

Division of Licensing and Protection
HC 2 South, 280 State Drive
Waterbury VT 05671-2060
<http://www.dail.vermont.gov>
Survey and Certification Voice/TTY (802) 241-0480
Survey and Certification Fax (802) 241-0343
Survey and Certification Reporting Line: (888) 700-5330
To Report Adult Abuse: (800) 564-1612

July 15, 2016

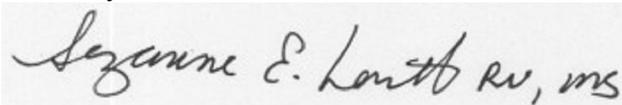
Dr. Fred Kniffin, Interim CEO
Porter Hospital, Inc
115 Porter Drive
Middlebury, VT 05753-8423

Dear Dr. Kniffin:

The Division of Licensing and Protection completed a survey at your facility on **June 10, 2016**. The purpose of the survey was to determine if your facility met the conditions of participation for Critical Access Hospitals found in 42 CFR Part 485.

Following the survey, your facility submitted a Plan of Corrections (POC) which was found to be acceptable.

Sincerely,



Suzanne Leavitt, RN, MS
Assistant Division Director
Director State Survey Agency

Enclosure

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

PRINTED: 06/17/2016
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 471307	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED C 06/10/2016
NAME OF PROVIDER OR SUPPLIER PORTER HOSPITAL, INC		STREET ADDRESS, CITY, STATE, ZIP CODE 115 PORTER DRIVE MIDDLEBURY, VT 05753	
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)
			(X5) COMPLETION DATE

C271 485.635(a)(1) PATIENT CARE POLICIES

In response to this finding, the following steps have been taken:

- The concurrent restraint review process currently in place in the Emergency Department was evaluated and was immediately implemented on the Medical Surgical Unit. The Nursing Supervisor shall be responsible for the required concurrent reviews. The review process includes the following elements to ensure continued compliance with the hospital's restraint policy:
 - o Concurrent reviews of 100% of restrained patient records upon application of either chemical or physical restraints and will be repeated not less than every four hours for the duration of restraint use for the given patient;
 - o Appropriateness of restraint use;
 - o Accuracy of documentation to include orders, assessments, and administration of restraints;
 - o Documentation of real time feedback and follow up with Providers and staff in relation to the findings of the concurrent review process to ensure continued compliance.
 - o Any findings of noncompliance with the hospital's restraint policy that are not resolved at the time of discovery will be immediately reported to the Director of Patient Care Services, CNO, or CMO for immediate review and follow up with the staff or Provider in question.
 - o The above noted concurrent reviews shall be validated monthly by the Director of Patient Care Services to ensure continued compliance with this review plan.
 - o The Director of Patient Care Services will forward the results of the concurrent reviews to the Director of Quality on a monthly basis beginning 7/6/16 for review of trends and identification of opportunities to improve the safety of patients and eliminate inappropriate use of restraints. The resulting review data, trends, and associated performance improvement plans will be presented at the Quality and Safety Committee meetings on a monthly basis.
- The hospital's Restraint Committee met on 6/15/16, and subsequently on 6/23/16. The Committee discussion has included:
 - o Review of the findings of this survey;
 - o Review of the restraint policy content for both compliance with current regulatory requirements and to determine educational requirements for staff and Providers in relation to this policy;
 - o Development of a plan of action in terms of education, policy updates, and changes to the documentation associated with restraint use in Porter's EMR to include ordering, assessments, and restraint administration.

The following additional steps will be taken to educate staff and Providers who provide care for patients in areas where restraints may be utilized to ensure safe, appropriate use in keeping with the hospital's policy:

- The policy titled "Physical and Chemical Restraints" will be updated and approved by 7/15/16. The policy will be forwarded to all staff and Providers through Healthstreams for review. The Healthstreams module will include an acknowledgment of their understanding of the content and whom to contact should they have additional questions or require further clarification. The module will be created no later than 7/18/16 and completed by all required staff and Providers no later than 8/15/16.
- Proposed edits to Porter's EMR associated with ordering, assessments and restraint application /administration will be completed no later than 7/22/16. The purpose of the edits will be to provide prompts and facilitate improved documentation by staff and Providers. A Healthstreams module related to these changes will be created no later than 8/1/16 and completed by all required staff and Providers no later than 8/15/16.

