Safety Committee. The title of the person responsible for implementing this plan of correction is the Senior Vice President for Patient Care Services and Chief Nurse. 2. The hospital acknowledges that Contact Precautions Plus were not in place for patient #66. However, based on our document review and staff interviews, we maintain that the hospital followed the appropriate process to identify and investigate potential infectious disease processes present in this patient, and that Contact Precautions was the appropriate level of protection instead of Contact Precautions Plus.	

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A 749	Continued From page 180 Virex 256 sitting on the cleaning supply cart. Staff CL, USA wrung the cloth to a damp state and wiped the metal wrapped corner by room 708 and then dried it. Staff CL, USA placed a clean dry cloth into a solution of Virex 256 sitting on the cleaning supply cart. Staff CL, USA wrung the cloth to a damp state and wiped the monitor with the first damp cloth then dried it with a second cloth. Staff CL, USA repeated this process with the keyboard, picture on the wall, chair rail along the wall and window. Staff CL, USA wiped the top of the heating system and window sill with the damp cloth and did not wipe it with the second cloth. On interview on 2/10/10 at 11:21 a.m. Staff CL, USA stated, I use a wet cloth and then dry it off with another cloth. No, I don't leave it wet. Observation on 2/10/10 at 11:32 a.m. on side of the unit across from the medication dispensing area, revealed Staff CM, USA dip a clean dry cloth into Virex 256, wring the cloth to a damp state enter the room and wipe the top of the soiled linen container first and then proceed to wipe the top of the bedside table. The table top remained wet for approximately 2 minutes. Interview with Nursing Director of , Staff CH at the time of the observation indicated that it would not be appropriate to use the same cloth to clean the soiled linen hamper and then a bedside table. The Nursing Director of), Staff CH asked to interrupt the cleaning process and redirect Staff CM, USA. Interview on 2/10/10 at 11:45 a.m. with Operations Manager for Environmental Care,	A 749	It is accurate that the documentation from 1/29/10 in the indicated the patient "continued to have loose stool and was incontinent." However, review of the record and interviews with nursing staff indicated that the patient, a paraplegic, did not have symptoms on admission on 2/3/10 which would have required him to be placed on Contact Precautions Plus for C. diff. Also, his most recent stool sample prior to this admission had been negative for C. diff. toxin. On admission the patient was placed on Contact Precautions for MRSA and VRE according to Infection Control (IC) policy because of his history of these organisms. These organisms are flagged as they are known to colonize and persist in low numbers on skin (MRSA) and in the GI tract (VRE) and thus require isolation precautions on readmission. C. diff. is not flagged continuously as it does not persist in the same manner. The C. diff. flag would have been re-activated if this patient had a new stool sample positive for C. diff toxin upon admission, or later in the course of his stay. A review of this patient's record revealed that on admission on 2/3/10 the patient was recommended to be treated prophylactically with oral vancomycin to prevent a re-occurrence of C. diff disease (CDAD) as he had a history of CDAD in 11/09 and was going to be placed on antibiotics on admission for treatment of a different condition. Prophylaxis was recommended because treatment with antibiotics during this admission would increase his risk for a re-occurrence of CDAD. When this case was identified by the CMS surveyor, IC Unit staff placed the patient on	

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A 749	Continued From page 181 Staff CP indicated that the top of the soiled linen hamper should be cleaned last. Observation on 2/10/10 at 12:20 p.m. revealed Staff CO, USA enter the negative pressure room on the north west corner of wearing gown and gloves. The room had a Precautions plus sign to the right side of the door. This is the sign used when the patient has Clostridium difficile (bacteria that causes symptoms ranging from diarrhea to life threatening inflammation of the bowel). Staff CO, USA took a cloth with Virex 256 that was still dry around the edges and wiped the door handle, window, front of a 5 drawer supply cart, and the wall behind the bed. Staff CO, USA exited the room placed his/her left hand on the left front corner of the housekeeping supply cart and retrieved supplies to clean the bathroom in the isolation room. Staff CO did not remove gloves or sanitize hands. Interview on 2/10/10 at 12:25 p.m. with Operations Manager for Environmental Care, Staff CP indicated that USA staff is to use a bleach solution when cleaning isolation rooms for Clostridium difficile. Observation of the housekeeping supply cart at 12:32 p.m. revealed a divided bucket on top of the cart with a bottle of Virex 256 inside. Both sides of the divided bucket were dry. Further interview on 2/10/10 at 12:32 p.m., with Operations Manager for Environmental Care, Staff CP revealed that the bucket should have been filled with Virex 256 solution and that the cloth should be saturated with the Virex 256 solution to clean a room. Environmental surfaces should stay wet 5-6 minutes after cleaning with	A 749	Contact Precautions Plus as a precautionary measure until the questions raised by the surveyor could be answered. It was later determined that the patient had been isolated appropriately on Contact Precautions for MRSA and VRE and that he did not have active CDAD, thus the C. diff specific precautions (Contact Precautions Plus) sign was taken down and replaced with the original Contact Precautions sign. In the 3 hand hygiene observations noted in this report, MGH staff was compliant with the hand hygiene practice required for Contact Precautions. The hospital acknowledges that on 2/2/10 at 11:55 a.m. in , two white packs with blue labeling were observed in a patient nourishment refrigerator. The patient refrigerator was labeled "Food only." The packs were identified as "Cryotherm" cold packs. The packs had the hand written word "pathology" in black marker printed on one side. The two "Cryotherm" cold packs were in a partially opened clear plastic bag. The cold packs were removed and discarded by the Charge Nurse. It is MGH policy that only patient food items may be stored in the patient nutrition station refrigerator/freezer. In order to correct this deficiency, this policy has been reviewed by Nursing Leadership and reinforced with all Staff. The patient nutrition station temperature log is kept daily by an Operating Room Assistant, and reviewed by the Resource Nurse. We will integrate the checking of the patient nutrition refrigerator/ freezer for inappropriate storage into this existing process. The Clinical Nurse Specialist and	

