16.19.4.11 CONSULTANT PHARMACIST:

A. DUTIES AND RESPONSIBILITIES:

(1) To abide by the code of ethics of the American Society of Consultant Pharmacists. Must be qualified to practice as a consultant pharmacist and is to be aware of all federal and state drug laws, rules and regulations related to pharmacy services, and to provide the facility with current information pertaining to drug service.

(2) Ensure that drugs are handled in the facility in which he/she is the consultant pharmacist, in a manner that protect the safety and welfare of the patient.

(3) Set the policy and procedures in the facility as related to all facits of drug handling and distribution; these policies and procedures to be reviewed and updated on an annual basis.

(4) To visit the facility, commensurate with his duties, as specified by Board regulations relative to the facility or by written contract with the administration of the facility not inconsistent with Board regulations.

(5) His/her primary goal and objective shall be the health and safety of the patient, and he/she shall make every effort to assure the maximum level of safety and efficacy in the provision of pharmaceutical services.

(6) The consultant pharmacist shall not condone or participate in any transaction with any practitioner of another health profession, or any other persons whosoever under which fees are divided, or rebates or kickbacks paid or caused to be paid, or which may result in financial exploitation of patients or their families in connection with the provision of drugs and medication or supplies or pharmaceutical services.

B. CONSULTANT PHARMACIST SERVING SKILLED NURSING FACILITIES AND INTERMEDIATE CARE FACILITIES - UPPER LEVEL CARE - LONG TERM CARE FACILITIES BY ANY OTHER TITLE:

(1) The consultant pharmacist's agreement with the facility shall include but is not limited to the following duties and responsibilities.

(a) Serve as a member of appropriate committees, and attend these meetings.

(b) Development of the Drug Control Procedures Manual.

(c) Monitor on a routine basis all aspects of the total drug distribution system - to be accomplished in a manner designed to monitor and safeguard all areas of the drug distribution system.

(d) Maintain active pharmacist status registration in the state.

(e) Assume responsibility for the destruction or removal of unwanted dangerous drugs and any controlled substances as prescribed by law and regulations.

(f) Maintain a log of all visits and activities in the facility indicating dates and other pertinent data; such logs are to be available to inspection by state drug inspectors upon request.

(g) Furnish and replenish emergency drug supply in acceptable containers. Maintain a log of use and replacement of drugs in the emergency tray.

(h) Make routine inspections of drug storage areas, patient health records, and review drug regimen of each patient at least once a month. Report irregularities, contraindication, drug interactions, etc., to the medical staff.

(i) Provide or make arrangements for provision of pharmacy services to the facility on a 24-hour 7 days a week basis, including stat orders.

(j) Provide in-service training of staff personnel as outlined in the procedures manual.

(k) Meet all other responsibilities of a consultant pharmacist as set forth in the Board regulations and federal or state laws and which are consistent with quality patient care.

(l) The contract consultant pharmacist to a SNF or ICF facility, that is required to review patients' drug regimen as set forth in Subparagraph h of Paragraph 1 of Subsection B of 16.19.4.11 NMAC, who is under contract as sole supplier of unit-doses/state of the art medications, shall be exempt from charges of Unprofessional Conduct under Paragraph 10 of Subsection B of 16.19.4.9 NMAC.

(m) The consultant pharmacist to a SNF or ICF facility who delivers drugs in a unit-dose system, approved by an agent of the Board, which is a tightly sealed, unopened, individual dose, shall be exempt from the requirements of 16.19.6.14 NMAC, Prohibition of Resale of Drugs. The regulation shall not prohibit the return to the pharmacy stock, where partial credit may be given in accordance with any federal or state law or regulation, to the patient for such medication, when the physician discontinues the drug therapy, the patient expires or for any other reason, other than an outdated drug.

(n) Customized Patient Medication Packages; In lieu of dispensing one, two, or more prescribed drug products in separate containers or standard vial containers, a pharmacist may, with the consent of the patient, the patient's care-giver, the prescriber, or the institution caring for the patient, provide a customized patient medication package. The pharmacist preparing a patient medication package must abide by the guidelines as set forth in the current edition of the U.S. Pharmacopoeia for labeling, packaging and record keeping.

