THE GOVERNMENT	THE SOCIALIST REPUBLIC OF VIETNAM
_____	**Independence - Freedom - Happiness**
No. 96/2023/ND-CP	_____
	Hanoi, December 30, 2023

DECREE

Detailing a number of articles of the Law on Medical Examination and Treatment

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Pursuant to the Law on Government Organization dated June 19, 2015; Law dated November 22, 2019 amending and supplementing a number of articles of the Law on Government Organization and the Law on Organization of Local Government;

Pursuant to the Law on Medical Examination and Treatment dated January 9, 2023;

At the proposal of the Minister of Health;

The Government hereby promulgates the Decree detailing a number of articles of the Law on Medical Examination and Treatment.

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Chapter I
GENERAL PROVISIONS

Article 1. Scope of regulation

1. This Decree details a number of articles of the Law on Medical Examination and Treatment regarding:

a) Grant of licenses to practice medical examination and treatment;

b) Grant of medical examination and treatment operation licenses;

c) Application of new techniques and methods in medical examination and treatment and clinical trials in medical examination and treatment;

d) Management of medical equipment at medical examination and treatment establishments;

dd) Mobilization and assignment of medical examination and treatment establishments to participate in medical examination and treatment in case of disasters, catastrophes, group-A infectious diseases and state of emergency;

e) Conditions for assurance of medical examination and treatment;

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g) Guidance on regulations on implementation roadmap; transitional regulations related to practicing licenses and operation licenses.

2. This Decree does not apply to some activities related to practitioners and medical examination and treatment establishments of the people's armed forces, including:

a) Medical examination and treatment internship and instruction, grant, re-grant, renewal, modification, suspension, and revocation of practicing licenses for practitioners;

b) Cases, conditions, dossiers, procedures for grant, re-grant, modification, suspension, and revocation of operation licenses for medical examination and treatment establishments and sample operation license;

c) Quality evaluation and certification for medical examination and treatment establishments;

d) Classification of technical and professional levels of medical examination and treatment establishments.

3. The financial autonomy regime by medical examination and treatment establishments that are public non-business units shall be implemented in accordance with law regulations on financial autonomy.

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Article 2. Interpretation of terms

1. Full-time practitioner means an employee who has been granted a practicing license and registered to practice medical examination and treatment on a full-time basis during administrative hours of a medical examination and treatment establishment.

2. Administrative hours of a medical examination and treatment establishment mean the period of time determined and officially announced by such medical examination and treatment establishment during which such establishment’s administrative tasks are carried out in compliance with law regulations on labor regarding working hours.

3. Working hours of a medical examination and treatment establishment mean the period of time during which the medical examination and treatment is provided, determined and registered by the medical examination and treatment establishment and recorded in the operation license granted by a competent authority, including administrative hours.

4. Change of the professional title means a practitioner's request to change from one professional title to another when meeting all the conditions and not continuing to practice under the professional title previously conferred by a competent authority.

5. Valid copy means a photocopy or a copy from the original register made

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by a competent authority or organization or a certified original copy, including an electronically authenticated copy or a print-out of the electronic document on the national database by a competent authority or organization in the cases where the original information is stored on the national database, or the copy has been compared with the original.

6. Not-for-profit medical examination and treatment establishment means a medical examination and treatment establishment that does not distribute profits earned during its operations to individuals or shareholders or members or capital contributors and, instead, use such profits to self-fund its operations.

7. Head of a medical examination and treatment establishment means a person who holds one of the positions including Chief Executive Officer, General Manager, or Director of a medical examination and treatment establishment (including the establishment that is a public non-business unit managed by a council) or a person assigned to lead a privately-owned medical examination and treatment establishment under such enterprise's organizational and operational charter.

The head of a medical examination and treatment establishment may not also be the person in charge of professional expertise of such medical examination and treatment establishment.

8. Specialist degree is a written certification that the learner has completed a postgraduate program of medical specialty to be conferred one of the respective titles specified at Points a, c, d, dd, e, g, h, Clause 1, Article 26 of the Law on Medical Examination and Treatment.

9. Scope of practice means what a practitioner is allowed to do, as outlined in one or more of the following documents:

a) The scope of practice stated on the practicing license;

b) The decision to modify the scope of practice, issued by the competent authority specified in Article 28 of the Law on Medical Examination and Treatment;

c) The written permission to perform technical task, given by the person in charge of professional and technical expertise of the medical examination and treatment establishment as specified in Clause 3, Article 10 and Clause 3, Article 125 of this Decree.

10. Specialized division of a medical examination and treatment establishment means an organization that performs medical examination and treatment tasks within the organizational structure of such medical examination and treatment establishment, which may be referred to as an institute, center, department, or unit

11. Spare parts and components of medical equipment mean parts and

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clusters constituting medical equipment, which are used for replacement or repair thereof in order to ensure or enhance the efficiency and operational capacity of the medical equipment employed in medical examination and treatment establishments.

12. Laboratory consumables mean medical equipment, including reagents, calibrators, control materials, instruments and other medical equipment products that are utilized individually or in combination, as designated by the owners thereof, to facilitate the examination of specimens derived from the human body during the testing process.

13. Risk management means the application by a competent health management authority of a system of professional measures and processes to identify, evaluate and classify the level of risk, as a basis for allocating and arranging reasonable resources to efficiently inspect, monitor and support medical examination and treatment management.

Chapter II

GRANT OF LICENSES TO PRACTICE MEDICAL EXAMINATION AND TREATMENT

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Section 1

MEDICAL EXAMINATION AND TREATMENT INTERNSHIP

Article 3. Duration and particulars of internship that a person must undertake to be granted a medical examination and treatment practicing license

1. The internship for doctors shall last 12 months, of which:

a) Medical examination and treatment internship shall last 09 months;

b) Intensive care medicine internship shall last 03 months.

2. The internship for assistant doctors shall last 09 months, of which:

a) Medical examination and treatment internship shall last 06 months;

b) Intensive care medicine internship shall last 03 months.

3. The internship for nurses, midwives, and medical technicians shall last 06 months, of which:

a) Medical examination and treatment internship shall last 05 months;

b) Intensive care medicine internship shall last 01 months.

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4. The medical examination and treatment internship for clinical nutritionists shall last 06 months.

5. The medical examination and treatment internship for pre-hospital emergency care provider shall last 06 months, of which:

a) Pre-hospital emergency care internship shall last 03 months;

b) Intensive care medicine internship shall last 03 months.

6. The medical examination and treatment internship for clinical psychologists shall last 09 months.

7. During the internship, the practitioners shall be also instructed in law regulations on medical examination and treatment, professional regulations, professional ethics, patient safety, communication skills and etiquette.

8. Based on the practicing scope issued by the Minister of Health and specified in Clauses 1 thru 7 of this Article, the internship-instructing establishments shall develop particulars for each professional title that the establishment expects to guide the internship thereof.

Article 4. Reservation of results of medical examination and treatment internship for professional titles

1. The internship-instructing establishment shall ensure that practitioners can work in accordance with its working regimes. During the internship, a practitioner, by reason of health conditions or force majeure, may temporarily suspend their internship for a maximum period of 12 months and reserve any result previously obtained during such internship.

2. Results of internship shall be reserved as follows:

a) The practitioner files a written request to reserve the results of his/her internship, enclosed with documents proving the reason for such request;

b) At the request of the practitioner, the head of the medical examination and treatment establishment shall consider and decide on the reservation. In case of refusal, the head of the medical examination and treatment establishment shall send a written reply clearly stating the reason for such refusal;

c) Within 30 days after the end of the reservation period, if the practitioner does not send any written request to resume the internship or to extend the reservation period, the reserved results will no longer be valid. The aggregated reservation period shall not exceed 12 months.

Article 5. Internship-instructing establishments

1. Establishments that can instruct the internship of doctors:

a) For medical doctors and preventive medicine doctors: medical examination and treatment establishments licensed to operate in the organization

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form of hospitals;

b) For traditional medicine doctors: medical examination and treatment establishments licensed to operate in the organization form of hospitals with the scope of professional activities in traditional medicine;

c) For odonto-stomatology doctors: medical examination and treatment establishments licensed to operate in the organization form of hospitals with the scope of professional activities in odontostomatology.

2. Establishments that can instruct the internship of assistant doctors:

a) For general assistant doctors: medical examination and treatment establishments licensed to operate in the organization form of hospitals; polyclinics; commune, ward and township health stations (hereinafter collectively referred to as commune health stations);

b) For traditional medicine assistant doctors: medical examination and treatment establishments licensed to operate in the organization form of hospitals or polyclinics or commune health stations; The scope of professional activities of such establishments must cover traditional medicine.

3. Establishments that can instruct the internship of nurses: medical examination and treatment establishments licensed to operate in the organization form of hospitals;

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4. Establishments that can instruct the internship of midwives: medical examination and treatment establishment licensed to operate in the organization form of hospitals or maternity hospitals or commune health stations, of which the scope of professional activities of the hospitals or commune health stations must cover obstetrics.

5. Establishments that can instruct the internship of medical technicians:

a) Medical technicians practicing medical testing: medical examination and treatment establishments licensed to operate in the organization form of hospitals or clinics or laboratories. The scope of professional activities of such establishments must be consistent with the practice of medical testing;

b) Medical technicians practicing medical imaging: medical examination and treatment establishments licensed to operate in the organization form of hospitals or clinics or diagnostic imaging establishments. The scope of professional activities of such establishments must be consistent with the practice of medical imaging;

c) Medical technicians practicing prosthodontics: medical examination and treatment establishments licensed to operate in the organization form of hospitals or clinics or prosthodontics establishments. The scope of professional activities of such establishments must be consistent with the practice of prosthodontics;

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d) Medical technicians practicing optometry: medical examination and treatment establishments licensed to operate in the organization form of hospitals or clinics or optical establishments that provide vision testing and eye examination services. The scope of professional activities of such establishments must be consistent with the practice of optometry;

dd) Medical technicians practicing functional rehabilitation: medical examination and treatment establishments licensed to operate in the organization form of hospitals or clinics or functional rehabilitation establishments. The scope of professional activities of such establishments must be consistent with the practice of functional rehabilitation.

6. Establishments that can instruct the internship of clinical nutritionists: medical examination and treatment establishments licensed to operate in the organization form of hospitals with divisions specialized in nutrition;

7. Establishments that can instruct the internship of pre-hospital emergency care providers: medical examination and treatment establishments licensed to operate in the organization form of hospitals or pre-hospital emergency care establishments.

8. Establishments that can instruct the internship of clinical psychologists: medical examination and treatment establishments licensed to operate in the organization form of hospitals or clinical psychology establishments of which the hospitals must have the scope of professional activities in psychiatry or have divisions specialized in clinical psychology.

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Article 6. Conditions and responsibilities of internship-instructing establishments

1. Regarding conditions, an internship-instructing establishment must:

a) Be a medical examination and treatment establishment that has been licensed to operate in the organizational forms of establishments that can instruct the internship specified in Article 5 of this Decree;

b) Have a scope of professional activities consistent with the practice as specified in Article 3 of this Decree. In the case where there are not enough specialties of each practice as specified in Article 3 of this Decree, cooperation contracts can be signed with other medical examination and treatment establishments that satisfy such practice.

2. Before instructing the internship, the medical examination and treatment establishment shall send a declaration that it meets the requirements to be an internship-instructing establishment, made using Form No. 01 provided in Appendix I to this Decree, enclosed with particulars of the internship, to:

a) The Ministry of Health, applicable to medical examination and treatment establishments under the Ministry's management;

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b) Specialized health authorities under provincial-level People's Committees, applicable to medical examination and treatment establishments in their respective localities (including private medical examination and treatment establishments), other than those subject to the management of the Ministry of Health, the Ministry of National Defense, and the Ministry of Public Security.

3. After receiving the declaration that the medical examination and treatment establishment meets the requirements to be an internship-instructing establishment, the receiving authority shall issue the establishment a dossier receipt note made using Form No. 02 provided in Appendix I to this Decree.

4. Within 15 days from the date stated on the dossier receipt note specified in Clause 3 of this Article, the receiving authority shall post information about the internship-instructing establishment on its own web portal or website and the information system on management of medical examination and treatment activities.

In the case where the requirements are not met, the receiving authority must send a document to the medical examination and treatment establishment clearly stating the reason.

The information to be posted shall include at least: name and address of the internship-instructing establishment, scope of instruction (if the internship is instructed under partnership, the particulars of such internship and name of the internship-instructing partner must be posted), and instruction fees.

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5. In the case where, after 15 days from the date stated on the dossier receipt note, the receiving authority neither sends a document to the medical examination and treatment establishment stating that it is not qualified to be an internship-instructing establishment nor post the information specified in Clause 4 of this Article, the internship-instructing establishment may begin to instruct the internship.

Article 7. Organization of internship

1. Admitting practitioners:

a) The practitioner must send a written application for internship made using Form No. 03 provided in Appendix I to this Decree and a valid copy of one of the professional degrees specified in Article 8 of this Decree to the internship-instructing establishment where he/she registers for internship.

b) After receiving the written application for internship, if agreeing to admit the practitioner, the head or person in charge of professional and technical expertise of the medical examination and treatment establishment that is the internship-instructing establishment shall:

- Sign a medical examination and treatment internship agreement, made using Form No. 04 provided in Appendix I to this Decree, with the practitioner;

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- Send a written registration of the list of practitioners who are undertaking the medical examination and treatment internship, which shall be made using Form No. 05 provided in Appendix I to this Decree and clearly state the start time and expected end time of the internship, to the authority that receives its declaration specified in Clause 2, Article 6 of this Decree;

- Upload the list of practitioners who are undertaking the medical examination and treatment internship on the website of the establishment and on the information system on management of medical examination and treatment activities.

2. Assigning instructors:

a) The assignment of instructors shall be made using Form No. 06 provided in Appendix I to this Decree;

b) An internship instructor can only guide a maximum of 05 practitioners at the same time.

3. An internship instructor must:

a) Have a practicing license with a title and scope of practice appropriate to the instruction and instructees;

b) Have the same or higher educational attainment than the practitioners;

c) Have continuously practiced medical examination and treatment for 3 years or more.

4. Some specific cases regarding the title and scope of practice of internship instructors:

a) The internship instructor for a practitioner holding a diploma of medical doctor shall be a medical doctor or a specialist doctor, not a traditional medicine doctor, preventive medicine doctor, or odonto-stomatology doctor;

b) The internship instructor for a practitioner holding a diploma of preventive medicine doctor shall be a preventive medicine doctor, medical doctor or specialist doctor, not a traditional medicine doctor or odonto-stomatology doctor;

c) The internship instructor for a practitioner holding a diploma of general assistant doctor shall be a general assistant doctor or a medical doctor or a specialist doctor, not a traditional medicine doctor, preventive medicine doctor, or odonto-stomatology doctor;

d) The internship instructor for a practitioner holding a diploma of traditional medicine assistant doctor shall be a traditional medicine assistant doctor or a traditional medicine doctor;

dd) The internship instructor for a practitioner holding a degree in nursing shall be a nurse;

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e) The internship instructor for a practitioner holding a degree in midwifery shall be a midwife or doctor practicing obstetrics and gynecology;

g) The internship instructor for a practitioner holding a degree in medical imaging shall be a medical imaging technician or a specialist doctor practicing medical imaging;

h) The internship instructor for a practitioner holding a degree in medical testing shall be a medical testing technician or a specialist doctor practicing medical testing;

i) The internship instructor for a practitioner holding a degree in functional rehabilitation shall be a functional rehabilitation technician or a specialist doctor practicing functional rehabilitation;

k) The internship instructor for a practitioner holding a degree in prosthodontics shall be a prosthodontic technician or an odonto-stomatology doctor;

l) The internship instructor for a practitioner holding a degree in optometry shall be an optometrist technician or a doctor practicing specialist ophthalmology;

m) The internship instructor for a practitioner holding a degree in nutrition shall be a clinical nutritionist or a doctor practicing specialist nutrition;

n) The internship instructor for a practitioner holding a degree in pre-hospital emergency care shall be a pre-hospital emergency care provider or a specialist doctor practicing intensive care medicine;

o) The internship instructor for a practitioner holding a degree in clinical psychology shall be a clinical psychologist or a doctor practicing psychiatry with a certificate of basic specialist training in clinical psychology as specified in Clause 2, Article 128 of this Decree.

5. The instructor shall ensure safety for patients when instructing the internship and be held accountable if the practitioners make professional errors during the internship that affect the patients' health, unless the practitioners intentionally make such errors.

6. After the practitioners complete the internship and the instructors give their assessments and comments on the practitioners, the internship-instructing establishment shall:

a) Issue a certificate of completion of the internship, made using Form No. 07 provided in Appendix I to this Decree, to the practitioner;

b) Upload the list of practitioners who have completed the internship on the website of the internship-instructing establishment and on the information system on management of medical examination and treatment activities.

7. Objectivity and truthfulness of the assessments and comments of the

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instructors and the certification of completion of the internship must be ensured.

Section 2
TESTING FOR ASSESSMENT OF CAPACITY FOR PRACTICING MEDICAL EXAMINATION AND TREATMENT

Article 8. Conditions regarding degrees for practitioners to take the test for evaluation of practicing capacity in order to be granted practicing licenses with respective professional titles

1. A practitioner who holds one of the following degrees may take the test for evaluation of practicing capacity in order to be granted a practicing license under the title of doctor:

a) Practicing medicine:

- A diploma of medical doctor, including a graduate degree in health issued by a foreign educational institution and recognized by the Minister of Education and Training as a diploma of medical doctor;

- A bachelor's degree in medicine issued by a foreign educational institution and recognized by the Minister of Education and Training as an undergraduate degree, for which a certificate of completion of the additional medical doctor training program as specified by the Minister of Health has been issued.

b) Practicing traditional medicine:

- A diploma of traditional medicine doctor, including a graduate degree issued by a foreign educational institution and recognized by the Minister of Education and Training as a diploma of traditional medicine doctor;

- A bachelor's degree in traditional medicine issued by a foreign educational institution and recognized by the Minister of Education and Training as an undergraduate degree, for which a certificate of completion of the additional traditional medicine doctor training program as specified by the Minister of Health has been issued.

c) Practicing preventive medicine:

A diploma of preventive medicine doctor, including a graduate degree issued by a foreign educational institution and recognized by the Minister of Education and Training as a diploma of preventive medicine doctor;

d) Practicing odontostomatology:

- A diploma of odonto-stomatology doctor, including a graduate degree issued by a foreign educational institution and recognized by the Minister of

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Education and Training as a diploma of odonto-stomatology doctor;

- A bachelor's degree in medicine issued by a foreign educational institution and recognized by the Minister of Education and Training as an undergraduate degree, for which a certificate of completion of the additional odonto-stomatology doctor training program as specified by the Minister of Health has been issued.

dd) Practicing medical specialty: A diploma of specialist doctor as specified in Clause 1, Article 12 of this Decree.

2. A practitioner who holds one of the following degrees may take the test for evaluation of practicing capacity in order to be granted a practicing license under the title of assistant doctor:

a) Practicing general medicine:

- An associate diploma of general assistant doctor, including a graduate degree issued by a foreign educational institution and recognized by the Minister of Labor, Invalids and Social Affairs that it is equivalent to an associate diploma of general assistant doctor;

- A bachelor's degree in medicine issued by a foreign educational institution and recognized by the Minister of Education and Training as an undergraduate degree.

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b) Practicing traditional medicine:

An associate diploma of traditional medicine assistant doctor or an associate degree in traditional medicine, including a graduate degree issued by a foreign educational institution and recognized by the Minister of Labor, Invalids and Social Affairs that it is equivalent to an associate diploma of traditional medicine assistant doctor or an associate degree in traditional medicine.

3. A practitioner who holds one of the following degrees may take the test for evaluation of practicing capacity in order to be granted a practicing license under the title of nurse:

a) Practicing nursing:

- An intermediate degree in nursing, including a graduate degree issued by a foreign educational institution and recognized by the Minister of Labor, Invalids and Social Affairs that it is equivalent to an intermediate degree in nursing;

- An associate degree in nursing, including a graduate degree issued by a foreign educational institution and recognized by the Minister of Labor, Invalids and Social Affairs that it is equivalent to an associate degree in nursing;

- A bachelor's degree in nursing, including a graduate degree issued by a foreign educational institution and recognized by the Minister of Education and Training as a bachelor of nursing;

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b) Practicing specialist nursing: A diploma of specialist nurse as specified in Clause 1, Article 12 of this Decree.

4. A practitioner who holds one of the following degrees may take the test for evaluation of practicing capacity in order to be granted a practicing license under the title of midwife:

a) Practicing midwifery:

- An intermediate degree in midwifery, including a graduate degree issued by a foreign educational institution and recognized by the Minister of Labor, Invalids and Social Affairs that it is equivalent to an intermediate degree in midwifery;

- An associate degree in midwifery, including a graduate degree issued by a foreign educational institution and recognized by the Minister of Labor, Invalids and Social Affairs that it is equivalent to an associate degree in midwifery;

- A bachelor's degree in midwifery, including a graduate degree issued by a foreign educational institution and recognized by the Minister of Education and Training as a bachelor of midwifery;

b) Practicing specialist midwifery: A diploma of specialist midwife as specified in Clause 1, Article 12 of this Decree.

5. A practitioner who holds one of the following degrees may take the test for evaluation of practicing capacity in order to be granted a practicing license under the title of medical technician:

a) Practicing medical testing:

- An intermediate degree in medical testing, including a graduate degree issued by a foreign educational institution and recognized by the Minister of Labor, Invalids and Social Affairs that it is equivalent to an intermediate degree in medical testing;

- An associate degree in medical testing, including a graduate degree issued by a foreign educational institution and recognized by the Minister of Labor, Invalids and Social Affairs that it is equivalent to an associate degree in medical testing;

- A bachelor's degree in medical testing, including a graduate degree issued by a foreign educational institution and recognized by the Minister of Education and Training as a bachelor of medical testing;

b) Practicing specialist medical testing: A specialist degree in medical testing as specified in Clause 1, Article 12 of this Decree.

c) Practicing medical imaging:

- An intermediate degree in medical imaging, including a graduate degree issued by a foreign educational institution and recognized by the Minister of

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Labor, Invalids and Social Affairs that it is equivalent to an intermediate degree in medical imaging;

- An associate degree in medical imaging, including a graduate degree issued by a foreign educational institution and recognized by the Minister of Labor, Invalids and Social Affairs that it is equivalent to an associate degree in medical imaging;

- A bachelor's degree in medical imaging, including a graduate degree issued by a foreign educational institution and recognized by the Minister of Education and Training as a bachelor of medical imaging;

d) Practicing specialist medical imaging: A specialist degree in medical imaging as specified in Clause 1, Article 12 of this Decree.

dd) Practicing prosthodontics:

- An intermediate degree in prosthodontics, including a graduate degree issued by a foreign educational institution and recognized by the Minister of Labor, Invalids and Social Affairs that it is equivalent to an intermediate degree in prosthodontics;

- An associate degree in prosthodontics, including a graduate degree issued by a foreign educational institution and recognized by the Minister of Labor, Invalids and Social Affairs that it is equivalent to an associate degree in prosthodontics;

- A bachelor's degree in prosthodontics, including a graduate degree issued by a foreign educational institution and recognized by the Minister of Education and Training as a bachelor of prosthodontics;

e) Practicing specialist prosthodontics: A specialist degree in prosthodontics as specified in Clause 1, Article 12 of this Decree.

g) Practicing optometry:

- An associate degree in optometry, including a graduate degree issued by a foreign educational institution and recognized by the Minister of Labor, Invalids and Social Affairs that it is equivalent to an associate degree in optometry;

- A bachelor's degree in optometry, including a graduate degree issued by a foreign educational institution and recognized by the Minister of Education and Training as a bachelor of optometry;

h) Practicing specialist optometry: A specialist degree in optometry as specified in Clause 1, Article 12 of this Decree.

i) Practicing functional rehabilitation:

- One of the following degrees: An intermediate degree in functional rehabilitation or an intermediate degree in physiotherapy or an intermediate degree in both functional rehabilitation and physiotherapy, including a graduate

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degree issued by a foreign educational institution and recognized by the Minister of Labor, Invalids and Social Affairs that it is equivalent to an intermediate degree in functional rehabilitation or physiotherapy;

- One of the following degrees: An associate degree in functional rehabilitation or an associate degree in physiotherapy or an associate degree in both functional rehabilitation and physiotherapy, including a graduate degree issued by a foreign educational institution and recognized by the Minister of Labor, Invalids and Social Affairs that it is equivalent to an associate degree in functional rehabilitation or physiotherapy;

- One of the following degrees: A bachelor's degree in functional rehabilitation or a bachelor's degree in physiotherapy or a bachelor's degree in occupational therapy or a bachelor's degree in speech–language pathology, including a graduate degree issued by a foreign educational institution and recognized by the Minister of Education and Training as a bachelor of functional rehabilitation, physiotherapy, occupational therapy or speech–language pathology;

k) Practicing specialist functional rehabilitation: A specialist degree in functional rehabilitation as specified in Clause 1, Article 12 of this Decree.

6. A practitioner who holds one of the following degrees may take the test for evaluation of practicing capacity in order to be granted a practicing license under the title of clinical nutritionist:

a) Practicing clinical nutrition:

- An associate degree in nutrition, including a graduate degree issued by a foreign educational institution and recognized by the Minister of Labor, Invalids and Social Affairs that it is equivalent to an associate degree in nutrition;

- A bachelor's degree in nutrition, including a graduate degree issued by a foreign educational institution and recognized by the Minister of Education and Training as a bachelor of nutrition;

b) Practicing specialist clinical nutrition: A diploma of specialist clinical nutritionist as specified in Clause 1, Article 12 of this Decree.

7. A practitioner who holds one of the following degrees may take the test for evaluation of practicing capacity in order to be granted a practicing license under the title of pre-hospital emergency care provider:

a) The degree specified in one of Clauses 1, 2, 3, 4 or 5 of this Article;

b) An associate degree in pre-hospital emergency care, including a graduate degree issued by a foreign educational institution and recognized by the Minister of Labor, Invalids and Social Affairs that it is equivalent to an associate degree in pre-hospital emergency care;

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c) A bachelor's degree in pre-hospital emergency care, including a graduate degree issued by a foreign educational institution and recognized by the Minister of Education and Training as a bachelor of pre-hospital emergency care;

d) The specialist degree as specified in Clause 1, Article 12 of this Decree;

8. A practitioner who holds one of the following degrees may take the test for evaluation of practicing capacity in order to be granted a practicing license under the title of clinical psychologist:

a) Practicing clinical psychology:

- A diploma of doctor as specified in Clause 1 of this Article and a certificate of basic specialist training in clinical psychology as specified in Clause 2, Article 128 of this Decree;

- A bachelor's degree in psychology, including a degree issued by a foreign educational institution and recognized by the Minister of Education and Training as a bachelor of psychology, and a certificate of basic specialist training in clinical psychology as specified in Clause 2, Article 128 of this Decree.

b) Practicing specialist clinical psychology:

- A master’s diploma in clinical psychology, including a graduate diploma issued by a foreign educational institution and recognized by the Minister of Education and Training as a master;

- A doctoral diploma in clinical psychology, including a graduate diploma issued by a foreign educational institution and recognized by the Minister of Education and Training as a doctorate;

- The specialist degree in clinical psychology as specified in Clause 1, Article 12 of this Decree;

9. A practitioner who holds a graduate degree in health issued by a foreign educational institution and recognized by the Minister of Labor, Invalids and Social Affairs that it is equivalent to a diploma, or recognized by the Minister of Education and Training that it has the same level of education as that of the professional title as specified in this Article, may take the test for evaluation of practicing capacity in order to be granted a practicing license under such professional title with respective scope of practice.

Article 9. Organization of testing for evaluation of medical examination and treatment practicing capacity

1. Details of testing for evaluation of medical examination and treatment practicing capacity of doctors, assistant doctors, nurses, midwives, medical technicians, clinical nutritionists, pre-hospital emergency care providers and clinical psychologists shall be based on professional competency standards of each respective title and a set of tools for evaluation of medical examination and

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treatment practicing capacity.

2. The National Medical Council shall develop the regulations on testing for evaluation of medical examination and treatment practicing capacity and the criteria for the establishment to be the venue for the test for evaluation of medical examination and treatment practicing capacity and then submit them to the Minister of Health for approval.

3. The National Medical Council shall:

a) Preside over the organization of testing for evaluation of medical examination and treatment practicing capacity in accordance with the Regulations on testing for evaluation of medical examination and treatment practicing capacity specified in Clause 2 of this Article;

b) Select an establishment that meets approved criteria to be the venue for the test for evaluation of medical examination and treatment practicing capacity.

4. The National Medical Council shall set specific fees and regulations on the collection, remittance, management and use thereof for testing for evaluation of medical examination and treatment practicing capacity and submit them to the Minister of Health for approval.

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Section 3

GENERAL REGULATIONS ON GRANT OF LICENSES TO PRACTICE MEDICAL EXAMINATION AND TREATMENT

Article 10. Procedures for grant of a medical examination and treatment practicing license to a doctor, assistant doctor, nurse, midwife, medical technician, clinical nutritionist, pre-hospital emergency care provider or clinical psychologist

1. After completing the training program, the practitioner with a degree in health will be able to choose one of two options related to licensing to practice medical examination and treatment as follows:

a) Carry out procedures for applying for a new practicing license. Before preparing a dossier of application for a new practicing license, he/she must complete the internship as specified in Section 1, Chapter II of this Decree and must take the test for evaluation of his/her practicing capacity as specified in Article 9 of this Decree;

b) Continue studying the specialty and, after completing the specialty training, carry out the procedures for applying for a new practicing license with the scope of specialist practice.

Before preparing a dossier of application for a new practicing license,

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he/she shall not undertake the internship as specified in Section 1, Chapter II of this Decree but must take and pass the test for evaluation of his/her practicing capacity as specified in Article 9 of this Decree.

2. In the case where, after being granted a practicing license in accordance with Point a, Clause 1 of this Article, if such practitioner continues to attend specialty training and then is granted a specialist degree, he/she may prepare a dossier of request for modification of his/her practicing license to add the specialty without re-undertaking the internship and re-taking the test for evaluation of practicing capacity.

3. In the case where a practitioner participates in training courses and then is granted a certificate of professional technical training as specified in Clause 2, Article 12 of this Decree, but it is not within the scope of practice that has been licensed, he/she may not carry out the procedures for modification of the scope of practice. Based on the certificate of professional technical training as specified in Clause 2, Article 12 of this Decree and the actual professional technical capacity of the practitioner, the person in charge of professional expertise of the medical examination and treatment establishment shall decide in writing to allow such practitioner to perform the techniques he/she has been trained.

In the case where a practitioner receives the transfer of a technique that is not yet within his/her licensed scope of practice, he/she may not carry out the procedures for modification of the scope of practice but, based on the certificate of his/her capacity for performing the technique as specified at Point c, Clause 4, Article 85 of this Decree, the person in charge of professional expertise of the medical examination and treatment establishment shall decide in writing to allow the practitioner to perform the transferred technique.

4. In the case where a person has completed a specialist training program as specified at Point b, Clause 1 of this Article but fails to file a dossier for application to the test for evaluation of capacity within 24 months from the date on which his/her specialist degree is granted, he/she must re-undertake the internship for such specialty within the respective period of time as specified in Article 3 of this Decree before filing the dossier of application to the test for evaluation of capacity.

