

UNIT 4: Regulation of the Pharmacy Practice (Pharmacy Licensure, Practice Standards and Ethics, and Organizations Influencing the Practice of Pharmacy)

Learning Outcomes:

- Explain the structure, coverage, and requirements of the PRC Licensure Examination
- Identify key laws, regulations, agencies, and organizations that influence pharmacy practice in the Philippines.
- Discuss the Philippine Practice Standards for Pharmacists
- Compare the Code of Ethics for Filipino Pharmacists with the FIP Code of Ethics.
- Describe major professional pharmacy associations

1. Pharmacy Licensure Examination (Article III of RA 10918)

1.1. Structure of the Exam

- A. Administered by: Professional Regulation Commission (PRC), Board of Pharmacy.
- B. Format: Written examination, usually multiple-choice questions (MCQs).
- C. Frequency: Conducted twice a year (typically in April and November, subject to PRC scheduling).
- D. Duration: Two-day examination, divided into subjects.
- E. Passing Average: 75%, with no subject lower than 50%.

1.2. Coverage of the Exam

The licensure exam is based on Republic Act 10918 (Philippine Pharmacy Act of 2016) and the CHED Pharmacy curriculum. It is divided into six major subject areas: (Refer to unit 3 for the contents and percentage.)

- A. Pharmaceutical Chemistry
- B. Pharmacognosy and Plant Chemistry
- C. Practice of Pharmacy
- D. Pharmacology and Pharmacokinetics
- E. Pharmaceutics
- F. Quality Assurance and Manufacturing Pharmacy

1.3. Requirements

Eligibility:

- Must be a graduate of Bachelor of Science in Pharmacy or Doctor of Pharmacy from a CHED-recognized school.
- A citizen of the Philippines or a foreign country with reciprocity for pharmacy practice.
- Of good moral character and reputation.
- Must have graduated with the degree of Bachelor of Science in Pharmacy or an equivalent degree from an HEI in the Philippines or a foreign institution recognized by CHED.
- Must have completed an Experiential program approved by the Board (in consultation with pharmacy schools and CHED) (at least 1,200 hours)

COURSE TITLE	CREDIT UNITS	HOURS	PRE-REQUISITE
EPP in Institutional Pharmacy*	2.4	120	4th year standing
EPP in Public Health and Regulatory Pharmacy	3.6	180	
EPP in Community Pharmacy	6	300	
EPP in Hospital Pharmacy	6	300	
EPP in Industrial Pharmacy	6	300	

*Student may opt to enroll in Community Pharmacy for the 120 hours in addition to the required 300 hours for Community Pharmacy, for a total of 420 hours.

Documentary Requirements:

- A. Duly accomplished PRC Application Form.
- B. PSA/NSO Birth Certificate.
- C. PSA/SO Marriage Contract (for married female applicants)
- D. Transcript of Records (with Special Order & remarks 'for Board Examination purposes').
- E. College Diploma.
- F. Certificate of Good Moral Character from any of the following:
 - Barangay
 - School of Pharmacy
 - Church
 - Employer
- G. 4 passport-sized ID pictures with white background & full name tag.
- H. Cedula / Community Tax Certificate.
- I. Valid NBI Clearance (First Timers & Repeaters)
- J. Payment of examination fee 900 PHP
- K. *Daily Time Record (DTR)
- L. *After three (3) failures, REFRESHER Course

SGrounds for Non-registration (Board shall not register any successful examinee who has been):

- Convicted of an offense involving moral turpitude by a court of competent jurisdiction;
- Summarily adjudged by the Board as guilty for misrepresentation or falsification of documents in connection with the application for examination or for violation of the General Instructions to Examinees;
- Found guilty of immoral or dishonorable conduct by the Board;
- Medically proven to be addicted to any drug or alcohol by a medical or drug testing facility accredited by the government;
- Declared of unsound mind by a court of competent jurisdiction.