(o) Repackaging of Patient Medication Packages; In the event a drug is added to or discontinued from a patient's drug regimen, when a container within the patient medication package has more than one drug within it, the pharmacist may repackage the patient's patient medication package and either add to or remove from the patient medication packaged as ordered by the physician. The same drugs returned by the patient for repackaging must be reused by the pharmacist in the design of the new patient medication package for the new regimen, and any drug removed must either be destroyed, returned to the DEA or returned to the patient properly labeled. Under no circumstances may a drug within a container of a patient medication package which contains more than one drug be returned to the pharmacy stock.

(p) Return of Patient Medication Package Drugs.

(i) Patient medication package's with more than one drug within a container: Patient medication packages with more than one drug within a container may not under any circumstances be returned to a pharmacy stock.

(ii) Patient Medication Package's with only one drug within a container: 1 Non-Institutional: A patient medication package stored in a non-institutional setting where there is no assurance of storage standards may not be returned to pharmacy stock. 2 Institutional: A patient medication package stored in an institutional setting where the storage and handling of the drugs are assured and are consistent with the compendia standards may be returned to the pharmacy stock provided the following guidelines are followed: (1) the drug is to be kept within the patient medication package and it is to remain sealed and labeled until dispensed; (2) the expiration date of drug shall become 50% of the time left of the expiration for the drug; (3) no Schedule II drugs may be returned to inventory; and (4) proper record keeping for the addition of other scheduled drugs into inventory must be done.

(2) When a consultant pharmacist enters into a written contractual agreement with a facility to which he/she will provide service.

(a) The consultant pharmacist whose practice is not in the immediate vicinity of the facility for which he has entered into a written service agreement, shall have a written agreement with a local pharmacist to be available on any emergency basis. The consultant pharmacist shall be responsible for the proper training and instruction of such local pharmacist. Said local pharmacist shall be known as a "co-consultant". The vendor shall be responsible for the safety and efficacy of back-up pharmaceutical services he provides.

(b) A copy of these agreements must be filed with the Board of Pharmacy and the facility. Any termination of such agreement shall be reported in writing, within ten (10) days, of termination to the Board and to the administrator.

(c) Should a local pharmacist (co-consultant) not be available, the consultant pharmacist must provide an alternative procedure approved by the Board. If the consultant is also the vendor, then such alternative procedure must reasonably assure rapid delivery of drugs; medical supplies and pharmacy service to the facility.

C. CONSULTANT PHARMACIST - CLINIC FACILITY:

(1) The consultant pharmacist providing services to a clinic shall.

(a) Assume overall responsibility for clinic pharmacy services, for clinic pharmacy supportive personnel, and for procedures as outlined in the procedures manual, including all records of drugs procured, administered, transferred, distributed, repackaged or dispensed from the clinic.

(b) Assume responsibility for the destruction or removal of unwanted or outdated dangerous drugs, including controlled substances, as required by laws and regulations.

(c) Develop the pharmacy services procedures manual for the clinic establishing the system for control and accountability of pharmaceuticals.

(d) Provide in-service education and training to clinic staff, as applicable.

(e) Report in writing to the Board within ten (10) days, any termination of services to the clinic. Report in writing to the Board the names and places of employment of any pharmacy technicians under the supervision of the consultant pharmacist.

(f) Comply with all other provisions of Part 10, Limited Drug Clinics, as applicable to the individual clinic facility.

(g) The consultant pharmacist shall personally visit the clinic on the minimum basis described in subparagraphs (a) through (c) [(i) through (iv)] to ensure that the clinic is following set policies and procedures. Visitation schedules are as follows.

(i) Class A clinics shall have the on-site services of a consultant pharmacist for the dispensing or distribution of dangerous drugs. The consultant pharmacist shall comply with Paragraphs 4, 5 and 7 of Subsection A of 16.19.4.16 NMAC of this regulation.