5. In the case where a person is granted a specialist degree as specified in Clause 2 of this Article but fails to file a dossier of application for modification of his/her practicing license within 24 months from the date on which his/her degree is granted, he/she must re-undertake the internship for such specialty within the respective period of time as specified in Article 3 of this Decree before filing the dossier of application for modification of his/her practicing license.

6. In the case where a practitioner has both a degree in health and one or more of the following certificates: a certificate of herbalist, a certificate of family herbal remedy or a certificate of family treatment method, he/she may apply for

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a practicing license under one of the titles specified in Article 26 of the Law on Medical Examination and Treatment and follow the procedures for grant of a practicing license as specified in Clause 1 or Clause 2 of this Article. The scope of practice stated in the practicing license granted in accordance with this Clause shall cover:

a) The scope of practice of the title for which he/she is granted the practicing license and the scope of practice relative to one or more of the following certificates: the certificate of herbalist, the certificate of family herbal remedy or the certificate of family treatment method, if he/she is granted a practicing license under one of the following titles: doctor, assistant doctor, nurse, midwife, medical technician, clinical nutritionist, pre-hospital emergency care provider, or clinical psychologist;

b) The scope of practice of the title for which he/she is granted the practicing license and the scope of practice relative to the results of the test for evaluation of capacity, if he/she is granted a practicing license under one of the following titles: herbalist, of a family herbal remedy, or of a family treatment method.

Article 11. Procedures for grant of a medical examination and treatment practicing license to an herbalist, owner of a family herbal remedy or treatment method

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1. A practitioner who has a certificate of herbalist, a certificate of family herbal remedy, or a certificate of family treatment method shall carry out the procedures to apply for grant of a new practicing license, or re-grant or renewal of a practicing license in accordance with Section 5, Chapter II of this Decree.

2. In the case where the practitioner has been granted a practicing license under one of the following titles: herbalist, owner of family herbal remedy, or owner of family treatment method, then obtain another degree in health and apply for a practicing license under one of the following titles: doctor, assistant doctor, nurse, midwife, medical technician, clinical nutritionist, pre-hospital emergency care provider, or clinical psychologist, he/she must follow the procedures specified in Article 10 of this Decree.

The practice licensing authority issues new practicing licenses and revokes previously issued practicing licenses. The scope of practice stated in the new practicing license shall cover: the scope of practice of the newly granted title and the scope of practice previously granted.

Article 12. Requirements in terms of specialist degrees and certificates of technical training in professional medical examination and treatment, and clinical psychology

1. A specialist degree in medical examination and treatment issued by an educational institution must:

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a) Be issued by a lawful educational institution in accordance with the law regulations;

b) Be obtained after a training period of at least 18 months.

2. A certificate of technical training in professional medical examination and treatment must:

a) Be issued by an educational institution that provides at least 01 training course in the field or at the level of graduation in order to obtain a medical examination and treatment practicing license under the corresponding title, or by a medical examination and treatment establishment permitted by a competent authority to implement the respective professional technique after a training period of at least 06 months;

b) Be obtained through a program and documents on professional technical training, which are developed, appraised, and issued either by the educational institution itself or by another authorized educational institution, and utilized with the written consent of the respective institution. The program's content, learning volume, and lecturers must align with the list of professional and technical expertise specified by the Ministry of Health.

3. In the case where a specialist degree is employed to adjust the scope of practice as specified at Point a, Point b, or Point c, Clause 1, Article 19 of this Decree, the training process shall commence subsequent to the date of grant or modification of the respective practicing license.

4. The training of degrees and certificates specified in Clauses 1 and 2 of this Article must be officially announced by the educational institutions on their websites.

Section 4

GRANT OF MEDICAL EXAMINATION AND TREATMENT PRACTICING LICENSES FOR PROFESSIONAL TITLES INCLUDING DOCTORS, ASSISTANT DOCTORS, NURSES, MIDWIVES, MEDICAL TECHNICIANS, CLINICAL NUTRITIONISTS, PRE-HOSPITAL EMERGENCY CARE PROVIDERS AND CLINICAL PSYCHOLOGISTS

Subsection 1

GRANT OF NEW MEDICAL EXAMINATION AND TREATMENT PRACTICING LICENSES TO PROFESSIONAL TITLES INCLUDING DOCTORS, ASSISTANT DOCTORS, NURSES, MIDWIVES, MEDICAL TECHNICIANS, CLINICAL NUTRITIONISTS, PRE-HOSPITAL

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EMERGENCY CARE PROVIDERS AND CLINICAL PSYCHOLOGISTS

Article 13. Cases and conditions for grant of new practicing licenses to professional titles including doctors, assistant doctors, nurses, midwives, medical technicians, clinical nutritionists, pre-hospital emergency care providers or clinical psychologists

1. Practicing licenses shall be granted to the following persons:

a) Practitioners who apply for practicing licenses for the first time as specified at Point a, Clause 1, Article 30 of the Law on Medical Examination and Treatment.

b) Practitioners whose professional titles stated in the practicing licenses are changed, as specified at Point b, Clause 1, Article 30 of the Law on Medical Examination and Treatment.

c) Practitioners specified in:

- Point c, Clause 1, Article 33 of this Decree;
- Clause 2, Article 33 of this Decree;
- Point c, Clause 3, Article 33 of this Decree;
- Point b, Clause 4, Article 33 of this Decree;
- Point c, Clause 5, Article 33 of this Decree;
- Clause 6, Article 33 of this Decree;
- Clause 7, Article 33 of this Decree;
- Clause 8, Article 33 of this Decree;
- Point c, Clause 9, Article 33 of this Decree.

d) Practitioners who fail to carry out the renewal procedures as specified at Point a, Clause 2, Article 18 of this Decree.

dd) Practitioners who have been granted practicing licenses by the licensing authorities of the people's armed forces but no longer worked for the people's armed forces and do not want to continue using the practicing licenses granted to them as well as wish to continue practicing at medical examination and treatment establishments that are not affiliated to the people's armed forces within the period of more than 60 months from the end of practice at medical examination and treatment establishments affiliated to the people's armed forces to the date of filing a dossier of application for a practicing license.

2. Conditions for a new practicing license to be granted: Specified in Clause 2, Article 30 of the Law on Medical Examination and Treatment.

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Article 14. Dossiers and procedures for grant of new practicing licenses to professional titles including doctors, assistant doctors, nurses, midwives, medical technicians, clinical nutritionists, pre-hospital emergency care providers or clinical psychologists

1. A dossier of application for a new practicing license to a practitioner who applies for a practicing license for the first time, as specified at Point a, Clause 1, Article 30 of the Law on Medical Examination and Treatment and Point dd, Clause 1, Article 13 of this Decree, shall comprise of:

a) A written application made using Form No. 08 provided in Appendix I to this Decree.

b) An original or valid copy of one of the following documents:

- A written confirmation of successful results of the test for evaluation of medical examination and treatment practicing capacity (not applicable to cases where the results of such test have been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database);

- A practicing license recognized in accordance with Article 37 of this Decree (not applicable to cases where the recognition of such practicing license has been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database).

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c) An original or valid copy of medical certificate issued by a qualified medical examination and treatment establishment (not applicable to cases where health examination results have been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database) or a valid copy of the work permit in cases where a work permit is required in accordance with the Labor Code.

d) A self-declared résumé of the practitioner made using Form No. 09 provided in Appendix I to this Decree (not applicable to cases where the résumé of the practitioner has been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database).

dd) 02 profile photos sized 04 cm x 06 cm against a white background taken within a maximum period of six months from the date of filing the dossier of application for a new practicing license (not applicable for cases where the applicant has already uploaded his/her photos when completing administrative procedures electronically).

e) A valid copy of one or more of the following documents (not applicable in the cases where these documents have been uploaded or shared on the information system on management of medical examination and treatment activities or the national health database) in the case specified at Point a, Clause

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6, Article 10 of this Decree:

- A certificate of herbalist;

- A certificate of family herbal remedy;

- A certificate of family treatment method.

2. A dossier of application for new practicing license to a practitioner whose professional title stated in his/her existing practicing license is changed, as specified at Point b, Clause 1, Article 30 of the Law on Medical Examination and Treatment, shall comprise of:

a) A written application made using Form No. 08 provided in Appendix I to this Decree.

b) An original or valid copy of the written confirmation of successful results of the test for evaluation of medical examination and treatment practicing capacity which have been recognized in accordance with Article 37 of this Decree for any person who have been granted a practicing license and request for change of his/her professional title to doctor, assistant doctor, nurse, midwife, medical technician, clinical nutritionist, pre-hospital emergency care provider or clinical psychologist (not applicable to cases where the results of the capacity test have been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database);

c) An original or valid copy of medical certificate issued by a qualified medical examination and treatment establishment (not applicable to cases where health examination results have been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database) or a valid copy of the work permit in cases where a work permit is required in accordance with the Labor Code;

d) A self-declared résumé of the practitioner made using Form No. 09 provided in Appendix I to this Decree (not applicable to cases where the résumé of the practitioner has been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database).

dd) 02 profile photos sized 04 cm x 06 cm against a white background taken within a maximum period of six months from the date of filing the dossier of application for a new practicing license (not applicable for cases where the applicant has already uploaded his/her photos when completing administrative procedures electronically).

3. A dossier of application for grant of a new practicing license in the case where the practicing license is revoked as specified at Point c, Clause 1, Clause 2, Point c, Clause 3, Point b, Clause 4, Clause 6, Clause 7, Clause 8 and Point c, Clause 9, Article 33 of this Decree because documents in the dossier of

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application for the practicing license are forged (Point b, Clause 1, Article 35 of the Law on Medical Examination and Treatment):

a) The documents specified in Clause 1 of this Article;

b) An original or valid copy of the decision on revocation of the practicing license (not applicable to cases where the decision on revocation of the practicing license has been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database).

4. A dossier of application for grant of a new practicing license in the case where the practicing license is revoked as specified at Point c, Clause 5, Article 33 of this Decree due to one of the reasons specified in Clauses 1, 2, 3, 4 or 6, Article 20 of the Law on Medical Examination and Treatment (Point dd, Clause 1, Article 35 of the Law on Medical Examination and Treatment):

a) The documents specified in Clause 1 of this Article;

b) An original or valid copy of the decision on revocation of the practicing license (not applicable to cases where the decision on revocation of the practicing license has been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database).

c) One of the following documents:

- An original or valid copy of a document from a competent authority concluding that the practitioner is neither guilty nor banned from practicing medical examination and treatment in cases where a person has been examined for penal liability, but a written conclusion was rendered that he/she is neither guilty nor banned from practicing (Clause 1, Article 20 of the Law on Medical Examination and Treatment).

- An original or valid copy of the certificate of completion of either the probation period or the sentence or court ruling (Clause 2, Clause 3, Clause 4, Article 20 of the Law on Medical Examination and Treatment);

- An original or valid copy of a document from a competent authority determining that the practitioner has full civil act capacity or has no difficulty in cognition or behavior control or no longer has civil act capacity restricted (Clause 6, Article 20 of the Law on Medical Examination and Treatment).

5. A dossier of application for a new practicing license in the case where the former practicing license is not renewed as specified at Point a, Clause 2, Article 18 of this Decree within 24 months:

a) The documents specified in Clause 1 of this Article;

b) An original or valid copy of the decision on revocation of the practicing license (not applicable to cases where the decision on revocation of the practicing license has been uploaded and shared on the information system on management

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of medical examination and treatment activities or the national health database).

6. Procedures for grant of a new practicing license

a) The applicant for a practicing license shall send 01 dossier in each respective case specified in Clauses 1 to 5 of this Article and pay fees specified in law regulations on fees and charges to the authority that grants practicing licenses as specified in Article 28 of the Law on Medical Examination and Treatment (hereinafter referred to as a practice licensing authority for short);

b) The practice licensing authority shall grant the practicing license within 30 days from the date of receiving a complete dossier. In case of refusal to grant the practicing license, it shall send a written reply clearly stating the reasons for such refusal.

In the case where the verification of documents with foreign factors included in the dossier of application for the practicing license is required, the time limit for granting the practicing license is 30 days after the verification result is available.

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Subsection 2

RE-GRANT OF MEDICAL EXAMINATION AND TREATMENT PRACTICING LICENSES TO PROFESSIONAL TITLES INCLUDING DOCTORS, ASSISTANT DOCTORS, NURSES, MIDWIVES, MEDICAL TECHNICIANS, CLINICAL NUTRITIONISTS, PRE-HOSPITAL EMERGENCY CARE PROVIDERS AND CLINICAL PSYCHOLOGISTS

Article 15. Cases and conditions for re-grant of practicing licenses to professional titles including doctors, assistant doctors, nurses, midwives, medical technicians, clinical nutritionists, pre-hospital emergency care providers or clinical psychologists

1. Practicing licenses shall be re-granted in the following cases:

a) The practicing license is lost or damaged.

b) There is a change to the information specified at Point a, Clause 3, Article 27 of the Law on Medical Examination and Treatment, or error in the information specified in Clause 3, Article 27 of the Law on Medical Examination and Treatment.

c) Practitioners specified in:

- Points a and b, Clause 1, Article 33 of this Decree;

- Points a and b, Clause 3, Article 33 of this Decree;

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- Point a, Clause 4, Article 33 of this Decree;

- Points a and b, Clause 5, Article 33 of this Decree;

- Points a and b, Clause 9, Article 33 of this Decree;

d) The practice certificate is granted ultra vires as specified in Clause 1, Article 28 of the Law on Medical Examination and Treatment.

dd) Practitioners who have been granted practicing licenses by the licensing authorities of the people's armed forces but no longer worked for the people's armed forces and do not want to continue using the practicing licenses granted to them as well as wish to continue practicing at medical examination and treatment establishments that are not affiliated to the people's armed forces within the period of no more than 24 months from the end of practice at medical examination and treatment establishments affiliated to the people's armed forces to the date of filing a dossier of application for a practicing license.

e) Practitioners who have been granted practicing licenses by the licensing authorities of the people's armed forces but no longer worked for the people's armed forces and do not want to continue using the practicing licenses granted to them as well as wish to continue practicing at medical examination and treatment establishments that are not affiliated to the people's armed forces within the period of between more than 24 months to less than 60 months from the end of practice at medical examination and treatment establishments affiliated to the people's armed forces to the date of filing a dossier of application for a practicing license.

2. Conditions for a practicing license to be re-granted: Specified in Clause 2, Article 31 of the Law on Medical Examination and Treatment.

Article 16. Dossiers and procedures for re-grant of practicing licenses to professional titles including doctors, assistant doctors, nurses, midwives, medical technicians, clinical nutritionists, pre-hospital emergency care providers or clinical psychologists

1. A dossier of application for re-grant of a practicing license in the case where the former practicing license is lost or damaged as specified at Point a, Clause 1, Article 15 of this Decree:

a) A written application made using Form No. 08 provided in Appendix I to this Decree.

b) An original or valid copy of the practicing license that has been granted (if any) (not applicable to cases where the practicing license has been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database).

c) 02 profile photos sized 04 cm x 06 cm against a white background taken within a maximum period of six months from the date of filing the dossier of

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application for a new practicing license (not applicable for cases where the applicant has already uploaded his/her photos when completing administrative procedures electronically).

2. A dossier of application for re-grant of a practicing license in the case specified at Point b, Clause 1, Article 15 of this Decree (in case of changing one of the information specified at Point a, Clause 3, Article 27 of the Law on Medical Examination and Treatment or the information specified in Clause 3, Article 27 of the Law on Medical Examination and Treatment are incorrect):

a) A written application made using Form No. 08 provided in Appendix I to this Decree.

b) An original copy of the practicing license that has been granted;

c) Original or valid copies of the documents proving modified or incorrect information (if any) (not applicable to cases where such information can be searched or verified on the information system on management of medical examination and treatment activities or the national health database).

d) 02 profile photos sized 04 cm x 06 cm against a white background taken within a maximum period of six months from the date of filing the dossier of application for a new practicing license (not applicable for cases where the applicant has already uploaded his/her photos when completing administrative procedures electronically).

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3. A dossier of application for re-grant of a practicing license in the case where the practicing license is revoked as specified at Point a, Clause 1, Article 33 of this Decree because the dossier of application for the practicing license has been made in contravention of regulations (Point a, Clause 1, Article 35 of the Law on Medical Examination and Treatment):

a) The documents specified in Clause 1, Article 14 of this Decree;

b) An original or valid copy of the decision on revocation of the practicing license (not applicable to cases where the decision on revocation of the practicing license has been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database).

4. A dossier of application for re-grant of a practicing license in the case where the practicing license is revoked as specified at Point b, Clause 1, Article 33 of this Decree because the dossier of application for the practicing license has been made in contravention of regulations (Point a, Clause 1, Article 35 of the Law on Medical Examination and Treatment):

a) The documents specified in Clause 1, Article 14 of this Decree;

b) An original or valid copy of the decision on revocation of the practicing license (not applicable to cases where the decision on revocation of the practicing license has been uploaded and shared on the information system on management

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of medical examination and treatment activities or the national health database).

c) A valid copy of the certificate of completion of the internship made using Form No. 07 provided in Appendix I to this Decree (not applicable to the cases where internship results have been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database);

5. A dossier of application for re-grant of a practicing license in the case where the practicing license is revoked as specified at Point a, Clause 3, Article 33 of this Decree because the granted practicing license states the wrong professional title or scope of practice as compared to the dossier of application for the practicing license (Point c, Clause 1, Article 35 of the Law on Medical Examination and Treatment):

a) The documents specified in Clause 1, Article 14 of this Decree;

b) An original or valid copy of the decision on revocation of the practicing license (not applicable to cases where the decision on revocation of the practicing license has been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database).

6. A dossier of application for re-grant of a practicing license in the case where the practicing license is revoked as specified at Point b, Clause 3, Article 33 of this Decree because the granted practicing license states the wrong professional title or scope of practice as compared to the dossier of application for the practicing license (Point c, Clause 1, Article 35 of the Law on Medical Examination and Treatment):

a) The documents specified in Clause 1, Article 14 of this Decree;

b) An original or valid copy of the decision on revocation of the practicing license (not applicable to cases where the decision on revocation of the practicing license has been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database).

c) A valid copy of the certificate of completion of the internship made using Form No. 07 provided in Appendix I to this Decree (not applicable to the cases where internship results have been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database);

7. A dossier of application for re-grant of a practicing license in the case where the practicing license is revoked as specified at Point a, Clause 4, Article 33 of this Decree because the practitioner has not practiced for 24 consecutive months (Point d, Clause 1, Article 35 of the Law on Medical Examination and Treatment):

a) The documents specified in Clause 1, Article 14 of this Decree;

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b) An original or valid copy of the decision on revocation of the practicing license (not applicable to cases where the decision on revocation of the practicing license has been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database).

c) A valid copy of the certificate of completion of the internship made using Form No. 07 provided in Appendix I to this Decree (not applicable to the cases where internship results have been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database);

8. A dossier of application for re-grant of a practicing license in the case where the practicing license is revoked as specified at Point a, Clause 5, Article 33 of this Decree because the practitioner falls into one of the cases banned from practice specified in Clauses 1, 2, 3, 4 or 6, Article 20 of the Law on Medical Examination and Treatment (Point dd, Clause 1, Article 35 of the Law on Medical Examination and Treatment):

a) The documents specified in Clause 1, Article 14 of this Decree.

b) An original or valid copy of the decision on revocation of the practicing license (not applicable to cases where the decision on revocation of the practicing license has been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database).

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c) One of the following documents:

- An original or valid copy of a document from a competent authority concluding that the practitioner is neither guilty nor banned from practicing medical examination and treatment in cases where a person has been examined for penal liability, but a written conclusion was rendered that he/she is neither guilty nor banned from practicing (Clause 1, Article 20 of the Law on Medical Examination and Treatment).

- An original or valid copy of the certificate of completion of either the probation period or the sentence or court ruling (Clause 2, Clause 3, Clause 4, Article 20 of the Law on Medical Examination and Treatment);

- An original or valid copy of a document from a competent authority determining that the practitioner has full civil act capacity or has no difficulty in cognition or behavior control or no longer has civil act capacity restricted (Clause 6, Article 20 of the Law on Medical Examination and Treatment).

9. A dossier of application for re-grant of a practicing license in the case where the practicing license is revoked as specified at Point b, Clause 5, Article 33 of this Decree because the practitioner falls into one of the cases banned from practice specified in Clauses 1, 2, 3, 4 or 6, Article 20 of the Law on Medical Examination and Treatment (Point dd, Clause 1, Article 35 of the Law on Medical Examination and Treatment):

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a) The documents specified in Clause 1, Article 14 of this Decree.

b) An original or valid copy of the decision on revocation of the practicing license (not applicable to cases where the decision on revocation of the practicing license has been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database).

c) One of the following documents:

- An original or valid copy of a document from a competent authority concluding that the practitioner is neither guilty nor banned from practicing medical examination and treatment in cases where a person has been examined for penal liability, but a written conclusion was rendered that he/she is neither guilty nor banned from practicing (Clause 1, Article 20 of the Law on Medical Examination and Treatment).

- An original or valid copy of the certificate of completion of either the probation period or the sentence or court ruling (Clause 2, Clause 3, Clause 4, Article 20 of the Law on Medical Examination and Treatment);

- An original or valid copy of a document from a competent authority determining that the practitioner has full civil act capacity or has no difficulty in cognition or behavior control or no longer has civil act capacity restricted (Clause 6, Article 20 of the Law on Medical Examination and Treatment).

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d) A valid copy of the certificate of completion of the internship made using Form No. 07 provided in Appendix I to this Decree (not applicable to the cases where internship results have been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database);

10. A dossier of application for re-grant of a practicing license in the case where the practicing license is revoked as specified at Point a, Clause 9, Article 33 of this Decree because the practitioner himself/herself requests revocation of his/her practicing license (Point i, Clause 1, Article 35 of the Law on Medical Examination and Treatment):

a) The documents specified in Clause 1, Article 14 of this Decree;

b) An original or valid copy of the decision on revocation of the practicing license (not applicable to cases where the decision on revocation of the practicing license has been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database).

11. A dossier of application for re-grant of a practicing license in the case where the practicing license is revoked as specified at Point b, Clause 9, Article 33 of this Decree because the practitioner himself/herself requests revocation of his/her practicing license (Point i, Clause 1, Article 35 of the Law on Medical Examination and Treatment):

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a) The documents specified in Clause 1, Article 14 of this Decree;

b) An original or valid copy of the decision on revocation of the practicing license (not applicable to cases where the decision on revocation of the practicing license has been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database).

c) A valid copy of the certificate of completion of the internship made using Form No. 07 provided in Appendix I to this Decree (not applicable to the cases where internship results have been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database);

12. A dossier of application for re-grant of a practicing license in the case where the former practicing license is granted ultra vires as specified at Point d, Clause 1, Article 31 of the Law on Medical Examination and Treatment:

a) A written application made using Form No. 08 provided in Appendix I to this Decree.

b) An original copy of the practicing license that has been granted;

c) 02 profile photos sized 04 cm x 06 cm against a white background taken within a maximum period of six months from the date of filing the dossier of application for a new practicing license (not applicable for cases where the applicant has already uploaded his/her photos when completing administrative procedures electronically).

13. A dossier of application for re-grant of a practicing license in the case specified at Point dd, Clause 1, Article 15 of this Decree:

a) A written application made using Form No. 08 provided in Appendix I to this Decree.

b) An original or valid copy of the written certification that the practicing license has been granted by the licensing authority of the people's armed forces, which clearly states the practicing license number, date of grant, place of grant, and personal information, professional title, and scope of practice;

c) An original or valid copy of medical certificate issued by a qualified medical examination and treatment establishment (not applicable to cases where health examination results have been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database) or a valid copy of the work permit in cases where a work permit is required in accordance with the Labor Code;

d) A self-declared résumé of the practitioner made using Form No. 09 provided in Appendix I to this Decree (not applicable to cases where the résumé of the practitioner has been uploaded and shared on the information system on management of medical examination and treatment activities or the national

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health database).

dd) 02 profile photos sized 04 cm x 06 cm against a white background taken within a maximum period of six months from the date of filing the dossier of application for a new practicing license (not applicable for cases where the applicant has already uploaded his/her photos when completing administrative procedures electronically).

14. A dossier of application for re-grant of a practicing license in the case specified at Point e, Clause 1, Article 15 of this Decree:

a) A written application made using Form No. 08 provided in Appendix I to this Decree.

b) An original or valid copy of the written certification that the practicing license has been granted by the licensing authority of the people's armed forces, which clearly states the practicing license number, date of grant, place of grant, and personal information, professional title, and scope of practice;

c) An original or valid copy of medical certificate issued by a qualified medical examination and treatment establishment (not applicable to cases where health examination results have been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database) or a valid copy of the work permit in cases where a work permit is required in accordance with the Labor Code:

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d) A self-declared résumé of the practitioner made using Form No. 09 provided in Appendix I to this Decree (not applicable to cases where the résumé of the practitioner has been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database).

dd) A valid copy of the certificate of completion of the internship made using Form No. 07 provided in Appendix I to this Decree (not applicable to the cases where internship results have been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database);

e) 02 profile photos sized 04 cm x 06 cm against a white background taken within a maximum period of six months from the date of filing the dossier of application for a new practicing license (not applicable for cases where the applicant has already uploaded his/her photos when completing administrative procedures electronically).

15. Procedures for re-grant of a practicing license

a) The applicant for re-grant of a practicing license shall send 01 dossier of application for such re-grant in each respective case specified in Clauses 1 to 14 of this Article and pay fees specified in law regulations on fees and charges to the

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practice licensing authority;

b) The practice licensing authority shall re-grant a practicing license within 15 days after receiving a complete dossier. In case of refusal to re-grant a practicing license, it shall send a written reply clearly stating the reasons for such refusal;

c) In the case where the verification of documents with foreign factors included in the dossier of application for re-grant of a practicing license is required, the time limit for re-grant is 15 days after the verification result is available.

Subsection 3

RENEWAL OF MEDICAL EXAMINATION AND TREATMENT PRACTICING LICENSES OF PROFESSIONAL TITLES INCLUDING DOCTORS, ASSISTANT DOCTORS, NURSES, MIDWIVES, MEDICAL TECHNICIANS, CLINICAL NUTRITIONISTS, PRE-HOSPITAL EMERGENCY CARE PROVIDERS AND CLINICAL PSYCHOLOGISTS

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Article 17. Cases and conditions for renewal of practicing licenses of professional titles including doctors, assistant doctors, nurses, midwives, medical technicians, clinical nutritionists, pre-hospital emergency care providers or clinical psychologists

1. A practicing license that expires as specified in Clause 2, Article 27 of the Law on Medical Examination and Treatment shall be renewed.

2. Conditions for a practicing license to be renewed: Specified in Clause 2, Article 32 of the Law on Medical Examination and Treatment.

Article 18. Dossiers and procedures for renewal of practicing licenses of professional titles including doctors, assistant doctors, nurses, midwives, medical technicians, clinical nutritionists, pre-hospital emergency care providers or clinical psychologists

1. A dossier of application for renewal of a practicing license to a doctor, assistant doctor, nurse, midwife, medical technician, clinical nutritionist, pre-hospital emergency care provider or clinical psychologist:

a) A written application made using Form No. 08 provided in Appendix I to this Decree.

b) A valid copy of the practicing license that has been granted (not applicable to cases where the practicing license has been uploaded and shared on the information system on management of medical examination and treatment

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activities or the national health database).

c) Documents proving that medical knowledge in medical examination and treatment has been continuously updated in accordance with regulations of the Minister of Health (not applicable to cases where the results of continuously updating medical knowledge have been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database);

d) An original or valid copy of medical certificate issued by a qualified medical examination and treatment establishment (not applicable to cases where health examination results have been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database) or a valid copy of the work permit in cases where a work permit is required in accordance with the Labor Code.

2. Procedures for renewal of a practicing license

a) The applicant for renewal of a practicing license shall send 01 dossier as specified in Clause 1 of this Article and pay fees specified in law regulations on fees and charges to the practice licensing authority at least 60 days before the practicing license expires.

In case of illness, accident or force majeure at the time of filing the dossier of application for renewal, he/she must send a written notice to the practice licensing authority to delay the filing of his/her dossier of application for renewal of the practicing license.

A practitioner may delay the renewal date multiple times, but the total period of delay must not exceed 22 months from the date on which the practicing license expires;

b) Within the period from the date of receiving a complete dossier to the expiry date stated in the practicing license, the practice licensing authority shall renew the practicing license or shall, if refusing to renew the practicing license, issue a written reply clearly stating the reason for such refusal. In the case where no reply is issued by the expiry date stated in the practicing license, the practicing license will continue to be valid in accordance with the regulations;

c) In the case where it is necessary to verify the practitioner's continued updating of medical knowledge organized by foreign authorities, the time limit for renewal of the practicing license is 15 days after the verification result is available.

Subsection 4

MODIFICATION OF MEDICAL EXAMINATION AND TREATMENT PRACTICING LICENSES TO PROFESSIONAL TITLES INCLUDING

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DOCTORS, ASSISTANT DOCTORS, NURSES, MIDWIVES, MEDICAL TECHNICIANS, CLINICAL NUTRITIONISTS, PRE-HOSPITAL EMERGENCY CARE PROVIDERS AND CLINICAL PSYCHOLOGISTS

Article 19. Cases and conditions for grant of modified practicing licenses of professional titles including doctors, assistant doctors, nurses, midwives, medical technicians, clinical nutritionists, pre-hospital emergency care providers or clinical psychologists

1. Modification can be made to the practicing license of a person who:

a) Has been granted a practicing license with the scope of practice that does not cover a specialty and requests to add such specialty to the scope of practice;

b) Has been granted a practicing license with the scope of practice that already covers a specialty, but requests to add another specialty different from such specialty to the scope of practice;

c) Has been granted a practicing license with the scope of practice that already covers a specialty, but requests to replace the specialty already licensed to practice by another specialty and no longer practices the previously licensed specialty within the scope of practice;

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d) Has been granted a practicing license and then obtains a certificate as the owner of a family herbal remedy or treatment method.

2. Conditions for modification of practicing licenses:

a) In the case where the practitioner has been granted a practicing license with the scope of practice that does not cover a specialty and requests to add such specialty to the scope of practice: He/she shall have a specialist degree as specified in Clause 1, Article 12 of this Decree relative to the title on the practicing license and the specialty to be added;

b) In the case where the practitioner has been granted a practicing license with the scope of practice that already covers a specialty, but requests to add another specialty different from such specialty to the scope of practice: He/she shall have a specialist degree as specified in Clause 1, Article 12 of this Decree relative to the title on the practicing license and the specialty to be added;

c) In the case where a practitioner has been granted a practicing license with the scope of practice that already covers a specialty, but requests to replace such specialty by another specialty: He/she shall have a specialist degree relative to the title and the substitutive specialty as specified in Clause 1, Article 12 of this Decree.

Article 20. Dossiers and procedures for modification of a practice

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license

1. A dossier of application for modification of a practicing license in the case where new specialties as specified at Points a, b, c, Clause 1, Article 19 of this Decree are added:

a) A written application made using Form No. 08 provided in Appendix I to this Decree.

b) A valid copy of the practicing license that has been granted (not applicable to cases where the practicing license has been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database).

c) A valid copy of the specialist diploma specified in Clause 1, Article 12 this Decree (not applicable to the cases where such specialist diploma has been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database);

d) An original or valid copy of the certificate of completion of the internship made using Form No. 07 provided in Appendix I to this Decree, for practitioners specified in Clause 4, Article 10 of this Decree (not applicable to the cases where internship results have been uploaded and shared on the information system on medical examination and treatment management or the national health database).

