PART Ph 709 2300 INSTITUTIONAL PRACTICES

Ph 709.01 2301.00 Definitions

(a) "Automated medication supply system" means an electronically controlled system that performs operations or activities relative to the storage and distribution of medications for administration and which collects, controls, and maintains all transaction information.

(b) "Electronic identifier", for purposes of paragraph (a) above, means a unique security code or other identifier which specifically identifies the person entering information into a data processing system.

(c) "ADM" Automatic dispensing machines (ADM) or (automated drug cabinets) are a computerized drug storage and dispensing device used in the health care settings.

Source. #2260, eff 01-05-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-22-95, EXPIRED, 1-19-96.

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04.

New. #8316, eff 3-26-05; ss by #8572, eff 2-23-06; ss by #10225, eff 11-7-12; ss by #10903, eff 8-5-15.

Ph 709.02 2302 Licensing

(a) A pharmacy permit shall be required for each institution with an on-premise pharmacy. Such permit shall be issued to an pharmacist-in-charge institution, who shall be licensed in the state of New Hampshire. When an institution procures prescription drugs for its patients only on individual prescriptions for specific patients from an off-premise licensed pharmacy, the institution shall not be required to obtain a pharmacy permit.

(b) If an institution does not have a pharmacy on its premises, it may enter into an agreement with a pharmacy licensed to provide such services. Such agreement shall be in writing and shall state the policy and procedures as required by Ph 709. A copy of the agreement shall be made available by the consultant pharmacist to the board upon request. The consultant pharmacist shall be responsible for
the maintenance of all records and the compliance with state and federal laws and rules governing the practice of pharmacy.

(c) When applicable, the corporate officer, or the officer's replacement, who signs the pharmacy permit shall be held accountable, along with the pharmacist-in-charge, regarding compliance to federal, state, and local laws related to the practice of pharmacy. Both individuals shall be held accountable regarding compliance as required by the New Hampshire board of pharmacy or other governmental agency regarding the practice of pharmacy.

(d) When applicable, the corporate officer, or the officer's replacement, who signs the pharmacy permit, and the pharmacist-in-charge, shall comply with federal, state and local laws related to the practice of pharmacy.

<table>
<thead>
<tr>
<th>Ph 709.02 2303 Practice Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NOTES:</strong> The board suggests separating Licensing from Practice Standards. The administration rule numbers will need to be changed accordingly.</td>
</tr>
</tbody>
</table>

| (ae) An institutional license permit shall permit the pharmacy to dispense medications to inpatients of the institution, staff or employees of the institution, interim supplies of medication to outpatients in emergency situations and home infusion therapy to contractual patients not requiring hospitalization. If a pharmacist is on the premises, outpatient prescription services may be provided by the pharmacy, on a one-time, no-refill basis, to an ambulatory care patient and any patient who is being discharged with medications related to the patient's hospitalization. Labeling for all outpatient prescriptions shall be according to RSA 318:47-a and RSA 318-B: 11. |

| (bd) Members of the board and/or their agents shall inspect the pharmacy, drug room/medication room and all areas or departments of the institution facility where drugs are stored, manufactured, compounded, dispensed or distributed to ensure: |

1. That adequate drug security and storage requirements are met;
2. That proper records are maintained; and
3. That the facility is in compliance with all local, state and federal drug and pharmacy laws and rules.
(ce) Those facilities obtaining prescription drugs only on individual prescriptions for specific patients from an off-premise licensed pharmacy shall not be exempt from inspection.

(df) Each institution shall have a pharmacy and therapeutics committee or a comparable committee of its medical staff. This committee shall be composed of representatives of the medical staff and the pharmacist-in-charge, or a licensed staff pharmacist designated by the pharmacist-in-charge, and representatives of the administrative and nursing departments. The pharmacy representative shall be a voting member of the committee and the committee shall meet at least twice a year. The major functions of this committee shall be to establish the written policies and procedures governing the practice of pharmacy medication management, use of drugs, drug specifications and drug distribution.

(e) The Institutional Pharmacy has the authority to develop and implement clinical pharmacy practice policies and procedures which provide optimum pharmaceutical care for patients.

(fg) An institutional pharmacy may dispense a generic or therapeutic equivalent or bio-similar that has been approved by the pharmacy and therapeutics committee or its equivalent only to inpatients of the institution, staff or employees of the institution and their dependents, or interim supplies of medication to outpatients in emergency situations.

