

*Pharmacy (Pharmacy Practice and the Conduct of Business of Pharmacy)*

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THE PHARMACY ACT,  
(CAP. 311)

REGULATIONS

*(Made under section 55(e) and (f))*

THE PHARMACY (PHARMACY PRACTICE AND THE CONDUCT OF  
BUSINESS OF  
A PHARMACY) REGULATIONS, 2020

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THE PHARMACY ACT,  
(CAP. 311)

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**REGULATIONS**

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*(Made under section 55(e) and (f))*

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THE PHARMACY (PHARMACY PRACTICE AND THE CONDUCT OF  
BUSINESS OF PHARMACY) REGULATIONS, 2020

PART I  
PRELIMINARY PROVISION

- Citation 1. These Regulations may be cited as the Pharmacy (Pharmacy Practice and the Conduct of Business of Pharmacy) Regulations, 2020.
- Interpretation 2. In these Regulations, unless the context otherwise requires-
- Cap.311 “Act” means the Pharmacy Act;  
“community pharmacy” means a business of a pharmacy located in community in which pharmaceuticals are sold in retail;  
“consultant pharmacy” means a pharmacy that provide specialized pharmaceutical services;  
“Dispense” has the same meaning ascribed to it under the Act;  
“institutional pharmacy” means pharmacy situated in health facilities registered by the Minister;
- Cap. 219 “medicine” has the same meaning ascribed to it under the Tanzania Medicine and Medical Devices Act;  
“minor ailment” means a less serious medical condition that does not require lab or blood test, and includes cold sores, mild eczema, oral thrush, heartburn, hay fever, skin rash or fungal skin infections;  
“outlet” means a pharmacy or an Accredited Drugs Dispensing Outlet registered under the Act or health facilities registered by the Ministry responsible for health which among other things provide pharmaceutical services;  
“pharmaceutical personnel” means a specialty pharmacist, registered pharmacist, enrolled pharmaceutical

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- technician, enlisted pharmaceutical assistant or recognized medicines dispenser;
- “pharmacy practice” has the same meaning ascribed to it under the Act;
- “pharmacy” has the same meaning ascribed to it under the Act;
- “sell” has the same meaning ascribed to it under the Tanzania Medicine and Medical Devices Act;
- “specialty pharmacist” means a pharmacist who has received a postgraduate or specialized qualification in the discipline of specialization recognized by the Council;
- “superintendent” has the same meaning ascribed to it under the Act; and
- “wholesale pharmacy” has the same meaning ascribed to it under the Act.

PART II

SCOPE OF PHARMACY PRACTICE

General Scope of practice of pharmaceutical personnel

3. Every pharmaceutical personnel shall discharge duties and responsibilities within the scope of pharmacy practice prescribed under these Regulations.

Scope of specialty pharmacist

4. Scope of practice of specialty pharmacist shall be to-
- (a) lead at various levels within the health sector;
  - (b) provide specialized opinion in their specialties;
  - (c) provide consultancy services in areas of specialization;
  - (d) participate in therapeutic management and pharmaceutical care;
  - (e) manage and participate in pharmacist only ward rounds for patients file reviews and major ward rounds;
  - (f) design and formulate policies and regulations for provision of pharmaceutical services;
  - (g) undertake research and development of pharmaceuticals;
  - (h) design and conduct operational, scientific research, clinical trials and pharmacovigilance;
  - (i) mentor and appraise staff offering pharmaceutical services; and
  - (j) undertake any other duty within the area of specialization as determined by the Council.

Scope of practice of

5. Scope of practice of a pharmacist shall be to-
- (a) manage and administer pharmaceutical services at

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pharmacist

- various levels;
- (b) plan and implement the provision of pharmaceutical services;
  - (c) develop, interpret and transmit pharmaceutical data and reports;
  - (d) engage in therapeutic management, ward rounds, pharmaceutical care;
  - (e) manage minor alignments and processing of prescriptions;
  - (f) implement regulations, guidelines and standards for pharmaceutical services;
  - (g) undertake research, develop, formulate pharmaceuticals, prepare and compile scientific dossiers;
  - (h) manage pharmaceutical services, supply chain, quality control, assurance and information system;
  - (i) participate in disaster preparedness; emergency response, disease prevention, surveillance and control;
  - (j) initiate and conduct operational, scientific research, clinical trials and pharmacovigilance;
  - (k) supervise and appraise staff offering pharmaceutical services;
  - (l) monitor and evaluate pharmaceutical policy and services;
  - (m) promote pharmaceuticals, rational use of medicines and public health; and
  - (n) undertake any other duty as determined by the Council.