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2. A dossier of application for modification of a practicing license in the case where the practitioner has been granted a practicing license and then obtain a certificate as the owner of a family herbal remedy or a certificate as the owner of family treatment method as specified at Point d, Clause 1, Article 19 of this Decree:

a) A written application made using Form No. 08 provided in Appendix I to this Decree.

b) A valid copy of the practicing license that has been granted (not applicable to cases where the practicing license has been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database).

c) A valid copy of the certificate as the owner of a family herbal remedy or treatment method (not applicable to the cases where such certificate has been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database);

3. Procedures for modification of a practicing license in the case specified in Clause 1, Article 19 of this Decree:

a) The applicant for modification of a practicing license shall send 01 dossier in each respective case specified in Clause 1 or Clause 2 of this Article

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and pay fees specified in law regulations on fees and charges to the practice licensing authority;

b) The practice licensing authority shall modify the practicing license within 15 days after receiving a complete dossier. In case of refusal to modify the practicing license, it shall send a written reply clearly stating the reasons for such refusal.

Modification of a practicing license shall be made in the form of a decision on modification of the scope of practice using Form No. 10 provided in Appendix I to this Decree. The decision on modification of the scope of practice is an integral part of the granted practicing license;

c) In the case where the verification of documents with foreign factors included in the dossier is required, the time limit for modification is 15 days after the verification result is available.

Section 5
GRANT OF MEDICAL EXAMINATION AND TREATMENT PRACTICING LICENSES FOR PROFESSIONAL TITLES INCLUDING HERBALISTS, OWNERS OF FAMILY HERBAL REMEDIES OR TREATMENT METHODS

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Subsection 1

GRANT OF NEW MEDICAL EXAMINATION AND TREATMENT PRACTICING LICENSES TO PROFESSIONAL TITLES INCLUDING HERBALISTS, OWNERS OF FAMILY HERBAL REMEDIES OR TREATMENT METHODS

Article 21. Cases and conditions for grant of a new practicing license to an herbalist or owner of a family herbal remedy or treatment method

1. Practicing licenses shall be granted to the following persons:

a) Practitioners who apply for practicing licenses for the first time as specified at Point a, Clause 1, Article 30 of the Law on Medical Examination and Treatment;

b) Practitioners whose professional titles stated in the practicing licenses are changed, as specified at Point b, Clause 1, Article 30 of the Law on Medical Examination and Treatment;

c) Practitioners who have been granted practicing licenses but have them revoked in one of the cases specified in Clause 2, Clause 4, Clause 5, Clause 6, Clause 7 or Clause 8, Article 34 of this Decree;

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d) Practitioners who fail to carry out the renewal procedures as specified at Point a, Clause 2, Article 26 of this Decree.

2. Conditions for a new practicing license to be granted: Specified in Clause 3, Article 30 of the Law on Medical Examination and Treatment.

Article 22. Dossiers and procedures for grant of a new practicing license to an herbalist or owner of a family herbal remedy or treatment method

1. A dossier of application for a new practicing license to a practitioner who applies for a practicing license for the first time, as specified at Point a, Clause 1, Article 30 of the Law on Medical Examination and Treatment, shall comprise of:

a) A written application made using Form No. 08 provided in Appendix I to this Decree.

b) A valid copy of one or more of the following documents (not applicable in the cases where these documents have been uploaded or shared on the information system on management of medical examination and treatment activities or the national health database):

- Certificate of herbalist, granted by a competent authority;

- Certificate of owner of a family herbal remedy, granted by a competent authority;

- Certificate of owner of a family treatment method, granted by a competent authority.

c) An original or valid copy of medical certificate issued by a qualified medical examination and treatment establishment (not applicable to cases where health examination results have been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database) or a valid copy of the work permit in cases where a work permit is required in accordance with the Labor Code.

d) A self-declared résumé of the practitioner made using Form No. 09 provided in Appendix I to this Decree (not applicable to cases where the résumé of the practitioner has been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database).

dd) 02 profile photos sized 04 cm x 06 cm against a white background taken within a maximum period of six months from the date of filing the dossier of application for a new practicing license (not applicable for cases where the applicant has already uploaded his/her photos when completing administrative procedures electronically).

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e) A valid copy of one of the following documents in the case specified at Point b, Clause 6, Article 10 of this Decree:

- A written confirmation of successful results of the test for evaluation of medical examination and treatment practicing capacity (not applicable to cases where the results of such test have been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database);

- A practicing license recognized in accordance with Article 37 of this Decree (not applicable to cases where the recognition of such practicing license has been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database).

2. A dossier of application for new practicing license to a practitioner whose professional title stated in his/her existing practicing license is changed, as specified at Point b, Clause 1, Article 30 of the Law on Medical Examination and Treatment, shall comprise of:

a) A written application made using Form No. 08 provided in Appendix I to this Decree.

b) A valid copy of one or more of the following documents (not applicable in the cases where these documents have been uploaded or shared on the information system on management of medical examination and treatment activities or the national health database):

- Certificate of herbalist in the case where the practitioner has been granted a practicing license and want to change his/her title to herbalist;

- Certificate of family herbal remedy in the case where the practitioner has been granted a practicing license and want to change his/her title to owner of a family herbal remedy;

- Certificate of family treatment method in the case where the practitioner has been granted a practicing license and want to change his/her title to owner of a family treatment method.

c) An original or valid copy of medical certificate issued by a qualified medical examination and treatment establishment (not applicable to cases where health examination results have been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database) or a valid copy of the work permit in cases where a work permit is required in accordance with the Labor Code.

d) A self-declared résumé of the practitioner made using Form No. 09 provided in Appendix I to this Decree (not applicable to cases where the résumé of the practitioner has been uploaded and shared on the information system on management of medical examination and treatment activities or the national

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health database).

dd) 02 profile photos sized 04 cm x 06 cm against a white background taken within a maximum period of six months from the date of filing the dossier of application for a new practicing license (not applicable for cases where the applicant has already uploaded his/her photos when completing administrative procedures electronically).

3. A dossier of application for grant of a new practicing license in the case where the practicing license is revoked as specified in Clause 4, Article 34 of this Decree because the practitioner has not practiced for 24 consecutive months (Point d, Clause 1, Article 35 of the Law on Medical Examination and Treatment):

a) The documents specified in Clause 1 of this Article;

b) An original or valid copy of the decision on revocation of the practicing license (not applicable to cases where the decision on revocation of the practicing license has been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database).

4. A dossier of application for grant of a new practicing license in the case where the practicing license is revoked as specified in Clause 5, Article 34 of this Decree because the practitioner falls into one of the cases banned from practice specified in Clauses 1, 2, 3, 4 or 6, Article 20 of the Law on Medical Examination and Treatment (Point dd, Clause 1, Article 35 of the Law on Medical Examination and Treatment):

a) The documents specified in Clause 1 of this Article;

b) An original or valid copy of the decision on revocation of the practicing license (not applicable to cases where the decision on revocation of the practicing license has been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database).

c) One of the following documents:

- An original or valid copy of a document from a competent authority concluding that the practitioner is neither guilty nor banned from practicing medical examination and treatment in cases where a person has been examined for penal liability, but a written conclusion was rendered that he/she is neither guilty nor banned from practicing (Clause 1, Article 20 of the Law on Medical Examination and Treatment).

- An original or valid copy of the certificate of completion of either the probation period or the sentence or court ruling (Clause 2, Clause 3, Clause 4, Article 20 of the Law on Medical Examination and Treatment);

- An original or valid copy of a document from a competent authority determining that the practitioner has full civil act capacity or has no difficulty in

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cognition or behavior control or no longer has civil act capacity restricted (Clause 6, Article 20 of the Law on Medical Examination and Treatment).

5. A dossier of application for grant of a new practicing license in the case where the practicing license is revoked as specified in Clause 6, Clause 7 or Clause 8, Article 34 of this Decree (Point e, g, and h, Clause 1, Article 35 of the Law on Medical Examination and Treatment):

a) The documents specified in Clause 1 of this Article;

b) An original or valid copy of the decision on revocation of the practicing license (not applicable to cases where the decision on revocation of the practicing license has been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database).

6. A dossier of application for a new practicing license in the case where the former practicing license is not renewed as specified at Point a, Clause 3, Article 24 of this Decree:

a) The documents specified in Clause 1 of this Article;

b) An original or valid copy of the decision on revocation of the practicing license (not applicable to cases where the decision on revocation of the practicing license has been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database).

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7. Procedures for grant of a practicing license:

a) The applicant for a practicing license shall send 01 dossier in each respective case specified in Clauses 1 to 6 of this Article and pay fees specified in law regulations on fees and charges to the authority that grants practicing licenses as specified in Article 28 of the Law on Medical Examination and Treatment (hereinafter referred to as a practice licensing authority for short);

b) The practice licensing authority shall grant the practicing license within 30 days from the date of receiving a complete dossier. In case of refusal to grant the practicing license, it shall send a written reply clearly stating the reasons for such refusal.

In the case where the verification of documents with foreign factors included in the dossier of application for the practicing license is required, the time limit for granting the practicing license is 30 days after the verification result is available.

Subsection 2

RE-GRANT OF MEDICAL EXAMINATION AND TREATMENT PRACTICING LICENSES TO PROFESSIONAL TITLES INCLUDING HERBALISTS, OWNERS OF FAMILY HERBAL REMEDIES OR

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TREATMENT METHODS

Article 23. Cases and conditions for re-grant of a practicing license to an herbalist or owner of a family herbal remedy or treatment method

1. Practicing licenses shall be re-granted in the following cases:

a) The practicing license is lost or damaged;

b) There is a change in the information specified at Point a, Clause 3, Article 27 of the Law on Medical Examination and Treatment, or error in the information specified in Clause 3, Article 27 of the Law on Medical Examination and Treatment.

c) The practitioner has been granted a practicing license, but have it revoked in one of the cases specified in Clause 1, Clause 3, and Clause 9, Article 34 of this Decree;

d) The practicing certificate is granted ultra vires as specified in Clause 1, Article 28 of the Law on Medical Examination and Treatment.

2. Conditions for a practicing license to be re-granted: Specified in Clause 2, Article 31 of the Law on Medical Examination and Treatment.

Article 24. Dossiers and procedures for re-grant of a practicing license to an herbalist or owner of a family herbal remedy or treatment method

1. A dossier of application for re-grant of a practicing license in the case where the former practicing license is lost or damaged as specified at Point a, Clause 1, Article 21 of this Decree:

a) A written application made using Form No. 08 provided in Appendix I to this Decree.

b) An original or valid copy of the practicing license that has been granted (if any) (not applicable to cases where the practicing license has been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database).

c) 02 profile photos sized 04 cm x 06 cm against a white background taken within a maximum period of six months from the date of filing the dossier of application for a new practicing license (not applicable for cases where the applicant has already uploaded his/her photos when completing administrative procedures electronically).

2. A dossier of application for re-grant of a practicing license in case of changing one of the information specified at Point a, Clause 3, Article 27 of the Law on Medical Examination and Treatment or in the case where the information specified in Clause 3, Article 27 of the Law on Medical Examination and Treatment are incorrect as specified at Point b, Clause 1, Article 23 of this Decree:

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a) A written application made using Form No. 08 provided in Appendix I to this Decree.

b) An original copy of the practicing license that has been granted;

c) Original or valid copies of the documents proving modified or incorrect information (if any) (not applicable to cases where such information can be searched or verified on the information system on management of medical examination and treatment activities or the national health database).

d) 02 profile photos sized 04 cm x 06 cm against a white background taken within a maximum period of six months from the date of filing the dossier of application for a new practicing license (not applicable for cases where the applicant has already uploaded his/her photos when completing administrative procedures electronically).

3. A dossier of application for re-grant of a practicing license in the case where the practicing license is revoked as specified in Clause 1, Article 34 of this Decree because the dossier of application for the practicing license has been made in contravention of regulations (Point a, Clause 1, Article 35 of the Law on Medical Examination and Treatment):

a) The documents specified in Clause 1, Article 22 of this Decree;

b) An original or valid copy of the decision on revocation of the practicing license (not applicable to cases where the decision on revocation of the practicing license has been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database).

c) 02 profile photos sized 04 cm x 06 cm against a white background taken within a maximum period of six months from the date of filing the dossier of application for a new practicing license (not applicable for cases where the applicant has already uploaded his/her photos when completing administrative procedures electronically).

4. A dossier of application for re-grant of a practicing license in the case where the practicing license is revoked as specified at Clause 3, Article 34 of this Decree because the granted practicing license states the wrong professional title or scope of practice as compared to the dossier of application for the practicing license (Point c, Clause 1, Article 35 of the Law on Medical Examination and Treatment):

a) A written application made using Form No. 08 provided in Appendix I to this Decree.

b) An original or valid copy of the decision on revocation of the practicing license (not applicable to cases where the decision on revocation of the practicing license has been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database).

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c) 02 profile photos sized 04 cm x 06 cm against a white background taken within a maximum period of six months from the date of filing the dossier of application for a new practicing license (not applicable for cases where the applicant has already uploaded his/her photos when completing administrative procedures electronically).

5. A dossier of application for re-grant of a practicing license in the case where the practicing license is revoked as specified in Clause 4, Article 34 of this Decree because the practitioner has not practiced for 24 consecutive months (Point d, Clause 1, Article 35 of the Law on Medical Examination and Treatment):

a) A written application made using Form No. 08 provided in Appendix I to this Decree.

b) An original or valid copy of the decision on revocation of the practicing license (not applicable to cases where the decision on revocation of the practicing license has been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database).

c) 02 profile photos sized 04 cm x 06 cm against a white background taken within a maximum period of six months from the date of filing the dossier of application for a new practicing license (not applicable for cases where the applicant has already uploaded his/her photos when completing administrative procedures electronically).

6. A dossier of application for re-grant of a practicing license in the case where the practicing license is revoked as specified in Clause 5, Article 34 of this Decree due to one of the reasons specified in Clauses 1, 2, 3, 4 or 6, Article 20 of the Law on Medical Examination and Treatment (Point dd, Clause 1, Article 35 of the Law on Medical Examination and Treatment):

a) The documents specified in Clause 1 of this Article;

b) An original or valid copy of the decision on revocation of the practicing license (not applicable to cases where the decision on revocation of the practicing license has been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database).

c) One of the following documents:

- An original or valid copy of a document from a competent authority concluding that the practitioner is neither guilty nor banned from practicing medical examination and treatment in cases where a person has been examined for penal liability, but a written conclusion was rendered that he/she is neither guilty nor banned from practicing (Clause 1, Article 20 of the Law on Medical Examination and Treatment).

- An original or valid copy of the certificate of completion of either the

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probation period or the sentence or court ruling (Clause 2, Clause 3, Clause 4, Article 20 of the Law on Medical Examination and Treatment);

- An original or valid copy of a document from a competent authority determining that the practitioner has full civil act capacity or has no difficulty in cognition or behavior control or no longer has civil act capacity restricted (Clause 6, Article of 20 of the Law on Medical Examination and Treatment).

d) 02 profile photos sized 04 cm x 06 cm against a white background taken within a maximum period of six months from the date of filing the dossier of application for a new practicing license (not applicable for cases where the applicant has already uploaded his/her photos when completing administrative procedures electronically).

7. A dossier of application for re-grant of a practicing license in the case where the practicing license is revoked as specified in Clause 9, Article 34 of this Decree at the request of the practitioner:

a) A written application made using Form No. 08 provided in Appendix I to this Decree.

b) An original or valid copy of the decision on revocation of the practicing license (not applicable to cases where the decision on revocation of the practicing license has been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database).

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c) 02 profile photos sized 04 cm x 06 cm against a white background taken within a maximum period of six months from the date of filing the dossier of application for a new practicing license (not applicable for cases where the applicant has already uploaded his/her photos when completing administrative procedures electronically).

8. A dossier of application for re-grant of a practicing license in the case where the former practicing license is granted ultra vires as specified in Clause 1, Article 28 of the Law on Medical Examination and Treatment:

a) A written application made using Form No. 08 provided in Appendix I to this Decree.

b) The practicing license that has been granted;

c) 02 profile photos sized 04 cm x 06 cm against a white background taken within a maximum period of six months from the date of filing the dossier of application for a new practicing license (not applicable for cases where the applicant has already uploaded his/her photos when completing administrative procedures electronically).

9. Procedures for re-grant of a practicing license

a) The applicant for re-grant of a practicing license shall send 01 dossier

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for such re-grant in each respective case specified in Clauses 1 to 8 of this Article and pay fees specified in law regulations on fees and charges to the practice licensing authority as specified in Clause 1, Article 28 of the Law on Medical Examination and Treatment;

b) The practice licensing authority shall re-grant a practicing license within 15 days after receiving a complete dossier. In case of refusal to re-grant a practicing license, it shall send a written reply clearly stating the reasons for such refusal;

c) In the case where the verification of documents with foreign factors included in the dossier of application for re-grant of a practicing license is required, the time limit for re-grant is 15 days after the verification result is available.

Subsection 3

RENEWAL OF MEDICAL EXAMINATION AND TREATMENT PRACTICING LICENSES OF PROFESSIONAL TITLES INCLUDING HERBALISTS, OWNERS OF FAMILY HERBAL REMEDIES OR TREATMENT METHODS

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Article 25. Cases and conditions for renewal of a practicing license of an herbalist or owner of a family herbal remedy or treatment method

1. Cases where a practicing license shall be granted to an herbalist or an owner of a family herbal remedy or treatment method: The practice license expires as specified in Clause 2, Article 27 of the Law on Medical Examination and Treatment.

2. Conditions for a practicing license of an herbalist to be renewed: Specified in Clause 2, Article 32 of the Law on Medical Examination and Treatment.

3. Conditions for a practicing license of an owner of a family herbal remedy or treatment method to be renewed: Specified in Clause 3, Article 32 of the Law on Medical Examination and Treatment.

Article 26. Dossiers and procedures for renewal of a practicing license of an herbalist or owner of a family herbal remedy or treatment method

1. A dossier of application for renewal of a practicing license of an herbalist or owner of a family herbal remedy or treatment method shall comprise of:

a) A written application made using Form No. 08 provided in Appendix I to this Decree.

b) A valid copy of the practicing license that has been granted (not

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applicable to cases where the practicing license has been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database).

c) An original or valid copy of medical certificate issued by a qualified medical examination and treatment establishment (not applicable to cases where health examination results have been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database) or a valid copy of the work permit in cases where a work permit is required in accordance with the Labor Code.

2. Procedures for renewal of a practicing license

a) The applicant for renewal of a practicing license shall send a dossier as specified in Clauses 1 and 2 of this Article and pay fees specified in law regulations on fees and charges to the practice licensing authority at least 60 days before the practicing license expires.

In case of illness, accident or force majeure at the time of filing the dossier of application for renewal, he/she must send a written notice to the practice licensing authority to delay the filing of his/her dossier of application for renewal of the practicing license.

A practitioner may delay the renewal date multiple times, but the total period of delay must not exceed 22 months from the date on which the practicing license expires;

b) Within the period from the date of receiving a complete dossier to the expiry date stated in the practicing license, the practice licensing authority shall renew the practicing license or shall, if refusing to renew the practicing license, issue a written reply clearly stating the reason for such refusal. In the case where no reply is issued by the expiry date stated in the practicing license, the practicing license will continue to be valid in accordance with the regulations.

Section 6

MEDICAL EXAMINATION AND TREATMENT PRACTICE REGISTRATION

Article 27. Guidelines for practice registration

In addition to complying with the principles of practice registration specified in Article 36 of the Law on Medical Examination and Treatment, practice registration shall follow the guidelines below:

1. A practitioner may hold multiple positions in the same medical examination and treatment establishment as assigned by the person in charge of

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professional and technical expertise of such medical examination and treatment establishment and must be consistent with the practitioner's scope of practice.

2. In the case where a practitioner is working as a full-time practitioner at a hospital or takes charge of a specialized division of the hospital or is in charge of professional and technical expertise of the hospital, he/she may register to practice at another medical examination and treatment establishment either as:

a) A practitioner of another medical examination and treatment establishment that does not have the same administrative hours;

b) A person in charge of professional and technical expertise of another medical examination and treatment establishment that does not have the same administrative hours.

3. In the case where a practitioner is working as a practitioner at a medical examination and treatment establishment other than a hospital, he/she may also register to practice either as:

a) A practitioner of another medical examination and treatment establishment provided that the practicing hours he/she registers at the two establishments do not overlap;

b) A person in charge of professional and technical expertise of another medical examination and treatment establishment provided that the practicing hours he/she registers at the two establishments do not overlap.

4. In the case where a practitioner is working as the person in charge of professional and technical expertise at a medical examination and treatment establishment other than a hospital, he/she may register as a practitioner of another medical examination and treatment establishment provided that the practicing hours he/she registers at the two establishments do not overlap.

5. In the case where a practitioner is working as the person in charge of professional and technical expertise of a health station, he/she may also register to practice either as:

a) A practitioner of another medical examination and treatment establishment that does not have the same administrative hours;

b) A person in charge of professional and technical expertise of another medical examination and treatment establishment that does not have the same administrative hours.

6. A practitioner can only take charge of one specialized division in the same hospital.

7. A practitioner who is in charge of the professional and technical expertise of a hospital can concurrently be in charge of a specialized division of such hospital but must be consistent with his/her scope of practice.

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8. A practitioner at a medical examination and treatment establishment with many medical examination and treatment locations may register as a practitioner at all locations of such medical examination and treatment establishment.

9. A practitioner who has registered to practice at a medical examination and treatment establishment when performing medical examination and treatment under a contract between medical examination and treatment establishments may not register to practice at the medical examination and treatment establishment signing the contract with the medical examination and treatment establishment where the practitioner has registered.

10. In the case where a practitioner registers to practice at multiple medical examination and treatment establishments, he/she must ensure reasonable travel time between registered practice locations.

11. In the case where the person in charge of technical and professional expertise of a medical examination and treatment establishment is absent from such medical examination and treatment establishment due to illness, leaves, training or other reasons, the person in charge of professional and technical expertise must:

a) Authorize in writing a person working at such medical examination and treatment establishment who has a practicing license with a scope of practice appropriate to one of the specialties in which the medical examination and treatment establishment is registered to operate and has been practicing for at least 36 months, if his/her absence from the medical examination and treatment establishment lasts less than 15 days;

b) Authorize a person as specified at Point a of this Clause and notify in writing the operation licensing authority, if f his/her absence from the medical examination and treatment establishment lasts from 15 days to less than 90 days;

c) Authorize a person as specified at Point a of this Clause and notify in writing the operation licensing authority, and obtain a written approval from such authority if his/her absence from the medical examination and treatment establishment lasts from 90 days to 180 days;

d) If his/her absence from the medical examination and treatment establishment lasts more than 180 days, the medical examination and treatment establishment must prepare a dossier and carry out procedures for change of the person in charge of its professional and technical expertise.

12. When there is any change in the practitioners of a medical examination and treatment establishment, the head of such medical examination and treatment establishment shall:

a) In the case where a practitioner is no longer working at the establishment:

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- Temporarily stop providing medical examination and treatment services within the scope of practice of such practitioner if there is no substitutive practitioner from the time the practitioner stops practicing at the establishment;

- Report to the competent authority within 03 days from the time the practitioner stops practicing at the establishment.

b) In the case where a new practitioner is added: Carry out practice registration procedures as specified in this Decree. Practitioners can only practice after completing practice registration procedures.

Article 28. Details of practice registration

1. Details of a practitioner to be registered:

a) Full name, and number of the practicing license, of the practitioner;

b) Professional title and position for the practitioner in charge of professional and technical expertise of a medical examination and treatment establishment or taking charge of a specialized division of a hospital;

c) Place of practice, including name and address of the medical examination and treatment establishment where the practice is registered;

d) Duration of practice;

dd) Scope of practice of the practitioner;

e) Language used by the foreign practitioner in medical examination and treatment, for the cases specified at Points a and b, Clause 2, Article 21 of the Law on Medical Examination and Treatment.

2. The list of practice-registering practitioners shall be made by the medical examination and treatment establishment using Form No. 01 provided in Appendix II to this Decree and must be signed off and stamped by the person in charge of professional and technical expertise of such medical examination and treatment establishment (if any).

3. In the case where on the list of practice-registering practitioners of one medical examination and treatment establishment, there is practitioner(s) who is practicing at other medical examination and treatment establishment(s), he/she must declare additional information about his/her practice at the respective other medical examination and treatment establishment(s).

Article 29. Process of practice registration

1. To register the medical practice for its practitioners, a medical examination and treatment establishment shall:

a) Send a list of practice-registering practitioners at the same time with the establishment's application for an operation license to an authority competent to grant operation licenses.

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b) In the case where there is a change in the practitioner while the grant of the operation license is pending: Make the list of practice-registering practitioners that has been changed using Form No. 01 provided in Appendix II to this Decree and send it to the operation licensing authority.

c) In case there is a change in practitioner in the course of operation: Send the request for practice registration to the operation licensing authority, specifically as follows:

- In the case where the practitioner no longer works at the establishment: Report to the competent authority within 03 working days from the time the practitioner stops practicing at the establishment;

- In the case where a new practitioner is added: Send the supplemented list of practice-registering practitioners made using Form No. 01 provided in Appendix II to this Decree to the operation licensing authority within 10 days from the time of adding the practitioner.

2. An authority competent to grant operation licenses shall officially announce the list of practitioners on its own web portal or website and the information system on management of medical examination and treatment activities:

a) At the same time, it grants the operation license, unless otherwise specified at Points a and b Clause 1 of this Article;

b) Within 5 working days after receiving the request for practice registration, in the case specified at Point c, Clause 1 of this Article.

c) In case of refusal, it shall send a written reply clearly stating the reasons for such refusal;

Section 7
SUSPENSION, REVOCATION, AND CONSEQUENCES OF REVOCATION OF PRACTICING LICENSES

Article 30. Procedures for suspension from practice

1. In cases where a practitioner is suspended according to the conclusion of a professional council specified in Article 101 of the Law on Medical Examination and Treatment (Point a, Clause 1, Article 34 of the Law on Medical Examination and Treatment):

a) In the case where the professional council is established by the medical examination and treatment establishment itself in accordance with Point a, Clause 4, Article 101 of the Law on Medical Examination and Treatment:

- Within 05 working days from the date of conclusion, the chairperson of

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the professional council shall sign and send the signed document to the medical examination and treatment establishment;

- Within 05 working days from the date of receiving the document from the chairperson of the council, the medical examination and treatment establishment shall send a written report to the competent State authority in charge of health that directly manages the medical examination and treatment establishment, clearly stating the reason for the request to suspend the practitioner from practice;

- Within 05 working days from the date of receiving the written report from the medical examination and treatment establishment, the competent State authority in charge of health that directly manages the medical examination and treatment establishment shall issue a decision on suspension. The decision on suspension shall be based on the conclusions of the professional council.

b) In the case where the professional council is established by the competent State authority in charge of health that directly manages the medical examination and treatment establishment in accordance with Point b, Clause 4, Article 101 of the Law on Medical Examination and Treatment:

- Within 05 working days from the date of conclusion, the chairperson of the professional council shall sign and send the signed document to the competent State authority in charge of health that directly manages the medical examination and treatment establishment, clearly stating the reason for the request to suspend the practitioner from practice;

- Within 05 working days from the date of receiving the written request from the chairperson of the professional council specified at Point b of this Clause, the competent State authority in charge of health that directly manages the medical examination and treatment establishment shall issue a decision on suspension. The decision on suspension shall be based on the conclusions of the professional council.

2. In the case where a practitioner is suspended based on a competent agency's conclusion stating his/her violation of professional ethics, but such violations are not serious enough for revocation of practicing license (Point b, Clause 1, Article 34 of the Law on Medical Examination and Treatment):

a) In the case where a competent authority concludes that the practitioner violates professional ethics, but such authority is not authorized to revoke the practicing license:

- The competent authority sends a written conclusion on the violation of professional ethics, including the request and clearly stating the reason for suspension of practice, to the competent State authority in charge of health that directly manages the practitioner;

- Within 05 working days from the date of receiving the written conclusion

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from the competent authority, the competent State authority in charge of health that directly manages the practitioner shall issue a decision on suspension from practice. The decision on suspension of practice shall be based on the conclusions of the competent authority.

b) In the case where a competent authority concludes that the practitioner violates professional ethics, and it is authorized to revoke the practicing license:

Within 05 working days from the date of the written conclusion, the competent authority shall issue a decision on suspension of practice. The decision on suspension of practice shall be based on the written conclusion.

3. In the case where a practitioner is suspended due to not being physically fit to practice (Point c, Clause 1, Article 34 of the Law on Medical Examination and Treatment):

Within 05 working days from the date of receiving the written conclusion from the competent authority (including: the court, assessment authority, health check-up establishment) that the practitioner is not healthy enough to practice, the competent State authority in charge of health that directly manages the practitioner shall issue a decision on suspension. The decision on suspension shall be based on the conclusions of the competent authority.

4. The decision on partly or wholly suspension of a practitioner's scope of practice shall include the following information:

a) Partly or wholly suspension of a practitioner's scope of practice. In case of partial suspension, the suspended part shall be clearly stated;

b) Suspension period;

c) Request the practitioner to continuously update medical knowledge, unless otherwise the practitioner is an herbalist, owner of a family herbal remedy, or owner of a family treatment method;

d) Conditions for continuing to practice.

5. Within 05 working days from the date of the decision on partly or wholly suspension of the practitioner's scope of practice, the authority issuing the suspension decision shall:

a) Send the suspension decision to the practitioner and limit the scope of practice of the suspended practitioner on the information system on management of medical examination and treatment activities or send it to the medical examination and treatment establishment where the practitioner is working for implementation thereof and to socio-professional medical examination and treatment associations for supervision thereof;

b) Send the suspension decision to the authority that issued the practitioner's practicing license in case the authority issuing the suspension

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decision is not the authority that issued the practitioner's practicing license.

Article 31. Consequences of suspension

1. In the case where the decision on partly or wholly suspension of a practitioner's scope of practice (hereinafter referred to as suspension decision) does not require continued updating of medical knowledge by the suspended practitioner, such practitioner may continue to practice after the expiration of the suspension period stated in the suspension decision.

2. In the case where the suspension decision requires continued updating of medical knowledge by the suspended practitioner:

a) Within 12 months from the date on which the suspension decision takes effect, the practitioner must complete continued updating of medical knowledge under the conclusion of the professional council;

b) After completing the continued updating of medical knowledge, the practitioner shall send the results of continued updating of medical knowledge to the practice licensing authority in order to continue practicing;

c) Within 05 working days, the practice licensing authority shall notify the practitioner of the permission to continue practicing and update the continued practice of such practitioner on its web portal or website or the information system on management of medical examination and treatment activities;

d) In the case where the suspension decision expires and the practitioner fails to submit documents proving that he/she has completed continued updating of medical knowledge, within 15 days from the date on which the suspension decision expires, the practice licensing authority shall issue another suspension decision. Practitioners shall implement the regulations at Points a and b of this Clause.

In the case where the total period of suspension exceeds 24 months, the practice licensing authority shall revoke the practicing license within 15 working days and the practitioner must carry out procedures for grant of a new practicing license.

