



TO: Chapter Presidents
FROM: Bennett Napier, CAE
DATE: July 5, 1999
SUBJECT: PRESCRIPTION DRUG REPACKAGING LAW FOR NURSING HOME RESIDENTS TOOK EFFECT JULY 1

- *Florida Statutes 400.141* was amended by the legislature this year to allow a licensed pharmacist to repackage bulk medications for qualified nursing home residents into a unit dose system. The provision applies to residents whose prescription drugs are furnished under "qualified" pension plans, federal retirement or long-term care insurance plans. These terms are defined in the attached document, which also includes a copy of the law.
- A "qualified" nursing home resident has the right to request that a pharmacist/pharmacy of his or her choice provide this service. (The law specifies that a reasonable fee may be charged by the pharmacist/pharmacy.) The nursing home, in turn, must accept the repackaged medication for use by the resident.
- The law protects the repackaging pharmacist and the nursing home in which the resident lives from liability if the medication is correctly repackaged and relabeled and correctly administered.
- The law does not require that a nursing home provide this service. However, there is an expectation by some legislators that nursing homes will work with resident leaders to facilitate repackaging if there is a need for it.
- Rep. Nancy Argenziano, Chair of the House Aging and Long-term Care Committee, sponsored the nursing home bill (HB 1971) that led to this change. It was a priority of the Florida Life Care Residents Association (FLiCRA) this year.
- To minimize differences in interpretations of the new law, the attached sample resident consent forms and question and answer document. The packet is for information only and is not to be considered as legal advice. If you have specific legal questions about implementing the law, please consult your attorney.
- The forms included in the packet are samples of what a pharmacist/facility may use when carrying out the law. Nothing in s.400.141 (5), F.S., restricts a pharmacist or nursing home from developing its own policies and procedures for the repackaging of bulk medications into a unit dose system.
- Interest from residents in this service will probably be the greatest in retirement communities with a number of retired military or government employees with retirement benefits that include generous bulk packaged prescription drug coverage.

SAMPLE FORM

NURSING HOME RESIDENT INFORMED CONSENT AND REQUEST FOR PHARMACEUTICAL REPACKAGING SERVICES

This document is signed by the administrator of _____ (Name of Facility), the pharmacist, and _____ (Resident of Facility), and is to be considered a disclosure of Florida Law regarding repackaging of certain bulk prescriptive medicines into a unit dose system, and an informed consent and request for such services on behalf of the undersigned resident.

Florida Law (s. 400.141 (5), F.S.) authorizes a licensed pharmacist to repackage certain bulk medications packaged by another pharmacist into a unit dose system. Residents of nursing homes whose prescription drugs are furnished under qualified pension plans, federal retirement, or long-term care insurance plans are eligible to request this service from a pharmacy of their choice. In addition, some nursing homes may have an agreement with a pharmacy to provide the service.

Among the law's provisions is a limitation of liability for both the pharmacist and the nursing home. The law states, "A pharmacist who correctly repackages and re-labels 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 accordance with s.400.141 (5), F.S., _____ (Name of Facility) will accept medication repackaged by a pharmacy on behalf of a qualified resident. **[ONLY IF APPLICABLE** -- In addition, as a service to residents, we have made arrangements with a pharmacy to repackage bulk medications provided through a qualified pension plan, a federal retirement program or a long-term care insurance plan into a unit dose system compatible with the system used by _____(Name of Facility).]

I, the undersigned, have read the attached questions and answers about Florida's law allowing for the repackaging of bulk medications into a unit dose system. I understand that there are certain risks associated with one licensed pharmacist repackaging medications packaged by another pharmacist. Since the repackaging pharmacist is not the pharmacist who will be filling and labeling the original container, he/she cannot guarantee the accuracy or quality of the medications that will be repackaged. I also understand that if the repackaging of the prescription and the administration of the repackaged drugs are carried out correctly, neither the repackaging pharmacist nor the nursing home will be held liable under Florida law.

By signing this form, I am formally requesting that (Name of Pharmacy or Pharmacist) repackage bulk medications that I receive through a qualified insurance plan into a unit dose system. Attached to this Informed Consent form is a set of Questions and Answers about the law and a Schedule of Fees that are to be charged by _____(Pharmacy) for the services which I am requesting. The schedule is to be considered a part of this Informed Consent. The fees may be

increased after written notice to the resident if they do not adequately cover the pharmacist's time and other costs associated with the service.

