

The Pharmacy Practice Regulations, 2015

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The Pharmacy Practice Regulations, 2015¹

In exercise of the powers conferred by Sections 10 and 18 of the Pharmacy Act, 1948 (8 of 1948), the Pharmacy Council of India, with the approval of the Central Government hereby makes the following regulations, namely—

CHAPTER 1

1. Short title and commencement.—(a) These regulations may be called the Pharmacy Practice Regulations, 2015.

(b) They shall come into force from the date of their publication in the Official Gazette.

2. Definitions:

(a) “Act” means the Pharmacy Act, 1948 (8 of 1948).

(b) “Practice of Pharmacy” means—

- i. Interpretation, evaluation and implementation of medical orders, dispensing of prescriptions, drug orders;
- ii. Participation in drug and device selection, drug administration, drug regimen reviews and drug or drug related research,
- iii. Provisions of patient counselling and the provision of those acts or services necessary to provide pharmaceutical care in all areas of patient care including primary care; and
- iv. responsibility for Compounding and labelling of drugs and devices (except labelling by a manufacturer, re-packer or distributor of non-prescription drugs and commercially packaged legend drugs and devices) proper and safe storage of drugs and devices and maintenance of proper records for them.

(c) “Compounding” means the preparation, mixing, assembling, packing or labelling of a drug or device—

- (i) as the result of a practitioner’s prescription drug order (or) initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice, or
- (ii) for the purpose of, or as an incident to research, manufacturing, teaching, clinical trial or chemical analysis including drug analysis and not for sale or dispensing.

Note.—Compounding also includes the preparation of drugs or devices in anticipation of prescription, observed prescribing patterns.

(d) “Dispensing” means the interpretation, evaluation, supply and implementation of a prescription, drug order, including the preparation and delivery of a drug or device to a patient or patient’s agent in a suitable

1. Pharmacy Council of India (Pharmacy Practice Regulations, 2015), Noti. No. 14-148/2012-PCI, dated January 15, 2015, published in the Gazette of India, Extra., Part III, Section 4, dated 16th January, 2015, pp. 27-52, No. 17.

container appropriately labelled for subsequent administration to, or use by, a patient.

- (e) “Distribute” means the delivery of a drug or device other than by administering or dispensing.
- (f) “Patient counselling” means the oral communication by the pharmacist of information to the patient or caregiver, in order to ensure proper use of drugs and devices.
- (g) “Pharmaceutical care” means the provision of drug therapy and other patient care services intended to achieve outcomes related to the care or prevention of a disease, elimination or reduction of a patient’s symptoms, or arresting or slowing of a disease process, as defined by the Pharmacy Council of India.
- (h) “Pharmacy Practitioner” means an individual (Community Pharmacist/Hospital Pharmacist/Clinical Pharmacist/Drug information Pharmacist) currently licensed, registered or otherwise authorised under the Act to counsel or otherwise and administer drugs in the course of professional practice.
 - i. “Community pharmacist” means an individual currently registered and who works according to legal and ethical guidelines to ensure the correct and safe supply of medical products to the general public. They are involved in maintaining and improving people’s health by providing advice and information as well as supplying prescription medicines.
 - ii. “Hospital Pharmacist” means an individual currently registered and who works in a hospital pharmacy service, primarily within the public/private sector. They are responsible for ensuring the safe, appropriate and cost-effective use of medicines. Hospital pharmacists use their specialist knowledge to dispense drugs and advise patients about the medicines which have been prescribed. They work collaboratively with other health care professionals to devise the most appropriate drug treatment for patients. Some pharmacists are also involved in manufacturing required drug treatments.
 - iii. “Drug Information Pharmacist” means an individual currently registered who works in a community pharmacy/hospital Pharmacy/teaching hospital/other health care settings and provides information and advice regarding drug interactions, side effects, dosage and proper medication storage to patients/physicians/dentists/other health care professionals.
 - iv. “Clinical Pharmacist” means an individual currently registered and who provides patient care that optimizes the use of medication and promotes health, wellness and disease prevention. Clinical pharmacists care for patients in all health care settings.

Clinical pharmacists often collaborate with physicians and other healthcare professionals.

- (i) “Registered Pharmacist” means a person whose name is for the time being entered in the register of the State in which he is for the time being residing or carrying on his profession or business of pharmacy under the Pharmacy Act, 1948.
- (j) “Prescription” means a written or electronic direction from a Registered Medical Practitioner or other properly licensed practitioners such as Dentist, Veterinarian, etc. to a Pharmacist to compound and dispense a specific type and quantity of preparation or prefabricated drug to a patient.

Note.—Types of prescriptions and content of prescription are given below—

Types of Prescription:

- (i) Prescription for Extemporaneous preparations.
- (ii) Prescription for Official preparations.
- (iii) Prescription for Patent preparations

Contents of the Prescription:

- (i) *Prescribers office information*—[Name, qualification, address and Regn. No.]
- (ii) *Patient information*—[Name and address, Age, Sex, Ref. No.]
- (iii) Date
- (iv) Rx Symbol or superscription
- (v) Medication prescribed or inscription
- (vi) Dispensing directions to Pharmacist (or) subscription
- (vii) Directions for patient [to be placed on label]
- (viii) Refill, special labelling and/or other instructions
- (ix) Prescriber’s signature and licence (or) Drug Enforcement Agency (DEA) number as required.

CHAPTER 2

3. Code of Pharmacy Ethics:

- 3.1 *Declaration.*—Each applicant, at the time of making an application for registration under the provisions of the Act, shall be provided a copy of the declaration as specified in Appendix I along with copies of Code of Pharmaceutical Ethics and Pharmacist’s oath by the state pharmacy council, who shall submit it duly signed.
- 3.2 *Privileges of persons registered as a pharmacist on the register of State Pharmacy Council.*—Subject to the conditions and restrictions laid down in these regulations regarding practice of profession of pharmacy by persons possessing approved pharmacy qualifications, every person whose name is for the time being entered in the register of the state in which he is for the time being residing or carrying on his profession or business of pharmacy shall be entitled to practice as “registered

pharmacist” and engage in the practice of profession of pharmacy and to recover in due course of law in respect of such practice of pharmacy any expenses, charges or any fee to which he/she is entitled in lieu of his/her discharging duties as defined by the PCI from time to time.

3.3 *Displaying name of owner and registered pharmacist:*

- (a) Name of the owner of pharmacy business shall be displayed at or near the main entrance of each premises in which the business is carried on.
- (b) Name of the registered pharmacist along with his registration number and qualification along with his/her photograph shall be displayed adjacent to the area where dispensing is carried on in the pharmacy. Registered Pharmacist shall also comply with a dress code of being dressed formally and wearing clean white overall (coat/apron) with a badge displaying the name and registration number.
- (c) Registered Pharmacists shall display as suffix to their names only recognized pharmacy qualification/degrees or such certificates/diplomas and memberships/honours which confer professional knowledge or recognizes any exemplary qualification/achievements.