3. Suspension period: no more than 24 months.

Article 32. Procedures for revocation of a practicing license

1. In the cases specified at Points a, b, c, d, Clause 1, Article 35 of the Law on Medical Examination and Treatment:

a) An authority, organization, or individual discovers that a practitioner falls in the cases where his/her practicing license should be revoked and notifies the competent authority to revoke such practicing license;

b) The authority competent to revoke the practicing license shall verifying dossiers, documents and information provided by the organization or individual.

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If the licenses must be revoked, it shall issue a decision on revocation of such practicing license.

2. In the case specified at Point dd, Clause 1, Article 35 of the Law on Medical Examination and Treatment:

The competent State authority in charge of health that directly manages the practitioner shall issue a decision on revocation of the practitioner's practicing license within 05 working days from the date of receiving the notice served by a competent authority regarding the practitioner being banned from practice in accordance with Clauses 1, 2, 3, 4 and 6, Article 20 of the Law on Medical Examination and Treatment

3. In the cases specified at Points e and g, Clause 1, Article 35 of the Law on Medical Examination and Treatment:

a) In the case where the professional council is established by the medical examination and treatment establishment itself in accordance with Point a, Clause 4, Article 101 of the Law on Medical Examination and Treatment:

- Within 05 working days from the date of conclusion, the chairperson of the professional council shall sign and send the signed document to the medical examination and treatment establishment;

- Within 05 working days from the date of receiving the document from the chairperson of the council, the medical examination and treatment establishment shall send a written report to the competent State authority in charge of health that directly manages the medical examination and treatment establishment, clearly stating the reason for the request to revoke the practicing license;

- Within 05 working days from the date of receiving the written report from the medical examination and treatment establishment, the competent State authority in charge of health that directly manages the medical examination and treatment establishment shall issue a decision on revocation of the practicing license. The revocation decision shall be based on the conclusions of the professional council.

b) In the case where the professional council is established by the competent State authority in charge of health that directly manages the medical examination and treatment establishment in accordance with Point b, Clause 4, Article 101 of the Law on Medical Examination and Treatment:

- Within 05 working days from the date of conclusion, the chairperson of the professional council shall sign and send the signed document to the competent State authority in charge of health that directly manages the medical examination and treatment establishment, clearly stating the reason for the request to revoke the practicing license;

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- Within 05 working days from the date of receiving the written request from the chairperson of the professional council specified at Point b of this Clause, the competent State authority in charge of health that directly manages the medical examination and treatment establishment shall issue a decision on revocation of the practicing license. The revocation decision shall be based on the conclusions of the professional council.

4. In the case specified at Point h, Clause 1, Article 35 of the Law on Medical Examination and Treatment:

Within 05 working days from the date of receiving the competent authority's written conclusion that the practitioner has for the second time been concluded by a competent state agency as committing breaches of professional ethics that are serious enough for suspension from practice during the validity period of his/her practicing license, the competent State authority in charge of health that directly manages the practitioner shall issue a decision on revocation of his/her practicing license. The decision on revocation of the practicing license shall be based on the written conclusion of the competent authority.

5. In the cases specified at Point i, Clause 1, Article 35 of the Law on Medical Examination and Treatment: the practice licensing authority shall issue a decision on revocation of the practicing license after 15 days from the date of receiving the written application and the practicing license enclosed therewith.

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6. The decision on revocation of the practicing license shall include the following information:

a) Full name, and number of the practicing license, of the practitioner;

b) Decision on revocation of the practicing license and reasons for such revocation;

c) Conditions for continuing to practice.

7. Within 10 working days from the date of the revocation decision, the authority shall send the revocation decision to the practitioner and the medical examination and treatment establishment for which he/she works and cancels the practitioner's practice registration on the web portal or website of the practice licensing authority and the information system on management of medical examination and treatment activities.

Article 33. Consequences of revocation of practicing licenses from professional titles including doctors, assistant doctors, nurses, midwives, medical technicians, clinical nutritionists, pre-hospital emergency care providers or clinical psychologists

1. In the case where the practicing license is revoked because the dossier of application for the practicing license has been made in contravention of regulations as specified at Point a, Clause 1, Article 35 of the Law on Medical

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Examination and Treatment: the person whose license is revoked must complete and re-file a dossier of application for a practicing license.

a) In the case where the person whose practicing license is revoked files a dossier of application for another practicing license within 24 months from the date of the revocation decision, he/she shall be re-granted a practicing license without re-undertaking the internship;

b) In the case where the person whose practicing license is revoked files a dossier of application for another practicing license within a period of between 24 months and 60 months from the date of the revocation decision, he/she shall complete the internship before carrying out the procedures for re-grant of the practicing license;

c) In the case where the person whose practicing license is revoked files a dossier of application for another practicing license within a period of more than 60 months from the date of the revocation decision, he/she shall complete the internship and be tested for evaluation of medical examination and treatment practicing capacity before carrying out the procedures for re-grant of the practicing license;

2. In the case where the practicing license is revoked due to forgery of documents in the dossier of application for a practicing license as specified at Point b, Clause 1, Article 35 of the Law on Medical Examination and Treatment (including cases of forgery of graduation diplomas or the certificate of completion of the internship submitted in order to take the test for evaluation of medical examination and treatment practicing capacity), the dossier of application for a new practicing license can only be filed after:

a) At least 05 years from date of the decision on revocation of the practicing license in case of forgery of diplomas or the certificate of passing the test for evaluation of medical examination and treatment practicing capacity in the dossier of application for the practicing license;

b) 03 years from the date of the decision on revocation of the practicing license in case of forgery of other documents in the dossier of application for the practicing license.

3. In the case where the practicing license is revoked because the granted practicing license states the wrong professional title or scope of practice as compared to the dossier of application for the practicing license as specified at Point c, Clause 1, Article 35 of the Law on Medical Examination and Treatment: The practitioner whose practicing license is revoked shall carry out the procedures to apply for a new practicing license and shall not pay fees.

a) In the case where the person whose practicing license is revoked files a dossier of application for another practicing license within 24 months from the date of the revocation decision, he/she shall be re-granted a practicing license

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without re-undertaking the internship;

b) In the case where the person whose practicing license is revoked files a dossier of application for another practicing license within a period of between 24 months and 60 months from the date of the revocation decision, he/she shall complete the internship before carrying out the procedures for re-grant of the practicing license;

c) In the case where the person whose practicing license is revoked files a dossier of application for another practicing license within a period of more than 60 months from the date of the revocation decision, he/she shall complete the internship and be tested for evaluation of medical examination and treatment practicing capacity before carrying out the procedures for re-grant of the practicing license;

4. For cases where the practicing license is revoked because the practitioner has not practiced for 24 consecutive months as specified at Point d, Clause 1, Article 35 of the Law on Medical Examination and Treatment:

a) Within 36 months from the date of the decision on revocation of the practicing license, if the practitioner whose practicing license is revoked completes the internship, the procedures for re-grant of the practicing license shall be followed;

b) If within 36 months from the date of the decision on revocation of the practicing license, if the practitioner whose practicing license is revoked fails to complete the internship, the procedures for grant of a new practicing license shall be followed.

5. In the case where the practicing license is revoked due to one of the reasons specified in Clauses 1, 2, 3, 4 or 6, Article 20 of the Law on Medical Examination and Treatment:

a) In the case where the person whose practicing license is revoked files a dossier of application for another practicing license within 24 months from the date of the revocation decision, he/she shall be re-granted a practicing license without re-undertaking the internship;

b) In the case where the person whose practicing license is revoked files a dossier of application for another practicing license within a period of between 24 months and 60 months from the date of the revocation decision, he/she shall complete the internship before carrying out the procedures for re-grant of the practicing license;

c) In the case where the person whose practicing license is revoked files a dossier of application for another practicing license within a period of more than 60 months from the date of the revocation decision, he/she shall complete the internship and be tested for evaluation of medical examination and treatment practicing capacity before carrying out the procedures for re-grant of the

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practicing license;

6. In the case where the practicing license is revoked because the practitioner is concluded by the professional council specified in Article 101 of the Law on Medical Examination and Treatment as committing professional and technical errors that are serious enough for revocation of practicing license (Point e, Clause 1, Article 35 of the Law on Medical Examination and Treatment): he/she shall re-undertake the internship and pass the test for evaluation of practicing capacity before carrying out the procedures to apply for a new practicing license.

7. In the case where the practicing license is revoked because the practitioner has for the second time been concluded by the professional council specified in Article 101 of the Law on Medical Examination and Treatment as committing professional and technical errors that are serious enough for suspension from practice during the validity period of his/her practicing license (Point g, Clause 1, Article 35 of the Law on Medical Examination and Treatment): he/she shall only file a dossier of application for a new practicing license after 12 months from the date of the decision on revocation of his/her practicing license.

8. In the case where the practicing license is revoked because the practitioner has for the second time been concluded by a competent state agency as committing breaches of professional ethics that are serious enough for suspension from practice during the validity period of his/her practicing license (Point h, Clause 1, Article 35 of the Law on Medical Examination and Treatment): the practitioner must re-undertake the internship and pass the test for evaluation of practicing capacity before carrying out the procedures to apply for a new practicing license.

9. In the case where the practicing license is revoked because the practitioner himself/herself requests revocation of his/her practicing license as specified at Point i, Clause 1, Article 35 of the Law on Medical Examination and Treatment:

a) In the case where the person whose practicing license is revoked files a dossier of application for another practicing license within less than 24 months from the date of the revocation decision, he/she shall be re-granted a practicing license without re-undertaking the internship;

b) In the case where the person whose practicing license is revoked files a dossier of application for another practicing license within a period of between 24 months and 60 months from the date of the revocation decision, he/she shall complete the internship before carrying out the procedures for re-grant of the practicing license;

c) In the case where the person whose practicing license is revoked files a

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dossier of application for another practicing license within a period of more than 60 months from the date of the revocation decision, he/she shall complete the internship and be tested for evaluation of medical examination and treatment practicing capacity before carrying out the procedures for re-grant of the practicing license;

Article 34. Follow-up handling of practicing licenses revoked from herbalists or owners of family herbal remedies or treatment methods

1. In the case where the practicing license is revoked because the dossier of application for the practicing license has been made in contravention of regulations as specified at Point a, Clause 1, Article 35 of the Law on Medical Examination and Treatment: the person whose license is revoked must complete and re-file the dossier following the procedures for grant of a new practicing license.

2. In the case where the practicing license is revoked because documents in the dossier of application for the practicing license are forged as specified at Point b, Clause 1, Article 35 of the Law on Medical Examination and Treatment: he/she shall only file a dossier of application for a new practicing license after 05 years from the date of the decision on revocation of his/her practicing license.

3. In the case where the practicing license is revoked because the granted practicing license states the wrong professional title or scope of practice as compared to the dossier of application for the practicing license as specified at Point c, Clause 1, Article 35 of the Law on Medical Examination and Treatment: The practitioner whose practicing license is revoked shall carry out the procedures to apply for re-grant of a practicing license and shall not pay fees.

4. For cases where the practicing license is revoked because the practitioner has not practiced for 24 consecutive months as specified at Point d, Clause 1, Article 35 of the Law on Medical Examination and Treatment: the practitioner whose license is revoked must file a dossier of application following the procedures for grant of a new practicing license.

5. In the case where the practicing license is revoked due to one of the reasons specified in Clauses 1, 2, 3, 4 or 6, Article 20 of the Law on Medical Examination and Treatment: the person whose license is revoked must file a dossier of application following the procedures for grant of a new practicing license.

6. In the case where the practicing license is revoked because the practitioner is concluded by the professional council specified in Article 101 of the Law on Medical Examination and Treatment as committing professional and technical errors that are serious enough for revocation of practicing license (Point e, Clause 1, Article 35 of the Law on Medical Examination and Treatment): he/she shall only carry out procedures for grant of a new practicing license after

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12 months from the date of the decision on revocation of his/her practicing license.

7. In the case where the practicing license is revoked because the practitioner has for the second time been concluded by the professional council specified in Article 101 of the Law on Medical Examination and Treatment as committing professional and technical errors that are serious enough for suspension from practice during the validity period of his/her practicing license (Point g, Clause 1, Article 35 of the Law on Medical Examination and Treatment): he/she shall only file a dossier of application for a new practicing license after 12 months from the date of the decision on revocation of his/her practicing license.

8. In the case where the practicing license is revoked because the practitioner has for the second time been concluded by a competent state agency as committing breaches of professional ethics that are serious enough for suspension from practice during the validity period of his/her practicing license (Point h, Clause 1, Article 35 of the Law on Medical Examination and Treatment): the practitioner shall only carry out procedures to apply for a new practicing license after 12 months from the date of the decision on revocation of his/her practicing license.

9. In the case where the practicing license is revoked because the practitioner himself/herself requests revocation of his/her practicing license as specified at Point i, Clause 1, Article 35 of the Law on Medical Examination and Treatment: He/she shall follow the procedures for re-grant of the practicing license.

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Section 8

USE OF LANGUAGES IN MEDICAL EXAMINATION AND TREATMENT

Article 35. Standards of interpreters for foreign practitioners

1. An interpreter for a foreign practitioner providing medical examination and treatment for patients who do not speak the same mother tongue as the practitioner, or patients who are unable to speak the same language as the registered language of the practitioner, shall be able to speak the languages used by the practitioner and patients.

2. An interpreter for a foreign practitioner providing humanitarian medical examination and treatment under campaigns; transferring techniques in medical examination and treatment under the cooperation agreement between a Vietnamese medical examination and treatment establishment and a foreign

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medical examination and treatment establishment shall:

a) Be able to speak the language used by the foreign practitioner;

b) Obtain a medical examination and treatment practicing license.

3. Indications and prescriptions must be written in Vietnamese. In the case where the practitioner is a foreigner, the indications and prescriptions must be written in the language the practitioner registers to use when providing medical examination and treatment, then translated into Vietnamese and signed off by the interpreter.

Article 36. Use of languages for foreigners, ethnic minorities who are unable to speak Vietnamese, and people with language disabilities seeking medical examination and treatment at medical examination and treatment establishments in Vietnam

1. Foreigners residing in Vietnam, ethnic minorities who are unable to speak Vietnamese, and people with language disabilities when undergoing medical examination and treatment shall register for medical examination and treatment with and request language support from the medical examination and treatment establishment so that such medical examination and treatment establishment can arrange a practitioner or interpreter capable of using the language used by such patients.

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In the case where the medical examination and treatment establishment cannot arrange one, the patient must arrange an interpreter him/herself and be responsible for the interpretation.

2. For foreigners, ethnic minorities who are unable to speak Vietnamese, people with language disabilities sent to medical examination and treatment establishments in emergencies who can communicate on their own and do not have their representatives:

a) In the case where at the time of emergency, the medical examination and treatment establishments have no practitioners who can use the patients' languages or no interpreter but only staff capable of using the patients' languages, then such staff can support medical examination and treatment. Such staff performing the interpretation shall not be held responsible for the interpretation they make;

b) In the case where at the time of emergency the medical examination and treatment establishments have no practitioner, no interpreter or no staff capable of using the language that the patients can speak, the medical examination and treatment shall comply with Article 15 of the Law on Medical Examination and Treatment.

3. For foreigners, ethnic minorities who are unable to speak Vietnamese, people with language disabilities sent to medical examination and treatment

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establishments in emergencies who cannot communicate on their own and do not have their representatives, the medical examination and treatment shall comply with Article 15 of the Law on Medical Examination and Treatment.

Section 9
REGULATIONS ON RECOGNITION OF PRACTICING LICENSES

Article 37. Conditions, dossiers, and procedures for consideration and recognition of practicing licenses granted by competent foreign authorities or organizations

1. An applicant for consideration and recognition of a practicing license granted by a competent foreign authority or organization shall meet the following conditions:

a) The applicant for consideration and recognition of the practicing license is Vietnamese or is working at a medical examination and treatment establishment in Vietnam or is subject to a work permit issued in accordance with the Labor Code;

b) The practicing license of such applicant must meet the conditions specified in Clause 1, Article 29 of the Law on Medical Examination and Treatment.

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2. A dossier of request for recognition of a practicing license granted by a competent foreign authority or organization:

a) A written request for recognition of the medical examination and treatment practicing license;

b) A valid copy of the granted practicing license medical examination and treatment.

3. Procedures for recognition of a practicing license:

a) The applicant for consideration and recognition of the practicing license shall send 01 dossier as specified in Clause 2 of this Article to the Ministry of Health.

b) In the case where the applicant’s practicing license issued by a foreign practice licensing authority or organization has been already evaluated for recognition:

- Within 30 days after receiving the application dossier, the Ministry of Health shall issue a written response to recognize or refuse to recognize the practicing license;

- In the case where the verification of the practitioner's training period in

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foreign countries is required, the time limit for recognition is 30 days after the verification result is available.

c) In the case where the applicant's practicing license issued by a foreign practice licensing authority or organization has not yet been evaluated for recognition:

- The Ministry of Health shall conduct the evaluation for recognition in accordance with Article 38 of this Decree;

- Within 30 days after the result of the evaluation for recognition is available, the Ministry of Health shall issue a written response to recognize or refuse to recognize the practicing license;

- In the case where the verification of the practitioner's training period in foreign countries is required, the time limit for recognition is 30 days after the verification result is available.

Article 38. Details, principles, and procedures of evaluation for recognition of the foreign authorities or organizations granting practicing licenses:

1. The Ministry of Health shall conduct the evaluation for recognition of foreign practice licensing authorities and organizations based on the contents specified in Clause 3, Article 29 of the Law on Medical Examination and Treatment. These contents must be provided by the competent foreign practice licensing authority as a basis for considering the evaluation and recognition of the practicing license.

2. Within 30 days from the date of receiving all documents as specified in Clause 1 of this Article, the Ministry of Health shall conduct the evaluation for recognition. In the case where it requires actual inspection in the country where the practicing license to be recognized, a specific inspection plan must be notified.

3. After completing the evaluation, the Ministry of Health shall announce the results of the evaluation and recognizes the foreign practice licensing authority.

Chapter III

GRANT OF MEDICAL EXAMINATION AND TREATMENT OPERATION LICENSES

Section 1

ORGANIZATIONAL FORMS AND CONDITIONS FOR GRANT OF OPERATION LICENSES OF MEDICAL EXAMINATION AND

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TREATMENT ESTABLISHMENTS

Article 39. Organizational forms of medical examination and treatment establishments

1. Hospitals, including:

a) General hospital;

b) Traditional medicine hospital;

c) Odontostomatology hospital;

d) Specialist hospital.

2. Clinics, including:

a) Polyclinic;

b) Specialist clinic;

c) Inter-specialty clinic;

d) Medical doctor's clinic;

dd) Traditional medicine clinic;

e) Odontostomatology clinic;

g) Nutrition clinic;

h) General assistant doctor's clinic.

3. Health centers.

4. Maternity hospitals.

5. Traditional medicine diagnosis and treatment clinics.

6. Paraclinical service providers, including:

a) Laboratories;

b) Diagnostic imaging establishments;

c) Testing and diagnostic imaging establishments.

7. Family medicine establishments.

8. Prosthodontics establishments.

9. Functional rehabilitation establishments.

10. Clinical psychology establishments.

11. Nursing service providers.

12. Midwifery service providers.

13. Palliative care establishments.

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14. Pre-hospital emergency care establishments.

15. Optical establishments that provide vision testing and eye examination services.

16. Dialysis establishments.

Article 40. Conditions for a pre-hospital emergency care establishment to be granted a co-operation license

1. Regarding size: It has a size appropriate to each category of medical examination and treatment establishments;

2. Regarding facilities:

a) It has a fixed location that meets requirements by law on: load-bearing, fire safety, infection control, environmental protection, radiation safety (if any); and has enough electricity and water to serve the operations of the medical examination and treatment establishment;

b) It has signs, diagrams and signposts to departments, divisions, professional and administrative departments;

c) It meets specific conditions for each organizational form as specified in Article 39 of this Decree in the case where there are additional establishments not located within the premise of the medical examination and treatment establishment.

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3. It has medical equipment consistent with the list of professional and technical expertise and scope of registered activities.

4. Regarding personnel:

a) It has enough practitioners commensurate with the scale and list of techniques and reach the ratio of practitioners as prescribed by the Minister of Health (including practitioners who have been granted practicing licenses by practice licensing authorities of the people's armed forces and continue using such practicing licenses after they no longer work in the people's armed forces);

b) The person in charge of professional and technical expertise must be a full-time practitioner of the establishment and have a scope of practice consistent with the scope of professional activities of the establishment, with a period of at least 36 months practicing within such scope, unless otherwise the practitioner is an assistant doctor, owner of a family herbal remedy, or owner of a family treatment method.

In the case where the medical examination and treatment establishment involves multiple specialties, the practicing license of the person in charge of professional and technical expertise must have a scope of practice appropriate to one of the specialties in which the establishment is registered to operate;

c) The person taking charge of the specialized division or unit of the

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establishment must have a practicing license appropriate to such specialty and must be a full-time practitioner at the establishment;

d) Practitioners must be assigned tasks within the scope of practice approved by competent authorities;

dd) Medical technicians practicing medical testing with undergraduate degrees shall be allowed to read and sign test results. In the case where the medical examination and treatment establishment does not have a practitioner who has been granted a practicing license under one of the following titles: medical testing specialist or medical technician practicing medical testing with an undergraduate degree, the doctor who prescribes the tests will read and sign the test results;

e) Medical technicians practicing medical imaging with undergraduate degrees shall be allowed to read and describe diagnostic images. In the case where the medical examination and treatment establishment does not have a practitioner who has been granted a practicing license under one of the following titles: medical imaging specialist or medical technician practicing medical imaging with an undergraduate degree, the doctor who prescribes the medical imaging will read and sign results of diagnostic images;

g) Other persons involved in the medical examination and treatment process but do not need practicing licenses as specified at Point d, Clause 2, Article 19 of the Law on Medical Examination and Treatment (medical physicists, radiotherapy engineers, biotechnology engineers, biotechnology bachelors and other persons, hereinafter referred to as employees) are allowed to perform professional activities as assigned by the person in charge of professional and technical expertise of the medical examination and treatment establishment. Such assignment must be consistent with the professional qualifications and abilities of such persons;

h) In the case where a practitioner is a lecturer at a health educational institution and concurrently works at a medical examination and treatment establishment that is an internship establishment of such educational institution, he/she may concurrently work as heads of other departments and specialized divisions of the medical examination and treatment establishment.

5. An establishment that organizes health check-ups, in addition to being organized in the form of a hospital or polyclinic, must also meet the following conditions:

a) Having enough clinical and paraclinical divisions, human resources and necessary medical equipment to examine and detect health conditions according to health standards and health check-up forms attached to health check-up guiding documents;

b) Ensuring the update of driver's health certificate data with the

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information system on management of medical examination and treatment activities or the national health database or the data portal of the information system on health insurance assessment.

6. An organization that provides examination and treatment of HIV/AIDS, in addition to being organized in the form of a hospital or polyclinic, must also meet the following conditions:

a) Regarding facilities: It has an area of at least 18m^2 (not including the waiting area), divided into two rooms to perform the function of examination and patient consultation;

b) Regarding personnel: The person in charge of professional and technical expertise of the clinic providing examination and treatment of HIV/AIDS must be a practitioner with the professional title of doctor and have a certificate of training in examination and treatment of HIV/AIDS provided by a legal educational institution;

c) It has anaphylaxis response kits, and enough specialist emergency drugs suitable for specialties within its scope of professional operations.

7. An establishment that organizes medical examination and treatment of occupational diseases, in addition to being organized in the form of a hospital or polyclinic or inter-specialty clinic or specialist clinic or medical doctor's clinic, must also meet the following conditions:

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a) It implements biochemical testing techniques in accordance with the occupational disease diagnosis guidelines that the establishment plans to implement.

b) It has medical equipment consistent with the list of professional and technical expertise and list of occupational diseases registered for medical examination and treatment.

c) The person performing medical examination and treatment of occupational diseases must have a practicing license with the title of doctor with the scope of medical practice and a certificate of training in occupational diseases, or a doctor with the scope of medical practice in preventive medicine having a certificate of training in occupational diseases.

d) In the case where the organization is organized in the form of an independent establishment that only performs medical examination and treatment for occupational diseases, the person in charge of professional and technical expertise of the establishment must:

- Be a doctor with a practicing license specializing in occupational diseases, or a doctor with a specialist practicing license and a certificate of training in occupational diseases, or a doctor with a practicing license with a scope of practice in medicine and a certificate of training in occupational

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diseases;

- Have practiced medical examination and treatment for at least 36 months after being granted a practicing certificate or practicing license.

8. A medical examination and treatment establishment that performs HIV/AIDS tests, in addition to being organized in the form of a hospital or polyclinic or inter-specialty clinic or specialist clinic or medical doctor's clinic or paraclinical service provider, must also meet additional conditions specified in Decree No. 75/2016/ND-CP dated July 1, 2016 of the Government regulating conditions for HIV testing.

9. A medical examination and treatment establishments that performs in vitro fertilization and surrogacy for humanitarian purposes, in addition to being organized in the form of a hospital, must also meet additional conditions specified in Decree No. 10/2015/ND-CP dated January 28, 2015 of the Government regulating in vitro fertilization and conditions for humanitarian surrogacy.

10. Medical examination and treatment establishments specified in Clauses 1, 2, 3, 4 and 7, Article 39 of this Decree may provide preventive examination, consultation and treatment services.

11. A medical examination and treatment establishment that has been granted an operation license in one of the forms specified in Article 39 of this Decree may provide services of other organizational forms or provide health check-ups, examination and treatment of HIV/AIDS or occupational diseases if it meets the conditions for such organizational form.

In the case where it meets the conditions for providing services in another organizational form or is eligible for providing services of health check-ups, examination and treatment of HIV/AIDS at the time of application for a new operation license, it may prepare a request for appraisal of such services at the same time with the appraisal for granting the operation license.

In the case where the conditions are met after being granted an operation license, the procedures for modification of operation licenses shall be followed. Particularly in the case of providing services of health check-ups and examination and treatment of HIV/AIDS, the operation license shall not be modified, but the declaration procedures must be carried out in accordance with Article 69 of this Decree.

In case of providing medical examination and treatment services according to family medicine principles, there must be a practitioner with the title of doctor who either:

- Have the scope of practice in family medicine.

- Have a certificate of training and refresher training in family medicine for at least 03 months;

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- Have a certificate of attendance in each course with the contents stated in the certificate or credit or training and refresher course in family medicine with a total duration of at least 03 months.

12. An establishment that provides the following cosmetic services or use products with pharmacological effects must be established in one of the organizational forms: a hospital, a polyclinic, or a specialist clinic:

a) Cosmetic services that use drugs, substances, and equipment to interfere with the human body (surgery, procedures, interventions including injections, infusions, radiation, electromagnetic waves, burns or other invasive interventions) in order to:

- Change skin color or body shape, gain or lose weight (liposuction and body fat reduction);

- Correct defects or create desired shapes for body parts (skin, nose, eyes, lips, face, chest, abdomen, buttocks and other parts of the human body);

- Regenerate and restore cells or parts or functions of the human body.

b) Tattooing, blushing, and microblading services using injectable anesthetics.

13. Humanitarian medical examination and treatment establishments or not-for-profit medical examination and treatment establishments, in addition to meeting the conditions specified in Clauses 1 to 12 of this Article, shall meet the following additional conditions:

a) Other specific conditions relative to the organizational forms of humanitarian medical examination and treatment establishments or not-for-profit medical examination and treatment establishments.

b) It has financial resources for humanitarian medical examination and treatment activities.

c) The signboards of the medical examination and treatment establishments must clearly state that they are either humanitarian medical examination and treatment establishments or not-for-profit medical examination and treatment establishments.

Article 41. Conditions for a hospital to be granted an operation license

In addition to the general conditions specified in Article 40 of this Decree, a hospital must also meet the following conditions:

1. Regarding size of the hospital:

a) General hospital: at least 30 patient beds;

b) Traditional medicine hospital or odontostomatology hospital: at least 20 patient beds;

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c) Specialist hospital: at least 20 patient beds; particularly for ophthalmology hospitals: at least 10 patient beds.

2. Regarding facilities:

a) It arranges specialized divisions appropriate to their respective functions and convenient for medical examination and treatment;

b) It meets construction requirements as specified by the law regulations, including: ensuring the floor area of at least 50 m^2/patient bed; the width of the front of the hospital of at least 10 m with passage for ambulances to enter and exit the emergency area. Examination rooms in the hospital must have the area at least equal to the area of the respective examination rooms specified in Articles 42, 43, 45, 46, Points b and c, Clause 1, Article 47, Article 53 of this Decree;

c) In the case where the hospital has specialized divisions that are not on the same premise, there must be a transportation infrastructure connecting such divisions to ensure the safety of patients, patients' families and medical staff.

3. Regarding means of transportation: There are emergency vehicles for transportation inside and outside the hospital. In the case where there are no emergency vehicles for transportation outside the hospital, there must be a contract with an establishment in the same locality that provides emergency services and supports patient transportation.

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4. Regarding organizational structure:

a) Leadership and management of the hospital.

b) Specialized divisions:

The hospital shall be organized into specialized divisions including examination, clinical, paraclinical, pharmacy and ancillary divisions:

- Outpatient department, which has a reception area, emergency room, short-stay units, examination room, and procedure room (if techniques and procedures are performed);

- Clinical departments: at least two of the four departments of internal medicine, surgery, obstetrics, and pediatrics if it is a general hospital, or one clinical department appropriate to the scope of professional activities if it is a specialist hospital, traditional medicine hospital, or odontostomatology hospital;

- Paraclinical department, which has at least one laboratory and one imaging room. Particularly, the ophthalmology hospital that does not have a diagnostic imaging division must have a professional support contract with a medical examination and treatment establishment that has been licensed to operate and has a diagnostic imaging division;

- Pharmacy department;

- Nutrition department if the hospital has 100 patient beds or more. For

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every 100 patient beds, there must be at least 1 person specializing in nutrition. A clinical nutrition division or a person taking charge of nutrition, if the hospital has less than 100 beds. The person specializing in nutrition must be a bachelor of nutrition or a practitioner with the title of doctor with a certificate of 06 months or more training in clinical nutrition or a nurse with an undergraduate degree and a certificate of 06 months or more training in clinical nutrition;

- Infection control department if the hospital has 150 patient beds or more. For every 150 patient beds, there must be at least 01 infection control supervisor. The infection control division if the hospital has less than 150 patient beds. The person in charge of infection control must hold an undergraduate degree or higher in health and obtain a certificate or credential or diploma in infection control training;

- Other specialized divisions in the hospital must be consistent with its scale, functions and tasks.

c) It has departments and divisions to perform the functions of general planning, human resources management, quality management, nursing, finance and accounting, information technology, medical equipment and other necessary functions.

d) Depending on the facilities and human resources, the head of the medical examination and treatment establishment shall decide to establish an inter-specialty specialized division. The person taking charge of such division must have a practicing license with a scope of practice appropriate to at least one of the specialties. In the case where there are not enough conditions to establish a department, units within clinical departments can be established. The person taking charge of such unit must have a practicing license with a scope of practice appropriate to the specialty of such unit.

dd) Operation licenses shall not be granted to specialized divisions that are affiliated institutes or centers located on the hospital's premise. Such institutes, centers and their specialized units must have persons taking charge of expertise who meet the conditions specified in this Decree.

