

SFJR



Protecting, Maintaining and Improving the Health of Minnesotans

Office of Health Facility Complaints Investigative Report
PUBLIC

Facility:

Health and Rehab New Brighton
825 First Avenue Northwest
New Brighton, MN 55112
Ramsey County

Report #: H5164086

Date: 12/8/2009

Date of Visit: 9/2/2009
Time of Visit: 1:00 p.m.

By: Lori Wear, R.N.
Special Investigator

Nature of Visit:

An unannounced visit was made in order to investigate the following allegation of neglect in accordance with federal regulations for long term care facilities at 42 CFR Part 483, Subpart B. In conjunction with the federal investigation, an investigation was also conducted in accordance with the Vulnerable Adults Act (VAA), Minnesota Statutes §626.557 and state nursing home licensing rules, Chapter 4658.

The allegation is: Neglect related to medication administration occurred when resident #1 was administered incorrect medication (the wrong complex of Amphotericin B Cholesteryl Complex (AMPHOTEC) at 300 mg) on 8/3/2009 and 8/4/2009. The error resulted in acute renal failure ultimately causing resident #1's death on 8/19/2009.

Investigative Findings:

All employees and persons were interviewed in private as desired and given the Tennessee Statement.

The investigation included a review of resident #1's medical record as well as the medical record of one additional resident receiving IV medications; staff schedules and assignments for 8/1 through 8/6/2009; the facility's internal investigation; policies and procedures related to IV medication administration and pharmacy services; medication errors for June, July and August 2009 and personnel files for two staff. In addition, observation of IV medication administration was conducted with no concerns noted.

Medical Record:

A review of resident #1's medical record revealed diagnoses including fungal pneumonia, multiple myeloma and acute renal failure. Documentation from the hospital dated 8/1/2009 shows an order for amphotericin B cholesteryl complex (AMPHOTEC) 300 mg IV (intravenous) daily with premedication before infusion, to be infused over 6 hours. The Medication Administration Record (MAR) dated 8/2009 shows an order for AMPHOTEC 300 mg IV daily with premedication before infusion to be infused over 6 hours. Resident #1's medical record contained a step-by-step instruction sheet for administration of the amphotericin and premedication. Additionally, it contained information about each of the IV medications to be given.

Interviews:

Employee (A)/administrative nurse was interviewed on 9/30/2009, at 8:02 a.m. and stated the following:

- She wrote out the protocol for resident #1's IV medication administration of the amphotericin to include assessing resident #1 prior to running the IV, running sodium chloride, giving IV push Demerol, giving extra strength Tylenol orally, giving IV push Benadryl, running more sodium chloride, giving IV Demerol again, flushing the IV with D5W (an IV solution) and then running the amphotericin. The IV took 6 hours to run. The first administration was completed by employee (A) and she stayed with resident #1 the entire time.
- She provided one to one education for the registered nurses (RN) who would be administering the IV amphotericin. She wrote out step-by-step instructions and placed them in the chart and made photocopies of information about the medications used during the procedure and placed them in the chart.
- She stated that the label on the IV amphotericin matched the MAR and both matched the physician order.
- She stated that on 8/3/2009 it was noted that resident #1 had purple splotches on his skin from his knees to his feet. He exhibited no other signs or symptoms and he stated that he had this happen at home and it would go away if he walked around. He was ambulated and the areas of discoloration went away. At 9:00 a.m. on 8/4/2009 the splotches were noted on all four extremities and his torso. Resident #1's physician was contacted, labs were ordered and his physician arrived at the facility to assess resident #1. Resident #1 was sent in to the hospital for evaluation.
- After resident #1 was transported to the hospital, employee (A) received a call from the facility's pharmacy provider stating that the IV amphotericin was sent in the wrong mixing solution. Employee (A) contacted the emergency room to inform them of this information.
- The conclusion of her internal investigation was that the facility received the IV amphotericin mixed in the wrong solution. Her investigation revealed that the facility could not have known that the medium used to mix the solution was wrong due to the label on the medication, the MAR and the physician order matching.

Employee (B)/registered nurse (RN) was interviewed on 9/2/2009, at 2:30 p.m. and stated the following:

- She administered one dose of the amphotericin to resident #1. The label on the medication matched the MAR and both matched the physician order.

