

GOVERNMENT NOTICE No. 140 published on 8/2/2019

THE PHARMACY ACT
(CAP.311)

REGULATIONS

(Made under section 52(2))

THE PHARMACY (INSPECTION) REGULATIONS, 2019

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PART I
PRELIMINARY PROVISIONS

Citation 1. These Regulations may be cited as the Pharmacy (Inspection) Regulations, 2019.

Interpretation 2. In these regulations, unless the context requires otherwise:

Cap.311 "Act" means the Pharmacy Act;
"Authorised officer" means a person authorised by the Council to carry out the functions or responsibilities of the Council;
"Council" means the Pharmacy Council established under the Act;
"Pharmaceutical personnel" means a registered pharmacist, enrolled pharmaceutical technician or enlisted pharmaceutical assistant;
"Inspector" has the same meaning as ascribe to it under the Act;
"Pharmacy" means any approved premises wherein or from which any service pertaining to practice of a pharmacist is provided, and shall include community pharmacy, consultant pharmacy, institutional pharmacy, or wholesale pharmacy;
"Premises" includes a land, building, structure, basements and a vessel and in relation to any building includes a part of a building, any cartilage, forecourt or yard, and in relation to a vessel includes a ship, boat, air craft, and a carriage or receptacle of any kind, whether open or closed or place of storage used in connection with any service pertaining to practice of a pharmacist;
"Pharmacy Practice" means any acts pertaining to the scope of practice of a pharmacist, pharmaceutical technician or pharmaceutical assistant as approved by the Council;
"Superintendent" means a pharmacist In-Charge who supervises a pharmacy and is registered as such by the Council under the Act.

PART II
CONDUCT AND STANDARDS OF PRACTICE OF INSPECTORS

Appointment of inspectors 3. The Registrar shall, appoint or authorize a person who has qualifications stipulated under these Regulation to be an inspector.

Qualifications of inspectors

4.-(1) A person shall not be appointed as an inspector unless he possess the following qualifications:

- (a) has sufficient knowledge and skills regarding inspection;
- (b) for the past three years has no record of disciplinary or criminal conviction to a sentence of more than six months.

(2) Notwithstanding the provisions of sub-regulation (1), the Registrar may on the advice of the Council and upon determination of the shortage of inspectors, appoint a pharmaceutical technician, pharmaceutical assistant or authorised officer to be an inspector.

Functions of inspectors

5. Functions of the Inspector shall be as follows:

- (a) enter and inspect any premises at any reasonable time;
- (b) issue directives on areas needing correction;
- (c) order temporary closure of premises pending rectification or Council's directives within specific period of time;
- (d) search article, premises or anything used or purported to be used in conducting or performing business of a pharmacy illegally;
- (e) take evidence by samples, photos or video in the respective premises or matter that is subject of investigation;
- (f) receive complaint or recommendations from the client;
- (g) supervise in person or in collaboration with any other authority, proper disposal of medicine and or medical supplies from closed premises;
- (h) prepare and submit quarterly and annual inspection reports to the Registrar in accordance with the prescribed reporting guidelines issued by the Council or as the Registrar may deem it appropriate for the operation of the Council;
- (i) provide recommendations to the Council on proper implementation of the Act; and
- (j) perform any other duty as may be assigned by the Registrar or the Council.

Powers of the Council

6. The Registrar shall, In respect to inspectors discharging their duties, have powers to:

- (a) monitor and evaluate the performance of every inspector;

- (b) assess the standard of practice and conduct of inspector;
- (c) investigate any allegations regarding the inspector and inspection process;
- (d) suspend or terminate the appointment or authorization of an inspector proven to have breached the provisions of the Act and code of ethics; and
- (e) assign to an inspector any other duty or duties as may deem necessary.

Suspension
and
termination
of
inspectors

7. The inspector may be suspended or terminated due to the following reasons:

- (a) commits a criminal offence and is sentenced to imprisonment for a term of six months or more;
- (b) resigns or terminated from service;
- (c) commits disciplinary offence;
- (d) incapable of discharging his duties as an inspector due to illness or mental disorder or any other factor occasioning his incompetence to perform duties of an inspector; and
- (e) death.

Right to copy
of inspection
findings

8.-(1) The inspector shall, after inspection, furnish the client or his representative with a copy of summary of the inspection findings.

(2) The inspector, a client or his representative shall undersign and date the prescribed inspection form.