3.4 *Owner to appoint registered pharmacist:*

- (a) The owner of a pharmacy business to which this clause applies shall appoint a registered pharmacist to be responsible for Regulations 3.3. There must be such an appointment in force at all times; otherwise the owner of the pharmacy business shall be deemed contravening the provisions of Section 42 of the Act.
- (b) To be effective the notice of appointment must be accompanied by a notice of acceptance of the appointment signed by the appointed person.
- (c) An appointment may be revoked by notice given either by the owner of the pharmacy business or by or on behalf of the appointed person. The appointment shall be automatically revoked if the person appointed ceases to be a registered pharmacist.

4. Duties and responsibilities of the registered pharmacist in general:

4.1 *Character of registered pharmacist:*

- (a) The prime object of the pharmacy profession is to render service to humanity; reward or financial gain is a subordinate consideration. Whosoever chooses his profession, assumes the obligation to conduct himself in accordance with its ideals. A registered pharmacist should be an upright man, instructed in the art of medicines. He shall keep himself pure in character and be diligent in caring for the sick; he should be modest,

sober, patient, prompt in discharging his duty without anxiety; conducting himself with propriety in his profession and in all the actions of his life.

- (b) A person having qualification in any other system of pharmacy is not allowed to practice modern system of pharmacy in any form.
- (c) A registered pharmacist shall uphold the dignity and honour of his profession.

4.2 *Renewal of Registration.*—For renewal of registration the pharmacist shall attend minimum 2 refresher courses in pharmacy of minimum one day duration each in a span of 5 years organized by any one of the following body.

- (i) Pharmacy Council of India.
- (ii) State Pharmacy Councils.
- (iii) Central Government/State Governments.
- (iv) Professional bodies recognized by the Council.

4.3 *Dispensing against prescription of Registered Medical Practitioner only.*—Every registered pharmacist shall dispense only those medicines as prescribed by the Registered Medical Practitioner and shall not substitute the prescription.

4.4 *Practical training to student pharmacists:*

- (a) The owner of the pharmacy shall seek prior approval of the PCI for approval of the pharmacy for the purpose of imparting practical teaching to student of Diploma in Pharmacy. In the absence of approval from the PCI, the student pharmacists shall not be treated to have completed their Diploma in Pharmacy (Part III) to make them eligible for registration as a pharmacist under the Act.
- (b) The registered pharmacist shall impart practical training to student pharmacists as prescribed from time to time under Education Regulations framed under Section 10 of the Act under intimation to the examining authority.
- (c) While imparting such practical training, the registered pharmacists shall comply with the prescribed norms relating to number of students pharmacists to be trained, nature of practical training, duration of practical etc. as laid down under the Education Regulations from time to time.

5. Pharmacy Inspectors to inspect pharmacies.—(a) The owner/registered pharmacist shall allow and co-operate with the inspectors appointed under the Drugs and Cosmetics Act, 1940 and Section 26-A 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;
- (v) exercise such other powers as may be necessary for carrying out the purposes of Chapters III, IV and V of the Pharmacy Act or any rules made thereunder.

6. Maintaining good pharmacy practice:

- 6.1 *Membership in Association:* For the advancement of his profession, a registered pharmacist shall affiliate with associations and societies of allopathic pharmacy professions and involve actively in the functioning of such bodies. A registered pharmacist shall participate in professional meetings as part of Continuing Pharmacy Education programmes, organized by reputed professional academic bodies or any other authorised associations/organisations. The compliance of this requirement shall be informed regularly to Pharmacy Council of India or the State Pharmacy Councils as the case may be.
- 6.2 *Maintenance of patient records:*
 - (a) Every registered pharmacist shall maintain the medical/prescription records pertaining to his/her patients for a period of 5 years from the date of commencement of the treatment as laid down by the Pharmacy Council of India in Appendix II.
 - (b) If any request is made for medical records either by the patients/authorised attendant or legal authorities involved, the same may be duly acknowledged and documents shall be issued within the period of 72 hours.
 - (c) Efforts shall be made to computerize medical/prescription records for quick retrieval.
- 6.3 *Highest Quality Assurance in patient care.*—Every registered pharmacist shall aid in safeguarding the profession against admission to it of those who are deficient in moral character or education. Registered pharmacist shall not employ in connection with his professional practice any attendant who is neither registered nor enlisted under the Pharmacy Act in force and shall not permit such persons to attend, to patients wherever professional discretion or skill is required.
- 6.4 *Exposure of Unethical Conduct.*—A registered pharmacist should expose, without fear or favour, incompetent or corrupt, dishonest or unethical conduct on the part of members of the profession.
- 6.5 *Payment of Professional Services.*—The registered pharmacist, engaged in the practice of pharmacy profession shall give priority to the interests

of patients. The personal financial interests of a registered pharmacist shall not conflict with the medical interests of patients. A registered pharmacist shall announce his fees before rendering service and not after. Remuneration received for such services shall be in the form and amount specifically announced to the patient at the time the service is rendered. It is unethical to enter into a contract of “no cure no payment”. Registered Pharmacist rendering service on behalf of the state shall refrain from anticipating or accepting any consideration.

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.

CHAPTER 3

8. Duties of registered pharmacists to their patients:

8.1 *Obligations to the Sick:*

- (a) Though a registered pharmacist is not bound to attend each and every person asking his services, he shall not only be ever ready to respond to the calls of the sick and the injured, but shall be mindful of the high character of his mission and the responsibility he discharges in the course of his professional duties. He shall never forget that the health and the lives of those entrusted to his care depend on his skill and attention.
- (b) Registered pharmacist having any incapacity detrimental to the patient or which can affect his performance vis-à-vis the patient shall not be permitted to practice his profession.
- (c) Pharmaceutical care (in addition to the provisions of Drugs and Cosmetics Rules, 1945 and Schedule N of the said rules) the following provisions shall be included—
 - 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 identifying—
 - (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 shall take appropriate steps to avoid or resolve the problem that shall, if necessary, include consultation with the Registered Medical Practitioner.

- 8.2 *Patience, Delicacy and Secrecy:* Patience and delicacy shall characterize the registered pharmacist. Confidences concerning individual or domestic life entrusted by patients to a registered pharmacist and defects in the disposition or character of patients observed during medical attendance shall never be revealed unless their revelation is required by the laws of the State. Sometimes, however, a registered pharmacist shall determine whether his duty to society requires him to employ knowledge, obtained through confidence as a registered pharmacist, to protect a healthy person against a communicable disease to which he is about to be exposed. In such instance, the registered pharmacist shall act as he would wish another to act toward one of his own family in like circumstances.
- 8.3 *Prognosis:* The registered pharmacist shall neither exaggerate nor minimize the gravity of a patient's condition. He shall ensure himself that the patient, his 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.
- 8.4 *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. Registered Pharmacist shall not wilfully commit an act of negligence that may deprive his patient or patients from necessary medical care.

