

**THE GOVERNMENT**

-----

No. 109/2016/ND-CP

**SOCIALIST REPUBLIC OF VIETNAM**

**Independence - Freedom - Happiness**

-----

*Ha Noi, July 01, 2016*

## **DECREE**

### **ON ISSUANCE OF PRACTICE CERTIFICATES TO HEALTHCARE PRACTITIONERS AND OPERATION LICENSES TO HEALTHCARE FACILITIES**

*Pursuant to the Law of Government organization dated June 19, 2015;*

*Pursuant to the Law on investment dated November 26, 2014;*

*Pursuant to the Law on Medical examination and treatment dated November 23, 2009;*

*At the request of the Minister of Health;*

*The Government hereby promulgates the Decree on issuance of practice certificates to healthcare practitioners and operation licenses to healthcare facilities.*

## **Chapter I**

### **GENERAL PROVISIONS**

#### **Article 1. Scope of regulation**

1. This Decree provides for:

- a) Composition of applications and procedures for issuance and reissuance of practice certificates to healthcare practitioners;
- b) Requirements, composition of applications and procedures for issuance, reissuance and modification of operation licenses for healthcare facilities.

2. This Decree does not cover the issuance of practice certificates to healthcare practitioners and operation licenses to healthcare facilities serving the military.

#### **Article 2. Regulated entities**

This Decree applies to Vietnamese and foreign agencies, organizations and individuals located in Vietnam (hereinafter referred to as organizations and individuals) that carrying out activities relevant to healthcare provision in Vietnam.

### **Article 3. Interpretation of terms**

1. A chief physician of a healthcare facility is the one having a practice certificate as prescribed in the Law on Medical examination and treatment who works full-time at the healthcare facility in an appropriate scope of practice and takes legal responsibility for all the professional activities of the healthcare facility.
2. A valid copy is a copy issued according to the master register or a copy authenticated by a competent agency or organization or a copy appended a signature (applicable to individuals) or a signature and a seal (applicable to organizations) proving that such copy has been compared with the original. Papers issued by foreign organizations shall be consularly legalized and enclosed with a Vietnamese translation which is authenticated according to Vietnamese law.
3. A full-time healthcare practitioner means a person working consecutively 8 hours per day within the time registered by his/her healthcare facility or working during the whole medical facility's working time if it is less than 8 hours per day.
4. A part-time healthcare practitioner means the one working at a healthcare facility whose working time is less than that prescribed in clause 3 of this Article.

## **Chapter II**

### **ISSUANCE AND REISSUANCE OF PRACTICE CERTIFICATES**

#### **Section 1. COMPOSITION OF APPLICATIONS AND PROCEDURES FOR ISSUANCE AND REISSUANCE OF PRACTICE CERTIFICATES**

#### **Article 4. Cases eligible for issuance and/or reissuance of practice certificates**

1. Procedures for issuance of a practice certificate apply to the following cases:
  - a) Initial issuance of a practice certificate.
  - b) Issuance of a modified practice certificate in case of change in contents of an issued practice certificate, including:
    - Supplementation of practice scope on the practice certificate when the practitioner applies for supplementation of a practice scope of a speciality different from the practice scope specified in the practice certificate;
    - Change in practice scope on the practice certificate when the practitioner applies for change in the practice scope of a speciality different from the expertise scope specified in the practice certificate;
    - Change in name or date of birth on the practice certificate.

2. Procedures for reissuance of practice certificates apply to the following cases:

- a) The practice certificate is revoked according to regulations on clause 1 Article 29 of the Law on Medical examination and treatment;
- b) The practice certificate is lost or damaged.

**Article 5. Composition of an application for the practice certificate applicable to Vietnamese citizens**

1. The Form No. 01 in Annex I enclosed with this Decree.

2. A valid copy of qualifications suitable for the practice scope applying for the practice certificate. To be specific:

- a) A medical degree;
- b) A bachelor's degree in medicine issued by a foreign authority and recognized by the Ministry of Education and Training to be equal to a university's degree enclosed with the certificate of completion of an additional professional course which lasts at least 12 months and lawfully held by a Vietnamese training institution according to regulations of the Minister of Health. The combination of such documents is equal to a medical certificate; their owner shall be issued with a practice certificate with doctor's title;
- c) A bachelor's degree in chemistry, biology or pharmacy of university level enclosed with a certificate of completion of a medical training in testing which lasts at least 3 months or a certificate of post-graduated education in testing;
- d) A certificate of traditional medicine practitioner or a certificate of owner of herbal remedies or treatment methods issued by the Minister of Health or the Director of a Department of Health.

If any of such qualification is lost, a certificate of graduation or a valid copy of the replacing document of the certificate of graduation issued by the issuer of such qualification shall be presented.

3. The form No. 02 in Annex I enclosed with this Decree or valid copies of qualifications of resident physician, level I medical specialist, level II medical specialist, excluding traditional medicine practitioners or owner of herbal remedies or treatment methods.

4. A certificate of health issued by a healthcare facility specified in clause 6 Article 23 and clause 5 Article 25 of this Decree.

5. A criminal record.

6. The form No. 03 in the Annex I enclosed with this Decree which is verified by the head of his/her office, applicable to applicants working at medical facilities by the time of application

submission, or by People's Committee of the commune where he/she resides, applicable to applicants not working for any healthcare facilities by the time of application submission.

7. 2 4x6 photos having white background which was made within 06 months before the date of submission.

**Article 6. Composition of an application for an initial practice certificate applicable to foreigners and overseas Vietnamese citizens**

1. The Form No. 04 in Annex I enclosed with this Decree.

2. Valid copies of qualifications suitable for professions specified in Article 17 of the Law on Medical examination and treatment.

3. A certificate of completion of internship:

a) The form No. 02 in Annex I enclosed with this Decree, applicable to internship performed in Vietnam;

b) If the internship is performed overseas, the certificate of completion of practice issued by a competent person shall contain the following information: full name of the intern; date of birth; resident address; passport number (date of issue, place of issue); qualifications; year of graduation; place of internship; time of internship; assessment of his/her professional capacity and professional ethics.

4. A valid copy of work permit issued by a Vietnamese labor-affair authority.

5. A valid copy of any of the following documents:

a) A certificate of proficiency in Vietnamese, applicable to foreigners registering to use Vietnamese when providing healthcare services;

b) A certificate of translators qualified for translation in healthcare suitable for the language the practitioner registered to use when providing healthcare services and a labor contract of the translator with the healthcare facility where he/she is working;

c) Regarding foreigners registering to use their native languages when providing healthcare services:

- A certificate of proficiency in the language that the practitioner registered to use according to regulations in Article 17 of this Decree;

- A certificate of translators qualified for translation in healthcare suitable for the language the practitioner registered to use when providing healthcare services as prescribed in Article 18 of this Decree and a labor contract of the translator with the healthcare facility where he/she is working.

6. A certificate of health suitable for providing healthcare services issued by an eligible healthcare facility or a certificate of health issued by a foreign healthcare facility within 12 months from the date of application submission.

7. A criminal record (applicable to persons not subject to issuance of work permits).

8. 2 4x6 photos having white background which was made within 06 months before the date of submission.

### **Article 7. Composition of applications for modification of practice certificates**

1. An application for supplementation to the practice scope on the practice certificate shall include:

a) The form No. 05 in Annex I enclosed with this Decree;

b) A valid copy of the issued practice certificate;

c) A valid copy of qualifications suitable for the practice scope to be modified;

d) A certificate of completion of internship specified in clause 3 Article 5 of this Decree suitable for the qualifications.

2. An application for change in the practice scope on the practice certificate shall include:

a) The form No. 06 in Annex I enclosed with this Decree;

b) A valid copy of qualifications suitable for the practice scope to be modified;

c) The original of the issued practice certificate;

d) A certificate of completion of internship specified in clause 3 Article 5 of this Decree;

dd) 2 4x6 photos having white background which was made within 06 months before the date of submission.

3. An application for change in name and/or date of birth on the practice certificate shall include:

a) The form No. 07 in Annex I enclosed with this Decree;

b) A valid copy of documents proving the change in name and/or date of birth of the practitioner;

c) The original of the issued practice certificate;

d) 2 4x6 photos having white background which was made within 06 months before the date of submission.

## **Article 8. Composition of applications for reissuance of practice certificates**

1. An application for reissuance of a practice certificate which is lost or damaged or revoked according to regulations in points a and b clause 1 Article 29 of the Law on Medical examination and treatment shall include:

- a) The Form No. 08 in Annex I enclosed with this Decree;
- b) 2 4x6 photos having white background which was made within 06 months before the date of submission.

2. An application for reissuance of a practice certificate which is revoked according to regulations in points c, d, dd e and g clause 1 Article 29 of the Law on Medical examination and treatment shall include:

- a) The form No. 09 in Annex I, applicable to Vietnamese citizens or the form No. 10 in Annex I, applicable to foreigners or overseas Vietnamese citizens, enclosed with this Decree;
- b) A certificate of consecutive updating of medical knowledge according to regulations of the Minister of Health;
- c) Papers and documents specified in clauses 2, 4, 5, 6 and 7 Article 5 of this Decree, applicable to Vietnamese citizens; papers and documents specified in clauses 2, 4, 5, 6, 7 and 8 Article 6 of this Decree, applicable to foreigners and overseas Vietnamese citizens.

## **Article 9. Submission of applications for issuance/reissuance of practice certificates**

1. The submission of an application for issuance/reissuance of a practice certificate specified in Articles 5, 6, 7 and 8 of this Decree shall be carried out as follows:

- a) The applicant for issuance/reissuance of a practice certificate of cases specified in points a, b and c clause 1 Article 26 of the Law on Medical examination and treatment shall send 01 set of application to the Ministry of Health;
- b) The applicant for issuance/reissuance of a practice certificate who is working at a healthcare facility under the management of the Department of Health, excluding cases specified in point a of this clause shall send 01 set of application to the Department of Health.

2. If the practitioner having a practice certificate issued by the Ministry of Health or the Department of Health changes his/her workplace, the application for issuance/reissuance of a practice certificate shall be submitted as follows:

- a) Any practitioner working at a healthcare facility under the management of the Department of Health shall send the application to the Department of Health of the province where such healthcare facility is located;

b) Any practitioner working at a healthcare facility under the management of the Ministry of Health shall send the application to the Ministry of Health.