(3) Where the client or his representative refuses to sign the inspection form, the inspector shall in writing enter the name of the owner or his representative or premises and reasons for refusal to sign the inspection form:

Provided that the inspector shall cause the written entry to be endorsed by the village executive officer or in the absence, any other local leader or representative of the local government authority.

Confidentiality

9. The inspector shall not, without the consent of the Council or in compliance with the law, divulge any matter or information concerning the Client's business, which shall come to his knowledge in the course of or incidental to discharge of his duties.

Inspectors
Code of

10.-(1) Every inspector in discharging his duties shall abide to inspectors code of ethics and professional conduct

Ethics and Conduct	<p>as prescribed in the First Schedule to these Regulations.</p> <p>(2) A person appointed as an inspector or authorised officer shall not conduct himself in such manner as to put the pharmacy profession or Council reputation into disrepute.</p>
Conflict of interest	<p>11.-(1) The inspector shall refrain from any undertakings that may occasion a conflict of interest with his role as an inspector.</p> <p>(2) Every inspector shall observe respective inspectors Codes of Ethics and Conduct, including making a formal disclosure of any matter that is likely to occasion the conflict of interest.</p> <p>(3) The disclosure referred to under sub-regulation (2) shall be as prescribed in the Second Schedule, and shall be undersigned and dated by every inspector specifying any actual or potential conflict of interest.</p>
Duties and rights of client	<p>12.-(1) A Client shall furnish all necessary information and assist the inspector in the performance of his functions.</p> <p>(2) The client shall have the right to lodge a complaint in writing to the registrar regarding any dissatisfaction with the inspection process.</p> <p>(3) A person who obstructs an inspector from carrying out his functions under these Regulations commits an offence.</p>

PART III

MISCELLANEOUS PROVISIONS

<i>Bona fide</i> acts	<p>13. Notwithstanding the provisions of any other written law, no action or other proceedings shall lie or be instituted against any inspector or officer authorised by the Council for or in respect of any act or thing done or omitted to be done in good faith in the performance of his duties under the Act or these Regulations.</p>
Complaints against conduct of inspectors	<p>14.-(1) A person dissatisfied or aggrieved by the decision of an inspector may, within fourteen days from the date of such decision, lodge a complaint to the Council.</p> <p>(2) The Council shall, within twenty one days of such complaint being made, make determination of the complaint.</p> <p>(3) The Council shall in making decision under sub-</p>

regulation (2) have powers to-

- (a) order further inspection or fresh inspection be conducted in compliance with the procedure for conduct of inspection or in such a manner as the Council may direct;
- (b) reverse or endorse any decision or order made by an inspector; and
- (c) make any orders for or against the inspection report or findings.

Appeals

15. A person aggrieved by the decision of the Council may, within thirty days after receiving the notice of decision of the Council appeal to the Minister.

Offences
and
penalties

16. Any person who violates any provision of these Regulations commits an offence under the Act.

Revocation
GN. No.
300/2012

17. The Pharmacy Practice (Inspectors) Regulations, 2012 is hereby revoked.

FIRST SCHEDULE

PHARMACY COUNCIL



(Made under Regulations 9(2)(b))

Inspectors Code of Ethics and Conduct

The code of ethics and conduct for inspectors details the core principles to be followed by inspectors. These principles cover crucial issues such as conflicts of interest, integrity, confidentiality, objectivity, honesty, good faith and public perception, and are central pillars of inspection process for the entire profession.

The Code sets forth obligations of ethical conduct for the inspectors and provides high ethical standards to safeguard the interest of the public and profession. Inspectors shall comply with this Code, shall avoid association with any enterprise whose practices violate this Code, and shall strive to uphold, maintain, and improve the integrity, reputation, and practice of the inspection profession.

All inspectors shall abide by this Code of Ethics and conduct as stipulated herein:-

- 1. Inspectors shall avoid conflicts of interest or activities that compromise, or appear to compromise professional independence, objectivity or inspection integrity**
 - (a) Inspectors shall not inspect premises in which they have, or expect to have, a financial or affiliation or any other interest.
 - (b) Inspectors shall not receive commission or any form of payment which is not approved by the Council from premises owner or his representative or offer any commissions, rebates, profits or other benefits.
 - (c) Inspectors shall not accept commission, directly or indirectly, for recommending services, or products to clients or other parties having an interest in such premises.
- 2. Inspectors shall act in good faith towards each client and other interested parties.**
 - (a) Inspectors shall at all time perform their duties and responsibilities based on facts, genuine conviction and professional competence.
 - (b) Inspectors shall be objective in reporting and not knowingly understate or overstate the significance of reported conditions.
 - (c) Unless otherwise required by law or with Council approval, Inspectors shall not disclose inspection results or client information. Inspectors, at their discretion, may disclose observed immediate safety hazards to clients and public exposed to such hazards, when feasible.
 - (d) Every inspector shall have the duty of loyalty owed to a client hence prohibited from representing any other party with interests adverse to those of the client or have

differing roles that will prohibit him to act impartially or breach a duty of loyalty.