5. Regarding personnel:

a) The number of full-time practitioners in each department must reach at least 70% of the total number of practitioners in such department;

b) Heads of specialized divisions of the hospital must be full-time practitioners of such hospital and have practicing licenses appropriate to the specialties of the respective specialized divisions assigned to them and have been practicing in such specialties for at least 36 months. In the case where a practitioner is a lecturer at a health educational institution and concurrently works at a medical examination and treatment establishment that is an internship establishment of such educational institution, he/she may concurrently be heads

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of other departments of such medical examination and treatment establishment;

c) Heads of other specialized divisions that are not eligible for practicing licenses must hold undergraduate degrees in the specialties appropriate to the tasks assigned to them and work on a full-time basis at the hospital.

6. The hospital must provide inpatient treatment and organize professional shifts to provide 24/7 coverage.

Article 42. Conditions for a polyclinic to be granted an operation license

In addition to the general conditions specified in Article 40 of this Decree, the polyclinic must also meet the following conditions:

1. Scale and organizational structure of the clinic:

a) It has three or more specialties, including at least two of the four specialties of internal medicine, surgery, obstetrics, and pediatrics; having paraclinical divisions (medical testing and diagnostic imaging); having an emergency room and a minor procedure room (if minor procedures are performed), and short-stay units;

b) In the case where the polyclinic meets the respective conditions for another organizational form of medical examination and treatment establishments as specified in Article 39 of this Decree (except for hospital), it may extend the scope of professional activities corresponding to such organizational form.

2. Regarding facilities and personnel:

a) Examination rooms in a polyclinic must meet the following requirements in terms of area:

- An emergency room shall have an area of at least 12 m^2;

- A short-stay unit shall have an area of at least 15 m^2; in which there are at least 02 patient beds or more. If there are 03 beds or more, the area must be at least 05 m^2 per patient bed;

- Specialist examination rooms shall have a minimum area of 10 m^2 each;

- In the case where techniques and procedures are performed, in addition to the specialist examination rooms, there must be an additional room with an area of at least 10 m^2 where the techniques and procedures are performed. If occupational therapies are performed, the room where the techniques and procedures are performed must have an area of at least 20 m^2.

b) It has a sterilization area to reprocess reusable medical devices, unless otherwise there are no devices that need to be re-sterilized or there is a contract with another medical examination and treatment establishment to sterilize such devices.

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c) In case of processing and preparing traditional medicines, the standards for processing and preparing traditional medicines as prescribed by the Minister of Health shall be met.

3. It has anaphylaxis response kits, and enough specialist emergency drugs suitable for specialties within its scope of professional operations.

Article 43. Conditions for a specialist clinic to be granted an operation license

In addition to the general conditions specified in Article 40 of this Decree, the specialist clinic must also meet the following conditions:

1. Scale and organizational structure of the clinic:

a) It has at least one specialty;

b) In the case where the specialist clinic meets the conditions for another organizational form of medical examination and treatment establishments as specified in Article 39 of this Decree (except hospitals), it may extend the scope of professional activities corresponding to such organizational form, but not exceeding 3 organizational forms.

2. Regarding facilities:

a) The clinic must have a place to welcome patients and an examination room(s) of at least 10 $m^{2;}$

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b) In the case where techniques and procedures are performed, in addition to the examination rooms, there must be an additional room with an area of at least 10 m^2 where the techniques and procedures are performed. If occupational therapies are performed, the room where the techniques and procedures are performed must have an area of at least 20 m^2;

c) It has a sterilization area to reprocess reusable medical devices, unless otherwise there are no devices that need to be re-sterilized or there is a contract with another medical examination and treatment establishment to sterilize such devices.

3. It has anaphylaxis response kits, and enough specialist emergency drugs suitable for specialties within its scope of professional operations.

Article 44. Conditions for an inter-specialty clinic to be granted an operation license

In addition to the general conditions specified in Article 40 of this Decree, the inter-specialty clinic must also meet the following conditions:

1. Scale and organizational structure of the clinic:

a) It has at least two specialties (except for internal medicine, surgery, obstetrics, and pediatrics);

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b) In the case where the inter-specialty clinic meets the conditions for another organizational form of medical examination and treatment establishments as specified in Article 39 of this Decree (except hospitals), it may extend the scale and scope of professional activities corresponding to such organizational form but not exceeding 3 organizational forms.

2. Regarding facilities:

Each specialist examination room in an inter-specialty clinic must meet requirements specified in Clause 2, Article 43 of this Decree.

3. It has anaphylaxis response kits, and enough specialist emergency drugs suitable for specialties within its scope of professional operations.

4. The person in charge of each specialist examination room in an inter-specialty clinic must be a full-time practitioner of the clinic with a scope of practice appropriate to the specialty of the respective specialist examination room he/she is taking charge of and has been practicing within such scope for at least 36 months.

Article 45. Conditions for a medical doctor's clinic to be granted an operation license

In addition to the general conditions specified in Article 40 of this Decree, the medical doctor's clinic must also meet the following conditions:

1. Regarding the scale and organizational structure of the clinic: A medical doctor's clinic is a clinic run by a practitioner licensed to practice under one of the following titles: medical doctor or specialist doctor.

2. Regarding facilities:

a) The clinic must have a place to welcome patients and an examination room(s) of at least 10 m^2;

b) It has a sterilization area to reprocess reusable medical devices, unless otherwise there are no devices that need to be re-sterilized or there is a contract with another medical examination and treatment establishment to sterilize such devices;

c) In the case where techniques and procedures are performed, in addition to the examination rooms, there must be an additional room with an area of at least 10 m^2 where the techniques and procedures are performed. If occupational therapies are performed, the room where the techniques and procedures are performed must have an area of at least 20 m^2.

3. It has anaphylaxis response kits, and enough specialist emergency drugs suitable for specialties within its scope of professional operations.

Article 46. Conditions for a traditional medicine clinic to be granted an operation license

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In addition to the general conditions specified in Article 40 of this Decree, the traditional medicine clinic must also meet the following conditions:

1. Regarding facilities:

a) The clinic must have a place to welcome patients and an examination room(s) of at least 10 m^2.

b) Depending on the scope of registered professional activities, a traditional medicine clinic must meet the following additional conditions:

- In the case where techniques and procedures are performed, in addition to the examination rooms, there must be an additional room with an area of at least 10 m^2 where the techniques and procedures are performed. If occupational therapies are performed, the room where the techniques and procedures are performed must have an area of at least 20 m^2;

- In case of herbal sauna, there must be a sauna room with an area of at least 02 m^2 and must be closed but well lit;

- In case of processing and preparing traditional medicines, the standards for processing and preparing traditional medicines as prescribed by the Minister of Health shall be met.

2. Medical examination and treatment equipment:

a) If performing medical examination, prescribing and dispensing herbal medicines, there must be:

- Herbal cabinets and herbal medicines stored in drawers or glass or white plastic jars covered by lids with the medicines' names clearly written on the outside;

- Scales for weighing and dividing the medicines into packets wrapped in medicine wrappers.

b) In case of performing acupuncture, massage, or acupressure, there must be:

- Patient beds for acupuncture, massage, and acupressure;

- Enough tools for acupuncture, massage, and acupressure;

- Enough tools and instructions for handling complications during acupuncture.

c) In case of herbal sauna: There must be the system of herbal vaporizers, regulating valve, sauna instructions and alarm system in case of emergency.

d) It has anaphylaxis response kits, and enough specialist emergency drugs suitable for specialties within its scope of professional operations.

3. Regarding personnel:

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The person in charge of professional and technical expertise of the traditional medicine clinic shall be a practitioner with one of the following professional titles:

a) Traditional medicine doctor;

b) Specialist traditional medicine doctor.

Article 47. Conditions for an odontostomatology clinic to be granted an operation license

In addition to the general conditions specified in Article 40 of this Decree, the odontostomatology clinic must also meet the following conditions:

1. Regarding facilities:

a) The clinic must have a place to welcome patients and an examination room(s) of at least 10 $m^{2;}$

b) Arrange at least 01 dental chair, of which the area is at least 05 m^2;

c) In case of performing dental implant technique, there must be a separate room for performing such technique with an area of at least 10 m^2.

2. Regarding personnel:

The person in charge of professional and technical expertise shall be a practitioner with one of the following professional titles:

a) Odonto-stomatology doctor;

b) Specialist odonto-stomatology doctor.

3. It has anaphylaxis response kits, and enough specialist emergency drugs suitable for specialties within its scope of professional operations.

Article 48. Conditions for a nutrition clinic to be granted an operation license

In addition to the general conditions specified in Article 40 of this Decree, the nutrition clinic must also meet the following conditions:

1. It shall be organized under the form of an internal medicine clinic or medical doctor’s clinic.

2. The person in charge of professional and technical expertise shall be a doctor practicing clinical nutrition or a clinical nutritionist.

Article 49. Conditions for a general assistant doctor's clinic to be granted an operation license

In addition to the general conditions specified in Article 40 of this Decree, the assistant doctor's clinic must also meet the following conditions:

1. It shall only be organized in areas with exceptionally difficult socio-

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economic conditions as specified by the Minister of Labor, Invalids and Social Affairs.

2. The person in charge of professional and technical expertise must be a general assistant doctor.

3. It has anaphylaxis response kits, and enough specialist emergency drugs suitable for specialties within its scope of professional operations.

Article 50. Conditions for a health station to be granted an operation license

In addition to the general conditions specified in Article 40 of this Decree, the health station must also meet the following conditions:

1. Regarding personnel:

a) The person in charge of professional and technical expertise shall be a doctor or assistant doctor:

b) The number of practitioners at the health station must meet the professional staffing norms for State-run medical examination and treatment establishments in accordance with the law regulations;

c) Village health workers shall perform primary health care within their professional decentralization and directions of the person in charge of professional and technical expertise.

2. It has anaphylaxis response kits, and enough specialist emergency drugs suitable for specialties within its scope of professional operations.

Article 51. Conditions for a maternity hospital to be granted an operation license

In addition to the general conditions specified in Article 40 of this Decree, the maternity hospital must also meet the following conditions regarding the persons in charge of professional and technical expertise:

1. Regarding facilities:

a) It arranges departments and divisions appropriate to their respective functions and convenient for medical examination and treatment;

b) It has antenatal examination rooms, gynecologic examination rooms, delivery rooms, hospital wards where pregnant women are monitored and treated before and after giving birth with less than 20 patient beds, and neonatal rooms.

2. It has emergency vehicles for transportation inside and outside the maternity hospital. In the case where there are no emergency vehicles for transportation outside the maternity hospital, there must be a contract with a medical examination and treatment establishment that has been granted an operation license and allowed to provide emergency services and support patient

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transportation.

3. The person in charge of professional and technical expertise is a practitioner with one of the following titles:

a) Specialist doctor practicing obstetrics and gynecology;

b) Midwife with a bachelor's degree or higher.

4. It shall organize professional shifts to provide 24/7 coverage.

Article 52. Conditions for a traditional medicine diagnostic and treatment clinic to be granted an operation license

In addition to the general conditions specified in Articles 40 and 46 of this Decree, the traditional medicine diagnostic and treatment clinic must meet the following conditions regarding the persons in charge of professional and technical expertise:

He/she shall be a practitioner that has been granted a practicing license under one of the following professional titles:

1. Traditional medicine doctor.

2. Specialist traditional medicine doctor.

3. Traditional medicine assistant doctor.

4. Herbalist.

5. Owner of a family herbal remedy.

6. Owner of a family treatment method.

Article 53. Conditions for a paraclinical service provider, prosthodontics establishment, or functional rehabilitation establishment to be granted an operation license

In addition to the general conditions specified in Article 40 of this Decree, the paraclinical service provider or prosthodontics establishments or functional rehabilitation establishment must also meet the following conditions:

1. Laboratories:

a) Regarding facilities:

- It has a place to wait for specimens, a place to receive specimens, and a place to clean instruments;

- In case of performing one of the hematology or biochemistry or medical genetics or immunology tests, the laboratory shall have an area of at least 10 m^2;

- In case of performing 02 or 03 of the hematology or biochemistry or medical genetics or immunology tests, the laboratory shall have an area of at least 15 m^2;

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- In case of performing all 04 of the hematology, biochemistry, medical genetics and immunology tests, the laboratory shall have an area of at least 20 m^2;

- In case of performing anatomical pathology and cytology, the laboratory shall have an area of at least 20 m^2 which must be separate from the hematology, biochemistry, genetics, or immunology laboratory and other laboratories;

- In case of performing microbiological tests, the laboratory shall have an area of 20 m^2 which must be separate from the hematology, biochemistry, genetics, or immunology laboratory and other laboratories;

- The laboratory walls must be constructed using waterproof materials, extending from the floor to the ceiling;

- The laboratory floor must be waterproof, level, and devoid of any water accumulation;

- The testing table should be made of waterproof and anti-corrosion materials, and it must be equipped with a sink and a clean water faucet directly integrated into it.

b) Regarding personnel:

The person in charge of professional and technical expertise is a practitioner with one of the following titles:

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- Doctor practicing specialist medical testing.

- Medical technician practicing medical testing with a bachelor's degree or higher.

2. Diagnostic imaging establishments:

The person in charge of professional and technical expertise is a practitioner with one of the following titles:

a) Doctor practicing specialist medical imaging;

b) Medical technician practicing medical imaging with a bachelor's degree or higher.

3. Prosthodontics establishments:

The person in charge of professional and technical expertise is a medical technician with a bachelor's degree or higher in prosthodontics.

4. Functional rehabilitation establishments:

The person in charge of professional and technical expertise is a practitioner with one of the following titles:

a) Doctor practicing specialist functional rehabilitation.

b) Medical technician practicing functional rehabilitation with a bachelor's

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degree or higher.

5. For medical examination and treatment establishments that perform tests to confirm positive HIV results: In addition to meeting the conditions specified in this Decree, they must also meet the conditions specified in Decree No. 75/2016/ND-CP dated July 1, 2016 of the Government stipulating conditions for performing HIV tests.

6. For medical testing and imaging establishments: In addition to meeting the conditions specified at Point a, Clause 1 of this Article, the person in charge of technical expertise must meet the requirements specified at Point b, Clause 1 or Clause 2 of this Article.

Article 54. Conditions for a clinical psychology establishment to be granted an operation license

In addition to the general conditions specified in Article 40 of this Decree, the person in charge of professional and technical expertise of the clinical psychology establishment must be a practitioner with one of the following titles:

1. Clinical psychologist.

2. Doctor practicing psychiatry and completing a certificate of basic specialist training in clinical psychology as specified in Clause 2, Article 128 of this Decree.

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Article 55. Conditions for a nursing service provider, midwifery service provider, or palliative care establishment to be granted an operation license

In addition to the general conditions specified in Article 40 of this Decree, the nursing service provider or midwifery service provider or palliative care establishment must also meet the following conditions:

1. Regarding facilities: In case of performing techniques and procedures, in addition to the medical examination room, it shall have an additional room with an area of at least 10 m^2 where techniques and procedures are performed.

2. It has anaphylaxis response kits.

3. Regarding personnel:

a) Nursing service providers:

The person in charge of professional and technical expertise is a practitioner with one of the following titles:

- Doctor;

- Assistant doctor;

- Nurse;

- Midwife.

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b) Midwifery service providers:

The person in charge of professional and technical expertise is a midwife.

c) Palliative care service providers:

The person in charge of professional and technical expertise is a doctor practicing the following:

- Medicine;

- Traditional medicine;

- Preventive medicine;

- Specialties, except odontostomatology.

Article 56. Conditions for a pre-hospital emergency care establishment to be granted an operation license

In addition to the general conditions specified in Article 40 of this Decree, the pre-hospital emergency care establishment must also meet the following conditions:

1. Regarding facilities:

a) It has an area for decontamination of ambulances with full disinfection devices and tools or has a decontamination contract with a medical examination and treatment establishment that is qualified to carry out decontamination of ambulances in accordance with regulations of the Minister of Health.

b) It has an on-call room, on-call employees, and a call center at its headquarters available on a 24/7 basis, if it is a pre-hospital emergency care establishment.

c) The area of its headquarters does not include the parking area for emergency vehicles.

d) Emergency vehicles:

- It has at least 02 ambulances, if it is a pre-hospital emergency care establishment;

- The establishment's ambulances must meet standards as specified in applicable regulations.

dd) It has anaphylaxis response kits and enough emergency drugs to ensure safety and hygienic conditions for patients.

2. Regarding personnel:

The person in charge of professional and technical expertise of a pre-hospital emergency care establishment is a practitioner with one of the following titles:

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a) Doctor;

b) Pre-hospital emergency care provider.

Article 57. Conditions for an optical establishment that provides vision testing and eye examination services to be granted an operation license

1. Regarding facilities: A optometry room with an area of at least 10 m^2.

2. It has equipment for measuring and diagnosing refractive errors.

3. The person in charge of professional and technical expertise is a practitioner with one of the following titles:

a) Ophthalmologist;

b) Medical technician practicing optometry.

Article 58. Conditions for a dialysis establishment to be granted an operation license

In addition to the general conditions specified in Article 40 of this Decree, the dialysis establishment must also meet the following conditions:

1. Regarding facilities:

a) It has a reception area, waiting area, clean warehouse, wet warehouse, and dialyzer reprocessing room (if dialyzer reprocessing is performed);

b) It has a dialysis room with an area of at least 4.5 m^2 per one hemodialysis machine. For patients with infectious diseases, it shall have a separate dialysis area and a separate dialyzer reprocessing area;

c) It has a RO water filtration system for artificial kidneys and dialyzer reprocessing (if dialyzer reprocessing is performed);

d) It has a professional support contract with a hospital that specializes in hemodialysis in the same locality;

dd) It has emergency vehicles. In the case where there is no emergency vehicle, there must be an emergency transport contract.

2. Regarding human resources:

a) The person in charge of professional and technical expertise must be a practitioner with the title of doctor practicing: medicine, internal medicine, or intensive care medicine; have a certificate of professional technical training as specified in Clause 3, Article 12 of this Decree in hemodialysis;

b) Nurses shall obtain certificates of professional technical training as specified in Clause 3, Article 12 of this Decree in hemodialysis.

Section 2

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GRANT OF MEDICAL EXAMINATION AND TREATMENT OPERATION LICENSES

Article 59. Cases where new operation licenses shall be granted

1. New operation licenses shall be granted to:

a) Medical examination and treatment establishments applying for operation licenses for the first time;

b) Medical examination and treatment establishments having their operation licenses revoked, except the case specified at Point d, Clause 1, Article 56 of the Law on Medical Examination and Treatment;

c) Medical examination and treatment establishments already possessing operation licenses but changing their organizational forms;

d) Medical examination and treatment establishments already possessing operation licenses but changing locations of operation;

dd) Medical examination and treatment establishments already possessing operation licenses but undergoing splitting, consolidation or merger;

e) Medical examination and treatment establishments already possessing operation licenses but adding medical examination and treatment establishments outside the premises of the licensed establishments;

g) Medical examination and treatment establishments already possessing operation licenses but requesting to transform themselves into humanitarian medical examination and treatment establishments or not-for-profit medical examination and treatment establishments.

2. If a medical examination and treatment establishment that has been granted an operation license changes its owner but does not change its name, scale, scope of activities, or location, it is not required to apply for a new operation license.

Article 60. Dossiers of application for grant of new operation licenses

1. A dossier of application for grant of an operation license in the case specified at Points a, b, c, d, dd, e, Clause 1, Article 59 of this Decree:

a) A written application made using Form No. 02 provided in Appendix II to this Decree;

b) A valid copy of the establishment decision or the document with the name of the medical examination and treatment establishment issued by a competent State authority as for state-owned medical examination and treatment establishments, or the business registration certificate as for private medical examination and treatment establishments, or the investment certificate as for

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foreign-invested medical examination and treatment establishments;

c) A valid copy of the practicing license and the written confirmation of the practicing process made using Form No. 11 provided in Appendix I to this Decree of the person in charge of professional and technical expertise of the medical examination and treatment establishment (not applicable to cases where such documents have been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database);

d) A valid copy of the practicing license and the written confirmation of the practicing process made using Form No. 11 provided in Appendix I to this Decree of the person taking charge of a specialized division of the medical examination and treatment establishment (not applicable to cases where such documents have been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database);

dd) A declaration of facilities, a list of medical equipment, a list of personnel meeting the conditions for grant of an operation license in each respective organizational form, made using Form No. 08 provided in Appendix II to this Decree, and documents proving and certifying such declarations;

e) A list of full names and reference numbers of practicing licenses of every practitioner registered to practice at such establishment, made using Form No. 01 provided in Appendix II to this Decree;

g) A document, approved by a competent authority, defining the functions, tasks, organizational structure of a state-run hospital or the organizational and operational charter of a private hospital, made using Form No. 03 provided in Appendix II to this Decree;

h) A list of technical expertise proposed by the medical examination and treatment establishment pursuant to the list of technical expertise issued by the Minister of Health;

i) In the case where a humanitarian medical examination and treatment establishment or a not-for-profit medical examination and treatment establishment applies for an operation license for the first time, documents proving the financial resources for humanitarian or not-for-profit medical examination and treatment activities.

2. A dossier of application for another operation license in the case where the establishment has already granted an operation license but then changes its location as specified at Point d, Clause 1, Article 59 of this Decree:

a) A written application made using Form No. 02 provided in Appendix II to this Decree;

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b) A valid copy of the establishment decision or the document with the name of the medical examination and treatment establishment issued by a competent State authority as for state-owned medical examination and treatment establishments, or the business registration certificate as for private medical examination and treatment establishments, or the investment certificate as for foreign-invested medical examination and treatment establishments;

c) A declaration of facilities that meet the conditions for an operation license at the new location and documents proving and certifying such declarations;

d) A valid copy of the operation license that has been granted.

3. A dossier of application for another operation license in the case where the establishment has already granted an operation license but then requests to transform into a humanitarian medical examination and treatment establishment or a not-for-profit medical examination and treatment establishment that does not collect medical examination and treatment fees from patients as specified at Point g, Clause 1, Article 59 of this Decree:

a) A written application made using Form No. 02 provided in Appendix II to this Decree;

b) Documents proving financial resources for humanitarian medical examination and treatment activities.

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Article 61. Procedures for grant of a new operation license

1. File 01 dossier of application for grant of a new operation license and pay fees specified by the law regulations on fees and charges to the authority competent to grant operation licenses (hereinafter referred to as the operation licensing authority for short).

2. After receiving the dossier, the dossier-receiving authority shall issue to the requesting establishment a dossier receipt note made using Form No. 02 provided in Appendix I to this Decree.

3. In the case where amendment or supplementation of the dossier is not required:

a) The operation licensing authority shall organize the appraisal of operating conditions and the list of techniques implemented at the requesting establishment and prepare an appraisal record within 60 days from the date stated on the dossier receipt note;

b) In the case where amendment or supplementation is not required, a new operation license shall be granted and a decision on approval the list of techniques to be implemented at the establishment must be issued within 10 working days from the date on which the appraisal record is issued;

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c) In the case where amendment or supplementation is required, it must be clearly stated in the appraisal record.

Within 10 working days from the date of receiving the written notice and documents proving the completion of remediation and correction from the requesting establishment, the operation licensing authority may conduct an actual inspection of the remediation and correction of the requesting establishment in case of necessity or the grant of the operation license. In case of refusal to grant the operation license, it shall send a written reply clearly stating the reasons for such refusal.

4. In the case where amendment or supplementation of the dossier is required:

a) The operation licensing authority must send a written request to the applying establishment, which must specifically state the documents and contents that should be amended and supplemented, within 10 days from the date stated on the dossier receipt note.

b) After amending and supplementing the dossier, the requesting establishment sends a written notice and documents proving that the amendment and supplementation has been completed.

c) After receiving the amended and supplemented dossier, the operation licensing authority shall follow the procedures specified:

- In Clause 3 of this Article, in the case where amendment or supplementation is no longer required;

- At Points a and b of this Clause, in the case where the establishment has unsatisfactorily amended or supplemented the dossier.

5. Within 05 working days from the date on which the operation license is granted, the operation licensing authority shall publicly post on its web portal and the information system on management of medical examination and treatment activities the following information: name and address of the establishment granted the operation license; full name of the person in charge of professional and technical expertise and reference number of his/her practicing license; reference number of the operation license; scope and duration of professional activities.

6. The operation license is made into 02 counterparts using Form No. 06 provided in Appendix II to this Decree: 01 is given to the requesting establishment and 01 is archived by the licensing authority, unless otherwise the license is granted electronically.

7. In the case where an establishment is licensed to operate in the organization form of a hospital, when granting an operation license, the operation licensing authority shall issue a written temporary classification of such hospital

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into basic level. The temporary level shall be valid within 02 years from the date stated on the written temporary classification. Within 60 days before the expiration of the temporary level, the hospital must file a dossier for classification of its technical and professional level as specified in Article 90 of this Decree.

Article 62. Dossiers of application for re-grant of operation licenses

1. A written application made using Form No. 02 provided in Appendix I to this Decree.

2. In the case where the operation license is lost or damaged: A copy of the lost or original damaged operation license (if any).

3. In case of erroneous information: Documents proving that the erroneous contents and information should be corrected.

Article 63. Procedures for re-grant of an operation license

1. File 01 dossier of application for re-grant of an operation license and pay fees specified by the law regulations on fees and charges to the operation licensing authority.

2. After receiving the dossier, the operation licensing authority shall issue to the requesting establishment a dossier receipt note.

3. Within 20 days from the date stated based on the dossier receipt note, the operation licensing authority shall re-grant an operation license and update information about such re-grant on its own web portal or website and the information system on management of medical examination and treatment activities.

Article 64. Dossiers of application for modification of operation licenses

1. File 01 dossier of application for modification of the operation license in the case where the name, address (no change of location), or working hours have been changed:

a) A written application made using Form No. 02 provided in Appendix II to this Decree;

b) Documents proving the changes.

2. A dossier of application for modification of the operation license in case of changing the scale of operations, scope of professional activities or adding or removing the list of techniques:

a) A written application made using Form No. 02 provided in Appendix II to this Decree;

b) An original operation license;

c) A declaration of facilities, medical equipment and personnel records

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relative to the scale or scope of professional activities or list of techniques to be changed and documents proving the satisfaction of the conditions for such change.

Article 65. Procedures for modification of the operation license in case of changing working hours or changing the name and address of the medical examination and treatment establishment but not changing the location

1. File 01 dossier of application for change of name, address, or working hours of the medical examination and treatment establishment in accordance with Clause 1, Article 64 of this Decree and pay fees specified by the law regulations on fees and charges to the operation licensing authority.

2. After receiving the dossier, the operation licensing authority shall issue to the requesting establishment a dossier receipt note made using Form No. 02 provided in Appendix I to this Decree.

3. In the case where amendment or supplementation of the dossier is not required, the operation licensing authority shall modify the operation license within 20 days from the date stated on the dossier receipt note as specified in Clause 2 of this Article.

4. In the case where amendment or supplementation of the dossier is required, within 05 working days from the date stated on the dossier receipt note as specified in Clause 2 of this Article, the operation licensing authority shall send a written request to the requesting establishment, which must specifically state the documents and contents that should be amended and supplemented.

Within 06 months from the date on which the operation licensing authority issues a written notice requesting amendments and supplements, the requesting establishment must file an amended or supplemented dossier as requested. After the above time limit, if the requesting establishment fails to make any amendments and supplements, the dossier of application will be deemed invalid.

5. After receiving the amended and supplemented dossier, the operation licensing authority shall issue to the requesting establishment a receipt note of amended and supplemented dossier, made using Form No. 02 provided in Appendix I to this Degree:

a) In the case where the amended and supplemented dossier is unsatisfactory, the operation licensing authority must notify the requesting establishment in writing as specified in Clause 4 of this Article.

Within 06 months from the date on which the operation licensing authority issues a written notice requesting amendments and supplements, the requesting establishment must file an amended or supplemented dossier as requested. If the requesting establishment fails to make any amendments or supplements after the above time limit or the dossier is unsatisfactorily supplemented after 12 months from its first filing date, the filed dossier is deemed invalid.

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b) In the case where amendment or supplementation of the amended or supplemented dossier is not required, the operation licensing authority shall comply with Clause 3 of this Article.

6. Within 05 working days from the date on which the operation license is granted, the operation licensing authority shall publicly post and update such supplements on its web portal and on the information system on management of medical examination and treatment activities.

7. The operation license is made into 02 counterparts: 01 is given to the requesting establishment and 01 is archived by the licensing authority, unless otherwise the license is granted electronically.

Article 66. Procedures for modification of operation licenses in case of changing the scale of operations, scope of professional activities or adding or removing the list of techniques of a medical examination and treatment establishment

1. File 01 dossier as specified in Clause 2, Article 64 of this Decree and pay fees specified by the law regulations on fees and charges to the operation licensing authority.

2. After receiving the dossier, the operation licensing authority shall issue a dossier receipt note to the requesting establishment.

3. In the case where amendment or supplementation of the dossier is required, within 07 working days from the date stated on the dossier receipt note, the operation licensing authority shall send a written request to the requesting establishment, which must specifically state the documents and contents that should be amended and supplemented.

Within 06 months from the date on which the operation licensing authority issues a written notice requesting amendments and supplements, the requesting establishment must file an amended or supplemented dossier as requested. After the above time limit, if the requesting establishment fails to make any amendments and supplements, the dossier of application will be deemed invalid.

4. After receiving the amended and supplemented dossier, the operation licensing authority shall issue to the requesting establishment a receipt note of the mended and supplemented dossier

In the case where the amended and supplemented dossier is unsatisfactory, the operation licensing authority must notify the requesting establishment in writing as specified in Clause 3 of this Article.

Within 06 months from the date on which the operation licensing authority issues a written notice requesting amendments and supplements, the requesting establishment must file an amended or supplemented dossier as requested.

If the requesting establishment fails to make any amendments or

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supplements after the above time limit or the dossier is unsatisfactorily supplemented after 12 months from its first filing date, the filed dossier is deemed invalid.

5. In the case where amendment or supplementation of the dossier is not required or the dossier has been completed in accordance with Clauses 3 and 4 of this Article, the operation licensing authority shall:

a) Issue a document allowing changing the scale of operations, scope of professional activities or adding or removing the list of techniques within 20 days from the date stated on the dossier receipt note in the case where the on-site appraisal at the establishment is not required;

b) Organize the on-sit appraisal at the requesting establishment and prepare an appraisal record within 60 days from the date stated on the application receipt note in the case where the on-site appraisal at the establishment is required, which must clearly state what should be amended or supplemented (if any).

6. After conducting on-site appraisal at the establishment, the operation licensing authority shall:

a) Issue a document allowing changing the scale of operations, scope of professional activities or adding or removing the list of techniques within 10 working days from the date on which the appraisal record is issued in the case where no amendment or supplement is required;

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b) Issue a written notice of the contents that need to be remedied or corrected within 05 working days from the date on which the appraisal record is issued in the case where amendment or supplementation is required.

Within 06 months from the date on which the operation licensing authority issues a written notice of details that should be amended or added, if the requesting establishment fail to make such amendment or addition, the dossier is deemed invalid.

7. Within 10 working days from the date of receiving the written notice and documents proving the completion of amendments and supplements from the requesting establishment, the operation licensing authority shall:

a) Issue a document allowing changing the scale of operations, scope of professional activities or adding or removing the list of techniques in the case where actual inspection of the requesting establishment's amendment or supplementation is not required.

b) Conduct an actual inspection of the amendments and supplements of the requesting establishment in case an actual inspection is required:

- Issue a document allowing changing the scale of operations, scope of professional activities or adding or removing the list of techniques in the case where the requesting establishment completes the amendment or

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supplementation;

- Send a written reply clearly stating the reasons for not allowing changing the scale of operations, scope of professional activities or adding or removing the list of techniques if the requesting establishment completes the amendment or supplementation.