3. If the healthcare practitioner is not working for a healthcare facility by the time of application for issuance/reissuance of the practice certificate, the application shall be sent to the Department of Health of the province where he/she registers the permanent residence.

#### **Article 10. Procedures for issuance/reissuance and management of practice certificates**

1. After receiving an application for issuance/reissuance of a practice certificate, the Ministry of Health or the Department of Health (hereinafter referred to as application-receiving authority) shall issue an application receipt note using the form specified in Annex II enclosed with this Decree. To be specific:

a) If the application is submitted directly at the application-receiving authority and satisfactory according to regulation, the application-receiving authority shall give the applicant an application receipt note;

b) If the application is sent by post, then within 02 days from the day on which the application is received (pursuant to the coming postmark), the application-receiving authority shall send the receipt note to the applicant;

2. Within 20 days from the date written on the Receipt note, the application-receiving authority shall conduct the inspection of the application and make an appraisal record).

3. If the application is satisfactory, within 10 working days from the day on which the appraisal record is issued, the application-receiving authority shall issue/reissue the practice certificate.

4. Regarding unsatisfactory applications:

a) Within 05 working days from the day on which the appraisal record is issued, the application-receiving authority shall send the applicant a written notification containing a request for completion of the application. Such notification must specify the documents subject to supplementation and those subject to modification.

b) After receiving the request for completion of the application, the applicant shall comply with the request and send the revised application to the application-receiving authority. The application-receiving authority shall send the Receipt note for the revised application to the applicant.

c) The application-receiving authority shall continue the procedures as prescribed in clauses 2 and 3 and point a clause 4 of this Article. If the revised application is still unsatisfactory, the application-receiving authority shall continue guiding the applicant on the completion of the application.

d) If the applicant fails to make supplementation or modification of the application within 60 days from the day on which the application-receiving authority's request for completion of the application is received, the procedures for issuance/reissuance of the practice certificate shall be re-conducted.

#### 5. Management of practice certificates:

a) The practice certificate shall be issued by the Minister of Health using the form No. 01 in Annex III and the Decision on supplementation of practice scope on the practice certificate shall be issued by the Minister of Health or the Director of the Department of Health using the form No. 03 in Annex III enclosed with this Decree. The code of the practice certificate shall be in accordance with the form No. 04 in Annex III enclosed with this Decree; the practice scope specified on the practice certificate shall be conformable to the guidance of the Minister of Health.

b) Application-receiving authorities shall themselves print the samples of practice certificates using the form specified in point a of this clause, ensure the continuity of numbers of the practice certificates during the issuance and ensure that each practitioner is issued with no more than one practice certificate.

c) Departments of Health shall use the samples of practice certificates issued by the Ministry of Health until December 31, 2016.

#### **Article 11. Advisory councils for issuance/reissuance of practice certificates**

1. The Minister of Health or the Director of the Department of Health shall establish an advisory council for issuance/reissuance of practice certificates (hereinafter referred to as Advisory council) according to regulations in clause 4 Article 28 of the Law on Medical examination and treatment.

2. The Chairperson of the Advisory council shall direct the establishment and sending of the operation regulation for the Advisory council to the Minister of Health or the Director of the Department of Health for approval and implementation.

#### **Section 2. REGISTRATION OF HEALTHCARE PRACTICE**

##### **Article 12. Rules for registration of healthcare practice**

1. A healthcare practitioner shall work as a chief physician of only one healthcare facility.

2. A healthcare practitioner shall register to work as a person taking charge of only one department of one healthcare facility. A healthcare practitioner must not take charge of more than one department of one or multiple healthcare facilities.

3. A healthcare practitioner being the chief physician of a healthcare facility may also take charge of a department of such facility in accordance with the practice scope specified in the issued practice certificate.
4. A healthcare practitioner working at a healthcare facility may register to being a chief physician of a healthcare facility which operates overtime.
5. A healthcare practitioner working at a state-owned healthcare facility must not register to be the head of a private hospital or a healthcare facility established and operated according to the Law on Enterprise or the Law on Cooperatives unless he/she is appointed by a competent authority to participate in the management and/or direction of a state-owned healthcare facility.
6. Any healthcare practitioner having registered to work as a chief physician of a healthcare facility may register to work overtime at another healthcare facility.
7. Any healthcare practitioner may register to work at one or multiple healthcare facilities, provided that he/she does not register to work in a period of time at multiple healthcare facilities and the total amount of overtime work does not exceed 200 hours as prescribed in the Labor Code. The healthcare practitioner must ensure the reasonability of the travel between the registered places of practice.
8. If a healthcare practitioner having registered to work at a healthcare facility carries out healthcare activities in an alternate mode between humanitarian healthcare and healthcare on contract between healthcare facilities, he/she is not required to registered to practice at such facilities.

### **Article 13. Registration of healthcare practice**

1. The registration of practice shall be carried out by the chief physician of the healthcare facility using the form specified in Annex IV enclosed with this Decree.
2. Contents of practice registration:
  - a) Place of practice: name and address of the healthcare facility for practice;
  - b) Practice period: time of practice: time and days of a week when the practitioner works at each healthcare facility which ensure the convenience in travelling between the facilities that he/she has registered as prescribed in point a of this clause;
  - c) Titles and professional positions of the practitioner: the List of persons registering practice must contain their titles (chief physicians or other positions).
3. If a practitioner on the abovementioned list is practicing at another healthcare facility, his/her registration of practice must contain time, location and his/her professional position at such facility.

## **Article 14. Procedures for registration of healthcare practice**

### 1. Time of practice registration:

- a) Regarding healthcare facilities applying for operation licenses, the registration of practice for practitioners shall be carried out at the time of application for operation licenses;
- b) Regarding healthcare facilities having operation licenses which have changes in staff members, within 10 working days from the day on which the change is made, the chief physician working for such healthcare facilities shall notify the authority receiving the application for practice registration specified in clause 2 of this Article.

### 2. Receipt of application for practice registration in case of change in practitioners:

- a) The Ministry of Health is responsible for receiving applications for practice registration from healthcare facilities affiliated to the Ministry of Health;
- b) Departments of Health are responsible for receiving applications for practice registration of healthcare facilities located in the areas under their management, excluding healthcare facilities specified in point a of this clause.

## **Article 15. Management of practice registration information**

1. Within 05 working days from the day on which the operation license or the updated list of practitioners specified in clause 1 Article 14 of this Decree is received, the Department of Health shall, within their competence, receive the application for practice registration specified in point b clause 2 Article 14 of this Decree and send the list of practitioners to the Ministry of Health.

2. Within 05 working days from the day on which the operation license or the updated list of practitioners specified in clause 1 Article 14 of this Decree is received, the Ministry of Health shall, within their competence, receive the application for practice registration specified in point a clause 2 Article 14 of this Decree and send such application and list to the Department of Health where the healthcare facility is headquartered.

### 3. Publication of list of applicants:

- a) The Ministry of Health shall post the list of applicants which fully contains the information specified in Annex IV enclosed with this Decree on its website;
- b) Departments of Health shall post the list of applicants which fully contains the information specified in Annex IV enclosed with this Decree according to their registration-receiving competence provided for in point b clause 2 Article 14 of this Decree on their websites.

## **Section 3. PRACTICE FOR ISSUANCE OF PRACTICE CERTIFICATE**

### **Article 16. Organization of internship**

1. Acceptance of intern:

- a) The intern shall send an application for practice using the form No. 01 of Annex V enclosed with this Decree and valid copies of healthcare-related qualifications to the healthcare facility where he/she registered the internship;
- b) After receiving the application for internship, if the application is approved, the head of the healthcare facility shall conclude an internship contract with the intern using the form No. 02 of Annex V enclosed with this Decree.

2. Assignment of internship instructors:

Head of the healthcare facility shall issue a decision on assignment of practice instructors using the form No. 03 in Annex V enclosed with this Decree. An intern instructor may provide instruction for no more than 5 interns at once.

3. Any internship instructors shall satisfy the following requirements:

- a) Having a practice certificate;
- b) Having practice scope suitable for the qualification of the intern, having training level equivalent to or higher than that of the intern and having practiced healthcare for at least 3 consecutive years.

4. Responsibilities of internship instructors:

- a) Provide interns with guidance on healthcare internship;
- b) Assess the internship results and take responsibility for their assessment;
- c) Take responsibility in case the intern makes professional mistake during the internship process that affects the patient's health and such mistake is caused due to the instructor's fault.

5. Issuance of certificate of completion of internship: After receiving the assessment by the internship instructor of the intern, the head of the healthcare facility shall issue a certificate of completion of internship using the form No. 02 of Annex I enclosed with this Decree.

**Section 4. CRITERIA FOR RECOGNITION OF PROFICIENCY IN VIETNAMESE OR ANOTHER LANGUAGE OR ELIGIBILITY FOR MAKING TRANSLATION IN HEALTHCARE**

**Article 17. Criteria for recognition of proficiency in Vietnamese or another language or eligibility for making translation in healthcare**

1. A practitioner shall be recognized being proficient in Vietnamese used in healthcare if he/she has been tested and recognized by an educational institution specified in Article 19 of this Decree, excluding cases specified in clause 3 of this Article.

2. If the practitioner registers a non-native language or Vietnamese as the language to be used in healthcare activities, he/she shall be tested and recognized by an educational institution specified in Article 19 of this Decree to be proficient in the registered language, excluding cases specified in clause 3 of this Article.

3. A practitioner shall be eligible for being recognition proficient in Vietnamese or another language in healthcare if he/she has any of the following qualifications:

a) A medical degree of intermediate level or higher level issued by a Vietnamese or foreign lawful training institution with the training program conducted in Vietnamese or the language which the practitioner registers to use in healthcare;

b) A certificate of completion of a medical training course which lasts at least 12 months and is conducted in Vietnamese or the language which the practitioner registers to use in healthcare;

c) A university degree in Vietnamese or the language the practitioner registers to use in healthcare issued by a Vietnamese or foreign lawful training institution.

Qualifications specified in points a and b of this clause shall be issued within 05 years before the date of application submission.

#### **Article 18. Criteria for recognition of eligibility for making translation in healthcare**

1. A practitioner shall be recognized being eligible for making translation in healthcare if he/she has been tested and recognized by an educational institution specified in Article 19 of this Decree, excluding cases specified in clause 2 of this Article.

