



Article Content

Title : Pharmacists Act CH
Amended Date : 2020-01-15
Category : Ministry of Health and Welfare (衛生福利部)

Chapter One - General Provisions

- Article 1 Citizens of the Republic of China may serve as pharmacists by passing the pharmacist qualification examination.
- Article 2 Persons who holds one of the following qualifications may be eligible to register for the pharmacist qualification examination:
1. Persons who graduated from public university, registered private university, independent college or a foreign college or higher accredited by the Ministry of Education who have completed and passed the practical training, and received a diploma.
 2. Persons who graduated from department of pharmacy of junior college, completed and passed the practical training, and received a diploma before the amendment and promulgation on June 5th, 2012.
- Article 3 The term "competent authorities" as used in this Act means, at central government level, the Ministry of Health and Welfare; at the special municipality level, the city government; at county (city) level, the county (city) government.
- Article 4 Qualified persons by means of the pharmacist qualification examination may apply for the pharmacist certificates.
- Article 5 For the application of pharmacist certificate, application form and qualification attesting documents shall be submitted to the central competent authority for approval and issuance. Persons not holding pharmacist certificates shall not claim as pharmacists.
- Article 6 Persons with one of the following conditions shall not serve as pharmacists; those who are already serving as pharmacists, their pharmacist certificates shall be revoked or annulled:
1. The convicted persons in violation of the Narcotics Elimination Act or the Controlled Drugs Control Act;
 2. The convicted persons in violation of the Drug Control Act;
 3. Persons subject to disposition of annulment of pharmacist certificates in accordance with this Act.

Chapter Two - Practice

Article 7 Pharmacists may practice only after applying for registration of practice to the municipality or county (city) authority at the place of practice, and a practice license is acquired. Practicing pharmacists shall receive continuing education, and provide documents attesting the completion of the continuing education every six years for the renewal of the practice license.

Regulations governing the qualifications, conditions, documents to be attached, issuance of practice license, change and re-issuance of license for the application of practice license mentioned in Paragraph 1, and renewal of practice license mentioned in the preceding Paragraph and other matters to be complied with shall be decided by the central competent authority.

Regulations governing the curricula, scores, implementation methods, certificates and documents of completion of continuing education for pharmacists mentioned in Paragraph 2, and other matters to be complied with shall be decided by the central competent authority.

Article 8 In any of the following circumstances, the practice license shall not be issued; any license already issued shall be revoked or annulled:

1. A pharmacist certificate has been revoked or annulled.
2. A pharmacist practice license was annulled within one year.
3. The pharmacist has been determined by a team of specialist physicians, pharmacists and scholars/experts invited by the municipal or county (city) competent authority to be unable to practice due to objective facts.
4. Practice of pharmacist's activities despite suspension order. After the cause listed in subparagraph 3 of the preceding paragraph is eliminated, the pharmacist may still apply for practice license in accordance with this Act.

Article 9 Pharmacists may not practice if they do not join the local pharmacists' association. Pharmacists' associations may not reject applicants who are eligible for membership.

Article 10 Pharmacists, in the case of termination or suspension of business, shall report to the original competent authority that issued the practice license for reference within 30 days after the occurrence of the facts. The suspension of business mentioned in the preceding Paragraph shall be for one year; if it exceeds one year, termination of business shall be applied.

Regulations concerning practice shall apply to pharmacists changing place of practice or resuming practice. Upon death of pharmacists, the original competent authority that issued the practice license shall annul the practice license.

Article 11 Pharmacists shall practice at only one location, and shall practice at a medical care institution approved by and registered with the local competent authority, a legal place of practice or any other institution approved by the competent authority. However, pharmacists who practice at a medical care institution or pharmacy may engage in professional practices at places other than their place of practice if they meet any of the following criteria and have obtained prior permission:

1. Drug addiction treatment or communicable disease prevention and control services;
2. Volunteer medical consultation or mobile medical services;
3. Functions related to pharmaceutical care;
4. Practice of dispensations in correctional institutions or remote areas without pharmaceutical personnel as announced by the central competent authority;
5. Public welfare or urgent needs as recognized by the central competent authority.

The regulations for engaging in practice due to the proviso set forth in the preceding paragraph shall be established by the central competent authority.

Article 12 Pharmacist in practice of pharmaceutical dispensations, unless for rightful reasons, shall not refuse the dispensations. Pharmacies claim to day-and-night dispensations, pharmacists shall do so day-and-night.