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A 749	Continued From page 182 the Virex 256. Review of manufacturer recommendations received from the hospital on 2/11/10 at 10:05 a.m. revealed, Cautions: To disinfect hard, non-porous surfaces, treated surfaces must remain wet for 10 minutes. Allow surfaces to remain wet for 1-minute to kill HIV-1 (Human Immunodeficiency virus), 5-minutes to kill HBV (hepatitis B virus). Interview on 2/11/10 at 10:05 a.m. with the Director of Infection Control, Staff CQ, stated that it would depend on the bioburden (number of bacteria living on an area before it is sterilized) how long the surface would need to remain wet. Review of policy titled, "Room Cleaning Procedures" received 2/11/10 at 10:05 a.m. directed USA staff to use Clorox Germicidal Spray instead of Virex for cleaning all surfaces of a Contact Precautions Plus room with the exception of the floor. The policy further directed that the areas of the room to be cleaned are door knobs, light switches, chairs, counters, overbed table, bedside table, window sills, telephone; bed rails (if possible) spot wash window glass, doors, and walls. The policy further instructs that surfaces should be thoroughly cleaned and wet and allowed to air dry. A cloth should be used until it no longer wets the surface. It should take about 4 cloths for each side of a semi-private room. Interview on 2/10/10 at 3:00 p.m. with the Director of Infection Control, Staff CQ indicated that all horizontal surfaces and high touch areas should be cleaned by USA staff in patient rooms and that Virex 256 should not be wiped off but allowed to	A 749	Operations Manager will check compliance while doing the monthly unit based tracer for the Patient Care Services Office of Quality and Safety. Non-compliance will be documented in the monthly unit-based tracer report and will require follow-up by unit leadership. The completion date for this plan is March 12, 2010. The person responsible for monitoring compliance with this plan of correction is the Nurse Director. Updates on our performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through our General Executive Committee and through the Boards of Trustees Quality Subcommittee to the Boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that we are making progress as planned, and communicate our progress and concerns to the Boards through the mechanism above on a quarterly basis until the issue is resolved to prevent the likelihood of the deficient practice from reoccurring. Subsequent compliance will be reviewed through our quality and safety dashboards which will now include an explicit area to monitor our CoP compliance. In addition to these periodic reviews we will be flagging all safety event reports related to CoP issues so that ad hoc compliance issues can be addressed in a robust and timely fashion. The hospital acknowledges that the did not clean the sides of the equipment, as observed by the CMS surveyor. However, this piece of exercise equipment is	

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A 749	Continued From page 183 air dry. Review of medical record for patient #66 admitted 2/3/10 revealed the following: - History and Physical Examination and Anesthesia Assessment on 1/29/10 stated " Continues on antibiotics for C-Diff (Clostridium difficile). Continues with some loose stools and is incontinent. " -Nursing Admission Note on 2/3/10 listed C Diff in the past medical history however under the heading of Risk of Infection staff documented orders for both oral and IV (intravenous) Vancomycin (medication indicated for infections resistant to other antibiotics and colitis caused by C Diff). Observation on 2/4/10 at 12:30 p.m. showed staff exit patient #66's room use alcohol gel on hands and proceed to the nurses' station. Observation on 2/4/10 at 12:34 p.m. showed staff exit patient #66's room use alcohol gel on hands and proceed to the nurses' stations. Observation on 2/4/10 at 12:35 p.m. revealed a contact precaution sign outside of patient #66's room. The sign directed staff to use alcohol hand sanitizer when leaving the room. Interview with Infection Control Specialist CR on 2/4/10 at 3:10 p.m. revealed that even if a patient had a negative lab culture for C Diff if the patient continued to have diarrhea they should still be flagged as having C Diff. The patient should be treated presumptively and still placed on Contact Precautions Plus. Review of signage for Contact Precautions Plus revealed that hand should be washed and dried	A 749	used by clothed patients in an outpatient setting. It is classified as “Non-Critical Equipment” and requires cleaning and disinfections between patients. The seat cushion of the machine is covered with a permanent non-porous, sewn-on cover to allow the area on which the patient sits to be wiped down with a hospital-approved disinfectant. It is appropriate from an infection control standpoint to clean only the contact surface of the equipment (the seat). Cleaning and disinfection between the protective cover and the seat cushion are not indicated. Moreover, cleaning underneath or between the protective seat covering and cushion could trap moisture and potentially damage the fabric of the seat or the protective cover. The hospital also acknowledges that the staff person did not wear gloves when cleaning the equipment. It has been reinforced by the manager that gloves should be worn when cleaning and disinfecting equipment. It has also been reinforced with staff that when a room is “in use” for patient treatment they should use a sink in an alternate location or use alcohol-based hand sanitizer for hand hygiene. The MGH chief medical officer is responsible for ensuring the implementation of this plan of correction	

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A 749	Continued From page 184	A 749		

and then use alcohol hand sanitizer. (Alcohol hand sanitizer is not effective against C Diff.)Observation on 2/5/10 at 8:16 a.m. revealed Contact Precaution Plus outside of patient #66's room.