2. A translator may be recognized eligible for making translation if he/she has any of the following qualifications:

a) A medical degree of intermediate level or higher level issued by a Vietnamese or foreign lawful training institution with the training program conducted in Vietnamese or the language which the translator registers to make translation in;

b) A certificate of completion of a medical training course which lasts at least 12 months and is conducted in Vietnamese or the language which the translator registers to make translation in;

c) A medical degree of intermediate level or higher level or a certificate of traditional medicine practitioner and a university degree of foreign language suitable for the language the translator registers to make translation in.

Qualifications specified in points a and b clause 2 of this Article shall be issued within 05 years before the date of application submission.

3. A person shall work as the translator of only one healthcare practitioner who is providing healthcare for a patient at a time.

**Article 19. Requirements for educational institutions entitled to examine and recognize the proficiency in Vietnamese or another language or eligibility for making translation in healthcare**

An educational institution shall be entitled to examine and recognize the proficiency in Vietnamese or another language or eligibility for making translation in healthcare if it fully satisfy the following requirements:

1. Being a university of medicine of Vietnam.
2. Having a foreign language faculty or subject in any of the following languages: English, French, Russian, Chinese, Japanese and Korean.
3. Having a bank of exam questions for testing and recognizing proficiency in Vietnamese or good command of another language or qualification for translation in healthcare.

**Article 20. Composition of application and procedures for issuance of the certificate of educational institution eligible for examining and recognizing the proficiency in Vietnamese or another language or eligibility for making translation in healthcare**

1. Composition of an application:

- a) Valid copies of documents proving the establishment and operation of the educational institution;
- b) Documents proving that the educational institution has the foreign-language faculty or subject specified in clause 2 Article 19 of this Decree and the list of lecturers working full-time for the faculty or the subject;
- c) A bank of exam questions for testing and recognizing proficiency in Vietnamese or good command of another language or qualification for translation in healthcare of at least one of the languages: English, French, Russian, Chinese, Japanese and Korean.

2. If an educational institution which has the certificate of eligibility for examining and recognizing the proficiency in Vietnamese or another language or eligibility for making translation in healthcare applies for addition to languages for examination and recognition, then the application shall be conformable to regulations in points b and c of this clause.

3. Procedures:

- a) The educational institution shall send 01 set of application for a certificate of eligibility for examining and recognizing the proficiency in Vietnamese or another language or eligibility for making translation in healthcare (hereinafter referred to as language examination) according to regulations in clause 1 of this Article to the Ministry of Health;
- b) After receiving the application, the Ministry of Health shall give the educational institution a receipt note using the form No. 01 in the Annex enclosed with this Decree;
- c) Within 15 days from the day on which the application is received, if it is satisfactory, the Ministry of Health shall issue a certificate of eligibility for examining language in healthcare to the educational institution using the form No. 02 in Annex VI enclosed with this Decree. If the application is rejected, an explanation shall be made;
- d) If the application is unsatisfactory, within 5 working days from the date written on the application receipt note, the application-receiving authority shall send a written notification to the educational institution containing the instruction for completion.
- dd) Within 15 days from the day on which the revised application is received, the application-receiving authority shall issue the educational institution with a Certificate of eligibility for examining language using the form No. 02 in Annex VI enclosed with this Decree; if the application is rejected, a written response containing explanation shall be sent.
- e) Within 10 days from the date of issue of the Certificate of eligibility for examining language, the Ministry of Health shall post the name of the educational institution issued with the certificate on its website.

**Article 21. Composition of and procedures for application for examination and recognition of the proficiency in Vietnamese or another language or eligibility for making translation in healthcare**

- 1. An application for examination and recognition of proficiency in a language in healthcare shall include:
  - a) The form No. 01 in Annex VII enclosed with this Decree;
  - b) A valid copy of the effective ID card or passport;
  - c) 2 4x6 photos having white background which have been made within 06 months before the date of submission.
- 2. An application for recognition of proficiency in Vietnamese or another language or eligibility for making translation in healthcare shall include:
  - a) The form No. 02 in Annex VII enclosed with this Decree;
  - b) Documents specified in points b and c clause 1 of this Article;

c) Valid copies of qualifications specified in clause 3 Article 17 of this Decree, applicable to application for recognition of proficiency in Vietnamese or another language in healthcare, or qualifications specified in clause 2 Article 18 of this Decree, applicable to application for recognition of eligibility for making translation in healthcare.

3. Procedures for examination and recognition:

a) The applicant shall send 01 set of application specified in clause 1 of this Article to an educational institution specified in Article 19 of this Decree;

b) Within 30 days from the day on which the satisfactory application is received, the educational institution shall conduct examination and issue the certificate using the form No. 03 in Annex VII enclosed with this Decree to persons specified in clauses 1 and 2 Article 17 and clause 1 Article 18. Results of examination shall be published.

4. Recognition procedures:

a) The applicant shall send 01 set of application specified in clause 2 of this Article to an educational institution specified in Article 19 of this Decree;

b) Within 10 working days from the day on which the satisfactory application is received, the educational institution shall issue the certificate to persons specified in clause 3 Article 17 and clause 2 Article 18 of this Decree. If the application is rejected, a written response containing explanation shall be sent.

### **Chapter III**

## **REQUIREMENTS, COMPOSITION OF APPLICATIONS AND PROCEDURES FOR ISSUANCE, REISSUANCE AND MODIFICATION OF OPERATION LICENSE FOR HEALTHCARE FACILITIES**

### **Section 1. REQUIREMENTS FOR ISSUANCE OF OPERATION LICENSES TO HEALTHCARE FACILITIES**

#### **Article 22. Organization of healthcare facilities**

Any healthcare facility shall be established according to law and organized in any of the following forms:

1. Hospital, including general hospital and specialized hospital.
2. Infirmaries of people's public security forces.
3. Polyclinic.
4. Specialized clinic, including:

- a) General medicine clinic;
- b) Specialized clinic for internal medicine: cardiology, respiratory medicine, gastroenterology, pediatrics and other specialities in internal medicine;
- c) Clinic providing healthcare consultancy or clinic providing healthcare consultancy using information technology and telecommunications;
- d) General surgery clinic;
- dd) Antenatal clinic;
- e) Clinic of andrology;
- g) Clinic of odonto-stomatology;
- h) Clinic of otolaryngology;
- i) Clinic of ophthalmology;
- k) Clinic of cosmetology;
- l) Clinic of rehabilitation;
- m) Clinic of psychiatry;
- n) Clinic of oncology;
- o) Clinic of dermatology;
- p) Clinic of dietetics;
- q) Clinic of drug rehabilitation;
- r) Clinic of HIV/AIDS treatment;
- s) Clinic of opioid replacement therapy conformable to the Decree No. 90/2016/ND-CP dated July 01, 2016 by the Government;
- t) Other specialized clinics.

5. Traditional medicine facility.

6. Family medicine facilities (or healthcare facilities operated in the principle of family medicine): pilot establishment as prescribed by the Minister of Health.

7. Laboratory.

8. Image diagnosis clinic, X-ray room.

9. Medical assessment facility, forensic examination facility and mental forensics examination facility providing healthcare shall be organized as a healthcare facility specified in clause 3 of this Article. Forensic psychiatric assessment facility providing healthcare shall be organized as a healthcare facility specified in clause 1 and 3 or point m clause 4 of this Article. Such facilities shall satisfy the applicable requirements.

10. Maternity ward.

11. Preventive care clinic.

12. Clinic of occupational diseases.

13. Medical service providers, including:

a) Injection, dressing change, pulse counting and temperature and blood pressure measurement service provider;

b) Home healthcare service provider;

c) Facilities providing emergency and patient transportation services in Vietnam or abroad;

d) Optical glasses service provider;

dd) Cosmetological service provider;

e) Massage service provider;

g) Other healthcare service providers.

14. Commune-level health stations, infirmaries.

15. Any medical facility affiliated to an agency, unit or organization which conducts healthcare must be operated in a form specified in clause 3, point a clause 4 or clause 14 of this Article and must comply with the requirements applied to such form of organization.

16. Any medical center having a function of conducting medical examination and treatment shall be issued with an license to operate in form of a general hospital or a polyclinic.

17. If the healthcare facility conducts HIV examination, apart from provisions of this Decree, it must satisfy the provisions of the Decree No. 75/2016/ND-CP date July 01, 2016 by the Government.

18. If the healthcare facility provides inoculation, apart from provisions of this Decree, it must satisfy the provisions of the Decree No. 104/2016/ND-CP dated July 01 by the Government.

19. If the healthcare facility has a laboratory for testing microorganisms and pathology specimens likely to contain microorganisms which poses a risk of transmitting infectious diseases to human, apart from the provisions of this Decree, it must satisfy the provisions of the Decree No. 103/2016/ND-CP dated July 01, 2016 by the Government.

### **Article 23. Requirements for issuance of operation licenses to hospitals**

#### 1. Scale of hospitals:

- a) A general hospital must have at least 30 patient beds;
- b) A specialized or traditional hospital must have at least 20 patient beds. Particularly, a high-tech ophthalmologic hospital must have at least 10 patient beds.

#### 2. Facilities:

a) Depending on the scale of the hospital, general or specialized hospital, it shall be designed and built into a block building which satisfies the following conditions:

- Departments, rooms and hallways are arranged conveniently for technique expertise under the interconnected and self-contained complex model within the hospital premises; ensure aseptic and environmental sanitation conditions prescribed by law;

- A minimum construction floor area of 50 m<sup>2</sup> per patient bed is ensure, the hospital façade is at least 10 m wide.

b) Satisfying the conditions of radiation safety, hospital waste management and fire and explosion prevention according to law.

c) Ensuring the sufficiency of electricity and water supply and other conditions for patient care.

#### 3. Medical equipment:

a) Having sufficient medical equipment and instruments suitable to the practice scope of the hospital;

b) Having sufficient vehicles for internal and external emergency transportation Hospitals having no vehicles for external emergency transportation must have transportation contracts signed with healthcare facilities having operation licenses and providing services of emergency transportation.

