

Division of Licensing and Protection
103 South Main Street, Ladd Hall
Waterbury VT 05671-2306
<http://www.dail.vermont.gov>
Voice/TTY (802) 241-2345
To Report Adult Abuse: (800) 564-1612
Fax (802) 241-2358

December 10, 2010

Bradford Ellis, Administrator
Vernon Green Nursing Home
61 Greenway Drive
Vernon, VT 05354-9474

Provider ID #:475008

Dear Mr. Ellis:

Enclosed is a copy of your acceptable plans of correction for the survey conducted on **November 10, 2010**.

Follow-up may occur to verify that substantial compliance has been achieved and maintained.

Sincerely,



Pamela M. Cota, RN
Licensing Chief

PC:jl

Enclosure



F282 continued from page 1

2. RN/LPN will be educated on interventions to utilize prior to administering a medication (PRN antipsychotic drug) to resident #65. RN/LPNs will be counseled by DON on the utilization of PRN psychotropic medications and documentation of interventions performed prior to administering medications for resident #65. 11/15/10

How will you identify other residents having the potential to be affected by the same deficient practice and what corrective action will be taken?

1. All residents have the potential to be affected by this practice. Nursing staff received education verbally on care plan compliance. 11/15/10

2. Any resident on PRN antipsychotics have the potential to be affected by this practice. RN/LPNs will receive education on the utilization of PRN psychotropic medications, interventions prior to administering and proper documentation. 11/15/10

What measures will be put into place or what systemic changes you will make to ensure that the deficient practice does not recur?

1. Position sheet will be put in place as deemed necessary by the Care Plan team. Education on Care Plan compliance and review will take place at a nursing staff meeting. 12/10/10

2. RN/LPN will be educated on non-pharmacological interventions prior to the usage of PRN medications. RN/LPN will be educated on reviewing care plans for the non-pharmacological interventions. 12/03/10

How the corrective actions will be monitored to ensure the deficient practice will not recur, i.e., what quality assurance program will be put into place?

1. Director of Nurses or Designee will conduct Quality Assurance/Quality Improvement audits to ensure continued compliance of staff to assure the plan of care/repositioning/toileting is timely and the plan of care is being followed. The audits will be conducted weekly for one month, and then bi-monthly for 3 months until 100% compliance is obtained. 12/06/10

2. Director of Nurses or Designee will audit weekly for one month, and then bi-monthly for 3 months until 100% compliance is obtained. The DON or designee will report the results of the audits to the Quality Assurance Committee who will determine the need for further monitoring. 12/06/10

F282 POC Accepted 12/9/10 Amcokun BHOWERN

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

PRINTED: 12/03/2010
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 475008	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 11/10/2010
NAME OF PROVIDER OR SUPPLIER VERNON GREEN NURSING HOME			STREET ADDRESS, CITY, STATE, ZIP CODE 61 GREENWAY DRIVE VERNON, VT 05354		
(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	
F 282	Continued From page 1 manager confirmed that staff did not provide care in accordance with the plan of care. 2. Per record review, conducted on 11/9/10, staff failed to assure Resident #65's care plan was followed as evidenced by the failure to implement non pharmacological interventions to address behavior issues prior to administration of an as needed (PRN) antipsychotic drug. The resident's care plan directed staff to; provide 1:1 assistance, offer fluids, snacks or assess for pain. Per review of the MAR (Medication Administration Record) the patient received Zyprexa 5 mg at 1:30 AM on each of the following dates; 10/29/10, 10/30/10 and 10/31/10. Although nurses notes corresponding to those dates and times stated that the Zyprexa (antipsychotic) was given for "insomnia, wandering halls, up and down in and out of bed, restless", there was no evidence that any of the non pharmacological interventions had been tried prior to the use of the Zyprexa. Per interview on 11/10/10 at 11:00 AM the Unit manager confirmed that there was no documentation that non-pharmacological interventions were considered or used, prior to the PRN antipsychotic drug.	F 282			
F 329 SS=D	refer Tag F-329 483.25(l) DRUG REGIMEN IS FREE FROM UNNECESSARY DRUGS Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used in excessive dose (including duplicate therapy); or for excessive duration; or without adequate monitoring; or without adequate indications for its use; or in the presence of	F 329	F 329. The facility has and continues to ensure that each resident's drug regimen is free from unnecessary drugs. <u>What corrective action will be accomplished for those residents found to have been affected by the deficient practice?</u> RN/LPN will be educated on interventions to utilize prior to administering a medication (PRN antipsychotic drug) to resident #65. RN/LPNs will be counseled by DON on the utilization of PRN psychotropic medications and documentation of interventions performed prior to administering medications for resident #65.	11/15/10	