CHAPTER 4

9. Duties of registered pharmacist:

9.1 *Dispensing/Supply of Drugs:*

- (a) The various activities of dispensing (prescription assembly) like removal of drugs from the packing, filling the prescription etc. may be performed under the supervision of a registered pharmacist by any person who has been trained to perform these activities. However, the actual dispensing of drugs to patients shall only be performed by the registered pharmacist after due verification of the prescription filled by others.
- (b) A registered pharmacist shall undertake a pharmaceutical assessment of every prescription presented for dispensing. For the purpose of the act, pharmaceutical assessment is defined as

the point at which registered pharmacist applies his knowledge to establish the safety, quality, efficacy and rational use of drugs treatments specified by a prescriber.

- (c) Patient confidentiality shall be maintained at all times.
- (d) Appropriate information shall be provided to the patient or the care giver and, where possible, understanding of this information should be checked.
- (e) For all prescriptions handled by the pharmacy—
 - (i) Patient details shall be checked and confirmed;
 - (ii) Pharmaceutical assessment shall be made;
 - (iii) Proper documentation shall be maintained.
- (f) Assessment of the prescription should include but not be limited to assessment of whether—
 - (i) The prescription is legally valid.
 - (ii) The prescription includes an appropriate dosage form and appropriate route of administration.
 - (iii) Prescription is appropriate to the patient's condition.
 - (iv) Duration of treatment is correct.
 - (v) Prescription is appropriate according to patient's parameters (age, weight etc.) and previous medication.
 - (vi) Prescription is compatible with other medications.
 - (vii) Prescription is consistent with formulary and guidelines, if any.
 - (viii) Possibility of side effects and adverse drug reactions exist.
 - (ix) Contra-indicated.
 - (x) Potential for misuse and inappropriate use of the medicines in prescription by patient exists.
 - (xi) Prescription is complying with labelling requirements.
- (g) Compounding, dispensing and labelling of required drug products should ensure that—
 - (i) The drug product matches the prescription.
 - (ii) The drug product has not expired.
 - (iii) The drug product is appropriately compounded (if necessary), packed and labelled appropriately.
 - (iv) The accuracy of dispensing is checked by registered pharmacist.
 - (v) Proper documentation is made.
- (h) Delivery of the drug product to the patient/carer is done in such a way as to ensure that—
 - (i) The registered pharmacist hands over the drug to the patient/carer.
 - (ii) Appropriate information on drugs is provided to the patient/carer.



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 authorised 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) Upon receipt of a prescription (prescription drug order) and following a review of the patient's record, a registered pharmacist shall personally initiate discussion of matters that will enhance or optimize drug therapy with each patient or care given of such patient. Such discussion shall be in person, whenever practicable or by telephone and shall include appropriate elements of patient counselling. Such elements 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 contra indications 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 authorised (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.

- (d) Pharmacies providing patient counselling shall have regard to the following—
- i. Only registered pharmacists are involved in counselling.
 - 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 counselling should be avoided.
 - vi. *Counselling 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 counselling*: Utmost punctuality should be observed by a registered pharmacist in making themselves available for counselling.

CHAPTER 5

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 dependants.

- 10.1 *Conduct in Counselling*: In counselling, no insincerity, rivalry or envy shall be indulged in. All due respect shall be observed towards the registered pharmacist in-charge of the case and no statement or remark be made, which would impair the confidence reposed in him. For this purpose no discussion shall be carried on in the presence of the patient or his representatives.
- 10.2 *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. The registered pharmacist acting under such an appointment shall give the utmost consideration to the interests and reputation of the absent registered pharmacist and all such patients shall be restored to the care of the latter upon his return.

CHAPTER 6

11. Duties of registered pharmacist to the Public and to the Profession:

- 11.1 *Registered pharmacists as citizens*: Registered pharmacists, as good citizens, possessed of special training shall disseminate advice on public health issues. They should play their part in enforcing the laws of the community and in sustaining the institutions that advance the interests of humanity. They shall particularly co-operate with the authorities in the administration of sanitary/public health laws and regulations.

- 11.2 *Public and Community Health:* Registered Pharmacists, especially those engaged in public health work, shall enlighten the public concerning quarantine regulations and measures for the prevention of epidemic and communicable diseases. At all times the registered pharmacist shall notify the constituted public health authorities of every case of communicable disease under his care, in accordance with the laws, rules and regulations of the health authorities. When an epidemic occurs a registered pharmacist shall not abandon his duty for fear of contracting the disease himself.
- 11.3 *Physician/Nurses:* Registered Pharmacists shall seek cooperation from physicians, dentists and nurses wherever required.

CHAPTER 7

12. Unethical Acts.—A registered pharmacist shall not aid or abet or commit any of the following acts which shall be construed as unethical—

12.1 *Advertising:*

- (a) Soliciting of patients directly or indirectly, by a registered pharmacist, by a group of registered pharmacists or by institutions or organisations is unethical. A registered pharmacist shall not make use of him (or his name) as subject of any form or manner of advertising or publicity through any mode either alone or in conjunction with others which is of such a character as to invite attention to him or to his professional position, skill, qualification, achievements, attainments, specialities, appointments, associations, affiliations or honours and/or of such character as would ordinarily result in his self-aggrandizement. A registered pharmacist shall not give to any person, whether for compensation or otherwise, any approval, recommendation, endorsement, certificate, report or statement with respect of any drug, medicine, nostrum remedy, surgical, or therapeutic article, apparatus or appliance or any commercial product or article with respect of any property, quality or use thereof or any test, demonstration or trial thereof, for use in connection with his name, signature, or photograph in any form or manner of advertising through any mode nor shall he boast of cases, cures or remedies or permit the publication of report thereof through any mode. A registered pharmacist, however, shall be permitted to make a formal announcement in press regarding the following—

- i. on starting practice;
 - ii. on changing address.
- (b) Printing of self-photograph, or any such material of publicity in the letter head or on sign board of the Pharmacy or any such establishment shall be regarded as acts of self-advertisement

and unethical conduct on the part of the registered pharmacist. However, printing of sketches, diagrams, picture of medicines shall not be treated as unethical.

- 12.2 *Rebates and Commission.*—A registered pharmacist/Pharmacy shall not give, solicit, or receive nor shall he offer to give solicit or receive, any gift, gratuity, commission or bonus in consideration of or return for the referring, recommending or procuring of any patient for sale/dispensing of medicines. A registered pharmacist shall not directly or indirectly, participate in or be a party to act of division, transference, assignment, subordination, rebating, splitting or refunding of any fee for dispensing/sale of medicines.
- 12.3 *Secret Remedies:* The prescribing or dispensing by a registered pharmacist of secret remedial agents of which he does not know the composition, or the manufacture or promotion of their use is unethical and as such prohibited. All the drugs dispensed by a registered pharmacist shall carry a proprietary formula and clear name.
- 12.4 *Human Rights:* The registered pharmacist shall not aid or abet torture nor shall he be a party to either infliction of mental or physical trauma or concealment of torture inflicted by some other person or agency in clear violation of human rights.