8. Within 05 working days from the date of permission for supplementation the list of techniques, the licensing authority shall publicly post and update such supplements on its web portal or website and on the information system on management of medical examination and treatment activities.

9. The written permission for supplementation of the list of techniques is made into 02 counterparts: 01 is given to the requesting establishment and 01 is archived by the operation licensing authority, unless otherwise the license is granted electronically.

10. In case of adding techniques to the list of special techniques:

a) The medical examination and treatment establishment shall file 01 dossier as specified in Clause 2, Article 64 of this Decree to the Ministry of Health to request consideration of the ability to perform techniques in the list of special techniques.

b) Within 05 working days from the date of receiving the dossier, the Ministry of Health shall examine and evaluate the level and ability of the medical examination and treatment establishment to perform these special techniques in order to determine whether the pilot application is required, or the medical examination and treatment establishment is eligible for pilot application or not.

c) In the case where it is necessary to pilot special techniques, the procedures specified in Article 97 of this Decree shall be followed.

d) In the case where the medical examination and treatment establishment has finished pilot application of special techniques and sent a written report on the results of the pilot application, which proposes the official application of such special techniques, the following needs to be done:

- The medical examination and treatment establishment shall file 01 dossier including a report on the results of pilot application of the special techniques as specified at Point c of this Clause and the process for performing the special techniques proposed by the medical examination and treatment establishment;

- Within 15 days from the date of receiving the complete dossier, the Ministry of Health shall appraise the results of pilot application and technical process proposed by the medical examination and treatment establishment;

- Within 05 working days from the date on which the appraisal record of pilot application results and technical process is issued, the Ministry of Health

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shall decide to allow the medical examination and treatment establishment to officially apply the special techniques. In case of refusal, it shall send a written reply clearly stating the reasons for such refusal;

- The medical examination and treatment establishment shall carry out procedures as prescribed in Clauses 1 to 9 of this Article to add special techniques that have been allowed to be officially applied within its scope of professional activities.

dd) In the case where it is not necessary to pilot special techniques, the following procedures should be carried out:

- Within 05 working days, the Ministry of Health shall decide to allow the medical examination and treatment establishment to officially apply special techniques without pilot application. In case of refusal, it shall send a written reply clearly stating the reasons for such refusal;

- The medical examination and treatment establishment shall carry out procedures as prescribed in Clauses 1 to 9 of this Article to add special techniques that have been allowed to be officially applied within its scope of professional activities.

Article 67. Authority to grant, re-grant and modify operation licenses

1. The Minister of Health shall:

a) Grant and re-grant of operation licenses to medical examination and treatment establishments under his/her management;

b) Modify operation licenses of medical examination and treatment establishments under its management when they change their scope of professional activities: adding or reducing techniques within the scope of professional activities.

c) Modify operation licenses of medical examination and treatment establishments under its management when they change their scale of operations, including:

- Adding or reducing professional departments and divisions, including the case specified at Point dd, Clause 1, Article 54 of the Law on Medical Examination and Treatment;

- Changing the patient bed availability by 10% or more or adjusting the patient bed availability by less than 10% but the adjustment exceeds 30 beds;

- Changing the patient bed availability in accordance with Clause 4 of this Article.

d) Modify operation licenses of medical examination and treatment establishments under its management when they change their working hours:

dd) Modify operation licenses of medical examination and treatment

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establishments under its management when they change their names and addresses without changing their locations.

2. Specialized health authorities under provincial-level People's Committees shall:

a) Grant and re-grant operation licenses to medical examination and treatment establishments in the localities under their management, except for medical examination and treatment establishments managed by the Ministry of Health, the Ministry of National Defense, and the Ministry of Public Security.

b) Modify operation licenses of medical examination and treatment establishments in the localities under their management, except for medical examination and treatment establishments managed by the Ministry of Health, the Ministry of National Defense, and the Ministry of Public Security when they change their scope of professional activities: adding or reducing techniques within the scope of professional activities.

c) Modify operation licenses of medical examination and treatment establishments in the localities under their management, except for medical examination and treatment establishments managed by the Ministry of Health, the Ministry of National Defense, and the Ministry of Public Security when they change their scale of operations, including:

- Adding or reducing professional departments and divisions, including the case specified at Point dd, Clause 1, Article 54 of the Law on Medical Examination and Treatment;

- Changing the patient bed availability by 10% or more or adjusting the patient bed availability by less than 10% but the adjustment exceeds 30 beds;

- Changing the patient bed availability in accordance with Clause 4 of this Article.

d) Modify operation licenses of medical examination and treatment establishments in the localities under their management, except for medical examination and treatment establishments managed by the Ministry of Health, the Ministry of National Defense, and the Ministry of Public Security when they change their working hours.

dd) Modify operation licenses of medical examination and treatment establishments in the localities under their management, except for medical examination and treatment establishments managed by the Ministry of Health, the Ministry of National Defense, and the Ministry of Public Security when they change their names and addresses but do not change their locations.

3. Hospitals may adjust the patient bed availability of departments and divisions by less than 10% of the total number of beds stated in their operation licenses, but not exceeding 30 beds, and must report in writing to the direct

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management authority, clearly stating:

a) The adjusted number of patient beds in departments and divisions;

b) Declaration of facilities, medical equipment and personnel records proving that they meet the conditions for changing the patient bed availability.

4. In the case where the hospital has adjusted the bed availability by less than 10% and wish to further adjust the bed availability, it must carry out the procedures for adjusting the operation license specified in Article 66 of this Decree. Dossiers of application for modification of operation licenses shall be sent to:

a) The Ministry of Health, as for hospitals directly affiliated to the Ministry of Health;

b) Specialized health authorities under provincial-level People's Committees, applicable to hospitals in the localities under their management, other than hospitals affiliated to the Ministry of Health, Ministry of National Defense, and Ministry of Public Security.

5. After adjusting the operation license as specified at Clause 4 of this Article, if the hospital wishes to further adjust the bed availability, subsequent adjustments of bed availability shall comply with Clause 3 and Clause 4 of this Article, respectively.

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Article 68. Dossiers declaring the eligibility to perform health check-ups or examination and treatment of HIV/AIDS

1. A document declaring eligibility to perform health check-ups or examination and treatment of HIV/AIDS, made using Form No. 04 provided in Appendix II to this Decree.

2. A valid copy of the medical examination and treatment operation license, enclosed with a list of professional and technical expertise of the medical examination and treatment establishment.

3. A list of personnel and medical equipment to perform health check-ups or examination and treatment of HIV/AIDS, made using Form No. 05 provided in Appendix II to this Decree.

4. A valid copy of the professional assistance contract of the medical examination and treatment establishment (if any).

Article 69. Procedures for declaring the eligibility to perform health check-ups or examination and treatment of HIV/AIDS

1. Before performing health check-ups for the first time, the medical examination and treatment establishment shall file 01 dossier declaring eligibility to perform health check-ups or examination and treatment of HIV/AIDS as specified at Article 68 of this Decree to the State authority in charge of health,

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specifically as follows:

a) For medical examination and treatment establishments affiliated to the Ministry of Health and other ministries and sectoral authorities (other than the Ministry of National Defense and the Ministry of Public Security): documents sent to the Ministry of Health;

b) For medical examination and treatment establishments managed by the Ministry of National Defense: documents sent to the Ministry of National Defense;

c) For medical examination and treatment establishments managed by the Ministry of Public Security: documents sent to the Ministry of Public Security;

d) If the medical examination and treatment establishment is subject to the management of a specialized health authority under the provincial-level People's Committee (other than those specified at Points a, b, c of this Clause): The dossier shall be sent to the specialized health authority under the provincial-level People's Committee of the locality where the medical examination and treatment establishment is located.

2. Processing of a dossier declaring the establishment's eligibility to perform health check-ups or examination and treatment of HIV/AIDS:

a) Upon receiving the dossier declaring eligibility to perform health check-ups or examination and treatment of HIV/AIDS, the State authority in charge of health specified in Clause 1 of this Article (hereinafter referred to as the dossier-receiving authority for short) shall send to the medical examination and treatment eligibility-declaring establishment to perform health check-ups (hereinafter referred to as the eligibility-declaring establishment for short) a dossier receipt note made using Form No. 02 provided in Appendix I to this Decree;

In the case where the dossier is not complete and valid as specified at Article 68 of this Decree, the dossier-receiving authority must send a document to the eligibility-declaring establishment to request it to supplement and complete the dossier. After the eligibility-declaring establishment amends or supplements its dossier, the dossier-receiving authority shall issue to such establishment another dossier receipt note made using Form No. 02 provided in Appendix I to this Decree.

b) In the case where the dossier is complete and valid as specified in Article 68 of this Decree and the dossier-receiving authority does not send a written request for supplementation or completion of the dossier, after 15 working days from the date of receiving the dossier receipt note, the eligibility-declaring establishment shall perform health check-ups or examination and treatment of HIV/AIDS in accordance with the declared scope of professional expertise;

c) In the case where the establishment that has declared its eligibility to perform health check-ups or examination and treatment of HIV/AIDS changes its

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name, address, facilities, personnel and declared scope of professional, it shall send a written notice to the dossier-receiving authority.

Article 70. Regulations on signage of medical examination and treatment establishments

After being granted an operation license, a medical examination and treatment establishment must set up a sign as specified by law regulations on signage which shall do not display the red cross symbol and contain all the following basic information:

1. Full name of the establishment.

2. Its organizational form.

3. The reference number of the medical examination and treatment operation license.

4. The address of the establishment stated in the medical examination and treatment operation license; phone number.

5. Its working hours.

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Section 3
EVALUATION AND CERTIFICATION OF THE QUALITY OF MEDICAL EXAMINATION AND TREATMENT ESTABLISHMENTS

Article 71. Evaluation according to basic quality standards

1. On an annual basis, medical examination and treatment establishments must conduct quality self-evaluation as specified at Clause 3, Article 58 of the Law on Medical Examination and Treatment and send the self-evaluation results to State authorities.

2. The results of quality evaluation must be publicly posted on the web portal of the competent State authority in charge of health and on the information system on management of medical examination and treatment activities.

3. Based on the self-evaluation results self-declared by the medical examination and treatment establishment, the State authority randomly selects the medical examination and treatment establishment to perform the re-evaluation according to the principle of risk management.

Article 72. Evaluation according to advanced quality standards of medical examination and treatment establishments, and quality standards for each specialty or technical service

1. Evaluation and certification according to advanced quality standards and quality standards for each specialty or technical service issued by the Ministry of

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Health shall be conducted as follows:

a) Quality accreditation organizations shall evaluate the quality of medical examination and treatment according to advanced quality evaluation standards or quality standards for each specialty or technical service set by the Ministry of Health and their internal processes;

b) Quality evaluation results must be reported to the competent State authority in charge of health and publicly posted on such State authority's web portal and the information system on management of medical examination and treatment activities;

c) The competent State authority in charge of health can randomly select establishments to conduct re-evaluation according to principle of risk management.

2. Evaluation and certification according to advanced quality standards and quality standards for each specialty or technical service recognized by the Ministry of Health shall be conducted as follows:

a) Quality accreditation organizations shall evaluate the quality of medical examination and treatment establishments according to advanced quality evaluation standards or quality standards for each specialty or technical service set by the Ministry of Health and their internal processes;

b) Quality evaluation results must be reported to the competent State authority in charge of health and publicly posted on such State authority's web portal and the information system on management of medical examination and treatment activities.

Article 73. Operation principles of medical examination and treatment establishment quality accreditation organizations

1. To comply with Clauses 1 and 2, Article 58 of the Law on Medical Examination and Treatment.

2. To make quality evaluation and accreditation in conformity with quality control standards promulgated or recognized by the Ministry of Health.

3. To evaluate and accredit quality on a voluntary basis under service contracts with medical examination and treatment establishments.

4. To keep confidential information collected in the quality evaluation and accreditation process.

Article 74. Functions and tasks of medical examination and treatment establishment quality accreditation organizations

1. To provide consultancy and guidance for medical examination and treatment establishments to apply quality control standards to improve medical examination and treatment quality.

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2. To grant quality certificates of definite term to medical examination and treatment establishments after evaluating these establishments' satisfaction of quality control standards or notify non-renewal of quality certificates if these establishments fail to retain accredited quality control standards.

3. To supervise establishments having obtained quality certificates in assuring their maintenance of medical examination and treatment quality according to accredited quality control standards.

4. To make periodic or ad-hoc reports at the request of competent State authorities in charge of health and submit to the examination and inspection of competent State authorities in charge of health.

Article 75. Conditions for an organization to be allowed to make quality evaluation and certification of medical examination and treatment establishments

1. It is legally established.

2. It has appropriate organizational structure in conformity with the evaluation quality standards in order to perform at least the following functions:

a) Professional and technical expertise;

b) Data management.

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3. It has at least 05 evaluators who work on full-time basis at the organization and meet the following specific conditions:

a) The person in charge of professional expertise must:

- Hold an undergraduate degree or higher;

- Have at least 05 years of experience in management of professional expertise at medical examination and treatment establishments or State authorities in charge of health that directly manage medical examination and treatment establishments.

- Be trained and granted a certificate of completion of a training course on skills to evaluate and accredit the quality of medical examination and treatment establishments by an educational institution announced or recognized by the Ministry of Health in accordance with the law regulations.

b) An evaluator must:

- Hold an undergraduate degree or higher;

- Be trained and granted a certificate of completion of a training course on skills to evaluate and accredit the quality of medical examination and treatment establishments by an educational institution announced or recognized by the Ministry of Health in accordance with the law regulations;

- Have at least 03 years of experience in medical examination and treatment

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at medical examination and treatment establishments or State authorities in charge of health that directly manage medical examination and treatment establishments.

Article 76. Dossiers of application for certificates of registration of quality evaluation and accreditation for medical examination and treatment establishments

In addition to meeting the requirements for dossiers of application for grant of registration certificates for accreditation of products and management systems as specified in Decree No. 107/2016/ND-CP dated July 1, 2016 of the Government stipulating business conditions for conformity assessment services, which has been amended and supplemented by Decree No. 154/2018/ND-CP dated November 9, 2018, the dossier of application for a new certificate of registration of accreditation shall comprise the following additional documents:

1. A list of personnel

2. Valid copies of the certificates of completion of the training courses on skills to evaluate and accredit the quality of medical examination and treatment establishments of the evaluators.

3. Documents proving the appropriate organizational structure in conformity with the evaluation quality standards.

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Article 77. Process for grant, suspension and revocation of certificates of registration of quality evaluation and certification for medical examination and treatment establishments

Process for grant, suspension and revocation of certificates of registration of quality evaluation and certification for medical examination and treatment establishments shall comply with the law regulations on conformity assessment.

Section 4
SUSPENSION AND REVOCATION OF MEDICAL EXAMINATION AND TREATMENT OPERATION LICENSES

Article 78. Process for revocation of operation licenses and suspension of activities of medical examination and treatment establishments

1. Partial or wholly suspension of professional activities of a medical examination and treatment establishment:

a) Within 05 working days from the date of conclusion of the professional council specified in Article 101 of the Law on Medical Examination and Treatment or examination and inspection conclusion by a competent State authority that the medical examination and treatment establishment is subject to

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suspension of part or the whole of its operation because it has committed one of the violations as specified in Clause 1, Article 55 of the Law on Medical Examination and Treatment, the competent authority as specified in Article 51 of the Law on Medical Examination and Treatment shall issue a decision on suspension of the establishment's operation.

b) The decision on suspension of a medical examination and treatment establishment's operation shall include the following contents:

- Name of the medical examination and treatment establishment;

- The reason for operation suspension;

- Scope of suspension: part or the whole of the operation license based on the nature and severity of the violation committed by the medical examination and treatment establishment;

- Suspension period;

- Conditions for continuing to operate.

c) Within 03 working days from the date of the decision on partly or wholly suspension of the medical examination and treatment establishment's professional activities, the authority issuing the suspension decision shall:

- Upload information about the suspension of professional activities of the medical examination and treatment establishment and limit the scope of professional activities of the suspended medical examination and treatment establishment on the information system on management of medical examination and treatment activities in the case where the medical examination and treatment establishment fall under its management;

- Send the suspension decision to the authority that granted the operation license to such medical examination and treatment establishment.

d) Within 03 working days from the date of receiving the suspension decision specified at Point d of this Clause, the authority that has issued the operation license to the suspended medical examination and treatment establishment shall upload information about the suspension of professional activities of such medical examination and treatment establishment and at the same time limit the scope of professional activities of the suspended medical examination and treatment establishment on the information system on management of medical examination and treatment activities.

dd) The suspension of the operation license in the case where a medical examination and treatment establishment is detected committing administrative violations shall comply with law regulations on handling of administrative violations.

2. Revocation of an operation license:

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a) Within 05 days from the date of conclusion of the professional council specified in Article 101 of the Law on Medical Examination and Treatment or examination and inspection conclusion by a competent State authority that the operation license of the medical examination and treatment establishment shall be revoked because it has committed one of the violations as specified in Clause 1, Article 56 of the Law on Medical Examination and Treatment or the medical examination and treatment establishment itself requests the revocation of its operation license, the operation licensing authority shall issue a decision on revocation of the establishment's operation license.

b) The decision on revocation of the operation license of a medical examination and treatment establishment shall include the following information:

- Name of the medical examination and treatment establishment;

- The reason for revocation of the operation license;

- Consequences of revocation of the operation license, and legal liabilities after revocation of the operation license.

c) Within 03 working days from the date on which the decision on revocation of the operation license of the medical examination and treatment establishment is issued, the operation licensing authority must post information about the revocation of the operation license of such medical examination and treatment establishment on the authority's web portal or website.

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Article 79. Consequences of revocation of the operation license or partial or wholly suspension of the professional activities of a medical examination and treatment establishment

1. In the case where the operation license is revoked as specified at Clause 1, Article 56 of the Law on Medical Examination and Treatment: the establishment whose operation license is revoked must carry out again the procedures for application for a new operation license as specified in this Decree.

2. In the case where a part or the whole of a medical examination and treatment establishment’s professional activities is suspended as specified at Clause 1, Article 55 of the Law on Medical Examination and Treatment, the competent authority shall issue a suspension decision clearly stating the details and suspension period.

3. After completing the remediation, the suspended medical examination and treatment establishment is responsible for sending a remediation report to the operation licensing authority.

4. After receiving the remediation report, the operation licensing authority shall issue the requesting establishment a dossier receipt note.

5. In the case where amendment or supplementation of the dossier is not required, the operation licensing authority shall either:

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a) Issue a decision on termination of the suspension within 15 days from the date stated on the dossier receipt note, if the remediation report is satisfactory;

b) Organize on-site inspection at the requesting establishment within 30 days from the date stated on the dossier receipt note, if necessary.

6. In the case where amendment or supplementation of the remediation report is required, within 10 working days from the date stated on the dossier receipt note, the operation licensing authority shall send a written request to the requesting establishment, which must specifically state the documents and contents that should be amended and supplemented.

Within 06 months from the date on which the authority granting operation licenses issues a written notice requesting amendments and supplements, the requesting establishment must submit a report on amendments and supplements as requested. After the above time limit, if the requesting establishment fails to make any amendments and supplements, the report that has been submitted will be deemed invalid.

7. After receiving the report on amendments and supplements, the operation licensing authority shall issue to the requesting establishment a receipt note of the mended and supplemented dossier

a) In the case where the report on amendments and supplements is unsatisfactory, the operation licensing authority must notify the requesting establishment in writing as specified in Clause 6 of this Article.

Within 06 months from the date on which the authority granting operation licenses issues a written notice requesting amendments and supplements, the requesting establishment must submit a report on amendments and supplements as requested. If the requesting establishment fails to make any amendments or supplements after the above time limit or the report is unsatisfactorily supplemented after 12 months from its first filing date, the filed dossier is deemed invalid.

b) In the case where amendment or supplementation of the report on amendments and supplements is not required, the licensing authority shall comply with Clause 5 of this Article.

8. After the on-site inspection at the establishment, the operation licensing authority shall either:

a) Issue a decision on termination of the suspension within 15 days from the date of completing the on-site inspection, if the remediation is satisfactory;

b) Issue a written notice of the contents that need to be remedied or corrected within 05 working days from the date on which the on-site inspection is completed in the case where on-site inspection is required.

Within 06 months from the date on which the operation licensing authority

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issues a written notice of details that should be remedied or corrected, if the requesting establishment fail to make such remediation or correction, the dossier is deemed invalid.

9. Within 20 days from the date of receiving the written notice and documents proving the completion of the remediation or correction from the requesting establishment, the operation licensing authority shall carry out the procedures as specified in Clause 5 of this Article.

Section 5
HUMANITARIAN MEDICAL EXAMINATION AND TREATMENT AND MOBILE MEDICAL EXAMINATION AND TREATMENT

Article 80. Humanitarian medical examination and treatment

1. Forms of humanitarian medical examination and treatment include:

a) Humanitarian medical examination and treatment establishments, organized in one of the forms specified in Article 48 of the Law on Medical Examination and Treatment and Article 39 of this Decree;

b) Humanitarian medical examination and treatment teams;

c) Individuals providing humanitarian examination and treatment;

2. No fees or money are collected from patients for medical examination and treatment activities specified in Clause 1 of this Article.

Article 81. Conditions, documents, procedures for grant, re-grant, modification, suspension and revocation of operation licenses of humanitarian medical examination and treatment establishments

Conditions, documents, procedures for grant, re-grant, modification, suspension and revocation of operation licenses of humanitarian medical examination and treatment establishments shall comply with Chapter III of this Decree.

Article 82. Conditions for organizing humanitarian medical examination and treatment under campaigns, humanitarian medical examination and treatment by individuals, and mobile medical examination and treatment (including health check-ups)

1. Humanitarian medical examination and treatment under campaigns must be provided by medical examination and treatment establishments that have been granted medical examination and treatment operation licenses.

2. Humanitarian medical examination and treatment activities by individuals must be performed by licensed practitioners whose scope of practice

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is appropriate to the respective humanitarian medical examination and treatment activities.

3. Mobile medical examination and treatment activities must be performed by medical examination and treatment establishments that have been granted medical examination and treatment operation licenses with the scope of professional activities appropriate to the mobile medical examination and treatment activities.

4. Regarding conditions in terms of facilities for providing humanitarian medical examination and treatment under campaigns or mobile medical examination and treatment, and health check-ups at a location other than that stated in the operation license, such location must meet the following conditions:

a) It has a reception area and medical examination and treatment areas that meet the following conditions:

- Infection control, radiation safety, management of healthcare waste, fire safety in accordance with law regulations;

- Enough electricity, water and other conditions for medical examination and treatment.

b) It has enough practitioners, medical equipment and other conditions appropriate to the scale and scope of providing medical examination and treatment services.

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5. Conditions in terms of personnel for organizing delegations to provide humanitarian medical examination and treatment under campaigns or mobile medical examination and treatment, or health check-ups:

a) The person in charge of the professional expertise of the humanitarian or mobile medical examination and treatment team must have a valid practicing license at the time of request with the scope of professional activities stated in such practicing license consistent with the list of professional techniques that the team has registered, and have been practicing medical examination and treatment for at least 36 months by the time of request for permission to provide humanitarian medical examination and treatment;

b) Other members directly participating in medical examination and treatment must have practicing licenses. In the case where a member directly participates in medical examination and treatment but is not required to have a practicing license in accordance with law regulations on medical examination and treatment, he/she must have a degree or certificate appropriate to the scope of practice assigned to him/her;

c) In case of dispensing medicines, the person dispensing the medicines must have at least a professional qualification as a pharmacist or a practicing license under the title of doctor;

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d) The person providing humanitarian medical examination and treatment is a foreigner must be accompanied by an interpreter, unless he/she speaks Vietnamese fluently.

6. Personnel conditions for one practitioner providing humanitarian medical examination and treatment as an independent practitioner shall comply with Clause 2 of this Article. Practitioners who provide humanitarian medical examination and treatment may prescribe but may not dispense medicines.

7. Conditions regarding medical equipment and drugs:

a) It has enough medical equipment, anaphylaxis response kits, emergency drugs and medicines appropriate to the scope of professional activities registered for medical examination and treatment;

b) Medical equipment must have a clear origin and drugs used for humanitarian medical examination and treatment must be on the list authorized for marketing in Vietnam and used before their expiry dates. In the case where the drugs are not yet authorized for marketing in Vietnam, there must be a written commitment that the drugs have been legally authorized for marketing in other countries (only applicable to foreign humanitarian medical examination and treatment teams).

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Article 83. Dossiers and procedures for request for permission to organize humanitarian medical examination and treatment under campaigns, mobile medical examination and treatment activities in the cases specified in Clause 1, Article 79 of the Law on Medical Examination and Treatment, or humanitarian medical examination and treatment provided by individuals

1. A dossier of request for permission to organize humanitarian medical examination and treatment under campaigns or mobile medical examination and treatment activities in the cases specified in Clause 1, Article 79 of the Law on Medical Examination and Treatment:

a) A written application for permission to provide humanitarian medical examination and treatment under campaigns or mobile medical examination and treatment, made using Form No. 01 provided in Appendix IV to this Decree;

b) A list of members providing humanitarian medical examination and treatment or mobile medical examination and treatment, made using Form No. 02 provided in Appendix IV to this Decree, which must clearly state the person in charge of professional and technical expertise and be enclosed with a valid copy of the practicing license of the person assigned to be in charge of professional and technical expertise of the team;

c) Valid copies of professional diplomas and certificates of people directly participating in medical examination and treatment but may not obtain practicing license in accordance with law regulations on medical examination and treatment

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(if any);

d) A plan to provide humanitarian medical examination and treatment or mobile medical examination and treatment, made using Form No. 03 provided in Appendix IV to this Decree;

dd) A written permission from the medical examination and treatment establishment or the head of the location where the medical examination and treatment activities are expected to be held.

2. A dossier of request for permission for an individual to provide humanitarian medical examination and treatment:

a) A written application for permission to provide humanitarian medical examination and treatment or mobile medical examination and treatment, made using Form No. 01 provided in Appendix IV to this Decree;

b) A valid copy of the practicing license of the person suggesting humanitarian medical examination and treatment.

c) A plan to provide humanitarian medical examination and treatment, made using Form No. 03 provided in Appendix IV to this Decree;

d) A written permission from the medical examination and treatment establishment or the head of the location where the humanitarian medical examination and treatment activities are expected to be held.

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3. Dossiers of request for permission to provide humanitarian medical examination and treatment under campaigns or mobile medical examination and treatment shall be sent to:

a) The Ministry of Health for permission:

- In the case where foreign organizations and individuals provide humanitarian medical examination and treatment under campaigns or mobile medical examination and treatment in 02 or more provinces and municipalities;

- Humanitarian medical examination and treatment under campaigns or mobile medical examination and treatment is provided at medical examination and treatment establishments affiliated to the Ministry of Health and other ministries, other than those affiliated to the Ministry of National Defense and the Ministry of Public Security.

b) The Ministry of National Defense, in cases of providing humanitarian medical examination and treatment under campaigns or mobile medical examination and treatment at medical examination and treatment establishments or agencies and units affiliated to the Ministry of National Defense.

c) The Ministry of Public Security, in cases of providing humanitarian medical examination and treatment under campaigns or mobile medical examination and treatment at medical examination and treatment establishments

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or agencies and units affiliated to the Ministry of Public Security.

d) Specialized health authorities under provincial-level People's Committees, applicable to organizations and individuals providing humanitarian medical examination and treatment under campaigns or mobile medical examination and treatment, unless otherwise specified at Points a, b and c of this Clause.

4. Procedures for permitting the provision of humanitarian medical examination and treatment activities under campaigns or mobile medical examination and treatment:

Within 10 days from the date of receiving the complete dossier, the dossier-receiving agency specified in Clause 3 of this Article shall be responsible for responding in writing that whether it permits the provision of humanitarian medical examination and treatment under campaigns or mobile medical examination and treatment or not. In case of refusal, it shall send a written reply clearly stating the reasons for such refusal;

Section 6

TRANSFER PROFESSIONAL TECHNIQUES IN MEDICAL EXAMINATION AND TREATMENT OR COOPERATION IN MEDICAL TRAINING INVOLVING MEDICAL EXAMINATION AND TREATMENT

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Article 84. Cases and conditions for transfer and receipt of transferred techniques among medical examination and treatment establishments

1. Techniques transferred between domestic medical examination and treatment establishments that are transferred or received must be on the list of techniques promulgated by the Ministry of Health. In the case where techniques are transferred to foreign countries, such techniques shall not be prohibited from transfer abroad in accordance with the law regulations on technology transfer.

2. Conditions for the medical examination and treatment establishment which transfers the technique:

a) The technique to be transferred must be within the scope of professional activities, approved by a competent authority, of the medical examination and treatment establishment transferring such technique;

b) The transferor of the technique must have experience in implementing the technique to be transferred and have a written authorization to conduct such transfer by the person in charge of professional and technical expertise of the medical examination and treatment establishment transferring the technique.

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3. Conditions for the medical examination and treatment establishment that receive the transferred technique:

a) It has a scope of professional activities appropriate to the technique to be transferred;

b) It has enough human resources, facilities, and medical equipment to be able to receive the technique to be transferred.

Article 85. Process for transferring a technique

1. Conducting surveys to determine the need for transfer of the technique.

2. Developing a plan for transfer of techniques.

3. Signing a technique transfer contract, under which the medical examination and treatment establishment transferring the technique and the person directly transferring the technology must be responsible for the medical examination and treatment results.

In case of transfer of techniques on the list of special techniques, the medical examination and treatment establishment receiving such techniques shall carry out the procedures as specified in Clause 10, Article 66 of this Decree before signing the contract on transfer of such techniques.

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4. The transfer of a technique includes the following steps:

a) Providing theoretical and practical training of the technique for the transfer recipient. After completing the training, the medical examination and treatment establishment transferring the technique shall issue to the trainee a written confirmation of completion of training in the technique.

In the case where the medical examination and treatment establishment transferring the technique is also a continuing educational institution, the written confirmation of completion of training in the technique as specified at this Point shall be also used as a certificate of continued training;

b) Organizing the transfer of the technique to the establishment receiving the technique;

c) Testing for acceptance, evaluating the transferred technique, liquidate the contract and issuing a certificate of capacity of performing the technique.

5. After completing the transfer, the medical examination and treatment establishment shall carry out procedures to modify the scope of professional activities as specified in this Decree.

Article 86. Conditions, dossiers, and procedures for permission for foreigners to enter Vietnam and transfer professional techniques in medical examination and treatment or cooperate in medical training involving medical examination and treatment internship

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1. Conditions for permission for foreigners to enter Vietnam and transfer professional techniques in medical examination and treatment or cooperate in medical training involving medical examination and treatment (hereinafter referred to as medical examination and treatment under campaigns):

a) They shall have practicing licenses issued by foreign competent authorities that are still valid at the time of implementation;

b) They meet the conditions for foreigners entering Vietnam to study and work in accordance with the law regulations;

c) Be accompanied by an interpreter as specified in Clause 2, Article 35 of this Decree, unless he/she speaks Vietnamese fluently;

d) Medicines and medical equipment used must be consistent with the scope of professional activities requested by such individuals or organizations; have clear origins and have been authorized for marketing by foreign competent authorities or in Vietnam; have not yet expired and are usable;

dd) Vietnamese authorities, organizations, or medical examination and treatment establishments accept them.

