64B16-27.4001 Delegation to and Supervision of Pharmacy Technicians; Responsibility of Supervising Pharmacist.

(1) Delegation: A pharmacist shall not delegate more tasks than he or she can personally supervise and ensure compliance with this rule. A pharmacist may delegate those non-discretionary delegable tasks enumerated in rule 64B16-27.420, F.A.C., to the following types of pharmacy technicians:

(a) Registered Pharmacy Technicians (RPT): are those technicians who are duly registered with the board pursuant to section 465.014(2), F.S.;

(b) Pharmacy Technicians in Training (PTT): are those technicians who are receiving practical (non-didactic) training in delegable tasks as part of employer-sponsored or non-employer sponsored board-approved pharmacy technician training programs who are not required to be duly registered with the board as pharmacy technicians.

(2) Supervision: Delegated tasks must be performed under the direct supervision of a pharmacist and pursuant to the following definitions and requirements:

(a) Direct Supervision: means supervision by a pharmacist who is readily and immediately available at all times the delegated tasks are being performed; who is aware of delegated tasks being performed; and who provides personal assistance, direction and approval throughout the time the delegated tasks are being performed. “Readily and immediately available” means the pharmacist and technician(s) are on the same physical premises, or if not, technology is used to enable real time, two-way communications between the pharmacist and technician(s).

(b) Use of Technology: A pharmacist, as an adjunct to assist in the direct supervision of the pharmacy technician, may employ technological means to communicate with or observe the pharmacy technician. A pharmacist shall make certain all applicable state and federal laws, including, but not limited to confidentiality, are fully observed when employing technological means of communication and observation. If technology is being used to provide direct supervision of pharmacy technician(s), such technology shall be sufficient to provide the personal assistance, direction and approval required to meet the standard of practice for the delegated tasks.

Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.014 FS. History–New 12-31-14, Amended 12-17-18.

64B16-27.410 Registered Pharmacy Technician to Pharmacist Ratio.

(1) General Conditions. When the pharmacist delegates tasks to a registered pharmacy technician, such delegation must enhance the ability of the pharmacist to practice pharmacy to serve the patient population. A pharmacist shall not supervise more than one (1) registered pharmacy technician nor shall a pharmacy allow a supervision ratio of more than one (1) registered pharmacy technician to one (1) pharmacist (1:1), unless specifically authorized to do so pursuant to the provisions of this rule.

(2) Required Documentation. Regardless of the technician ratio, every pharmacy, pharmacist, Prescription Department Manager (PDM) and Consultant Pharmacist (CP) that employs or utilizes registered pharmacy technicians must comply with the following conditions:

(a) Establish and maintain a written Policy and Procedures Manual regarding the number of registered pharmacy technician positions and their utilization that includes the specific scope of delegable tasks of the technicians, job descriptions, and task protocols. The Policy and Procedures Manual or Manuals must include policies and the procedures for implementing the policies for each category enumerated below:

1. Supervision by a pharmacist;

2. Minimum qualifications of the registered pharmacy technician as established by statute and rule;

3. In-service education or on-going training and demonstration of competency specific to the practice site and job function;

4. General duties and responsibilities of the registered pharmacy technicians;

5. All functions related to prescription processing;

6. All functions related to prescription legend drug and controlled substance ordering and inventory control, including procedures for documentation and recordkeeping;

7. All functions related to retrieval of prescription files, patient files, patient profile information and other records pertaining to the practice of pharmacy;

8. All delegable tasks and non-delegable tasks as enumerated in rule 64B16-27.420, F.A.C.;

9. Confidentially and privacy laws and rules;

10. Prescription refill and renewal authorization;

11. Registered pharmacy technician functions related to automated pharmacy systems; and,

12. Continuous Quality Improvement Program.

(b) Establish and maintain documentation that is signed by the registered pharmacy technician acknowledging the technician has reviewed the Policy and Procedures Manual(s). Compliance with this paragraph must be achieved by April 7, 2015, or within ninety (90) days from the date the registered pharmacy technician is hired.