CHAPTER 8

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 which are required to be dispensed on prescription only.
- (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 as per Regulation 6.2-a and refuses to provide the same within 72 hours when the patient or his authorised representative makes a request for it.
- (g) Not displaying the registration certificate accorded to him by the State Pharmacy Council in his pharmacy.
- (h) Wilfully obstructing an inspector appointed under the Drugs and Cosmetics Act, 1940 and/or Pharmacy Act, 1948 for inspecting/enquiring/investigating.

- (i) Committing adultery or improper conduct with a patient or by maintaining an improper association with a patient abusing his professional position. This will render a registered pharmacist liable for disciplinary action as provided under Section 36 of the Pharmacy Act, 1948.
- (j) Conviction by a Court of Law for offences involving moral turpitude/ Criminal acts.
- (k) *Signing Professional Certificates, Reports and other Documents:* Registered Pharmacist may be in certain cases bound by law to give, or may from time to time be called upon or requested to give certificates, notification, reports and other documents of similar character signed by them in their professional capacity for subsequent use in the courts or for administrative purposes etc. Any registered pharmacist who is shown to have signed or given under his name and authority any such certificate, notification, report or document of a similar character which is untrue, misleading or improper.
- (l) Issuing of certificates of efficiency in modern medicine to unqualified person.
(*Note.*—The foregoing does not restrict the proper training and instruction of bona fide student pharmacists under the personal supervision of registered pharmacists.)
- (m) Contributing to the lay press articles and giving interviews regarding diseases and treatments which may have the effect of advertising himself or soliciting practices; but is open to write to the lay press under his own name on matters of public health, hygienic living or to deliver public lectures, give talks on the radio/TV/internet chat for the same purpose and send announcement of the same to lay press.
- (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.
- (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, in any medical or other journal in a manner by which their identity could be made out. However, if the identity is not to be disclosed, the consent is not needed.
- (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.
- (u) If a registered pharmacist working in pharmacy is also found working in another pharmacy/pharmacy college/institution/industry/any other organization as a teaching faculty or otherwise, shall be construed as misconduct.

CHAPTER 9

14. Punishment and disciplinary action.—(a) It must be clearly understood that the instances of offences and of professional misconduct which are given above do not constitute and are not intended to constitute a complete list of the infamous acts which calls for disciplinary action, and that by issuing this notice the Pharmacy Council of India and or State Pharmacy Councils are in no way precluded from considering and dealing with any other form of professional misconduct on the part of a registered pharmacist. Circumstances may and do arise from time to time in relation to which there may occur questions of professional misconduct which do not come within any of these categories. Every care should be taken that the code is not violated in letter or spirit. In such instances as in all others, the Pharmacy Council of India and/or State Pharmacy Councils have to consider and decide upon the facts brought before the Pharmacy Council of India and/or State Pharmacy Councils.

(b) Any complaint with regard to professional misconduct can be brought before the Pharmacy Council of India/concerned State Pharmacy Council for disciplinary action. Upon receipt of any complaint of professional misconduct, the Pharmacy Council of India/concerned State Pharmacy Council would hold an enquiry and give opportunity to the registered pharmacist to be heard in person or by pleader. If the registered pharmacist is found to be guilty of committing professional misconduct, the Pharmacy Council of India/concerned State Pharmacy Council may award such punishment as deemed necessary or may direct the removal altogether or for a specified period, from the register of the name of the delinquent registered practitioner. Deletion from the register shall be widely publicized in local press as well as in the publications of different Pharmacy Associations/Societies/Bodies.

(c) 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.

(d) Decision on complaint against delinquent registered pharmacist shall be taken within a time limit of 6 months.

(e) 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.

(f) Professional incompetence shall be judged by peer group as per guidelines prescribed by Pharmacy Council of India.

(g) For wilful obstruction of an inspector appointed under the Drugs and Cosmetics Act, 1940 and Pharmacy Act, 1948, offence is punishable as provided under the respective Acts.

APPENDIX I

Declaration

(See Regulation 3.1)

(To be submitted at the time of application to the state pharmacy council for registration of name in the register of pharmacists)

1. I solemnly pledge myself to consecrate my life to service of humanity.
2. Even under threat, I will not use my pharmacy knowledge contrary to the laws of Humanity.
3. I will maintain the utmost respect for human life from the time of conception.
4. I will not permit considerations of religion, nationality, race, party politics or social standing to intervene between my duty and my patient.
5. I will practice my profession with conscience and dignity.
6. The health of my patient will be my first consideration.
7. I will respect the secrets which are confined in me.
8. I will give to my teachers the respect and gratitude which is their due.
9. I will maintain by all means in my power, the honour and noble traditions of pharmacy profession.
10. I will treat my colleagues with all respect and dignity.
11. I shall abide by the code of ethics as laid down by the Pharmacy Council of India.

I certify that I have read and agree to abide by the declarations made above.

I make these promises solemnly, freely and upon my honour.

Signature

Name

Place

Address:
.....

Date.....

APPENDIX II

Format for Prescription Record

[See 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.

APPENDIX III

Details of Position Title and job responsibilities of Pharmacist at Hospital Pharmacy practice site:

1. JOB IDENTIFICATION:

1.1 *Position Title:* Pharmacist

1.2 *Job Location (As appropriate):*

Ministry: Health;

Department: Medical Services;

Division: Health Care and Diagnostic Services;

Section: Pharmaceutical Services;

Unit: Hospital Pharmacy/dispensary/Warehouse

1.3 *Title of First Level Supervisor (Official title of the Supervisor):* Dy. Chief/Sr. Pharmacist

2. PURPOSE, DUTIES AND RESPONSIBILITIES:

Purpose: Provide technical services and logistics support for effective delivery of pharmaceutical care and services.

Duties and responsibilities	Percentage of time
In Hospital:	
• Dispense medicines to patients on the prescription of the Registered Medical practitioner	35
• Provide counselling 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

<ul style="list-style-type: none"> • Documentation of records and literature 	5
Essential Drugs and vaccines	
<ul style="list-style-type: none"> • Review of quantification of annual drug requirements of the country/state 	20
<ul style="list-style-type: none"> • Verification of the annual indents received from storekeepers of different hospitals 	20
<ul style="list-style-type: none"> • To visit the hospitals for inventory monitoring, physical verification and analysis 	15
<ul style="list-style-type: none"> • To correspond with suppliers on the supply of drugs and non-drugs 	15
<ul style="list-style-type: none"> • To discuss issues related to the Pharmaceutical supplies with the other health staff of the department to improve quality of service 	10
<ul style="list-style-type: none"> • To correspond with the different hospitals and mobilize the shortly expiring drugs 	10
<ul style="list-style-type: none"> • Miscellaneous work 	10

3. **KNOWLEDGE AND SKILLS REQUIREMENTS** (Minimum requirements for performance of work described (Level of Education, Knowledge, Skill and Ability)—

3.1 *Education:* Diploma in Pharmacy/Bachelor in Pharmacy.

3.2 *Training:* None.

3.3 *Length and type of practical experience required:* New recruit.

