Louisiana Board of Pharmacy

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Blueprint for Inspection of Pharmacies

Module I – Basic Pharmacy Services

Pharmacy Practice Profile

01.00 Name, location, contact information, and key personnel

02.00 Is the Pharmacist-in-Charge (PIC) or pharmacy manager/director present for the inspection?

03.00 Are there any other businesses located at this address?

04.00 Does the pharmacy have any other websites?

05.00 Do any other websites link to the pharmacy website (such as a provider or other affiliate?

06.00 Does the pharmacy allow patients to enter/update profile and medical information through the website?

07.00 Are patients able to order or refill prescriptions through the website?

08.00 Are photographs allowed during the inspection (no PHI)?

09.00 List of additional personnel interviewed as part of the inspection.

10.00 List of personnel present at the time of the inspection.

11.00 Business licensure information for Louisiana and Federal (La. Board of Pharmacy, CDS, La. Board of Drug & Device Distributors, DEA, FDA, etc.)

12.00 Type(s) of practice; Facility Size; Volume of Dispensing & Distribution; Staffing Summary; Interstate Activity.

13.00 If the pharmacy mails or delivers filled prescriptions (patient-specific, labeled with patient name when it leaves the pharmacy), are any of the deliveries to a provider or facility for administration to the patient?

14.00 Does the pharmacy provide prescription products to a provider or facility for 'office use' (not pursuant to a prescription received prior to delivery, not patient-specific, and not labeled with the patient name)?

15.00 Does the pharmacy provide prescription products to providers or facilities (including other pharmacies) as a wholesale distributor (sold to the provider or facility for their use, administration, or providing/dispensing to patients)?

15.01 If so, is the percentage of product distributed at wholesale to providers or facilities ***within this state*** less than 5%? Indicate actual percentage and whether percentage is based on a number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.

15.02 If so, is the percentage of products distributed at wholesale to providers or facilities *in other states* less than 5%? Indicate actual percentage and whether percentage is based on a number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.

General Operations and Licensure

16.00 Are pharmacy licenses, permits, and registrations posted in customers' view and current?

17.00 Is the most recent board of pharmacy inspection report available for review?

18.00 Were any repeat deficiencies noted?

19.00 Has this pharmacy been inspected by any other state for which it holds a license? Any noted deficiencies?

20.00 Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed?

21.00 Has this pharmacy been inspected as part of the NABP Verified Pharmacy Program?

22.00 Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed?

23.00 Does the pharmacy have any additional restrictions, limitations, or waivers with regards to any federal licenses or registrations (FDA, DEA, etc.)?

24.00 Has the pharmacy been inspected by the DEA?

25.00 Has the pharmacy been inspected by the FDA?

26.00 Does the pharmacy hold any accreditations or certifications?

27.00 Has the pharmacy held any accreditations or certifications in the past that have been relinquished, rescinded, or suspended?

28.00 Does the pharmacy perform patient lab testing such as blood glucose tests, cholesterol tests, etc.?

29.00 Does the pharmacy maintain all required records, including but not limited to prescription files and invoices on site?

29.01 Are written and verbal prescriptions (reduced to writing) kept on site for the entire retention period?

29.02 Are electronic prescriptions (e-scripts but not fax) kept on site for the entire retention period?

29.03 Are all dispensing records (refills, verifications, DUR overrides) kept on-site for the entire retention period?

Personnel

30.00 Are all pharmacist, pharmacy intern, pharmacy technician, and pharmacy technician candidate credentials issued by the board current?

31.00 Is there a process for periodic verification of credential validity?

32.00 Are pharmacists or other personnel providing patient services that require additional training or certification appropriately trained and certified?

33.00 Does the pharmacy maintain the proper staffing ratios for pharmacy interns, pharmacy technicians, and pharmacy technician candidates?

Facility and Security

34.00 Does the pharmacy have a working security/alarm system in place that is in compliance with the laws and regulations of the resident state?

35.00 Are Schedule II controlled substances secured in a locked cabinet or safe?

36.00 Are there contingency plans in the event the pharmacy cannot be secured?

37.00 Is the pharmacy clean and sanitary, and is there appropriate space for the prescription volume?

38.00 Does the pharmacy have a private area for patient counseling and providing patient services?

39.00 Is temperature in the drug storage area monitored?

39.01 Is the temperature in the drug storage area within the USP range for controlled room temperature (20°C to 25°C or 68°F to 72°F)?