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

Carrie Wilfman MD, CMO

TITLE

(X6) DATE

6-27-16

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

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- Director of Patient Care Services will meet with all Emergency Department and Hospitalist Providers in person to review the restraint policy and regulatory requirements no later than 8/15/16. The discussion will include, at a minimum:
 - o Determining appropriateness of restraint use;
 - o Ordering of chemical and physical restraints;
 - o Required assessments; and
 - o Required documentation elements as per hospital policy.
- A mandatory restraint education training class will be developed by the Director of Education with classes to begin the week of 8/29/16. All required staff must attend the class no later than 9/15/16. The class will include, at a minimum:
 - o Review of the hospital's restraint policy;
 - o Review of the management of confused and/or agitated patients;
 - o Hands on demonstration of the application of physical restraints and required assessments associated with restraint use as per policy; and
 - o Documentation requirements as per hospital policy, to include documentation of the presence of other staff during the administration/application of restraints and whether the patient's actions posed a safety threat to the patient and or staff.
- The CNO will be responsible for development of a policy related to the management of confused and/or agitated patients, to include assessments and documentation requirement. The policy will be developed no later than 7/15/16. The policy will be forwarded to all staff and Providers via Healthstreams module with completion no later than 8/15/16.

The Director of Patient Care Services and Director of Education shall be responsible for ensuring the above educational steps are completed in keeping with the established timeframes. The Director of Education shall conduct a monthly audit of the above required mandatory education modules and classes to ensure completion by required staff. The result of the monthly audit shall be forwarded to the CNO and CMO for validation and follow up with staff and Providers, respectively, as required.

C 271 Plan of Care accepted. J. Cummins MD MS

C 272 485.635(a)(2), (a)(4) PATIENT CARE POLICIES

In response to this finding, the following steps have been taken:

- The policy titled "Physical and Chemical Restraints" was reviewed to ensure compliance with current regulatory requirements. The policy will receive any required updates and approval no later than 7/15/16. In addition to routine annual review and approvals, the Director of Patient Care Services will maintain ongoing responsibility for monitoring regulatory changes and updating the policy as required to ensure continued compliance with regulations.
- Expired policies within the organization's current policy management system have been reviewed and forwarded to the appropriate policy owner for review, update, and approval with completion of this process no later than 7/15/16.
- The Director of Quality will conduct a monthly audit beginning 7/15/16 of the organization's policy management system to ensure policies are kept up to date, with results of the audit forwarded to the Quality and Safety Committee on an ongoing monthly basis. In addition, policies found to be expired will be forwarded to Administration for follow up with the appropriate policy owners.

*C 272 Plan of Care accepted
J. Cummins MD MS*

*Carrie Wulfman, MD, CMO
6-27-16*

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In addition, the following steps have been taken to ensure ongoing review and compliance with regulatory requirements as they relate to policy management:

- The Policy Steering Committee was implemented on 6/3/16. The Committee is a multidisciplinary committee, including the CNO, CMO, and midlevel providers, as well as representation from Quality, Compliance, and both clinical and nonclinical departments. The Committee will provide oversight for policy development, review, and approval processes for all organizational policies. The Committee will provide a monthly report to the Quality and Safety Committee to facilitate dissemination of Committee activities as well as policy updates to all clinical and nonclinical departments.
- A new policy system, MCN, is scheduled to go live in September 2016. The new system will include a robust tracking and auditing system to facilitate improved compliance with policy management, updates and approvals.
- The above noted monthly audit of the policy system by the Director of Quality shall continue following the implementation of the new policy system, with monthly reports to the Policy Steering Committee and the Quality and Safety Committee, and to Administration as required for follow up with appropriate policy owners.

C302 Plan of Care accepted J. Cummins R.N.M.S.

C 302 485.638(a)(2) RECORDS SYSTEMS

As noted above, the following steps will be taken to ensure all staff and Providers are aware of the ordering and documentation requirements associated with the use of chemical and physical restraints:

- The policy titled "Physical and Chemical Restraints" will be forwarded to all staff and Providers through Healthstreams for review. The Healthstreams module will include an acknowledgment of their understanding of the content and whom to contact should they have additional questions or require further clarification. The module will be created no later than 7/18/16 and completed by all required staff and Providers no later than 8/15/16.
- Proposed edits to Porter's EMR associated with ordering, assessments and restraint application /administration will be completed no later than 7/22/16. The purpose of the edits will be to provide prompts and facilitate improved documentation by staff and Providers. A Healthstreams module related to these changes will be created no later than 8/1/16 and completed by all required staff and Providers no later than 8/15/16.
- Director of Patient Care Services will meet with all Emergency Department and Hospitalist Providers in person to review the restraint policy and regulatory requirements no later than 8/15/16. The discussion will include, at a minimum:
 - o Determining appropriateness of restraint use;
 - o Ordering of chemical and physical restraints;
 - o Required assessments; and
 - o Required documentation elements as per hospital policy.

