Prescription Department Managers: Role and Responsibilities

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1

SPEAKER DISCLOSURE

I do not have (nor does any immediate family member have):

- a vested interest in or affiliation with any corporate organization offering financial support or grant monies for this continuing education activity
- any affiliation with an organization whose philosophy could potentially bias my presentation

2

CPE INFORMATION

iCARE Pharmacy Services, Inc. is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider for continuing pharmacy education.

This activity offers 1.5 contact hours (0.15 CEU).

- Target Audience: Pharmacist and Technicians
- UAN #: 0675-0000-24-017-L03
- Activity Type:
  Knowledge based

3

Pharmacist Objectives

•Discuss the Role and Responsibilities of the PDM within the pharmacy

•Identify training that may help PDM

•Describe common misunderstandings regarding role of the PDM

•Discuss the consequences for not following rules

4

Technician Objectives

•Recognize the responsibilities of the Prescription Department Manager (PDM)

•Identify training that may help the PDM

•List the consequences for not following the rules.

5

Background

- The disciplined brought for the Board against Prescription Department Managers is usually related to lack of knowledge regarding rules and responsibilities
- There is no formalized training or requirements for a PDM currently
- A trend identified of Pharmacists “lending” their license without stepping foot into the pharmacy

6

Responsibility

Rule 64B16-27.104(5), *Florida Administrative Code, requires community pharmacy permittee to designate a*

prescription department manager for maintaining all drug records, providing for the security of the prescription

department and following such other rules as relate to the practice of the profession of pharmacy.

7

Responsibility

Record Retention

- The board requires that you keep all records for a minimum of 4 years
- They want to be able to see records for 2 inspections cycles
- These records can be kept electronically
- This does not supersede DEA requirements for retention of CII prescriptions
  - *Paper CII prescriptions must be maintained for 2 years CFR 21.1304(a)*

8

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9

Responsibility

64B16-28.1081 Regulation of Daily Operating Hours.

Any person who receives a community pharmacy permit pursuant to Section 465.018, F.S., and commences to operate such an establishment shall keep the prescription department of the establishment open for a minimum of forty (40) hours per week and a minimum of five (5) days per week.

A sign in block letters not less than one inch in height stating the hours the prescription department is open each day shall be displayed either at the main entrance of the establishment or at or near the place where prescriptions are dispensed in a prominent place that is in clear and unobstructed view.

10

Responsibility

64B16-28.102 Sink and Running Water, Sufficient Space, Refrigeration, Sanitation, Equipment.

There shall be provided for the prescription department of each pharmacy:

(1) A sink in workable condition and water accessible to the prescription counter

(2) Sufficient shelf, drawer or cabinet space for the neat and orderly storage of pharmaceutical stock, prescription containers, prescription labels, the required equipment, and all other items, articles or equipment stored therein and there shall be sufficient walking space and sufficient work counter space within each prescription department of said establishment so as to allow employees or pharmacists employed therein to adequately, safely, and accurately fulfill their duties related to prescriptions.

(3) Adequate facilities for the proper storage of pharmaceuticals which require refrigeration, and pharmaceuticals shall be stored to preserve their therapeutic activity.

(4) Adequate sanitation to ensure the prescription department is operating under clean, sanitary, uncrowded, and healthy conditions.

(a) A current pharmacy reference compendium such as the United States Pharmacopoeia/National Formulary, the U.S. Dispensatory, USP DI, (United States Pharmacopoeial Drug Information), the Remington Practice of Pharmacy, Facts and Comparisons or an equivalent thereof sufficient in scope to meet the professional practice needs of that pharmacy, and a current copy of the laws and rules governing the practice of pharmacy in the State of Florida. It shall be acceptable, in lieu of an actual hard copy, to maintain these materials in a readily available electronic data format.

11

Question #1

Q. Pharmacies are allowed to have their references electronically

A. True
B. False

12

Question #1

Q. Pharmacies are allowed to have their references electronically

A. True
B. False

13

Responsibility

64B16-28.1035 Patient Consultation Area.

A community pharmacy shall provide a private consultation area so all patients of the pharmacy will be able to obtain counseling without being overheard by others in the prescription dispensing area of the pharmacy. The consultation area must be accessible by the patient from the outside of the prescription dispensing area of the pharmacy without having to traverse a stockroom or the prescription dispensing area. In determining whether the area is suitable, consideration shall be given to the proximity of the counseling area to the check-out or cash register area, the volume of pedestrian traffic in and around the consultation area, and the presence of walls or other barriers between the counseling area and the prescription dispensing area of the pharmacy. The consultation area may consist of designated private counter space. The area shall be designated with a sign bearing "Patient Consultation Area", or words that are substantially similar.