Interview with Infection Control Specialist CR on 2/5/10 at 8:50 a.m. revealed that there was a "break in the system." The nurse didn't call the infection control department and that would be the only way we would know to come up and assess the situation. The plan is to get a stool sample and check for C Diff because of the change from 1/15/10 from soft stool to diarrhea on 1/29/10. If you hadn't found it; it would not have been caught.

Review of Infection Control policy titled, "Isolation Precautions" received 2/10/10 at 2:10 p.m. indicated in part under the Contact Precautions Plus heading subheading 3.1 Indication/Duration "Patients being admitted/readmitted with a history of C. difficile disease, who have completed a course of appropriate antibiotic therapy and are asymptomatic need not be put on precautions. Patients who have completed a course of antibiotic therapy for C difficile disease, but continue to be symptomatic, should be put on precautions upon admission/readmission."

Interview with Infection Control Specialist CS on 2/5/10 at 2:21 p.m. revealed that VRE (Vancomycin resistant enterococci) and MRSA (methicillin resistant staphylococcus aureus) are the only two infectious processes that stay flagged in the system from admission to admission. If a patient is admitted with documentation of an infections process, the nurse usually notifies the infection control department.

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A 749	Continued From page 185	A 749		

Infection Control Specialist CS did not know if there was a policy to notify the infection control department, but stated it was the practice. The infection control department verifies there has not been a diagnosis of an infectious process from an outside source. However there is not a system in place to document either the nurse's call to the infection control department. Infection control staff don't document the review of the patient to determine if there was an infection unless it is confirmed there is an infection.

Review of Infection Control policy titled, "Nursing Service" documented in part under the heading of Patient Care Standards #10 "Infection Control Unit notification: The registered nurse will notify the Infection Control Department when: a. A patient is diagnosed or suspected of having an infectious or communicable disease, which requires infection control precautions."

During observations on 2/2/10 at 11:55 a.m. in

building, two white packs with blue labeling were observed in a patient nourishment refrigerator. The patient refrigerator was labeled "Food only." The packs were identified as "Cryotherm" cold packs. The packs had the hand written word "pathology" in black marker printed on one side. The two "Cryotherm" cold packs were in a partially opened clear plastic bag. The cold packs were removed and discarded by the Charge Nurse, PACU-Ellison.

In an interview on 2/2/10 at 11:56 a. m., with the Charge Nurse , she stated this is not normal procedure. She also stated the cold packs should not be kept in the nourishment refrigerator.

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A 749	Continued From page 186 During observation of equipment cleaning demonstration by the at MGH on 2/5/10, the sides of the cushion on the equipment were not cleaned, and cleaning was performed without gloves. Following equipment cleaning, staff washed dirty hands in an examination room during another patient ' s treatment.	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 interview and document review, it was determined that the hospital failed to have a system in place to actively track infections in short stay or outpatient surgical cases, employee illnesses, or volunteer illnesses. The findings include: During the tour of the at acility on 02/08/10 at approximately 10:30 a.m., the Regional Office Evaluator (ROE) asked the Executive Director of if there was any system for patient follow-up for post operative infections. It was stated that the outpatient staff make a phone call usually within a day of surgery. They inquire how the patient feels, where they have any pain and if there are questions about post operative care. The staff normally does not ask any questions about infections. If the patient experienced an infection they would go to their primary physician for treatment. When the ROE said, therefore there is	A 750	The hospital acknowledges that we did not have a system in place to actively track volunteer illnesses. The MGH does have a system to track employee illnesses, and we will integrate volunteers into the process in order to correct the deficiency cited. All new employees are informed during new employee orientation of the requirement to report the following: exposure to, diagnosis of, or symptoms that are consistent with a communicable disease. Volunteers will be notified of the same at their orientation. The Occupational Health Service (OHS) maintains a log of reported staff illness, and volunteers will be added to the existing log. OHS and Infection Control (IC) will initiate a standard communication plan to reinforce this reporting requirement to employees, and the staff of the Volunteer Department will communicate the change in policy to all volunteers. Going forward, these requirements will be communicated hospital-wide on a regular basis. The MGH will send a quarterly all user e-mail reminding staff of the requirement to report the following: exposure to, diagnosis of, or symptoms that are consistent with a communicable disease to OHS. Additionally, a quarterly e-mail will be sent to Managers and Directors at the MGH reminding them of these requirements.	03/15/10