(c) Establish and maintain documentation that demonstrates the registered pharmacy technician has received training in the established job description, delegable tasks, task protocols, and policy and procedures in the specific pharmacy setting where the delegable tasks will be performed. Documentation shall consist of one of the following items:

1. Certification by the supervising licensee;

2. Certification by an instructor, trainer, or other similar person;

3. Training attendance logs or completion certificates, accompanied by an outline of the materials addressed; or

4. Exam or written questionnaires.

(3) The Policy and Procedures Manual(s) required by paragraph (2)(a), must be maintained onsite where the pharmacy technician will perform the delegable tasks and must be available during a Department inspection or at the request of the Board of Pharmacy. However, any and all documentation required by paragraphs (2)(b) and (c), must be maintained and must be provided to the Board of Pharmacy or a Department inspector within 72 hours of a request.

(4) Three to One (3:1) Ratio: Any pharmacy or any pharmacist engaged in sterile compounding shall not exceed a ratio of up to three (3) registered pharmacy technicians to one (1) pharmacist (3:1). The 3:1 ratio only applies to pharmacists and technicians engaged in sterile compounding, and does not affect the technician ratios for other activities not involving sterile compounding in areas of the pharmacy physically separated from the area in which sterile compounding activities take place.

(5) Six to One (6:1) Ratio: Any pharmacy or any pharmacist may allow a supervision ratio of up to six (6) registered pharmacy technicians to one (1) pharmacist (6:1), as long as the pharmacist or registered pharmacy technicians are not engaged in sterile compounding.

(6) Eight to One (8:1) Ratio:

(a) Non-dispensing pharmacies. Any pharmacy which does not dispense medicinal drugs, and the pharmacist(s) employed by

such pharmacy, may allow a supervision ratio of up to eight (8) registered pharmacy technicians to one (1) pharmacist (8:1), as long as the pharmacist or registered pharmacy technicians are not engaged in sterile compounding.

(b) Dispensing pharmacies. A pharmacy which dispenses medicinal drugs may utilize an eight to one (8:1) ratio in any physically separate area of the pharmacy from which medicinal drugs are not dispensed. A "physically separate area" is a part of the pharmacy which is separated by a permanent wall or other barrier which restricts access between the two areas.

(7) The determination of the appropriate pharmacist-technician supervision ratio shall be made by the Prescription Department Manager or Consultant Pharmacist of Record. No other person, permittee, or licensee shall interfere with the exercise of the Prescription Department Manager or Consultant Pharmacist of Record's independent professional judgment in setting the pharmacist to technician ratio(s).

Rulemaking Authority 465.005, 456.069(1), 465.014, 465.017, 465.022 FS. Law Implemented 465.014, 465.022 FS. History–New 2-14-77, Amended 3-31-81, Formerly 21S-4.02, Amended 8-31-87, Formerly 21S-4.002, Amended 9-9-92, Formerly 21S-27.410, 61F10-27.410, Amended 1-30-96, Formerly 59X-27.410, Amended 2-23-98, 10-15-01, 1-1-10, 1-7-15, 7-6-15, 5-8-18, 1-16-19.

64B16-27.420 Pharmacy Technician – Delegable and Non-Delegable Tasks.

A pharmacy technician may only assist a pharmacist in executing or carrying out the practice of the profession of pharmacy, but shall never themselves engage in the practice of the profession of pharmacy as defined in Chapter 465, F.S. Therefore, pharmacy technicians may only perform delegable tasks as identified and defined pursuant to this rule.

