State of New Jersey
DEPARTMENT OF HEALTH
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CHRIS CHRISTIE
Governor

KIM GUADAGNO
Lt. Governor

MARY E. O'DOWD, M.P.H.
Commissioner

January, 2013

Dear Administrator:

Since its inception, licensure of Assisted Living Facilities (ALFs), Assisted Living Programs (ALPs) and Comprehensive Personal Care Homes (CPCHs) has been a cooperative and pioneering endeavor. In September 2008 the Department of Health (Department) first allowed Certified Medication Aides (CMAs) to administer insulin using fixed insulin cartridge & injector devices under N.J.A.C. 8:36-11.5 (b)3i. Today, I am pleased to announce that after careful consideration, the Department will accept a waiver request from facilities to expand the role of the Certified Medication Aide. If granted the approved waiver request will allow the registered professional nurse (RN) to delegate to certified medication aides (CMAs), the administration of injectable medications (other than the previously approved insulin) via disposable, integrated, mechanical, medication delivery devices that are prefilled by the manufacturer (commonly known as "pens").

In accordance with N.J.A.C. 8:36-11.5(b)(1)(i-ii) b) "The registered professional nurse may choose to delegate the task of administering medications in accordance with N.J.A.C. 13:37-6.2 to certified medication aides, as defined in this chapter. 1. A unit-of-use/unit dose drug distribution system shall be developed and implemented whenever the administration of medication is delegated by the registered professional nurse to a certified medication aide." Currently the regulations limit the delegation of injectable medications. The Chapter specifies at N.J.A.C. 8:36-11.5(b)(3)(i) that "(3) The certified medication aide shall not: i. Administer any injection other than pre-drawn properly packaged and labeled insulin as described in (b)1 above." Therefore, a facility that wants to institute such a program must apply for a waiver of N.J.A.C. 8:36-11.5(b)(3)(i).

The waiver request must conform to Department developed guidelines; the Instructor's Rating Sheet for Duty Area 2.1(a) and the Questions and Answers (enclosed). The Application for Waiver form CN-28 can be found at http://web.doh.state.nj.us/apps2/forms/index.aspx. If you have any questions or require additional information, please contact Pamela Z. Gendlek, Program Manager, Assessment & Survey at pamela.gendlek@doh.state.nj.us or (609) 633-8981.

Sincerely,

Barbara Goldman, R.N., J.D.
Assistant Director
Office of Certificate of Need and
Healthcare Facility Licensure

Enclosures: Department developed guidelines
Instructor's Rating Sheet for Duty Area 2.1(a)
Questions and Answers

CERTIFIED MEDICATION AIDES USE OF DISPOSABLE, INTEGRATED, MECHANICAL, MEDICATION DELIVERY DEVICES THAT ARE PREFILLED BY THE MANUFACTURER

N.J.A.C. 8:36 STANDARDS FOR LICENSURE OF ASSISTED LIVING RESIDENCES, COMPREHENSIVE PERSONAL CARE HOMES, AND ASSISTED LIVING PROGRAMS allows the registered professional nurse to delegate the task of administering medications to certified medication aides.

In accordance with 8:36-11.5(b)(1)(i-ii) b) “The registered professional nurse may choose to delegate the task of administering medications in accordance with N.J.A.C. 13:37-6.2 to certified medication aides, as defined in this chapter. 1. A unit-of-use/unit dose drug distribution system shall be developed and implemented whenever the administration of medication is delegated by the registered professional nurse to a certified medication aide.”

However, the delegation of injectable medications is limited. The Chapter specifies at 8:36-11.5(b)(3)(i) that “(3) The certified medication aide shall not: i. Administer any injection other than pre-drawn properly packaged and labeled insulin as described in (b)1 above.”

After careful consideration the Department of Health will accept and review waiver requests by facilities that allow the registered professional nurse (RN) to delegate the administration of injectable medications other than insulin via disposable, integrated, mechanical, medication delivery devices that are prefilled by the manufacturer (commonly known as “pens") to certified medication aides (CMAs).

The following is required, for any facility that plans to request this waiver.

Prior to allowing CMAs to administer medication via the “pen” method, policies and procedures must be developed for the use of the pens in the facility and for residents out on pass. Policies and procedures must address at a minimum the following:

A. <u>Packaging and Storage</u>

1. Original pharmacy box of pens / cartridges must be stored as specified by the manufacturer.

2. The pen / cartridge in use must be stored at the temperature specified by the manufacturer. If the recommendation is to store the medication at room temperature, store it in the medication cart up to the amount of time specified by the manufacturer. If the recommendation is to refrigerate the pen in use, check with the RN for specific storage details.