RESIDENT'S SIGNATURE DATE

ADMINISTRATOR'S SIGNATURE DATE

PHARMACIST'S SIGNATURE DATE

-over-

Please attach a copy of your insurance card, insurance policy, or other documentation that indicates that you receive prescription drug coverage through an insurance program that qualifies for repackaging of medications as permitted under s.400.141 (5), F.S. It is important for the pharmacist and nursing home to have this documentation in the event that compliance with the law is questioned by a regulatory agency.

SAMPLE FORM

SCHEDULE OF FEES AND CHARGES

The undersigned, _____ (nursing home resident), and _____ (licensed Florida pharmacy/pharmacist), hereby agree to the following services and charges to be performed and purchased in relation to the nursing home resident's request for repackaging of bulk prescription medications by the pharmacy/pharmacist. This schedule is to remain in effect from the date both parties have signed it for a period of one year, unless one of the parties notifies the other of its cancellation in writing.

Service

Fee

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

Total Fees

Both the nursing home resident and the pharmacy/pharmacist retain the right to cancel or amend this schedule by written notice to the other.

Signature of Nursing Home Resident

Date

Authorized Signature – Pharmacy or Pharmacist
Florida License Number

Date

Repackaging Bulk Medications for Qualified Nursing Home Residents Into Unit Dose -- Questions and Answers About Florida Law

1. **QUESTION:** Is a pharmacist permitted to repackage bulk prescription drugs packaged by another pharmacist into a unit dose blister packet for a nursing home resident?

ANSWER: Yes, Florida's nursing home law (s.400.141(5), Florida Statutes) was amended in 1999 to allow a registered pharmacist to repackage bulk medications into unit dose if certain conditions are met.

2. **QUESTION:** Can any nursing home resident ask a licensed pharmacist to repackage bulk medications into a unit dose system?

ANSWER: No, the law applies only to nursing home residents who have bulk prescription medication benefits covered under a qualified pension plan, a federal retirement program or a long-term care insurance policy.

3. **QUESTION:** What is a "qualified pension plan" and a "federal retirement program"?

ANSWER: Based on the definitions in s.4972 of the Internal Revenue Code, and under 5 CFR s.831, the following would be classified as either a "qualified pension plan" or a "federal retirement program": any civil service employee retirement plan, any military retirement plan, any state government employee retirement plan, any municipal government employee retirement plan, and any private sector retirement plan that provide coverage for bulk prescription drugs.

4. **QUESTION:** What is "long-term care insurance"?

ANSWER: Section 627.9404 (1), Florida Statutes, defines "long-term insurance" as "any insurance policy or rider advertised, marketed, offered, or designed to provide coverage on an expense-incurred, indemnity, prepaid, or other basis for one or more necessary or medically necessary diagnostic, prevention, therapeutic, curing, treating, mitigating, rehabilitative, maintenance, or personal care services provided in a setting other than an acute care unit of a hospital. Long-term care insurance shall not include any insurance policy which is offered primarily to provide basic Medicare supplemental coverage, basic hospital expense coverage, basic medical-surgical expense coverage, hospital confinement indemnity coverage, major medical expense coverage, disability income protection coverage, accident only coverage, specific disease or specific accident coverage, or limited benefit health coverage."

5. **QUESTION:** Are nursing homes required to repackage a qualified resident's bulk medications into a unit dose system?

ANSWER: A nursing home is not required to repackage medication into unit dose. Instead, a resident who qualifies under the law for repackaging has the right under s.400.022 (1)(q), Florida Statutes, to request that a community pharmacy of his/her choice repackage bulk medication into a unit dose system compatible with the system used by the nursing home. The nursing home must accept the repackaged medication for use by the resident. The pharmacy selected by the resident must be one that provides service delivery.

The pharmacy used by the facility may be willing to provide this service. Please ask your nursing home administrator if this would be possible.

6. **QUESTION:** Why would a licensed pharmacist be reluctant to repackage unopened bulk medication packaged by another licensed pharmacist?

ANSWER: Since two or more individuals would handle a drug that is packaged by one pharmacist and then repackaged by another, if an error occurred in the process, it would be very difficult to determine who was at fault. Protocol adopted by various pharmacy groups discourages this practice because of the potential liability and the fact that the second pharmacist cannot verify that the prescription was accurately followed and the drug was properly packaged and labeled by the originating pharmacy. Some pharmacists may also be reluctant to provide the service because of the additional record keeping and storage of bulk medications that may be involved.