3.4 *Knowledge of language(s) and other specialized requirement:* Should be fluent in English and regional language

4. **COMPLEXITY OF WORK** (details of the intricacy of tasks, steps, processes or methods involved in work, difficulty and originality involved in work)—

The responsibilities involve monitoring the patient and providing health education which will have direct impact on the overall health of the population and disease management. Its jurisdiction encompasses a wide range of pharmaceutical services be it in a dispensary or a hospital. The laid out procedures and techniques needs to be carried out in precise technical efficacy and accuracy. The working process involves scrutinizing every step to prevent any mistakes in the work as it deals with human life. The management of life saving drugs is very important and involves many steps so as to ensure timely supply of drugs to the needy patients.

5. **SCOPE AND EFFECT OF WORK** (Details of the breadth of work performance, and the effect the work has on the work of others or the functions of the organization):

Drugs are the lifelines of the health system. The success of the health care system depends on how various factors like patient compliance to the medicines, cost, and supply, rational utilization of resources, minimization of wastages and rational prescribing. Pharmacist is fully involved in carrying out and promoting them, thus contributing to the overall economy of the nation. The pharmacist is directly involved in counselling the patients, advising the prescribers on rational selection of drugs and therefore it has a direct impact on the overall patient care.

6. **INSTRUCTIONS AND GUIDELINES AVAILABLE:**

6.1 Instructions (Details of the controls exercised over the work by the Superior; how work is assigned, reviewed and evaluated):

Work is carried out based on the annual work plan and regular supervision from the senior pharmacists.

6.2 Guidelines (written or unwritten guidelines that are available, and the extent to which the employees may interpret, adapt or devise new guidelines):

- Annual work plan
- Standard Operating Procedures/hospital guidelines on pharmaceutical care and services
- Standard Manufacturing Instructions
- Pharmacy Act and other laws as specified above in the regulations.

7. WORK RELATIONSHIPS (The frequency, nature and purpose of contacts with others within and outside the assigned organization (other than contacts with superiors):

A pharmaceutical service requires constant interaction with patients and other professionals to monitor, advise and follow-up on drug efficacy, any side effects and complications. The profession also requires constant interaction with different health professionals at various levels to provide the best patient care.

8. SUPERVISION OVER OTHERS (the responsibility that this position has for supervision of other employees, including the nature of supervisory responsibilities and categories and number of subordinates, both directly and indirectly supervised are):

Supervises the technicians and other health workers in the Basic Health Unit on the proper storage management, distribution and proper utilization of medicines.

9. JOB ENVIRONMENT (the physical demands that are required, such as walking, standing, lifting heavy objects, etc., and/or any risks or discomforts like exposure to hazards such as exposure to chemicals infections, radiation, extreme weather and other hostile working conditions):

Compounding involves the use of chemicals and it is risky to have contact or inhale certain substances and may give rise to chronic diseases in the long run. The contact with patients increases the risk of contacting communicable diseases and other profession related work hazards such as risk of needle pricks exposing him/her to diseases like HIV and Hepatitis.

Details of Position Title and job responsibilities of Senior Pharmacist at Hospital Pharmacy practice site:

1. JOB IDENTIFICATION:

1.1 *Position Title:* Sr. Pharmacist

1.2 Job Location (Complete as appropriate):

Ministry: Health;

Department: Medical Services;

Division: Health Care and Diagnostic Services;

Section: Pharmaceutical Services;

Unit: Hospital Pharmacy/dispensary/warehouse

1.3 *Title of First Level Supervisor (Official title of the Supervisor):* Chief/Deputy Chief of the respective fields.

2. PURPOSE, DUTIES AND RESPONSIBILITIES (the purpose, duties and responsibilities, indicating what is done how it is done. Purpose should be a short statement linking the position to the mission and goals of the organization and specifying outputs of the position. Duties should be presented in decreasing order of percentage of time spent on them, or in order of relative importance):

Purpose: Provide technical services and logistics support for effective delivery of pharmaceutical services, efficient production and supply management; enforce regulation

and promote quality assurance of the drugs and other medical supplies; and manages the pharmacy services at a hospital.

Duties and responsibilities	Percentage of time
In Hospital:	
• 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 pharmaco-therapeutics	05
• Provide continuing education and assist superiors	05
• Supervise and train subordinates (Pharmacists and pharmacy technician and other health workers)	20
In Supplies Management	
• Monitor quantification, procurement and distribution of medical supplies	20
• Monitor indents and suppliers	20
• Supervise subordinates and train other staff	20
• Prepare plans and budget	20
• Provide continuing education to the health workers	20
• Assist superiors as and when required	20

3. **KNOWLEDGE AND SKILLS REQUIREMENTS** (Minimum requirements for performance of work described (Level of Education, Knowledge, Skill and Ability):

- 3.1 *Education:* Diploma in Pharmacy/Bachelor in Pharmacy/Doctor of Pharmacy (Pharm.D).
- 3.2 *Training:* Short courses in Drug Administration, Pharmaco-economics, and Pharmaco-Epidemiology, Toxicology, Research and Project design.
- 3.3 Length and type of practical experience required:
 D.Pharm. — Minimum of 4 years experience as a Pharmacist.
 B.Pharm./Pharm.D — direct recruitment
- 3.4 Knowledge of language(s) and other specialized requirement:
 Should be fluent in regional languages and English and ability to converse in other dialects is a good asset.

4. **COMPLEXITY OF WORK** (the intricacy of tasks, steps, processes or methods involved in work, difficulty and originality involved in work):

Pharmaceutical services are a very technical profession and it requires self-motivation and professional ethics; its jurisdiction encompasses a wide range of services. Under general supervision, senior pharmacist performs duties of broad scope, which requires extensive experience, and application of knowledge of the total pharmacy services in a 60 bedded hospital or in relevant pharmaceutical fields. The position also requires management of life saving drugs involving many steps so as to ensure timely supply of drugs to the needy patients.
5. **SCOPE AND EFFECT OF WORK** (the breadth of work performance, and the effect the work has on the work of others or the functions of the organization):

The position is a hospital-wide recognized professional authority in such areas such as Pharmacokinetics, infectious disease therapy, adverse reactions, pharmacovigilance, provide authoritative professional guidance to the staff of the hospital and related organizations. The work consists of execution of specific rules, regulations or procedures effecting the accuracy, reliability or acceptability of other processes and services having direct bearing on the patients.
6. **INSTRUCTIONS AND GUIDELINES AVAILABLE:**
 - 6.1 **Instructions** (controls exercised over the work by the Superior; how work is assigned, reviewed and evaluated):

Assignment of work is based on the annual work plan. The work requires evaluation by self and the supervisors in order to monitor the work efficiency and maintain progress.
 - 6.2 **Guidelines** (Indicate which written or unwritten guidelines are available, and the extent to which the employees may interpret, adapt or devise new guidelines):
 - Financial Manual
 - Pharmacy Act and other legislations mentioned in these regulations
 - Policy documents
 - Five-year plan document
7. **WORK RELATIONSHIPS** [the frequency, nature and purpose of contacts with others within and outside the assigned organization (other than contacts with superiors)]:

A pharmaceutical service requires constant interaction with patients and other professionals to monitor, advise and follow-up on drug efficacy, any side effects and complications. Besides above, the position needs to interact with agencies such as state/central government, Pharmacy retailers, international pharmaceutical firms to prevent drug related problems, legalize retailers, monitor drug quality and compliance of retailers to standard practices and for supply of drugs with pharmaceutical firms.
8. **SUPERVISION OVER OTHERS** (responsibility of this position has for supervision of other employees, including the nature of supervisory responsibilities and categories and number of subordinates, both directly and indirectly supervised):

Supervises the pharmacists, trainees and other related professionals in the hospitals and the Basic Health Units on the proper utilization of the medicines and proper store management of the medicines.
9. **JOB ENVIRONMENT** (physical demands required, such as walking, standing, lifting heavy objects, etc., and/or any risks or discomforts like exposure to hazards such as exposure to chemicals infections, radiation, extreme weather and other hostile working conditions):

The pharmaceutical services in all the area of work need long hour duties with constant standing and frequent exposure to chemicals and other toxins. The contact with patients increases the risk of contacting communicable diseases and other profession related work hazards. The position is also required to travel frequently to the districts to monitor the pharmaceutical activities, to conduct research and assure quality of drugs and supplies.

Details of Position Title and job responsibilities of Chief Pharmacist at Hospital Pharmacy practice site:

1. **JOB IDENTIFICATION:**

1.1 *Position Title:* Chief Pharmacist

1.2 *Job Location (Complete as appropriate):*

Ministry: Health;

Department: Medical Services;

Division: Pharmaceutical services

Section: Pharmaceutical Services;

Unit: Hospital/dispensary/warehouse

1.3 *Title of First Level Supervisor (Official title of the Supervisor):* Head of the Department/hospital

2. **PURPOSE, DUTIES AND RESPONSIBILITIES** (Describe the purpose, duties and responsibilities, indicating what is done how it is done. Purpose should be a short statement linking the position to the mission and goals of the organization and specifying outputs of the position. Duties should be presented in decreasing order of percentage of time spent on them, or in order of relative importance):

Purpose: Provide advanced technical services and logistics support for effective delivery of clinical services, efficient production and supply management; and ensure regulation and quality assurance of the drugs and other medical supplies; and manages the pharmacy department of the hospital.

Duties and responsibilities (for all categories)		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

3. **KNOWLEDGE AND SKILLS REQUIREMENTS** (Minimum requirements for performance of work described (Level of Education, Knowledge, Skill and Ability):

3.1 **Education:**

By promotion failing which by : Diploma in Pharmacy with 10 years of experience.
Direct Recruitment

OR

Bachelor of Pharmacy with 5 years experience.

OR

Master in Pharmacy/Pharm.D.

- 3.2 *Training:* Short course in organizational management, human resource development and management, and financial management and policies, research and specialization in pharmaceutical related fields.
- 3.3 Length and type of practical experience required: Minimum of 4 years experience as a Sr. Pharmacist or equivalent experience.
- 3.4 Knowledge of language(s) and other specialized requirement:
Fluent in regional languages and English. Should be also conversant in government policies, rules and regulations.
4. **COMPLEXITY OF WORK** (Describe the intricacy of tasks, steps, processes or methods involved in work, difficulty and originality involved in work):
The position needs a competent person with in-depth technical knowledge and policy issues and must be capable of executing responsibilities independently. The position is required to fulfil the professional and administrative responsibilities for the department that provides comprehensive pharmaceutical services through large number of professional and technical personnel. It involves advising the technical bodies and commissions (National Drug Committee, Drug Advisory Committee, National HIV/AIDS Commission) on embarking right policy decisions. The position is also required to give constant feedback and assistance to the higher authorities.
5. **SCOPE AND EFFECT OF WORK** (Describe the breadth of work performance, and the effect the work has on the work of others or the functions of the organization):
The success and image of the health system is directly influenced by the clinical care provided to the patients. The pharmaceutical service is the backbone of the clinical services and has direct impact on the overall health care. The quality of the pharmaceutical services will entirely depend on how they are planned and implemented and this position category play a vital role in extending the services to the public.
6. **INSTRUCTIONS AND GUIDELINES AVAILABLE:**
- 6.1 **Instructions** (Describe controls exercised over the work by the Superior; how work is assigned, reviewed and evaluated):
The work output will be reviewed through meetings, reports, publications and successful implementation of the planned activities. However, supervision is received from the head of the department on policy and management issues, and from the specialists on technical areas as and when required.
- 6.2 **Guidelines** (Indicate which written or unwritten guidelines are available, and the extent to which the employees may interpret, adapt or devise new guidelines):
- Indian Civil Service Rules and Regulations
 - Financial Manual
 - Indian legislations relating to health
7. **WORK RELATIONSHIPS** (Indicate the frequency, nature and purpose of contacts with others within and outside the assigned organization (other than contacts with superiors):
The position is required to collaborate with various international agencies and intergovernmental organizations for constant upgrading of the policies and programs relating to matters of pharmaceutical services. The position is required to co-ordinate in-

puts from relevant professional groups and agencies in order to promote the professional integrity and for better developmental goals and better patient care.

8. SUPERVISION OVER OTHERS (Describe responsibility this position has for supervision of other employees, including the nature of supervisory responsibilities and categories and number of subordinates, both directly and indirectly supervised):

Supervises the Deputy Chief Pharmacists and Pharmacists; and oversees the private pharmaceutical dealers to improve the quality of work and to ensure the quality, efficacy and safety of medicinal products to safeguard the public health.

9. JOB ENVIRONMENT (Describe physical demands required, such as walking, standing, lifting heavy objects, etc., and/or any risks or discomforts like exposure to hazards such as exposure to chemicals infections, radiation, extreme weather and other hostile working conditions):

The work involves frequent exposure to chemicals and other toxins. The contact with patients through research works also increase the risk of contacting communicable diseases and other profession related work hazards.

The position is also required to travel frequently to the districts to monitor the pharmaceutical activities, to conduct research and assure quality of drugs and supplies.

Details of Position Title and job responsibilities of Community Pharmacist at community Pharmacy practice site (Drug Store/Pharmacy)

1. JOB IDENTIFICATION:

1.1 *Position Title:* Community Pharmacist

1.2 *Job Location (As appropriate):*

Section: Private sector

Unit: Community Pharmacy/Dispensary/Drug Warehouse

2. PURPOSE, DUTIES AND RESPONSIBILITIES

Purpose: Provide technical services and logistics support for effective delivery of pharmaceutical care and services.