(e) Pharmacists may initiate or modify drug therapy by approved protocol according to institution policy. Drug therapy initiated or modified by protocol shall be documented in the medical record per hospital policy. The Pharmacist shall document in the medical record and this documentation shall be reviewed and signed by the provider per hospital institutional policies and procedures. Examples of protocols include but not limited to the following:

- Renal dosing
- Antibiotic per Pharmacy
- Medication Reconciliation
- Outpatient IV

(h) When applicable, the corporate officer, or the officer’s replacement, who signs the pharmacy permit shall be held accountable, along with the pharmacist-in-charge, regarding compliance to federal, state, and local laws related to the practice of pharmacy. Both individuals shall be held accountable regarding compliance as required by the New Hampshire Board of Pharmacy or other governmental agency regarding the practice of pharmacy.

(i) When applicable, the corporate officer, or the officer's replacement, who signs the pharmacy permit, and the pharmacist-in-charge, shall comply with federal, state, and local laws related to the practice of pharmacy.
(h) Drugs shall be dispensed in compliance with state and federal pharmacy-related laws and rules.

(i) Written policies and procedures shall be adopted which establish the method utilized in the procurement, storage and distribution of drugs in all areas or departments of the facility, and which are consistent with state and federal pharmacy laws and rules.

(j) Orders shall be reviewed by a pharmacist before the medication is initially dispensed except in emergencies or when a pharmacist is unavailable. Medication orders must be reviewed by a pharmacist within 24 hours. This regulation shall not be construed to prevent the distribution of drugs for floor stock or systems that perform auto-verification, which will be established in policy. Review will may include, but is not limited to the following:

(1) Over-utilization or under-utilization;

(2) Therapeutic duplication;

(3) Drug-disease contraindication;

(4) Drug-drug interactions;

(5) Incorrect drug dosage or duration of drug treatment;

(6) Drug-allergy interactions

(7) Clinical abuse or misuse.

(k) Upon recognizing a clinical problem, the pharmacist shall take appropriate steps to avoid or correct the problem.

Source. #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96; amd by #6933, eff 2-1-99; paragraphs (a), (h), (d), (e), and (f) EXPIRED: 2-5-04; amd by #8316, eff 3-26-05; amd by #8572, eff 2-23-06; paragraphs (c) & (h) EXPIRED: 2-1-07; ss by #10225, eff 11-7-12; ss by #10903, eff 8-5-15

(a) The institutional pharmacy shall be enclosed, lockable and capable to be alarmed.
(b) The institutional pharmacy shall have adequate space necessary for the storage, compounding, labeling, dispensing and sterile preparation of drugs prepared in the pharmacy.

(c) The institutional pharmacy shall be arranged in an orderly fashion and shall be kept clean.

(d) A sink with hot and cold running water shall be available to all pharmacy personnel.

(e) The institutional pharmacy shall have locked storage for schedule II controlled all controlled substances based on institutional policies and procedures, and other controlled drugs requiring additional security.

(f) The institutional pharmacy shall have designated areas for the storage of flammable and caustic materials. Such areas shall meet the requirements set by local and state fire laws.

(g) The institutional pharmacy shall have a designated area for the preparation of sterile products if sterile products are prepared. The pharmacy shall be in compliance with all board rules and regulations as they pertain to sterile compounding.

Source. #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05; ss by #10225, eff 11-7-12; ss by #10903, eff 8-5-15; ss by #10903, eff 8-5-15

Ph 709-04_2305 Drug Security.

(a) Drugs stored in any area or department of the facility shall be plainly labeled and kept in a specifically designated, well-illuminated cabinet, closet or storage area or ADM or automated systems and shall be accessible only to authorized personnel.
(b) When controlled drugs are stored in authorized areas other than in the pharmacy, special locked storage for all controlled substances requiring additional security shall be used, based on institutional policies and procedures.

(c) When using an automated medication supply system, the pharmacist-in-charge or designee shall have the responsibility for developing a secure system to assign, discontinue or change personnel access codes.

(d) A pharmacist or registered pharmacy technician or a designee, under the direction of a pharmacist shall visit and create a retrievable record, at least monthly, all areas or departments of the institution where drugs, biologicals, pharmaceutical chemicals or other pharmaceutical preparations are stored to ensure they are properly labeled, have not reached their expiration date and show no signs of deterioration. Any substance not conforming to these standards shall be removed from stock.