#### 4. Organization:

a) Departments:

- There shall be at least 2 of the 4 departments of internal medicine, surgery, obstetrics and pediatrics, applicable to general hospitals, or an appropriate clinical department, applicable to specialized hospital;
- The medical examination department shall have a place for patient reception, emergency and patient stay rooms, consulting rooms and minor surgery rooms (if any minor surgery is carried out);
- The subclinical department shall have at least one unit for testing and one unit for image diagnosis. Particularly, any ophthalmologic hospital having no image diagnosis unit must have a contract concluded with a healthcare facility having an operation license and image diagnosis unit;
- Pharmaceutical department;
- Other specialized departments and sections which must be suitable for the scale, functions and tasks of the hospital.

b) There shall be functional sections of general planning, organization and personnel, quality control, convalescence, finance and accounting and other functional sections.

5. Personnel:

a) The number of full-time (tenured) practitioners in each department must account for at least 50% of the total number of practitioners in such department.

b) The number of staff members and title structures and standards shall comply with regulations prescribed by the Minister of Health.

c) Any chief physician of a hospital shall satisfy the following conditions:

- Being a doctor with a practice certificate with practice scope suitable for at least one of medical speciality registered by the hospital;

- Having worked as a healthcare practitioner for at least 54 months. The assignment and appointment of the chief physician of the hospital shall be performed in writing;

- Working on a full-time basis at the hospital.

d) The head of the clinical department must satisfy the following conditions:

- Being a doctor with a practice certificate suitable for the speciality;

- Having worked as a healthcare practitioner in such speciality for at least 54 months. The assignment and appointment of the head of a department shall be carried out in writing;

- Working on a full-time basis at the hospital.

dd) Requirements for heads of subclinical departments:

- Head of the laboratory department: being a doctor or a physician specialized in testing or a chemical or biological bachelor or a pharmacist with a degree of university or higher level and a practice certificate for testing.

A testing physician with a university degree is qualified for read and append his/her signature on the testing results. If the healthcare facility does not have a doctor specialized in testing, the doctor requesting the testing shall make the diagnosis conclusion.

- Requirements for the head of the department of microbiology (applicable to hospitals having departments of microbiology): being a doctor or a physician having a university degree and a practice certificate specialized in microbiology, or a bachelor's degree in chemistry, biology or pharmacy of university or higher level, applicable to persons employed to conduct medical test before the effective date of this Decree and issued with a certificate of practice in microbiology.

- Requirements for the head of the department of surgery (applicable to hospitals having departments of surgery): being a doctor specialized in surgery or having a certificate of training in surgery and practice certificate specialized in surgery.

- Having worked for a suitable laboratory department or a department of microbiology or a department of surgery for at least 54 months or having worked as a practitioner specialized in testing or microorganism or surgery for at least 36 months, including the period of post-graduation study in such specialities, from the day on which his/her job relevant to testing, microorganism or surgery starts (determined from the time on which the labor contract is signed or the recruitment decision is issued) to the day on which he/she is assigned or appointed to be the chief physician of the department.

- Working on a full-time basis in the hospital.

e) Requirements for heads of departments of image diagnosis or X-ray departments:

- The lead of a department of image diagnosis must be a doctor having a practice certificate specialized in image diagnosis and having conducted medical examination and treatment in image diagnosis for at least 54 months or having practiced image diagnosis for at least 36 months, including the period of post-graduation study in such speciality, from the day on which his/her job relevant to image diagnosis starts (determined from the time on which the labor contract is signed or the recruitment decision is issued) to the day on which he/she is assigned or appointed to be the chief physician of the department;

- The lead of an X-ray department must be a doctor having a university or higher level degree, a practice certificate and having conducted medical examination and treatment involving X-ray for at least 54 months or having practiced X-ray speciality for at least 36 months, including the period of post-graduation study in such speciality, from the day on which his/her job relevant to X-ray (determined from the time on which the labor contract is signed or the recruitment decision is issued) to the day on which he/she is assigned or appointed to be the chief physician of the department. An X-ray bachelor (of university level) may read and describe the diagnosis images but must not make diagnosis conclusions;

- If the healthcare facility does not have a doctor specialized in image diagnosis or X-ray doctor, the doctor requesting the image diagnosis shall make the diagnosis conclusion;

- Working on a full-time basis in the hospital.

g) The lead of the Pharmaceutical department must be a person working full-time at the hospital and must satisfy law provisions on pharmacy;

h) Leads of other departments who are not required practice certificates must fulfill the following conditions:

- Having a university degree and having worked in such speciality for at least 36 months from the day on which the degree is issued to the day on which he/she is assigned/appointed to be the department's lead. The assignment and appointment of the head of a department shall be carried out in writing;

- Working on a full-time basis in the hospital.

i) Apart from entities specified in points c, d, dd, e, g and h of this clause, any other entity working at the hospital who conducts medical examination and treatment must have a practice certificate and must conduct medical examination and treatment within the assigned scope of task. The assignment must be made in writing and conform with the practice scope written on the practice certificate;

k) There must be persons taking charge of radiation safety (if the facility uses radiological equipment with radiation sources, radiopharmaceuticals used in healthcare and equipment used in radiological medicine).

6. Apart from requirements specified in this Article, any hospital conducting check-up and issuing Health certificates must satisfy the following requirements:

a) Personnel:

- A person in charge of making check-up conclusions must be a doctor having a healthcare practice certificate and having conducted medical examination and treatment for at least 54 months and assigned by a competent person of the healthcare facility to make check-up

conclusions, append signatures on health certificates and periodic health check records. The assignment shall be carried out in writing.

- Apart for the abovementioned conditions, any healthcare facility conducting check-up for foreigners or overseas Vietnamese citizens and Vietnamese citizens working overseas on contract or studying abroad (hereinafter referred to as health-check facility involving foreign elements) must satisfy the following requirements:

+ The persons conducting clinic examination and persons making check-up conclusions must be level I medical specialists or masters of medicine or resident physicians or persons with higher educational level;

+ If the persons providing check-up and persons receiving check-up are not proficient in the same language, a translator is required. The translator must have a certificate of eligibility for making translation in healthcare activities as prescribed in Article 18 of this Decree;

b) Professional requirements:

- For health-check facilities without foreign elements: having sufficient clinic departments, including rooms for internal medicine, pediatrics, surgery, obstetrics, optics, otorhinolaryngology, odontostomatology and dermatology and subclinical departments, including X-ray rooms and laboratories.

- For healthcare facilities involving foreign elements, apart from the abovementioned conditions, the following subclinical techniques must be carried out:

+ Blood testing: blood formula, ABO blood type, Rh blood type, rate of blood sedimentation, hemoglobin rate and rate of uremia;

+ Finding of plasmodium in blood;

+ Testing for A, B, C and E hepatitis;

+ Serological test for syphilis;

+ HIV test;

+ Mantoux reaction test;

+ Pregnancy test;

+ Drug test;

+ Fecal screening for parasites;

+ Electrocardiogram measurement;

- + Electroencephalography measurement;
- + Supersonic test;
- + Diagnostic tests for leprosy.

If the facility is not eligible for carrying out an HIV test, a diagnostic tests for leprosy and an EEG measurement, it must conclude a professional support contract with a healthcare facility having an operation license and eligible for performing such technique.

- For healthcare facility performing driver health check, apart from the requirements applied to healthcare facilities without foreign element, the following subclinical techniques must be carried out:

- + EEG measurement;
- + Visual-field measurement;
- + Testing for determination of blood alcohol concentration and breath alcohol concentration;
- + Drug tests and psychotropic substance tests.

If the facility performing driver health check is not eligible for conducting an EEG measurement or a visual-field measurement, it must conclude a professional support contract with a healthcare facility having an operation license and eligible for performing such technique.

c) Facilities: having medical equipment and instruments suitable for the professional activities and the check-up contents.

d) Any healthcare facility conducting check-up must apply for declaration of eligibility for performing check-up according to regulations in clause 8 Article 43 and clauses 4 and 5 Article 44 of this Decree when it has been issued with an operation license.

#### **Article 24. Requirements for issuance of operation licenses to infirmaries affiliated to People's Police force**

1. Scale:

The infirmary must have at least 10 patient beds.

2. Facilities:

a) Having places for patient reception, consulting rooms, emergency rooms, patient rooms and laboratories with an area sufficient for the use of means and instruments serving the medical examination and treatment;

b) Satisfying the conditions of radiation safety, hospital waste management and fire and explosion prevention according to law;

c) Ensuring sufficient electricity and water supply and other conditions for patient care.

### 3. Medical equipment:

Having sufficient medical equipment and instruments suitable to the registered practice scope.

4. Organization: Having at least 02 departments specialized in internal medicine and surgery which have emergency rooms, patient rooms and subclinical divisions.

### 5. Personnel:

a) Any chief physician of an infirmary must be a doctor with a practice certificate suitable for one of the specialities registered by the infirmary and have conducted medical examination and treatment in such speciality for at least 54 months;

b) Apart from the chief physician of the infirmary, any other entity working at the hospital who conducts medical examination and treatment must have a practice certificate and must conduct medical examination and treatment within the assigned scope of task. The assignment must be made in writing and conform with the practice scope written on the practice certificate.

## **Article 25. Requirements for issuance of operation licenses to polyclinics**

### 1. Scale of polyclinic:

a) Any polyclinic shall have at least the following:

- 02 of the 04 specialized departments of internal medicine, surgery, obstetrics and pediatrics;

- Emergency rooms, minor surgery rooms (if any minor surgery is carried out), patient stay rooms;

- Units of testing and image diagnosis.

b) Any polyclinic satisfying the requirements for healthcare facilities specified in Articles 33, 34, 35, 36, 37 and 38 of this Decree may apply for enlargement of the corresponding scale and practice scope.

### 2. Facilities:

a) Having location fixed and separate from areas for daily-life activities, having sufficient light, dustproof ceiling and wall and floor made of materials which can be cleansed easily.

b) Having a place for patient reception, emergency and patient stay rooms, specialized consulting rooms and minor surgery rooms (if any minor surgery is carried out). Consulting rooms in a polyclinic must satisfy the following requirements:

- The emergency room has an area of at least 12 m<sup>2</sup>;
- The patient stay room has an area of at least 15 m<sup>2</sup> with at least 2 patient beds. If the patient stay room has 3 or more patient beds, the area for each bed is at least 5 m<sup>2</sup>;
- Specialized consulting rooms and the minor surgery room have the area of at least 10 m<sup>2</sup>.

c) Satisfying the conditions of radiation safety, hospital waste management and fire and explosion prevention according to law.

d) Ensuring the sufficiency of electricity and water supply and other conditions for patient care.