(1) Delegable Tasks – Delegable tasks are those tasks that are performed pursuant to a pharmacist's direction, without the exercise of the pharmacy technician's own judgment and discretion, and which do not require the pharmacy technician to exercise the independent professional judgment that is the foundation of the practice of the profession of pharmacy. The following tasks are delegable:

(a) Data entry;

(b) Labeling of preparations and prescriptions;

(c) Retrieval of prescription files, patient files and profiles, and other similar records pertaining to the practice of pharmacy;

(d) The counting, weighing, measuring, and pouring of prescription medication or stock legend drugs and controlled substances, including the filling of an automated medication system;

(e) The initiation of communication to confirm the patient's name, medication, strength, quantity, directions, number of refills, and date of last refill;

(f) The initiation of communication with a prescribing practitioner or their agents to obtain clarification on missing or illegible dates, prescriber name, brand or generic preference, quantity, license numbers or DEA registration numbers;

(g) The acceptance of authorization to dispense medications pursuant to a prescribing practitioner's authorization to fill an existing prescription that has no refills remaining (refill authorization);

(h) The receiving, in a permitted nuclear pharmacy, of diagnostic orders only;

(i) Organizing of or participating in continuous quality improvement related events, meetings, or presentations;

(j) Participation in a monitoring program to remove deteriorated pharmaceuticals to a quarantine area; and,

(k) While under the direct supervision of the pharmacist, performance of any other mechanical, technical or administrative tasks which do not themselves constitute practice of the profession of pharmacy.

(2) Non-Delegable Tasks – The following tasks may not be delegated and the pharmacy technician shall not:

(a) Receive new non written prescriptions or receive any change in the medication, strength, or directions of an existing prescription;

(b) Interpret a prescription or medication order for therapeutic acceptability and appropriateness;

(c) Conduct final verification of dosage and directions;

(d) Engage in prospective drug review;

(e) Monitor prescription usage;

(f) Override clinical alerts without first notifying the pharmacist;

(g) Transfer a prescription;

(h) Prepare a copy of a prescription or read a prescription to any person for purposes of providing reference concerning treatment of the person or animal for whom the prescription was written;

(i) Engage in patient counseling;

(j) Receive therapy or blood product procedures in a permitted nuclear pharmacy, or

(k) Engage in any other act that requires the exercise of a pharmacist's professional judgment.

Rulemaking Authority 465.005, 465.014 FS. Law Implemented 465.014 FS. History–New 8-31-87, Formerly 21S-4.0025, Amended 7-30-91, Formerly 21S-27.420, 61F10-27.420, 59X-27.420, Amended 2-23-98, 1-1-10, 8-26-12, 2-5-15, 7-6-15.

64B16-27.220 Medicinal Drugs Which May Be Ordered by Pharmacists.

A Pharmacist may order and dispense from the following formulary, within their professional judgment, subject to the stated conditions.

(1) Oral analgesics for mild to moderate pain. The pharmacist may order these drugs for minor pain and menstrual cramps for patients with no history of peptic ulcer disease. The prescription shall be limited to a six (6) day supply for one treatment. If appropriate, the prescription shall be labeled to be taken with food or milk.

(a) Magnesium salicylate/phenyltoloxamine citrate.

(b) Acetylsalicylic acid (Zero order release, long acting tablets).

(c) Choline salicylate and magnesium salicylate.

(d) Naproxen sodium.

(e) Naproxen.

(f) Ibuprofen.

(2) Urinary analgesics. Phenazopyridine, not exceeding a two (2) day supply. The prescriptions shall be labeled about the tendency to discolor urine. If appropriate, the prescription shall be labeled to be taken after meals.

(3) Otic analgesics. Antipyrine 5.4%, benzocaine 1.4%, glycerin, if clinical signs or symptions of tympanic membrane perforation do not exist. The product shall be labeled for use in the ear only.

(4) Anti-nausea preparations.

(a) Meclizine up to 25 mg., except for a patient currently using a central nervous system (CNS) depressant. The prescription shall be labeled to advise the patient of drowsiness and to caution against concomitant use with alcohol or other depressants.

(b) Scopolamine not exceeding 1.5 mg. per dermal patch. Patient shall be warned to seek appropriate medical attention if eye pain, redness or decreased vision develops.