(e) A retrievable record of each monthly inspection specified in (d) above shall be maintained in the pharmacy for at least 2 years and shall be available to the board upon request.

(f) The pharmacist-in-charge shall ensure that the areas specified in (d) above are in compliance with federal and state drug laws relative to security, drug distribution and product tampering.

(g) The pharmacist-in-charge shall develop a distribution system which shall prevent designed to prevent the illicit diversion of drugs.

(h) Discrepancies shall be reported to the pharmacy within 24 hours and resolved within 72 hours. Missing or unaccounted controlled drugs shall be reported to the NH board of pharmacy and Drug Enforcement Agency (DEA) as specified by. Controlled drug discrepancies shall be reported to the pharmacy within 24 hours and resolved within 72 hours. If the drug is determined to be missing or unaccounted for, it will be reported to the board and DEA as specified by 21 CFR § 1301.76-b.

(i) When an emergency drug kit other than regulated by Ph 705.03, containing controlled substances is opened, shift counts shall be done by the nursing staff on all controlled substances until resealed by a pharmacist.
(a) Drugs shall be dispensed only by or in the presence of and under the supervision of a pharmacist, or prescriber in compliance with local, state and federal pharmacy-related laws and rules. Upon the written order of a prescriber a nurse may leave a properly labeled container of any non-controlled drug at the patient's bedside. A licensed nurse shall not dispense or compound drugs except as permitted by RSA 318:42.

(b) The pharmacy shall dispense medications pursuant of an order from a prescriber. Drugs shall be provided to patients in institutions only on the order of a practitioner legally authorized to write prescriptions. No change in the order for drugs shall be made without the approval of a practitioner qualified to write prescriptions.

(c) Each order pursuant to (b) above shall include at least the:

(1) Patient's name and location;

(2) Date of the order;

(3) Name and dosage of the drug;
(4) Directions; and

(5) Signature of the prescriber or licensed health-care professional receiving the order.

Written policies and procedures shall be adopted which establish the method utilized in the procurement, storage and distribution of drugs in all areas or departments of the facility, and which are consistent with state and federal pharmacy laws and rules.

Orders shall be reviewed by a pharmacist before the medication is initially dispensed except in emergencies or when a pharmacist is unavailable. Medication orders must be reviewed by a pharmacist within 24 hours. This regulation shall not be construed to prevent the distribution of drugs for floor stock. Review will include, but is not limited to the following:

- Over-utilization or under-utilization;
- (2) Therapeutic duplication;
- (3) Drug-disease contraindication;
- (4) Drug-drug interactions;
- (5) Incorrect drug dosage or duration of drug treatment;
- (6) Drug-allergy interactions
- (7) Clinical abuse or misuse.

Upon recognizing a clinical problem, the pharmacist shall take appropriate steps to avoid or correct the problem.

Source. #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05; amd by#8572, eff 2-23-06; ss by #10225, eff 11-7-12; ss by #10903, eff 8-5-15

Ph 799-06 2306 Access to the Pharmacy.
(a) Only a pharmacist shall open and close the pharmacy for dispensing. The pharmacist-in-charge of each institutional pharmacy shall establish written policies identifying specific situations where pharmacy technicians may be present in the pharmacy in the absence of a licensed pharmacist.

(b) In the absence of a pharmacist and in accordance with RSA 318:38, I licensed nurses, designated for this purpose by the pharmacist-in-charge, may obtain from the pharmacy or night cabinet such drugs as needed in an emergency when these drugs are not available in floor stock supplies.

(c) The authorized nurse may enter the pharmacy area and remove the following:

(1) A drug in its original container or a drug prepackaged for use within the facility subject to these rules; or

(2) An emergency supply of a drug from the original container to be administered to a specific patient.

(d) The authorized nurse shall leave a copy of the physician's order in the pharmacy or night cabinet and on a suitable form record the following:

(1) Name and strength of the drug taken;

(2) Dosage form taken;

(3) Quantity taken;

(4) Time and date of withdrawal;

(5) Patient name and/or location, where applicable and; and

(6) Nurse's signature,
(e) The nurse shall leave with the record the bulk container from which the medication was taken or a representative sample of the unit-dose medication. In the event that a representative sample of a medication is not available to be left, then a photocopy of the label of the medication shall be acceptable.

