

## **ARTICLE XXX: LONG-TERM CARE FACILITIES (LTCF)**

### **A. CONSULTING PHARMACISTS TO NURSING HOMES**

1. Unless specifically authorized by the Board, no person shall serve as a consultant pharmacist or act or purport to act in this capacity to any nursing home unless he/she possesses the following qualifications:
  - A. Have and maintain a license to practice pharmacy within the State of Mississippi;
  - B. Have attended within the last two years a training course of not less than eight (8) hours in LTC or geriatric related pharmacy services that has been approved by the Board of Pharmacy;
  - C. In order to be approved by the Board of Pharmacy, the training course for a consultant pharmacist shall provide instruction in the areas of clinical pharmacy services, drug distribution systems and state and federal pharmacy regulations governing the practice of long-term care pharmacy.
  
2. For purposes of this ARTICLE, a Consultant Pharmacist shall mean a Mississippi licensed pharmacist who is responsible for developing, coordinating and supervising pharmaceutical services on a regularly scheduled basis in a LTCF, as well as the following responsibilities.
  - A. Reviewing policies and procedures regarding the distribution and storage of medications within the facility and as necessary making recommendations to the facility and provider pharmacist;
  - B. Monitoring utilization and therapeutic response of medications prescribed for and administered to residents of the facility as well as providing consultation on matters related to medications;
  - C. Serving as a resource for pharmacy related educational services within the facility;
  - D. Communication and discussion with the provider pharmacist regarding areas of concern and resolution thereof;
  - E. Serving on appropriate committees;
  - F. Supervising and assisting in the disposal of all discontinued, expired, or otherwise unneeded controlled substance medications;
  - G. Reviewing records of the destruction of all medications and verification of the reasons for destruction;
  - H. Ensuring that complete and accurate records of the acquisition and disposition of controlled substance medications which have been dispensed for residents of the institutional facility are maintained;
  - I. Attending, within the last two (2) years, a consultant pharmacist seminar which has been approved by the Board;
  - J. Maintain consultant pharmacist eligibility as described in Section 1.
  
3. A LTCF which is permitted by the Board and where the services of a consultant pharmacist are required shall have the following responsibilities:
  - A. Policy Manual. The institution shall develop policies and procedures regarding

- pharmacy services which include, but are not limited to, proper labeling of patient medications and emergency drugs, security of patient medications and emergency drugs, administration and controlled substances record-keeping and accountability. This procedural manual shall be the responsibility of the institution and is to be promulgated with the concurrence of the consultant pharmacist, nursing home administrator and the directors of medical and nursing services.
- B. Reference. Reference materials shall be readily available in the nursing stations(s) and contain current editions of appropriate reference materials as may be deemed necessary by the consultant pharmacist and the medical and nursing directors.
  - C. Reporting. The institution shall establish policies and procedures which assures that all medication errors and adverse drug reactions are reported immediately to the patient's physician and the consultant pharmacist, and an entry made in the patient's record. These procedures should assure that corrective measures are implemented. The consultant pharmacist should be notified within twenty-four (24) hours of discovery of any discrepancy in counts or of a loss of any controlled substances. The consultant pharmacist should notify the Board immediately upon his/her notification with a plan to investigate the loss.
  - D. Emergency Medication Kits. The institution shall establish policies and procedures which assure that the institution is in compliance with ARTICLE XXXV INSTITUTIONAL EMERGENCY MEDICATION KIT PERMITS (FIRST DOSE KITS) FOR LONG TERM CARE FACILITIES AND OTHER APPROVED INSTITUTIONAL FACILITIES of these Pharmacy Practice Regulations.
  - E. Disposal of Patient Medication. The LTCF, with the assistance of the consultant pharmacist shall establish policies and procedures which assures the proper disposal of any discontinued, expired, or otherwise unwanted patient medications. Policies and procedures should ensure that any medication removed subject to destruction does not have a current valid order for the medication on the patient's medication profile. Policies and Procedures for disposal of these medications should include as follows:
    - (1) All unwanted patient medications should remain in a secured location at the institution until proper disposal is made;
    - (2) Documentation of any disposal of patient medications should include a paper trail from the time the medication was logged into the discontinued drug storage area until destruction is made. This paper trail shall include a log containing the patient name, medication and strength, and quantity to be destroyed as well as the initials of the person logging in the medication for destruction. This documentation should be stored at the institution and be readily retrievable for inspection by Board Agents for a period of two (2) years;
    - (3) Discontinued and unwanted patient medications shall be destroyed on a timely basis not to exceed sixty (60) days from the date that the medication was discontinued. Any such destruction shall be performed by two licensed personnel and documented by their signatures. The consultant pharmacist is valid personnel to participate in this activity.
4. A consultant pharmacist shall document communication of the findings of his/her reviews to the attending physician and director of nursing along with their responses and maintain these records for a period of two (2) years. A copy of these reviews must be maintained at the facility and available for inspection.

