

Pharmacy Practice Regulations, 2015

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1. Short Title: Pharmacy Practise Regulations, 2015

Published by PCI on 15th Jan 2015

2. Definitions

A. Practise of Pharmacy:

- Interpretation, Evaluation and implementation of medical orders, dispensing of prescriptions, drug orders
- Dispensing, compounding and administration of drugs
- Participation in drug and device selection and drug related research
- Patient Counselling, Patient care and Pharmaceutical Care



B. Patient Counselling:

- Oral communication by the pharmacist to the patient or caregiver to inform about proper use of drug and drug devices

C. Pharmaceutical Care:

- Patient centred practise in which pharmacists assumes responsibilities for a patients drug related needs and helps in prevention, elimination or reduction of patients symptoms or diseases



D. Pharmacy Practitioner

An individual currently licensed, registered or authorized under the Pharmacy Act to counsel or administer drugs to the patients.

- **Community Pharmacist:** Supply prescription medicines and provides advice and information on people's health
- **Hospital Pharmacist:** Dispensing of drugs to the patients and advise them about medicines.



- **Clinical Pharmacist:** Provides patient care that optimize the use of medication and promotes health, wellness and disease prevention. They work in collaboration with physicians and other healthcare professionals
- **Drug Information Pharmacist:** Provides information and advise regarding drug interactions, side effects, dosage and proper medication storage to patients and other health professionals.
- **Registered Pharmacist:** A person whose name is entered in the register of state pharmacy council



3. Code of Pharmacy Ethics

Displaying name of Owner and Registered Pharmacist

- Name of the registered Pharmacist is displayed at the main entrance of the premises/building
- A registered pharmacist may display his/her name on sign board along with educational qualifications, registration number and photograph.
- The Pharmacists during working times should wear a white clean apron, badge plate consists of Name and Registration Number of Pharmacists.

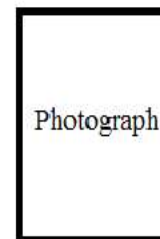


Owner to Appoint Registered Pharmacist

Registered Pharmacist

Name: XYZ (D. Pharm/B. Pharm)

Regist. Number: G1234



Badge with name
and
registration number

XYZ G0123

4. Duties and Responsibilities of the registered Pharmacist in General

4. 1 Character of registered Pharmacist

4.2 Renewal of Registration

4.3 Dispensing against prescription of Registered medical Practitioner only


4.3 Practical Training to student Pharmacist



5. Pharmacy Inspectors to inspect Pharmacies

A. The owner/registered pharmacist shall allow and co-operate with the inspectors appointed under the Drugs & Cosmetics Act, 1940 and section 26A of the Pharmacy Act, 1948 by the State Pharmacy Council to inspect premises where drugs are compounded or dispensed

B. Any Inspector may –

- (i) Inspect any premises where drugs are compounded or dispensed and submit a written report to the Registrar
 - (ii) Enquire whether a person who is engaged in compounding or dispensing of drugs is a registered pharmacist
 - (iii) Investigate any complaint made in writing in respect of any contravention of the Act and report to the Registrar
 - (iv) Institute prosecution under the order of the Executive Committee of the State Pharmacy Council
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6. Maintaining good pharmacy practice

- ✓ Membership in Association
- ✓ Maintenance of patient records
- ✓ Highest Quality Assurance in patient care
- ✓ Exposure of Unethical Conduct
- ✓ Payment of Professional Services

7. Application of other laws not barred

The registered pharmacist shall observe the laws of the country in regulating the practice of pharmacy and shall also not assist others to evade such laws. He shall be cooperative in observance and enforcement of sanitary laws and regulations in the interest of public health.

A registered pharmacist shall have regard to the provisions of the acts like Drugs and

Cosmetics Act, 1940; Indian Medical Council Act, 1956; Narcotic Drugs and Psychotropic

Substances Act, 1985; Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954.