2. Pharmacy Practice Standards and Ethics

A. Laws relating to the Pharmacy Practice

1. **Republic Act No. 10918 – Philippine Pharmacy Act (2016):** Regulates and modernizes the practice of pharmacy, standardizes pharmacy education, governs licensure examinations, and ensures continuing professional development for pharmacists.
Amendment: This law repealed Republic Act No. 5921 (Philippine Pharmacy Act of 1969).
2. **Republic Act No. 9994 – Expanded Senior Citizens Act of 2010:** Provides additional benefits and privileges to senior citizens, further expanding rights in healthcare, discounts, and social services.
Amendment: This law amended Republic Act No. 7432 (Senior Citizens Act of 1992).
3. **Republic Act No. 8203 – Special Law on Counterfeit Drugs (2010):** Prohibits counterfeit drugs, provides penalties for violations, and appropriates funds for enforcement.
4. **Republic Act No. 9711 – Food and Drug Administration (FDA) Act of 2009:** Strengthened and rationalized the regulatory capacity of the Bureau of Food and Drugs (BFAD), transforming it into the Food and Drug Administration with expanded powers and resources.
Amendment: This law amended Republic Act No. 3720 (Foods, Drugs, Devices, and Cosmetics Act of 1987).
5. **Republic Act No. 9165 – Comprehensive Dangerous Drugs Act of 2002:** Institutes comprehensive policies to combat illegal drugs, created the Philippine Drug Enforcement Agency (PDEA), and imposes stricter penalties on drug-related offenses.
Amendment: This law repealed Republic Act No. 6425 (Dangerous Drugs Act of 1972).
6. **Republic Act No. 7581 – Price Act (1992):** Protects consumers by stabilizing prices of basic necessities and prime commodities, especially during emergencies, and prevents profiteering, hoarding, and price manipulation.
Amendment: This law was amended by Republic Act No. 10623 (2013) - expanding the list of necessities and prime commodities
7. **Republic Act No. 7394 – Consumer Act of the Philippines (1992):** Protects consumer interests, promotes general welfare, and establishes standards for business and industry. Covers product quality, deceptive practices, and consumer education.
8. **Republic Act No. 6675 – Generics Act of 1988:** Promotes, requires, and ensures the production, distribution, use, and acceptance of drugs and medicines identified by their generic names.
Amendment: This law was amended by Republic Act No. 9502 (Cheaper and Quality Medicines Act of 2008).
9. **Republic Act No. 3720 – Foods, Drugs, Devices, and Cosmetics Act (1987):** Ensures safety and purity of foods, drugs, and cosmetics; created the Food and Drug Administration to administer standards for these products.
Amendment: This law was amended by Republic Act No. 9711 (FDA Act of 2009).

B. Philippine Practice Standards for Pharmacists

1. The Pharmacist and their Credentials

- Only duly registered and licensed pharmacists can use the title "Registered Pharmacist" or "RPh".
- Pharmacists must include their Professional Identification Card (PIC) and APO Certificate of Membership serial numbers and expiry dates on all documents they sign.
- A public registry of all registered pharmacists is maintained and updated annually.

2. Display, Responsibility, and Sales

- Pharmacists must display their original Certificate of Registration (COR) conspicuously in their workplace. A duplicate COR is also required for Category B establishments.
- Pharmacists must not allow their COR to be displayed where they are not actually employed.
- Pharmaceutical products can only be compounded, dispensed, sold, or resold through an FDA-licensed retail drug outlet.
- Prescription drugs and pharmacist-only Over-The-Counter (OTC) medicines must be dispensed only by a registered and licensed pharmacist.
- A pharmacist may refuse to dispense drugs not in accordance with the Act or established standards.
- Manufacturers, importers, distributors, and wholesalers can only sell products to licensed pharmaceutical outlets.
- Pharmacists must ensure all pharmaceutical products meet safety, quality, and efficacy standards.
- Owners, managers, or pharmacists-in-charge are jointly responsible for product quality.
- It is unlawful to manufacture, prepare, sell, or dispense fraudulent or adulterated pharmaceutical products.

3. Establishment Categories and Supervision

- **Category A establishments** (e.g., selling prescription/ethical medicines, pharmacist-only OTC, manufacturing facilities, government health units) require direct and immediate control and supervision by a pharmacist.
- **Category B establishments** (e.g., selling household remedies/general OTC, satellite institutional pharmacies, telepharmacy) require supervision and oversight by a pharmacist.
- A pharmacist in a Category A establishment may also work concurrently in Category B establishments.
- All government procurement, storage, distribution, or dispensing of pharmaceutical products must be under the supervision of a registered and licensed pharmacist.

4. Prescription Handling and Labelling

- All prescriptions and pharmacist-only OTC medicines must be filled, compounded, and dispensed only by a registered and licensed pharmacist.
- Prescription medicines require a valid prescription from a physician, dentist, or veterinarian.
- Pharmacists shall not compound or dispense prescriptions with ciphers, codes, secret keys, or unusual names.
- Substitution of medicine is prohibited without prior consultation and written consent of the prescriber, except as allowed by the "Generics Act of 1988".
- Every dispensed medicine package must have a label including the patient's name, generic name (and brand if any), strength, expiry date, directions for use, pharmacy name/address, doctor's name, and dispensing pharmacist.
- Auxiliary labels with special instructions are required for certain drugs like dangerous drugs or those for external use.
- Physician's samples ("Sample, Not for Sale") cannot be sold to any outlet or the public.
- Antimicrobials (including anti-TB) and other FDA-prescribed medicines cannot be given as physician's samples.

