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SECRETARY OF STATE
BY

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Department

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CERTIFICATION OF AUTHORIZED OFFICER

I Hereby Certify That The Attached Rules Were Adopted In Compliance With Act 434 of 1967 As Amended.

Lester Hosto
SIGNATURE

Executive Director
TITLE

11/18/93
DATE

070.00.93--000

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MAY 19 1993

W. J. "BILL" McCUEN
SECRETARY OF STATE

9 B.

NURSING HOME CONSULTANTS PERMIT 10/9/80 (Reg. Revised 2/17/82 & 6/25/83)

DEFINITIONS:

1. Consultant Pharmacist in Charge

A Nursing Home Pharmacist in Charge hereinafter referred to as a Consultant Pharmacist in charge is a Pharmacist who assumes the ultimate responsibility to assure adherence to all law and regulation concerning pharmacy services in the Nursing home permitted in his or her name.

The Consultant Pharmacist in Charge is required to perform a majority of the consultative services provided in the home and must assure that other consultant pharmacists assisting him or her in the home are aware of and abide by pharmacy law and regulations and policy and procedures of the home.

2. Consultant Pharmacist

A Nursing Home Consultant Pharmacist is herein-after referred to as Consultant Pharmacist is a Pharmacist who practices as a consultant in one or more homes to assist the Consultant Pharmacist in Charge.

3. The number of residents shall be the number of patients in the home on the first day of the proceeding month.

GENERAL REQUIREMENTS:

Any pharmacist desiring to serve as a Consultant Pharmacist in Charge for a nursing home shall so notify the Board of Pharmacy and secure a Nursing Home Consultant's Permit which shall designate the home for which he or she is responsible.

Before a pharmacist is licensed as a Consultant Pharmacist or Consultant Pharmacist in Charge, he or she must certify to the Board of Pharmacy that he or she has satisfactorily completed a test on requirements developed by the Board to explain the pharmaceutical duties and responsibilities in a nursing home and that the Pharmacist has read and understands these regulations and will abide by them.

A Consultant Pharmacist in Charge shall not be issued in any instance where a full-time Consultant Pharmacist in Charge is already responsible for 1,500 or more residents, unless that pharmacist has submitted a written explanation of need and that request has been approved by the Director of the Board of Pharmacy.

In no instance shall a Consultant Pharmacist in Charge Permit be issued if the pharmacist is already responsible for more than 2,000 residents.

For renewal of a Nursing Home Consultant's Permit, it is required that in addition to the C.E. required for all pharmacists, Consultant Pharmacists must annually obtain three (3) hours of C.E. specifically relating to his/her role as a consultant in a nursing home.

RESPONSIBILITIES:

The Consultant Pharmacist or Consultant Pharmacist in Charge in a nursing home is involved in drug storage, distribution and utilization in that home.

These responsibilities might be divided into five general areas.

I. Supervision of services
II. Control and accountability
III. Patient drug regiment review
IV. Labeling of drugs and biologicals and proper storage
V. Quality Assurance and Assessment Committee

I. Supervision of Services

The Pharmaceutical services are under the supervision of a qualified Consultant Pharmacist or Consultant Pharmacist in Charge who is responsible for developing, coordinating, and supervising all pharmaceutical services. The Consultant Pharmacist in charge in the contract with the home must assure that pharmacist consultation is available on a 24-hour-per-day basis. A Pharmacist (if not a full-time employee) devotes a sufficient number of hours based upon the needs of the facility, during regularly scheduled visits to carry out these responsibilities. The Consultant Pharmacist in Charge submits a written report at least quarterly to the Quality Assurance and Patient Assessment Committee on the status of the facility's pharmaceutical services and staff performance.

The Consultant Pharmacist or Consultant Pharmacist in Charge shall assist the home in developing procedures to assure provisions of emergency drugs and shall report to the Board of Pharmacy any pharmacy refusing to provide emergency drugs for the pharmacy's regular patients in the home.

The Consultant Pharmacist in Charge shall be responsible for full compliance with Federal and State laws governing legend drugs (including controlled substances).