40.00 Are the refrigerator and freezer restricted to drug products only (no food)?

41.00 The pharmacy has a process for how the refrigerator temperature is monitored for excursions 24/7.

41.01 Is the temperature in the refrigerator within the USP range (2°C to 8°C or 36°F to 46°F)?

42.00 The pharmacy has a process for how the freezer temperature is monitored for excursions 24/7.

42.01 Is the temperature in the freezer within the USP range (-25°C to -10°C or -13°F to 14°F)?

43.00 Are there contingency plans in the event of power outage or refrigerator/ freezer failure?

44.00 Are there contingency plans in the event of heating or air conditioning failure?

45.00 Is there a plan of action if there are any temperature or humidity excursions to determine if the integrity of the products has been compromised?

46.00 Does the pharmacy utilize any automated apparatuses for prescription processing/counting (such as robotics, Baker cells, etc.)?

Product Receipt and Inventory

47.00 Does the pharmacy restrict ordering to only approved wholesale distributors or manufacturers?

47.01 If the pharmacy is not restricted to vendors approved by the corporate office, or the pharmacy can purchase from other sources, are the other sources verified? If so, how?

47.02 Are all products received from authorized trading partners?

47.03 Does the pharmacy ensure transaction data (transaction history, transaction information, transaction statement) is received at the same time or before the product is received?

47.04 Does the pharmacy have a procedure to verify product (suspect or illegitimate) including quarantine of product and reporting?

48.00 Does the pharmacy utilize paper DEA-222 forms to procure Schedule II substances? If so, who has power of attorney to sign the forms?

49.00 Does the pharmacy utilize CSOS (electronic Schedule II ordering) to procure Schedule II substances?

50.00 Is the receipt of Schedule II orders documented appropriately? Does the DEA-222 form indicate quantity received and date on each line of product received? Does the CSOS record indicate verification of receipt and staff performing verification?

51.00 Are invoices for controlled substances (Schedules I-V) that are received filed separately and are the invoices signed/initialed and dated upon receipt and every item checked in?

52.00 Are all orders received when the pharmacy is open?

53.00 Does the pharmacy purchase any compounded preparations from other entities for dispensing to patients?

54.00 Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft?

54.01 Are incidents of diversion or resignation/termination of personnel for cause appropriately reported?

55.00 Does the pharmacy keep a perpetual inventory log of all Schedule II controlled substances (including APIs, if applicable)?

56.00 Is the Schedule II perpetual inventory log reconciled regularly?

57.00 Is the most recent complete controlled substance inventory available for review?

57.01 Does the pharmacy maintain other required inventories (such as change in PIC, theft/loss, etc.)?

58.00 Does the pharmacy stock and sell OTC pseudoephedrine (an/or ephedrine) products?

58.01 Are these products mailed, sent, or delivered into other states?

59.00 Does the pharmacy stock and sell other OTC restricted products for which identification is required and a log kept of the sale?

59.01 Are these products mailed, sent, or delivered into other states?

60.00 Are outdated, damaged, or recalled products segregated? How often does the pharmacy check for out-of-date products? Does it include OTC products?

60.01 If the pharmacy destroys products on site, are appropriate records kept of the destruction?

60.02 Does the pharmacy use a reverse distributor?

60.03 Does the pharmacy have a hazardous waste handling and collection system? How does the pharmacy handle empty bottles of chemotherapy medications or warfarin or hazardous drug compounding waste?

61.00 Does the pharmacy *repackage* bulk containers of prescription medications into smaller containers for ease of use? What expiration date is used on the repackaged container?

62.00 Does the pharmacy *prepackage* bulk containers of prescription medications into unit-of-use quantities? What expiration date is used on the prepackaged container?

63.00 Does the pharmacy return to stock prescription drugs that were filled but never picked up?

Prescription Processing

64.00 *Patient Profile:* Is patient profile data organized and readily accessible to facilitate consultation with the prescriber, patient, or caregiver?

64.01 If the pharmacy dispenses veterinary prescriptions, does the information gathered and recorded include the species, and name of the animal/owner as required by resident state law?

65.00 *Prescription:* Are adequate processes in place to assure the integrity, legitimacy, and authenticity of prescription orders?

