Louisiana Board of Pharmacy

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Blueprint for Inspection of Pharmacies

Module I – Basic Pharmacy Services

Version 1.3

The criteria in this blueprint are identified in the National Association of Boards of Pharmacy's Universal Inspection Form*, v.8, which was approved for use on June 20, 2018.*

Pharmacy Practice Profile

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

02.00 Is the PIC employed full-time at the pharmacy?

03.00 Are there any other businesses located at this address?

04.00 Does the pharmacy have any other websites?

04.01 Does the pharmacy hold *.pharmacy* verification?

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 securely enter/update profile and medical information through the website (such as through a secure patient portal)?

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, including name and title.

10.00 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?

11.00 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)?

12.00 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)?

13.00 If yes, 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.

14.00 If yes, 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

15.00 Are pharmacy licenses, permits, and registrations (state, controlled substances, DEA, etc.) posted in customers' view and current?

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

17.00 Were any deficiencies noted?

18.00 Does the pharmacy hold any wholesale, distributor, or manufacturer licenses?

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

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 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?

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

23.00 Has the pharmacy been inspected or visited by the DEA?

24.00 Has the pharmacy been inspected by the FDA?

25.00 Does the pharmacy hold any accreditations or certifications?

26.00 Has the pharmacy held any accreditations or certifications in the past that they no longer hold?

27.00 Does the pharmacy perform patient lab testing such as blood glucose tests, cholesterol tests, etc.? Verify that the lab director (usually the PIC) is current.

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

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

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

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

28.04 Are there systems in place to prevent a pharmacy record from being deleted after the prescription has been dispensed?

28.05 If records are stored off site, are they secure in a HIPAA compliant manner and readily retrievable?

29.00 Is there a statement in the P&P (Policy & Procedure Manual), or are other means used to ensure that the most stringent laws/regulations are followed?

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 If pharmacists are providing patient services that require additional training or certification [CPR, MA, CDTM], are they 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?

37.01 Is the working area well-lit and free of tripping hazards?

37.02 Is there a sink with hot and cold running water?

37.03 If the pharmacy destroys prescription products on site (e.g., expired, damaged, recalled, etc.), do they appropriately document the destruction?

37.04 Does the pharmacy return prescription products to the manufacturer, distributor, or send to a reverse distributor for destruction?

37.05 Does the pharmacy have a hazardous waste handling and collection system? For example, empty bottles that contained chemotherapy medications or warfarin, or hazardous drug compounding waste?

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 maintained to provide controlled room temperature of 20°C to 25°C (68°F to 77°F), or more restrictive if warranted by specific drug product storage requirements?

39.01 Is temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max? Temperature records are maintained.

39.02 Are excursion action plans in place including evaluating excursion effects on drug product integrity?

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

41.00 Does the pharmacy have 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° to 8°C or 36° to 46°F) or as specified by FDA approved labeling for drug product storage?

42.00 Does the pharmacy have 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° to -10°C or -13° to 14°F) or as specified by FDA approved labeling for drug product storage?

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.)?

46.01 If yes, do they have and follow policies and procedures addressing cross-contamination and identification of drug products?

Product Receipt and Inventory

47.00 Does the pharmacy have a documented process for establishing sources (vendors) of prescription drugs?

47.01 Does the pharmacy purchase all prescription drugs directly from the manufacturer?

47.02 Does the pharmacy purchase (obtain) prescription drugs from other pharmacies?

47.03 Does the pharmacy purchase (obtain) prescription drugs from wholesale distributors (non-manufacturer sources)?

47.04 Does the pharmacy require wholesale distributor sources to purchase prescription drugs directly from the manufacturer?

47.05 Does the pharmacy purchase drugs from wholesale distributors that purchased the drug from other wholesale distributors?

47.06 Does the pharmacy determine that all sources listed on transaction histories have requisite state licensing?

47.07 Does the pharmacy determine that all sources listed on transaction histories have reported to FDA's Wholesale Distributor database?

47.08 Does the pharmacy have a process to handle suspect and illegitimate product investigations?

47.09 Has the pharmacy conducted any suspect or illegitimate product investigations?

47.10 Does the pharmacy ensure transaction data (transaction history, transaction information, transaction statement, also known as 3T data) is received at the same time or before the product is received?

47.11 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?

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 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 (and/or ephedrine) products? If yes, indicate if the sale is recorded electronically or manually in a logbook.

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?

60.01 Are all drugs within active stock within expiration date?

60.02 How often is active stock examined for drugs past the expiration date?

61.00 Does the pharmacy *prepackage* bulk containers of prescription medications into smaller containers for ease of use?

62.00 Does the pharmacy *prepack* multiple drugs into a single container for compliance packaging?

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

63.01 If yes, are they maintained in the appropriate container, with PHI removed and BUD adjusted?

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?

65.04 If the pharmacy accepts electronic prescriptions for controlled substances, are they in compliance with federal regulations?

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 Does the DUR include:

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 In addition to the pharmacy DUR software, does the pharmacy staff obtain other 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 required 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?

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 gave the approval 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:* Does the system have adequate safeguards to prevent a user from performing functions under a different user account or beyond what they are authorized to perform?

70.01 Does the pharmacy 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 If yes, is the other location under common ownership?

72.02 If yes, is that location in a different state than this facility?

72.03 If yes, are there policies and procedures for identifying who is responsible for each step of prescription processing?

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 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 preparations?

Patient Counseling and Communication

75.00 Does the pharmacist 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?

79.00 Is patient counseling provided for mailed prescriptions?

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.)?

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

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?

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

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 drug 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)?

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 *Consumer 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 every patient. Each pharmacy should use the results of its consume 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

05-14-2018	Version 1.3	**15.00**	Added examples of credentials.
		27.00	Added verification of lab director.
		29.00	Added check for compliance with most stringent provisions of laws and rules.
		32.00	Added examples of credentials at issue.
		93.00	Replaced ‘customer’ with ‘consumer.’
02-05-2018	Version 1.2	**01.00**	Moved name and other demographic information to separate document.
		02.00	Asks whether PIC is full-time at pharmacy.
		04.01	Asks whether pharmacy website(s) have *.pharmacy* verification.
		10.00	Demographic information moved.
		11.00	Demographic information moved.
		12.00	Demographic information moved; subsequent criteria re-numbered.
		18.00	Asks whether other credentials (manufacturer, distributor, etc.) credentials are held.
		21.00	Removed question about previous inspections by NABP; subsequent criteria re-numbered.
		28.04	New item asking whether system is in place to prevent a pharmacy record from being deleted after the prescription is dispensed.
		28.05	New item asking whether records stored off site are stored in HIPAA compliant manner and readily retrievable.
		37.01-05	New items asking about lighting, running water, destruction of products on site, and handling of hazardous waste on site.
		39.02	New item asking about temperature excursion

	action plans.
46.01	New item asking about policies and procedures for drug product identification and cross-contamination in automated apparatuses for prescription processing/counting.
47.01-11	Re-structured and new items relative to sources of drug products.
60.01-02	Items-restructured.
60.03	Contents of item relocated to earlier standard and number deleted.
61.00	Changed focus of item from *repackaged* to *prepackaged* drug products.
63.01	New item asking about removal of PHI and adjustment of BUD for dispensed drug products returned to active dispensing stock.
65.04	New item verifying electronic prescriptions for controlled substance comply with federal rules.
72.00-11	Subparts consolidated and restructured.