STANDARDS FOR ACCREDITED MEDICINE STORES

Liberia Medicines & Health Products Regulatory Authority
and
The Pharmacy Board of Liberia

April 2012

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ACRONYMS

AMS	Accredited Medicine Store
LMHRA	Liberia Medicine and Health Products Regulatory Authority
MOHSW	Ministry of Health and Social Welfare
NMP	National Medicine Policy
PAL	Pharmaceutical Association of Liberia
PBL	Pharmacy Board of Liberia

INTRODUCTION

The Pharmacy Board of Liberia[1] (PBL) is a semi-autonomous institution that was created by an act under the Public Health and Safety Law of the Republic of Liberia, and approved on April 20, 1967. The passage into law of the 2010 Act of the Liberia Medicines and Health Products Regulatory Authority (LMHRA) repeals certain provisions of the Public Health Law of July 1976 regarding the functions of the Pharmacy Board of Liberia.

The PBL meets monthly and is chaired by a pharmacist who is appointed by the Minister of Health and Social Welfare with the advice of the Pharmaceutical Association of Liberia (PAL), a professional body of Liberian pharmacists. The Board is a policy and regulatory body concerned with pharmaceutical matters.[2]

The Pharmacy Board currently registers two kinds of pharmaceutical outlets in Liberia: pharmacies and medicine stores.

Pharmacies are allowed to sell all classes of medicines:

- Class A medicines—restricted or prescription-only medicines
- Class B medicines—medicines in pharmacies that are under the supervision of the pharmacist and may be dispensed by the pharmacist without a prescription
- Class C medicines—approved medicines list that can be sold in registered facilities other than pharmacies
- Class D products—drug sundries; that is, those products that are related and supplementary to medicines such as health aids, therapeutic devices and appliances, baby products, toiletries and cosmetics

Accredited medicine stores (AMSs) are allowed to sell:

- Class C medicines and a limited approved list of class B medicines
- Class D products

In addition to the two kinds of pharmaceutical outlets in Liberia currently registered by the PBL—pharmacies and medicine stores—the PBL will register AMSs when they meet accreditation standards.

[1] This is also known as Pharmacy Council in other countries.
[2] Pharmacy Board of Liberia. January 2009. *Basic Requirements and Application Forms for Registration of Pharmacies and Medicines Stores in the Republic of Liberia.*

APPLICATION AND ACCREDITATION PROCEDURE FOR MEDICINE STORES

Issuance of Application Forms for Accreditation

In the accreditation process, all medicine stores intending to be accredited shall submit their applications to the PBL office. All applications shall be submitted and discussed in a timely manner at the Pharmacy Board's regular meeting. Following discussions by the PBL, the joint inspection team of the Pharmacy Board and the LMHRA will inspect the sites of the proposed premises. The PBL and the LMHRA shall not be under any obligation to approve an application because of financial commitments made for premises or for any such reason. Approval or rejection of any premises by the PBL shall be based on the report submitted by the joint inspection team of the PBL and LMHRA. Approval by the PBL shall be valid for a specific period, within which business is expected to commerce.

Pre-Inspection Assessment and Inspection of Premises

There shall be a pre-inspection assessment of all candidate AMSs to qualify the premises' geographic locations.

In the accreditation process, a joint PBL and LMHRA inspection team shall inspect the stores that have applied for accreditation. There shall be a preliminary inspection (see tool attached in annex C) of the premises, during which inspectors will identify deficiencies as per expected standards of the AMS and will advise accordingly. Medicine stores with noted deficiencies shall be re-inspected to ascertain whether corrective action was taken, prior to accreditation. Following the final inspection, the PBL shall either issue a registration certificate to the owner or provide advice on next options.

Accreditation

The accreditation process involves authorizing existing medicine stores and new premises that wish to meet the standards to operate as an AMS. Following a final inspection of premises, the inspection report shall be submitted to the PBL to be reviewed and approved during the Board's regular monthly meeting.

The successful applicant will be issued an accreditation certificate upon fulfillment of requirements to operate the AMS, which include attending training for both the owner and the dispenser.

STANDARDS OF OPERATION

(a) Personnel

Accredited Medicine Store Dispenser Basic Knowledge

(1) A minimum qualification of a high school diploma shall be required for any person intending to be trained as an AMS dispenser and/or proprietor.