7. **QUESTION:** If there are risks to repackaging bulk medications packaged by one pharmacist into unit dose by another, why would the Florida Legislature pass a law that allows nursing home residents to request this service?

ANSWER: Some nursing home residents have bulk prescription drug benefits that are part of a private or government pension plan or long-term insurance policy. The drugs are provided at little or no cost, but they are not available in a unit dose system. Since many nursing home residents use eight or more prescription drugs, the cost of purchasing multiple medications at market value could be substantial. Some residents would be willing to accept the risks associated with repackaging their medications into a unit dose system in order to avoid purchasing these same drugs at full cost. Since the repackaging of bulk medication into a unit dose system has been greatly restricted by rules of the Florida Board of Pharmacy, the extent of the risk is unknown.

All nursing homes use a unit dose system because it helps to reduce medication errors and is more efficient than using bulk medications. The law gives qualified nursing home residents the option to ask a pharmacy of their choice to repackage bulk medications into a unit dose system if the resident is willing to sign an informed consent form. The resident basically accepts the risks associated with repackaging as a trade off for the service.

8. **QUESTION:** Does the law do anything to encourage the repackaging of bulk medications into unit dose for qualified nursing home residents?

ANSWER: Yes, it relieves the pharmacist responsible for repackaging and the nursing home in which the resident resides from liability in any civil or administrative action arising from the repackaging if the pharmacist correctly repackages and labels the medication and the nursing home correctly administers it. Nonetheless, some pharmacists may not be willing to take on the responsibility and risks.

9. **QUESTION:** May a pharmacist charge a fee for repackaging a drug?

ANSWER: Yes, the law allows the pharmacist to charge a reasonable fee that will probably take into account the pharmacist's time and the cost of repackaging materials, storing bulk medications, and record keeping.

10. **QUESTION:** If a licensed pharmacist of my choice is willing to repackage my bulk medication into a unit dose system and I meet all the qualification in law to receive this service, does this mean that I no longer need a local pharmacy?

ANSWER: A resident would still need to use either the pharmacy affiliated with the nursing home or another local pharmacy that provides evening and weekend delivery of medications that are needed immediately. This is especially important for residents who receive their prescription drug benefits through the mail.

In addition, a nursing home resident who receives this service would still need a local pharmacy to fill prescriptions for medications that are not covered by their insurance plan.

11. **QUESTION:** How do I request this service?

ANSWER: You can start by asking your nursing home administrator if the facility has an arrangement or is exploring an arrangement with a licensed pharmacist willing to provide the service. A nursing home resident also has the right under Florida law to ask a community pharmacy of his/her choice to repackage bulk medications into unit dose. A copy of the law is attached to this document for you to share with your pharmacist.

12. **QUESTION:** Since the law takes effect July 1, will a qualified resident be able to request and receive the service immediately?

ANSWER: It will take some time and research for a nursing home resident or his/her family to identify a pharmacy willing to repackage medication packaged by another pharmacist into a unit dose system. Likewise, if the pharmacy used by the facility is willing to provide the service, specific procedures and fees associated with the services will have to be developed. The development of an agreement to this effect could be time consuming.

**Prescription Drug Benefits – Provision to Allow Repackaging of Bulk
Prescriptions
Passed into law July 1, 1999**

400.141 Administration and management of nursing home facilities.—

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

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

(b) 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.

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

(d) 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 this paragraph may 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 in this paragraph. A pharmacist who repackages and relabels prescription medications, as authorized under this paragraph, may charge a reasonable fee for costs resulting from the implementation of this provision.

400.022 Residents' rights.— (Referenced Section)

(1) All licensees of nursing home facilities shall adopt and make public a statement of the rights and responsibilities of the residents of such facilities and shall treat such residents in accordance with the provisions of that statement. The statement shall assure each resident the following:

(q) The right to freedom of choice in selecting a personal physician; to obtain pharmaceutical supplies and services from a pharmacy of the resident's choice, at the resident's own expense or through Title XIX of the Social Security Act; and to obtain information about, and to participate in, community-based activities programs, unless

medically contraindicated as documented by a physician in the resident's medical record. If a resident chooses to use a community pharmacy and the facility in which the resident resides uses a unit-dose system, the pharmacy selected by the resident shall be one that provides a compatible unit-dose system, provides service delivery, and stocks the drugs normally used by long-term care residents. If a resident chooses to use a community pharmacy and the facility in which the resident resides does not use a unit-dose system, the pharmacy selected by the resident shall be one that provides service delivery and stocks the drugs normally used by long-term care residents.