### 3. Medical equipment:

a) Having sufficient medical equipment and instruments suitable to the practice scope that the polyclinic registered;

b) Having anti-shock first aid kits and sufficient specialized emergency drugs.

### 4. Personnel:

a) The number of full-time doctors must account for at least 50% of the total number of doctors of the polyclinic who provide healthcare.

b) Any chief physician of a polyclinic shall satisfy the following conditions:

- Being a doctor with a practice certificate suitable for at least one of the specialities registered by the polyclinic;

- Having worked as a healthcare practitioner for at least 54 months. The assignment and appointment of the chief physician of the polyclinic shall be performed in writing;

- Working on a full-time basis at the polyclinic.

c) The number of staff members, the structures and the professional titles in the polyclinic shall comply with regulations prescribed by the Minister of Health.

If wishing to provide healthcare, persons other than the chief physicians of a polyclinic working in the polyclinic must have a practice certificate and the assignment shall be suitable for the practice scope specified in such practice certificate.

5. Any polyclinic wishing to conduct check-ups shall satisfy the requirements specified in clause 6 Article 23 of this Decree.

6. Family medicine facilities shall comply with the pilot program prescribed by the Minister of Health.

### **Article 26. Requirements for issuance of operation licenses to specialized clinics**

1. Facilities:

a) Satisfying the requirements specified in point a clause 2 Article 25 of this Decree.

b) Having consulting rooms whose area is at least 10 m<sup>2</sup> and a place for patient reception (excluding clinics providing healthcare consultancy or clinics providing healthcare consultancy using information technology and telecommunications). Particularly, surgery or cosmetological clinics must have patient stay rooms whose area is at least 12 m<sup>2</sup>; clinics of rehabilitation must have rehabilitation rooms whose area is at least 10 m<sup>2</sup>; clinics of HIV/AIDS treatment must have an area of at least 18 m<sup>2</sup> (excluding the waiting area) and be divided into 2 rooms for carrying out the examination and treatment.

c) Apart from provisions of points a and b of this clause, depending on the registered practice scope, any specialized clinic must satisfy the following requirements:

- If any operation is conducted, including implanting operation, the operation room shall have an area of at least 10 m<sup>2</sup>;

- If any functional probe is conducted, the probing room shall have an area of at least 10 m<sup>2</sup>;

- If any gynecological examination or examination of sexually transmitted diseases is conducted, the consulting room shall have an area of at least 10 m<sup>2</sup>;

- If the family planning techniques are performed, the room specialized for such activities shall have an area of at least 10 m<sup>2</sup>;

- The room for forming surgical cast shall have an area of at least 10 m<sup>2</sup>;

- The room for therapeutic exercise shall have an area of at least 20 m<sup>2</sup>;

- For an odonto-stomatology clinic having more than 01 dental chair, the space for each dental chair must be at least 5 m<sup>2</sup>;

- Specialized clinics using radiological equipment (including dental X-ray equipment mounted on dental chairs) must satisfy radiation safety requirements;

- Clinics of HIV/AIDS treatment providing antiretroviral drugs (ARV) must have a place for antiretroviral drugs storage and dispersal which satisfies the requirements specified by the Minister of Health.

d) There shall be a sterilization area for treating medical instruments for reuse which is separated from other areas.

dd) Satisfying the conditions of radiation safety, hospital waste management and fire and explosion prevention according to law; ensuring the aseptic operation.

e) Ensuring the sufficiency of electricity and water supply and other conditions for patient care.

## 2. Medical equipment:

a) Having sufficient medical equipment and instruments suitable to the practice scope that the facility registered;

b) Having anti-shock first aid kits and sufficient specialized emergency drugs;

c) Clinics providing healthcare consultancy or clinics providing healthcare consultancy using information technology and telecommunications are not required to have medical equipment and instruments specified in points a and b of this clause but means of information technology and telecommunications suitable for the registered practice scope.

## 3. Personnel:

a) Any chief physician of a specialized clinic shall satisfy the following conditions:

- Being a doctor with a practice certificate suitable for at least one of the specialities registered by the clinic.

- Having worked as a healthcare practitioner in such speciality for at least 54 months.

Any chief physician of the following specialized clinics shall satisfy the corresponding conditions as follows:

+ Clinic of rehabilitation: being a doctor with a practice certificate relevant to physical therapy or rehabilitation;

+ Clinics for drug rehabilitation: being a psychiatric doctor or a general practitioner with a certificate of training in psychiatry or a traditional medicine practitioner with a certificate of training in drug rehabilitation using traditional medicine;

+ Clinics of HIV/AIDS treatment: being a doctor of infectious disease speciality or a general practitioner with a certificate of training in HIV/AIDS treatment;

- + Clinics of dietetics: being a nutrition expert or a general practitioner with a certificate of training in dieting;
  - + Clinics of cosmetic: being a plastic surgeon or an cosmetological doctors;
  - + Clinics of andrology: being an andrological doctor or a general practitioner with a certificate of training in andrology.
- b) If wishing to provide healthcare, persons other than the chief physicians of a specialized clinic working in the specialized clinic must have a practice certificate and be assigned in accordance with the practice scope specified in such practice certificate.

## **Article 27. Requirements for issuance of operation licenses to traditional medicine facilities**

### 1. Facilities:

- a) Satisfying the requirements specified in point a clause 2 Article 25 of this Decree.
- b) Having an area of at least 10 m<sup>2</sup> and having a place for patient reception.
- c) Depending on the registered practice scope, the clinic of traditional medicine shall satisfy the following requirements:
  - If providing acupuncture, massage and acupressure, it must have a room or a place with beds for acupuncture, massage and acupressure and an area at least 05 m<sup>2</sup> for each bed;
  - If providing medicinal sauna (anemopathy), it must have a sauna chamber which is at least 2 m<sup>2</sup> in area, closed and well-lit.
- d) Satisfying the conditions of radiation safety (if any radiological equipment is used), hospital waste management and fire and explosion prevention according to law.
- dd) Ensuring the sufficiency of electricity and water supply and other conditions for patient care.

### 2. Medical equipment:

- a) For clinics providing medical examination, giving prescriptions and medicinal herb recipes:
  - There must be herb cabinets with medicinal herbs and substances contained in drawers and securely covered bottles or pots which carry labels showing names of the medicinal herbs;
  - There must be medical scales and herbs wrapping papers; medicinal herbs shall be divided according to recipes.
- b) For clinics providing acupuncture, massage and acupressure:

- There must be beds for acupuncture, massage and acupressure;
  - There must be sufficient instruments for acupuncture, massage and acupressure;
  - There must be sufficient instruments for and guidance on relief of over-acupuncture.
- c) Clinics providing medicinal sauna must have a medicinal steam system, control valves, sauna instructions and alarm system for emergencies.

### 3. Personnel:

a) Any person working at a healthcare facility who wishes to provide healthcare shall have a practice certificate and be assigned according to the practice scope stated in his/her practice certificate.

b) Any chief physician of a traditional medicine clinic must be a doctor or a medical assistant specialized in traditional medicine or a person having a certificate of traditional medicine practitioner issued by the Minister of Health or the Director of a Department of Health or a person who has family remedies or treatment methods and a certificate of traditional medicine practice.

- Having provided healthcare using traditional medicine for at least 54 months, applicable to traditional medicine doctors;

- Having provided healthcare using traditional medicine for at least 48 months, applicable to traditional medicine assistants;

- Having provided healthcare using traditional medicine for at least 36 months, applicable to traditional medicine practitioners or persons having family remedies or treatment methods;

- Working on a full-time basis at the traditional medicine facility.

## **Article 28. Requirements for issuance of operation licenses to laboratories**

### 1. Facilities:

a) Satisfying the requirements specified in points a, dd and e clause 1 Article 26 of this Decree and the following requirements according to the registered practice scope:

- For tests of one of the four aspects: hematology, biochemistry, genetics and immunity, the laboratory shall have an area of at least 10 m<sup>2</sup>;

- For tests of two or three of the four aspects: hematology, biochemistry, genetics and immunity, the laboratory shall have an area of at least 15 m<sup>2</sup>;

- For tests of four aspects: hematology, biochemistry, genetics and immunity, the laboratory shall have an area of at least 20 m<sup>2</sup>;
- For pathoanatomic or cytological tests, the laboratory shall have an area of at least 20 m<sup>2</sup> and be separated from the laboratories for tests of hematology, biochemistry, genetics and other laboratories;
- For tests of microorganism, the laboratory shall have an area of at least 20 m<sup>2</sup> and be separated from the laboratories for tests of hematology, biochemistry, genetics and other laboratories;
- Walls of laboratories shall have waterproof surface;
- Floors of laboratories shall have waterproof and flat surface which can prevent water standing;
- Testing tables shall be made of watertight and anti-corrosive materials and associated with wash-basins and fresh-water tap;
- There shall be places for taking medical waste, places for keeping medical waste and place for cleansing medical instruments;
- Any laboratory conducting tests of microorganisms likely to transmit infectious diseases to human must satisfy the requirements prescribed by law on laboratory's biosafety;
- HIV testing laboratories shall comply with law on HIV/AIDS prevention and fighting.

b) Satisfying the conditions of hospital waste management and fire and explosion prevention according to law.

c) Ensuring the sufficiency of electricity and water supply and other conditions for patient care.

## 2. Medical equipment:

Having sufficient testing equipment and medical instruments for the registered practice scope, including at least sufficient equipment for conducting a test of one of the six types: microorganism, biochemistry, hematology, immunity, pathoanatomy and cytology and medical genetics.

## 3. Personnel:

a) Any person working at a healthcare facility who wishes to provide healthcare shall have a practice certificate and be assigned according to the practice scope stated in his/her practice certificate.

b) Any chief physician of a laboratory shall satisfy the following conditions:

- Being a doctor or a physician having a university degree and a practice certificate specialized in testing; or a bachelor's degree in chemistry, biology or pharmacy of university higher level, applicable to persons employed to conduct medical test before the effective date of this Decree and issued with a certificate of practice in testing with a title of physician.

- Having worked for a suitable laboratory department for at least 54 months or having worked as a testing practitioner for at least 36 months, including the period of post-graduation study in testing, from the day on which his/her testing job starts (determined from the time on which the labor contract is signed or the recruitment decision is issued) to the day on which he/she is assigned or appointed to be the chief physician of the laboratory.

- Working on a full-time basis at the laboratory.