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A 750	Continued From page 187 no system to report post operative infection, the Executive Director said yes. Interview with Director of Infection Control, Staff CQ and Chief of Infection Control, Staff CT on 2/9/10 at 3:05 p.m., revealed that infection control staff looks at the return to surgery report and the physicians performing the above surgical procedures are asked to respond if there is an infection. Staff CQ indicated that the system would be blind to the infections treated in the community. The hospital asks physicians and case managers to self-report any surgical infections of which they become aware. Further interview with Director of Infection Control Staff CQ on 2/10/10 at 8:30 a.m., revealed that infection control monitoring of outpatient surgical centers, health centers, and ambulatory practices is passive. Staff would review admission logs or re-operative reports to determine if the patient appeared to have a surgical wound infection and would follow it up. There is no system in place to determine if a patient that is treated in the community has a wound infection. Review of the Infection Control Plan for 2010 lacked a system to monitor community acquired infections. Interview with Director of Infection Control Staff CQ on 2/11/10 at 2:15 p.m. revealed there is no log of community acquired infections. Further interview with Director of Infection Control Staff CQ on 2/11/10 at 2:15 p.m., revealed that there is no tracking of hospital acquired pneumonia with the exception of ventilator acquired pneumonia in . When asked, Director of Infection Control Staff CQ indicated that there is no tracking mechanism for	A 750	When a volunteer calls off duty due to illness, staff of the Volunteer Department will refer the volunteer to OHS. OHS will record information for each volunteer in the Occupational Health log. OHS will screen employees and volunteers and record in the OHS log staff and volunteers with suspected and/or confirmed communicable illnesses. A monthly review of volunteer illness reporting will be completed by the Director of the Volunteer Department in conjunction with the Director of Occupational Health until the process is established. This plan of correction will be implemented by 3/15/10. The persons responsible for the implementation of this plan are the Directors of the Volunteer Department, Infection Control, and Occupational Health Services Updates on our performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through our General Executive Committee and through the Boards of Trustees Quality Subcommittee to the Boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that we are making progress as planned, and communicate our progress and concerns to the Boards through the mechanism above on a quarterly basis until the issue is resolved to prevent the likelihood of the deficient practice from reoccurring. Subsequent compliance will be reviewed through our quality and safety dashboards which will now include an explicit area to monitor our CoP compliance. In addition to these periodic reviews we will be flagging all safety event reports related to CoP issues so that ad hoc compliance issues	

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A 750	Continued From page 188 catheter associated urinary tract infections or for any urinary tract infections at all. Review of policy titled, "Work Health Clearance" documented in part under Definitions and Regulations at 2.4 and 2.5 "All employees who have been exposed to an infectious disease or have a condition which might place them at increased risk of being exposed (refer to isolation Precautions-Infection Control Policies), think they might have an infectious disease, or have been diagnosed with an infectious disease must report to Occupational Health Services for a work clearance and /or exposure assessment. Infectious diseases and conditions include, but are not limited to the following common diseases which are potentially transmissible to patients and/or employees ...2. Strep throat." On 2/8/10 at approximately 11:45 a.m., Registered Nurse (RN) II, a Nurse Clinician in Patient Care Services, verbalized that s/he hoped the surveyor did not become ill over the previous week-end (2/6/10 and 2/7/10). RN II said s/he had a very sore throat during the day on 2/5/10 while escorting the surveyor around the facility. RN II said on 2/6/10 s/he was diagnosed with Strep throat (an infection of the mucous membranes lining the throat and caused by Streptococcus bacteria; the disease passes directly from person to person by coughing, sneezing, and close contact) and prescribed an antibiotic. Interview with Staff CU regarding employee health indicated that they captured some strep throat in the reporting system but not all of it and that there were no reports of strep throat for the month of February. Occupational health is not	A 750	can be addressed in a robust and timely fashion. The hospital acknowledges that the infection control officer must maintain a log of incidents related to infectious and communicable diseases. However, we respectfully maintain that our infection control log follows the CMS guidelines and that we have a system in place to actively track infections in areas that are identified by our institution-wide infection control risk assessment. The CMS Interpretive Guidelines for 42 CFR 482.42 state that “the hospital's program for prevention, control and investigation of infections and communicable diseases should be conducted in accordance with nationally recognized infection control practices or guidelines, as well as applicable regulations of other federal or state agencies. Examples of organizations that promulgate nationally recognized infection and communicable disease control guidelines, and/or recommendations include: the Centers for Disease Control and Prevention (CDC), the Association for Professionals in Infection Control and Epidemiology (APIC), the Society for Healthcare Epidemiology of America (SHEA), and the Association of Perioperative Registered Nurses (AORN). The hospital must document its surveillance activities, including the measures selected for monitoring, and collection and analysis methods. Surveillance activities should be conducted in accordance with recognized infection control surveillance practices, such as, for example, those utilized by the CDC's National Healthcare Safety Network (NHSN). Consistent with the requirement cited above, the MGH Healthcare-Associated Infection Surveillance Plan was developed in	