The Consultant Pharmacist or Consultant Pharmacist in Charge should inform himself of all laws and regulations pertaining to nursing homes and should communicate with the state agencies involved with enforcement and regulation of nursing homes.

To properly perform his duties, the Consultant Pharmacist or Consultant Pharmacist in Charge shall spend sufficient time to evaluate discontinued medication, destroy unused medication, check entries in Bound Controlled Drugs Book, file the completed disposition sheets with the patient's permanent record, and make general observations at the nursing stations.

This record shall indicate the day the Consultant Pharmacist in Charge or any assisting Consultant Pharmacist visited the home, a brief statement of purpose, finding, and actions.

II. Control and Accountability of All Legend Drugs (Including Controlled Substances)

Control and Accountability

The Consultant Pharmacist supervises and develops procedures for control and accountability of all drugs and biologicals throughout the facility. Only approved drugs and biologicals are used in the facility and are dispensed in compliance with Federal and State laws. Records of receipt and disposition of all controlled drugs are maintained in sufficient detail to enable an accurate reconciliation. The pharmacist determines that drug records are in order and that an account of all controlled drugs is maintained and reconciled.

A. All legend drugs must be stored in a secured location and under lock.

B. Proper records of receipt and administration of con-trolled drugs must be maintained for review by the pharmacist consultant.

C. All discontinued and outdated non-controlled legend drugs shall be inventoried and destroyed jointly by a designated nurse and the Consultant Pharmacist or Consultant Pharmacist in Charge with a jointly signed record kept.

D. All discontinued and outdated controlled drugs shall be jointly inventoried by a designated nurse and the Consultant Pharmacist or Consultant Pharmacist in Charge and an inventory signed by both shall be maintained for at least two (2) years.

The controlled drugs shall be sent to the Health Department by the Administrator and the Health Department receipt of drugs destroyed shall be reconciled with the nurse/pharmacist inventory by the Consultant Pharmacist in Charge.

III. Patient Drug Regimen Review

The primary responsibility of the Consultant Pharmacist or Consultant Pharmacist in Charge to the patient concerns applying his or her expertise on drugs to the patient's specific situation. To assist the Consultant Pharmacist or Consultant Pharmacist in Charge, the Department of Health and Human Services has developed INDICATORS FOR SURVEYOR ASSESSMENT OF THE PERFORMANCE OF DRUG REGIMEN REVIEWS. These shall be considered to the minimum standards for an adequate drug regimen review. Adherence to the INDICATORS shall not be the sole criteria for considering a review to be adequate; however, failure to consider and utilize the INDICATORS shall be justification for the finding of inadequate review.

In conjunction with, or in addition to, the INDICATORS the Consultant Pharmacist or Consultant Pharmacist in Charge should routinely and systematically review each patient's chart considering:

1. Ascertains that patient history and drug utilization is being properly recorded.
2. Reviews drug usage (including O.T.C. and prescriptions).
3. Reviews patient compliance with drug regimen.
4. Reviews drug allergies or sensitivities.
5. Determines whether patient is predisposed to side effects due to disease, illness, or age.
6. Determines whether potential exists for significant drug interaction.
7. Develops procedures to monitor patient's records for signs that indicate abuse or misuse of drugs by the patient or other personnel involved.
8. Makes recommendations regarding drug therapy to the physician, nurse or other persons involved in the patient's care.
9. Assures that adequate pharmacy services are available for emergencies that might develop in the home for a specific patient.
10. Promote pharmacists' ability and knowledge to all persons involved in patient's care and to offer assistance in solving specific problems relating to patient drug regimen.

A Consultant Pharmacist or Consultant Pharmacist in Charge shall quarterly in ICF/MR facilities and monthly in nursing facilities review each patient's medication record, consult with the director of nursing or the patient's physician, and check orders against medication card, Kardex, and actual medication.