## **Article 29. Requirements for issuance of operation licenses to image diagnosis clinics and X-ray rooms**

### 1. Facilities:

a) Satisfying the requirements specified in points a clause 2 Article 25 of this Decree and the following requirements according to the registered practice scope:

- Ultrasonic and endoscopic diagnosis rooms must be independent and have an area of at least 10 m<sup>2</sup>;

- Gastroendoscopic diagnosis rooms which conduct both upper and lower gastroendoscopic techniques must have 02 separate rooms with an area of at least 10 m<sup>2</sup>.

b) Satisfying the conditions of radiation safety, hospital waste and hazardous waste (if any) management and fire and explosion prevention according to law.

c) Ensuring sufficient electricity and water supply and other conditions for patient care.

### 2. Medical equipment:

a) Having sufficient medical equipment and instruments suitable to the registered practice scope;

b) Having personal protection devices required by law on radiation safety.

### 3. Personnel:

a) Any person working at a healthcare facility who wishes to provide healthcare shall have a practice certificate and be assigned according to the practice scope stated in his/her practice certificate;

b) Any chief physician of an image diagnosis clinic shall be a doctor with a practice certificate in image diagnosis and have conduct medical examination and treatment in image diagnosis speciality for at least 54 months and work on the full-time basis at the image diagnosis clinic;

c) Any chief physician of an X-ray room must be an image diagnosis doctor or have a bachelor's degree of X-ray therapy of university or higher level and have worked in the speciality of X-ray therapy for at least 54 months. X-ray bachelors (of university level) may read and describe the diagnosis images but must not make diagnosis conclusions. They must work on a full-time basis at X-ray rooms.

### **Article 30. Requirements for issuance of operation licenses to maternity wards**

#### 1. Facilities:

a) Satisfying the requirements specified in point a clause 2 Article 25 of this Decree;

b) Functional rooms must be interconnected and convenient for emergency and medical examination and treatment;

c) Having rooms for pre-natal and gynecological checkup and family planning techniques which have an area of at least 10 m<sup>2</sup>; delivery rooms with an area of at least 16 m<sup>2</sup> having an area for women who have just delivered and their newborn babies; rooms for lying-in women with an area of at least 10 m<sup>2</sup>. If the room for lying-in women has more than 2 beds, the space for each beds shall be at least 5 m<sup>2</sup>;

d) Satisfying the conditions of radiation safety (if any radiological equipment is used), hospital waste management and fire and explosion prevention according to law;

dd) Ensuring the sufficiency of electricity and water supply and other conditions for patient care.

#### 2. Medical equipment:

a) Having sufficient medical equipment and instruments suitable to the registered practice scope;

b) Having sufficient vehicles for internal and external emergency transportation. Maternity wards having no vehicles for external emergency transportation must have transportation contracts signed with healthcare facilities having operation licenses and permitted to provide emergency transportation services;

c) Having anti-shock first aid kits and sufficient specialized emergency drugs.

#### 3. Organization and personnel:

a) Any person working at a maternity ward who wishes to provide healthcare shall have a practice certificate and be assigned according to the practice scope stated in his/her practice certificate.

b) Any chief physician of a maternity ward shall satisfy the following conditions:

- Being a gynecological doctor or a midwife who graduated from a university and has a practice certificate;
- Having conducted examination and treatment in gynecology for at least 54 months;
- Working on a full-time basis at the maternity ward.

4. Any maternity ward eligible for providing perinatal healthcare services according to regulations in Article 26 of this Decree and provide immunity according to law on immunity may add such specialities to its practice scope.

### **Article 31. Requirements for issuance of operation licenses to preventive care clinics**

1. Scale:

A preventive care clinic may have a scale equivalent to that of a polyclinic or a specialized clinic, depending on the legal basis for establishment of such clinic.

2. Facilities:

Any preventive care clinic with a scale equivalent to that of a polyclinic shall have facilities satisfying the regulations in clause 2 Article 25 of this Decree. Any preventive care clinic with a scale equivalent to that of a specialized clinic shall have facilities satisfying the regulations in clause 1 Article 26 of this Decree.

3. Medical equipment:

Satisfying requirements for medical equipment suitable for the scale of a polyclinic specified in clause 3 Article 25 or the scale of a specialized clinic specified in clause 2 Article 26 of this Decree.

4. Personnel:

a) Any person working at a healthcare facility who wishes to provide healthcare shall have a practice certificate and be assigned according to the practice scope stated in his/her practice certificate;

b) Any chief physician of a preventive care clinic shall be a general practitioner with a practice certificate or a doctor with a practice certificate suitable for the speciality and have conducted medical examination and treatment for at least 54 months and work on the full-time basis at the clinic.

5. Any clinic providing immunity of vaccine or treatment biologics must comply with law on immunity.

## **Article 32. Requirements for issuance of operation licenses to clinics of occupational diseases**

### 1. Scale:

A clinic of occupational disease may have a scale equivalent to a polyclinic or a specialized clinic, depending on the legal basis for establishment of such clinic.

### 2. Facilities:

a) Any clinic of occupational diseases with a scale equivalent to that of a polyclinic shall have facilities satisfying the regulations in clause 2 Article 25 of this Decree. Any clinic of occupational diseases with a scale equivalent to that of a specialized clinic shall have facilities satisfying the regulations in clause 1 Article 26 of this Decree;

b) Having at least 2 divisions for testing (for tests in biochemistry, toxicity or microorganism) and image diagnosis.

### 3. Medical equipment:

a) Any clinic of occupational diseases with a scale equivalent to that of a polyclinic shall have medical equipment satisfying the regulations in clause 3 Article 25 of this Decree. Any clinic of occupational diseases with a scale equivalent to that of a specialized clinic shall have medical equipment satisfying the regulations in clause 2 Article 26 of this Decree;

b) Satisfying the requirements for medical equipment used for testing specified in clause 2 Article 28, requirements for medical equipment used for image diagnosis specified in clause 2 Article 29 of this Decree.

### 4. Personnel:

a) Any person working at the healthcare facility who wishes to provide healthcare shall have a practice certificate and a certificate of training in occupational diseases and be assigned according to the practice scope stated in his/her practice certificates.

b) Any chief physician of a clinic of occupational diseases shall satisfy the following conditions:

- Being a doctor specialized in occupational diseases with a practice certificate or a general practitioner with a practice certificate and a certificate of training in occupational diseases;

- Having provided healthcare in occupational diseases for at least 54 months;

- Working on a full-time basis in the clinic.

## **Article 33. Requirements for issuance of operation licenses for injection, dressing change, pulse counting and temperature and blood pressure measurement service providers**

1. Facilities:

- a) A service provider shall be built firmly in a fixed location, well-lit and separated from places for daily-life activities;
- b) A room for injection or dressing change must have an area of at least 10 m<sup>2</sup>;
- c) A service provider must have sufficient electricity and water supply and satisfy other sanitation conditions for patient care.

2. Medical equipment:

- a) Having sufficient medical equipment and instruments suitable to the registered practice scope;
- b) Having anti-shock first aid kits.

3. Personnel:

- a) Any person working at the facility who wishes to provide healthcare shall have a practice certificate and be assigned according to the practice scope stated in his/her practice certificate.
- b) Any chief physician of a facility providing injection, dressing change, pulse counting and temperature and blood pressure measurement services shall satisfy the following requirements:
  - Having an intermediate or higher degree in medicine and a practice certificate;
  - Having conducted injection, dressing change, pulse counting and temperature and blood pressure measurement for at least 45 months.
  - Working on a full-time basis at the facility.

**Article 34. Requirements for issuance of operation licenses to home healthcare service providers**

Any facility providing home healthcare services including dressing change, suture removal; physical therapy, rehabilitation; mother and baby care; collection of blood samples for testing, result provision; care of patients with cancer and other home nursing services must satisfy the following requirements:

1. Medical equipment:

Having sufficient medical equipment and instruments suitable to the registered practice scope.

2. Personnel:

a) Any person working at a healthcare facility who wishes to provide healthcare shall have a practice certificate and be assigned according to the practice scope stated in his/her practice certificate.

b) Any chief physician of a home healthcare service provider must possess a practice certificate and have provided healthcare for at least 45 months.

- Working on a full-time basis at the facility.

### **Article 35. Requirements for issuance of operation licenses to emergency or patient transportation service providers**

#### 1. Facilities:

a) Being built firmly in a fixed location, well-lit and separated from places for daily-life activities;

b) Ensuring the sufficiency of electricity and water supply and other sanitary conditions for patient care.

#### 2. Medical equipment and transportation vehicles:

a) Any facility must have transportation vehicles with sufficient medical equipment and instruments;

b) Any facility must have anti-shock first aid kits and first-aid medicines for keeping patients safe.

#### 3. Personnel:

a) Any person working at the facility who wishes to provide healthcare shall have a practice certificate and be assigned according to the practice scope stated in his/her practice certificate.

b) Any chief physician of a facility providing emergency and patient transportation services in Vietnam or abroad must satisfy the following conditions:

- Being a doctor with a practice certificate

- Having a qualification or certificate of study in the speciality of recuperation and first aid;

- Having conducted medical examination and treatment for 54 months.

- Working on a full-time basis at the facility.

4. In case of registration for patient transportation abroad, an emergency service provider must have a contract signed with an aviation service company.

## **Article 36. Requirements for issuance of operation licenses to optical glasses service providers**

### 1. Facilities:

- a) Being built firmly in a fixed location, well-lit and separated from places for daily-life activities;
- b) Having an area of at least 15 m<sup>2</sup>;
- c) Ensuring the sufficiency of electricity and water supply and other sanitary conditions for patient care.

### 2. Medical equipment:

- a) Having sufficient medical equipment and instruments suitable to the registered practice scope.

### 3. Personnel:

- a) Any person working at an optical glasses service provider shall have a practice certificate of examination and treatment in the optical speciality or measurement and/or diagnosis of refractive eye defects and be assigned according to the practice scope stated in his/her practice certificate.

### b) Requirements for chief physicians of optical glasses service providers;

- Having an intermediate or higher degree in medicine and a practice certificate of the speciality of ophthalmology or refractive eye defect measurement and diagnosis;

- Having worked as a ophthalmologist at a healthcare facility or conducted the measurement, checking and diagnosis of refractive eye defect at an optical glasses service providers for at least 36 months.