3. Inspectors shall avoid activities that may harm the public, discredit themselves, or reduce public confidence in the profession.

- (a) Advertising, marketing, and promotion of services or information and qualifications which are fraudulent, false, deceptive, or misleading.
- (b) Inspector shall report substantive and wilful violations of this Code by other inspectors to the Council.
- (c) The inspector shall not discriminate in any business activities on the basis of race, colour, religion, sex, national origin, familial status, or handicap and shall comply with all government laws concerning discrimination.
- (d) The Inspector shall not engage in any act or practice that could be deemed damaging, seditious or destructive to the Council, fellow Inspectors, Council employees, leadership or directors.

4. Duty to Public

- (a) The Inspector shall comply with all government rules and licensing requirements of the jurisdiction while conducting inspection.
- (b) The inspector shall abide by Council's current inspection requirements.

5. Duty to Continue Education

The Inspector shall comply with regular Council training requirements.

6. Duty to the Council and the Profession

- (a) The Inspector shall strive to improve the Inspection profession by sharing his lessons and experiences for the benefit of all.
- (b) The Inspector shall assist the Council in disseminating and publicizing the benefits of Inspection and compliance with inspection directives and guidelines.

7. Disrepute by inspectors

No person appointed as an inspector or authorised officer under the Act shall conduct himself in such manner as to put the profession or Council reputation into disrepute.

8. Application of code of ethics of pharmaceutical personnel

The Relevant provisions of Codes of Ethics and conduct for pharmaceutical personnel shall apply *mutatis mutandis* to the inspectors.

I _____ As an inspector of the Council, DO HEREBY subscribe to adhere to these Code of Ethics and Conduct as aforementioned

Signature

Location/Place

Date

SECOND SCHEDULE

PHARMACY COUNCIL

CONFLICT OF INTEREST DISCLOSURE STATEMENT

(Made under Regulation 15(3))

Registrar,
Pharmacy Council,
P.O. Box 31818,
DAR ES SALAAM.

PART I: Inspector Particulars

1. Full Name
2. Qualifications:.....
3. Professional registration number:.....
4. Contacts: Postal address.....
TelFax.....Email.....
5. Physical address.....
6. Professional registration Status.....
7. Name and Contacts of the Employer, if any.....



PART II: Conflict of Interest disclosure statement

With regard to my voluntary service as of the Pharmacy Council, I have the following potential conflict of interest to report:-

1. I am affiliated to another organization/association namely.....

Note: Affiliated refers to the following: spouse, child, mother, father, brother or sister or close associates; any corporation, business or non-profit organization of which you serve as staff, officer, board member, partner, participate in management or are employed by; any trust or other estate in which you have a substantial interest or as to which you serve as a trustee or in a similar capacity

2. Affiliated to any vendor, supplier, or any other party providing or bidding for providing services, having a direct or indirect interest in any business transaction(s),

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agreement, application, investment with Organization/association.

3. Having any business dealings or transaction with a vendor, supplier, applicant or any other party, which could result in benefit to me
4. I or person(s) I have affiliation which have interest in purchasing services from organization/association.
5. Affiliated person(s) involved is a party to or have an interest in any pending legal proceedings involving
6. Others

Please elaborate on the potential conflict arising from the above situation with regards to the transaction concerned (e.g. nature of service/transaction, if affiliated person involved, the identity of the affiliated person and your relationship with that person):

.....
.....

(For further explanation you may use a separate sheet)

I DO hereby confirm that the disclosure made above are complete and correct to the best of my information and belief. I shall not be participating in the inspection, discussion and decision making of this matter. I agree that if I become aware of any information that might indicate that this disclosure is inaccurate or that I have not complied with the conflict of interest policy, I will notify the Registrar or the Council immediately.

.....

Signature

Name and Designation

Date

Dodoma,
....., 2019

UMMY MWALIMU,
*Minister For Health, Community
Development Gender, Elderly and Children*