IV. Labeling of Drugs and Biologicals and Proper Storage

All legend drugs (including controlled substances) on the premises of a nursing home except for the emergency tray as defined by the State Board of Pharmacy, shall be stored under lock and always be in a properly labeled container as dispensed upon a prescription by the pharmacy of the patient's choice.

It is the responsibility of the Consultant Pharmacist or Consultant Pharmacist in Charge to ascertain that medications are properly labeled, properly stored, refrigerated when needed, expiration dates routinely checked, and that appropriate accessory and cautionary instructions are on all medications when required.

V. Quality Assurance and Patient Assessment Committee

1. The Consultant Pharmacist or Consultant Pharmacist in Charge shall be a member of the Quality Assurance and Patient Assessment Committee (or its equivalent) and make official reports to this Committee as often as needed to assure quality pharmaceutical care.
2. The Consultant Pharmacist in Charge shall assure that there are written policies and procedures for safe and effective drug therapy, distribution, control, and use.

3. The policies and procedures shall include and are not limited to:

(a) Stop order policies or other methods to assure appropriateness of continued drug therapy.

(b) Determine the contents of the emergency medication, but which must comply with law and regulation.

(c) Policies for the safe procurement, storage, distribution, and use of drugs and biologicals.

Amend Regulation 37

(Make existing Regulation "A." and new "B.")

Recognizing the emergency and or unanticipated need for certain legend (non-controlled) drugs to be available to nurses employed by Arkansas Licensed Home Health Agencies, an Arkansas Licensed Pharmacy may provide certain medications under the following conditions:

(1) A written contract must exist between the Arkansas Licensed Home Health Agency and the Arkansas Licensed Pharmacy, and this must be available for review by the Board of Pharmacy upon request.

(2) The legend drugs remain the property of and under the responsibility of the Arkansas Licensed Pharmacy.

(3) All medications are administered only on physicians orders and medications administered from the nurses supply must be recorded as a prescription by the pharmacy prior to the pharmacy's replacement of the drug in the emergency supply.

(4) All medication records must be maintained as required by law, and out of date drugs must be properly destroyed by the pharmacy.

(5) The emergency supply may be carried by each nurse or an emergency kit may be provided for each patient's home.

(6) Careful patient planning should be a cooperative effort between the pharmacy and the nursing agency to make all medications available and this emergency supply should ONLY be used for emergency or unanticipated needs and shall NOT become a routine source or supply.

(7) The following medications can be supplied by the pharmacy in sufficient but limited quantities:

Heparin Flush -- Pediatric (one strength)

Heparin Flush -- Adult (one strength)

Sterile Water For Injection -- small volume

Sodium Chloride For Injection -- small volume

Adrenalin (Epinephrine) Injection -- ampoules only

Benadryl (Diphenhydramine) Injection -- ampoules only

* Note: For Heparin, Adrenalin and Benadryl, all patients should have a precalculated dose.

This list can be expanded only by the Board of Pharmacy; and if expanded, notice will be provided in the Board's Newsletter.

(8) The pharmacy is responsible to assure compliance with this regulation, and any abuse or misuse of the intent of this regulation shall be immediately reported to the Board of Pharmacy.

(9) The pharmacy and the agency shall develop policy and procedures to address storage conditions for medications.

52. Facsimile (Fax) Prescription Drug Order -- A prescription drug order which is transmitted by an electronic device which sends an exact copy image to the receiver (pharmacy) over telephone lines.

I. Pharmacist/Pharmacy:

A. A pharmacist may accept a facsimile prescription drug order in lieu of an oral or written prescription drug order for any drug except Schedule II drugs. However, an emergency order may be accepted by FAX as an alternative to the telephone, if all other requirements for emergency Schedule II prescriptions are met.

B. All law and regulation applicable to oral prescription drug orders shall also apply to facsimile orders including but not limited to generic substitution, maintenance of records, information required, etc.

C. A prescription order transmitted by facsimile device shall contain all prescription information required by federal and state law.

D. A pharmacist may dispense prescription orders transmitted by FAX only when signed by the authorized prescribing practitioner and transmitted from the practitioner's office by the practitioner or his designated agent.