**Source.** #2250, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

**New.** #6181-B, eff 2-5-96, EXPIRED: 2-5-04

**New.** #8316, eff 3-26-05; ss by #10225, eff 11-7-12; ss by #10903, eff 8-5-15

**Ph 709.07 2307 Drug Control in Ambulatory Patient Treatment Areas:**

(a) In the ambulatory patient treatment areas, a medical practitioner may dispense drugs for the immediate needs of the patient, not in excess of a 72-hour supply, except that, for Schedule II controlled substances, a maximum of 48-hour supply shall be allowed, if permitted by the institution. The drug container shall be properly labeled.

(b) If a licensed pharmacist is on the premises, that pharmacist may fill one-time, full amount, non-refillable prescriptions for patients for medications related to the ambulatory patient treatment visit.

(c) A readily retrievable record shall be made of all administrations and dispensing of controlled drugs in the ambulatory patient area.

(d) This record shall include:

1. Name and address of the patient;

2. Name of the medical practitioner;

Comment [KB3]: Need to understand the definition of "Ambulatory Patient Treatment Areas." And, how does it apply to "Institution"? And, how does it also work with the other 700 rules?
(3) Name, strength and quantity of the drug(s);

(4) Date of administration or dispensing; and

(5) Signature or electronic identifier, as defined in Ph 709.01(b), of the agent removing the drug(s) from the inventory.

Source. #2260, eff 01-05-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96; amd by #6933, eff 2-1-99; paragraph (b) EXPIRED: 2-5-04; amd by #8316, eff 3-26-05; amd by #8572, eff 2-23-06; paras. (a) & (c) EXPIRED: 2-1-07; ss by #10225, eff 11-7-12; ss by #10903, eff 8-5-15

Ph 709.08 Investigational Drugs. Investigational drugs for research shall be used only under the supervision and authority of the principal investigator, and shall be approved by an appropriate medical staff committee. Such drugs shall be controlled by the pharmacy and shall be properly labeled according to the research protocols. The principal investigator shall provide essential information on such drugs to the current treatment team. A central unit, which may be the pharmacy, shall be established where essential information on investigational drugs is maintained. Nurses shall be given basic pharmacologic information about the drug before administering.

Source. #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05; ss by #8572, eff 2-23-06 ss by #10225, eff 11-7-12; ss by #10903, eff 8-5-15

Ph 709.09 Purchase of Drugs.
(a) The pharmacist-in-charge, with the consent of the institution's pharmacy and therapeutics committee or comparable committee of its medical staff shall be responsible for the quality of all drugs, biologicals and pharmaceutical chemicals.

(b) Purchasing of drugs, pharmaceuticals, biologicals, intravenous and irrigation fluids shall be subject to approval of the pharmacist-in-charge with the consent of the institution's pharmacy and therapeutics committee or comparable committee of its medical staff.

(c) Radiopharmaceuticals, blood products, radiopaque media and medical devices may be exempted from the approval and/or control of the pharmacist-in-charge by the institution's pharmacy and therapeutics committee.

Source. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05; ss by #10225, eff 11-7-12; ss by #10903, eff 8-5-15

Ph. 209.10 INITIATION OR MODIFICATION OF DRUG THERAPY

Pharmacists may initiate or modify drug therapy by approved protocol according to institution policy. Drug therapy initiated or modified by protocol shall be documented in the medical record per hospital policy. The pharmacist shall document in the medical record and this documentation shall be reviewed and signed by the provider per hospital policy. Examples of protocols include but not limited to the following:

- Renal dosing
- Vancomycin per Pharmacy
- Medication Reconciliation
- Outpatient IV

Ph. 709.11 PHARMACEUTICAL CARE

(a) The Institutional Pharmacy shall develop and implement clinical pharmacy practice policies and procedures which provide optimum pharmaceutical care for in-patients. These programs should include medication management by a pharmacist through transitions of care and other pharmaceutical care services intended to achieve outcomes which improve the patient's quality of life as it is related to the cure or prevention of a
disease; elimination or reduction of a patient's symptoms; or arresting or slowing of a
disease process. Clinical pharmacy practice policy and procedures should include but are
not limited to the following:

(b)
(c) Systems for monitoring and detecting drug interactions, contraindications,
   incompatibilities, and allergic reactions;
(d) Systems for monitoring dosages and serum blood levels of drugs for correct ranges
   where appropriate;
(e) Systems for monitoring, detecting, and reporting adverse drug reactions;
(f) Systems for monitoring and evaluating therapeutic duplications;
(g)(a) Provision of drug therapeutic consultations and drug information by a
pharmacist(s) to patients at transitions of care.
PART Ph 709 INSTITUTIONAL PRACTICES

Ph 709.01 Definitions

(a) "Automated medication supply system" means an electronically controlled system that performs operations or activities relative to the storage and distribution of medications for administration and which collects, controls, and maintains all transaction information.