## B. UNIT DOSE DISPENSING FOR LTCF

### Definitions:

For the purpose of this ARTICLE XXX, the following definitions apply:

- (1) “Provider pharmacist” means a pharmacist licensed to practice pharmacy by the Board who is responsible for supervising the accurate dispensing and proper delivery of medications to a LTCF located within this state. These services shall include, at a minimum, proper medication labeling, storage, transport, record keeping, and prospective drug utilization review in compliance with all federal, state and local laws and regulations.
  - (2) “Provider Pharmacy” means any pharmacy permitted by the Board where medications are dispensed to residents of a long-term care facility located in this state.
  - (3) “Unit dose package” is a package, which contains one dose of a medication for administration to a patient. A unit dose package may contain one or more individual units or fractions of units of a distinct medication.
  - (4) “Unit of issue package” is a medication package issued by a provider pharmacy, which provides multiple units/dosages of medications attached to each other but separated in a card or a specifically designed container.
  - (5) “Multi-dose strip packaging” (MDS) is a medication package issued by a provider pharmacy which provides multiple distinct medications to be administered at the same time.
1. Packaging for all non-sterile medications stored and dispensed in single unit dose, unit dose, unit of issue or MDS packages for use in a LTCF shall:
    - A. Preserve and protect the identity and integrity of the drug medication from the point of packaging to the point of patient administration;
    - B. When packaged by the manufacturer or distributor, be in compliance with Federal Food and Drug Administration guidelines;
    - C. Shall be in containers clean and free of extraneous matter when the dosage unit(s) are placed into the package;
    - D. Utilize containers, which are classified according to USP Standard 671 as being Class A or Class B for oral solid dosage forms or tight containers for liquid dosage forms.
  2. Labeling for unit dose packaging or multi-dose strip packaging shall comply with the following:
    - A. When packaged by the manufacturer or distributor shall be

properly labeled according to Federal Food and Drug Administration requirements;

- B. Unit doses or multi-dose strip packaging packaged by the provider pharmacy shall be properly labeled according to ARTICLE XXIX. If needed, the provider pharmacy may utilize an external container to provide required labeling elements. The name of the patient, drug, dosage strength and form must be on the primary packaging.
  - C. Labeling for unit of issue packages shall contain the following information: Name and facility specific patient identifier (e.g., room or bed number of patient), name of prescribing practitioner, name and strength of drug, directions for use, and the name and address of the provider pharmacy when utilized for patients in an LTCF setting.
3. If a pharmacist selects a generically equivalent drug product for a brand name drug product prescribed by a practitioner, labeling must comply with ARTICLE X of the Pharmacy Practice Regulations of the Board.
4. Expiration dating for non-sterile medications dispensed and packaged into single unit doses, unit doses, and unit of issue packages shall meet the following conditions:
- A. Not exceed the manufacturer's original expiration date;
  - B. Have an expiration date assigned based on the unit dose container manufacturer's recommendations;
  - C. May exceed ninety (90) days from date of repackaging provided that the container is classified according to USP Standard 671 as being Class A or Class B for oral solid dose forms or is a tight container for liquid dosage forms, the container is light resistant when the manufacturer has labeled the drug product "sensitive to light", and the expiration date is not greater than twelve (12) months;
  - D. Drugs or dosage forms having known stability problems or that are not packaged as defined in Article XXX are assigned an expiration date of less than ninety (90) days.