Article 13 Pharmacist shall not make false statements or reports when inquired or entrusted for assessment by agencies concerned.

Article 14 Pharmacists shall not disclose confidential information of others acquired during practice without reasons.

Chapter Three - Functions and Responsibilities

Article 15 Pharmacist shall carry out the following functions:

1. sale or management of pharmaceuticals;
2. dispensations of pharmaceuticals;
3. assessment of pharmaceuticals;
4. supervision of the manufacturing of pharmaceuticals;
5. supervision of the storage, supply, and packaging of pharmaceuticals;
6. supervision of the manufacturing of medicated cosmetics;
7. Other functions to be carried out by pharmacists according to law;
8. functions related to pharmaceutical care.

The manufacturing, supply and dispensation of Chinese pharmaceutical products, in addition to the management in accordance with relevant regulations of the Pharmacists Act, pharmacists who have studied Chinese medicine to a fair standard of proficiency may also do so; the standards shall be decided by the central competent authority in collaboration with the central competent authority of education.

Pharmacists may sell or manage medical devices of certain level. The scope and classifications of the medical devices of certain level mentioned in the preceding Paragraph shall be decided by the central competent authority.

- Article 16 Pharmacists, upon receipt and dispensation of a medical prescription, shall take prudent notice of the year-month-day, name, sex, and age of the patient, name, dosage, and use of the prescribed pharmaceuticals, and the signature or seal of the responsible physician; in the case of any suspicions or doubts, an enquiry to confirm with the prescribing physician shall be made before dispensations.
- Article 17 Pharmacists shall dispense according to the prescriptions without any mistakes; in the case that pharmaceuticals are not available or in short supply, pharmacists shall inform the prescribing physician for change, and shall not omit or substitute pharmaceuticals at will.
- Article 18 Pharmacists shall only dispense pharmaceuticals once per physician's prescription and sign or seal on the prescription slip after the pharmaceutical dispensations with the marking of date, which shall be kept for three years; and five years if it contains narcotics or poisonous pharmaceuticals. In the case of enquiries or requests to change of prescription to the physicians in accordance with regulations of Article 16 and Article 17, remarks shall be made.
- Article 19 Pharmacists shall indicate the following items on the package or container labels at the dispense:
1. patient's name and gender;
 2. drug names, dosage, quantities dispensed, and directions for use;
 3. indications;
 4. warnings or adverse reactions;
 5. name and address of the dispensing pharmacy, and name of the dispensing person;
 6. date dispensed.
- Article 20 Pharmacists shall personally administer their pharmacy business, receive physician's prescription and dispense accordingly, or

dispense according to the Chinese Pharmacopoeia or National Formula.

Article 20-1 Pharmacists administering and managing a pharmacy shall have two years and above experience of dispensation practice before providing the service of pharmaceutical dispensations. Medical care institutions employing pharmacists for the service of pharmaceutical affairs shall provide the service of pharmaceutical dispensations only when at least one of the pharmacists have two years and above experience of dispensation practice.

Chapter Four – Penal Provisions

Article 21 Pharmacists with one of the following matters shall be submitted to disciplines by pharmacists' association or competent authority:

1. pharmacists not personally practicing and leasing or lending the practice license to others for use;
2. grave or repeated negligence in practice;
3. sale of counterfeit or prohibited drugs knowingly;
4. criminal conduct in the name of practice, convicted by court;
5. acting as a product spokesman using the professional identity in pharmaceuticals to endorse or imply exaggerative and untruthful effects so that the consumers would likely be misled by the commercials to purchase;
6. violating pharmaceutical ethics;
7. other unlawful conducts in addition to the six preceding Subparagraphs.

Article 21-1 Disciplines imposed on pharmacists are as follows:

1. demerit of warning;
2. additional continuing education or clinical studies of certain number of hours by disposition;
3. restrict scope of practice or practice suspension for one month up to one year;
4. annulment of practice license;
5. annulment of pharmacist certificate.

The disciplines in the preceding Subparagraphs, if not incompatible by nature, may be jointly rendered.

Article 21-2 Incidents concerning pharmacists submitted to disciplines shall be handled by the Pharmacists' Disciplinary Committee. The Pharmacists' Disciplinary Committee shall notify the pharmacists to be disciplined about the disciplinary submission and order the said pharmacists to provide statement of defense within 20 days starting from the following day of service of notification or present themselves before the said Committee on an appointed date for personal statement; failing to provide

statement of defense or to present for personal statement in due time, the Pharmacists' Disciplinary Committee may directly render a resolution.