(ii) Class B clinics shall have the services of a consultant pharmacist as listed below: 1. Category 1 clinics shall be visited by the consultant pharmacist at least bi-monthly. 2. Category 2 clinics shall be visited by the consultant pharmacist at least monthly. 3. Category 3 clinics shall be visited by the consultant pharmacist at least bi-weekly.

(iii) Class C clinics shall be visited by the consultant pharmacist at least every three months.

~~(iv) Class D clinic shall be reviewed at least once yearly during school session.~~

(h) The consultant pharmacist shall review the medical records of not less than 5% of a Class B clinics patients who have received dangerous drugs (as determined by the dispensing or distribution records) since the consultant pharmacist's last visit. Such review shall be for the purpose of promoting therapeutic appropriateness, eliminating unnecessary drugs, and establishing the medical necessity of drug therapy, by identifying over-utilization or under-utilization, therapeutic duplication, drug-disease contraindications, drug-drug contraindications, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, appropriate medication indication, and/or clinical abuse/misuse. Upon recognizing any of the above, the consultant pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the prescriber.

(i) The consultant pharmacist shall maintain a log or record of all visits and activities in the clinic. Such record shall include a log of all medical records reviewed, along with a record of all consultant pharmacist interventions and/or consultations. This log or record shall be available for inspection by state drug inspectors upon request.

~~(j) The consultant pharmacist shall review Class D clinics annually to ensure the clinic is in compliance with training and protocols required by the department of health (DOH).~~

~~(i) clinic staff designated by the department of health shall complete a board of pharmacy self-inspection form;~~

~~(ii) self-inspection form shall be approved by the consultant pharmacist; and~~

~~(iii) clinic staff shall submit the self-inspection form to the board upon initial licensure and at each renewal.~~

(2) A clinic may petition the Board for an alternative visitation schedule as set forth in R of 16.19.10.11 NMAC.

D. CONSULTANT PHARMACISTS SERVING CUSTODIAL CARE FACILITIES:

(1) Custodial Care Facility as used in this regulation includes: Any Facility which provides care and services on a continuing basis, for two or more in-house residents, not related to the operator, and which maintains custody of the residents' drugs.

(2) Any facility which meets the requirements outlined in Paragraph 1 of Subsection D of 16.19.4.11 NMAC of this section shall be licensed by the Board of Pharmacy, engage a consultant pharmacist, whose duties and responsibilities are indicated in Paragraph 3 of Subsection D of 16.19.8.11.A NMAC.

(3) Procurement of drugs or medications for residents will be on the prescription order of a licensed physician - written or by oral communication, which order shall be reduced to writing by the pharmacist as required by law. Refills shall be as authorized by the physician. When refill authorization is indicated on the original prescription, a refill for a resident may be requested by the administrator of the licensed facility or his designee by telephone to the consultant pharmacist, or the providing pharmacy.

(4) The administrator or a designated employee of the facility will sign a receipt for prescription drugs upon delivery.

(5) All prescription drugs will be stored in a locked cabinet or room and the key will be assigned to a designated employee or the administrator as indicated in the procedures manual.

(6) Proper storage as stipulated in the official compendium USP/NF will be the responsibility of the licensed facility.

(7) Records - the consultant pharmacist shall be responsible for the following records:

(a) incoming medications - including refills;
(b) record of administration;
(c) waste or loss; This accountability record shall be maintained on a patient log, on forms provided to the consultant pharmacist by the Board of Pharmacy.

(8) All prescription containers shall be properly labeled as required in 16.19.11 NMAC. No bulk containers of legend drugs will be kept on the premises~~.~~, except in a facility with a 24-hour/365 day per year on-site nurse:

(1) Tuberculin testing solution; and

(2) Vaccines as recommended by the centers for disease control (CDC) and prevention's advisory committee on immunization practices and appropriate for the facility population served.

(9) Consultant pharmacist shall include in the procedures manual the name of individual(s) responsible for the assistance with the medication.