The shortest time span of any of the listed conditions shall be the expiration date assigned to the medication.

#### C. RETURN OF MEDICATIONS FROM A LTCF TO THE PROVIDER PHARMACY

1. Medication that has been dispensed for a patient residing in a LTCF facility may be returned to the provider pharmacy provided that the medication has an approved reason for return as follows:
- A. Medication was discontinued prior to delivery;
  - B. Patient no longer a patient or expired prior to medication being delivered;
  - C. Medication dosage changed prior to delivery;
  - D. Medication is considered to be dispensed when it leaves the dispensing pharmacy and is delivered to the LTCF.

Any medication subject to return must be intact with no doses removed from blister package (unit dose) and must not have had contact with other medications. Medications, which have been dispensed and placed in bulk packages and accepted by a responsible person at the LTCF, shall not be returned to the dispensing pharmacy for any reason. All medication subject to return, must be returned to the provider pharmacy by pharmacy personnel within five (5) days. No controlled substances may be returned.

The provider pharmacy must implement approved procedures, which ensure that any returned medication has been properly stored, has not been tampered with, and the integrity of the medication remains intact. Paper trails tracking these procedures must be maintained by the provider pharmacy for a period of two (2) years and be readily retrievable for inspection by agents of the Board.

## **ARTICLE XXX ~~INSTITUTIONAL~~/LONG-TERM CARE FACILITIES (LTCF)**

### **A. CONSULTING PHARMACISTS TO ~~INSTITUTIONAL (LTC) FACILITIES~~ NURSING HOMES**

1. Unless specifically authorized by the Board ~~to do so~~, no person shall serve as a consultant pharmacist or act or purport to act in this capacity to any nursing home ~~institutional facility~~ unless he/she possesses the following qualifications:
  - A. Have and maintain a license to practice pharmacy within the State of Mississippi;
  - B. Have attended within the last two years a training course of not less than eight (8) hours in LTC or geriatric related ~~institutional~~ pharmacy services that has been approved by the Board of Pharmacy;
  - C. In order to be approved by the Board of Pharmacy, the training course for a consultant pharmacist ~~to an institutional facility~~ shall provide instruction in the areas of clinical pharmacy services, drug distribution systems and state and federal pharmacy regulations governing the practice of ~~institutional~~ long term care pharmacy.
2. For purposes of this ARTICLE, a Consultant Pharmacist shall mean a Mississippi licensed pharmacist who is responsible for developing, coordinating and supervising pharmaceutical services on a regularly scheduled basis in an ~~institutional facility~~ LTCF, as well as the following responsibilities.
  - A. Reviewing policies and procedures regarding the distribution and storage of medications within the facility and as necessary making recommendations to the facility and provider pharmacist;
  - B. Monitoring utilization and therapeutic response of medications prescribed for and administered to residents of the facility as well as providing consultation on matters related to medications;
  - C. Serving as a resource for pharmacy related educational services within the facility;
  - D. Communication and discussion with the provider pharmacist regarding areas of concern and resolution thereof;