2. A dossier of application for permission for foreigners to enter Vietnam and transfer professional techniques in medical examination and treatment or cooperate in medical training involving medical examination and treatment internship:

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a) A written request for permission for foreigners to enter Vietnam to provide medical examination and treatment under campaigns, made by the receiving Vietnamese authority or organization;

b) A list of foreigners directly performing medical examination and treatment activities expected to enter Vietnam with the stamp of the receiving Vietnamese authority or organization, which must contain all of the following information: full names; passport numbers; professional titles; the tasks expected to be performed in Vietnam and commitment to take responsibility for the quality of medical examination and treatment of foreigners, enclosed with the receiving Vietnamese authority or organization’s valid copy of each foreigner’s practicing license;

c) A list of people who interpret for foreigners entering Vietnam to provide medical examination and treatment under campaigns with confirmation from the receiving Vietnamese authority or organization, which must contain all the following information: full name; number of identity card or passport or citizen identification card, or personal identification number; professional diploma and commitment to take responsibility for the quality of interpretation, enclosed with the receiving Vietnamese authority or organization’s valid copy of each interpreter's professional diploma;

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d) A list of medical equipment certified by the receiving Vietnamese authority or organization (if any), which must contain all of the following information: names and origins of the equipment and commitment that the equipment is in good working condition.

In case of combined use of medical equipment from a domestic medical examination and treatment establishment, the medical equipment supply agreement of the authority or organization where the medical examination and treatment is expected to be carried out must be attached.

In the case where a foreigner enters Vietnam to provide medical examination and treatment under campaigns and plans to give or donate used medical equipment to a Vietnamese authority or organization after completing the medical examination and treatment under campaigns, the Vietnamese authority or organization expects to receive the medical equipment shall carry out respective procedures as specified by the Government;

dd) A statement of drugs (if any), which must contain all of the following information: drug names, active ingredients, expiry dates, marketing authorization numbers and the commitment that the drugs are legally authorized for marketing in at least one country in the world;

e) A written agreement between the Vietnamese authority or organization and the foreigner or foreign authority or organization on the implementation of medical examination and treatment activities in Vietnam.

3. Dossiers of application for permission for foreigners to enter Vietnam and transfer professional techniques in medical examination and treatment or cooperate in medical training involving medical examination and treatment and send internship shall be sent to:

a) The Ministry of Health, as for foreigners working at medical examination and treatment establishments affiliated to the Ministry of Health and other ministries, other than those affiliated to the Ministry of National Defense and the Ministry of Public Security;

b) The Ministry of National Defense, as for foreigners working at medical examination and treatment establishments affiliated to the Ministry of National Defense;

c) The Ministry of Public Security, as for foreigners working at medical examination and treatment establishments affiliated to the Ministry of Public Security;

d) Specialized health authorities under provincial-level People's Committees in case foreigners come to work at medical examination and treatment establishments affiliated to the specialized health authorities under provincial-level People's Committees or in the localities under their management.

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4. Procedures for permission for foreigners to enter Vietnam and transfer professional techniques in medical examination and treatment or cooperate in medical training involving medical examination and treatment internship:

Within 15 days from the date of receiving the complete dossier, the dossier-receiving agency specified in Clause 3 of this Article shall be responsible for responding in writing that whether it permits the foreigners to provide medical examination and treatment in Vietnam. In case of refusal, it shall send a written reply clearly stating the reasons for such refusal.

Section 7

TELEHEALTH AND TELEHEALTH SUPPORT

Article 87. Telehealth

1. Conditions for providing telehealth:

a) It is performed by a practitioner of a medical examination and treatment establishment in one of the organizational forms specified in Article 39 of this Decree;

b) The establishment has a scope of professional activities consistent with the establishment's telehealth;

c) It has enough practitioners within the establishment's scope of telehealth;

d) It has technical infrastructure, information technology equipment, special-use devices, information technology software appropriate to the type of service provided and ensures safe and secure transmission, display, processing, and storage of data. Data storage and backup time shall meet law regulations.

2. A dossier declaring eligibility for providing telehealth:

a) A written request to provide telehealth, which must clearly state the start time of telehealth;

b) An original or valid copy of the medical examination and treatment operation license of the establishment (not applicable to cases where the operation license has been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database).

c) The list of registered practitioners of the establishment enclosed with reference numbers of their practicing licenses in the case where the operation license has been uploaded and shared on the information system on management

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of medical examination and treatment activities or the national health database. In the case where the operation license has not been updated or shared on the information system for management of medical examination and treatment activities or the national medical database, valid copies of practicing licenses of every practitioner providing telehealth shall be submitted;

d) A list of telehealth services;

dd) Documents proving the satisfaction of the conditions specified at Point d, Clause 1 of this Article.

3. Procedures for declaring eligibility for providing telehealth:

a) The medical examination and treatment establishment shall send 01 dossier declaring eligibility to perform telehealth as specified at Clause 2 of this Article to:

- The Ministry of Health, applicable to medical examination and treatment establishments under the Ministry's management;

- Specialized health authorities under provincial-level People's Committees, applicable to medical examination and treatment establishments in their respective localities (including private medical examination and treatment establishments), other than those subject to the management of the Ministry of Health, the Ministry of National Defense, and the Ministry of Public Security.

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b) After receiving the dossier declaring that the medical examination and treatment establishment is eligible for providing telehealth, the receiving authority shall issue the establishment a dossier receipt note made using Form No. 02 provided in Appendix I to this Decree.

c) Within 10 days from the date stated on the dossier receipt note specified in Clause 2 of this Article, the receiving authority shall post information about the establishment eligible for providing telehealth on its own web portal or website and the information system on management of medical examination and treatment activities.

In the case where the requirements are not met, the receiving authority must send a document to the medical examination and treatment establishment clearly stating the reason.

Information to be uploaded shall include at least: name and address of the establishment providing telehealth, and the list of the establishment's telehealth services.

d) In the case where, after 10 days from the date stated on the receipt note for the dossier declaring the eligibility for providing telehealth, the receiving authority neither sends a document to the medical examination and treatment establishment stating that it is eligible for providing telehealth nor post the information specified at Point c of this Clause, the medical examination and

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treatment establishment may begin to provide telehealth.

dd) During its operation, if the information that have been already uploaded as specified in Clause 2 of this Article has been changed, the medical examination and treatment establishment shall carry out again the procedures for uploading such information as specified in this Clause.

4. Scope of telehealth: As specified at Point a, Clause 1, Article 80 of the Law on Medical Examination and Treatment.

5. In the case where a medical examination and treatment establishment requests to carry out telehealth for diseases and conditions that are not on the list as specified in Clause 4 of this Article, it must meet the conditions specified in Clause 1 of this Article and file a dossier of request for pilot application of telehealth as specified at Clause 6 of this Article to the operation licensing authority for consideration and approval.

6. Procedures for pilot application of telehealth:

a) The establishment requesting pilot application of telehealth shall send a dossier comprising the following documents to the operation licensing authority:

- A written request for pilot application of telehealth, which must clearly state the start time of telehealth;

- The medical examination and treatment operation license of the establishment (not applicable to cases where the operation license has been uploaded and shared on the information system on management of medical examination and treatment activities or the national health database);

- A list of telehealth services;

- Documents proving the satisfaction of the conditions specified at Point d, Clause 1 of this Article;

- A list clearly stating the full names of practitioners expected to participate in the pilot application of telehealth and reference numbers of practicing licenses granted to them;

- Documents proving that other conditions are met.

b) After receiving the dossier, the operation licensing authority shall issue to the establishment requesting to provide telehealth a dossier receipt note.

c) In the case where amendment or supplementation of the dossier is not required, the operation licensing authority shall organize the appraisal within 30 days from the date stated on the dossier receipt note. In case of necessity, the on-site appraisal can be organized at the establishment requesting pilot application of telehealth.

d) Within 15 days from the date of the appraisal record, the operation licensing authority shall issue a written permission for pilot application of

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telehealth, which must clearly state the number of cases subject to the pilot application. In case of refusal, it shall send a written reply clearly stating the reasons for such refusal.

dd) In the case where amendment or supplementation of the dossier is required, within 15 days from the date stated on the dossier receipt note, the dossier-receiving authority shall send a written request to the telehealth-piloting establishment, which must specifically state the documents and contents that should be amended and supplemented.

e) After receiving the amended and supplemented dossier, the dossier-receiving authority shall issue to the establishment requesting pilot application of telehealth the receipt note of the amended dossier and carry out again the procedures as specified at Points c and d of this Clause.

g) In the case where the amended or supplemented dossier is unsatisfactory, the operation licensing authority shall send a written notice to the establishment requesting pilot application of telehealth as specified at Point dd of this Clause.

h) Within 06 months from the date on which the operation licensing authority issues a written notice requesting amendments and supplements, the establishment requesting to pilot telehealth must file an amended or supplemented dossier as requested. If the establishment requesting to pilot telehealth fails to make any amendments or supplements after the above time limit or the dossier is unsatisfactorily supplemented after 12 months from its first filing date, the filed dossier is deemed invalid.

7. After completing the pilot application, the establishment shall send a report on pilot application results to the operation licensing authority for escalation to the Ministry of Health.

8. Prices for telehealth services, applicable to cases subject to pilot application of telehealth:

a) Medical examination service prices: the telehealth provider may apply the medical examination prices approved by the competent authority, including the prices of medical examination and treatment upon request (if any);

b) Service prices for inpatient days, prices for technical services in medical examination and treatment: the medical examination and treatment establishments receiving the patients seeking treatment (hereinafter referred to as the receiving establishments) may apply prices approved by competent authorities, including the prices of required services (if any);

c) Prices of drugs, medical equipment, whole blood and blood products in the case where the patient is prescribed to use them: Pay reasonable and valid costs incurred related to the services (if any) in accordance with regulations.

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9. In the case where a patient referred by one medical examination and treatment establishment to receive telehealth at another medical examination and treatment establishment, the receiving establishment shall collect the medical examination and treatment charges from the patient as specified at Clause 8 of this Article and pay the telehealth establishment in accordance with the level agreed in the contract to provide telehealth services between the medical examination and treatment establishments as specified in Clause 11 of this Article.

The health insurance fund pays expenses for health insurance policyholders within the coverage according to the health insurance benefits specified by the law regulations on health insurance. Co-pay expenses and out-of-pocket expenses not covered by health insurance (if any) must be borne by the patients themselves.

The health insurance fund shall not pay for the cases subject to pilot application of telehealth as specified in Clause 5 of this Article.

People who do not participate in health insurance must pay the out-of-pocket expenses of telehealth themselves at to the prices of medical examination and treatment services approved by competent authorities.

10. In the case where the patient receives telehealth without going to another medical examination and treatment establishment, medical examination and treatment charges shall be paid under the agreement between the two parties.

11. A contract to provide telehealth services shall contain at least the following information:

a) Responsibilities and rights of the telehealth establishment and the receiving establishment;

b) Technical infrastructure, information technology equipment, special-use equipment, information technology software, assurance of information safety and security appropriate to the type of telehealth services;

c) Data storage and backup and satisfaction of information safety and security requirements in accordance with the law regulations;

d) Telehealth service charges;

dd) Telehealth costs agreed between medical examination and treatment establishments.

Article 88. Telehealth support

1. Conditions for providing support for telehealth activities:

a) The establishment providing telehealth support services appropriate to the scope of licensed professional activities.

b) There is a contract to provide telehealth support services clearly stating:

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- Responsibilities and rights of the support service provider and the support recipient;

- Technical infrastructure, information technology equipment, special-use equipment, information technology software, assurance of information safety and security appropriate to the type of support services;

- Data storage and backup and satisfaction of information safety and security requirements in accordance with the law regulations;

- Telehealth support service charges;

- Telehealth support costs agreed between medical examination and treatment establishments.

2. Patients are provided with information about telehealth support services during the medical examination and treatment process.

3. A medical examination and treatment establishment that provides telehealth support shall properly implement the contract to provide telehealth support services, and annually report to the management authority.

4. Principles for paying telehealth support charges:

a) Medical examination and treatment service prices comply with the prices approved by competent authorities for supported medical examination and treatment establishments;

b) The supported medical examination and treatment establishment must pay expenses for the supporting medical examination and treatment establishment according to the expenses agreed upon between the two medical examination and treatment establishments and specified in the telehealth support service contract.

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Section 8

PROFESSIONAL AND TECHNICAL LEVELS IN MEDICAL EXAMINATION AND TREATMENT

Article 89. Regulations on classification of medical examination and treatment establishments according to technical and professional levels

1. Medical examination and treatment establishments without inpatient treatment, commune health stations and regional polyclinics with patient beds shall be classified to primary level of medical examination and treatment.

2. Hospitals (medical centers with patient beds) shall be classified to basic and intensive levels of medical examination and treatment.

3. The classification of medical examination and treatment establishments

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to basic or intensive level is specified in Appendix V to this Decree.

Article 90. Dossiers and procedures for classification of professional and technical levels

1. A dossier of application for classification of professional and technical level:

a) A written request for classification;

b) A self-assessment scorecard according to the assessment criteria and contents specified in Appendix V to this Decree;

c) Documents and statistical data proving the scores;

d) Other relevant documents.

2. Procedures for classification of professional and technical levels:

a) The hospital requesting classification of its level shall file 01 dossier as specified in Clause 1 of this Article to the authority specified in Clause 3 of this Article.

b) After receiving the dossier, the dossier-receiving authority shall issue to the requesting establishment a dossier receipt note made using Form No. 02 provided in Appendix I to this Decree.

c) In the case where amendment or supplementation of the dossier is not required, the authority specified in Clause 3 of this Article shall issue a written classification within 60 days from the date stated on the dossier receipt note.

d) In the case where amendment or supplementation of the dossier is required, the authority as specified in Clause 3 of this Article shall issue a written request for amendment or supplementation of the dossier within 10 days from the date stated on the dossier receipt note, which must specifically state the documents and contents that should be amended and supplemented.

dd) After amending and supplementing the dossier, the hospital requesting the classification of its level sends a document enclosed with documents proving that the amendment and supplementation has been completed.

e) After receiving the amended and supplemented dossier, the authority specified in Clause 3 of this Article shall follow the procedures specified:

- At Point c of this Clause, in the case where amendment or supplementation is no longer required;

- At Points d and dd of this Clause, in the case where the establishment has unsatisfactorily amended or supplemented the dossier.

g) Within 05 working days from the date of classification, the authority specified in Clause 3 of this Article shall publicly post on its web portal and the information system on management of medical examination and treatment

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activities the following information: name, address of the establishment being classified and the professional and technical level of such establishment.

3. The competence to classify professional and technical levels:

a) The Ministry of Health shall classify the professional and technical levels of hospitals directly affiliated to the Ministry of Health;

b) Specialized health authorities under provincial-level People's Committees shall classify the technical and professional levels of hospitals in the localities under their management and private hospitals granted operation licenses by the Ministry of Health, other than hospitals affiliated to the Ministry of Health, Ministry of National Defense, and Ministry of Public Security.

Section 9
COMPULSORY MEDICAL TREATMENT

Article 91. Cases subject to compulsory medical treatment

1. Persons subject to compulsory medical treatment under this Decree include:

a) Persons infected with Group-A infectious diseases as specified by the law regulations on prevention and control of infectious diseases (hereinafter referred as Group-A infectious disease patients for short);

b) Persons suffering depression which gives rise to the idea or act of committing suicide or suffering a mental disease in a state of loss of self-control that may harm themselves or engage in acts that cause harm to others or damage property (hereinafter referred to as mental disorder patients for short)

2. Compulsory medical treatment for persons who violate the law regulations or are suspected of committing crimes and suffer from mental disorders as specified at Point b, Clause 1 of this Article shall comply with the criminal laws, aw regulations on criminal proceedings and judgment execution.

3. Based on the practical situation, the Ministry of Health shall report to the Government to consider and decide on the addition of other persons subject to compulsory medical treatment as specified at Point c, Clause 1, Article 82 of the Law on Medical Examination and Treatment.

Article 92. Compulsory medical treatment of Group-A infectious disease patients

1. In the case where a person with a definitive diagnosis is being subjected to medical quarantine at his/her house or at a quarantine establishment not conducting medical examination and treatment activities (hereinafter referred to

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collectively as at home):

a) In the case where the patient's condition can allow him/her to be treated at his/her house or follow the instructions on at-home treatment of the anti-pandemic steering committee, the chairperson of the commune-level People's Committee of the locality where such person resides shall issue a decision on compulsory at-home treatment, which must specifically stipulate that the medical examination and treatment establishment shall provide at-home treatment guidance and support to the patient at the same-level health authority's proposal;

b) In the case where a patient's condition cannot allow him/her to be treated at his/her house, the chairperson of the commune-level People's Committee of the locality where the patient is residing shall issue a decision on compulsory treatment and organize the transfer of the patient from his/her house to an appropriate medical examination and treatment establishment for compulsory medical treatment;

c) In the case where the patient's condition must be subject to compulsory medical treatment but he/she cannot be transported to a medical examination and treatment establishment, the chairperson of the commune-level People's Committee of the locality where such person resides shall issue a decision on compulsory at-home treatment, which must the reason for impossible transportation of the patient to a medical examination and treatment establishment as well as specifically stipulate that an appropriate medical examination and treatment establishment shall provide at-home treatment guidance and support to the patient at the same-level health authority's proposal;

2. In the case where a person with a definitive diagnosis is being subjected to medical quarantine at a quarantine establishment conducting medical examination and treatment activities:

a) In the case where the patient's condition can be treated at a quarantine establishment conducting medical examination and treatment activities, the head of the quarantine establishment where the patient is being quarantined shall issue a decision on compulsory medical treatment at the quarantine establishment and provide treatment to the patient;

b) In the case where a patient's condition cannot allow him/her to be treated at the quarantine establishment, the head of the quarantine establishment shall issue a decision on compulsory treatment and organize the transfer of the patient from the quarantine establishment to another medical examination and treatment establishment for compulsory medical treatment;

c) In the case where the patient cannot be treated at a quarantine establishment but cannot be transported to a medical examination and treatment establishment, the head of the quarantine establishment where the patient is being quarantined shall issue a decision on compulsory medical treatment, which must

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clearly state the reason for not transporting the patient to a medical examination and treatment establishment and at the same time contact another medical examination and treatment establishment for treatment guidance and support to the patient.

3. In the case where the patient is undergoing medical examination and treatment at a medical examination and treatment establishment and is diagnosed with a group-A infectious disease:

a) In the case where the patient's condition can be treated at a medical examination and treatment establishment, the head of the medical examination and treatment establishment where the patient is being treated or the person authorized by the head of the medical examination establishment and treatment (hereinafter referred to as the head of the establishment) shall issue a decision on compulsory medical treatment and provide treatment to the patient;

b) In the case where a patient's condition cannot allow him/her to be treated at the medical examination and treatment establishment, the head of the establishment shall issue a decision on compulsory treatment and organize the transfer of the patient from the quarantine establishment to another medical examination and treatment establishment appropriate to the patient's condition for compulsory medical treatment;

c) In the case where the patient cannot be treated at a medical examination and treatment establishment but cannot be transported to another medical examination and treatment establishment Others, the head of the establishment shall issue a decision on compulsory medical treatment, which must clearly state the reason for not transporting the patient to another medical examination and treatment establishment and at the same time contact another medical examination and treatment establishment for treatment guidance and support to the patient.

Article 93. Compulsory medical treatment of mental disorder patients

1. In the case where a person is discovered by the community with signs specified at Point b, Clause 1, Article 91 of this Decree:

a) The commune-level People's Committee of the locality where the person is discovered shall take measures to transport such person to a medical examination and treatment establishment for definitive diagnosis;

b) In the case where the person is determined to have a mental disorder and requires compulsory treatment, such medical examination and treatment establishment shall organize compulsory treatment or transport the patient to a medical examination and treatment establishment that can treat mental disorders for compulsory treatment and at the same time notify the patient's relatives to coordinate in management and care of the patient;

c) In the case where the patient's relatives cannot be identified or the

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patient's relatives refuse the patient, a dossier shall be sent to the Labor - Invalids and Social Affairs authorities to coordinate in management, care, and settlement of benefits in accordance with the law regulations on social protection.

2. During the process of medical examination and treatment, if a person is detected with signs specified at Point b, Clause 1, Article 91 of this Decree:

a) The medical examination and treatment establishment shall provide compulsory treatment or transport the patient to a medical examination and treatment establishment that can treat mental disorders for treatment. The patient's relatives shall be notified for coordination in monitoring and care of the patient;

b) In the case where the patient's relatives cannot be identified or the patient's relatives refuse the patient, a dossier shall be sent to the Labor - Invalids and Social Affairs authorities to coordinate in management, care, and settlement of benefits in accordance with the law regulations on social protection.

Section 10

PROCESSING A NUMBER OF PROCEDURES RELATED TO FOREIGN PATIENTS WITH NO RELATIVES AND DECEASED PATIENTS WHO ARE FOREIGNERS WITH NO RELATIVES

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Article 94. Handling of foreign patients with no relatives

1. Medical examination and treatment of foreign patients with no relatives shall comply with Article 15 of the Law on Medical Examination and Treatment.

2. In the case where the patient who dies is a foreigner with no relatives: Article 95 of this Decree shall prevail.

Article 95. Handling of deceased patients who are foreigners with no relatives

1. In the case where the deceased patient is a foreigner with no relatives and whose nationality cannot be determined: the medical examination and treatment establishment shall comply with Article 73 of the Law on Medical Examination and Treatment.

2. In the case where the deceased patient is a foreigner with no relatives and whose nationality can be determined: the medical examination and treatment establishment shall notify the district-level People's Committee in the locality where the medical examination and treatment establishment is located for handling in accordance with the law regulations on citizenship.

While the case is being handled, the medical examination and treatment establishment shall preserve the body or hire another establishment to preserve

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the patient's body.

Chapter IV

APPLICATION OF NEW TECHNIQUES AND METHODS IN MEDICAL EXAMINATION AND TREATMENT AND CLINICAL TRIALS IN MEDICAL EXAMINATION AND TREATMENT

Article 96. Process of permission for application of new techniques or methods

1. The medical examination and treatment establishment shall send the Minister of Health a request for identification of techniques or methods that are not included in the list of technical expertise issued by the Minister of Health as new techniques or methods. Such a dossier comprises:

a) A written request for identification of the new technique or method, made using Form No. 01 provided in Appendix VI to this Decree;

b) For new techniques and new methods researched in Vietnam or abroad: documents on research and development of the new techniques and new methods, which must contain a review of relevant domestic and foreign research that has been published, technical characteristics, usage, route of administration, dosage (if any) and risk factors;

c) For new techniques and new methods permitted to be applied by foreign competent authorities: In addition to the documents specified at Point b of this Clause, there must be the processes of performing the techniques and documents proving that new techniques and new methods have been approved for application by foreign competent authorities.

2. After receiving the dossier, the Ministry of Health shall issue a dossier receipt note made using Form No. 02 provided in Appendix I of this Decree to the establishment requesting the determination of new techniques or methods.

3. In the case where amendment or supplementation of the dossier is not required, the dossier-receiving authority shall send a written reply within 30 days from the date stated on the dossier receipt note, which must clearly state the new technique or method that the establishment proposes to identify falls into one of the following cases:

a) The new technique or method is subject to clinical trial;

b) The new technique or method do not require clinical trial but must be subject to pilot application;

c) The new technique or method is not subject to clinical trial and pilot application.

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4. After receiving the written reply from the Ministry of Health, the establishment requesting to identify the new technique or method shall:

a) In the case where the new technique or method is subject to clinical trial: carry out the clinical trial process as specified in this Decree. After obtaining a written approval the outcomes of the clinical trial, the establishment shall prepare a dossier as specified at Point c of this Clause and carry out procedures as specified in Clause 6 of this Article;

b) In the case where the new technique or method do not require clinical trial but must be subject to pilot application: carry out the pilot application process as specified in Article 97 of this Decree. After completing the pilot application, the establishment shall prepare a dossier as specified at Point c of this Clause enclosed with a written request for official application of the new technique or method in medical examination and treatment made using Form No. 03 provided in Appendix VI to this Decree and a report on the results of pilot application, and carry out the procedures as specified in Clause 6 of this Article;

c) In the case where the new technique or method is not subject to clinical trial and pilot application: Develop technical processes as specified at Point a, Clause 1, Article 97 of this Decree; economic-technical norms of the new technique or method, and expected prices, and then send them to the Ministry of Health for approval.

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5. Within 60 days from the date of receiving the dossier specified at Point c, Clause 4 of this Article, the Ministry of Health shall:

a) Approve the technical process of the new technique or method;

b) Approve economic-technical norms of the new technique or method;

c) Approve prices of the new technique or method;

d) Classify new techniques and methods;

dd) Issue a written permission for the medical examination and treatment establishment to apply the new technique or method.

6. After receiving the written permission for the medical examination and treatment establishment to apply the new technique or method specified in Clause 5 of this Article:

a) In the case where the medical examination and treatment establishment is an establishment managed by the Ministry of Health: The Ministry of Health's written permission for application of the new technique or method is also the document on expansion of the scope of operations of the medical examination and treatment establishment;

b) In the case where the medical examination and treatment establishment is not managed by the Ministry of Health: based on the written permission for

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application of the new technique or method from the Ministry of Health, the medical examination and treatment establishment shall carry out procedures to modify the scope of professional activities as specified in this Decree;

c) In the case where the medical examination and treatment establishment is subject to the Ministry of Health's regulations on pricing of medical examination and treatment services, after the Ministry of Health has a written approval of the prices, the medical examination and treatment establishment shall submit to the competent authority for approval of prices applicable by such establishment as specified at Article 110 of the Law on Medical Examination and Treatment.

7. After the Ministry of Health has approved the technical process and classification of the techniques, any other medical examination and treatment establishment that wants to do so must:

a) For techniques on the list of special techniques:

- Prepare a dossier of request for pilot application;

- Prepare a dossier of request for official approval after completing the pilot application.

b) For techniques not on the list of special techniques: Follow the procedure for modification of the scope of operation of the medical examination and treatment establishment as specified in this Decree.

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Article 97. Procedures for pilot application of a new technique or method in medical examination and treatment

1. A medical examination and treatment establishment requesting for pilot application of a new technique or method in medical examination and treatment must meet the following conditions:

a) It has a technical process to deploy and apply the new technique or method approved by the head of the medical examination and treatment establishment.

The process must include at least the following: process name; outline and definitions; indications; contraindications; guidelines for the preparation and implementation of the process (personnel requirements, facilities, drugs, medical equipment and other conditions); steps; monitoring; complication treatment and other notes (if any).

b) It has enough human resources, facilities, medical equipment and other conditions to meet the requirements for implementing the new technique or method following the approved technical process specified in Clause 3 of this Article, in which the person performing the new technique or method must fully meet the following conditions:

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- Possessing a practice license with the scope of practicing conformable to the new technique or method;

- Having one of the following documents: a credential or certificate of training in the new technique or method to be applied, issued by an educational institution, or a certificate of training in transfer of the new technique or method, issued by a domestic or foreign medical examination and treatment establishment;

- Being a person who has registered to practice at a medical examination and treatment establishment.

2. A dossier of application for pilot application of a new technique or method:

a) A written request for pilot application of the new technique or method, made using Form No. 02 provided in Appendix VI to this Decree;

b) Technical process for application of new techniques or methods.

c) Documents proving that they meet the requirements for human resources, establishments, medical equipment and other conditions to apply the new technique or method, including:

- A list clearly stating the full names of practitioners expected to participate in the application of the new technique or method and reference numbers of practicing licenses granted to them;

- The floor plan of the place where the new technique or method is expected to be applied;

- A list of medical equipment for application of the new technique or method;

- Documents proving that other conditions are met.

d) Estimated price schedule for technical services with economic and technical norms for pricing.

4. Procedures for pilot application of a new technique or method:

a) The establishment requesting pilot application of the new technique or method shall send the dossier as specified in Clause 2 of this Article to the Ministry of Health;

b) After receiving the dossier, the Ministry of Health shall issue a dossier receipt note to the establishment requesting pilot application of the new technique or method;

c) In the case where amendment or supplementation of the dossier is not required, the dossier-receiving authority shall organize the appraisal within 30 days from the date stated on the dossier receipt note. In case of necessity, the on-

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site appraisal can be organized at the establishment requesting pilot application of the new technique or method;

d) Within 15 days from the date of the appraisal record, the Ministry of Health shall issue a written permission for pilot application of the new technique or method, which must clearly state the number of cases subject to the pilot application. In case of refusal, it shall send a written reply clearly stating the reasons for such refusal.

dd) In the case where amendment or supplementation of the dossier is required, within 15 days from the date stated on the dossier receipt note, the dossier-receiving authority shall send a written request to the establishment piloting the application of the new technique or method, which must specifically state the documents and contents that should be amended and supplemented;

e) After receiving the amended and supplemented dossier, the dossier-receiving authority shall issue to the establishment requesting application of the new technique or method the receipt note of the amended dossier and carry out again the procedures as specified at Points c and d of this Clause;

g) In the case where the amended or supplemented dossier is unsatisfactory, the Ministry of Health shall send a written notice to the establishment requesting application of the new technique or method as specified at Point dd of this Clause;

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h) Within 06 months from the date on which the dossier receiving authority issues a written notice requesting amendments and supplements, the establishment requesting the application of the technique must file an amended or supplemented dossier as requested. If new methods requesting to pilot the new technique or method fails to make any amendments or supplements after the above time limit or the dossier is unsatisfactorily supplemented after 12 months from its first filing date, the filed dossier is deemed invalid.

Article 98. Clinical trial phases for medical examination and treatment activities

Phases of the clinical trial of a new technique or method in medical examination and treatment:

1. Phase 1: the first phase of human trial in order to evaluate the safety and initially evaluate the efficacy of the new technique or method in medical examination and treatment.

2. Phase 2: the research phase to determine the efficacy and safety of the new technique or method so that the outcomes of the trial will be recognized and allowed to be applied in medical examination and treatment.

3. Phase 3: the phase implemented after the new technique or method have been permitted to be applied in Vietnam in order to collect more evidence about

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the safety and efficacy of the new technique or method in actual application upon request of State authorities.

Article 99. Cases where the clinical trial of the new technique or method or some phases thereof are exempted

1. Exemption from clinical trials of the new technique or method in the cases specified at Point b, Clause 2, Article 92 of the Law on Medical Examination and Treatment and low-risk new techniques and methods, including non-invasive or minimally invasive techniques and methods, or those with negligible risk of affecting the patients' health.

2. Cases where some phases of the clinical trial of the new technique or method are exempted:

a) New techniques and methods researched in Vietnam and applied for the first time in Vietnam: medium-risk new techniques and methods researched for the first time in Vietnam, including invasive techniques and methods that have an average risk of affecting patients' health and are exempt from Phase 1 clinical trials.

b) New techniques and methods are researched in foreign countries and applied in Vietnam for the first time:

- New techniques and methods of which the trial has been completed in the phase before the proposed trial phase and the trial results reported in the phase before the proposed trail phase in a foreign country are available: Continue to carry out the next phase in such country and shall be considered by the Ministry of Health to allow simultaneous trial in Vietnam;

- New techniques and methods, of which the trial has been completed in all phases in accordance with local regulations and have their trial results accepted or published in reputable specialty journals but not yet applied in foreign countries and Vietnam, shall be deemed exempt from Phase 1 clinical trials.

Article 100. Requirements for new techniques and methods:

Requirements for new techniques and methods subject to clinical trial:

1. They have been researched in the pre-clinical phase, with documents proving safety so that they can be subject to trial in the next phases.