65.01 Is there a procedure to follow when a prescription is suspected of (or actually is) fraudulent?

65.02 Are adequate processes in place for assuring that prescription medications are not prescribed or dispensed based on online medical consultations without there being a pre-existing prescriber-patient/client relationship?

65.03 Does the pharmacy have electronic prescription capability?

66.00 *Accuracy:* Is the accuracy of the information entered into the computer system verified (patient information and prescription information?

67.00 *DUR:* Does staff conduct prospective DUR prior to the dispensing of a medication or product?

67.01 The DUR process includes:

67.01.01 Drug-drug interaction (prescription and OTC);

67.01.02 Drug-allergy interaction;

67.01.03 Therapeutic duplication;

67.01.04 Under- or over-utilization (including clinical abuse/misuse);

67.01.05 Disease state or condition contraindication;

67.01.06 Incorrect dosage or duration of therapy; and

67.01.07 Gender or age-related contraindications.

67.02 Does the pharmacy staff obtain additional information to use in the DUR process?

67.03 Does the pharmacy have adequate resources/references related to the type of pharmacy practice it operates?

67.04 Does the pharmacy report appropriate data to the state PMP, in this state and the other states in which the pharmacy is licensed?

67.05 Does the pharmacy access state PMP data for specific patients?

67.06 Are DUR overrides/bypasses documented? Indicate if documented via a password/biometric override or by computer logs.

67.07 Is the DUR process performed electronically by the computer system?

67.08 If the DUR is manual, is there a system to document:

- How manual DUR is performed;
- Specific issues that were identified; and
- Pharmacist that considered the identified issues and gage the order to proceed.

67.09 If the pharmacy dispenses veterinary prescriptions, does it have a veterinary drug database integrated into the computer system for electronic DUR?

68.00 Are filled prescriptions verified for accuracy prior to dispensing?

69.00 Are filled prescriptions appropriately labeled?

70.00 *Confidentiality:* Is access to the pharmacy computer system limited to appropriate personnel?

70.01 Does the pharmacy appropriately destroy PHI including labeled prescription vials?

71.00 *Mail/Delivery:* If applicable, are packing materials designed to maintain the physical integrity, stability, and purity of prescription medications and compounded preparations in transport?

72.00 *Off-Site Processes:* Are any portions of the prescription processing (in the questions below) performed at a different location?

72.01 Is patient information (demographics and contact information) and profile information (allergies, disease states, etc.) entered into the computer at another location?

72.02 Are prescriptions received by another location (including written, telephone, fax, electronic)?

72.03 Is prescription information entered into the computer system at another location?

72.04 Is the accuracy of the prescription information entered into the computer verified at another location?

72.05 Is any part of the DUR process (including assessing and acting on DUR alerts and warnings) performed at another location?

72.06 Are any prescriptions dispensed or sold from this facility filled at another location?

72.07 If any of the above functions are performed at another location, is the other location under common ownership?

72.08 If any of the above functions are performed at another location, is that location in a different state than this facility?

72.09 If any of the above functions are performed at another location, are there policies and procedures for the function that include maintaining records of the person(s) performing the function and accountability?

72.10 Is the other pharmacy and any personnel at another location licensed in this state?

73.00 *Off-Site Inventory:* Does the pharmacy maintain any emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, emergency medical services, ambulances, correctional facilities, etc.)?

73.01 Do the emergency kits contain any compounded sterile preparations?

74.00 *Off-Site Devices:* Does the pharmacy maintain any automated medication dispensing devices outside the pharmacy such as Pyxis in a nursing home, or a secure mailbox device that patients access after hours, etc.?

74.01 If so, are the automated devices appropriately licensed, registered, or approved by the board of pharmacy?

74.02 Do the automated dispensing devices contain any compounded sterile preparations?

Patient Counseling and Communication

75.00 Does the pharmacy provide counseling for all new prescriptions picked up at the pharmacy (proactively, no 'offer')?

75.01 Is an 'offer' to counsel made for all new prescriptions picked up at the pharmacy?

76.00 Does the pharmacist provide counseling for all refilled prescriptions picked up at the pharmacy (proactively, no 'offer')?

76.01 Is an 'offer' to counsel made for all refilled prescriptions picked up at the pharmacy?

77.00 Does the pharmacist provide counseling for refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist (proactively, no 'offer)?