- Working on a full-time basis at the facility;

## **Article 37. Requirements for issuance of operation licenses to cosmetological service providers**

1. A cosmetological service provider shall only do tattoos or spray or embroider pictures on the surface of the skin without use of anesthetics in injection form and satisfy the following requirements:

### a) Facilities:

- Being built firmly in a fixed location;

- Ensuring the sanitary conditions.

b) Equipment:

Having sufficient equipment, instruments and materials with clear origin which are suitable for the operation scale of the facility.

c) Personnel:

Any person doing tattoos or spraying or embroidering pictures on the surface of the skin without use of anesthetics in injection form at a cosmetological service provider shall possess a certificate of study in the corresponding speciality lawfully issued by a training institution or a vocational training facility.

d) Cosmetological service providers are exempt from operation license but must send a written notification of fulfillment of requirements specified in points a, b and c of this clause to the Department of Health of the province where it is headquartered at least 10 days before it begins providing the services. The notification shall be conformable to the form in Annex VIII enclosed with this Decree.

2. Cosmetological services involving the intervention of drugs, substances and equipment in human's body (surgery, operation, intervention involving the injection, pumping, ray emission, firing or other types of intervention) that change the color of skin, shape, weight and shortcomings of human's body (skin, nose, eyes, lips, face, belly, buttock and other parts of human' body) or services of doing tattoos or spraying or embroidering pictures on the surface of the skin without use of anesthetics in injection form shall be conducted only at hospitals having cosmetological specialist or cosmetological clinics or healthcare facilities with the practice scope in cosmetological speciality approved by competent authorities.

**Article 38. Requirements for issuance of operation licenses to massage service providers**

1. Facilities:

a) Being built firmly in a fixed location, well-lit and separated from places for daily-life activities.

b) Massage rooms must ensure the following conditions:

- Each massage room must have an emergency bell for one-way contact from the massage room to the doctor's room or the customer reception place;

- Having the massage technical process printed in big readable letters (on A1-size paper) affixed on the wall of each room.

c) Being furnished with hygienic bathroom ensuring the sufficiency of electricity and water supply and other sanitary conditions for customer care.

2. Equipment:

- a) Having massage beds or chairs or pads with mattress, pillows and bath towels ensuring hygienic conditions;
- b) Having examination beds, first aid kits, desks and medical instruments (stethoscope, blood pressure meter, thermometer, syringe) at doctors' room;
- c) Having sufficient common first-aid drugs.

### 3. Personnel:

- a) Any chief physician of a massage service provider must be a doctor or a medical assistant or physician specialized in rehabilitation, physical therapy or traditional medicine or having a certificate of training in any of such speciality. If the making of prescription is required, only doctors specialized in rehabilitation, physical therapy or traditional medicine are assigned to be the chief physician;
- b) Any person working at the facility who performs massage technique must have a certificate of training in massage lawfully issued by a training institution.

Any massage technician must wear tidy, clean and beautiful with badge inscribed with the name of the facility, his/her name and photo of 3x4 size.

4. Massage service providers are exempt from operation license but must send a written notification of fulfillment of requirements specified in clauses 1, 2 and 3 of this Article to the Department of Health of the province where it is headquartered within 10 days before it begins providing the services. The notification shall be conformable to the form in Annex IX enclosed with this Decree.

## **Article 39. Requirements for issuance of operation licenses to commune-level health stations and infirmaries**

### 1. Facilities:

- a) Having a design under the regulations of the Minister of Health;
- b) Satisfying the conditions of radiation safety, hospital waste management and fire and explosion prevention according to law;
- c) Ensuring sufficient electricity and water supply and other conditions for patient care.

### 2. Medical equipment:

- a) Having sufficient medical equipment and instruments suitable to the registered practice scope;
- b) Having anti-shock first aid kits.

### 3. Personnel:

a) Any chief physician shall satisfy the following conditions:

- Being a doctor or a medical assistant with a practice certificate;
- Having conducted medical examination and treatment for 54 months, applicable to doctors, or 45 months, applicable to medical assistants.

b) The number of practitioners working for commune-level health stations must satisfy the payroll standards of state-owned medical facilities according to law.

c) Village health workers shall provide primary healthcare according to the assignment and professional direction by heads of commune-level health stations.

4. Any commune-level health stations conduct healthcare according to family medicine shall comply with the pilot program prescribed by the Minister of Health.

### **Article 40. Practice scope of healthcare facilities**

Pursuant to the organization of the healthcare facility and the requirements for issuance of the operation license to healthcare facilities specified in this Decree, the Minister of Health shall decide the practice scope for each type of healthcare facility, except cosmetological service providers and massage service providers.

### **Article 41. Contents of signboards of healthcare facilities**

Any healthcare facilities having a operation license shall have signboards conformable to law on signboards which must not contain red-cross symbols and contain the following main information:

1. Full name of the facility, the number of the operation license.
2. Address of the facility as written on the operation license; phone number.
3. Daily work time.

## **Section 2. ENTITLEMENT TO, COMPOSITION OF APPLICATION AND PROCEDURES FOR ISSUANCE, REISSUANCE AND MODIFICATION OF OPERATION LICENSES FOR HEALTHCARE FACILITIES**

### **Article 42. Entitlement to issuance, reissuance and modification of operation licenses for healthcare facilities**

1. The Minister of Health is entitled to issue, reissue or modify operation licenses for healthcare facilities specified in clause 1 Article 45 of the Law on Medical examination and treatment.

2. Directors of the Departments of Health are entitled to issue, reissue or modify operation licenses for healthcare facilities specified in clause 2 Article 45 of the Law on Medical examination and treatment.

**Article 43. Composition of applications for issuance, reissuance and modification of operation licenses and change of chief physicians of healthcare facilities, declaration of eligibility for conducting check-up**

1. An application for the operation license applicable to healthcare facilities shall comply with regulations in clause 1 Article 46 of the Law on Medical examination and treatment. To be specific:

- a) The form No. 01 in Annex XI enclosed with this Decree;
- b) A valid copy of the establishment decision or a document containing the name of the healthcare facility issued by a competent authority, applicable to state-owned healthcare facilities, or a certificate of enterprise registration, applicable to private healthcare facilities, or an investment certificate, applicable to foreign-invested healthcare facilities;
- c) Valid copies of practice certificates of chief physicians of the healthcare facilities; persons taking charge of professional department of the healthcare facility;
- d) The form in Annex IV enclosed with this Decree;
- dd) The form No. 02 in Annex XI enclosed with this Decree;
- e) Documents proving that the healthcare facility satisfies the requirements for facilities, medical equipment and organization suitable for the practice scope of any healthcare facility form specified in section 1 Chapter III of this Decree;
- g) The Charter of organization and operation using the form regulated by the Minister of Health, applicable to state-owned hospitals, or the Form No. 03 in Annex XI enclosed with this Decree, applicable to private hospitals, and the initial operation plan of the hospital;
- h) Valid copies of contracts on patient transport, applicable to hospitals and maternity wards without vehicles for external emergency transportation;
- i) A professional and technical list proposed by the healthcare facility on the basis of the professional and technical list issued by the Minister of Health;
- k) Regarding emergency transportation service providers: a valid copy of the contract on professional support for the hospital. In case of provision of service of patient transportation abroad, a valid copy of the contract on patient transportation signed with an aviation service company.

2. The application for the operation license applicable to any healthcare facility which changes its organization or is split, amalgamated or merged shall be conformable to regulations in clause 1 of this Article.

3. An application for the operation license applicable to any healthcare facility which changes its location shall contain:

a) The form No. 04 in Annex XI enclosed with this Decree;

b) Documents specified in clause 1 of this Article (if there is change in the former application).

4. An application for the operation license applicable to any healthcare facility which changes its name shall contain:

a) The form No. 05 in Annex XI enclosed with this Decree;

b) Documents specified in clause 1 of this Article (if there is change in the former application).

5. An application for modification of the operation license applicable to any healthcare facility which changes the scale of patient beds or organizational structure or its practice scope shall be conformable to regulations in clause 3 Article 46 of the Law on Medical examination and treatment, including:

a) The form No. 06 in Annex XI enclosed with this Decree;

b) The form No. 02 in Annex XI enclosed with this Decree.

6. An application for change in chief physicians of a healthcare facility shall include:

a) The form No. 07 in Annex XI enclosed with this Decree;

b) A Decision to dismiss the current chief physician of the facility;

c) A Decision to appoint a new chief physician of the facility;

d) A valid copy of the practice certificate of the person appointed to take charge of professional aspects of the healthcare facility;

dd) The contract or the recruitment decision of the person appointed to take charge of professional aspects of the facility;

e) The form No. 10 in Annex XI enclosed with this Decree;

g) The original of the issued operation license of the healthcare facility.

7. An application for the reissuance of an operation license which is lost or damaged or revoked according to regulations in point a clause 1 Article 48 of the Law on Medical examination and treatment shall contain:

- a) The form No. 08 in Annex XI enclosed with this Decree;
- b) The original of the damaged license (if any).

8. A declaration of eligibility for conducting check-up:

- a) The form No. 01 in Annex X enclosed with this Decree;
- b) A valid copy of the issued operation license of the healthcare facility;
- c) The form No. 02 in Annex X enclosed with this Decree;
- d) The form No. 02 in Annex XI enclosed with this Decree;
- dd) A valid copy of the professional and technical list of the healthcare facility;
- e) A valid copy of the contract on professional support (if any).

**Article 44. Procedures for issuance, reissuance and modification of operation licenses and change of chief physicians of healthcare facilities, declaration of eligibility for conducting check-up**

1. The application for issuance, reissuance or modification of an operation license and change of chief physicians of a healthcare facility specified in Article 43 of this Decree shall be made in 01 set and sent to competent authorities, including:

- a) The Ministry of Health, applicable to applications sent by healthcare facilities affiliated to the Ministry of Health, private hospitals or hospitals affiliated to other Ministries;
- b) Departments of Health, applicable to applications sent by healthcare facilities in local areas, excluding healthcare facilities specified in point a of this clause.