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A 750	Continued From page 188 catheter associated urinary tract infections or for any urinary tract infections at all. Review of policy titled, "Work Health Clearance" documented in part under Definitions and Regulations at 2.4 and 2.5 "All employees who have been exposed to an infectious disease or have a condition which might place them at increased risk of being exposed (refer to isolation Precautions-Infection Control Policies), think they might have an infectious disease, or have been diagnosed with an infectious disease must report to Occupational Health Services for a work clearance and /or exposure assessment. Infectious diseases and conditions include, but are not limited to the following common diseases which are potentially transmissible to patients and/or employees ...2. Strep throat." On 2/8/10 at approximately 11:45 a.m., Registered Nurse (RN) II, a Nurse Clinician in Patient Care Services, verbalized that s/he hoped the surveyor did not become ill over the previous week-end (2/6/10 and 2/7/10). RN II said s/he had a very sore throat during the day on 2/5/10 while escorting the surveyor around the facility. RN II said on 2/6/10 s/he was diagnosed with Strep throat (an infection of the mucous membranes lining the throat and caused by Streptococcus bacteria; the disease passes directly from person to person by coughing, sneezing, and close contact) and prescribed an antibiotic. Interview with Staff CU regarding employee health indicated that they captured some strep throat in the reporting system but not all of it and that there were no reports of strep throat for the month of February. Occupational health is not	A 750	accordance with the guidance provided in the APIC 2003 recommended practices for surveillance. These recommended practices state that rather than institute a one size fits all approach to surveillance, each health care organization must tailor its surveillance systems to maximize resources by focusing on population characteristics, outcome priorities, and organizational objectives. To ensure quality of surveillance, the following elements must be incorporated: A written plan should serve as the foundation of any surveillance program. The plan should outline important goals, objectives, and elements of the surveillance process so that resources can be targeted appropriately. This is commonly integrated into a comprehensive infection control risk assessment process. Each organization serves different types of patients who are at varied risks for health outcomes (both negative and positive). Development of surveillance systems should be based on evaluation of the populations of interest. Such a risk assessment is critical so that resources can be targeted at populations who are at risk for the outcomes of greatest importance. This, in turn, enables clinicians to use surveillance information to enhance and improve care provided to those targeted populations." The Department of Infection Control conducts a hospital-wide risk assessment to identify clinical areas that require heightened surveillance. The risk assessment is based on rates of infection reported by surgeons or as identified by routine review of culture data, admission data, daily review of surgical procedures and/or reports from case managers. The risk assessment identifies rates that are above expected when compared with the NHSN national dataset and any procedures that are assessed as being either	

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A 750	Continued From page 189 made aware of every employee call-in and the system relies on the employee to do the right thing and the person receiving the call-in to notify us. Interview with Director of Volunteer Service, Staff CV on 2/11/10 at 8:24 a.m., revealed the hospital doesn't log when a volunteer calls in ill and there are no hard and fast rules about not coming to the hospital if the volunteer has an illness.	A 750		
A 940	482.51 SURGICAL SERVICES If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered the services must be consistent in quality with inpatient care in accordance with the complexity of services offered. This CONDITION is not met as evidenced by: Based on observation, interview and record review, the facility failed to meet the Condition of Participation, Surgical Services. Surgical Services must be well organized and provided in accordance with acceptable standards of practice. Policies governing surgical services must be designed to assure the achievement and maintenance of standards of medical and patient care. The facility failed to demonstrate the immediate availability of an emergency medication to treat Malignant Hyperthermia (MH) in the according to accepted high standards of medical practice and patient care. (See A941) The findings include: The facility failed to ensure that in the event of an	A 940	Please see plan of correction for A951 below.	04/22/10

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A 940	Continued From page 190 episode of Malignant Hypothermia, the medication necessary to reverse life threatening event was immediately available. No additional information was provided by the facility.	A 940		
A 951	482.51(b) OPERATING ROOM POLICIES Surgical services must be consistent with needs and resources. Policies governing surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care. This STANDARD is not met as evidenced by: Based on observation, interview and record review, it was determined that the facility failed to demonstrate the immediate availability of an emergency medication to treat Malignant Hyperthermia (MH) according to accepted high standards of medical practice and patient care. The findings include: During observations on 2/5/10 at 10:50 a.m. in the :, Anesthesiologist #1 was asked to locate the Malignant Hyperthermia (MH) Kit. This kit is stocked with Dantrolene, a medication that is required to be immediately available for the treatment of MH according to the Malignant Hyperthermia Association of the United States (MHAUS). The MH crisis is a biochemical chain reaction response, "triggered" by commonly used general anesthetics and the paralyzing agent succinylcholine, within the skeletal muscles of susceptible individuals. Severe complications include: cardiac arrest, brain damage, internal bleeding or failure of other body systems. Thus, death, primarily due to a	A 951	To ensure that MGH Surgical Services is well organized and provided in accordance with acceptable standards of practice, the surgical department, in collaboration with the clinical director of the Department of Anesthesia, Critical Care and Pain Medicine, has revised our standard policy and response protocol. The revised protocol delineates a single phone number that anyone in the hospital can contact to obtain both the drugs needed to treat malignant hyperthermia and additional anesthesiologist(s) to aid in the patient care in a timely manner. Over the next 5 weeks, clinicians in all anesthetizing locations will be educated about Malignant Hyperthermia and the revised response protocol. Such education will include information about, but not limited to, where the standard malignant hyperthermia kits are located and how to obtain the malignant hyperthermia kits. Training will also focus on re-emphasizing the definition of the standard protocol for responding to a malignant hyperthermia emergency to ensure that it is well understood by all staff in all areas where this issue could occur. To improve the process that led to this deficiency, the MGH will re-educate all clinicians and staff on units with anesthetizing locations about the danger of malignant hyperthermia and the standard protocol for obtaining the malignant hyperthermia kits in the most expedient manner possible. Training will also include ensuring that all appropriate	04/22/10