14

Responsibility

64B16-28.109 Prescription Department; Padlock; Sign: "Prescription Department Closed."

(1) The prescription department of any community pharmacy permittee shall be considered closed whenever the establishment is open and a pharmacist is not present and on duty. A sign with bold letters not less than two (2) inches in width and height, shall be displayed in a prominent place in the prescription department so that it may easily be read by patrons of that establishment. The sign shall contain the following language: "Prescription Department Closed."

(2) The term "not present and on duty" shall not be construed to prevent a pharmacist from exiting the prescription department for the purpose of consulting or responding to inquiries or providing assistance to patients or customers, attending to personal hygiene needs, taking a meal break pursuant to Rule 64B16-27.1001, F.A.C., or performing any other function for which the pharmacist is responsible, provided that such activities are conducted in a manner consistent with the pharmacist's responsibility to provide pharmacy services.

(3) At all times when the prescription department is closed, either because of the absence of a pharmacist or for any other reason, it shall be separated from the remainder of the establishment by partition or other means of enclosure, thereby preventing access to the prescription department by persons not licensed in Florida to practice the profession of pharmacy.

(4) The partition or other means of enclosure shall be securely locked or padlocked and only a pharmacist shall have the means to gain access to the prescription department.

(5) Whenever the prescription department of any community pharmacy establishment is closed, no person other than a pharmacist shall enter

15

Responsibility

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16

Responsibility

64B16-28.110 Outdated Pharmaceuticals.

Persons qualified to do so shall examine the stock of the prescription department of each pharmacy at a minimum interval of four months, and shall remove all deteriorated pharmaceuticals, or pharmaceuticals which bear upon the container an expiration date which date has been reached, and under no circumstances will pharmaceuticals or devices which bear upon the container an expiration date which has been reached be sold or dispensed to the public.

17

Responsibility

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.

18

Responsibility

(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.

19

Responsibility

64B16-27.820 Patient Counseling.

(1) Upon receipt of a new or refill prescription, the pharmacist shall ensure that a verbal and printed offer to counsel is made to the patient or the patient's agent when present. If the delivery of the drugs to the patient or the patient's agent is not made at the pharmacy the offer shall be in writing and shall provide for toll-free telephone access to the pharmacist. If the patient does not refuse such counseling, the pharmacist, or the pharmacy intern, acting under the direct and immediate personal supervision of a licensed pharmacist, shall review the patient's record and personally discuss matters which will enhance or optimize drug therapy with each patient or agent of such patient. Such discussion shall be in person, whenever practicable, or by toll-free telephonic communication and shall include appropriate elements of patient counseling. Such elements may include, in the professional judgment of the pharmacist, the following:

(a) The name and description of the drug;

(b) The dosage form, dose, route of administration, and duration of drug therapy;

(c) Intended use of the drug and expected action (if indicated by the prescribing health care practitioner);

(d) Special directions and precautions for preparation, administration, and use by the patient;

(e) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(f) Techniques for self-monitoring drug therapy;

(g) Proper storage;

(h) Prescription refill information;

(i) Action to be taken in the event of a missed dose; and

(j) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(2) Patient counseling as described herein, shall not be required for inpatients of a hospital or institution where other licensed health care practitioners are authorized to administer the drug(s).

(3) A pharmacist shall not be required to counsel a patient or a patient's agent when the patient or patient's agent refuses such consultation.

20

Responsibility

64B16-28.108 All Permits – Labels and Labeling of Medicinal Drugs.

(2) The label affixed to each container dispensed to a patient shall include:

(a) Name and address of the pharmacy.

(b) Date of dispensing.

(c) Serial number.

(d) Name of the patient or, if the patient is an animal, the name of the owner and the species of animal.

(e) Name of the prescriber.

(f) Name of the drug dispensed (except where the prescribing practitioner specifically requests that the name is to be withheld).

(g) Directions for use.

(h) An Expiration Date or Beyond-Use Date: The expiration date must be the date provided by the manufacturer, repackager, or other distributor. The beyond-use date must not exceed the expiration date and it shall not be a date greater than one year from the date the medicinal drug is filled. The board finds that the use of a "discard-after-date" or "do not use after date" to be equivalent of a beyond-use date.

(i) If the medicinal drug is a controlled substance, a warning that it is a crime to transfer the drug to another person.

21

Responsibility

64B16-27.900 Standards of Practice - Continuous Quality Improvement Program.

(1) "Continuous Quality Improvement Program" means a system of standards and procedures to identify and evaluate quality-related events and improve patient care.