E. A pharmacist may accept a FAX prescription from a long term care facility provided:

(1) All requirements of an oral prescription are met.

(2) The order is written and faxed by the nurse designated by the physician as his/her "agent" to be transmit the order.

(3) The pharmacist verifies the FAX is from the machine in the L.T.C. facility.

(4) The "agent" signs the order as the person authorized to transmit the order.

F. The pharmacist shall assure that the FAX paper is of such quality to last long enough to meet legal requirements.

The original FAX shall be assigned the number of the prescription dispensed, and maintained in pharmacy records for at least two years.

G. The receiving FAX machine must be in the prescription department of the pharmacy to protect patient/pharmacist/authorized prescribing practitioner confidentiality and security.

H. Refill authorizations for prescriptions may be transmitted using a facsimile device.

II. Patient/Prescriber Consideration:

A. No pharmacist shall enter into any agreement with a practitioner or health care facility concerning the provision of facsimile machine services or equipment which adversely affects any person's freedom to choose the pharmacy at which a prescription will be filled.

B. No pharmacist shall provide a FAX machine to any prescribing practitioner or other health care facilities unless the charge equals or exceeds the pharmacists cost of the machine.

C. A pharmacist/pharmacy shall not lease FAX machines to prescribing practitioners or health care facilities.

D. No agreement between a prescriber and a pharmacy shall require that prescription orders be transmitted by facsimile machine from the prescriber to only that pharmacy.

53. Practice After Inactivity when Reciprocating or Reinstating a License.

To be reinstated and immediately practice without supervision, the pharmacist's license shall not have lapsed more than two calendar years.

To be reciprocated and immediately practice without supervision, the pharmacist shall have practiced the profession of pharmacy, as defined by law, and in a licensed facility at least 40 hours per year in the previous two calendar years.

If these criteria are not met, the pharmacist must:

(1) Prior to resuming the unsupervised practice of pharmacy, practice 40 hours under direct supervision of an Arkansas licensed pharmacist for each year or part of year out of practice. This time under supervision shall not exceed 240 hours.

(2) Cause the supervising pharmacist to document, in writing to the Board, that the pharmacist has completed the designated number of hours of supervised practice.

(3) Meet with a Board representative in a practice situation so that the Board representative, by observation, questioning, and other methods as required, can assure the pharmacist is able to competently practice pharmacy.

55. GOOD COMPOUNDING PRACTICES APPLICABLE TO ARKANSAS LICENSED PHARMACIES

GOOD COMPOUNDING PRACTICES

The following Good Compounding Practices (GCPs) are meant to apply only to the compounding of drugs by Arkansas licensed pharmacies.

A. General Provisions

The recommendations contained herein are considered to be the minimum current good compounding practices for the preparation of drug products by licensed pharmacies for dispensing and/or administration to humans or animals.

Pharmacists, engaged in the compounding of drugs, shall operate in conformance with applicable pharmacy law and regulations.

The following definitions apply to these Good Compounding Practices.

"Compounding" -- The preparation, mixing, assembling, packaging, or labeling of a drug (including radiopharmaceuticals) or device (i) as the result of a Practitioner's Prescription Drug Order or initiative based on the Practitioner/patient/pharmacist relationship in the course of professional practice, or (ii) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or Dispensing. Compounding also includes the preparation of Drugs or Devices in anticipation of Prescription Drug Orders based on routine, regularly observed prescribing patterns.

"Manufacturing" -- The production, preparation, propagation, conversion, or processing of a Drug or Device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis, and includes any packaging or repackaging of the substance(s) or Labeling or relabeling of its container, and the promotion and marketing of such Drugs or Devices. Manufacturing also includes the preparation and promotion (other than by personal communication between pharmacist/physician/patient) of commercially available products from bulk compounds for resale by pharmacies, Practitioners, or other Persons.

"Component" -- Any ingredient used in the compounding of a drug product.

Based on the existence of a pharmacist/patient/prescriber relationship and the presentation of a valid prescription, or in anticipation of Prescription Drug Orders based on routine regularly observed prescribing patterns, pharmacists may compound, for an individual patient, drug products that are commercially available in the marketplace.