(b) "Electronic identifier", for purposes of paragraph (a) above, means a unique security code or other identifier which specifically identifies the person entering information into a data processing system.

(c) "ADM" Automatic dispensing machines (ADM) or (automated drug cabinets) are a computerized drug storage and dispensing device used in the health care settings.

Source. #2260, eff 01-05-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05; ss by #8572, eff 2-23-06; ss by #10225, eff 11-7-12; ss by #10903, eff 8-5-15

Ph 709.02 Licensing and Practice Standards.

(a) A pharmacy permit shall be required for each institution with an on-premise pharmacy. Such permit shall be issued to a pharmacist in charge of institution, who shall be licensed in the state of New Hampshire. When an institution procures prescription drugs for its patients only on individual prescriptions for specific patients from an off-premise licensed pharmacy, the institution shall not be required to obtain a pharmacy permit.

(b) If an institution does not have a pharmacy on its premises, it may enter into an agreement with a pharmacy licensed to provide such services. Such agreement shall be in writing and shall state the policy and procedures as required by Ph 709. A copy of the agreement shall be made available by the consultant pharmacist to the board upon request. The consultant pharmacist shall be responsible for
the maintenance of all records and the compliance with state and federal laws and rules governing the practice of pharmacy.

(c) When applicable, the corporate officer, or the officer's replacement, who signs the pharmacy permit shall be held accountable, along with the pharmacist-in-charge, regarding compliance to federal, state, and local laws related to the practice of pharmacy. Both individuals shall be held accountable regarding compliance as required by the New Hampshire board of pharmacy or other governmental agency regarding the practice of pharmacy.

(d) When applicable, the corporate officer, or the officer's replacement, who signs the pharmacy permit, and the pharmacist-in-charge, shall comply with federal, state and local laws related to the practice of pharmacy.

**Practice Standards**

**Ph-200.02**

(NOTE: the group suggested separating Licensing from Practice Standards. The administration rule numbers will need to be changed accordingly).

(ae) An institutional license permit shall permit the pharmacy to dispense medications to inpatients of the institution, staff or employees of the institution, interim supplies of medication to outpatients in emergency situations and home infusion therapy to contractual patients not requiring hospitalization. If a pharmacist is on the premises, outpatient prescription services may be provided by the pharmacy, on a one-time, no-refill basis, to an ambulatory care patient and any patient who is being discharged with medications related to the patient's hospitalization. Labeling for all outpatient prescriptions shall be according to RSA 318:47-a and RSA 318-B: 11.

(bsd) Members of the board and/or their agents shall inspect the pharmacy, drug room/medication room and all areas or departments of the institution facility where drugs are stored, manufactured, compounded, dispensed or distributed to ensure:

(1) That adequate drug security and storage requirements are met;

(2) That proper records are maintained; and

(3) That the facility is in compliance with all local, state and federal drug and pharmacy laws and rules.

Commented [KB3]: How are (c) and (d) different?? Perhaps only need one of these sections.
(ce) Those facilities obtaining prescription drugs only on individual prescriptions for specific patients from an off-premise licensed pharmacy shall not be exempt from inspection.

(gg) Each institution shall have a pharmacy and therapeutics committee or a comparable committee of its medical staff. This committee shall be composed of representatives of the medical staff and the pharmacist-in-charge, or a licensed staff pharmacist designated by the pharmacist-in-charge, and representatives of the administrative and nursing departments. The pharmacy representative shall be a voting member of the committee and the committee shall meet at least twice a year. The major functions of this committee shall be to establish the written policies and procedures governing the practice of pharmacy medication management, use of drugs, drug specifications and drug distribution.

(e) The Institutional Pharmacy has the authority to develop and implement clinical pharmacy practice policies and procedures which provide optimum pharmaceutical care for patients.

(fg) An institutional pharmacy may dispense a generic or therapeutic equivalent or bio-similar that has been approved by the pharmacy and therapeutics committee or its equivalent only to in-patients of the institution, staff or employees of the institution and their dependents, or interim supplies of medication to outpatients in emergency situations.