(2) In addition to requirement (1), every dispenser shall be required to successfully complete an AMS dispenser-training course to be approved by the LMHRA/PBL. The course shall include but not be limited to the following:

a. AMS guidelines, regulations, and standards
b. Code of ethics
c. Common medical illnesses in the community
d. Basic medicine management and dispensing skills
e. Communication skills
f. Record keeping and reporting

The content and duration of the dispenser-training course shall be determined by the LMHRA/PBL.

Dispenser Requirements

(3) Every dispenser, while working in an AMS, shall observe and maintain the following standards:

a. Keep a high standard of personal hygiene

b. Dress in a professional manner—that is, wearing a clean blue coat or dress

c. Never work under the influence of alcohol or illicit drugs

d. Prominently display his/her dispensing certificate

e. Wear a photo identification badge which identifies him/her as an AMS dispenser

f. Be accountable for all activities conducted therein

g. Observe all regulations pertaining to operating the AMS

h. Observe provisions contained in the National Medicine Policy (NMP)/LMHRA Act 2010 and PBL Act

i. Be of sound mind and in sound medical condition

j. Conduct him/herself in a manner that does not cause professional disrepute

Contract between Proprietor and Dispenser

(4) Commitment letters shall be written and signed by the AMS dispensers, committing to work with an AMS for a specific period of time. The letters will be endorsed by the AMS proprietor. Three months' notice shall be required if a dispenser is to resign from a particular AMS.

Proprietor's Requirements

(5) Every owner of the AMS store shall:

a. Ensure that operating procedures comply with the AMS standards and the existing provisions in the NMP/LMHRA Act 2010 and PBL Act

b. Ensure the presence of a trained dispenser at the AMS at all times when the AMS is open

c. If he/she works in the capacity of dispenser, ensure that he/she has a valid AMS certificate

d. Display accreditation certificate prominently in the premises for which the certificate is issued

e. Notify the PBL/LMHRA in writing within seven days when the AMS is permanently closed; and upon receipt of such notice, the LMHRA shall inspect the inventory and provide advice for proper disposal of any inventory or medication

f. Notify the PBL/LMHRA in writing within seven days when an AMS is temporarily closed and inform of the anticipated date of re-opening; and in case the AMS is closed for one year it shall be considered as a new applicant

g. Report immediately to the nearest police station and PBL/LMHRA offices in the case of theft or any unexplained loss of medicines and records.

Proprietor's Training Requirements

(6) Every AMS proprietor shall be required to attend a training course formulated and approved by the PBL/LMHRA; and such course shall include but shall not be limited to the following:

a. AMS guidelines, regulations, and standards
b. Code of ethics
c. Record keeping and reporting
d. Basic business skills

Continuing Education

(7) All AMS dispensers shall be required to attend and complete continuing education to be organized by PBL/LMHRA. The continuing education shall be mandatory and shall constitute a prerequisite for annual license or permit and their renewal.

(b) Premises

Location

(8) Any person wishing to operate an AMS shall:

a. Clearly state the location and address of his/her premises in the application when applying for registration

b. On the basis of local demand and need for such service, locate his/her business in an appropriate location to reduce unnecessary congestion and provide services to underserved communities

c. Prioritize opening an AMS in a rural location near dispensaries and health facilities

d. Search for a location that is a minimum of 2 miles (3.2 km) from any existing retail pharmacy and a distance of 500 ft. from another AMS; and if a new pharmacy is opened within 2 miles from the AMS, the AMS shall be given an opportunity to upgrade to a pharmacy within 1 calendar year or from the time a new retail pharmacy starts operation in the location

e. Not operate an AMS within the radius from the Catholic Hospital to Caldwell Junction in the city of Monrovia

Premises Requirements

(9) All AMS premises shall be required to meet minimum requirements as follows:

a. The premises shall be geographically and structurally permanent.

b. They shall be roofed with materials which shall make the roof free from leakages and with a leak-proof ceiling.

c. They shall be well protected from entry of rodents, birds, vermin and pests.

d. They shall have adequate space to carry out the primary functions of storage, dispensing and sales.

e. They shall have doors and windows which are well secured to prevent theft and unauthorized entry.

f. They shall be fixed with glass counters and the main door shall include a glass panel for safety.

g. They shall provide adequate ventilation and lighting (fan, air-conditioner, open airways, etc.).

h. They shall have surfaces/floors with a smooth finish that can be washed with disinfectants.

i. They shall be painted with a washable white color.

j. They shall have adequate supply of soap, and clean and safe drinking water.

k. They shall have facilities to wash hands which are clearly marked with a "WASH HANDS" sign.

l. They shall have adequate toilet facilities in clean and good working order.

m. They shall observe general hygiene inside and outside the premises.

n. They shall not be shared with any medical clinic, veterinary surgery or any other business of a similar nature.

o. They shall have a minimum floor length of 13 ft., floor width of 12 ft. and a minimum ceiling height of 9 ft.