(5) Antihistamines and decongestants. The following, including their salts, either as a single ingredient product or in combination, including nasal decongestants, may be ordered for a patient above 6 years of age.

(a) Antihistamines. The pharmacist shall warn the patient that an antihistamine should not be used by patients with bronchial asthma or other lower respiratory symptoms, glaucoma, cardiovascular disorders, hypertension, prostate conditions and urinary retention. An antihistamine shall be labeled to advise the patient of drowsiness and caution against the concomitant use with alcohol or other depressants.

1. Diphenhydramine.

2. Carbinoxamine.

3. Pyrilamine.

4. Dexchlorpheniramine.

5. Brompheniramine.

(b) Decongestants. The pharmacist shall not order an oral decongestant for use by a patient with coronary artery disease, angina, hyperthyroidism, diabetes, glaucoma, prostate conditions, hypertension, or a patient currently using a monoamine oxidase inhibitor.

1. Phenylephrine.

2. Azatadine.

(6) Topical antifungal/antibacterials. The pharmacist shall warn the patient that any of the products should not be used near deep or puncture wounds and contact with eyes or mucous membranes should be avoided. Iodochlorhydroxyquin preparations shall be labeled with staining potential.

(a) Iodochlorhydroxyquin with 0.5% Hydrocortisone (not exceeding 20 grams).

(b) Haloprogin 1%.

(c) Clotrimazole topical cream and lotion.

(d) Erythromycin topical.

(7) Topical anti-inflammatory. The pharmacist shall warn the patient that hydrocortisone should not be used on bacterial infections, viral infections, fungal infections, or by patients with impaired circulation. The prescription shall be labeled to advise the patient to avoid contact with eyes, mucous membranes or broken skin. Preparations containing hydrocortisone not exceeding 2.5%.

(8) Otic antifungal/antibacterial. Acetic acid 2% in aluminum acetate solution which shall be labeled for use in ears only.

(9) Keratolytics. Salicylic acid 16.7% and lactic acid 16.7% in flexible collodion, to be applied to warts, except for patients under two (2) years of age, and those with diabetes or impaired circulation. Prescriptions shall be labeled to avoid contact with

normal skin, eyes and mucous membranes.

(10) Vitamins with fluoride (This does not include vitamins with folic acid in excess of 0.9 mg.).

(11) Medicinal drug shampoos containing Lindane. The pharmacist shall:

(a) Limit the order to the treatment of head lice only;

(b) Order no more than four (4) ounces per person; and,

(c) Provide the patient with the appropriate instructions and precautions for use.

(12) Ophthalmics. Naphazoline 0.1% ophthalmic solution.

(13) Histamine H2 antagonists. The pharrmacist shall advise the patient to seek medical attention if symptom persist longer than 14 days while using the medication or if stools darken or contain blood.

(a) Cimetidine.

(b) Famotidine.

(c) Ranitidine HC1.

(14) Acne products. Benzoyl Peroxide. The prescription shall be labeled to advise the patient to avoid use on the eye, eyelid, or mucous membranes.

(15) Topical Antiviral.

(a) Acyclovir ointment may be ordered for the treatment of herpes simplex infections of the lips.

(b) Penciclovir.

Rulemaking Authority 465.186(2) FS. Law Implemented 465.186 FS. History–New 5-1-86, Amended 10-7-90, Formerly 21S-18.003, Amended 7-30-91, Formerly 21S-27.220, 61F10-27.220, Amended 3-12-97, Formerly 59X-27.220, Amended 6-15-98, 11-30-99, 11-18-07.

64B16-27.230 Fluoride Containing Products That May Be Ordered by Pharmacists.

Oral medicinal drug products containing fluoride may be ordered by pharmacists for their patients who do not have fluoride supplement in their drinking water, pursuant to the following limitations:

(1) The fluoride content of drinking water does not exceed 0.5 ppm.

(2) Once a fluoride treatment has been initiated with one specific fluoride medicinal drug product it should not be interchanged with a product of a different manufacturer for the course of the treatment.