5. Record Keeping

- All dispensed prescriptions must be recorded in a patient medication profile for at least two (2) years, open for inspection.
- Information on dangerous drugs dispensed must be recorded in a Dangerous Drugs Book or equivalent system.
- All referrals (e.g., for tuberculosis patients) must be recorded in a Referral Registry for at least two (2) years, open for inspection.

6. Opening of Outlets and Non-Pharmacist Roles

- The opening of a retail pharmaceutical outlet requires compliance with FDA rules and regulations.
- Applications for opening an outlet must be made by a Filipino registered and licensed pharmacist (as owner or pharmacist-in-charge).
- Non-pharmacists handling pharmaceutical products (e.g., pharmacy assistants) must be duly certified after completing an accredited training program. Generally, only pharmacy graduates can render these services without such training.
- Licensed and trained pharmacists administering adult vaccines need a doctor's prescription (not more than 7 days old) and must submit monthly vaccination and Adverse Event Following Immunization (AEFI) reports to DOH

*****For Immunizing Pharmacists:** Only PRC-BOP certified immunizing pharmacists shall provide vaccination services in pharmacies.

Requirements:

- Certificate of Current Employment in the Pharmaceutical Outlet
- Valid Certificate in Basic Life Support Training
- Valid Certificate of Training in Vaccination Issued by PRC-BOP
- Must be a registered pharmacist (RPh)

C. Code of Ethics for Filipino Pharmacists

The Pharmacists' Code of Ethics, promulgated by the Professional Regulatory Board of Pharmacy, outlines the ethical rules and principles to ensure the safety and interest of patients and the public. It sets forth professional responsibilities in relationships with patients, the profession, colleagues, allied health professionals, society, and the industry.

Preamble

Pharmacists are valued and recognized health professionals primarily responsible for promoting the safe, effective, and responsible use of medicines within the overall health system. They work with other health professionals to help patients achieve maximum therapeutic benefit from their medicines. Pharmacists are also involved in the discovery, development, manufacture, and supply management of medicines, as well as education, research, regulations, and policy development. They help individuals, families, and communities maintain good health and prevent illness.

Principles

The Code's principles guide pharmacists in their relationships and obligations:

1. Focus Area: The Pharmacist's Patients and Clients

- A pharmacist places the health and well-being of the individual and the community at the center of professional practice. They commit to improving self-care, maintaining good health, preventing illness, and making the best use of medications, establishing therapeutic relationships to gain trust.
- A pharmacist respects the autonomy and rights of the patient and recognizes cultural differences. This includes promoting self-care, decision-making in health, and rights regarding treatment choice, respecting personal, gender, cultural, and racial differences.
- A pharmacist cares for each individual with competence and compassion, providing pharmaceutical care and assisting patients with compassion.

2. Focus Area: The Pharmacy Profession

- A pharmacist acts with honesty, integrity, and professionalism in relationships with patients, carers, and other healthcare stakeholders. They build trusting relationships, commit to transparency and accountability.
- A pharmacist abides by regulatory requirements, scientific principles, professional practice, and ethical standards. They are responsible for their actions and face consequences when standards are not met.
- A pharmacist is committed to lifelong learning to enhance professional competence, ensuring continuous updating and upgrading of knowledge and skills.
- A pharmacist demonstrates commitment to the development and enhancement of the profession, taking leadership roles and involvement in initiatives critical to its evolution.

3. Focus Area: Other Health Professionals

- A pharmacist respects and collaborates with other healthcare professionals and colleagues to achieve optimal treatment outcomes and ensure a continuum of care for patients. This involves professionalism, diplomacy, tact, and recognizing individual contributions within the team.

4. Focus Area: Professional Business Practices

- A pharmacist conducts the business of pharmacy in an ethical and professional manner. Business practices must be in the best interest of patients, respecting confidentiality and proprietary information, and respecting competitors.

5. Focus Area: The Society

- A pharmacist, in coordination with government and non-government organizations, actively participates in the formulation and implementation of healthcare policies, standards, and programs designed for the benefit of society.
- A pharmacist advocates equitable distribution of health resources, health promotion, disease prevention, and wellness. This means making essential medicines available, providing cheaper quality alternatives when appropriate, and conducting public health education on rational and responsible medication use.

Violations of this Code of Ethics can lead to the revocation or suspension of a pharmacist's Certificate of Registration.