8. DUTIES OF REGISTERED PHARMACISTS TO THEIR PATIENTS

A. Obligations to the Sick:

Pharmaceutical care

- No person other than a Registered Pharmacist shall compound, prepare, mix, dispense or supply of any medicine on the prescription of a Registered Medical Practitioner (Schedule H & X drugs);
- A Registered Pharmacist shall review the patient record and each prescription presented for supply for the purpose of promoting therapeutic appropriateness by indentifying :
 - (i) Over utilization or under utilization
 - (ii) Therapeutic duplication
 - (iii) Drug–disease interactions




- (iv) Drug-drug interactions
- (v) Incorrect drug dosage or duration of drug treatment
- (vi) Drug-allergy interactions
- (vii) Correlation of availability of drugs (to avoid artificial shortage of drugs)
- (viii) Clinical abuse/misuse

Note : upon recognizing any of the above, the Registered Pharmacist include consultation with the Registered Medical Practitioner.

B. Prognosis:

Patient relatives or his responsible friends have such knowledge of the patient's condition as will serve the best interests of the patient and the family.

c. The Patient must not be neglected: A registered pharmacist is free to choose whom he will serve. However, he shall respond to any request for his assistance in an emergency.



9. DUTIES OF REGISTERED PHARMACIST

9.1 Dispensing/Supply of Drugs:

9.2 Pharmacist for promotion of rational drug use:

To promote rational use of drugs, the pharmacist shall involve himself in activities such as:

- (i) Preparation of formularies both at the hospital level and at state/ national levels.
- (ii) Critical assessment of promotional materials prepared by the drug companies.
- (iii) Dissemination of evaluated information through authorized sources.
- (iv) Updating the knowledge of drugs through continuing education programmes and also to organize educational programmes for health professionals.
- v) Preparation and dissemination of patient information leaflets.

9.3 Patient counselling :

a) Elements of patient counselling may include the following :

(i) Name and description of the drugs

(ii) The dosage form, dose, route of administration, and duration of drug therapy

(iii) Intended use of the drug and expected action

(iv) Special directions and precautions for the drug

(v) Common severe side effects or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur

(vi) Techniques for self monitoring drug therapy

(vii) Proper storage of the drugs




- (viii) Prescription refill information
- (ix) Action to be taken in the event of a missed dose
- (x) To ensure rational use of drugs

Note : The pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultations.

- (b) The pharmacist shall maintain the records pertaining to drugs administered to the patients (drug card) that may be utilized for the evaluation of the drug therapy
- (c) The pharmacist is authorized (as a Health care professional) to undertake process and outcome research, health promotion and education and provide health information. Also to undertake the Pharmacoepidemiological studies.

(a) Pharmacies providing patient counseling shall have regard to the following:


- i. Only Registered pharmacists are involved in counseling.
 - ii. Facilities are provided for confidential conversation and patient confidentiality is maintained.
 - iii. Patient information leaflets are provided.
 - iv. Proper documentation is made.
 - v. Unnecessary counseling should be avoided.
 - vi. Counseling for Patient's Benefit: In every consultation, the benefit to the patient is of foremost importance. All registered pharmacists engaged in the case should be frank with the patient and his attendants.
 - vii. Punctuality in counseling: Utmost punctuality should be observed by a registered pharmacist in making themselves available for counseling.
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10. RESPONSIBILITIES OF REGISTERED PHARMACISTS TO EACH OTHER.

A registered pharmacist shall consider it as a pleasure and privilege to render gratuitous service to all registered pharmacists and their immediate family dependents.

Conduct in Counselling: In counselling, no insincerity, rivalry or envy shall be indulged in.

Appointment of Substitute: Whenever a registered pharmacist requests another registered pharmacist to attend his patients during his temporary absence from his practice, professional courtesy requires the acceptance of such appointment only when he has the capacity to discharge the additional responsibility along with his other duties.