- A mandatory restraint education training class will be developed by the Director of Education with classes to begin the week of 8/29/16. All required staff must attend the class no later than 9/15/16. The class will include, at a minimum:
 - o Review of the hospital's restraint policy;
 - o Review of the management of confused and/or agitated patients;
 - o Hands on demonstration of the application of physical restraints and required assessments associated with restraint use as per policy; and
 - o Documentation requirements as per hospital policy, to include documentation of the presence of other staff during the administration/application of restraints and whether the patient's actions posed a safety threat to the patient and or staff.

C 302 Plan of Care accepted J. Cummins R.N.M.S.

*Carrie Wilfman, MD, EMO
6-27-16*

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- The Director of Patient Care Services and Director of Education shall be responsible for ensuring the above educational steps are completed in keeping with the established timeframes. The Director of Education shall conduct a monthly audit of the above required mandatory education modules and classes to ensure completion by required staff. The result of the monthly audit shall be forwarded to the CNO and CMO for validation and follow up with staff and Providers, respectively, as required.
- In addition, the above noted concurrent review process of 100% of restrained patient records by the Nursing Supervisor includes the review of the documentation requirements as per hospital policy. The Director of Patient Care services will conduct monthly audits of the concurrent review process, as noted, to ensure compliance with the plan as written.

C 302 Plan of Care Accepted J. Cummins RN MS.

C 336 485.641(b) QUALITY ASSURANCE

The following steps have and will be taken to ensure restraint review data is continuously reviewed for opportunities to improve patient safety, eliminate inappropriate use of restraints, and to ensure compliance with the hospital's policy and regulatory requirements:

- The Emergency Department's concurrent review process has now been implemented on the Medical Surgical Unit. The Nursing Supervisor shall be responsible for the required concurrent reviews. The review process includes the following elements to ensure continued compliance with the hospital's restraint policy:
 - o Concurrent reviews of 100% of restrained patient records upon application of either chemical or physical restraints and will be repeated not less than every four hours for the duration of restraint use for the given patient;
 - o Appropriateness of restraint use;
 - o Accuracy of documentation to include orders, assessments, and administration of restraints;
 - o Documentation of real time feedback and follow up with Providers and staff in relation to the findings of the concurrent review process to ensure continued compliance.
 - o Any findings of noncompliance with the hospital's restraint policy that are not resolved at the time of discovery will be immediately reported to the Director of Patient Care Services, CNO, or CMO for immediate review and follow up with the staff or Provider in question.
 - o The above noted concurrent reviews shall be validated monthly by the Director of Patient Care Services to ensure continued compliance with this review plan.
 - o The Director of Patient Care Services will forward the results of the concurrent reviews to the Director of Quality on a monthly basis beginning 7/6/16 for review of trends and identification of opportunities to improve the safety of patients and eliminate inappropriate use of restraints. The resulting review data, trends, and associated performance improvement plans will be presented at the Quality and Safety Committee meetings on a monthly basis.

C 336 Plan of Care Accepted J. Cummins RN MS.

*Carrie Wulffman, MD, CMO
6-27-16*

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C 000	INITIAL COMMENTS An unannounced onsite complaint investigation was conducted by the Division of Licensing and Protection on 6/9/16 - 6/10/16 to determine compliance with Condition of Participation related to complaint #14676. The following regulatory violations were identified.	C 000			
C 271	485.635(a)(1) PATIENT CARE POLICIES The CAH's health care services are furnished in accordance with appropriate written policies that are consistent with applicable State law. This STANDARD is not met as evidenced by: Based on staff interview and record review, the hospital failed to provide care in accordance with its policy and procedure, Physical and Chemical Restraint Policy regarding the use of a chemical restraint for 1 applicable patient in the sample. (Patient #1). Findings include: Per record review during a survey related to a complaint regarding patient care, a hospital provider ordered chemical restraints for Patient #1 in violation of hospital policy and a RN (Registered Nurse) failed to provide the required documentation per the hospital policy, Physical and Chemical Restraints. 1. Patient #1's provider ordered chemical restraints for the patient due to increasingly agitated behaviors. The provider entry of 5/11/16 at 0041 hours noted the patient 'continued to strike out at staff and 'not able to be calmed down....swinging arms'.. The provider wrote orders for "Restraint Violent Patient, RN Q2H" at 0031 on 5/11/16. The provider noted that the family agreed to have a chemical restraint used and wrote orders for	C 271			