Typical 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;
- counselling 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;
- 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;
 - arranging the delivery of prescription medicines to patients;
 - overseeing the ordering and safe storage of medical products;
 - maintaining computerised 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.
3. **KNOWLEDGE AND SKILLS REQUIREMENTS** (Minimum requirements for performance of work described (Level of Education, Knowledge, Skill and Ability):
- 3.1 *Education*: Diploma in Pharmacy/Bachelor in Pharmacy.
- 3.2 *Training*: None.
- 3.3 *Length and type of practical experience required*: New recruit.
- 3.4 *Knowledge of language(s) and other specialized requirement*: Should be fluent in English and regional language.
4. **COMPLEXITY OF WORK** (details of the intricacy of tasks, steps, processes or methods involved in work, difficulty and originality involved in work):
- The responsibilities involve monitoring the patient and providing health education which will have direct impact on the overall health of the population and disease management. Its jurisdiction encompasses a wide range of pharmaceutical services be it in a dispensary or a hospital. The laid out procedures and techniques needs to be carried out in precise technical efficacy and accuracy. The working process involves scrutinizing every step to prevent any mistakes in the work as it deals with human life. The management of life saving drugs is very important and involves many steps so as to ensure timely supply of drugs to the needy patients.
5. **SCOPE AND EFFECT OF WORK** (Details of the breadth of work performance, and the effect the work has on the work of others or the functions of the organization):
- Drugs are the lifelines of the health system. The success of the health care system depends on how various factors like patient compliance to the medicines, cost, and supply, rational utilization of resources, minimization of wastages and rational prescribing. Pharmacist is fully involved in carrying out and promoting them, thus contributing to the overall economy of the nation. The pharmacist is directly involved in counselling the patients,

advising the prescribers on rational selection of drugs and therefore it has a direct impact on the overall patient care.

6. INSTRUCTIONS AND GUIDELINES AVAILABLE:

6.1 Instructions (Details of the controls exercised over the work by the Superior; how work is assigned, reviewed and evaluated):

Work is carried out based on the annual work plan and regular supervision from the senior pharmacists.

6.2 Guidelines (written or unwritten guidelines that are available, and the extent to which the employees may interpret, adapt or devise new guidelines):

- Annual work plan
- Standard Operating Procedures/guidelines on pharmaceutical care and services
- Pharmacy Act and other laws as specified above in the regulations.

7. WORK RELATIONSHIPS (The frequency, nature and purpose of contacts with others within and outside the assigned organization (other than contacts with superiors):

A pharmaceutical service requires constant interaction with patients and other professionals to monitor, advise and follow-up on drug efficacy, any side effects and complications. The profession also requires constant interaction with different health professionals at various levels to provide the best patient care.

8. SUPERVISION OVER OTHERS (the responsibility that this position has for supervision of other employees, including the nature of supervisory responsibilities and categories and number of subordinates, both directly and indirectly supervised are)—

Supervises the technicians and other health workers in the community Pharmacy on the proper storage management, distribution and proper utilization of medicines.

9. JOB ENVIRONMENT (the physical demands that are required, such as walking, standing, lifting heavy objects, etc., and/or any risks or discomforts like exposure to hazards such as exposure to chemicals infections, radiation, extreme weather and other hostile working conditions):

Compounding involves the use of chemicals and it is risky to have contact or inhale certain substances and may give rise to chronic diseases in the long run. The contact with patients increases the risk of contacting communicable diseases and other profession related work hazards such as risk of needle pricks exposing him/her to diseases like HIV and Hepatitis.

Details of Position Title and job responsibilities of Drug Information Pharmacist at Pharmacy practice site in a health care setting (Drug Store/Pharmacy)

1. JOB IDENTIFICATION:

1.1 *Position Title:* Drug Information Pharmacist

1.2 *Job Location (As appropriate):*

Unit: Hospital Pharmacy/dispensary/teaching hospital/other health care setting

2. PURPOSE, DUTIES AND RESPONSIBILITIES

Purpose: Provide patient care that optimizes the use of medication and promotes health, wellness and disease prevention.

Core Responsibilities and Activities:

- Provide drug information services
- Supervise pharmacy/Pharm.D students during the drug information rotation.

- Participate in the administrative activities of the drug information centre along with other faculty/health care providers.
- Develop and assist in developing drug monographs and reviews for the Pharmacy and Therapeutics Committee.
- Write and edit drug information centre publications such as newsletters and other publications.
- Contribute to continuous quality improvement efforts related to drug information services.
- Contribute to didactic drug information courses.
- Complete at least 1 major research project related to drug information or other area of interest that is suitable for publication.
- Present research activity at various forum.

Other Responsibilities and Activities:

- Participate in Pharmacy and Therapeutics Committee meetings
 - Contribute to drug use management activities (DUE/DUR)
 - Work with other faculty on drug information service-related projects as needed
 - Attend a major/national pharmacy meeting.
 - Participate in entrepreneurial activities of the drug information centre.
3. **KNOWLEDGE AND SKILLS REQUIREMENTS** (Minimum requirements for performance of work described (Level of Education, Knowledge, Skill and Ability):
- 3.1 *Education:* Bachelor in Pharmacy/Pharm.D
- 3.2 *Training:* Drug information residency
- 3.3 *Length and type of practical experience required:* New recruit.
- 3.4 *Knowledge of language(s) and other specialized requirement:* Should be fluent in English and regional language
4. **COMPLEXITY OF WORK** (details of the intricacy of tasks, steps, processes or methods involved in work, difficulty and originality involved in work):
- The responsibilities involve monitoring the patient and providing health education which will have direct impact on the overall health of the population and disease management. Its jurisdiction encompasses a wide range of pharmaceutical services be it in a dispensary or a hospital.
5. **SCOPE AND EFFECT OF WORK** (Details of the breadth of work performance, and the effect the work has on the work of others or the functions of the organization):
- Drugs are the lifelines of the health system. The success of the health care system depends on how various factors like patient compliance to the medicines, cost, and supply, rational utilization of resources, minimization of wastages and rational prescribing. Pharmacist is fully involved in carrying out and promoting them, thus contributing to the overall economy of the nation. The pharmacist is directly involved in counselling the patients, advising the prescribers on rational selection of drugs and therefore it has a direct impact on the overall patient care.
6. **INSTRUCTIONS AND GUIDELINES AVAILABLE:**
- 6.1 **Instructions** (Details of the controls exercised over the work by the Superior; how work is assigned, reviewed and evaluated):

Work is carried out based on the annual work plan and regular supervision from the senior pharmacists.

- 6.2 Guidelines (written or unwritten guidelines that are available, and the extent to which the employees may interpret, adapt or devise new guidelines):
- Annual work plan
 - Standard Operating Procedures/hospital guidelines on pharmaceutical care and services
 - Pharmacy Act and other laws as specified above in the regulations.

7. WORK RELATIONSHIPS (The frequency, nature and purpose of contacts with others within and outside the assigned organization (other than contacts with superiors):

A pharmaceutical service requires constant interaction with patients and other professionals to monitor, advise and follow-up on drug efficacy, any side effects and complications. The profession also requires constant interaction with different health professionals at various levels to provide the best patient care.