2. Procedures for consideration of the issuance, reissuance or modification of an operation license and change of chief physicians of a healthcare facility:

- a) After receiving the application for issuance, reissuance or modification of the operation license, the Ministry of Health or the Department of Health (hereinafter referred to as the receiving authority) shall carry out the following procedures:

- If the application is submitted directly at the receiving authority, the receiving authority shall give the applicant an application receipt note using the form No. 09 in Annex XI enclosed with this Decree;

- If the application is sent by post, within 03 days from the day on which the application is received (pursuant to the coming postmark), the receiving authority shall send the receipt note to the applicant using the form No. 09 in Annex XI enclosed with this Decree.

b) If the application is satisfactory, the receiving authority shall consider the issuance, reissuance or modification of the operation license within 60 days, applicable to hospitals, or 45 days, applicable to other types of healthcare facilities, from the date written on the receipt note. If the application is rejected, a written response containing explanation shall be sent.

c) If the application is not satisfactory, then:

- Within 10 working days from the date written on the receipt note, the receiving authority shall send a written notification to the applicant containing the request for completion. Such notification must specify the contents subject to supplementation and those subject to modification;

- After receiving the request for completion of the application, the chief physicians of the healthcare facility shall comply with the request and send the revised application to the receiving authority;

- After 10 working days from the day on which the revised application is received, the receiving authority which does not request modification or supplementation to the application shall issue/reissue/modify the operation license within the period specified in point b of this clause; otherwise, written response containing explanation shall be sent;

- After 60 days from the day on which the request by the receiving authority is received, if the applicant fails to fulfill the request, the procedures for application shall be re-conducted.

3. The operation license shall be issued by the Minister of Health or the Director of the Department of Health using the form in Annex XII. The number of the operation license shall be pursuant to the table in the form No. 04 in Annex III enclosed with this Decree.

4. Procedures for declaration of eligibility for conducting check-up:

Before conducting the initial check-up, the healthcare facility shall send (directly or by post) a declaration of eligibility for conducting check-up according to regulations in clause 8 Article 43 of this Decree to a medical affair authority. To be specific:

a) For healthcare facilities affiliated to the Ministry of Health: the declaration shall be sent to Medical Service Administration - the Ministry of Health;

b) For healthcare facilities under the management of the Ministry of Public Security: the declaration shall be sent to Health Service Administration - the Ministry of Public Security; for healthcare facilities affiliated to the Ministry of Transport: the declaration shall be sent to Transport Health Service Administration - the Ministry of Transport;

c) For healthcare facilities under the management of Departments of Health (excluding healthcare facilities specified in points a and b of this clause): the declaration shall be sent to the Department of Health of the province where the healthcare facility is headquartered.

#### 5. Processing of declaration of eligibility for conducting check-up:

a) When the declaration of eligibility for conducting check-up has been received, the receiving authority shall send the healthcare facility declaring the eligibility for conducting check-up a receipt note using the form No. 3 in Annex X enclosed within this Decree. If the declaration is not satisfactory as prescribed in clause 8 Article 43, the receiving authority shall send the healthcare facility a written request for completion. When the healthcare facility has completed the declaration, the receiving authority shall send it a receipt note using the form No. 3 in Annex X enclosed with this Decree.

b) If the declaration is satisfactory as prescribed in clause 8 Article 43 and the receiving authority has not sent any request for supplementation or modification, then within 15 working days from the day on which the receipt note is received, the healthcare facility may conduct the check-up according to the declared practice scope.

c) If the healthcare facility which has declared the eligibility for conducting check-up makes change in name of the facility, address, facilities, personnel and practice scope which have been declared, it shall send a written notification to the authority receiving the declaration.

#### **Article 45. Inspection serving the issuance, reissuance and modification of operation licenses for healthcare facilities**

1. The Minister of Health or Directors of Departments of Health shall establish inspectorates to serve the issuance, reissuance and modification of operation licenses for healthcare facilities according to their competence.

2. The inspectorate shall conduct inspection according to the time specified in point b clause 2 Article 44 of this Decree and make records using the form specified in Annex XIII enclosed with this Decree.

A record of inspection of a healthcare facility under the management of the Minister of Health shall be made in 03 copies, 01 of which shall be retained at the Ministry of Health, another copy shall be retained at the Department of Health of the province where the healthcare facility is headquartered, the other one shall be retained at the healthcare facility.

A record of inspection of a healthcare facility under the management of the Director of the Department of Health shall be made in 02 copies, 01 of which shall be retained at the Department of Health, the other one shall be retained at the healthcare facility.

#### 3. Management of operation licenses:

a) Each healthcare facility shall be issued with no more than one operation license. If the healthcare facility has more than one places of operation, each of them must satisfy the requirements specified in Article 23 of this Decree and be issued with one operation license.

b) The valid copy of the operation license and the application for issuance, reissuance or modification of the operation license shall be retained at the operation license issuer.

c) After issuing, reissuing or modifying the operation license for a healthcare facility, the authority which has issued the operation license shall carry out the following procedures:

- Within 30 days from the day of issuance, reissuance or modification of the operation license, the Ministry of Health shall send a written notification to the People's Committee and the Department of Health of the province where the healthcare facility is headquartered;

- Within 30 days from the day of issuance, reissuance or modification of the operation license, the Department of Health shall send a written notification to the People's Committee and the medical office of the commune, district, town or provincial city where the healthcare facility is headquartered;

- The Ministry of Health shall post the list of healthcare facilities having their operation licenses issued, reissued or modified which are under its management on its website. The Department of Health shall post the list of healthcare facilities having their operation licenses issued, reissued or modified which are under its management on its website.

## **Chapter IV**

### **ONLINE ISSUANCE OF PRACTICE CERTIFICATES AND HEALTHCARE OPERATION LICENSES**

#### **Article 46. Requirements for composition of applications for online registration, issuance or reissuance of practice certificates, online issuance, reissuance or modification of healthcare operation licenses**

An application for online registration, issuance or reissuance of a practice certificate, online issuance, reissuance or modification of a healthcare operation license (hereinafter referred to as online application) shall be considered valid if it satisfies the following requirements:

1. Containing sufficient documents according to regulations applied to paper documents which are transferred into electronic files. Electronic documents shall be named according to those of the paper documents.

2. Information serving the application for online registration, issuance or reissuance of a practice certificate or online issuance, reissuance of a healthcare operation license shall be entered sufficiently and accurately according to the information in the originals.

#### **Article 47. Procedures for online registration**

1. The applicant or his/her legal representative shall declare information, download the e-document and confirm the submission of online application with a digital signature and pay fees according to the procedures specified on the website of the Ministry of Health or of the Department of Health.

If the declarant does not use a digital signature to confirm the submission of application, the scanned copies of the paper application shall be sent to the receiving authority through the registration system for comparison.

2. When the application has been sent online, the receiving authority shall send a receipt note to the applicant.

3. The receiving authority shall conduct the administrative procedures in accordance with provisions of Chapter II and Chapter III of this Decree.

4. The result of the online administrative procedures shall be a document appended a signature of the authority or an e-document bearing a digital signature confirming the receipt of the application and have legal value equivalent to that of the normal administrative procedures.

5. The Minister of Health shall provide guidance on the issuance or reissuance of practice certificates or issuance, reissuance or modification of healthcare operation licenses which are applied for online.

#### **Article 48. Retention of online applications**

1. If the application is sent online, the applicant shall retain the paper application to serve the inspection in case of necessity.

2. If documents in the application specified in clause 1 of this Article is lost or damaged, the applicant and the receiving authority shall carry out the following procedures:

a) The applicant shall send a written notification to the receiving authority and complete the application; send a written notification to the receiving authority when the application has been completed; only update the application after being approved by the receiving authority;

b) Within 60 days from the day on which the receiving authority is notified of the loss of the application, if the applicant fails to complete the application, then the receiving authority shall annul the information posted on the website of the Ministry of Health or the Department of Health which is relevant to the issued practice certificate and/or healthcare operation license;

c) The issued practice certificate and/or healthcare operation license shall be revoked;

d) Practitioners must not continue practicing, the healthcare facility must shut down from the time the receiving authority annuls the information as prescribed in point b clause 2 of this Article.

## **Chapter V**

### **IMPLEMENTARY CLAUSE**

#### **Article 49. Effect**

1. This Decree comes into force from July 01, 2016.
2. Article 3 of the Decree No. 87/2011/ND-CP dated September 27, 2011 by the Government shall be annulled from the effective date of this Decree. Previous regulations which are contrary to this Decree shall be annulled.

#### **Article 50. Transitional clause**

1. Any applicant for issuance/reissuance of a practice certificate or issuance/reissuance/modification of a operation license before the effective date of this Decree shall comply with legislative documents promulgated before the effective date of this Decree.
2. Any entity providing cosmetological services specified in clause 1 Article 37 and massage services specified in Article 38 of this Decree shall, within 12 months from the day on which this Decree takes effect, fulfill the requirements and the procedures prescribed in this Decree.
3. Clinics of occupational diseases; clinics of HIV/AIDS treatment; clinics of dietetics and clinics for drug rehabilitation operating before the effective date of this Decree may continue their operation and must complete the procedures for issuance of the operation license before June 30, 2017.
4. Denture prosthesis service providers specified in legislative documents pertaining to private medicine practice before the effective date of this Decree shall be issued with an operation license only when the following requirements are satisfied:
  - a) Facilities:
    - Being built firmly in a fixed location;
    - Satisfying the conditions of hospital waste management and fire and explosion prevention according to law;
    - Ensuring the sufficiency of electricity and water supply and other conditions for patient care;
    - A dental and denture prosthesis room must have an area of at least 10 m<sup>2</sup>;
    - A denture prosthesis room must have an area of at least 10 m<sup>2</sup> or is rent under a contract from another denture prosthesis facility.

b) Medical equipment: having sufficient medical equipment and instruments suitable to the registered practice scope.

c) Personnel: A person in charge of professional aspects must be a tooth implanter having practice since 1980 or earlier with a certificate issued by a People's Committee of commune using the form provided in Annex XIV enclosed with this Decree, a certificate of eligibility for practice or a denture prosthesis service operation license according to law on private medicine practice.

### **Article 51. Implementation**

1. The Minister of Health is responsible for guiding the implementation of this Decree.
2. Ministers, Heads of ministerial-level agencies, Heads of governmental agencies and Presidents of People's Committees of provinces are responsible for implementing this Decree./.

**ON BEHAFT OF THE GOVERNMENT  
PRIME MINISTER**

**Nguyen Xuan Phuc**

---

*This translation is made by **LawSoft** and for reference purposes only. Its copyright is owned by **LawSoft** and protected under Clause 2, Article 14 of the Law on Intellectual Property. Your comments are always welcomed*