(3) If the fluoride content is less than 0.5 ppm then the following dosage schedule for oral usage shall be followed.

(a)1. For ages 0-6 months.

a. Less than 0.3 ppm in water – no supplementation,

b. 0.3-0.6 ppm in water – no supplementation,

c. 0.6 ppm in water – no supplementation,

2. For ages 6 months – 3 years,

a. Less than 0.3 ppm in water – supplement with 0.25 mg. F/day,

b. 0.3-0.6 ppm in water – no supplementation,

c. 0.6 ppm in water – no supplementation.

3. For ages 3-6 years.

a. Less than 0.3 ppm in water – supplement with 0.5 mg. F/day,

b. 0.3-0.6 ppm in water – supplement with 0.25 mg. F/day,

c. 0.6 ppm in water – no supplementation.

4. For ages 6-16 years.

a. Less than 0.3 ppm in water – supplement with 1.00 mg. F/day,

b. 0.3-0.6 ppm in water – supplement with 0.5 mg. F/day,

c. 0.6 ppm in water – no supplementation.

(b) No more than 264 mg. of sodium fluoride may be dispensed at any one time to a patient.

(c) Notwithstanding the provisions of subsection 64B16-27.210(3), F.A.C., a pharmacist may continue a course of therapy with fluoride products until appropriate referral to another health care practitioner is indicated or in no event shall the course of therapy be more than one (1) year.

Rulemaking Authority 465.186(2) FS. Law Implemented 465.186 FS. History–New 5-1-86, Formerly 21S-18.004, 21S-27.230, 61F10-27.230, 59X-27.230, Amended 6-15-98.

64B16-27.830 Standards of Practice – Drug Therapy Management.

(1) “Prescriber Care Plan” means an individualized assessment of a patient and orders for specific drugs, laboratory tests, and other pharmaceutical services intended to be dispensed or executed by a pharmacist. The Prescriber Care Plan shall be written by a physician licensed pursuant to Chapter 458, 459, 461, or 466, F.S., or similar statutory provision in another jurisdiction, and may be transmitted by any means of communication. The Prescriber Care Plan shall specify the conditions under which a pharmacist shall order laboratory tests, interpret laboratory values ordered for a patient, execute drug therapy orders for a patient, and notify the physician.

(2) “Drug Therapy Management” means any act or service by a pharmacist in compliance with orders in a Prescriber Care Plan.

(3) A pharmacist may provide Drug Therapy Management services for a patient, incidental to the dispensing of medicinal drugs or as a part of consulting concerning therapeutic values of medicinal drugs or as part of managing and monitoring the patient’s drug therapy. A pharmacist who provides Drug Therapy Management services for a patient shall comply with orders in a Prescriber Care Plan, insofar as they specify:

(a) Drug therapy to be initially dispensed to the patient by the pharmacist, or

(b) Laboratory values or tests to be ordered, monitored and interpreted by the pharmacist, or

(c) The conditions under which the duly licensed practitioner authorizes the execution of subsequent orders concerning the drug therapy for the patient, or

(d) The conditions under which the pharmacist shall contact or notify the physician.

(4) A pharmacist who provides Drug Therapy Management services shall do so only under the auspices of a pharmacy permit that provides the following:

(a) A transferable patient care record that includes:

1. A Prescriber Care Plan that includes a section noted as “orders” from a duly licensed physician for each patient for whom a pharmacist provides Drug Therapy Management services,

2. Progress notes; and,

(b) A pharmaceutical care area that is private, distinct, and partitioned from any area in which activities other than patient care activities occur, and in which the pharmacist and patient may sit down during the provision of Drug Therapy Management services; and,

(c) A continuous quality improvement program that includes standards and procedures to identify, evaluate, and constantly improve Drug Therapy Management services provided by a pharmacist.

Rulemaking Authority 465.005, 465.0155 FS. Law Implemented 465.003(13), 465.0155, 465.022(1)(b) FS. History–New 4-4-00.