(10) The premises shall have the following required signage:

a. An officially approved identification logo, to differentiate it from non-AMSs (see AMS logos in annex F)

b. The name of the AMS and any other authorized branding conspicuously displayed on the wall or store boards, displayed after the final approval of the premises by the PBL/LMHRA

c. A "NO SMOKING" sign conspicuously placed to prohibit smoking in the store

d. All certificates and registration documents on display

(c) Product Quality and Dispensing Procedures

Source of Supply

(11) Products shall meet the following requirements:

a. All health products sold by an AMS shall be registered by the LMHRA in accordance with the LMHRA Act 2010 or other written regulations.

b. The products shall be procured from a registered wholesaler or local manufacturer.

c. AMSs shall not sell expired products. All expired products shall be retrieved from the sales area, warehouse areas, etc., and disposed of by the LMHRA/PBL in collaboration with other relevant agencies.

d. In addition to class C medicines and some medical sundries (e.g., medicated soap, baby products, toothpaste and brushes), there shall be an approved list of medicines to be sold by the AMSs.

e. In addition to class C medicines, wholesalers shall sell products on the approved medicines list to the AMSs.

f. It shall be the responsibility of the wholesalers to verify the credentials of an AMS prior to the sale of medicines provided in the approved medicines list. The wholesalers shall honor orders from the AMS only when the store presents a copy of its accreditation certificate.

g. Wholesalers selling approved medicines to AMSs shall be required to keep easily retrievable documents related to sales and shall also provide to the AMS an invoice/sales receipt for all medicines sold to them.

h. It shall be an offense for a wholesaler to sell any medicine on the approved list to non-AMSs, and also an offense for a wholesaler to sell to AMSs any medicine not permitted for sale in an AMS.

Storage

(12) All medicines shall be properly labeled, packaged, and stored.

a. All pharmaceutical products held in inventory shall be stored in the manufacturer's original packaging and properly labeled with the manufacturer's original label.

b. Removal of labels from containers is prohibited; removal renders the product unfit for dispensing.

c. Repackaging and relabeling of pharmaceutical products not for the purpose of immediate dispensing to clients is prohibited.

d. Measures shall be taken to protect pharmaceutical products from heat, sunlight, moisture, adverse temperatures, insects, rodents and contamination.

e. Damaged and/or expired medicines shall be recorded, sealed, quarantined and labeled with red ink with the statement "Expired/damaged medicines – Not for sale" by the AMS dispenser.

Dispensing Procedure

(13) Medicines shall be dispensed according to proper procedures.

a. Every AMS dispenser shall bear legal liability and professional responsibility for the pharmaceutical products and services provided under his/her care.

b. Every AMS shall only dispense pharmaceutical products registered by the LMHRA in accordance with the NMP/LMHRA Act 2010.

c. The dispenser shall not dispense damaged, counterfeit, substandard or expired medicines.

d. The dispenser shall not dispense or sell medicines to children less than 12 years.

e. Every dispenser shall ensure that—

i. Prescription medicines are only dispensed against a prescription

ii. A full dose is dispensed

iii. Tablets and capsules are dispensed using an appropriate device for counting and packaging

iv. A record of all medicines dispensed by him/her is maintained in a register approved by the PBL/LMHRA

v. Medicines are dispensed in accordance with approved regulations

Counseling of Clients

(14) Clients will be counseled about their medicines to ensure proper use.

a. An AMS dispenser shall ensure that the client understands the information and advice given (including directions on the labels of dispensed products) well enough to ensure safe and effective use of the medicine.

b. Information for medicines requiring particular instructions for use must be clearly pointed out to the clients before they leave the AMS.

c. Clients or their representatives must be warned to keep medicines well out of reach of children.

Dispensing Containers

(15) Appropriate containers will be used.

a. All oral liquid preparations must be dispensed in their original re-closable containers.

b. All containers for medicines must be protected from and free of contamination.

c. The containers must be appropriate for both the medicines dispensed and the users.

Dispensing Labels

(16) Appropriate labels will be used.

a. Labeling of dispensed medicines must be clear and legible.

b. Dispensed medicines must bear the necessary cautionary and advisory labels.

c. The label on the container must indicate the name, strength, dosage and total quantity of the medicine sold.