11. DUTIES OF REGISTERED PHARMACIST TO THE PUBLIC AND TO THE PROFESSION



Registered
Pharmacists
as Citizens

Public and
Community
Health

Physician/
Nurses

12. UNETHICAL ACTS :

**Rebates and
Commission**

Advertising

**Human
Rights**

**Secret
Remedies**

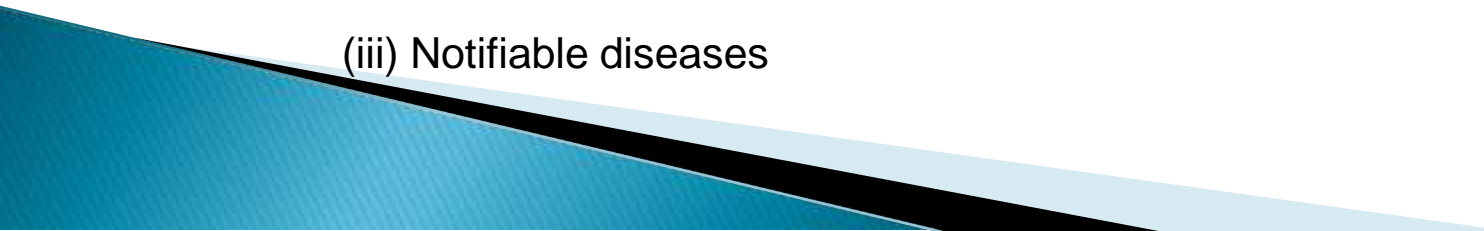
13. MISCONDUCT


The following acts of commission or omission on the part of a registered pharmacist shall constitute professional misconduct rendering him/her liable for disciplinary action.

- (a) Violation of the regulations framed under the Act
- (b) Dispensing medicines without the prescription of the Registered Medical Practitioner
- (c) Substitution of the prescription without approval/consent of the Registered Medical Practitioner.
- (d) Allowing the owner of the pharmacy to use his pharmacist registration certificate without attending the pharmacy
- (e) Giving his pharmacist registration certificate at more than one pharmacies.
- (f) Not maintaining the prescription/dispensing records of his patients for a period of five years




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- (g) Not displaying the registration certificate
 - (h) Willfully obstructing an inspector for inspecting/enquiring/investigating.
 - (i) Committing adultery or improper conduct with a patient
 - (j) Conviction by a Court of Law for offences involving moral turpitude/Criminal acts.
 - (k) Signing Professional Certificates, Reports and other Documents:
 - (l) Issuing of certificates of efficiency in modern medicine to unqualified person.
 - (J)Contributing to the lay press articles and giving interviews regarding diseases and treatments which may have the effect of advertising himself or soliciting practices
 - (n) Disclosing the secrets of a patient that have been learnt in the exercise of his profession except –
 - (i) in a court of law under orders of the presiding judicial officer
 - (ii) in circumstances where there is a serious and identified risk to a specific person and /or community;
and
 - (iii) Notifiable diseases
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- (o) Refusing on religious grounds alone to dispense medicines on the prescription of Registered Medical Practitioner.
 - (p) Publishing photographs or case reports of his patients without their permission
 - (q) In the case of running of pharmacy by a registered pharmacist and employing Registered Pharmacists to help him, the ultimate responsibility rests on the registered pharmacist.
 - (r) Using touts or agents for procuring patients.
 - (s) Claiming himself to be specialist.
 - (t) If a registered pharmacist posted in rural area is found absent on more than two occasions during inspection by the Head of the District Health Authority or the Chairman, Zila Parishad without information, the same shall be construed as a misconduct .
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14. PUNISHMENT AND DISCIPLINARY ACTION

- a) Any complaint with regard to professional misconduct can be brought before the Pharmacy Council of India/concerned State Pharmacy Council for disciplinary action.
 - b) In case the punishment of removal from the register is for a limited period, the concerned State Pharmacy Council may also direct that the name so removed shall be restored in the register after the expiry of the period for which the name was ordered to be removed.
 - c) Decision on complaint against delinquent registered pharmacist shall be taken within a time limit of 6 months.
 - d) During the pendency of the complaint the concerned State Pharmacy Council may restrain the registered pharmacist from performing the procedure or practice which is under scrutiny.
 - e) Professional incompetence shall be judged by peer group as per guidelines prescribed by Pharmacy Council of India.
 - f) For willful obstruction of an inspector appointed under the Drugs & Cosmetics Act, 1940 and Pharmacy Act, 1948, offence is punishable as provided under the respective Acts
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FORMAT FOR PRESCRIPTION RECORD[Regulation 6.2]

☐Name of the patient :

☐Age :

☐Sex :

☐Address :

☐Occupation :

☐Date of 1st visit :

☐Diagnosis :

☐Prescription :

☐Follow up

☐Date:

☐Observations:

☐Signature in full

☐Name of Registered pharmacist
and registration No.

