CHAPTER 27

MEDICATIONS BROUGHT INTO THE NURSING HOME
Medications Brought Into the Nursing Home

1. A policy and procedure should indicate whether or not medications may be brought into the facility.

2. Pros and cons relating to permitting medications to be brought into facility.

3. Audit trail

4. Proper labeling

5. Freedom of choice

6. Safety closure

7. Repackaging of medications from approved retirement mail order programs
SUBJECT: MEDICATIONS SUPPLIED BY OUTSIDE PHARMACIES

DATE REVIEWED: 2/01/02

SECTION: PHARMACY

1. When a resident or a resident's guardian chooses to obtain medications from a pharmacy other than ncs healthcare pharmacy, the resident's name will be included with a list of other residents in this category. This list will be easily accessible to nursing staff and will include the source pharmacies with phone numbers.

2. When an outside pharmacy is used an "agreement to purchase medications from an outside pharmacy" form will be signed and witnessed. This to be coordinated by admissions personnel during the admitting process.

3. When the desire to use an outside pharmacy is communicated to nursing staff, they will in turn notify ncs healthcare pharmacy.

4. The outside pharmacy must provide delivery service. The medications must be shipped directly from the pharmacy to the nursing station. Deliveries are to be accomplished by one of the following routes: A. Dispensing pharmacist B. Outside pharmacy's delivery personnel C. Independent delivery services D. U.s. mail

5. All deliveries will be made to the nurse on duty. Medications, prescription or non-prescription, may not be delivered directly to the resident.

6. Medications may not be brought into the facility by the resident, family, or guardian.

7. Upon admission, medications brought in with the resident will not be accepted. These medications are to be returned to the family or guardian immediately. If the family or guardian are unavailable, the medications are to be turned over to the director of nursing services for disposal. A medication disposition form is to be utilized for this procedure.
8. If a situation occurs wherein the delivery of medications from the outside pharmacy is delayed or uncertain, this facility reserves the right to order a small supply from ncs healthcare pharmacy.

9. The outside pharmacy must provide 24 hour emergency service.

10. New medication orders being obtained from an outside pharmacy will be handled on the same forms utilize for all other orders. However, additional documentation will accompany the written order indicating the specific pharmacy from which the medication is being supplied.

11. Medications are to be supplied by outside pharmacies in packaging consistent with packaging used with the drug distribution system in place at palm shores retirement center.

12. When accepting a delivery from an outside pharmacy, the nurse should:
   A. Check to see that the correct medication was sent.
   B. Verify the accuracy of the prescription label with the medical record.
   C. See that all labeling requirements have been met.

13. If medication label requirements have not been met for any reason, it should be returned to the dispensing pharmacy for correction.
AGREEMENT TO PURCHASE MEDICATIONS FROM AN OUTSIDE PHARMACY

I, _______________________________ request the privilege of purchasing medication for
____________________________ (resident) from ______________________ pharmacy for use in the
_________________ nursing center.

I understand that a resident is allowed to freely choose a provider pharmacy as long as the pharmacy agrees to
follow the policies and procedures promulgated by the quality assurance committee of the facility.

1. The outside pharmacy chosen by the resident or responsible party must provide delivery service. Pharmaceuticals must be shipped directly from the pharmacy to the facility. These deliveries must be
made by the pharmacist, a pharmacy's delivery person, an independent delivery service or the U.S. mail. At no point can a family member or responsible party deliver these medications.

2. If a resident (or resident's family) brings drugs into the facility with no physician's order, they must be
returned to the family member or responsible party for safe keeping or may be destroyed using the
established procedures.

3. The outside pharmacy shall only dispense pharmaceuticals pursuant to orders that appear in the
resident's medical record. These orders must be written by a physician or other person licensed to
prescribe in the state of Florida. The drug order should be initiated by the facility by either a fax transmission, a phone call from a facility nurse or via a specially approved order form.

4. The outside pharmacy must agree to provide 24 hour access to a pharmacist for emergency service.

5. All delivered medications must meet the labeling standards of the facility. Whenever possible the
medication should be provided in a compatible drug delivery system and should include lot number
and expiration dates.

6. The facility retains the right to refuse the delivery of medication if it is determined by the facility that
the packaging or prescription label does not meet facility standards.

I understand that while every attempt will be made to use the above pharmacy, occasionally a medication order
may be obtained from the facility's regular provider pharmacy. I agree to accept the cost of these services when
the facility deems them necessary.

___________________________________     _________________________
Resident or Responsible Party      Date

___________________________________    _________________________
Pharmacy Provider Representative      Date
Michael J. Mascali, R.Ph., FASCP  
Senior Vice President  
Operations & Compliance  
NCS HealthCare  
3201 Enterprise Parkway, Suite 220  
Beachwood, Ohio 44122

Dear Mr. Mascali:

This is in response to your correspondence dated November 6, 2000, and received on December 8, 2000, indicating your concerns regarding Senate Bill 1280, 1st engrossed, amending Florida Statute § 400.141(4). This statute requires pharmacies, providing contracted medication services to long term care facilities (LTCFs), to repackaged medications that have been dispensed to LTCF residents by other pharmacies, if allowable. The medications are required to be repackaged into a unit dose system compatible with the system used by the LTCF. You have requested that the Drug Enforcement Administration (DEA) review NCS HealthCare’s repackaging procedures to assure compliance with DEA regulations.