Hygiene

(17) Proper hygiene will be observed.

a. No AMS dispenser should be allowed to work if he/she is suffering from a contagious disease, such as scabies, tuberculosis, etc.

b. Dispensing must always be carried out under conditions which meet acceptable standards of hygiene, including high standards of personal cleanliness.

c. Use of bare hands for counting tablets and capsules is prohibited.

(d) Record Keeping and Documentation

Standards for Record Keeping and Documentation

(18) Proper record keeping and documentation should be followed:

a. All invoices and receipts for approved medicines shall be stored in the premises in an easily retrievable file for not less than two years.

b. A purchase record book shall be kept, which shall minimally include: name of supplier; date of purchase; name and quantity of the medicine, manufacturer; batch number; and expiry date.

c. All AMSs shall maintain, for selected, approved prescription medicines, a register book, which shall minimally include:

    i. Name and age of the client for which the prescription was written or prescription medicine dispensed

    ii. Name of medicine and quantity dispensed

    iii. Date on which the medicine was dispensed

    iv. Origin of the prescription

d. There shall be a record for expired products which shall be kept and maintained by the AMS dispenser and be ready for inspection by PBL/LMHRA.

e. There shall be LMHRA adverse medicine reaction forms maintained in each AMS for the purpose of recording client medicine-related adverse reactions.

f. Every AMS shall keep and maintain:

    i. A special file for keeping all correspondence related to medicines, guidelines from the PBL, LMHRA and other regulatory authorities

    ii. An inspector's record book for the purposes of recording all inspections undertaken therein

(e) Reference Materials

Reference Books

(19) Each AMS shall have and maintain, for easy reference, the following reference books:

a. Accredited medicine store approved medicines list
b. Accredited Medicine Store Standards and Code of Ethics
c. Accredited medicine dispenser training manual
d. National Standard Treatment Guidelines

e. Other recommended references, including *Essential Medicines List for Liberia*, relevant legislation, and the National Medicine Policy

(f) Offenses and Penalties

(20) Any person who contravenes any provisions of these standards commits an offense and shall be held liable. The violator may be subject to an administrative hearing or appear before a court of law and upon conviction shall be punished either by paying a prescribed fine or serving a prison sentence or both as specified under the LMHRA Act 2010.

Example 1

Any AMS found selling expired medicines or medicines not on the approved medicines list.

Example 2

A person who illegally opens an AMS or medicine store.

Example 3

Like any other business, an AMS shall be liable for taxation. Tax evasion may lead to closure of the premises by law-enforcing bodies and bring about inconveniences to the AMS proprietor, dispenser, and the community served by the store.

Example 4

Purchase of medicines from non-licensed dealers: medicines from unauthorized dealers are often counterfeit, so this practice is prohibited.

Example 5

Dispensing to medicines purchased from unauthorized dealers to clients may cause harm. Such violations of law are punishable on conviction by courts of law. It is therefore important for AMS proprietors and dispensers to adhere strictly to the provisions of the law, guidelines, and standards of operations.

ROUTINE INSPECTIONS

Inspection and Monitoring Levels

(1) Inspection and monitoring of AMSs shall be provided jointly in partnership involving the following:

a. PBL
b. LMHRA national and zonal levels
c. Pharmacy Division/MOH

Appointment of Inspectors

(2) All AMS inspectors shall be appointed by the PBL or LMHRA. The persons shall undertake a special PBL/LMHRA training course and receive operational tools such as IDs and an inspection checklist.

Limited Authority

(3) Decision-making authority shall principally rest with the central-level PBL or LMHRA. For the purpose of avoiding abuse of power, all AMS inspectors shall have limited decision-making authority.

Accusations and Complaints

(4) Any accusation related to inspectors' impropriety or disagreement with inspectors' findings made by an outlet owner as well as consumer complaints associated with medicine store services shall be directed to the PBL Registrar or LMHRA Managing Director.

