PHARMACY COUNCIL OF INDIA

(Constituted under the Pharmacy Act, 1948)

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Announcements

1. Extract of the minutes of the 107th/Central Council meeting of PCI held in August, 2019.

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<u>01.107.1205</u> : Sub: Amendment in Pharmacy Practice Regulations, 2015 for –		
a) inclusion of the post of Clinical Pharmacist with qualification, duties and responsibilities.b) creation of Drug Information Centres in Hospitals.		
(14-126/2019-PCI)		
1205.1 The latest information on record was placed.		
 1205.2 It was decided to approve the proposed amendments in the Pharmacy Practice Regulations, 2015 for - a) inclusion of the post of Clinical Pharmacist with qualification, duties and responsibilities. 		
b) creation of Drug Information Centres in Hospitals.		
1205.3 It was further decided to -		
a) forward the amendments to Health Ministry.		
b) simultaneously initiate action u/s 10(3) of Pharmacy Act, 1948 for seeking comments of the State Govts. / Union Territories.		

2. Comments on the proposed amendments in the Pharmacy Practice Regulations, 2015 are invited so as to reach the Pharmacy Council of India on or before 13.11.2019.

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SPEED-POST

Ref No: 14-148/2016-PCI 4534-71

The Principal Secretary (Health) All State Governments /Union Territories

- Sub: Comments of the State Governments /Union Territories on the proposed Amendments in the Pharmacy Practice Regulations, 2015.
- Sir

With reference to the subject cited above, it is informed that -

- 1. The Pharmacy Council of India (PCI) is a statutory body working under the Ministry of Health and Family Welfare, Government of India, New Delhi. It is constituted under the Pharmacy Act, 1948 to regulate the profession and practice of pharmacy in the country.
- 2. With due approval of the Ministry of Health & Family Welfare, Govt. of India, the PCI has notified the Pharmacy Practice Regulations, 2015 in Gazette of India, No.17, Part III Section 4, dated January 16, 2015. These Regulations are available on the Council's website www.pci.nic.in
- 3. Though the Pharmacy Practice Regulations, 2015 define the term "Clinical Pharmacist" as pharmacy practitioner under regulation 2(4) (iv), the details of Position Title and job responsibilities in respect of Clinical Pharmacist is not included in Appendix-III of the said Regulation alongwith Pharmacist, Senior Pharmacist, Chief Pharmacist, Community Pharmacist and Drug Information Pharmacist.
- 4. Accordingly, the 107th Central Council in its meeting held in August, 2019 decided to initiate action for amendment of the Pharmacy Practice Regulations, 2015 by incorporating the details of Position Title and job responsibilities in respect of Clinical Pharmacists also. In addition, a provision to create Drug Information Centres in hospitals should also be included in these Regulations. A copy of the proposed amendments is enclosed herewith as **Appendix-1**.

The Council would, therefore, appreciate to have considered comments of the State Governments / Union Territories on the enclosed proposed amendments within 3 months of issuance of this letter as required under sub-section (3) of section 10 of the Pharmacy Act, 1948 to enable the Pharmacy Council of India to take further action in the matter.

Yours faithfully

(ARCHNA MUDGAL) Registrar-cum-Secretary

Proposal for amendment in the Pharmacy Practice Regulations, 2015

To include the following before the heading "Objectives For Making Practice Regulations" in the Pharmacy Practice Regulations, 2015:-

"A. 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

Purpose: To provide patient care that optimizes the use of medication and promotes health, wellness and disease prevention in collaboration with physicians and other health care professionals.

Core Responsibilities and Activities

- Evaluate all Medicare coverage requirement requests and ensure compliance to all clinical procedure and coordinate with pharmacy and medical staff to perform regular interventions according to present drugs.
- Perform regular evaluation on all usage and dosage and ensure absence of all reactions and assist all patients with assessment of patient orders and prescription infusion and ensure adherence to all laws and regulations.
- Gather, maintain and analyze all laboratory data and record all required patient information and make recommendations to change dosage if required.
- Administer and complete all pharmacy care plans and perform reconciliation of all medication and supervise all sterile mixing processes.
- Review all medications and equipments and ensure accuracy and effective functioning and manage all communication with physicians and patients and assist to resolve all patients within required timeframe.
- Maintain record of all medication for patients and ensure absence of all discrepancies and analyze all side effects and drug interactions.
- Retrieves clinical information for monitoring and revision of the medication use process
- Coordinate with all medical case managers and evaluate all high risk members to prevent all risks and participate in all patient associated meetings.
- Prepare all clinical documents and participate in all on call activities for pharmacy and evaluate all pharmacy claim data and identify all clinical savings.

- Attend all therapeutic and pharmacy committee meetings.
- Design and maintain all medication protocols for all clinical pharmacists and coordinate with all clinical team members to ensure optimal services.
- Provide support to all clinical programs and ensure compliance to all medication process and evaluate all data to administer all drug utilization patterns.
- Monitor all departmental activities and analyze all Quality improvement activities and present all annual studies for management.
- Serve as a Drug Information resource.

Other Responsibilities and Activities:

- Contribute to drug use management activities.
- Work with other faculty on drug information service-related projects as needed.
- Attend a major/ national pharmacy meeting.
- 3. Knowledge and Skills Requirements (Minimum requirements for performance of work described (Level of Education, Knowledge, Skill and Ability):
 - **3.1 Education**: Pharm.D from an institution approved by the PCI.
 - 3.2 Training:
 - 1. Involvement in formulary development, drug use evaluation, and quality assurance activities. Ambulatory care experience
 - 2. Ability to research and analyze the medical literature including drug information, disease states, and clinical practice guidelines.
 - 3. 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.
 - **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.

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 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 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 statutory laws as specified 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.

B. Creation of Drug Information Centre in Hospitals

All hospitals shall have a Drug Information Centre headed by Drug Information Pharmacist.

Objectives of Drug Information Centre

The Drug Information Centre shall provide information and advice regarding drug interactions, side effects, dosage and proper medication storage to patients/ physicians/ dentists/other health care professionals.

Drug Information Centre Activities

- 1. Providing Drug Information to patients, caregivers, and health care professionals.
- 2. Creating and maintaining currency of a variety of print and online educational resources for patients (e.g., tip sheets, pamphlets) and health care professionals (e.g., in-service documents, newsletters) on topics such as optimal medication use, general health, or select clinical questions.
- 3. Educating health care professionals on safe and effective medication-use policies and processes, including development of resources to communicate this information.
- 4. Leading or participating in continuing education services for health care professionals.
- 5. Precepting and educating pharmacy students and residents.
- 6. Participating in quality improvement research projects and drug cost analyses.
- 7. Contributing to the biomedical literature and providing peer review for other contributors."