Duties and Responsibilities of Pharmacist at Hospital Pharmacy practice site:

Duties & responsibilities	Percentage of time
❖ Dispense medicines to patients on the prescription of the registered Medical practitioner	35
❖ Provide counseling and health education to the patient	10
❖ Assist in the management of pharmacy department	10
❖ Maintain records of ADR	5
❖ Provide pharmaceutical services to the inpatients	5
❖ Formulate extemporaneous preparation and specialized products	5
❖ Discuss with clinician/health professional to provide better patient care.	5
❖ Conduct prescription surveys and propose changes on the Essential Drug List	5
❖ Attend emergency duty as and when required	5
❖ Indent and check the drugs and non-drugs.	5
❖ Maintain records of the equipments and other supplies of the unit.	5
❖ Documentation of records and literature	5

Duties and Responsibilities of Senior Pharmacist at Hospital Pharmacy practice site:

Duties & responsibilities	Percentage of time
❖ Develop plans on pharmaceutical supplies and mobilize necessary funds.	15
❖ Plan and coordinate the departmental activities.	15
❖ Manage pharmaceutical services at a hospital	10
❖ Monitor and provide supervision to the staff including student trainees	10
❖ Supervise and monitor the ADR of inpatients.	10
❖ Participate in educational and research programs.	10
❖ Conduct the Antibiotic Resistance studies.	10
❖ Go ward round and Provide inpatient pharmaceutical services.	10
❖ Interact with the specialist and prescribing clinicians to discuss on pharmacotherapeutics.	05
❖ Provide continuing education and assist superiors.	05
❖ Supervise and train subordinates (Pharmacists and pharmacy technician and other health workers)	20

Duties and Responsibilities of Chief Pharmacist at Hospital Pharmacy practice site:

Duties & responsibilities	Percentage of time
❖ Coordinate planning and implementation of relevant activities including mobilization of resources.	40
❖ Conduct research activities and facilitates international networking.	20
❖ Conduct supervision and training for subordinates and health workers.	15
❖ Manage the pharmacy department of a hospital	10
❖ Monitor and evaluates relevant activities.	10
❖ Carry out any other duties assigned by superiors.	05

Job responsibilities of Community Pharmacist at community Pharmacy practice site

Work activities include

- ❖ Dispensing prescription medicines to the public;
- ❖ Ensuring that different treatments are compatible;
- ❖ Checking dosage and ensuring that medicines are correctly and safely supplied and labelled (pharmacists are legally responsible for any dispensing errors);
- ❖ Supervising the preparation of any medicines (not all are supplied ready made-up by the manufacturer);
- ❖ Keeping a register of controlled drugs for legal and stock control purposes;
- ❖ Liaising with doctors about prescriptions;
- ❖ Selling over-the-counter medicines;
- ❖ Counseling and advising the public on the treatment of minor ailments;
- ❖ Advising patients of any adverse side-effects of medicines or potential interactions with other medicines/treatments;

Work activities include

- ❖ Preparing dosette and cassette boxes, usually for the elderly but also for those with memory/learning difficulties, Where tablets are placed in compartments for specified days of the week;
- ❖ Undertaking Medicine Use Reviews (MUR), an advanced service to help patients understand how their medicines work and why they have to take them;
- ❖ Providing a prescription intervention service;
- ❖ Managing a needle and syringe exchange;
- ❖ Dispensing emergency hormonal contraception;
- ❖ Measuring and fitting compression hosiery;
- ❖ Monitoring blood pressure and cholesterol levels;
- ❖ Offering a diabetes screening service;
- ❖ Providing pregnancy testing;

Work activities include

- ❖ Arranging the delivery of prescription medicines to patients;
- ❖ Overseeing the ordering and safe storage of medical products;
- ❖ Maintaining computerized records;
- ❖ Managing, supervising and training pharmacy support staff;
- ❖ Selling healthcare and other products, such as toiletries, cosmetics and photographic items;
- ❖ Budgeting and financial management;
- ❖ Promoting sales and developing the business;
- ❖ Keeping up to date with current pharmacy practice, new drugs and their uses.

T H A N K Y O U