Inspection

(5) Upon visiting an AMS for the purpose of inspection, each inspector in the team shall:

a. Provide an official identification to the owner or dispenser

b. Register himself/herself in the Inspectors Register Book provided by the LMHRA/PBL to AMS upon accreditation

c. Upon completion of inspection, write all required information in the Inspectors Register Book and the owner or seller and all inspectors in the team shall sign therein

d. After the inspection, prepare an inspection report, copies of which shall be submitted to the inspectors' immediate supervisory body

ACCREDITED MEDICINE STORE CODE OF ETHICS AND CONDUCT

Honesty and integrity	All AMS dispensers and proprietors shall, in the course of discharging their duties, act with honesty and integrity.
Patient care	All AMS dispensers and proprietors shall provide their services in a caring and compassionate manner. The well-being of a patient shall be the center of AMS business practice, and therefore dispensers and proprietors shall make sure that the needs of the patient are always given first priority.
Special relationship with clients	AMS dispensers and proprietors shall: • Maintain a special relationship with each client based on ethical agreement • Uphold their moral obligations in return for the trust given to them by the community • Respect the autonomy, individuality, and dignity of each client • Acknowledge the right of clients to participate in decisions related to their health • Respect personal, cultural, and religious differences and shall not in any way practice any form of discrimination
Confidentiality	Every AMS dispenser and proprietor shall observe the confidentiality of clients' information acquired in the course of practice and shall not in any way disclose the information given except where authorized by the client or required by the law.
Quality of medical service	AMS dispensers and proprietors shall not either condone the dispensing, promotion, or distribution of medicines or medical services that are not of good quality or participate in any promotional methods or campaigns that encourage the irrational use of medicines or undermine the role played by other health care providers.
Collaboration with other health providers	AMS dispensers and proprietors shall be required to collaborate with other health care providers to achieve the best possible outcomes for clients and to understand the role of other health care providers and refer clients to them when it is appropriate to do so.
Responsibility for assuring and improving competence	Each AMS service provider shall assume responsibility for assuring and improving his/her competence and shall strive for continuous improvement of the quality of service and care he/she provides. AMS providers may offer limited client advisory services but they shall not, in any way, make diagnosis and/or prescribe any medicine.
Illegal conditions	It shall be the duty of AMS owners to make sure that there are no conditions or terms which prohibit the AMS dispensers and proprietors from practicing in accordance with the provisions of these regulations.
Health promotion	Each AMS service provider shall advocate for health promotion at the individual, community and society levels and shall promote the use of cost-effective therapies and rational medicine use.
Commercial relationships	No commercial relationship shall be permitted between health care practitioners and AMS providers.

ANNEX A. LIST OF APPROVED MEDICINE TO BE SOLD AT THE AMS

Approved Medicines for Accredited Medicine Stores (AMS)

February 2013

TYPE OF MEDICINE	MEDICINE NAME	STRENGTH (if applicable)
Analgesics and other non-steroidal anti-inflammatories	Annusol suppositories	
	ASA (acetylsalicylic acid)	
	Diclofenac sodium tablets	25 mg, 50 mg
	Hydrocortisone ointment/cream	0.5% or 1% (ointment)
	Ibuprofen 200 mg	
	Paracetamol (also known as acetaminophen)*	
Antacids	Aluminum hydroxide	
	Magnesium carbonate	
	Magnesium trisilicate	
	Milk of magnesia	
	Sodium bicarbonate	
Anthelmintic	Albendazole	
	Mebendazole	
Anti-allergics/ Antihistamines	Cetirizine hydrochloride tablets	
	Chlorpheniramine (Chlonnene,® Chlortrimeton,® Piriton®)	10 mg
	Cetirizine hydrochloride oral solution	5 mg/5 mL
Anti-amebic	Metronidazole tablets and syrup only	
Anti-asthmatics	Cromolyn sodium (only)	
Antibacterial *NOTE: Sales of the injectable forms of any medicine in AMSs are prohibited.*	Amoxicillin trihydrate capsules	250 mg, 500 mg
	Amoxicillin trihydrate oral suspension	125 mg/5 mL, 250 mg/mL
	Ampicillin	
	Chloramphenicol eye drops/ointment	1%