Pharmacists shall first attempt to receive, store, or use drug substances for compounding that have been made in an FDA inspected facility. If unobtainable from an FDA-inspected facility or if the FDA and/or the company cannot document FDA inspection, pharmacists shall receive, store, or use drug components in compounding prescriptions that meet official compendia requirements. If neither of these requirements can be met, pharmacists shall use their professional judgment in the procurement of acceptable alternatives.

Pharmacists may compound drugs in limited quantities prior to receiving a valid prescription based on a history of receiving valid prescriptions that have been generated solely within an established pharmacist/patient/prescriber relationship, and provided that they maintain the prescriptions on file for all such products compounded at the pharmacy (as required by State law). The compounding of inordinate amounts of drugs in anticipation of receiving prescriptions without any historical basis is considered manufacturing.

Pharmacists shall not offer compounded drug products to other State-licensed persons or commercial entities for subsequent resale, except in the course of professional practice for a prescriber to administer to an individual patient. Compounding pharmacies/pharmacists may advertise or otherwise promote the fact that they provide prescription compounding services; however, they shall not solicit business (e.g., promote, advertise, or use salespersons) to compound specific drug products.

The distribution of inordinate amounts of compounded products without a prescriber/patient/pharmacist relationship is considered manufacturing.

B. Organization and Personnel

As in the dispensing of all prescriptions, the pharmacist has the responsibility and authority to inspect and approve or reject all components, drug product containers, closures, in-process materials, and labeling; and the authority to prepare and review all compounding

records to assure that no errors have occurred in the compounding process. The pharmacist is also responsible for the proper maintenance, cleanliness, and use of all equipment used in prescription compounding practice.

All pharmacists who engage in drug compounding, shall be competent and proficient in compounding and shall maintain that proficiency through current awareness and training. Competency and proficiency in the art of compounding for all pharmacists shall be evaluated, documented, and maintained in the files of the pharmacy. Every pharmacist who engages in drug compounding must be aware of and familiar with all details of these Good Compounding Practices.

Only personnel authorized by the responsible pharmacist shall be in the immediate vicinity of the drug compounding operation.

c. Drug Compounding Facilities

Pharmacies engaging in compounding shall have a specifically designated and adequate area (space) for the orderly compounding of prescriptions, including the placement of equipment and materials. The drug compounding area for sterile products shall be separate and distinct from the area used for the compounding of non-sterile drug products. The area(s) used for the compounding of drugs shall be maintained in a good state of repair.

Bulk drugs and other chemicals or materials used in the compounding of drugs must be stored adequately labeled containers in a clean, dry area or, if required, under proper refrigeration.

Adequate lighting and ventilation shall be provided in all drug compounding areas. Potable water shall be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any compounded drug product.

The area(s) used for the compounding of drugs shall be maintained in a clean and sanitary condition.

1. Sterile Products

If sterile (aseptic) products are being compounded, the following conditions shall be met: See Board Regulation #43

If radiopharmaceuticals are being compounded, the following conditions shall be met: See Board Regulation #38

2. Special Precaution Products
If drug products with special precautions for contamination, such as penicillin, are involved in a compounding operation, appropriate measures, including either the dedication of equipment for such operations or the meticulous cleaning of contaminated equipment prior to its use for the preparation of other drugs, must be utilized in order to prevent cross-contamination.

D. Equipment

Equipment used in the compounding of drug products shall be of appropriate design, appropriate capacity, and suitable located to facilitate operations for its intended use and for its cleaning and maintenance. Equipment used in the compounding of drug products shall be of suitable composition so that surfaces that contact components, in-process materials, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product beyond that desired.

Equipment and utensils used for compounding shall be cleaned and sanitized immediately prior to use to prevent contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond that desired. In the case of equipment, utensils, and containers/closures used in the compounding of sterile drug products, cleaning, sterilization, and maintenance procedures as set forth in Board Regulation #43 must be followed.