D. FIP Code of Ethics

1. FIP Recommendations

The International Pharmaceutical Federation (FIP) recommends:

- Pharmacist associations in every country should create or support an updated Code of Ethics for pharmacists and ensure compliance.
- Opportunities should be explored to contribute to transdisciplinary Codes of Ethics.
- Pharmacy education and continuing professional development should include the Code of Ethics and principles of autonomy, beneficence, non-maleficence, and justice.

2. Obligations of Pharmacists

- Act with honesty and integrity, avoiding actions that discredit the profession.
- Prioritize patient safety, well-being, and best interests at all times.
- Always act professionally, guided by science and professional standards.
- Collaborate with colleagues, health professionals, patients, and carers to provide quality healthcare.
- Respect and protect patient confidentiality, disclosing information only with consent or when legally required.
- Respect patients' rights and cultural differences, even in conflicts with personal beliefs.
- Ensure continuity of care when personal beliefs conflict with patient needs.
- Comply with laws and standards in all services and safeguard the integrity of the medicine supply chain.
- Maintain competence through continuing professional development.

3. Private, government, and non-governmental organizations impacting Pharmacy Practice

Professional Organizations influencing the Pharmacy Practice in the Philippines

Agency	Function in Pharmacy Practice	Website
Philippine Association of Colleges of Pharmacy (PACOP)	Sets standards in pharmacy education, aligns curricula with global competencies, and prepares students for licensure.	https://pacop.org.ph/
Philippine Pharmacists Association, Inc. (PPhA)	National professional organization of licensed pharmacists; provides CPD programs, sets ethical standards, and represents the profession in policymaking.	https://ppha.org.ph/
Federation of Asian Pharmaceutical Associations (FAPA) – Philippine Chapter	Regional private organization promoting collaboration, pharmaceutical sciences, and advancement of pharmacy practice across Asia.	https://fapa.asia/

Government Agencies Affecting the Pharmacy Practice

Agency	Function in Pharmacy Practice	Legal Basis
Professional Regulation Commission (PRC)	Regulates the practice of pharmacy; administers licensure examinations; enforces the Philippine Pharmacy Act.	R.A. 10918 – Philippine Pharmacy Act
Food and Drug Administration (FDA, formerly BFAD)	Ensures safety, efficacy, and quality of drugs, cosmetics, and devices; issues licenses to manufacturers, distributors, and pharmacies.	R.A. 9711 – FDA Act of 2009; R.A. 3720 – Food, Drug, and Cosmetic Act
Department of Health (DOH)	Oversees national health programs, hospital pharmacies, essential drug programs, and medicine accessibility.	Mandate under Executive Orders and Health Acts
Department of Trade and Industry (DTI)	Regulates fair pricing and trade practices of pharmaceuticals; works with FDA in consumer protection.	Consumer Act of the Philippines (R.A. 7394)
Intellectual Property Office (IPO)	Protects pharmaceutical patents, trademarks, and copyrights.	R.A. 8293 – Intellectual Property Code
Philippine Drug Enforcement Agency (PDEA)	Implements the Comprehensive Dangerous Drugs Act; regulates and monitors handling of controlled substances.	R.A. 9165 – Comprehensive Dangerous Drugs Act of 2002
PhilHealth (Philippine Health Insurance Corporation)	Provides insurance coverage including drug benefits; influences dispensing, reimbursement, and pricing of medicines.	R.A. 7875 – National Health Insurance Act
Department of Science and Technology (DOST)	Supports pharmaceutical R&D through PCHRD and other agencies; funds studies on medicines and herbal drugs.	Mandates under science and technology policies

Non-Government Agencies affecting the Pharmacy Practice

Agency	Function in Pharmacy Practice	Website
World Health Organization (WHO – Philippines Office)	Provides global and national health guidelines, essential medicines lists, and good pharmacy practice standards.	https://www.who.int/philippines
United Nations Children's Fund (UNICEF – Philippines)	Supports child health, immunization, and medicine access programs; pharmacists ensure vaccine storage and distribution.	https://www.unicef.org/philippines
Médecins Sans Frontières (MSF – Doctors Without Borders)	Delivers medical and pharmaceutical services in emergencies; improves access to medicines in underserved areas.	https://msf.org.ph/
Philippine NGO Council on Population, Health and Welfare (PNGOC)	Coordinates NGOs for public health programs, medicine access, and community pharmacy involvement.	https://pngoc.ph/
Family Planning Organization of the Philippines (FPOP)	Provides reproductive health and family planning services, including contraceptive distribution and counseling.	https://www.fpop1949.org/

Professional Pharmacy Associations

Purpose of Organizations:

- Working toward common goals and objectives to advance pharmacy as a profession and enhance pharmacy services.
- Serving as the unified voice of members in defining standards of practice and professional conduct.
- Organized at international, national, local, or specialized fields (e.g., PSHP).