It appears that NCS HealthCare cannot legally take possession of LTCF residents’ controlled substance medications and repackaged them into a unit dose delivery system. The Controlled Substances Act (CSA) and its implementing regulations established a closed distribution system. The closed distribution system facilitates an accurate accountability of all controlled substances from their manufacture through and including the dispensing pharmacy and, therefore, reduces the potential for diversion of controlled substances. Once the controlled substances have been dispensed by a pharmacy to a LTCF resident, the controlled substances are outside the closed distribution system. LTCFs that have custodial care of residents’ medications are not DEA registrants and there are no provisions in the CSA for a registrant to acquire controlled substances from a non-registrant. Therefore, NCS HealthCare cannot accept controlled substances from residents of LTCFs for repackaging.

In addition, NCS HealthCare cannot accept dispensed controlled substances from another pharmacy for repackaging into a unit dose system. Federal laws require dispensed controlled substances to be delivered to the ultimate user, i.e. the LTCF resident. However, pharmacies may distribute limited amounts of controlled substances to other registrants, such as NCS Healthcare.
Pharmacies are allowed to distribute controlled substances, without registering as a distributor, as long as the total number of dosage units of controlled substances does not exceed five percent of the total number of dosage units of all controlled substances dispensed and distributed by the pharmacy within a calendar year. Proper records must be maintained by both registrants. In this situation, NCS Healthcare would be responsible for the dispensing of the controlled substances to the LTCF residents.

While the proposed methods for repackaging are not acceptable to the DEA, there appears to be an alternative repackaging solution that would meet state and federal requirements. Repackaging of the residents' controlled substances could be performed on-site at the LTCF by NCS HealthCare personnel. In this situation NCS HealthCare is providing a service to the residents of the LTCF and does not take possession of the resident's controlled substances.

I trust this information addresses your concerns. DEA appreciates your desire to comply with controlled substance regulations. Information regarding the Diversion Control Program is available on our web site at www.deadiversion.usdoj.gov. If you have additional questions, please contact Vickie B. Seeger, R.Ph., at (202) 307-7296.

Sincerely,

[Signature]
Patricia M. Good, Chief
Liaison and Policy Section
Office of Diversion Control

cc: DPM Marsha R. Jones, Detroit Division
    G/S Ron Townsend, Cleveland Resident Office
    DPM Wilbur G. Corbitt, Miami Division
Florida Law Section 400.022 (1) (q)

A registered pharmacist licensed in Florida, that is under contract with a facility licensed under this chapter, shall repackage a nursing facility resident's bulk prescription medication which has been packaged by another pharmacist licensed in any state in the United States into a unit dose system compatible with the system used by the nursing facility, if the pharmacist is requested to offer such service. To be eligible for repackaging, a resident or the resident’s spouse must receive prescription medication benefits provided through a former employer as part of his or her retirement benefits, a qualified prescription plan as specified in s. 4972 of the Internal Revenue Code, a federal retirement program as specified under 5 C.F.R S.831, or a long term care policy as defined in s. 627.9404 (1). A pharmacist who correctly repackages and relabels the medication and the nursing facility which correctly administers such repackaged medication under provisions of this subsection shall not be held liable in any civil or administrative action arising from the repackaging. In order to be eligible for repackaging, a nursing facility resident for whom the medication is to be repackaged shall sign an Informed Consent form provided by the facility which includes an explanation of the repackaging process and which notifies the resident of the immunities from liability provided herein. A pharmacist who repackages and relabels prescription medications as authorized under this subsection, may charge a reasonable fee for cost resulting from the implementation of this provision.

400.141 Administration and management of nursing home facilities.

Every licensed facility shall comply with all applicable standards and rules of the agency and shall:

(1) Be under the administrative direction and charge of a licensed administrator.

(2) Appoint a medical director licensed pursuant to chapter 458 or chapter 459. The agency may establish by rule more specific criteria for the appointment of a medical director.

(3) Have available the regular, consultative, and emergency services of physicians licensed by the state.

(4) Provide for resident use of a community pharmacy as specified in s. 400.022(1)(q). Any other law to the contrary notwithstanding, a registered pharmacist licensed in Florida, that is under contract with a facility licensed under this chapter or chapter 429, shall repackage a nursing facility resident's bulk prescription medication which has been packaged by another pharmacist licensed in any state in the United States into a unit dose system compatible with the system used by the nursing facility, if the pharmacist is requested to offer such service. In order to be eligible for the repackaging, a resident or the resident's spouse must receive prescription medication benefits provided through a former employer as part of his or her retirement benefits, a qualified pension plan as specified in s. 4972 of the Internal Revenue Code, a federal retirement program as specified under 5 C.F.R. s. 831, or a long-term care policy as defined in s. 627.9404(1). A pharmacist who correctly repackages and relabels the medication and the nursing facility which correctly administers such repackaged medication under the provisions of this subsection shall not be held liable in any civil or administrative ...
action arising from the repackaging. In order to be eligible for the repackaging, a nursing facility resident for whom the medication is to be repackaged shall sign an informed consent form provided by the facility which includes an explanation of the repackaging process and which notifies the resident of the immunities from liability provided herein. A pharmacist who repackages and relabels prescription medications, as authorized under this subsection, may charge a reasonable fee for costs resulting from the implementation of this provision.

NOTE: Chapter 429 – Florida Statute for Assisted Living Facilities