3. Pharmacy to label individual pens / cartridges with the resident's name and provide space for the date that use starts. Label must be on the pen / cartridge body not the cap.

4. Safety needles must be used on the pens in accordance with N.J.A.C. 8:43E-7.

B. Training

1. Each pen type and medication is unique. The RN must instruct the CMA on the use of each type of pen and on any unique medication administration instructions.

2. Before allowing the CMA to administer any medication via a pen, the attached Instructor's Rating Sheet for Duty area 2.1(a) must be completed for the CMA for each type of pen they will be using.

3. Whenever an RN delegates the administration of a new medication via a pen to a CMA, the RN shall observe the first doses administered by the CMA. The RN shall remain on-site for at least four hours following administration of a new medication via the pen method to monitor for adverse side effects. The Facility shall establish a policy for the number of doses that the RN shall observe that is based upon the pharmaceutical manufacturers' recommendations. However, in no case shall the RN observe administration of less than the first three doses or the first three days; whichever covers a longer period of time.

4. The RN should review with the CMA the special instructions that will be entered on the MAR re: the pen including:

    i. Priming instructions.
    ii. Mixing instructions.
    iii. Duration requirements: Specify the amount of time that the needle is to remain in the injection site before withdrawal.
    iv. Site rotation requirements.

5. The RN should review with the CMA at least the following cautions & warnings.

    i. Pens can become contaminated with fluid, cells and particles from the resident. They must never be used on more than one resident.
    ii. A drop may remain on skin after administration. This may be from the priming dose or early withdrawal of the needle. Symptoms of inadequate dosage must be monitored.

iii. Extreme care must be exercised in checking that the correct medication is being given. The names of medications are often similar.
iv. Do not rely on color-coding. There is no standard. Therefore, colors from different manufacturers may not match.
v. Priming methods can differ when using safety needles. Some require that the safety needle be pointed down, NOT up, when priming the needle. You cannot withdraw the needle guard to visualize the needle while priming. This will lock the guard over the needle preventing further use of that needle.
vi. Do not push in injector button without a needle on the pen.
vii. Needles lock closed after the injection or if the guard is pushed down. One brand of safety needle has a red band that appears after use indicating that it is locked, but others have no indicator.

DUTY AREA 2.1(a) EVALUATION

DEMONSTRATE PROPER INJECTION WITH PEN

INSTRUCTOR'S RATING SHEET

Rate Each Trainee Individually

Trainee Name: _____ **Date:** _____

Instructor Name: _____

Type of Pen: _____

THE TRAINEE	COMMENTS	RATING	
1. Wash hands.			
2. Check MAR for dosage and other instructions.			
3. Check pen: expiration date and appearance.			
4. Follow RN's instructions re: preparation of the pen and medication.			
5. Wipe tip of cartridge with alcohol sponge.			
6. Attach safety needle to syringe and remove cap from the needle.			
7. Prime pen as instructed by RN.			
8. Dial correct dose as ordered.			
9. Choose site and cleanse skin with alcohol sponge.			
10. Pinch up skin and hold pen in a fist-like grasp with thumb clear of the injector button. Push the needle into the skin at a 90-degree angle.			
11. Depress the injector button with the thumb. Hold the needle in place for the time specified by the nurse on the MAR.			
12. Withdraw the needle from the skin.			
13. Dispose of safety needle in the sharps container.			
14. Replace cap on the pen.			
15. Return Pen to proper storage area.			

RATING DESIGNATION: **A = ACCEPTABLE;** **U = UNACCEPTABLE**

USE BY CERTIFIED MEDICATION AIDES (CMA) of Pen Injector Devices (pen) QUESTIONS & ANSWERS

ADMINISTRATION

Q. Should the CMA shake the pen to mix the medication?
A. Check the label or the manufacturer's literature. Some medications need to be shaken or agitated others may not require shaking and some such as insulin could be damaged by severe shaking. NEVER SHAKE insulin. The CMA should mix insulin suspensions by gently rolling the insulin pen between his/her palms 10 times, then alternate pointing the insulin pen up and down 10 times. Vigorous shaking can break up insulin molecules and decrease the potency of insulin.

Q. Does the needle on all pens need to be primed before each dose or just the first time the pen is used?
A. All pens must be primed each time they are used.

Q. Can the type of medication in a pen be identified by the color of the label or the color of the pen?
A. No Always read the label. Never choose any item by the color. There is no standard color system. Manufacturers may use any color they want and can change the color system at any time.

Q. When using a pen must the injection sites be rotated?
A. Generally Yes. Injection site rotation is generally needed for medications that are injected on a regular basis such as daily or more often. Check with the delegating nurse for direction on site rotation and record it on the MAR.