TYPE OF MEDICINE	MEDICINE NAME	STRENGTH (if applicable)
	Co-trimoxazole suspension	240 mg/5 mL in 100 mL bottle
	Co-trimoxazole tablets	480 mg
	Doxycycline capsules/tablets	100 mg
	Erythromycin oral suspension	125 mg/5 mL, 250 mg/5 mL
	Erythromycin tablets	250 mg, 500 mg
	Metronidazole tablets	200 mg, 250 mg, 400 mg
	Metronidazole suspension	200 mg/5 mL in 100 mL
	Nitrofurantoin tablets	50 mg, 100 mg
	Phenoxymethyl penicillin suspension	125 mg/5 mL 250 mg/5 mL in 100 mL
	Phenoxymethyl penicillin tablets	250 mg
	Silver sulfadiazine cream	10 mg
	Tetracycline eye drop/ointment	1%
Antidiarrheals	Metronidazole (tablet or syrup dosage form)	
	Oral rehydration salt (ORS)	
Anti-emetics	Metoclopramide	
	Promethazine syrup	
Anti-epileptic	Phenytoin tablets/capsules (sodium salt)	50 mg (tablet), 100 mg (capsule)
	Phenobarbital tablet	50 mg, 100 mg
Anti-fungal	Clotrimazole cream	1%
	Gentian violet, for 1% solution	25 g
	Griseofulvin tablets	500 mg, 100 mg
	Ketoconazole tablets	200 mg
	Nystatin oral suspension	100,000 IU/mL in 30 mL bottle
	Nystatin pessaries	100,000 IU
	Nystatin skin ointment	100,000 IU/g
	Nystatin tablets	500,000 IU, 100,000 IU
Antihemorrhoidal	Bland soothing preparations (e.g. Annusol,® yeast extract, or Preparation H®)	
Antimalarials *NOTE: Injectable forms of antimalarials and pyrimethamine in a non-combined form are prohibited.*	Artemether + lumefantrine tablets	20 mg + 120 mg
	Artemether + amodiaquine tablets (AS/AQ)	100 mg +270 mg
	Quinine tablets (sulfate or bisulfate)	300 mg

TYPE OF MEDICINE	MEDICINE NAME	STRENGTH (if applicable)
Antispasmodics	Hyoscine butyl bromide tablets	10 mg
Cardiovascular (anti-arrhythmic drugs)	Propranolol tablets (hydrochloride)	10 mg, 40 mg, 80 mg
Dermatological	Benzoic acid / salicylic acid preparation (e.g., Whitfield ointment)	
	Benzyl benzoate (emulsion/lotion)	
	Calamine (e.g., lotion)	
	Clotrimazole (ointment or cream or pessaries)	
	Crystal violet (also gentian violet G.V., /methyl violet)	
	Hydrogen peroxide	
	Povidone iodine	
	Miconazole (ointment, cream, or pessaries)	
	Penicillin ointment (skin)	
	Sulfacetamide (preparations)	
	Sulfadiazine (ointment or cream)	
	Sulfur (ointment or cream)	
	Zinc oxide and other zinc preparations	
Diuretics	Hydrochlorothiazide tablets	25 mg, 50 mg
	Honey preparations	
	Menthol and volatile oils (e.g., eucalyptol)	
Hematinic	Folic acid preparations (single and combined forms)	
	Oral iron preparations (single and combined forms)	
Laxatives	Bisacodyl tablets	5 mg
	Castor oil	
	Magnesium hydroxide	
	Magnesium sulfate (e.g., Andrew's Liver Salt®)	
Mechanical contraceptives	Condom	
Nutrition supplements	Vitamin B complex preparations	
	Vitamin C	
	Mineral preparations	
	Multivitamin preparations (NOTE: except vitamin K)	

TYPE OF MEDICINE	MEDICINE NAME	STRENGTH (if applicable)
	Neurobion forte	
	Zinc sulfate tablets	20 mg
Ophthalmic preparations	Chloramphenicol (eye) drops and ointment	
	Sodium cromoglycate (Optrex® drops/ointment)	
	Sulfacetamide eye drops/ointment	
	Tetrahydroxoline (Visine®) wash/drops	
Oral contraceptives	Ethinylestradiol + novethisterone	(0.03 mg) + (0.3 mg)
	Ethinylestradiol + levonorgestrel	(0.03 mg) + (0.15 mg)
Oral hygiene and otics	Gargles/mouth washes (e.g., Listerine®)	
	Alcohol ear wash	
	Chloramphenicol ear drops	
	Hydrogen peroxide	
Sexual stimulants or aphrodisiacs	Ayuverdic preparation (except those with steroids)	
	Non-steroidal aphrodisiacs	
Therapeutic dressing materials	Adhesive tape (or plasters)	
	Antiseptics (or disinfectants,) including rubbing alcohol 50%	
	Bandages	
	Cotton	
	Gauze (compresses)	
Throat preparations	Amylmetacresol, dichlorobenzyl alcohol–contained lozenges (e.g., Strepsils®)	

ANNEX B. FUNCTIONS AND DUTIES OF THE PBL AND LMHRA

Functions and Duties of the Pharmacy Board and Liberia Medicines and Health Products Regulatory Authority *[LMHRA Act 2010]*

Functions of the Board

1. Administers examinations for the qualification of graduate pharmacists and dispensers who have completed the requirements for licensure