1. Philippine Pharmacists Association (PPhA)

- A national organization of Pharmacists accredited by the Professional Regulation Commission. Organized on August 20, 1920
- Registered with the Securities and Exchange Commission (SEC)
- Formerly Philippine Pharmaceutical Association (until 2008)
- First national pharmaceutical organization
- First recipient of "The Outstanding Accredited Professional Association of the Year Award" by PRC in 1994

Core values:

Solidarity
Professionalism
Integrity
Competence
Social Responsibility

2. Philippine Association of Colleges of Pharmacy (PACOP)

- An association of duly government-recognized colleges of pharmacy. Established in 1965.
- Deans are regular members.
- Associate members are licensed pharmacists who are faculty members.
- Pharmacy members are auxiliary members.

3. **Philippine Association of Pharmacists in Pharmaceutical Industry (PAPPI)**
 - Association of pharmacists in private and government hospitals. Established in 1986.
 - Leader in establishing and supporting the healthcare regulatory affairs profession.
 - Actively undertaking CPE programs, mostly seminars and lecture workshops.
 - Committed to members in bringing opportunities for networking and uplifting the roles of pharmacists in the Philippine Pharmaceutical Industry.
4. **Philippine Society of Hospital Pharmacists (PSHP)**
 - An association of licensed pharmacists working in government and private hospitals. Founded in 1962.
 - *The PSHP Bulletin* is its official organ.
5. **Department of Health-League of Pharmacists (DOHLP)**
 - An organization of pharmacists from different fields of the DOH.
 - Organized on July 14, 1962, by Pharmacy Advice to Secretary of Health
6. **Institutional Pharmacists Association of the Philippines (IPAP)**
 - Composed of industrial/corporate pharmacists from the medical services department of various private and government institutions. Established on April 4, 2004.
7. **Philippine Association of Pharmacists in Veterinary Industry (PAPVI)**
 - A professional group of RPh in the veterinary industry, committed to its role in dealing with veterinary drugs and products in relation to supply, chain, quality control, sales, marketing, and regulatory aspects.
8. **Federation of Junior Chapters of the PPhA (FJCPhA)**
 - Composed of Pharmacy student officers.
 - Officers are elected every school year, and PPhA selects its adviser.
 - Aims:
 - Promote greater participation in PPhA activities.
 - Foster closer relationships among pharmacy students, pharmacists, and the public.
 - Engage students in scientific investigations via lab visits, industrial concerns, educational films, lectures, and programs.
 - Uphold ethical and professional standards, defend and protect infringed member rights.
9. **Young Pharmacists Group (YPG) Philippines**
 - An organization that brings together young professionals and encourages them to act as a critical and innovative force.
10. **Drugstore Association of the Philippines (DSAP)**
 - An organization of drugstore owners established on April 14, 1984. Its official organ is *The Tablet*.
11. **Pharmaceutical Healthcare Association of the Philippines (PHAP)**
 - Association composed of local and multinational pharmaceutical manufacturers, traders, distributors, and retailers.
12. **Federation of Asian Pharmaceutical Associations (FAPA)**
 - Professional organization of Asian Pharmacists. Founded in 1964 with headquarters based in Manila, Philippines.
 - Has 17 members from different Asian countries. FAPA Online is its official organ.
13. **Asian Association of Schools of Pharmacy (AASP)**
 - An international organization of Asian Schools of Pharmacy, established on April 27, 2001, in Bangkok, Thailand.
 - Conducts biennial congresses in different Asian countries.
14. **Asian Conference on Clinical Pharmacy (ACCP)**
 - Original name was East Asia Conference on Developing Clinical Pharmacy Practice and Education.
 - Formed by Asian pharmacists seeking a practical conference to exchange ideas on clinical pharmacy.
 - First conference was in Seoul, Korea, in 1996.
15. **Federacion Internationale Pharmaceutique (FIP)**
 - International Pharmaceutical Federation.
 - Aims to promote and defend the interest of the profession worldwide.
 - Focuses on the development of Pharmacy at the international level (professional and scientific) and the extension of the pharmacist's role in healthcare.
 - *International Pharmacy Journal* is its official publication.

Reference:

1. Professional Regulation Commission. (n.d.). *Pharmacist licensure requirements*. PRC. Retrieved September 1, 2025, from <https://www.prc.gov.ph/requirements/pharmacist>
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3. International Pharmaceutical Federation (FIP). (2012). *FIP Global Pharmacy Workforce Report*. The Hague: FI