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A 951	Continued From page 191 secondary cardiovascular collapse, can result according to MHAUS. Anesthesiologist #1 looked in several places within the Endoscopy clinic for the MH kit. Anesthesiologist #1 was unable to locate the MH kit. He indicated it is normally kept on a cart in this hallway. Anesthesiologist #1 was then asked what he would do in case of an emergency. He indicated he would call the pharmacy for an MH emergency kit. At 10:55 a.m., he was asked to implement his secondary emergency protocol. Anesthesiologist #1 called the pharmacy and stated he had a MH emergency in the . The MH kit arrived in Room #6 at 11:04 a.m. The emergency MH kit arrived nine minutes after the medical emergency was first announced by Anesthesiologist #1. Interview on 2/8/10 at 9:45 a.m. with the Executive Medical Director of ; he stated he a heard about the confusion with the MH kit. He stated the kits are not required to be in the operating room. He was informed the MH kit took nine minutes to arrive from the pharmacy. Review of the endoscopy operating room schedule for 2/5/10 revealed ten general anesthetic cases were performed that day. The facility's policy entitled, "Policy for the Treatment of Malignant Hyperthermia," was reviewed 1/2009 by the Clinical Director of Anesthesia. Page 1, paragraph 4 documents, "Because these processes, unless interrupted, causes more calcium ions to enter the muscle, a self-perpetuating cycle ensues from which the patient cannot recover."	A 951	how to access those clinicians who have been trained to assist with the necessary treatment and resuscitation. Clinicians working in all anesthetizing locations throughout the hospital and all anesthesia providers in the Department of Anesthesia, Critical Care and Pain Medicine will be educated. The education plan will consist of broadcast emails to clinicians who work in such locations, as well as department- and unit-specific educational forums, including case conferences and staff meetings. The updated policy and education will be completed by 4/22/10, and the senior vice president for Surgical and Anesthesia Services and Clinical Business Development will be responsible for implementation and completion of this plan. To ensure compliance with the plan of correction, the MGH will initiate a regular assessment program with at least quarterly monitoring during the first year and semi-annual monitoring in subsequent years. The MGH, in fact, began its monitoring program 3/11/10, rigorously testing the standard response protocol. The result of this initial test was that starting from the time the phone number was dialed, it took 2 minutes and 39 seconds for the malignant hyperthermia kit to be dispatched from the and arrive in the . Updates on performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC).	

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A 951	Continued From page 191 secondary cardiovascular collapse, can result according to MHAUS. Anesthesiologist #1 looked in several places within the Endoscopy clinic for the MH kit. Anesthesiologist #1 was unable to locate the MH kit. He indicated it is normally kept on a cart in this hallway. Anesthesiologist #1 was then asked what he would do in case of an emergency. He indicated he would call the pharmacy for an MH emergency kit. At 10:55 a.m., he was asked to implement his secondary emergency protocol. Anesthesiologist #1 called the pharmacy and stated he had a MH emergency in the , Room #6. The MH kit arrived in Room #6 at 11:04 a.m. The emergency MH kit arrived nine minutes after the medical emergency was first announced by Anesthesiologist #1. Interview on 2/8/10 at 9:45 a.m. with the Executive Medical Director of (he stated he a heard about the confusion with the MH kit. He stated the kits are not required to be in the operating room. He was informed the MH kit took nine minutes to arrive from the pharmacy. Review of the endoscopy operating room schedule for 2/5/10 revealed ten general anesthetic cases were performed that day. The facility's policy entitled, "Policy for the Treatment of Malignant Hyperthermia," was reviewed 1/2009 by the Clinical Director of Anesthesia. Page 1, paragraph 4 documents, "Because these processes, unless interrupted, causes more calcium ions to enter the muscle, a self-perpetuating cycle ensues from which the patient cannot recover."	A 951	The QOC, which reports up through the MGH General Executive Committee and through the Board of Trustees Quality Subcommittee to the boards of Trustees of both the MGH and MGPO, will review data relevant to this deficiency, ensure that the hospital is making progress as planned, and communicate progress and concerns to the boards through the mechanism described above on a quarterly basis until the issue is resolved to prevent the deficient practice from recurring. Subsequent compliance will be reviewed through the hospital's quality and safety dashboards, which will include an explicit area to monitor compliance with this Condition of Participation. In addition to these periodic reviews the hospital will flag all safety event reports related to Condition of Participation issues so that ad hoc compliance issues can be addressed in a robust and timely fashion. The senior vice president for Surgical and Anesthesia Services is responsible for ensuring implementation of this plan of correction.	