²[7-A. *The duty of the Drug Information Pharmacist in the Drug Information Centre in Hospitals.*—The Drug Information Pharmacist shall—

- a) provide information and advice regarding drug interactions, side effects, dosage and proper medication storage to patients, physicians, dentists and other health care professionals;
- (i) provide drug information to patients, caregivers, and health care professionals;
 - (ii) create and maintain currency of a variety of print and online educational resources for patients, namely, tip sheets, pamphlets and health care material such as in-service documents, newsletters on topics namely, optimal medication use, general health, or select clinical questions;
 - (iii) educate health care professionals on safe and effective medication-use, policies and processes, including development of resources to communicate these informations;
 - (iv) lead or participate in continuing education services for health care professionals;
 - (v) precept and educate pharmacy students and residents;
 - (vi) participate in quality improvement research projects and drug cost analysis;
 - (vii) contribute to the biomedical literature, and
 - (viii) provide peer review for other contributors.]

³[7-B. Details of Position, Title and job responsibilities of Clinical Pharmacist

1. *Job Identification:*

- 1.1 Position Title : Clinical Pharmacist
1.2 Job Location (As appropriate) : Hospitals

2. *Purpose, duties and responsibilities.*—The Clinical Pharmacist shall—

- (a) provide patient care which optimises the use of medication and promotes health, wellness and disease prevention in collaboration with physicians and other health care professionals;

2. *Ins.* by Noti. No. 14-148/2020-PCI, dated 30-6-2021 (w.e.f. 5-7-2021).

3. *Ins.* by Noti. No. 14-148/2020-PCI, dated 30-6-2021 (w.e.f. 5-7-2021).

- (b) evaluate all medicare coverage requirement requests;
- (c) ensure compliance to all clinical procedures;
- (d) coordinate with pharmacy and medical staff to perform regular interventions according to present drugs;
- (e) perform regular evaluation on all usage and dosage of drugs;
- (f) ensure absence of all reactions;
- (g) assist all patients with assessment of patient orders;
- (h) assist prescription infusion and ensure adherence to all laws and regulations;
- (i) gather, maintain and analyze all laboratory data;
- (j) record all required patient information;
- (k) make recommendations to change dosage if required;
- (l) administer and complete all pharmacy care plans;
- (m) perform reconciliation of all medications and supervise all sterile mixing processes;
- (n) review all medications and equipments and ensure accuracy and effective functioning;
- (o) manage all communications with physicians and patients;
- (p) assist to resolve all patients within required timeframe;
- (q) maintain record of all medications for patients;
- (r) ensure absence of all discrepancies;
- (s) analyse all side effects and drug interactions;
- (t) retrieve clinical information for monitoring;
- (u) revision of the medication use process;
- (v) coordinate with all medical case managers;
- (w) evaluate all high risk members to prevent all risks;
- (x) participate in all patient associated meetings;
- (y) prepare all clinical documents;
- (z) participate in all on call activities for pharmacy;
- (za) evaluate all pharmacy claim data and identify all clinical savings;
- (zb) attend all therapeutic and pharmacy committee meetings;
- (zc) design and maintain all medication protocols for all clinical pharmacists;
- (zd) coordinate with all clinical team members to ensure optimal services;
- (ze) provide support to all clinical programs;
- (zf) ensure compliance to all medication process;
- (zg) evaluate all data to administer all drug utilization patterns;
- (zh) monitor all departmental activities;
- (zi) analyse all quality improvement activities;
- (zj) present all annual studies for management;
- (zk) serve as a drug information resource;

- (zl) contribute to drug use management activities;
 - (zm) work with other faculty on drug information service-related projects as needed;
 - (zn) attend a major and national pharmacy meeting.
3. *Qualification and skill for clinical pharmacist requirements for performance of work.*—
- The Clinical Pharmacist—
- (i) should possess Pharm.D from an institution approved by the Pharmacy Council of India;
 - (ii) should have undergone training in—
 - (a) involvement in formulary development, drug use evaluation, and quality assurance activities;
 - (b) ambulatory care experience;
 - (iii) should have the ability to research and analyse the medical literature including drug information, disease states, and clinical practice guidelines;
 - (iv) should have extensive knowledge of pharmacy and its related subdisciplines (therapeutics, pharmacology, physical pharmacy), formulary development, drug use review, quality assurance, legal, regulatory, and standards of practice;
 - (v) should have such length and type of practical experience for new recruits as specified by the Pharmacy Council of India;
 - (vi) should be fluent in English and regional language of the place in which the Clinical Pharmacist works.
4. *Complexity of Work.*—The Clinical pharmacist shall monitor the patient and provide health education which may have direct impact on the overall health of the population and disease management. Its jurisdiction encompasses a wide range of pharmaceutical services.
5. *Scope and effect of work.*—While discharging his duties, the Clinical pharmacist shall have regard to following matters, namely—
- (a) the factors like patient compliance to the medicines, cost, and supply, rational utilization of resources, minimization of wastages and rational prescribing;
 - (b) carry out and perform his duty, thus contributing to the overall economy of the nation;
 - (c) counseling the patients, advising the prescribers on rational selection of drugs and, therefore, it has a direct impact on the overall patient care.
6. *Instructions and guidelines.*—The Clinical pharmacist shall—
- (a) comply with the instructions issued by the superior officers regarding how the work is to be discharged and the review and evaluation of the same;
 - (b) carry out the annual work plan and regular supervision from the senior pharmacists;
 - (c) issue guidelines and the extent to which the employees may adapt or devise guidelines on—
 - (i) annual work plan;

- (ii) standard operating procedures and hospital guidelines on pharmaceutical care and services;
 - (iii) provisions of Pharmacy Act, 1948 (8 of 1948) and other statutory provisions as specified in the regulations.
7. *Work relationship.*—The clinical pharmacist shall, while discharging his duty shall have regard to—
- (a) constant interaction with patients and other professionals to monitor, advise and follow-up on drug efficacy, any side effects and complications;
 - (b) constant interaction with different health professionals at various levels to provide the best patient care.]

OBJECTIVES FOR MAKING PRACTICE REGULATIONS

Professions exist to serve society. The mission of the pharmacy profession is to render service to humanity with full respect for the dignity of profession and man, besides addressing the needs of society and of individual patients. The public places great trust in the knowledge, skills and professional judgments of pharmacists. This trust requires the pharmacists to ensure and maintain throughout their career high standards of personal and professional conduct, up-to date knowledge and professional competence relevant to their domain of practice. The registered pharmacist should merit the confidence of patients entrusted to their care, rendering to each a full measure of service and devotion. For which the registered pharmacist should try continuously to improve his knowledge and skills and should make available to their patients and colleagues the benefits of their professional attainments.

The registered pharmacist should practice methods of practice founded on scientific basis and should not associate professionally with anyone who violates this principle. The honoured ideals of the pharmacy profession imply that the responsibilities of the registered pharmacist extend not only to individuals but also to society.

This calls for framing of the regulations for practice of pharmacy laying down responsibilities of pharmacist towards patient, another registered pharmacist and the public in general. Primary reasons to regulate pharmacy profession are:

- ✓ To improve quality of health care
- ✓ To ensure that Pharmacists maintain high standards in their duty
- ✓ To reduce cost of health care
- ✓ To inhibit criminal abuse of medicines

It is also a call for laying down the activities which may be construed as misconduct and provision for taking disciplinary action.