Scope of practice of intern pharmacist

6. Scope of practice of an intern pharmacist shall be to-
- (a) prepare and dispense medicines;
  - (b) participate in ward rounds;
  - (c) prepare various pharmaceutical and technical reports;
  - (d) participate in continuous professional development;
  - (e) participate in provision of drug information and promotion of public health;
  - (f) undertake assignment as directed by the supervisor and be available at the intern centre all time; and
  - (g) comply with rules of work of the intern centre in which he is posted and code of ethics and professional conduct as specified by the Council.

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Scope of practice of a pharmaceutical technician shall be to-

7. Scope of practice of a pharmaceutical technician shall be to-

- (a) provide pharmaceutical services at primary health care facility;
- (b) compound and re-pack pharmaceuticals;
- (c) order, distribute and control pharmaceuticals at health facilities;
- (d) dispense medicines and provide information to clients;
- (e) keep and maintain updated proper records of medicines;
- (f) assists in data collection for research purposes;
- (g) supervise pharmaceutical assistant;
- (h) promote pharmaceuticals and public health; and
- (i) undertake any other duty as determined by the Council.

Scope of practice of a pharmaceutical assistant shall be to-

8. Scope of practice of a pharmaceutical assistant shall be to-

- (a) assist all duties performed by pharmaceutical personnel;
- (b) dispense medicines;
- (c) provide information to clients regarding dispensed medicines; and
- (d) undertake any other duty as determined by the Council.

Key areas of practice

9. The services or acts pertaining to the scope of practice of pharmaceutical personnel shall be provided in the following functional areas:

- (a) clinical pharmacy practice;
- (b) community;
- (c) public health practice;
- (d) pharmaceuticals supply chain management;
- (e) regulation of pharmaceuticals and practice;
- (f) pharmaceutical industrial practice;
- (g) academia, research and developments;
- (h) pharmaceutical consultancy;
- (i) health insurance schemes;
- (j) leadership, health policy, financing, economics and management within the health sector;
- (k) military health services; and
- (l) other areas as the Council may specify.

PART III  
CONDUCT OF BUSINESS OF A PHARMACY

Management  
of pharmacy

10.-(1) A person is qualified to manage a pharmacy if such person is a superintendent who is registered by the Council.

(2) For purpose of ensuring quality of services in a pharmacy, every superintendent shall-

- (a) establish a sound management structure for efficient provision of pharmacy service;
- (b) formulate a mechanism for the owner to follow up and implement on all matters advised by a superintendent on professional and any other matters related to provision of good pharmaceutical services;
- (c) ensure no interference of the owner with the performance on professional matters in the pharmacy;
- (d) manage and undertake all technical, professional matters and ensure pharmaceutical services are provided with due care in the pharmacy;
- (e) ensure name of a pharmacist in charge is displayed conspicuously in the main entrance of a pharmacy and certificate of registration of the superintendent or of some other pharmacist having control of the pharmacy are conspicuously exhibited in the premises;
- (f) ensure adequate competent pharmaceutical personnel and in good standing hired to undertake the provision of pharmaceutical services;
- (g) develop standard operating procedures (SOPs) and protocols for provision of various services within the pharmacy that will allow him to perform both direct and indirect supervision;
- (h) procure pharmaceuticals from credible sources and procedures for recalls and disposal of unfit medicines are in place;
- (i) correct and update records for the purchase, sale, possession, storage, safekeeping of medicines or scheduled substances;
- (j) ensure electronic device for monitoring attendance and functions of other pharmaceutical personnel are available and functional;
- (k) establish a functional and updated computerized systems for sales, purchases, records and

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- pharmacy operations in wholesale pharmacy;
- (l) ensure maintenance and improvements on the requirements, appearance, layout and specifications of a pharmacy;
- (m) display in a conspicuous place, original premises registration certificate, valid pharmacy permit and other relevant permits and licenses;
- (n) ensure pharmaceutical personnel at all time appear in a white coat with a tag displaying their name and designation;
- (o) store controlled drugs, substances and their records in designated places under lock and ensure keys are in his personal possession;
- (p) restrict arrangement of prescription and pharmacy only medicines in a display area;
- (q) ensure cold chain pharmaceuticals are stored in a functional and thermostated refrigerator;
- (r) handle radio pharmaceuticals as prescribed by the national and internationally recognized regulations;
- (s) ensure pharmacy management tools and necessary reference materials as per the standards of good pharmacy practice prescribed by the Council shall be made available at all time for pharmacy operations; and
- (t) ensure that pharmacy operation complies with all relevant legislations, standards and have reference materials.