Q. How long should the needle remain in the resident after the push button has been depressed?
A. Different brands of pens have different recommended times that vary from 5 to 10 seconds. Before initial use of a pen, the CMA must check the manufacturer's literature for the correct amount of time. The CMA must note the time required on the MAR after verifying it from the literature.

Q. What should the CMA do if there is not enough medication for a complete dose; e.g. the order is for 40 units but there are only 30 units in the pen-in the resident's medication drawer?
A. If there is not enough medication in a pen to give the complete dose, the CMA must obtain a new pen and give the complete dose in one injection. The pen with the insufficient amount of medication should be removed from the medication cart according to the facility policy.

USE BY CERTIFIED MEDICATION AIDES (CMA) of Pen Injector Devices (pen)
QUESTIONS & ANSWERS

Q. When using a pen are there any changes in infection control techniques?
A. No. Infection control techniques remain the same. The pen is an injection device. The aseptic technique used for a regular syringe is also used for the pen system. Hand washing is still required before and after administering the injection. Gloves must be worn. Alcohol swabbing of the pen is required before attaching the needle and the injection site must be clean and prepped with an alcohol wipe before injection.

Q. What should be done if a drop of liquid is noticed at the injection site after the pen is removed?
A. There are at least two reasons that a drop or more of liquid would be visible after an injection using a pen. If the pen has been primed pointing up some medication may have remained in the safety needle cover and then was left on the skin after the injection. Another reason could be that the needle was withdrawn before the entire amount of medication was injected into the resident and the remainder was deposited on the skin as the needle was withdrawn. (It can take up to 10 seconds for the entire amount of medication to pass through the needle.) If the latter reason was the cause, the resident did not receive the prescribed dose and should be monitored for signs of inadequate dosage. The registered nurse should be contacted and the resident monitored per the registered nurse's instructions.

It is important to keep the needle in the resident for the entire time that is required by the pen manufacturer.

CMA RESPONSIBILITIES

Q. Can the CMA label a pen with the resident name and date removed from refrigerator?
A. No. The Pharmacy must label the individual pens with the resident's name. Space must be provided for the date the pen is initially used. The CMA or Nurse who administers the initial dose from the pen fills in the date.

Q. Will CMAs be able to give injections with pens that use cartridge refills?
A. Yes

USE BY CERTIFIED MEDICATION AIDES (CMA) of Pen Injector Devices (pen)
QUESTIONS & ANSWERS

NEEDLES / SAFETY / DISPOSAL

Q. Can a CMA attach a clean needle after disposing of the used needle to save time in preparing the next dose?
A. No. Needles should only be attached shortly before administering the injection. A pen should never be stored, even for a short time, with the needle attached.

Q. Can a pen be used on different residents if a new needle is used?
A. No. Sharing any medication is prohibited. This is especially dangerous with pens because they may become contaminated with cells and proteins from the residents upon whom they were used.

Q. If no safety needle is available, can a CMA or nurse use a regular needle with a pen?
A. No. In licensed Health Care Facilities, staff are required to use safety needles. Regular needles should not be available in the facility for use by staff.

Q. Can a resident administer his/her own medication using a regular needle on a pen?
A. Yes; NJAC 8:43E-7.1(a) requires "All facilities shall purchase, for use by health care workers only available sharp devices containing integrated safety features or available needleless devices designed to prevent needle stick injuries..." If needles are purchased and used by the resident, safety needles are not required because the resident is self-administering their medication.

Q. How is an empty pen disposed of?
A. Since the pen is considered a syringe and may contain blood cells & proteins from a resident, it should be disposed of in the sharps container or as regulated medical waste.

ORDERING

Q. When should pens be re-ordered?
A. A facility should always have at least one pen available in the facility (per resident who needs them) in case the active pen becomes unusable. Therefore, order more pens after administering the initial dose from the next to last pen in stock. Order earlier if use history is heavy.

USE BY CERTIFIED MEDICATION AIDES (CMA) of Pen Injector Devices (pen) QUESTIONS & ANSWERS

STORAGE

Q. Is there any special place in the refrigerator for storing pens that require refrigeration?

A. The required refrigerator storage temperature is between 36 and 46 degrees Fahrenheit (F). If a refrigerator has a freezer or ice cube compartment the temperature next to it may be below freezing (32 degrees F). Therefore, do not store the pens next to the freezer or ice cube compartment since they may freeze in that area. Also, never place pens in the freezer or ice cube compartment of a refrigerator. If the medication freezes, it must be discarded since it may no longer be effective after it thaws.