(10) It shall be the responsibility of the pharmacist to give proper training/instruction to the person(s) at the facility who have day-to-day responsibility for receipt and administration of medications to resident when adverse reactions, special diet, or any other information relative to the administration of a drug is needed by the staff.

(11) The consultant pharmacist shall be required to maintain a patient profile on each individual, if applicable to the facility and individual.

(12) The consultant pharmacist shall visit the facility no less than once a quarter or more often, commensurate with patient drug regimen and shall be available in emergencies, when needed. A log shall be maintained indicating all visits to the facility and noting any activities or irregularities to be recorded or reported. This log shall be available for state drug inspectors' review upon request.

(13) The consultant shall be responsible for the preparation of a procedures manual outlining procedures for the receipt, storage, record keeping, maintenance of patient profiles, administration and accountability of all legend drugs and procedures for the removal and destruction of unwanted, unused, outdated or recalled drugs - controlled substances shall be handled pursuant to state and federal regulations.

E. Consultant Pharmacist serving a School Based Emergency Medicine (SBEM) Licensed Care Facility or a Community Based Organization (CBO) Licensed Care Facility

(1) Albuterol Aerosol Canisters with Spacers and Epinephrine Standard-Dose and Pediatric-Dose Auto-Injectors are the only dangerous drugs that may be stored at SBEM Licensed Care Facilities.

(2) Naloxone is the only dangerous drug that may be stored at CBO Licensed Care Facilities

(3) Shall review records at least annually. This annual review does not require a visit by the consultant pharmacist to the licensed location. This review shall include a review of a Self-Assessment Form, receipt records, and storage records.

(4) Shall assist in the removal of expired or unwanted dangerous drugs. Such removal shall require transfer to another licensed location or a reverse distributor.

(5) Within 72 hours of a dangerous drug is administered, the consultant pharmacist shall review. This review shall be documented and stored at licensed location for 3 years. Review shall include following of procedures and administration by trained personnel as required by NM Department of Health.

(6) Require the facility to keep a log of all comments and activities of consultant pharmacist at registered location and available for viewing by State Drug Inspector.

(7) Verify a current record is kept of NM Department of Health trained staff at licensed location available.

(8) Maintain active status licensure with the NMBOP.

(9) The approval of a policy and procedures manual outlining procedures for the receipt, storage, record keeping, administration and accountability of all dangerous drugs. This includes policies and procedures for the removal and destruction of unwanted, unused, outdated or recalled dangerous drugs. Must include compliance with all NM Department of Health training and protocols.

E. No drug that has been dispensed pursuant to a prescription and has left the physical premises of the facility licensed by the board shall be dispensed or reused again except the re-labeling and reuse of pharmaceuticals may be permitted in the following situations: in a correctional facility, licensed by the board, under the following circumstances dangerous drugs, excluding controlled substances, may be re-used:

(1) the patients must reside in the same facility;

(2) the reused medication must have been discontinued from the original patient's drug regimen;

(3) the drug was never out of the possession of the licensee "keep on person pharmaceuticals may never be reused";

(4) the drugs were originally dispensed in packaging that is unopened, single-dose or tamper-evident containers;

(5) the patient receiving the re-labeled medication must have a valid prescription/order for the medication that is to be reused;

(6) repackaging and re-labeling may only be completed on site by the consultant pharmacist designated for that facility.

F. The consultant pharmacist must maintain records at the facility for three years containing the following information:

(1) date when the re-labeling occurred;

(2) the name and ID of the patient for whom the medication was originally intended for and the date in which it was discontinued from his or her drug regimen;

(3) the name and ID of the patient who will receive the reused medication;

(4) the name, strength and amount of the medication being reused;

(5) the name of pharmacist re-labeling the medication;

(6) pursuant to 16.19.10.11 NMAC the pharmacist must label the reused pharmaceutical and maintain a dispensing log for all such re-issued pharmaceuticals and the expiration date for such re-issued drugs shall be no greater than 50 percent of the time remaining from the date of repackaging until the expiration date indicated on the original dispensing label or container.

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