(2) "Quality-Related Event" means the inappropriate dispensing or administration of a prescribed medication including:

(a) A variation from the prescriber's prescription order, including, but not limited to:

1. Incorrect drug;

2. Incorrect drug strength;

3. Incorrect dosage form;

4. Incorrect patient; or

5. Inadequate or incorrect packaging, labeling, or directions.

(b) A failure to identify and manage:

1. Over-utilization or under-utilization;

2. Therapeutic duplication;

3. Drug-disease contraindications;

4. Drug-drug interactions;

5. Incorrect drug dosage or duration of drug treatment;

6. Drug-allergy interactions; or

7. Clinical abuse/misuse.

Every 3 months

22

Responsibility

64B16-28.202 Closing of a Pharmacy; Transfer of Prescription Files.

(1) The term "prescription files" as used herein shall mean the drug dispensing records of a pharmacy which shall include all orders for drugs or medicinal supplies as defined by Section 465.003(7), F.S., inclusive of dispensing records for medicinal drugs listed within the provisions of Section 893.03, F.S., issued by a duly licensed practitioner, which serve to transfer possession of medicinal drugs from the pharmacy to the ultimate consumer.

(2) The term "closing of a pharmacy" as used herein shall mean the cessation or termination of professional and business activities within a pharmacy for which a permit has been issued under Chapter 465, F.S.

(3) Prior to closure of a pharmacy the permittee shall notify the Board of Pharmacy in writing as to the effective date of closure, and shall:

(a) Return the pharmacy permit to the Board of Pharmacy office or arrange with the local Bureau of Investigative Services of the Department to have the pharmacy permit returned to the Board of Pharmacy;

(b) Advise the Board of Pharmacy which permittee is to receive the prescription files;

(4) On the date of closure of a pharmacy the former permittee shall:

(a) Physically deliver the prescription files to a pharmacy operating within reasonable proximity of the pharmacy being closed and within the same locality. This delivery of prescription files may occur prior to the return of the pharmacy permit to the Board of Pharmacy office; and

(b) Affix a prominent sign to the front entrance of the pharmacy advising the public of the new location of the former permittee's prescription files or otherwise provide a means by which to advise the public of the new location of their prescription files.

(5) After the closing of a pharmacy as defined herein, the custody of the prescription files of the pharmacy shall be transferred to the new permittee, unless the former permittee and the new permittee inform the Board in writing that custody of the prescription files have been or are to be transferred to a pharmacy other than the new permittee.

(6) A pharmacy receiving custody of prescription files from another pharmacy shall maintain the delivered prescriptions in separate files so as to prevent intermingling with the transferee pharmacy's prescription files.

23

Training for PDM

No formalized training

Chain pharmacies have Policy and Procedures

Externship hours

Minimum years experience?

Special License?

24

Question #2

Q. A Prescription Department Manager must have practiced for 2 years?

A. True

B. False

25

Question #2

Q. A Prescription Department Manager must have practiced for 2 years?

A. True

B. False

26

Consultant of Record

12 Hours Consultant CE course

Within 1 year complete 40 hours of training under a preceptor

60 % must be done onsite

60% Regimen Review, process and documentation functions

20% Facility Review

20% Quality Committee, Policy and Procedures, Formulary Management, Professional Relationships

27

Nuclear Pharmacist

Board approved program

200 clock hours of didactic training

Includes Radiation Physics, Radiation protection, Mathematics pertaining to radioactivity, Radiation Biology and Chemistry

500 hours under the supervision of Nuclear Pharmacist

28

Vaccine Certification

20 hours coursework
MOA for vaccines, contraindications, interactions, and monitoring
Schedules
Screening questions
Storage and Handling, Waste Disposal
Physician Protocols
Adverse Events
Administration
Reimbursement
Epinephrine Auto-Injector, CPR

29

Discipline

Up to the discretion of the board

There are guidelines regarding maximum and minimum penalties

64B16-30.001

The most common discipline for rule infractions

Fine, Costs, 12 hours law and Rules, and possible restriction or probation

It remains on your license indefinitely

30

Discipline

Failure to supervise registered pharmacy technician
- Minimum $250 fine , 1 year probation, 12 hours Law and Rules
- Maximum $1,000 fine, 1 year suspension up to revocation

Selling or Dispensing Scheduled Drugs without a prescription
- Minimum $5,000 fine and 1 year probation
- Maximum $10,000 fine and up to revocation
- Does not exclude criminal charges

31

Question #3

Q. The Board of Pharmacy is in place to protect the licenses of pharmacists?

A. True
B. False

32

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A. True
B. False

33

34