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F 329	Continued From page 3 (antipsychotic) was given for "insomnia, wandering halls, up and down in and out of bed, restless", there was no evidence that any of the non pharmacological interventions had been tried prior to the use of the Zyprexa. The resident's care plan directed staff to; provide 1:1 assistance, offer fluids, snacks or assess for pain. Per interview on 11/10/10 at 11:00 AM the Unit manager confirmed that there was no evidence that non-pharmacological interventions were considered or used prior to the PRN antipsychotic drug.	F 329			
F 431 SS=D	Refer also to F282 483.60(b), (d), (e) DRUG RECORDS, LABEL/STORE DRUGS & BIOLOGICALS The facility must employ or obtain the services of a licensed pharmacist who establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled. Drugs and biologicals used in the facility must be labeled in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions, and the expiration date when applicable. In accordance with State and Federal laws, the facility must store all drugs and biologicals in locked compartments under proper temperature controls, and permit only authorized personnel to have access to the keys.	F 431	F 431 <u>What corrective action will be accomplished for those residents found to have been affected by the deficient practice?</u> All medications for resident #13 will have the expiration dates reviewed and any expired medication have been disposed of. <u>How will you identify other residents having the potential to be affected by the same deficient practice and what corrective action will be taken?</u> Any resident receiving medication has the potential to be affected by this practice. Medication Storage rooms and Medication Carts will be gone through for expired medications. All expired medications will be disposed of.	11/09/10 11/09/10	

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F 441 SS=E	<p>483.65 INFECTION CONTROL, PREVENT SPREAD, LINENS</p> <p>The facility must establish and maintain an Infection Control Program designed to provide a safe, sanitary and comfortable environment and to help prevent the development and transmission of disease and infection.</p> <p>(a) Infection Control Program The facility must establish an Infection Control Program under which it - (1) Investigates, controls, and prevents infections in the facility; (2) Decides what procedures, such as isolation, should be applied to an individual resident; and (3) Maintains a record of incidents and corrective actions related to infections.</p> <p>(b) Preventing Spread of Infection (1) When the Infection Control Program determines that a resident needs isolation to prevent the spread of infection, the facility must isolate the resident. (2) The facility must prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease. (3) The facility must require staff to wash their hands after each direct resident contact for which hand washing is indicated by accepted professional practice.</p> <p>(c) Linens Personnel must handle, store, process and transport linens so as to prevent the spread of infection.</p>	F 441	<p>F 441</p> <p>The facility requests informal dispute resolution for Tag 441; respectfully maintains that it was and is in substantial compliance with federal regulations in respect to F 441; respectfully denies and disputes the allegation that it was deficient in respect to F 441; respectfully denies and disputes that any action or inaction on the part of the facility in respect to F 441 caused any harm or potential for harm to any facility residents; requests that F 441 be deleted from the public record.</p> <p>The facility will demonstrate:</p> <p>(A) substantial compliance with F 441 by showing the facility has an infection control program to help prevent the development and transmission of disease and infection; (B) CMS State Operators Manual was followed to clean and disinfect the glucometer; (C) manufacturer guidelines were followed to clean and disinfect the glucometer; (D) FDA, CDC and CMS guidance for glucometer use was followed.</p> <p>The regulation states that "The facility must establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of disease and infections in the facility; decides which procedures, such as isolation, should be applied to an individual resident and maintains a record of incidents and corrective actions related to infections." The regulation further states that "When the Infection Control</p>		