Equipment and utensils used for compounding drugs must be stored in a manner to protect from contamination. Immediately prior to the initiation of compounding operations, they must be inspected by the pharmacist and determined to be suitable for use.

Automatic, mechanical, electronic, other types of equipment, and limited commercial scale manufacturing or testing equipment, may be used in the compounding of drug products. If such equipment is used, it shall be routinely inspected, calibrated (if necessary), or checked to ensure proper performance.

It is recognized that non-pharmacists may perform any of the set-up and maintenance procedures not defined as the practice of pharmacy.

E. Control of Components and Drug Product Containers and Closures

Components, drug product containers, closures, and bagged or boxed components of drug product containers and closures used in the compounding of drugs shall be handled and stored in a manner to prevent contamination and to permit unhindered cleaning of the work area, (e.g., floors) and inspection.

Drug product containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the compounded drug beyond the desired result. Components, drug product containers, and closures for use in the compounding of drug products shall be rotated so that the oldest stock is used first. Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the compounded drug product. Drug product containers and closures shall be clean and, where indicated by the intended use of the drug, sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use.

Drug product containers and closures intended for the compounding of sterile products must be handled, sterilized, stored, and in general maintained in keeping with Board Regulation #43. Methods of cleaning, sterilizing, and processing to remove pyrogenic properties shall be written and followed for drug product containers and closures used in the preparation of sterile pharmaceuticals.

F. Drug Compounding Controls

There shall be written procedures for the compounding of drug products to assure that the finished products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include a listing of the components (ingredients), their amounts (in weight or volume), the order of component mixing, and a description of the compounding process. All equipment and utensils and the container/closure system, relevant to the sterility and stability of the intended use of the drug, shall be listed. These written procedures shall be followed in the execution of the drug compounding procedure.

Components for drug product compounding shall be accurately weighed, measured, or subdivided as appropriate. These operations should be checked and rechecked by the compounding pharmacist at each stage of the process to ensure that each weight or measure is correct as stated in the written compounding procedures. If a component is

transferred from the original container to another (e.g., a powder is taken from the original container, weighed, placed in a container, and stored in another container) the new container shall be identified with the:

(a) component name
(b) lot and expiration date if available
(c) strength and concentration
(d) weight or measure

To assure the reasonable uniformity and integrity of compounded drug products, written procedures shall be established and followed that describe the tests or examinations to be conducted on the product compounded

(e.g., degree of weight variation among capsules). Such control procedures shall be established to monitor the output and to validate the performance of those compounding processes that may be responsible for causing variability in the final drug product. Such control procedures shall include, but are not limited to, the following (where appropriate):

(a) capsule weight variation;
(b) adequacy of mixing to assure uniformity and homogeneity;
(c) clarity, completeness, or pH of solutions.

Appropriate written procedures designed to prevent microbiological contamination of compounded drug products purporting to be sterile shall be established and followed. Such procedures shall include validation of any sterilization process.

G. Labeling Control of Excess Products

In the case where a quantity of a compounded drug product in excess of that to be initially dispensed in accordance with Subpart A is prepared, the excess product shall be labeled or documentation referenced with the complete list of ingredients (components), the preparation date, and the assigned beyond-use date based upon the pharmacist's professional judgment, appropriate testing, or published data. It shall also be stored and accounted for under conditions dictated by its composition and stability characteristics (e.g., in a clean, dry place on a shelf or in the refrigerator) to ensure its strength, quality, and purity.

At the completion of the drug preparation operation, the product shall be examined by the pharmacist for correct labeling.

H. Records and Reports

Any procedures or other records required to be maintained in compliance with these Good Compounding Practices shall be retained for the same period of time as each State requires for the retention of prescription files.

All records required to be retained under these Good Compounding Practices, or copies of such records, shall be readily available for authorized inspection during the retention period at the establishment where the activities described in such records occurred. These records or copies thereof shall be subject to photocopying or other means of reproduction as part of any such inspection.

Records required under these Good Compounding Practices may be retained either as the original records or as true copies, such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records.