77.01 Is an 'offer' to counsel made for all refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issued determined by the pharmacist?

78.00 Is patient counseling provided for delivered prescriptions? How?

79.00 Is patient counseling provided for mailed prescriptions? How?

80.00 Are patient package inserts (PPIs) provided with every fill and refill of medications for which they are required (such as hormone products, inhalers, etc.)? How?

81.00 Are MedGuides provided with every fill and refill of medications for which they are required (such as NSAIDs, antidepressants, etc)? How?

82.00 Are REMS (Risk Evaluation Mitigation Strategy) implementation programs performed? Identify the programs and confirm procedures in place.

83.00 Is patient counseling, the offer to counsel, or the refusal of patient counseling documented? How?

84.00 Do patients have 24-hour access to a pharmacist? How?

85.00 Are processes in place to handle a drug recall?

86.00 Does the pharmacy accept prescription drugs back for destruction as part of a drug take-back program?

86.01 Does the take-back program include controlled substances?

86.02 Does the pharmacy have a modified DEA registration (Authorized Collector) for controlled substances take-back?

Quality Assurance / Quality Improvement Program

87.00 Is there a documented continuous quality improvement (CQI) program for the purpose of detecting, documenting, assessing, and preventing quality-related events (QREs)?

87.01 Policies and procedures for the program are maintained in the pharmacy in an immediately retrievable form.

87.02 "Quality Related Event" (QRE) is defined to mean any departure from the appropriate dispensing of a prescribed medication that is or is not corrected prior to the delivery and/or administration of the medication, including (but not limited to):

1. A variation from the prescriber's prescription drug order such as incorrect drug, strength, form, or patient; or inadequate or incorrect packaging, labeling, or directions;
2. A failure to identify and manage over-utilization or under-utilization, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of treatment, drug-allergy interactions, or clinical abuse/misuse;
3. Packaging or warnings that fail to meet recognized standards, the delivery of a medication to the wrong patient, or the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy.

87.03 There is documentation of initial/ongoing (at least yearly) review and training of all pharmacy employees on the CQI program and processes.

88.00 *Documentation of QREs* starts as soon as possible, but no more than three days after determining their occurrence.

88.01 Documentation includes all the pertinent data about the prescription involved including personnel involved at each step.

88.02 Documentation includes documenting the type of QRE details and how/who discovered the QRE.

88.03 Documentation includes possible contributing factors such as day and time the QRE occurred, number of pharmacists and technicians on duty, prescription volume that day, equipment failure, or other factors affecting workflow at the time.

88.04 Documentation includes steps taken to remediate, including communications with the patient and the provider, and if the medication was ingested, and disposition of the patient.

89.00 *QRE data* collected is analyzed to assess causes and any contributing factors (root cause)? Who performs that analysis and often is the analysis performed?

89.01 The pharmacy uses the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients.

89.02 For pharmacies utilizing a drug formulary, a periodic review of such formulary is undertaken to ensure that appropriate medications are being offered/selected in the best interest of the patients.

90.00 *Quality Meetings* are held at least annually by staff members of the pharmacy to consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.

90.01 The meeting reviews data showing evidence of the quality of care for patients and develops plans for improvements to increase good outcomes for patients.

90.02 Improvements or changes made are evaluated for performance to measure the effectiveness of the CQI program.

91.00 *Reporting:* Incidents of QREs are reported to a nationally recognized error reporting program, an outside peer review committee, or a patient safety organization.

91.01 Adverse events are reported to the appropriate entities such as the board of pharmacy, MedWatch, FDA, VAERS, etc?

91.02 Incidents involving malfunctioning or defective medical equipment or devices (blood glucose meters, DME, injection devices, etc.) are documented and reported to the manufacturer or distributor.

92.00 *Quality Self-Audits* are performed by the pharmacy at least quarterly (and upon change in PIC) to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI program in the future.

93.00 *Customer Surveys* are conducted at least yearly of patients who receive pharmaceutical products and services at the pharmacy. A statistically valid sampling technique may be used in lieu of surveying each patient. Each pharmacy should use the results of its customer survey to evaluate its own performance at a particular time and over a period of time.

94.00 *Patient Complaints* are documented, tracked, and investigated as appropriate and the information is used as part of the CQI program.

Revision History

08-30-2017 Version 1.1 027.00 Added relinquished.