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F 441	<p>Continued From page 6</p> <p>This REQUIREMENT is not met as evidenced by: Per observation and staff interview(s) the facility failed to clean the multiple use glucometer to prevent blood-borne pathogen transmission after checking the blood sugar for 1 resident (# 81) in the total sample. Findings include:</p> <p>Per observation at 4:00 PM on 11/19/10 the staff nurse failed to follow the standard of practice for disinfecting a multiple use glucometer (blood testing machine) when s/he used an alcohol wipe, containing only 70% alcohol, to clean the glucometer following its use to check Resident # 81's blood sugar. The Optium EZ Glucometer manufacturers booklet, Abbott Diabetes Care Abbott/Alameda California published in 2009, states the following may be used for cleaning the glucometer: 70% alcohol, 10% Ammonia, or 10% Bleach. Although the facility policy & procedure regarding glucometer cleaning included using alcohol wipes (per manufactures' instructions) as an acceptable cleaning method, the FDA states that 70% ethanol solutions are not effective against viral bloodborne pathogens and that the disinfection protocol should be effective against Hepatitis B virus.</p> <p>Per interview on 11/10/10 at 11:00 AM both the DNS and the Infection Control Coordinator confirmed that the facility policy for cleaning the multiple use glucometers included using an alcohol wipe.</p> <p>1. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm2279</p>	F 441	<p>F 441 continued from page 6</p> <p>Program determines that a resident needs isolation to prevent the spread of infection, the facility must isolate the resident; the facility must prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact transmits the disease. The facility must require staff to wash their hands after each direct resident contact for which hand washing is indicated by accepted professional practice and personnel must handle, store, process and transport linens so as to prevent the spread of infection.”</p> <p>The facility had and continues to have an infection control program to help prevent the development and transmission of disease and infections for all residents in the facility.</p> <p>The Appendix PP - Guidance to Surveyors for Long Term Care Facilities states:</p> <p>Indirect transmission involves the transfer of an infectious agent through a contaminated intermediate object.</p> <p>The following are examples of opportunities for indirect contact.</p> <ul style="list-style-type: none"> • Resident-care devices (e.g., electronic thermometers or glucose monitoring devices) may transmit pathogens if devices contaminated with blood or body fluids are shared without cleaning and disinfecting between uses for different residents. <p>The surveyor does correctly state that the staff used an alcohol wipe containing 70% alcohol to clean the glucometer following its use to check Resident #81's blood sugar.</p>		

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The surveyor does not clearly define how the facility has failed to meet the “standard of practice for disinfecting a multiple use glucometer”. The Surveyor’s reference made to

<http://www.fda/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm227935.htm> is a September 20, 2010 letter from the U.S. Food and Drug Administration (FDA) to manufacturers of blood glucose monitoring systems (BGMS). The facility was not, and cannot reasonably be expected to have been, aware of the letter from the FDA to manufacturers of blood glucose manufacturing systems (BGMS). Unlike the FDA alerts and notices referenced hereafter, the September 20, 2010 letter was not addressed to healthcare personnel who perform blood sampling, but rather manufacturers submitting new BGMS for approval. The facility cannot be expected to monitor all regulatory guidance from all governmental agencies in all fields. The facility can, of course, be expected to know and follow the regulations that pertain to it and, as shown below, the facility did follow such regulations. Furthermore, even if the facility was aware of the September 20, 2010 letter, the facility’s compliance with the existing guidelines provided in the device labeling would have been permissible since the FDA letter only applied to new devices yet to be submitted for approval. However, had the facility known about the September 20, 2010 letter it would have purchased individual BGMS for each resident as it has done since becoming aware of the September 20, 2010 letter.

The FDA letter to BGMS manufacturers does state the following:

During the week of August 23, 2010, the FDA, CDC, and CMS issued clinical reminders and public health notifications highlighting the risk of transmission of disease from shared use of finger stick (lancing) devices and point of care blood testing devices. The posting of these notifications was in response to recent outbreaks of viral hepatitis among patients where these devices were shared between users. The CDC and the FDA currently recommend the following:

- Lancing devices should never be used for more than one person. Only auto-disabling, single use lancing devices should be used for assisted blood glucose monitoring in multiple patients.
- Point of care blood testing devices such as blood glucose meters should be used only on one patient and not shared. If dedicating blood glucose meters to a single patient is not possible, *the meters must be properly cleaned and disinfected after every use following the guidelines provided in device labeling (emphasis added).*
- Healthcare personnel should change gloves between patients, even if patient dedicated testing devices and single-use, self-disabling lancing devices are used.

F441 continued from page 7a

The clinical reminders and public health notifications mentioned above and below did not state that the existing guidelines provided in the device labeling which recommended that the BGMS be cleaned with a 70% alcohol solution were no longer acceptable. As correctly stated by the surveyor, the glucometer, per the manufacturer's User's Guide, may be cleaned with 70% alcohol. The surveyor has taken his/her statement in reference to the FDA out of context and has presented it as a standard of practice. The FDA is providing guidance to manufacturers on validating cleaning and disinfection procedures when submitting products for review by the FDA. The following is the full quote of the information provided by the FDA to manufacturers of BGMS:

2. Validated cleaning and disinfection procedures:

Please provide validated cleaning and disinfecting procedures for your BGMS (regardless of its intended use) for our review. Your cleaning and disinfecting validation study should include the following:

- a. Selection of cleaning and disinfection solvents and procedures that do not result in physical deterioration of the device overall, or deterioration of any device component such as the housing or touch pad or buttons. Please make note of these physical indicators during your study and provide this information for our review. The disinfection solvent you choose should be effective against HIV, Hepatitis C, and Hepatitis B virus. Outbreak episodes have been largely due to transmission of Hepatitis B and C viruses. However, of the two, Hepatitis B virus is the most difficult to kill. Please note that 70% ethanol solutions are not effective against viral blood borne pathogens and the use of 10% bleach solutions may lead to physical degradation of your device. A list of Environmental Protection Agency (EPA) registered disinfectants effective against Hepatitis B can be found at the following website:
http://www.epa.gov/oppad001/list_d_hepatitisbhiv.pdf

As a follow up to the August 23, 2010 public health notification from the FDA, CDC and CMS the following documents have been published. Excerpts from the documents are included here which convey the recommendations of government agencies

<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>

Recommendations and FDA Action

The FDA and the CDC recommend that health care professionals and patients take the following immediate precautions:

- Never use finger stick devices for more than one person.
- Use auto-disabling, single-use finger stick devices for assisted monitoring of blood glucose. These

F441 continued from page 7b

devices are designed to be used only once, after which the blade is retracted, capped or otherwise made unusable. These are sometimes called "safety" lancets.

- Whenever possible, use POC blood testing devices, such as blood glucose meters and PT/INR anticoagulation meters, for one patient only. If dedicating POC blood testing devices to a single patient is not possible, *the devices should be properly cleaned and disinfected after every use as described in the device labeling* (emphasis added).
- Change gloves between patients, even when using patient-dedicated POC blood testing devices and single-use, auto-disabling finger stick devices.

<http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html>

Summary

The Centers for Disease Control and Prevention (CDC) has become increasingly concerned about the risks for transmitting hepatitis B virus (HBV) and other infectious diseases during assisted blood glucose (blood sugar) monitoring and insulin administration.

CDC is alerting all persons who assist others with blood glucose monitoring and/or insulin administration of the following infection control requirements:

- Finger stick devices should **never** be used for more than one person
- Whenever possible, blood glucose meters should **not** be shared. If they must be shared, *the device should be cleaned and disinfected after every use, per manufacturer's instructions* (emphasis added). If the manufacturer does not specify how the device should be cleaned and disinfected then it should not be shared.
- Insulin pens and other medication cartridges and syringes are for single-patient-use only and should **never** be used for more than one person

Center for Medicaid, CHIP, and Survey & Certification/Survey & Certification Group
Ref: S&C: 10-28-NH Date: August 27, 2010

Deficiency Identification

- Finger stick devices must never be used for more than one resident. Although the package instructions for some finger stick devices may indicate or imply the potential for multiple patient use, surveyors and health care workers must adhere to this CMS guidance regarding the avoidance of multiple patient use of finger stick devices, consistent with recent statements of the CDC and the FDA.

F441 continued from page 7c

- Point-of-care devices, such as blood glucose meters, can become contaminated with blood and, if used for multiple residents, *must be cleaned and disinfected after each use according to manufacturer's instructions* (emphasis added).
- If the manufacturer does not specify steps for cleaning and disinfection between uses of a point-of-care device, then the device generally should not be used for more than one resident. In the case of point-of-care devices where there are no manufacturers' instructions for cleaning between uses, we strongly advise nursing homes not to share the devices among residents. In such cases involving sampled residents (or when triggered for further investigation) where there are no manufacturer's instructions, surveyors will inquire as to the methods used for cleaning and disinfection between shared uses and will cite a deficiency for such a practice unless the nursing home can clearly establish that commonly accepted safe infection control practices are being followed (through authoritative references to published research, CDC recommendations, recommendations of professional societies, or similar references to commonly accepted professional practices).

Since there is ample evidence that the facility does follow FDA, CDC, CMS and manufacturer guidelines for use of the glucometer, and the facility was not, and cannot reasonably be expected to have been, aware of the letter from the FDA to manufacturers of BGMS, the facility requests this deficiency be deleted from the public record.

The facility has demonstrated:

- (A) substantial compliance with F 441 by showing the facility has an infection control program to help prevent the development and transmission of disease and infection;
- (B) CMS State Operators Manual was followed to clean and disinfect the glucometer;
- (C) manufacturer guidelines were followed to clean and disinfect the glucometer;
- (D) FDA, CDC and CMS guidance for glucometer use was followed.

The facility respectfully requests that this finding, F 441, be removed from the record.

The facility continues to have an infection control program to help prevent the development and transmission of disease and infections for all residents in the facility.

What corrective action will be accomplished for those residents found to have been affected by the deficient practice?

Each resident has their own glucometer for individual usage. The facility will follow the recommendations of appropriate federal agencies for cleaning of individual use glucometers.