(gg) Pharmacists may initiate or modify drug therapy by approved protocol according to institution policy. Drug therapy initiated or modified by protocol shall be documented in the medical record per hospital policy. The pharmacist shall document in the medical record and this documentation shall be reviewed and signed by the provider per hospital institutional policies and procedures. Examples of protocols include but not limited to the following:

- Renal dosing
- Vanciin Antibiotic per Pharmacy
- Medication Reconciliation
- Outpatient IV

(hh) When applicable, the corporate officer, or the officer’s replacement, who signs the pharmacy permit shall be held accountable, along with the pharmacist-in-charge, regarding compliance to federal, state, and local laws related to the practice of pharmacy. Both individuals shall be held accountable regarding compliance as required by the New Hampshire Board of Pharmacy or other governmental agency regarding the practice of pharmacy.

(ii) When applicable, the corporate officer, or the officer’s replacement, who signs the pharmacy permit, and the pharmacist-in-charge, shall comply with federal, state and local laws related to the practice of pharmacy.
Ph-709.05—Dispensing Practices. (The items below were originally in 709.05)

(NOTE: The group wanted to move all of 709.05 to be part of the new Practice Standards section items above)

(h) Drugs shall be dispensed in compliance with state and federal pharmacy-related laws and rules.

(i) Written policies and procedures shall be adopted which establish the method utilized in the procurement, storage and distribution of drugs in all areas or departments of the facility, which are consistent with state and federal pharmacy laws and rules.

(i) Orders shall be reviewed by a pharmacist before the medication is initially dispensed except in emergencies or when a pharmacist is unavailable. Medication orders must be reviewed by a pharmacist within 24 hours. This regulation shall not be construed to prevent the distribution of drugs for floor stock or systems that perform auto-verification, which will be established in policy. Review will may include, but is not limited to the following:

1. Over-utilization or under-utilization;
2. Therapeutic duplication;
3. Drug-disease contraindication;
4. Drug-drug interactions;
5. Incorrect drug dosage or duration of drug treatment;
6. Drug-allergy interactions;
7. Clinical abuse or misuse.

Upon recognizing a clinical problem, the pharmacist shall take appropriate steps to avoid or correct the problem.

Source. #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96;amd by #6933, eff 2-1-99; paragraphs (a), (b), (d), (e), and (f) EXPIRED: 2-5-04; amd by #8316, eff 3-26-05; amd by #8572, eff 2-23-06; paragraphs (c) & (h) EXPIRED: 2-1-07; ss by #10225, eff 11-7-12; ss by #10903, eff 8-5-15
Environment.

(a) The institutional pharmacy shall be enclosed, lockable and capable to be alarmed.

(b) The institutional pharmacy shall have adequate space necessary for the storage, compounding, labeling, dispensing and sterile preparation of drugs prepared in the pharmacy.

(c) The institutional pharmacy shall be arranged in an orderly fashion and shall be kept clean.

(d) A sink with hot and cold running water shall be available to all pharmacy personnel.

(e) The institutional pharmacy shall have locked storage for schedule II controlled substances based on institutional policies and procedures, and other controlled drugs requiring additional security.

(f) The institutional pharmacy shall have designated areas for the storage of flammable and caustic materials. Such areas shall meet the requirements set by local and state fire laws.

(g) The institutional pharmacy shall have a designated area for the preparation of sterile products if sterile products are prepared. The pharmacy shall be in compliance with all board rules and regulations as they pertain to sterile compounding.

Source. #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05; ss by #10225, eff 11-7-12; ss by #10903, eff 8-5-15; ss by #10903, eff 8-5-15

Drug Security
(a) Drugs stored in any area or department of the facility shall be plainly labeled and kept in a specifically designated, well-illuminated cabinet, closet or storage area or ADM or automated systems and shall be accessible only to authorized personnel.

(b) When controlled drugs are stored in authorized areas other than in the pharmacy, special locked storage for all controlled substances requiring additional security shall be used, based on institutional policies and procedures.

(c) When using an automated medication supply system, the pharmacist-in-charge or designee shall have the responsibility for developing a secure system to assign, discontinue or change personnel access codes.

(d) A pharmacist, or registered pharmacy technician or a designee, under the direction of a pharmacist shall visit and create a retrievable record, at least monthly, all areas or departments of the institution where drugs, biologicals, pharmaceutical chemicals or other pharmaceutical preparations are stored to ensure that they are properly labeled, have not reached their expiration date and show no signs of deterioration. Any substance not conforming to these standards shall be removed from stock.