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A 951	Continued From page 192 Paragraph 5 documents, "Dantrium (Dantrolene) I. V. is the first drug therapy available for the treatment of malignant hyperthermia." Paragraph 6 documents, "A successful outcome of this catastrophic disease depends on prompt initiation of aggressive therapy."	A 951		
A1037	482.53(b)(2) DISPOSAL OF RADIOACTIVE MATERIAL There is proper storage and disposal of radioactive material. This STANDARD is not met as evidenced by: Based on staff interview and document review, it was determined that the facility failed to confirm the final location of the disposal site for radio nuclides, unused radio pharmaceuticals and radioactive waste. The findings include: The Regional Office Evaluator (ROE) toured the Nuclear Medicine Department (NMD) on 02/02/10 at 10:15 a.m.. During the tour, the Technical Manager of the NMD was asked to explain what happens to the radioactive waste from the NMD. The manager answered that, it is picked up by a nuclear waste disposal but I don't know what they do with it. Review of the NMD policy on nuclear waste disposal confirmed that there is no policy to report final location of the disposal site for radioactive waste. The NMD was unable to verify that the radioactive materials were properly disposed.	A1037	The hospital acknowledges that during the survey the nuclear medicine technical manager, when approached, was unable to name the location of the disposal site for radionuclides, unused radiopharmaceuticals and radioactive waste. As was discussed with the surveyors at the time of the review, however, it is the responsibility of the MGH's radiation safety officer - not that of the nuclear medicine technical manager - to confirm the proper disposal of radioactive materials. These activities continue to be completed in full compliance with the CMS Hospital Conditions of Participation.	02/12/10
A1123	482.56 REHABILITATION SERVICES If the hospital provides rehabilitation, physical	A1123	Please see detailed responses below for A1124 and A1132.	

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A1123	Continued From page 193 therapy, occupational therapy, audiology, or speech pathology services, the services must be organized and staffed to ensure the health and safety of patients. This CONDITION is not met as evidenced by: Based on interview, record review, and observation, it was determined that the Hospital failed to provide appropriate numbers of qualified personnel necessary to furnish the physical therapy services offered by the Hospital; and failed to deliver services in accordance with orders of practitioners who are authorized by the Medical Staff to order the services. (See A1124 & A1132) The findings include: 1. Rehabiliation services are not staffed to ensure the needs of the patients are met as ordered. 2. Physical therapy, occupational therapy, and speech language pathology services are carried out through referrals and consults, without valid orders for evaluation and treatment.	A1123		
A1124	482.56(a) ORGANIZATION OF REHABILITATION SERVICES The organization of the service must be appropriate to the scope of the services offered. This STANDARD is not met as evidenced by: Based on record review and interview, it was determined that patients receiving physical therapy services are missing treatments that are expected according to their treatment plan.	A1124	The MGH respectfully disagrees with the surveyor's finding that rehabilitation services are not staffed to ensure the needs of the patients are met as ordered. We believe a misunderstanding occurred during discussions between the surveyor and our staff regarding staffing adequacy. This misunderstanding led the surveyor to believe the MGH was not in compliance with its own policy. Physical Therapy Services Policy 200.006, issued on 06/94, revised/reviewed without revision: 01/06, indicated, "Staffing	02/12/10

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A1124	Continued From page 194 The findings include: Record review for patient Patient #PP6 on 2/9/10 revealed that the patient missed a physical therapy visit on 2/3/10 per patient request, next scheduled to be seen on 2/4/10. The patient was seen on 2/4/10 and scheduled for followup on 2/5/10. The patient was not seen on 2/5/10 due to being off the floor for a procedure, scheduled for follow-up on 2/8/10. The patient was not seen on 2/8/10. The next scheduled visit for this patient was on 2/9/10. The patient was not seen by a physical therapist from 2/4/10 until 2/9/10, which was not in accordance with the patient's treatment plan. Physical Therapy Services Policy 200.006, issued on 06/1994, revised/reviewed without revision: 01/2006, indicated, "Staffing resources are deployed to both inpatient and outpatient settings based on clinical need (Demand). Prompt patient access and frequency of treatment (the ability to provide care at a frequency and intensity per the patient's treatment plan) are critical factors in establishing and modifying staffing levels." The hospital is not in compliance with its own staffing policy. During interview with PT1, PT8, PT36, and PT37, they stated that assignments are based on volume, not acuity, and are prioritized according to need.	A1124	resources are deployed to both inpatient and outpatient settings based on clinical need (demand). Prompt patient access and frequency of treatment (the ability to provide care at a frequency and intensity per the patient's treatment plan) are critical factors in establishing and modifying staffing levels." Thus, patient care is prioritized according to acuity, not overall volume. With regard to #PP6 the conclusion drawn about the patient's frequency of care is incorrect. It is our belief that this incorrect observation led the surveyor to pursue further discussions related to staffing adequacy. Review of the clinical record reveals the patient was reevaluated on 2/2/10 and a plan of care (POC) established with the frequency set as "3-4 times/week pending medical stability". The patient was seen on 2/2/10, refused care on 2/3/10, seen on 2/4/10, and was off the unit for post-operative procedures (patient in the operating room on 2/4/10) and on 2/5/10. We believe this reflects our adherence to the plan of care and the need to respond to this patients evolving/changing medical condition.	
A1132	482.56(b) WRITTEN PLAN OF REHABILITATION TREATMENT Services must be furnished in accordance with a written plan of treatment. Services must be given in accordance with orders of practitioners who are authorized by the medical staff to order the	A1132	To correct this deficiency, the hospital will obtain valid orders for Physical Therapy, Occupational Therapy, and Speech Language Pathology services by practitioners who are authorized by the Medical Staff to order the services.	04/30/10