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

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

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C 271 Continued From page 1

Zyprexa 2.5 mg. (milligrams) every 4 hours. Per review of the hospital's restraint policy under section H. Provider Guidelines (MD, PA, NP), #3. "PRN Orders for the use of restraints are not acceptable". The provider had written orders for a chemical restraint to be administered more than 1 time, in effect, making the order PRN very 4 hours. This process violates the hospital's policy. Per the order set under the Protocol Text - Provider Guidelines, any orders for restraint (physical and chemical) for an adult would need to be renewed every 4 hours, for a maximum of 24 H, (not routinely every 4 H as ordered).

2. Nursing staff documented that the medication Zyprexa was administered to the patient at 0138 and 0558 on 5/11/16. The policy Physical and Chemical Restraints, also stated under section I. Nursing Guidelines, 5. Documentation, a. Documentation will be completed for every patient restraint episode upon initiation, and will be maintained in the medical record., b. The following elements will be included: c. Chemical Restraints, Describe the specific behaviors necessitating chemical restraint., d., Monitoring of vital signs, sedation and behavior each time a chemical restraint is administered and every 15 minutes for 2 hours.

For the 0558 administration of Zyprexa IM, there were no documented complete VS (vital signs) found from the time of administration until 0900, when the patient's blood pressure (B/P) was recorded as 83/47. Additionally, the Registered Nurse (RN) wrote in the medical record at 0142 hours "Zyprexa 2.5 mg. administered IM to patient's right thigh. Patient fought nurse during administration, but medication was successfully administered."

C 271

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C 271	<p>Continued From page 2</p> <p>The documentation failed to note if any other staff were present at the time and whether the patient's actions posed a safety risk to the patient and /or the nurse. The RN did not document a note after administering the 0558 dose of IM Zyprexa; there was no information of how the injection affected the patient at that time, including information on whether or not they "fought" the nurse.</p> <p>Per interview with an RN supervisor during the survey, s/he stated that when administering IM medication as a chemical restraint, they would ask 2 staff (1 at each limb), to be there for administration of the medication, and to calm the patient.</p> <p>These above findings were confirmed during interviews with the Interim Vice President of Patient Care, RN Supervisor and the Director of Quality during survey.</p>	C 271		
C 272	<p>Refer also to C- 0302</p> <p>485.635(a)(2), (a)(4) PATIENT CARE POLICIES</p> <p>§485.635(a)(2) The policies are developed with the advice of members of the CAH's professional healthcare staff, including one or more doctors of medicine or osteopathy and one or more physician assistants, nurse practitioners, or clinical nurse specialists, if they are on staff under the provisions of §485.631(a)(1).</p> <p>§485.635(a)(4) These policies are reviewed at least annually by the group of professional personnel required under paragraph (a)(2) of this section, and reviewed as necessary by the CAH.</p>	C 272		

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C 272	Continued From page 3 This STANDARD is not met as evidenced by: Based on staff interview and record review, the Hospital failed to conduct an annual review of it's policy related to use of physical and chemical restraints for 1 applicable patient in the targeted sample. (Patient #1). Findings include: Per review of the hospital's policy entitled Physical and Chemical Restraint Policy on 6/10/16, the policy was last reviewed/on 6/20/14 and expired on 6/20/15. During interview, the Director of Quality confirmed that the policy/procedure was not reviewed on an annual basis. Although hospital staff had recently begun a revision of the policy, it was not complete and approved as required.	C 272			
C 302	485.638(a)(2) RECORDS SYSTEMS The records are legible, complete, accurately documented, readily accessible, and systematically organized. This STANDARD is not met as evidenced by: Based on staff interview and record review, the hospital failed to maintain a complete and accurately documented record for one of four patients in the sample. (Patient #1). Findings include: Per record review during a survey related to a complaint regarding patient care, hospital staff failed to document required elements per the hospital's Physical and Chemical Restraint Policy. 1. Patient #1's provider ordered chemical restraints for the patient due to increasingly agitated behaviors. The provider entry of 5/11/16 at 0041 hours noted the patient 'continued to	C 302			