(e) A retrievable record of each monthly inspection specified in (d) above shall be maintained in the pharmacy for at least 2 years and shall be available to the board upon request.

(f) The pharmacist-in-charge shall ensure that the areas specified in (d) above are in compliance with federal and state drug laws relative to security, drug distribution and product tampering.

(g) The pharmacist-in-charge shall develop a distribution system which shall prevent the illicit diversion of drugs.

(h) Discrepancies shall be reported to the pharmacy within 24 hours and resolved within 72 hours. Missing or unaccounted controlled drugs shall be reported to the NH board of pharmacy and Drug Enforcement Agency (DEA) as specified by. Controlled drug discrepancies shall be reported to the pharmacy within 24 hours and resolved within 72 hours. If the drug is determined to be missing or unaccounted for, it will be reported to the board and DEA as specified by 21 CFR § 1301.76-b.
When an emergency drug kit other than regulated by Ph 705.03, containing controlled substances is opened, shift counts shall be done by the nursing staff on all controlled substances until resealed by a pharmacist.

709.04 (f) Emergency drug kits; what is the modern definition? We have 12 emergency crash carts that once had controlled substances in them that this rule easily applied to; however, we now have paramedic narcotic kits that are returned to the ED with a red seal and kept in Omnicell for restocking by the Pharmacy, as well as, AIS kits that are handled in a similar manner. My question should we have wording that still requires a shift count or addresses practices similar to ours.

Source. #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05; amd by #8572, eff 2-23-06; ss by #10225, eff 11-7-12; ss by #10903, eff 8-5-15

Ph 709.06—Dispensing Practices.

(a) Drugs shall be dispensed only by or in the presence of and under the supervision of a pharmacist, or prescriber in compliance with local, state and federal pharmacy-related laws and rules. Upon the written order of a prescriber, a nurse may leave a properly labeled container of any non-controlled drug at the patient’s bedside. A licensed nurse shall not dispense or compound drugs except as permitted by RSA 318:42.

(b) The pharmacy shall dispense medications pursuant to an order from a prescriber. Drugs shall be provided to patients in institutions only on the order of a practitioner legally authorized to write prescriptions. No change in the order for drugs shall be made without the approval of a practitioner qualified to write prescriptions.

(c) Each order pursuant to (b) above shall include at least the:

(1) Patient’s name and location;

(2) Date and time of order;

(3) Name of drug;

(4) Route of administration;

(5) Dosage form;

(6) Quantity;

(7) Order number;

(8) Prescriber’s credentials and signature.
(3) Date of the order;

(3) Name and dosage of the drug;

(4) Directions; and

(5) Signature of the prescriber or licensed health care professional receiving the order.

(a) Written policies and procedures shall be adopted which establish the method utilized in the procurement, storage and distribution of drugs in all areas or departments of the facility, and which are consistent with state and federal pharmacy laws and rules.

(b) Orders shall be reviewed by a pharmacist before the medication is initially dispensed except in emergencies or when a pharmacist is unavailable. Medication orders must be reviewed by a pharmacist within 24 hours. This regulation shall not be construed to prevent the distribution of drugs for floor stock. Review will include, but is not limited to the following:

- Over-utilization or under-utilization;
- (2) Therapeutic duplication;
- (3) Drug-disease contra indication;
- (4) Drug-drug interactions;
- (5) Incorrect drug dosage or duration of drug treatment;
- (6) Drug-allergy interactions;
- (7) Clinical abuse or misuse.

Upon recognizing a clinical problem, the pharmacist shall take appropriate steps to avoid or correct the problem.

Source: #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04
(a) Only a pharmacist shall open and close the pharmacy for dispensing. The pharmacist-in-charge of each institutional pharmacy shall establish written policies identifying specific situations when pharmacy technicians may be present in the pharmacy in the absence of a licensed pharmacist.

(b) In the absence of a pharmacist and in accordance with RSA 318:38, licensed nurses, designated for this purpose by the pharmacist-in-charge, may obtain from the pharmacy or night cabinet such drugs as needed in an emergency when these drugs are not available in floor stock supplies.

(c) The authorized nurse may enter the pharmacy area and remove the following:

(1) A drug in its original container or a drug prepackaged for use within the facility subject to these rules; or

(2) An emergency supply of a drug from the original container to be administered to a specific patient.