For any objections to the resolution rendered by the Pharmacists' Disciplinary Committee, the disciplined may plead for a review to the Pharmacists' Disciplinary Review Committee within 20 days starting from the following day of service of the resolution.

The disciplinary resolutions rendered by the Pharmacists' Disciplinary Committee and the Pharmacists' Disciplinary Review Committee shall be executed by the competent authority in the jurisdiction.

Members of the Pharmacists' Disciplinary Committee and the Pharmacists' Disciplinary Review Committee shall be partly selected and invited from pharmaceutical and legal experts and scholars, and other public citizens, who are not representatives of the people; the ratio of the pharmaceutical and legal experts and scholars, and other public citizens shall not occupy less than one third of the total members.

The Pharmacists' Disciplinary Committee shall be established by the central, municipality, or county (city) competent authorities, and the Pharmacists' Disciplinary Review Committee shall be established by the central competent authority; regulations governing the establishment, organization, meetings, disciplines, review procedures, and other matters to be complied with shall be decided by the central competent authority.

Article 22 Violations of Paragraph 1 and Paragraph 2 of Article 7, Paragraph 1 of Article 9, Paragraph 1 of Article 10, and Article 12 through Article 14, or Article 16 through Article 19, shall be fined NT\$ 2,000 up to NT\$ 10,000.

Violations of Article 12 through Article 14, in addition to the punishment of the preceding Paragraph, in the case of recommitment or grave conditions, the practice license may be annulled; when necessary, the central competent authority may annul the pharmacist certificate.

Pharmacists' associations in violation of regulations of Paragraph 2 of Article 9 shall be fined NT\$ 10,000 up to NT\$ 50,000 by the competent authority of civil associations.

Article 23 Violations of regulations of Paragraph 2 of Article 5, Article 11, and Article 20 shall be fined NT\$ 30,000 up to NT\$ 150,000.

Article 24 Persons not qualified as pharmacists practicing pharmacy as per regulations of Paragraph 1 of Article 15 shall be fined NT\$ 60,000 up to NT\$ 300,000.

Article 25 The demerit of warning, fine, practice suspension, revocation or annulment of practice license mentioned in this Act, unless

otherwise provided by this Act, shall be executed by the municipality and county (city) authorities; revocation or annulment of pharmacist certificate shall be executed by the central competent authority.

Article 26 (Deleted)

Chapter Five - Pharmacists' Associations

Article 27 Pharmacists' associations come into municipality and county (city) associations, and a national union of pharmacists' association may be established.

Article 28 Districts of pharmacists' associations shall follow the currently valid administrative districts, and that only one association is allowed in each district, except associations had established before the adjusted, restructured or merged of the administrative regions.

Article 29 The municipality and county (city) pharmacists' associations shall be initiated by more than nine pharmacists in the district of jurisdiction;
For less than nine pharmacists, the pharmacists may join the association in the adjacent district or jointly establish an association.

Article 30 (Deleted)

Article 31 The national union of pharmacists' association shall only be initiated upon over half of the municipality and county (city) associations are established.

Article 32 Pharmacist associations of each level shall be administered by the competent authorities of civil associations; their business activities shall be supervised and monitored by the competent authority.

Article 33 Directors and supervisors of the pharmacists' associations at all levels shall be elected by the members (representatives of members) at members' (representatives of members) assembly and Board of Directors and Board of Supervisors shall be respectively established. Their numbers shall be as follows:

1. The number of directors of municipality and county (city) pharmacists' associations shall not exceed twenty-seven;
2. The number of directors of the national union of pharmacists' association shall not exceed thirty-five;
3. The number of directors of pharmacists' associations at all levels shall not exceed half of the total number of members (representatives of members);
4. The number of supervisors of pharmacists' associations at all

levels shall not exceed one-third of the number of directors in the respective associations.

All pharmacists' associations may establish alternate directors and alternate supervisors; the number of these alternates shall not exceed one-third of the number of directors or supervisors respectively in the associations.

When the quotas of directors and supervisors are both above three, the standing directors and standing supervisors may be elected from and by the directors and supervisors; the number of the standing directors and standing supervisors shall not exceed one-third of the numbers of directors and supervisors respectively and one president shall be elected from the standing directors by all the directors; the association without standing directors shall elect one chief director from the directors. For more than three standing supervisors, one convener of the Board of Supervisors shall be elected among them.