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C 302	<p>Continued From page 4</p> <p>strike out at staff and 'not able to be calmed down....swinging arms'..</p> <p>The provider wrote orders for "Restraint Violent Patient, RN Q2H" at 0031 on 5/11/16. The provider noted that the family agreed to have a chemical restraint used and wrote orders for Zyprexa 2.5 mg. (milligrams) every 4 hours. Per review of the hospital's restraint policy under section H. Provider Guidelines (MD, PA, NP), #3. "PRN Orders for the use of restraints are not acceptable". The provider had written orders for a chemical restraint to be administered more than 1 time, in effect, making the order PRN very 4 hours. This process violates the hospital's policy. Per the order set under the Protocol Text - Provider Guidelines, any orders for restraint (physical and chemical) for an adult would need to be renewed every 4 hours, for a maximum of 24 H, (not routinely every 4 H as ordered).</p> <p>2. Nursing staff documented that the medication was administered to the patient at 0138 and 0558 on 5/11/16. The policy also stated under section I. Nursing Guidelines, 5. Documentation, a. Documentation will be completed for every patient restraint episode upon initiation, and will be maintained in the medical record., b. The following elements will be included:, c. Chemical Restraints, Describe the specific behaviors necessitating chemical restraint., d., Monitoring of vital signs, sedation and behavior each time a chemical restraint is administered and every 15 minutes for 2 hours.</p> <p>For the 0558 administration of Zyprexa IM, there were no documented complete VS (vital signs) found from the time of administration until 0900, when the patient's blood pressure (B/P) was recorded as 83/47. Additionally, the Registered</p>	C 302		

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(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
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C 302	<p>Continued From page 5</p> <p>Nurse (RN) wrote in the medical record at 0142 hours "Zyprexa 2.5 mg. administered IM to patient's right thigh. Patient fought nurse during administration, but medication was successfully administered."</p> <p>The documentation failed to note if any other staff were present at the time and whether the patient's actions posed a safety risk to the patient and for the nurse. The RN did not document a note after administering the 0558 dose of IM Zyprexa; there was no information of how the injection affected the patient at that time, including information on whether or not they "fought" the nurse.</p> <p>Per interview with an RN supervisor during the survey, s/he stated that when administering IM medication as a chemical restraint, they would ask 2 staff (1 at each limb), to be there for administration of the medication, and to calm the patient.</p> <p>These above findings were confirmed during interviews with the Interim Vice President of Patient Care, RN Supervisor and the Director of Quality during survey.</p> <p>Refer also to C-0271</p>	C 302		
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C 336	<p>485.641(b) QUALITY ASSURANCE</p> <p>The CAH has an effective quality assurance program to evaluate the quality and appropriateness of the diagnosis and treatment furnished in the CAH and of the treatment outcomes. The program requires that --</p>	C 336		
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 06/17/2016
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 471307	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED C 06/10/2016
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NAME OF PROVIDER OR SUPPLIER PORTER HOSPITAL, INC	STREET ADDRESS, CITY, STATE, ZIP CODE 115 PORTER DRIVE MIDDLEBURY, VT 05753
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C 336	<p>Continued From page 6</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and record review, the hospital failed to use data collected on restraint use to identify opportunities to improve the safety of patients and eliminate inappropriate use of restraints, as stated in it's policy, Physical and Chemical Restraint Policy. This practice had the potential to affect all patients who are restrained. Findings include:</p> <p>Per review of the hospital policy, Physical and Chemical Restraint Policy, section G. Quality Assurance & Improvement, 1. c. Reports of restraints use and compliance with the restraint standards will be reported to the Quality Committee at least quarterly., d. Use the results of data analysis on the use of restraint to identify opportunities to improve the safety of patients and eliminate inappropriate use of restraint.</p> <p>The RN Supervisor for days on the medical-surgical unit confirmed during interview that s/he was responsible for conducting an audit of each instance of restraint use on the unit and then forwarded the results of the audit to QA staff. (The restraint use is entered into an electronic log, available to other departments). The audit used for this purpose does not identify nor review provider orders for appropriateness and adherence to hospital policies. The RN had not noted in the audit of this case (Patient #1) that the provider order was written as a PRN and violated the hospital policy.</p> <p>Per interview with the Director of Quality, all restraint incidents are also reviewed by the QA staff for adherence with policy guidelines and regulatory compliance. They are discussed at the monthly Safety Committee Meetings and</p>	C 336		
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C 336	Continued From page 7 quarterly at QA Committee meetings. For the restraint review for Patient #1, although the QA department staff had identified that the provider order was in violation of the hospital policy on restraints, there was no systemic plan/involvement to use the results of the restraint audits to identify opportunities to improve the safety of patients and eliminate inappropriate use of restraints. The Director identified that different units of the hospital use different audit tools for restraint reviews and there is not a hospital wide review protocol in practice currently at the hospital. Refer also to C-0271 and C-0302.	C 336	