- E. Serving on appropriate committees;
  - F. Supervising and assisting in the disposal of all discontinued, expired, or otherwise un- needed controlled substance medications;
  - G. Reviewing records of the destruction of all medications and verification of the reasons for destruction;
  - H. Ensuring that complete and accurate records of the acquisition and disposition of controlled substance medications which have been dispensed for residents of the institutional facility are maintained;
  - I. Attending, within the last two (2) years, a consultant pharmacist seminar which has been approved by the Board;
  - J. Maintain consultant pharmacist eligibility as described in Section 1.
3. A ~~Long Term Care Facility~~ LTCF which is permitted by the Board and where the services of a consultant pharmacist are required shall have the following responsibilities:
- A. Policy Manual. The institution shall develop policies and procedures regarding pharmacy services which includes, but ~~is~~are not limited to, proper labeling of patient medications and emergency drugs, security of patient medications and emergency drugs, administration and controlled substances record-keeping and accountability. This procedural manual shall be the responsibility of the institution and is to be promulgated with the concurrence of the consultant pharmacist, nursing home administrator and the directors of medical and nursing services.
  - B. Reference. Reference materials shall be readily available ~~located~~ in the nursing stations(s) and contain current editions of appropriate reference materials as may be deemed necessary by the consultant pharmacist and the medical and nursing directors.
  - C. Reporting. The institution shall establish policies and procedures which assures that all medication errors and adverse drug reactions are reported immediately to the patient's physician and the consultant pharmacist and an entry made in the patient's record. These procedures should assure that corrective measures are implemented. The consultant pharmacist should be notified within twenty-four (24) hours of discovery of any discrepancy in counts or of a loss of any controlled substances. The consultant pharmacist should notify the Board immediately upon his/her notification with a plan to investigate the loss.
  - D. Emergency Medication Kits. The institution shall establish policies and procedures which assure that the institution is in compliance with ARTICLE XXXV INSTITUTIONAL EMERGENCY MEDICATION KIT PERMITS (FIRST DOSE KITS) FOR LONG TERM CARE FACILITIES AND OTHER APPROVED INSTITUTIONAL FACILITIES of these Pharmacy Practice Regulations.
  - E. Disposal of Patient Medication. The ~~Long Term Care Facility~~ LTCF, with the assistance of the consultant pharmacist shall establish policies and procedures which assures the proper disposal of any discontinued, expired, or otherwise unwanted patient medications. Policies and procedures should ensure that any medication removed subject to destruction, does not have a current valid order for

the medication on the patient's medication profile. Policies and Procedures for disposal of these medications should include as follows:

- (1) All unwanted patient medications should remain in a secured location at the institution until proper disposal is made;
  - (2) Documentation of any disposal of patient medications should include a paper trail from the time the medication was logged into the discontinued drug storage area until destruction is made. This paper trail shall include a log containing the patient name, medication and strength, and quantity to be destroyed as well as the initials of the person logging in the medication for destruction. This documentation should be stored at the institution and be readily retrievable for inspection by Board Agents for a period of two (2) years;
  - (3) Discontinued and unwanted patient medications ~~should~~ shall be destroyed on a timely basis not to exceed ~~ninety~~ sixty ~~(90)~~ (60) days from the date that the medication was discontinued. Any such destruction ~~should~~ shall be performed by two licensed personnel and documented by their signatures. The consultant pharmacist is valid personnel to participate in this activity.
4. A consultant pharmacist shall document communication of the findings of his/her reviews to the attending physician and director of nursing along with their responses and maintain these records for a period of two (2) years. A copy of these reviews must be maintained at the facility and available for inspection.

#### B. UNIT DOSE DISPENSING SYSTEMS FOR (LTCF)

##### Definitions:

For the purpose of this ARTICLE XXX, the following definitions apply:

- (1) "Provider pharmacist" means a pharmacist licensed to practice pharmacy by the Board who is responsible for supervising the accurate dispensing and proper delivery of medications to a (LTCF) located within this state. These services shall include, at a minimum, proper medication labeling, storage, transport, record keeping, and prospective drug utilization review in compliance with all federal, state and local laws and regulations.
- (2) "Provider Pharmacy" means any pharmacy permitted by the Board where medications are dispensed to residents of a long term care facility located in this state.
- (3) ~~"Single unit dose package" is a package, which contains one discrete pharmaceutical medication dosage form.~~
- (4) ~~"Unit dose dispensing systems" are those drug medication distribution systems determined by the Board, which involve single unit, unit dose or unit of issue packaging in a manner which helps reduce or remove traditional drug stocks from patient care areas and enables the selection and distribution of~~

~~medications to be provider pharmacy based and controlled. A unit dose dispensing system shall preserve the identity and the integrity of the medication until the time of administration.~~