2. Registers and maintains the register for all pharmacists and dispensers practicing in Liberia

3. Supervises and controls the ethical behavior of practicing pharmacists and dispensers in Liberia

4. Ensures the continuing professional development of pharmacists and dispensers

5. Inspects pharmaceutical outlets for annual registration documents, conditions of premises and qualifications of dispensers in stores

6. Issues permits to retailers annually

7. Evaluates curricula and issues annual permits to pharmaceutical training institutions

8. Sets standards and defines requirements for establishing and operating retail pharmaceutical outlets

9. Prepares and maintains a Liberian Pharmacopoeia

10. Advises the Minister of Health on all matters relating to the conditions of the practice of pharmacy in Liberia

Functions and Duties of the Authority

1. Conduct registration of medicines and health products

2. Issue licenses or permits for premises and personnel to engage in the manufacture, import, export, transit into or out of the Republic of Liberia, and for supply, storage, distribution, or sale of medicines and health products, excluding retail pharmaceutical outlets

3. As and when deemed necessary by the Authority, suspend, cancel, or revoke such license or permits in accordance with regulations

4. Establish an inspectorate and conduct inspections of premises where medicines or health products are manufactured, stored, distributed, supplied and sold

5. Confiscate expired, substandard, counterfeit or unregistered medicines in accordance with regulations

6. Establish and operate quality control laboratories to ensure safe, effective, and good-quality medicines and health products for domestic and foreign markets

7. Conduct post-marketing surveillance of medicines and health products

8. Conduct pharmacovigilance of medicines and health products

9. Issue warnings and conduct recalls of products

10. Regulate the conduct of clinical studies of medicines and health products

11. Prepare, keep, and update a registry of medicines and health products registered and approved for marketing in the Republic of Liberia

12. Set standards of quality, safety and efficacy of medicines and health products

13. Promulgate regulations as necessary to meet its responsibilities under this Act, including regulations providing for administrative hearings necessary for effective enforcement of this Act

14. Develop and disseminate guidelines, procedures, guidance and other materials necessary for effective implementation of the functions of the Authority

15. Provide current and unbiased information on medicines and health products to health care professionals and the general public

16. Regulate advertising and promotion of medicines and health products

17. Be responsible for its human resources development

18. Promote, monitor, and evaluate the implementation of this Act

ANNEX C. PRELIMINARY INSPECTION TOOL

PHARMACY BOARD OF LIBERIA
PRELIMINARY INSPECTION CHECKLIST

Pre-inspection Checklist for Medicines Store Seeking Accreditation
(Two copies should be filed; one copy should remain in the premises and the other copy should be kept by inspectors for final inspection.]

	SECTION 1: BACKGROUND INFORMATION		
DATE:	NAME OF THE OUTLET:	PHONE NUMBER:	
INSPECTOR NAME:		GENDER:	
NAME OF THE PRORPIETOR:		MALE	FEMALE
LOCATION/COUNTY:		DISTRICT:	
LOCATION/ZONE:			
LOCATION/COMMUNITY/TOWN			
GIS COORINATES	EASTING_UTM:		
	NOTHING_UTM:		
	ELEVATION_in meters:		
	SECTION 2: REGISTRATION STATUS	**YES**	**NO**
	ASK AND OBSERVE: Does the outlet have the following valid documents? *ID for Dispenser [Pharmacy Board]*		
	ASK AND OBSERVE: Does the outlet have the following valid documents? *Certificate/Annual Permit [Pharmacy Board]*		
	ASK AND OBSERVE: Does the outlet have following valid documents? *Certificate of Registration [Pharmacy Board]*		
	Are the dispensers wearing uniform as required by the PBL?		
	Is the dispenser wearing his/her accreditation ID card?		
	SECTION 3: CONDITION OF THE PREMISES	**YES**	**NO**
	Are the surroundings clean?		
	Is the inside of the premises clean?		
	Is the floor cemented or tiled and without holes?		
	Are the walls well painted?		
	Does the outlet have electricity?		
	Are the doors and windows strong and secure to prevent unauthorized entrance to the premises?		
	Does the outlet have air-conditioning or a ceiling fan?		
	If yes, is air-conditioning or ceiling fan working?		
	Is the ceiling high and in good condition?		
	Does the outlet have water for hand washing?		
	Does the outlet have sufficient ventilation? Does it have at least one window?		