(3) A superintendent shall be responsible for day to day activities of the pharmacy.

(4) In the event of temporary absence of a superintendent, pharmacy operations shall be under direct supervision of another pharmacist.

(5) In such condition where there is no pharmacist, superintendent shall ensure that services provided in a pharmacy are restricted to the scope of available pharmaceutical personnel.

(6) A superintendent who contravenes the provisions of this regulation commits a professional misconduct and shall be dealt with in accordance with the procedures stipulated in the Act.

(7) For purpose of this regulation, “temporary absence” means an absence of a superintendent for a period exceeding seven days.



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Supervisor of institutional pharmacy and their responsibilities

11.-(1) Every institutional pharmacy shall have a supervisor who is a pharmacist.

(2) A supervisor shall be accountable for day to day activities of the pharmacy and available at all times.

(3) Notwithstanding subregulation (1), an institutional pharmacy which situates within a primary healthcare facility shall be supervised by-

(a) in case of a health centre, a pharmaceutical technician; and

(b) in case of a dispensary, a pharmaceutical assistant.

(4) A person who contravenes the provisions of this regulation commits an offence and shall upon conviction be liable to a fine not less than two million shillings or to imprisonment for a term of not less than six months or both.

Services provision in community pharmacy

12.-(1) A community pharmacy may provide the following services:

(a) management of minor alignments;

(b) processing, preparation and dispensing of medicines to clients;

(c) compound extemporaneous preparations;

(d) counselling and furnishing of information to clients;

(e) aiding in monitoring of Body Mass Index (BMI), blood pressure and blood glucose;

(f) documentation and reporting of Adverse Drug Reactions (ADR);

(g) promotion and implementation of services that are for public health interventions; and

(h) any other health promotions or acts as may be approved by the Council.

(2) A person who contravenes the provisions of this regulation commits an offence and shall upon conviction be liable to a fine not less than three million shillings or to imprisonment for a term of not less than six months or both.

Services provision in wholesale pharmacy

13.-(1) A wholesale pharmacy shall supply or distribute medicine or categorized substances to outlets according to its level of registration and the list of medicines allowed to be stocked in that facility.

(2) In supplying or distributing medicines or categorized substances, a wholesaler shall-

(a) keep records and invoices related to sale of all medicines capturing generic name, brand or manufacturer, batch number, quantity sold and

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- expire date;
- (b) verify credentials of an outlet prior to the sale of medicines;
- (c) furnish information to clients on delivery, recalls procedures, handling of product complains and on the list of medicines available from time to time; and
- (d) provide cooperation to researchers on issues related to pharmaceutical research.

(3) A wholesaler shall not sell medicines to unregistered and unlicensed outlet except those recognized by the Ministry responsible for health or Council in accordance with the Act.

(4) A person who contravenes the provisions of this regulation commits an offence and shall upon conviction be liable to a fine not less than five million shillings or to imprisonment for a term of not less than twelve months or both

Services provision in institutional pharmacy

14.-(1) An institutional pharmacy may provide services stipulated under regulation 12,

Provided that, such services shall be offered basing on the scope of practice of pharmaceutical personnel available in such pharmacy.

(2) A person who contravenes the provisions of this regulation commits an offence and shall upon conviction be liable to a fine not less than one million shillings or to imprisonment for a term of not less than six months or both.

Service provision in consultancy pharmacy

15. A consultancy pharmacy shall provide specialized pharmaceutical services under supervision of a specialty pharmacist recognized by the Council.

Provision of online pharmacy services

16.-(1) Any online pharmacy services shall only be provided by a registered pharmacy and shall comply to the provision of this regulation.

(2) Without prejudice to subregulation (1), a registered pharmacy before commencing online pharmaceutical services shall-

- (a) inform the Council the details and nature of online business;
- (b) have a valid registered domain; and
- (c) comply with the requirements prescribed by the relevant authorities.

(3) In providing online pharmaceutical services, the following standards shall apply-

- (a) online operations shall be under the authority of

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- superintendent;
- (b) homepage shall display the registration number of a pharmacy, name of superintendent, hours of operations, physical address and contacts;
- (c) prescription medicines shall not be displayed on a homepage; and
- (d) handling of prescription shall comply with the provisions of the Act, regulations made under it and a mechanism for verifying the authenticity of prescription shall be in place;

Change of management

17.-(1) A superintendent or owner of a pharmacy who wishes to change management of such pharmacy shall notify the Council immediately by filling in a form set out in the Schedule and submit to the Registrar before the desired change of management.