- (3) “Unit dose package” is a package, which contains one dose of a medication that particular dose of a medication ordered for the patient for one administration time. for administration to a patient. A unit dose package may contain one or more individual units or fractions of units of a distinct medication is not always a single unit dose package.
  - (4) “Unit of issue package” is a medication package issued by a provider pharmacy, which provides multiple units/dosages of medications attached to each other but separated in a card or a specifically designed container.
  - (5) “Multi-dose strip packaging” (MDS) is a medication package issued by a provider pharmacy which provides multiple distinct medications to be administered at the same time.
1. Packaging for all non-sterile medications stored and dispensed in single unit dose, unit dose, unit of issue or MDS packages for use in ~~(LTCF) other than hospitals shall:~~ a LTCF shall:
    - A. Preserve and protect the identity and integrity of the ~~drug~~ medication from the point of packaging to the point of patient administration;
    - B. When packaged by the manufacturer or distributor, ~~be in compliance~~ comply with Federal Food and Drug Administration guidelines;
    - C. Shall be in containers clean and free of extraneous matter when the dosage unit(s) are placed into the package;
    - D. Utilize containers, which are classified according to USP Standard 671 as being Class A or Class B for oral solid dosage forms or ~~is a tight containers~~ for liquid dosage forms.
  2. Labeling for ~~single unit dose or unit dose packaging or~~ multi-dose strip packaging shall comply with the following:
    - A. ~~Single unit doses or unit doses~~ When packaged by the manufacturer or distributor shall be properly labeled according to Federal Food and Drug Administration requirements;
    - B. ~~Single unit doses or~~ Unit doses or multi-dose strip packaging packaged by the provider pharmacy shall be properly labeled according to ARTICLE XXIX ~~paragraph 7. If needed, the provider pharmacy may utilize an external container to provide required labeling elements. The name of the patient, drug, dosage strength and form must be on the primary packaging.~~
    - C. Labeling for unit of issue packages shall contain the following information: Name and facility specific patient identifier (e.g., room or bed number of patient), name of prescribing practitioner, name and strength of drug, directions for use, and the name and address of the provider pharmacy when ~~a unit of issue package is utilized for patients in an (LTCF) setting.~~
  3. If a pharmacist selects a generically equivalent drug product for a brand name drug



product prescribed by a practitioner, labeling must comply with ARTICLE X of the Pharmacy Practice Regulations of the Board.

4. Expiration dating for non-sterile medications dispensed and packaged into single unit doses, unit doses, and unit of issue packages shall meet the following conditions:
  - A. Not exceed the manufacturer's original expiration date;
  - B. Have an expiration date assigned based on the unit dose container manufacturer's recommendations;
  - C. May exceed Ninety (90) days from date of repackaging provided that the container is classified according to USP Standard 671 as being Class A or Class B for oral solid dose forms or is a tight container for liquid dosage forms, the container is light resistant when the manufacturer has labeled the drug product "sensitive to light", and the expiration date is not greater than twelve (12) months;
  - D. Drugs or dosage forms having known stability problems or that are not packaged as defined in Article XXX are assigned an expiration date of less than ninety (90) days ~~or are not repackaged as determined by policies developed by the provider pharmacy.~~

The shortest time span of any of the listed conditions shall be the expiration date assigned to the medication.

#### C. RETURN OF MEDICATIONS FROM AN LTCF ~~INSTITUTIONAL FACILITY~~ TO THE PROVIDER PHARMACY

1. Medication that has been dispensed for a patient residing in an LTCF ~~institutional facility~~ may be returned to the provider pharmacy provided that the medication has an approved reason for return as follows:
  - A. Medication was discontinued prior to delivery;
  - B. Patient no longer a patient or expired prior to medication being delivered;
  - C. ~~Patient in the hospital (discharge status) at time of delivery;~~
  - D. Medication dosage changed prior to delivery;
  - E. ~~Patient has excessive medications remaining from previous cycle (requires written explanation by the Director of Nurses);~~
  - F. Medication is considered to be dispensed when it leaves the dispensing pharmacy and is delivered to the ~~institutional facility-LTCF.~~Any ~~such~~ medication subject to return must be intact with no doses removed from blister package (unit dose) and must not have had contact with other medications. Medications, which have been dispensed and placed in bulk packages and accepted by a responsible person at the LTCF, shall not be returned to the dispensing pharmacy for any reason. All medication subject to return, must be returned to the provider pharmacy by pharmacy personnel within five (5) days. No controlled substances may be returned.

The provider pharmacy must implement approved procedures, which ensure that any

returned medication has been properly stored, has not been tampered with, and the integrity of the medication remains intact. Paper trails tracking these procedures must be maintained by the provider pharmacy for a period of two (2) years and be readily retrievable for inspection by agents of the Board.