Individual (D)/pharmacist was interviewed on 10/13/2009, at 3:00 p.m. and stated the following:

- Amphotericin comes in four formulations including the traditional formulation which is more nephro (kidney) toxic, colloidal, lipid and liposomal.
- He was working on 8/1/2009, when the order for IV amphotericin came in for resident #1. He stated he was not aware that amphotericin came in more than one formulation.
- He stated the dispensing of the incorrect formulation was noted by the IV pharmacist on the Monday following the initial order when she was doing the Quality Assurance process on this dispensing. The IV pharmacist noticed that the order was filled with one formulation of amphotericin B and prescribed for a different formulation of the medication.
- He stated that traditional amphotericin was sent rather than the cholesteryl complex as was ordered.

Individual (E)/family member was interviewed on 10/15/2009, at 10:52 a.m. and stated the following:

- Resident #1 was concerned that the facility didn't know how to administer his IV amphotericin because they wanted to change his IV push medications to oral.
- He stated resident #1 was admitted to the hospital following the IV administration of the amphotericin in renal failure. He indicated that resident #1 was on dialysis due to receiving the wrong formulation of amphotericin and that because of his kidney function, he could not receive treatment for his multiple myeloma or the fungal pneumonia.
- He stated that resident #1 passed away while he was in the hospital.

Individual (C)/physician was interviewed on 10/19/2009, at 9:12 a.m. and stated the following:

- He followed resident #1 in the clinic for five years. He saw resident #1 in the hospital after his 8/4/2009 admission. Resident #1 received the traditional formulation of amphotericin which can be nephrotoxic.
- The purple discoloration on resident #1's trunk and extremities was likely related to his multiple myeloma.

Conclusion:

As defined by federal regulatory requirements at 42 CFR 483.13(c), and the current statutory definitions specified within Minnesota Statutes, §626.5572, the preponderance of evidence indicates that **neglect did occur** when resident #1 received an incorrect form of amphotericin. The pharmacy dispensed amphotericin for resident #1 in the traditional formulation rather than the cholesteryl complex as ordered by the physician. The facility administered the medication according to accepted standards of practice and had no way of knowing that the amphotericin had been mixed in an incorrect formulation. Resident #1 died on 8/19/2009, with an immediate cause of death of multiple myeloma and a contributing condition of acute renal failure.

The facility established, upon admission, a protocol for the IV administration of the amphotericin cholesteryl complex per the physician orders. Interviews with the RN's who administered the IV amphotericin established that the label on the IV medication matched the MAR and both matched the physician order. Resident #1 was noted to have a change in condition on 8/4/2009; his physician was contacted and arrived at the facility to assess him on that date. Resident #1 was transported to the hospital and was admitted. After resident #1's transportation to the hospital on 8/4/2009, employee (A) received notification from the pharmacy provider that the wrong formulation of the amphotericin had been dispensed for resident #1. Individual (D)/pharmacist stated he was not aware there was more than one formulation of amphotericin. He stated the traditional formulation of amphotericin was sent rather than the cholesteryl complex which was ordered.

A copy of this report will be sent to the Minnesota Board of Pharmacy.

The "mitigating factors" in Minnesota Statutes, §626.557, subdivision 9c (c) were considered and it was determined that the facility is not responsible for the neglect.

cc: Division of Compliance Monitoring - Licensing & Certification
Minnesota Board of Examiners for Nursing Home Administrators
Minnesota Board of Pharmacy
Ramsey County Medical Examiners
New Brighton Police Department
New Brighton City Attorney
Ramsey County Attorney

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

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FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 245164	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED C 10/01/2009
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NAME OF PROVIDER OR SUPPLIER HEALTH AND REHABILITATION OF NEW BRIGHTON	STREET ADDRESS, CITY, STATE, ZIP CODE 825 FIRST AVENUE NORTHWEST NEW BRIGHTON, MN 55112
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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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F 000	<p>INITIAL COMMENTS</p> <p>An abbreviated standard survey was conducted to investigate complaint H5164086. No deficiencies are issued.</p>	F 000		
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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
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Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.