Article 34 The term of office of directors and supervisors shall be three years; and the number of those consecutively elected shall not exceed one-half; the president is limited to only one consecutive office term.

Article 34-1 The elected directors and supervisors of pharmacists' associations at the higher level are not limited to the representatives of members designated by the pharmacists' associations at the lower level.
The representatives of members designated by the pharmacists' associations at the lower level for attending the pharmacists' associations at the higher level are not limited to directors and supervisors.

Article 35 Pharmacists' associations shall convene members' assembly (representative of members) once a year; provisional meetings may be convened whenever necessary.
Where the number of members of a pharmacists' association exceeds 300, pursuant to regulations of the Chapter of Association, members may be allocated by districts, and representatives of members may be elected in proportion to the number of members; assembly of representatives of members shall be convened to execute the duties of the members' assembly.

Article 36 Pharmacists' associations shall formulate s Chapter of the Association, registers of members, and rolls of brief resumes of the employees and submit those to the local competent authority of civil associations for registration, copies to the central and local competent authorities for reference.

Article 37

The Chapter of the Association for the pharmacists' associations at all levels shall manifest the following items:

1. Title, region, and location of the association;
2. Missions, organization, tasks, or enterprises;
3. Membership participation and withdrawal;
4. Membership fees and the payment periods;
5. Formulation and office term for the representatives of members;
6. Quotas, designated powers, office terms, election, and discharge of directors and supervisors;
7. Rules governing members' (representatives of members) assembly, and meetings of board of directors and board of supervisors;
8. Rules to be abided by members;
9. Budgets and accounting;
10. Amendment of the Chapter of Association;
11. Other necessary matters of the association to be manifested or handled according to law.

Article 38 Municipality and country (city) pharmacists' associations are obliged to abide by the Chapter of Association and resolutions of the higher level pharmacists' associations. For violations of laws and orders, Chapters of Association, or Chapter of Association or resolutions of the higher level pharmacists' associations committed by pharmacists' associations at all levels, the competent authorities of civil associations may render the follows dispositions:

1. Demerit of warning;
2. Revocation of the resolution;
3. Discharge of the directors, supervisors;
4. Rectification under a deadline.

The dispositions of Subparagraph 1 and Subparagraph 2 in the preceding Paragraph may also be rendered by competent authorities.

Article 39 Members of pharmacists' associations in violation of laws, orders, or Chapter of Association shall be disposed by the pharmacists' associations according to the Chapter of Association and resolutions rendered by board of directors, board of supervisors, or members' (representatives of members) assembly.

Chapter Six - Supplementary Provisions

Article 40 Regulations governing qualifications, practice, organization, and management of assistant pharmacists decided in accordance with the Pharmaceutical Affairs Act shall be decided by the central competent authority. Assistant pharmacists in violation of the regulations as prescribed in the preceding Paragraph shall be punished according to the ways and amounts applied to pharmacists.

- Article 41 For sales, supervision of manufacturing, and dispensations of Chinese pharmaceuticals, the central competent authority shall formulate management regulations in accordance with relevant regulations of the Pharmaceutical Affairs Act.
- Article 41-1 Upon issuance of certificates or licenses in accordance with this Act, the central, municipality, or county (city) competent authorities may collect fees of certificates or licenses; the amount of fees shall be decided by the central competent authority.
- Article 41-2 The national union of pharmacists' association and the provincial pharmacists' association established before the implementation of this Amendment shall reconstruct the association or proceed to disassemble according to this Act within one year upon the implementation of this Amendment.
- Article 41-3 A foreigner may attend a pharmacist examination in accordance with the laws of the Republic of China.
When a foreigner passes the examination under the preceding paragraph and receives a pharmacist certificate, his/her practice as a pharmacist in the Republic of China shall be subject to the approval by the central competent authority. Such a person shall also comply with the applicable laws of the Republic of China in relation to pharmaceutical affairs and medical treatment, as well as the articles of association of pharmacists' associations. The regulations for the approval and management of such practice shall be established by the central competent authority.
In case of breach of the preceding paragraph, in addition to sanctions in accordance with the law, the central competent authority may annul the approval.
- Article 42 The implementation regulations of this Act shall be decided by the central competent authority.
- Article 43 This Act shall be implemented on the date of promulgation.
Article 19 amended on January 10, 2011 shall take effect three months after the promulgation of this act.