	Is the dispensing/storage room completely sealed? [i.e., has no connection to a clinic or lab or other rooms in a house]		
	Is this the outlet size/space adequate?		
	What is the approximate size of the outlets?		
	Length (ft.):		
	Width: (ft.):		
	Height: (ft.):		
	SECTION 4: STORAGE AND QUALITY OF MEDICINES	**YES**	**NO**
	Are there enough shelves to store medicines?		
	Is there a glass counter?		
	Are any medicines kept on the floor?		
	Is there an appropriate device/container for counting and dispensing tablets/capsules?		
	OBSERVE if the outlets provide any of the following services? Injecting patients/lab services/diagnosis/wound dressing		
	Are there any expired medicines?		
	Are there any injectables in the outlet?		
	Are there any Government of Liberia medicines in the outlet?		
	Are there any medicine labels in languages other than English?		
	Is there a NO SMOKING sign?		
	SECTION 5: RECORD KEEPING AND REFERENCE MATERIALS	**YES**	**NO**
	Are there proper records for purchases?		
	Are there records for sales?		
	Are there any records for expired medicines?		
	Are there any reference materials?		

RESULTS AND RECOMMENDATIONS OF THE PRE-INSPECTION	
Class of Medicine Store: …… Name of the Proprietor: …… County:…… District:…… Zone/Community/Town:…… Phone number:……	
Observation of pre-inspection	**Recommendation**
…… ……	…… ……
Name of inspectors: Signature 1…… …… 2…… …… 3…… ……	Drug shop personnel: Signature 1…… …… 2…… …… 3…… ……

ANNEX D. ROUTINE INSPECTION CHECKLIST FOR ACCREDITED MEDICINE STORE

PHARMACY BOARD OF LIBERIA
PRELIMINARY INSPECTION CHECKLIST

[Inspection date, findings and name of inspectors to be signed in the Inspection Registers that remain in the premises]

SECTION A: General Information

Name of Accredited Medicine Store:	
Address:	
Accreditation Certificate No:	
Date of Accreditation:	
Accredited Medicine Store proprietor:	
Accredited Medicine Store dispensers:	
Name:	**Cert. No:**
Name:	**Cert. No:**
Name:	**Cert. No:**

SECTION B: Condition of Premises and Professional Conduct

Premises	**Yes**	**No**
Clean and tidy		
Posters well displayed		
Accreditation certificate displayed (original)		
Business license displayed		
Dispenser certificate (copy) displayed		
Extended list of medicines for accredited medicine store		
Hand washing facilities available		
Shelves available		
Lockable cupboards for prescription medicines available		
Drugs protected from heat		
Drugs protected from light		
Record keeping and reference materials	**Yes**	**No**
Which of the following are available?		
LMHRA Act 2010		
Liberia STG/Essential Medicines List		
Accredited medicine store standards		
Accredited medicine store code of ethics		
Accredited medicine store dispenser's training manual		
Other reference book(s)		
Drug register		
Purchase records book kept for each item purchased or otherwise obtained?[3]		
Packaging materials satisfactory?		
Labels, on stocks of medicines kept, satisfactory?		

[3] Check the following: date of receipt, invoice no, origin (supplier), quantity received, batch no. and expiry date.

SECTION C: Product registration and authorization

Conduct inspection of the medicines currently in the premises. If there are unauthorized medicines, the PBL/LMHRA inspectors should confiscate them. Unauthorized medicines include medicines that appear to be of questionable standard or fake, expired, not registered with LMHRA, not included in the list allowed to be stocked and sold in the accredited medicine store.

		Yes	**No**	**Quantity and batch confiscated**
1	Are there any unauthorized medicines in the accredited medicine store?			
2	Are there any unregistered (with LMHRA) medicines in the accredited medicine store?			
3	Are there any public medicines with Republic of Liberia label?			
4	Are there any medicines that are not included in the extended medicines list?			
5	Are there any expired medicines?			
6	Are there any medicines with questionble standard of quality/fake?			

Comments and Recommendations:

Inspector:

Signed:……Name……Designation……..Date……..

Signed:……Name……Designation……..Date……..

ANNEX E. FORM TO REPORT MEDICINES UNFIT FOR USE

Ministry of Health and Social Welfare
Liberia Medicine Health Product Regulatory Authority (LMHRA)

Date of reporting ……

Name and address of Accredited Medicines Store……
Complete name of Accredited Medicine Store ……..

Generic name of the medicine	Batch no.	Reason for retrieving medicine from the AMS	Date of expiry of medicine	Quantity of each medicine

Signature of reporting person _____

Position _____

ANNEX F. AMS APPROVED LOGOS