(2) Without prejudice to subregulation (1), where no other manager is secured, the owner shall-

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- (a) surrender the registration certificate and pharmacy permit;
- (b) comply with recall, handling and disposal of unfit medicines regulations; and
- (c) close the pharmacy immediately.

(3) A person who contravenes the provisions of this regulation commits an offence and shall upon conviction be liable to a fine not less than five million shillings or to imprisonment for a term of not less than twelve months or both.

PART IV  
GENERAL PROVISIONS

Resolution of disputes

18.-(1) Without prejudice to other written laws relating to employment, every owner of a pharmacy shall ensure that all disputes relating to management are amicably resolved within the earliest possible time.

(2) Where a dispute referred to under subregulation (1) has a direct and adverse impact to the services rendered by such pharmacy and that amicable settlement of the dispute may not be reached, the owner or any other person involved in such dispute may seek an intervention of the Registrar.

(3) Registrar shall, where satisfied that the dispute is of such nature that affects the provision of pharmacy services, order the closure of the pharmacy immediately.

Transitional provision

19. Every owner of a pharmacy whose registration was

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obtained before the commencement of these Regulations shall, within six months from the date of commencement of these Regulations, adjust the management, provision of pharmacy and online services so as to comply with the provisions of these Regulations.

Offence and  
penalty

20. A person who contravenes any provisions of Part III of these Regulations for which no other penalty has been prescribed, commits an offence and is liable on conviction to a fine of not less than one million shillings or to imprisonment for a term of not less than six months or both.

Revocation  
GN. No.  
301 of 2012

21. The Pharmacy (Pharmacy Practice) Regulations are hereby revoked.

SCHEDULE

*(Made under regulation 17(1))*

PHARMACY COUNCIL



NOTIFICATION FOR CHANGE OF MANAGEMENT OF A PHARMACY

A. TO BE COMPLETED BY THE SUPERINTENDENT AND OWNER  
*(Part A can be submitted on its own)*

DETAILS OF THE PHARMACY

Name of the pharmacy.....  
Physical address of  
Street.....  
Ward.....  
District/Municipal.....  
Region.....

DETAILS OF CURRENT MANAGER

Name.....  
Registration Number.....  
Phone Number.....  
Address.....

REASON(S) FOR CHANGE

.....  
.....  
.....

TIME FRAME

.....  
.....

Signature.....  
Date.....

OWNER REMARKS

.....  
.....  
.....

Name.....  
Phone Number.....  
Signature.....

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Date.....

FOR OFFICE USE ONLY

INSPECTION/REGISTRATION DEPARTMENT OR ZONAL MANAGER

Recommendations.....

.....

Name.....Designation.....Signature.....Date.....

REGISTRAR OFFICE

Decision by the Registrar.....

Name.....Signature.....Date .....

**B. TO BE COMPLETED BY THE OWNER ONLY**  
*(When submitting Part B, shall be accompanied with Part A)*

NEW MANAGER'S DETAILS

Name of New Manager.....

Physical address of New Manager:

Street.....

Ward.....

District/Municipal.....

Region.....

Contacts of previous Manager.....

Email of previous Manager.....

QUALIFICATION DOCUMENTS OF THE NEW MANAGER (To be attached)

- (i) copies of registration certificate and valid licence to practice
- (ii) curriculum Vitae
- (iii) one passport size photo

REASONS FOR CHANGING THE MANAGEMENT

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LEGAL DOCUMENTS FOR HANDING OVER THE PHARMACY

- (i) Memorandum and Article of Association with a pharmacist (if the owner is not a pharmacist)
- (ii) A copy of certificate of registration from BRELLA
- (iii) A copy of Director(s) ID
- (iv) Memorandum of Understanding (MOU) or Contracts (for Body Corporate)
- (v) proof of payment of current annual fees receipts (pharmacy and manager)

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C. FOR OFFICE USE ONLY

INSPECTION/REGISTRATION OR ZONAL MANAGER

Recommendations.....  
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.....  
Name.....Designation.....Signature.....Date.....

REGISTRAR OFFICE

Decision by the  
Registrar:.....  
Name.....Signature.....Date .....

Dodoma,  
27<sup>th</sup> December, 2019

UMMY A. MWALIMU,  
*Minister for Health, Community  
Development, Gender, Elderly and Children*