(d) The authorized nurse shall leave a copy of the physician's order in the pharmacy or night cabinet and on a suitable form record the following:

(1) Name and strength of the drug taken;

(2) Dosage form taken;

(3) Quantity taken;

(4) Time and date of withdrawal;

(5) Patient name and/or location, where applicable and; and
(e) The nurse shall leave with the record the bulk container from which the medication was taken or a representative sample of the unit-dose medication. In the event that a representative sample of a medication is not available to be left, then a photocopy of the label of the medication shall be acceptable.

Source. #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05; ss by #10225, eff 11-7-12; ss by #10903, eff 8-5-15

Ph-709.07 Drug Control in Ambulatory Patient Treatment Areas:

(a) In the ambulatory patient treatment areas, a medical practitioner may dispense drugs for the immediate needs of the patient, not in excess of a 72-hour supply, except that, for Schedule II controlled substances, a maximum of 48-hour supply shall be allowed, if permitted by the institution. The drug container shall be properly labeled.

(b) If a licensed pharmacist is on the premises, that pharmacist may fill one-time prescriptions for patients for medications related to the ambulatory patient treatment visit.

(c) A readily retrievable record shall be made of all administrations and dispensing of controlled drugs in the ambulatory patient area.

(d) This record shall include:

(1) Name and address of the patient;

Commented [KBB]: Need to understand the definition of "Ambulatory Patient Treatment Areas". And, how does it apply to "institution"? And, how does also work with the other 700 rules?
(2) Name of the medical practitioner;

(3) Name, strength and quantity of the drug(s);

(4) Date of administration or dispensing; and

(5) Signature or electronic identifier, as defined in Ph 709.01(b), of the agent removing the drug(s) from the inventory.

Source. #2260, eff 01-05-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED: 1-19-96

New. #6181-B, eff 2-5-96; amd by #6933, eff 2-1-99; paragraph (b) EXPIRED: 2-5-04; amd by #8316, eff 3-26-05; amd by #8572, eff 2-23-06; paras. (a) & (c) EXPIRED: 2-1-07; ss by #10225, eff 11-7-12; ss by #10903, eff 8-5-15

Ph 709.08 Investigational Drugs. Investigational drugs for research shall be used only under the supervision authority of the principal investigator, and shall be approved by an appropriate medical staff committee. Such drugs shall be controlled by the pharmacy and shall be properly labeled according to the research protocols. The principal investigator shall provide essential information on such drugs to the current treatment team. A central unit, which may be the pharmacy, shall be established where essential information on investigational drugs is maintained. Nurses shall be given basic pharmacologic information about the drug before administering.

Source. #2260, eff 1-5-83; ss by #2914, eff 11-27-84; ss by #4600, eff 8-1-89; ss by #6094-B, INTERIM, eff 9-21-95, EXPIRED, 1-19-96

New. #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New. #8316, eff 3-26-05; ss by #8572, eff 2-23-06 ss by #10225, eff 11-7-12; ss by #10903, eff 8-5-15

Ph 709.09 Purchase of Drugs.
(a) The pharmacist-in-charge, with the consent of the institution’s pharmacy and therapeutics committee or comparable committee of its medical staff shall be responsible for the quality of all drugs, biologicals and pharmaceutical chemicals.

(b) Purchasing of drugs, pharmaceuticals, biologicals, intravenous and irrigation fluids shall be subject to approval of the pharmacist-in-charge with the consent of the institution’s pharmacy and therapeutics committee or comparable committee of its medical staff.

(c) Radiopharmaceuticals, blood products, radiopaque media and medical devices may be exempted from the approval and/or control of the pharmacist-in-charge by the institution’s pharmacy and therapeutics committee.

Source: #6181-B, eff 2-5-96, EXPIRED: 2-5-04

New, #8316, eff 3-26-05; ss by #10225, eff 11-7-12; ss by #10903, eff 8-5-15
which improve the patient's quality of life as it is related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process. Clinical pharmacy practice policy and procedures should include but are not limited to the following:

- Systems for monitoring and detecting drug interactions, contraindications, incompatibilities, and allergic reactions;
- Systems for monitoring dosages and serum blood levels of drugs for correct ranges where appropriate;
- Systems for monitoring, detecting, and reporting adverse drug reactions;
- Systems for monitoring and evaluating therapeutic duplications;
- Provision of drug therapeutic consultations and drug information by a pharmacist(s) to patients at transitions of care.