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A1132	Continued From page 195 services, and the orders must be incorporated in the patient's record. The provision of care and the personnel qualifications must be in accordance with national acceptable standards of practice and must also meet the requirements of §409.17. This STANDARD is not met as evidenced by: Based on record review for 9 of 9 records reviewed (Patient # PP10, #PP9, #PP6,# PP7, #PP11, #PP12, # PP4, #PP13, and #PP14) and interview, it was determined that the Hospital failed to obtain valid orders for physical therapy, occupational therapy, and speech language pathology services by practitioners who are authorized by the Medical Staff to order the services. The findings include: Record review on 2/10/10 revealed an occupational therapy order dated 2/4/10 for a "consult" for Patient #PP10. The order did not specify reason and expectations for evaluation and treatment. Record review on 2/10/10 revealed an occupational therapy order dated 2/8/10 for a "consult" for Patient #PP9 without specifying reason and expectations for evaluation and treatment. Record review on 2/9/10 revealed a physical therapy order for "Consult: PT Physical Therapy" for Patient #PP6 that does not specify the reason and expectations for evaluation and treatment. Record review on 2/9/10 revealed a physical therapy order for "Consult: Physical Therapy," for Patient #PP7 that does not specify the reason	A1132	To address improving the processes that led to the deficiency, the hospital will educate the Medical staff regarding the requirement to include a “reason for referral” for rehabilitation services. The hospital will review options for improving both the electronic and paper-based referral process in order to accurately capture the “reason for referral”. The procedures for implementing this plan include conducting a physician education and issue communication regarding the need for including a “reason for rehabilitation therapy” when a referral is made. The hospital's electronic Provider Order Entry (POE) system and paper-based Rehabilitation referral system will be evaluated and revised to include mandatory fields for “reason for referral”, where applicable. The hospital's Health Information Systems team will develop technical specifications for these changes by 4/30/10, including sample screen shots. Coding, testing and implementation will be completed by 5/25/10. The completion date for correction of this deficiency is 4/30/10. Updates on our performance related to the deficiency cited will be reviewed on a quarterly basis by the MGH/MGPO Quality Oversight Committee (QOC). The QOC, which reports up through our General Executive Committee and through the Boards of Trustees Quality Subcommittee to the Boards of both the MGH and MGPO, will review data relevant to this deficiency, ensure that we are making progress as planned, and communicate our progress and concerns to the	

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A1132	Continued From page 196 and expectations for evaluation and treatment. Record review on 2/9/10 revealed speech-language pathology referral for speech-language evaluation/treatment signed on 3/19/08 for Patient #PP11. There is no order specifying the reason and expectations for speech-language evaluation and treatment. Record review on 2/9/10 revealed undated speech-language pathology referral for speech-language evaluation/treatment for Patient #PP12. There is no order specifying expectations for speech-language evaluation and treatment. Record review on 2/9/10 revealed the absence of a valid speech-language pathology order for "hearing screening requested ant (sic) Speech department" on 6/23/08, and conducted on 6/30/08; absence of speech-language pathology orders for individual treatment from 7/8/08-8/25/08 for Patient #PP4. Record review on 2/9/10 revealed the absence of a valid speech-language pathology order for evaluation and treatment provided on 9/30/08 and 4/10/09 for Patient #PP13. Record review on 2/9/10 revealed the absence of a valid speech-language pathology order for evaluation and treatment provided to Patient #PP14 on 4/3/09, 4/6/09 and 10/5/09. Draft Outpatient Services policy provided by SLP7 on 2/9/10 indicates, "Referrals are accepted from any source, including self referral. Requirements for prior approval or authorization is dependent on several factors, including but not limited to payor source or nature of the appointment."	A1132	Boards through the mechanism above on a quarterly basis until the issue is resolved to prevent the likelihood of the deficient practice from reoccurring. Subsequent compliance will be reviewed through our quality and safety dashboards which will not include an explicit area to monitor our CoP compliance. In addition to these periodic reviews, we will be flagging all safety event reports related to CoP issues so that ad hoc compliance issues can be addresses in a robust and timely fashion. Procedures for monitoring and tracking to ensure that the plan of correction is effective include conduct of periodic sampling of POE and paper-based rehabilitation therapy orders assessing the inclusion of the “reason for referral”. The senior vice president for Patient Care Services and chief nurse is responsible for implementing this plan of correction.	

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A1132	Continued From page 197 During interview with SLP7, she state that "doctors' orders are only required for swallowing, modified barium swallow, and pharyngeal insufficiency studies...All medicare patients are required to have an order."	A1132		