2. The outcomes of the clinical trial in the phases before the trial proposal phase are available if the clinical trial of the new technique or method is proposed in the next phase.

Article 101. Requirements for establishments hosting clinical trials of new techniques and new methods

1. They shall meet the good practice requirements for new technique or method trial as specified by the Minister of Health.

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2. A establishment hosting a clinical trial of a new technique or new method shall be a medical examination and treatment establishment with a scope of professional activities appropriate to the new technique or new method subject to the clinical trial.

Article 102. Dossiers for clinical trials of new techniques and methods in medical examination and treatment

1. Dossiers of the clinical trial of a new technique or method include a dossier of application for approval of the clinical trial; a dossier of application for approval of changes to the clinical trial; a dossier of application for approval of outcomes of the clinical trial.

2. A dossier of application for approval of the clinical trial of a new technique or method comprises:

a) A written request for approval of the trail, made by the organization or individual possessing the new technique or method using Form No. 04 provided in Appendix VI to this Degree.

b) A written request for approval of the trail, made by the establishment hosting the clinical trial of the new technique or method using Form No. 05 provided in Appendix VI to this Degree.

c) Information about the new technique or method subject to the clinical trial, including:

- Information about the products (in the case where the new technique or method employs the products): the name, ingredients, indications, origin, properties, production process of the products, quality standards, quality testing certificates of units assigned by the Ministry of Health, and other related information.

- Pre-clinical research documents of the new technique or method subject to the clinical trial, which must include research reports on safety and efficacy, and recommendations on usage and dosage (if any), approved by the professional council of the clinical trial-testing establishment as satisfactory.

For medium-risk new technique or method (invasive, with a moderate risk of affecting the patient's health) which does not require pre-clinical research documents.

- Clinical trial documents in the phases before the trial proposal phase.

d) Legal documents, including:

- A competent authority’s written permission for application of the new technique or method in medical examination and treatment subject to clinical trial in Phase 3;

- A written confirmation of participation from the organization

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participating in the trial;

- A clinical trial agreement between the organization or individual possessing the new technique or method and the establishment hosting the clinical trials of such new technique or method (if any); A trial support agreement between the organization or individual possessing the new technique or method clinical subject to clinical trial and the trail-supporting organization (if any).

dd) Scientific documents, including:

- A written explanation of the protocol of the clinical trial of the new technique or method, made using Form No. 06 provided in Appendix VI to this Decree;

- A case report form - CRF;

- Participant information sheets and informed consent forms of participants in the clinical trial of the new technique or method.

e) Administrative documents, including:

- The principal investigator's portfolio and a copy of his/her certificate of completion of a Good Clinical Practice course issued by the Ministry of Health or by an establishment providing training in good clinical practice;

- A record of appraisal of scientific and ethical aspects in research by the grassroots-level council of ethics in biomedical;

- Labels of products subject to the trial (in the case where the new technique or method employs the products).

3. A dossier of application for approval of changes to the clinical trial of a new technique or method:

a) For administrative modifications: The clinical trial-hosting establishment shall report them to the Ministry of Health for information summarization.

b) For change of the principal investigator or the establishment hosting the clinical trial of the new technique or method, a dossier comprises:

- A written request for approval of changes in the clinical trial of the new technique or method, made using Form No. 07 provided in Appendix VI to this Decree;

- Documentary evidence of the respective changes.

c) For changes not falling into the cases specified at Points a and b of this Clause, a dossier comprises:

- A written request for approval of changes in the clinical trial of the new technique or method, made using Form No. 07 provided in Appendix VI to this Decree;

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- The updated versions of the respective documents specified in Clause 1 of this Article which have been changed;

- A record of appraisal by the grassroots-level council of ethics in biomedical research.

4. A dossier of application for approval of outcomes of the clinical trial of a new technique or method comprises:

a) A written request for approval of outcomes of the clinical trial of the new technique or method, made using Form No. 08 provided in Appendix VI to this Decree;

b) A copy of the approved trial protocol;

c) A copy of the decision on approval of the trial;

d) A record of appraisal of the outcomes of the clinical trial of the new technique or method by the grassroots-level council of ethics in biomedical research;

dd) A clinical study report of the clinical trial of the new technique or method, made using Form No. 09 provided in Appendix VI to this Decree;

e) The technical process of the new technique or method as specified at Point a, Clause 1, Article 97 of this Decree.

5. Requirements for documents:

a) Dossiers for clinical trials of new techniques and methods shall be written in Vietnamese language. In the case where they are not written in Vietnamese, there must be notarized translations of such documents into Vietnamese;

b) Documents issued by foreign regulatory authorities shall be consularly legalized in accordance with regulations of law regulations on consular legalization, unless otherwise consular legalization is exempted in accordance with the law.

Article 103. Processes and procedures for allowance of clinical trial of a new technique or method in medical examination and treatment

1. Processes and procedures for allowance of clinical trial of a new technique or method in medical examination and treatment include: Approval of the clinical trial; approval of changes to the clinical trial; approval of outcomes of the clinical trial.

2. Process and procedures for approval of the clinical trial

a) The clinical trial-hosting establishment shall send directly, online or by post 01 dossier of application for approval of the clinical trial to Ministry of Health;

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b) The Ministry of Health shall check the validity of the dossier within 05 working days from the date of receiving of the dossier. In the case where the dossier is valid, within 02 working days, the Ministry of Health will transfer the dossier to the National Council of Ethics for appraisal and evaluation of ethic aspects in the trial. In the case where the dossier is invalid, within 02 working days, it shall issue a written notice and specific instructions for the establishment to supplement the dossier.

The clinical trial-hosting establishment shall complete the dossier within a maximum of 60 days from the date of receiving the written notice. After this deadline, the procedures for approval of clinical trial must be done again from the beginning;

c) The National Council of Ethics shall appraise and evaluate ethical aspects in the trial on a monthly basis;

d) Within 05 working days from the date of receiving the certificate of acceptance of the clinical trial from the National Council of Ethics and documents attached thereto, the Ministry of Health shall decide to approve the clinical trial.

3. Process and procedures for approval of changes to the clinical trial

a) The clinical trial-hosting establishment shall send directly, online or by post 01 dossier of application for approval of changes to the clinical trial to Ministry of Health.

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b) The Ministry of Health shall check the validity of the dossier within 05 working days from the date of receiving of the dossier. In the case where the dossier is invalid, within 02 working days, the Ministry of Health shall issue a written notice and specific instructions for the establishment to supplement the dossier until it is valid. The clinical trial-hosting establishment shall complete the dossier within a maximum of 60 days from the date of receiving the written notice. After this deadline, the procedures for approval of changes in the clinical trial must be done again from the beginning.

c) For changes specified at Point c, Clause 3, Article 102 of this Decree:

- In the case where the dossier is valid, within 02 working days, the Ministry of Health will transfer the dossier to the National Council of Ethics for approval;

- The National Council of Ethics shall appraise and evaluate ethical aspects in research on a monthly basis;

- Within 05 working days from the date of receiving the certificate of acceptance of changes to the clinical trial from the National Council of Ethics and documents attached thereto, the Ministry of Health shall decide to approve the changes to the clinical trial.

d) For changes specified at Point b, Clause 3, Article 102 of this Decree:

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within 07 working days from the date of receiving all valid documents, the Ministry of Health shall decide to approve the changes to the clinical trial.

4. Process, procedures, approval of outcomes of the clinical trial

a) The clinical trial-hosting establishment shall send directly, online or by post 01 dossier of application for approval of outcomes of the clinical trial in Vietnamese to the Ministry of Health;

b) The Ministry of Health shall check the validity of the dossier within 05 working days from the date of receiving of the dossier. In the case where the dossier is valid, within 02 working days, the Ministry of Health will transfer the dossier to the National Council of Ethics for appraisal. In the case where the dossier is invalid, within 02 working days, the Ministry of Health shall issue a written notice and specific instructions for the establishment to supplement the dossier.

The clinical trial-hosting establishment shall complete the dossier within a maximum of 60 days from the date of receiving the written notice. After this deadline, the procedures for approval of outcomes of the clinical trial must be done again from the beginning;

c) The National Council of Ethics shall appraise and evaluate ethical aspects in research on a monthly basis;

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d) Within 05 working days from the date of receiving the certificate of acceptance of outcomes of the clinical trial from the National Council of Ethics and documents attached thereto, the Ministry of Health shall decide to approve the outcomes of the clinical trials.

Article 104. Councils of ethics in biomedical research

1. The councils of ethics in biomedical research includes: National Ethics Committee in Biomedical Research and grassroots-level councils of ethics in biomedical research.

2. The Minister of Health shall specifically regulate the establishment, organization and operations of the councils of ethics in biomedical research.

Chapter V

MANAGEMENT AND USE OF MEDICAL EQUIPMENT AT MEDICAL EXAMINATION AND TREATMENT ESTABLISHMENTS

Article 105. Principles of management of medical equipment at medical examination and treatment establishments

1. Medical equipment employed at medical examination and treatment

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establishments must be authorized for marketing, purchased or sold, and received in accordance with law regulations on medical equipment management and relevant law regulations.

2. Medical examination and treatment establishments must ensure proper implementation of regulations on management and use of medical equipment in accordance with law regulations on medical equipment management and relevant law regulations.

3. Medical examination and treatment establishments shall ensure fundings for the maintenance, repair, inspection, calibration of medical equipment and training, improving, and updating knowledge on medical equipment used at the respective establishments for their staff in accordance with the laws.

4. Hospitals must arrange divisions and staff members to manage the use, inspection, maintenance, repair, inspection and calibration of medical equipment.

5. A staff member as specified in Clause 4 of this Article must obtain a certificate of training, refresher training, and updating of knowledge on medical equipment management in accordance with regulations of the Ministry of Health.

Article 106. Requirements for management, use, maintenance, repair, replacement of spare parts and components as well as inspection and calibration of medical equipment

1. Medical equipment employed in medical examination and treatment establishments must be recorded in files for management and monitoring in terms of: category; use; checking; maintenance; repair; replacement of spare parts and components; inspection and calibration.

2. The head of a medical examination and treatment establishment shall promulgate regulations on management, use, checking, maintenance, repair, replacement of spare parts and components, and preservation of medical equipment at the medical examination and treatment establishment following the manufacturers' user manuals and depending on the medical examination and treatment establishment's usage. For medical equipment that is public property, law regulations on management and use of public property shall prevail.

Chapter VI

MOBILIZATION AND ASSIGNMENT OF MEDICAL EXAMINATION AND TREATMENT ESTABLISHMENTS TO PARTICIPATE IN MEDICAL EXAMINATION AND TREATMENT IN CASE OF DISASTERS, CATASTROPHES, GROUP-A INFECTIOUS DISEASES OR STATE OF EMERGENCY

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Article 107. Assignment and mobilization of medical examination and treatment establishments to participate in medical examination and treatment in case of disasters, catastrophes, group-A infectious diseases or state of emergency

1. Chairpersons of People's Committees of provinces and centrally-run cities shall decide to establish, mobilize and assign medical examination and treatment establishments under their management to participate in medical examination and treatment in their localities or other localities in case of disasters, catastrophes, group-A infectious diseases or state of emergencies (hereinafter referred to as mobilized and assigned medical examination and treatment establishments).

2. The Minister of Health shall establish, mobilize and assign medical examination and treatment establishments under management to support localities and medical examination and treatment units in case of disasters, catastrophes, group-A infectious diseases or state of emergencies at their request.

3. The Minister of National Defense and the Minister of Public Security shall establish, mobilize and assign medical examination and treatment establishments under their management to support localities and medical examination and treatment units in case of disasters, catastrophes, group-A infectious diseases or state of emergencies at their request.

4. Mobilized and assigned medical examination and treatment establishments are obliged to participate in medical examination and treatment in case of disasters, catastrophes, group-A infectious diseases or state of emergencies under decisions on establishment, mobilization, and assignment of medical examination and treatment establishments issued by competent authorities.

Article 108. Recurrent expenditures of state-run medical examination and treatment establishments mobilized or assigned in accordance with Article 116 of the Law on Medical Examination and Treatment

1. Funds for assurance of recurrent expenditures of mobilized and assigned state-run medical examination and treatment establishments shall comply with the provisions of Clause 2, Article 117 of the Law on Medical Examination and Treatment.

2. Recurrent expenditures of state-run medical examination and treatment establishments that are established under Clause 1, Article 116 of the Law on Medical Examination and Treatment shall comply with the Government's regulations applicable to public non-business units that cover by themselves recurrent expenditures, including:

a) Salaries, wages, allowances, contributions specified by law and other regimes (if any), of persons working at other establishments who are mobilized

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or assigned to participate in medical examination and treatment in case of disasters, catastrophes, group-A infectious diseases or state of emergency (hereinafter referred to as mobilized and assigned persons);

b) Allowances and other regimes (if any) in accordance with the Government's regulations for mobilized or assigned persons who do not receive salaries or wages in accordance with the law provisions.

c) Medical examination and treatment expenses, and policies for patients treated in case of disasters, catastrophes, group-A infectious diseases or state of emergency, including other comorbidities (if any);

d) Food allowance (if any), accommodation rental (for persons staying at accommodation facilities) or group accommodation allowance in accordance with regulations on per diem regime; and travel expenses (drop off, pick up) for mobilized or assigned persons while working at medical examination and treatment establishments;

dd) Per diem allowances in accordance with regulations for mobilized or assigned persons;

e) Incurred expenses related to medical examination and treatment activities in case of disasters, catastrophes, group-A infectious diseases or state of emergency as specified.

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3. Recurrent expenditures of state-run medical examination and treatment establishments that are mobilized or assigned in accordance with Clause 2, Article 117 of the Law on Medical Examination and Treatment shall comply with the financial autonomy regimes of public non-business units, including expenditures as specified in Clause 2 of this Article.

In the case where medical examination and treatment establishments have the total revenue less than the total recurrent expenditures within a year, they are entitled to recurrent expenditure support from the state budget.

Article 109. Responsibilities to pay expenses

1. Authorities and non-business units managing cadres, civil servants, public employees and employees shall be responsible for:

a) Paying per diem allowance for the days of travel from assigning establishments to assigned establishments in accordance with regulations for mobilized or assigned persons;

b) Making a list of expenses paid to mobilized or assigned persons when participating in working at medical examination and treatment establishments that are established, mobilized or assigned in accordance with Point a of this Clause, then sending it to such medical examination and treatment establishments to be reimbursed.

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2. Medical examination and treatment establishments that receive mobilized or assigned persons shall be responsible for:

a) Paying the expenses specified in Clause 2, Article 108 of this Decree from the date of receiving mobilized or assigned persons;

b) Reimbursing expenses to authorities and non-business units managing cadres, civil servants, public employees, and employees according to the list of expenses specified at Point b, Clause 1 of this Article.

Article 110. Payment of medical examination and treatment costs for patients treated in case of disasters, catastrophes, group-A infectious diseases or state of emergency

1. The state budget funds shall cover medical examination and treatment costs in case of disasters, catastrophes, group-A infectious diseases or state of emergency, including:

a) Costs of medical examination, hospital stay, technical and testing services used for patients. Payment shall be carried out on the basis of the actual quantity of medical services used by patients and the prices for medical examination and treatment services covered by health insurance;

b) Costs of drugs, chemicals, medical equipment, whole blood and standard blood products not yet included in the prices for medical examination and treatment services or used in technical services that have been used for patients or are not covered by the health insurance fund while the prices for such services have not yet been issued. Payment shall be carried out on the basis of the actual quantity of used services and the purchase prices in accordance with the law provisions on bidding. Costs of whole blood and standard blood products shall be paid in accordance with the instructions of the Minister of Health;

c) Technical services are not covered by the health insurance fund. Payment shall be carried out on the basis of the actual quantity of used medical services and the prices for medical examination and treatment services approved by competent authorities for such establishments or managing medical examination and treatment establishments.

2. Medical examination and treatment costs for other diseases during the treatment of group-A infectious diseases: The health insurance fund shall cover the medical examination and treatment costs for eligible health insurance beneficiaries and health insurance benefits shall be determined from the time when patients contract group-A infectious diseases until they have finished the treatment process. Patients contracting group-A infectious diseases who participate in health insurance must pay their jointly-paid costs and other expenses beyond the scope of health insurance benefits (if any) in accordance with the law provisions on health insurance.

3. In the case where medical examination and treatment establishments

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cannot separate the medical examination and treatment costs for group-A infectious diseases and other diseases to make payment from sources or cannot collect the costs incurred during the treatment process that patients are obliged to pay in accordance with regulations due to any of the force majeure causes specified in Clause 7 of this Article, such costs shall be covered by the state budget on the basis of the actual quantity of used medical services and the prices for medical examination and treatment services covered by health insurance.

4. Prices of services and lists of medical examination and treatment drugs covered by health insurance: apply according to the prices of services, medical equipment, and lists of medical examination and treatment drugs of medical examination and treatment establishments that are established, mobilized or assigned, or receiving hospitals.

5. For payment of medical examination and treatment costs at private medical examination and treatment establishments that competent provincial-level authorities assign to receive, manage, provide health care for and treat patients in case of disasters, catastrophes, group-A infectious diseases or state of emergency, the following principles shall be applied:

a) Medical examination and treatment costs at private medical examination and treatment establishments shall be covered by the state budget and health insurance fund according to the principles specified in Clauses 1 and 2 of this Article;

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b) Prices of services, lists of drugs and medical equipment, and prices of medical examination and treatment under health insurance for medical examination and treatment: the prices of such medical examination and treatment establishments shall be applied but not exceed the highest price of medical examination and treatment services of state-run medical examination and treatment establishments in localities;

c) Specialized health authorities under provincial-level People's Committees shall be responsible for signing contracts with private medical examination and treatment establishments assigned by competent provincial-level authorities to receive, manage, provide health care for and treatment of patients in case of disasters, catastrophes, group-A infectious diseases or state of emergency.

6. For payment of medical examination and treatment costs at medical examination and treatment establishments in the case where the number of hospitalized patients exceeds the number of hospital beds and there is not enough human resources to perform medical examination and treatment (including statistics on costs and technical services used by patients):

a) The state budget shall cover medical examination and treatment costs on the basis of the actual quantity of used services and the purchase prices in

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accordance with the law provisions on bidding.

In the case where medical examination and treatment establishments are not qualified to perform a number of technical services, they may sign medical service contracts with other medical examination and treatment establishments in localities that are qualified to perform such services in accordance with professional regulations. In such case, the state budget shall cover expenses according to the prices of medical examination and treatment services covered by health insurance that competent authorities have approved for medical examination and treatment establishments in charge of performing the services;

b) The health insurance fund shall cover medical examination and treatment costs for other diseases during the treatment of group-A infectious diseases according to the same scope and level of health insurance benefits as that applicable to cases of in-network medical examination and treatment; patients with group-A infectious disease who participate in health insurance must pay their jointly-paid costs and other expenses beyond the scope of health insurance benefits (if any) in accordance with the law provisions on health insurance;

c) In the case where medical examination and treatment establishments cannot separate the costs of medical examination and treatment for group-A infectious diseases and other diseases to make payment from sources or cannot collect the costs incurred during the treatment process that patients are obliged to pay in accordance with regulations due to any of the force majeure causes specified in Clause 7 of this Article, such costs shall be covered by the state budget on the basis of the actual quantity of used medical services and their purchase prices in accordance with the law provisions on bidding.

7. Causes of force majeure specified in this Article include:

a) A patient dies during the treatment but it is impossible for the medical examination and treatment establishment to contact his/her relatives;

b) A patient has no relatives and no personal identification papers by the time of admission to the medical examination and treatment establishment.

8. Medical examination and treatment establishments that are set up, mobilized and assigned in accordance with Article 116 of the Law on Medical Examination and Treatment and receiving hospitals shall be responsible for the accuracy and legality of reported data, ensuring that there is no loss, waste or negative conduct.

Article 111. Guidance on payment from the state budget to medical examination and treatment establishments set up under Article 116 of the Law on Medical Examination and Treatment

1. Preparation of estimates: Established, mobilized and assigned medical examination and treatment establishments and receiving hospitals shall prepare their estimates of recurrent expenditures and sends them to management

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authorities according to budget decentralization for summing up and submitting to financial authorities in accordance with regulations.

2. Based on estimates assigned by competent authorities, superior management authorities shall allocate and assign the estimates to established, mobilized, assigned medical examination and treatment establishments, and receiving hospitals within the scope of management in accordance with the law provisions on state budget.

3. The management, use, and settlement of expenditures shall be carried out in accordance with the law provisions on state budget. The units shall be responsible for the accuracy of data on medical examination and treatment costs in accordance with the law provisions.

4. Payment control and dossiers of recurrent expenditure control of a medical examination and treatment establishment shall be carried out as follows:

a) For medical examination and treatment costs covered by the state budget:

The receiving medical examination and treatment establishment shall be responsible for preparing a general list of medical examination and treatment costs, made according to the form specified in Appendix VII to this Decree, and sending it to the state treasury of the locality where transactions are made to withdraw and transfer estimates to non-business deposit accounts opened at the state treasury of the established, mobilized, assigned medical examination and treatment establishment or the receiving hospital.

The preparation of the list must follow the payment principles specified in Clauses 1, 3 and 4, Article 110 of this Decree and the medical examination and treatment establishment shall be responsible for the accuracy of expenditures spent on medical examination and treatment in the general list of medical examination and treatment costs, and management, use, and settlement of expenditures in accordance with the law provisions;

b) For remaining payments: The payments shall comply with Article 7 of the Government's Decree No. 11/2020/ND-CP dated January 20, 2020, providing administrative procedures in the field of Treasury State and other relevant legal regulations;

c) For private medical examination and treatment establishments assigned by provincial-level local authorities to receive, manage, provide health care for, and treat patients in case of disasters, catastrophes, group A-infectious disease or state of emergency, the state treasury shall make payment based on contracts and minutes of acceptance and contract liquidation between specialized health authorities under provincial-level People's Committees and private medical examination and treatment establishments.

5. In the case where a state-run medical examination and treatment

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establishment set up, mobilized, assigned in accordance with Article 116 of the Law on Medical Examination and Treatment gains revenues within a year that fail to cover its recurrent expenditures, the state budget shall cover the difference between such revenues and recurrent expenditures.

Article 112. Transfer of drugs and medical equipment purchased by the finalized state budget or donated or aided for activities serving prevention, control, and remediation of consequences in case of disasters, catastrophes, group-A infectious diseases or state of emergency

Medical examination and treatment establishments are allowed to use drugs and medical equipment that have been purchased by the finalized state budget or donated or aided for activities serving prevention, control, and remediation of consequences in case of disasters, catastrophes, group-A infectious diseases or state of emergency but not yet fully used for medical examination and treatment in order to minimize waste.

1. Payment principles upon being used for medical examination and treatment

a) For drugs and medical equipment purchased by the state budget for activities serving prevention, control, and remediation of consequences in case of disasters, catastrophes, group-A infectious diseases or state of emergency that are included in the list of drugs and medical equipment covered by the health insurance fund:

- If patients participate in health insurance: medical examination and treatment establishments shall be only entitled to the payment and collect payment from the jointly-paid amount of patients at the purchase prices in accordance with the law provisions on bidding but it shall not be higher than the prices paid by social insurance authorities to medical examination and treatment establishments;

- If patients do not participate in health insurance: medical examination and treatment establishments shall only collect payment from patients at the purchase prices in accordance with the law provisions on bidding but it shall not be higher than the highest price paid by social insurance authorities to state-run medical examination and treatment establishments in localities;

If the prices paid by the health insurance fund are not available, medical examination and treatment establishments may collect payment at the prices paid by the health insurance fund to other medical examination and treatment establishments in provinces or centrally-run cities. If the prices paid by the health insurance fund to other medical examination and treatment establishments in centrally-run provinces or cities are not available, medical examination and treatment establishments may collect payment at the purchase prices in accordance with the law provisions on bidding;

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b) For drugs and medical equipment purchased by the finalized state budget for activities serving prevention, control, and remediation of consequences in case of disasters, catastrophes, group-A infectious diseases or state of emergency that are not included in the list of drugs and medical equipment covered by the health insurance fund: Medical examination and treatment establishments shall only collect payment from patients at the purchase prices in accordance with the law provisions on bidding.

c) For drugs and medical equipment donated or aided for activities serving prevention, control, and remediation of consequences in case of disasters, catastrophes, group-A infectious diseases or state of emergency: Medical examination and treatment establishments shall not collect payment from patients and the health insurance fund is not obliged to make payment for such establishments according to regulations.

2. The revenues collected by medical examination and treatment establishments shall be remitted into the state budget in accordance with the law provisions on state budget.

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Chapter VII

CONDITIONS FOR ASSURANCE OF MEDICAL EXAMINATION AND TREATMENT

Section 1

TRAINING SUBSIDIES, SCHOLARSHIPS, COST-OF-LIVING ALLOWANCES

Article 113. Policies on support and scholarships for learners majoring in psychiatry, anatomical pathology, forensic medicine, forensic psychiatry, infectious diseases and intensive care medicine

1. Subjects of support and scholarships:

a) The State shall subsidy tuition fees and cost-of-living expenses for postgraduate students of master's, doctoral level, level-I specialist, level-II specialist, resident doctor in psychiatry, anatomical pathology, forensic medicine, forensic psychiatry, infectious diseases and intensive care medicine (hereinafter referred to as leaners) at education institutions in the health discipline;

b) The State shall grant study promotion scholarships to learners at education institutions in the health discipline who have their academic training results reaching at least the good level and are not disciplined at the level of reprimand or higher during the period of consideration for scholarships.

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Study promotion scholarships for learners at private education institutions in the health discipline shall be carried out in accordance with current regulations;

c) The State shall grant policy scholarships to learners who are working at medical examination and treatment establishments in areas with difficult socio-economic conditions and areas with extremely difficult socio-economic conditions.

d) The State shall encourage organizations and individuals to grant scholarships or subsidy to learners.

2. The order and procedures for granting and considering scholarships; and principles for granting scholarships or subsidies shall be carried out in accordance with current regulations.

3. Levels of subsidies and scholarships:

a) Levels of subsidies for tuition fees:

- The levels of subsidies for tuition fees shall be carried out in accordance with the Government's Decree No. 81/2021/ND-CP dated August 27, 2021 on collection and management of tuition fees of education institutions affiliated to national education program; policies on tuition fee exemption, reduction, and financing for tuition fees; service fees in education and training sectors (hereinafter referred to as Decree No. 81/2021/ND-CP);

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- Learners at private education institutions in the health discipline shall pay the difference between the actual tuition fees of such education institutions and the State's subsidies.

b) The levels of cost-of-living allowances shall be carried out in accordance with the Government's Decree No. 116/2020/ND-CP dated September 25, 2020, providing policies on subsidy for tuition fees and cost-of-living expenses for pedagogical students (hereinafter referred to as Decree No. 116/2020/ND-CP).

c) The levels of study promotion scholarships shall be carried out in accordance with the Government's Decree No. 84/2020/ND-CP dated July 17, 2020 detailing a number of articles of the Law on Education (hereinafter referred to as Decree No. 84/2020/ND-CP).

d) The levels of policy scholarships:

- The learners who are working at medical examination and treatment establishments in areas with difficult socio-economic conditions shall be eligible for the scholarship levels equal to 80% of the base salary/month;

- The learners who are working at medical examination and treatment establishments in areas with extremely difficult socio-economic conditions shall be eligible for the scholarship levels equal to 100% of the base salary/month.

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4. Funding sources for implementation, preparation of estimates, payment of subsidies, grant of scholarships, management, use and settlement of funding sources, reimbursement of expenses, procedures for registering for grant of subsidies for tuition fees, cost-of-living allowances and scholarships shall comply with Decree No. 84/2020/ND-CP, Decree No. 116/2020/ND-CP, and Decree No. 81/2021/ND-CP.

Article 114. Determination of training needs, assignment of tasks, placement of orders or bidding

1. On an annual basis, provincial-level People's Committees shall a report on review, calculation and determination of the needs for recruitment and training of postgraduate students at master's, doctoral or specialist levels in psychiatry, anatomical pathology, forensic medicine, forensic psychiatry, infectious diseases and intensive care medicine in the enrollment year, send it to licensed education institutions before January 31, and publicize it through mass media or means of communication.

2. Based on the annual enrollment quotas according to regulations, education institutions shall publicly announce them to localities, organizations and individuals having the teacher training needs, and notify them on the portal of the Ministry of Education and Training, and their own websites.

3. Based on the annual enrollment quotas of education institutions and local training needs, authorities in charge of assigning tasks, placing orders, or bidding that have such needs shall issue decisions on assignment of tasks, placement of orders, or bidding for provision of training services with education institutions in one of the following forms:

a) Assigning tasks of postgraduate training at master's, doctoral, or specialist levels in psychiatry, anatomical pathology, forensic medicine, forensic psychiatry, infectious diseases and intensive care medicine to their affiliated education institutions;

b) Ordering services of postgraduate training at master's, doctoral, or specialist levels in psychiatry, anatomical pathology, forensic medicine, forensic psychiatry, infectious diseases and intensive care medicine from licensed education institutions;

c) Bidding for selection of education institutions providing services of postgraduate training at master's, doctoral, or specialist levels in psychiatry, anatomical pathology, forensic medicine, forensic psychiatry, infectious diseases and intensive care medicine.

4. Decisions on assignment of tasks and training contracts between authorities in charge of assigning tasks, placing orders, or bidding and education institutions must be based on the annual needs and plans for postgraduate training in psychiatry, anatomical pathology, forensic medicine, forensic psychiatry,

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infectious diseases and intensive care medicine, and must be compatible with the roadmaps specified in local educational development plans, or local annual and long-term plans on training human resources for the health sector.

5. The assignment of tasks, placement of orders, or bidding to train postgraduate students at master's, doctoral or specialist levels in psychiatry, anatomical pathology, forensic medicine, forensic psychiatry, infectious diseases and intensive care medicine shall comply with the Government's Decree No. 32/2019/ND-CP dated April 10, 2019, prescribing the assignment of tasks, placement of orders, or bidding for provision of public products and services covered by state budget funds for regular expenditures.

Section 2

FORMS OF ATTRACTING SOCIAL RESOURCES FOR MEDICAL EXAMINATION AND TREATMENT ACTIVITIES

Article 115. Borrowing loans to invest in infrastructure works and medical equipment

1. Medical examination and treatment establishments classified as 1, 2 or 3-group autonomy in accordance with regulations on the financial autonomy regimes of public non-business units may borrow loans to invest in infrastructure works and medical equipment in service of their operations.

2. Medical examination and treatment establishments shall report to superior management authorities for opinions on policies regarding investment loans before implementation. Units that have a management board or school board or university board shall report to the board for opinions on policies regarding investment loans before implementation. A report to superior management authorities shall include the following contents:

a) Necessity;

b) Objectives;

c) Scale and location of the project using loans;

d) Form of organization and operation;

dd) Plan on human resources to carry out activities using equipment or investment establishment using loans;

e) Project implementation period: construction duration and time of operation;

g) Feasibility of the loan plan;

h) Socio-economic efficiency of the project.

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3. Loan procedures shall comply with the law provisions on credit institutions and relevant documents.

4. Assets formed from loans shall be used as collateral in accordance with the Civil Code and relevant applicable laws.

5. The use of loans for investment shall comply with relevant laws.

Article 116. Regulations on socialization in medical examination and treatment activities

1. State-run medical examination and treatment establishments may rent or lease assets such as infrastructure and medical equipment in service of professional activities according to the assigned functions and tasks, or provide medical examination and treatment services as required. The renting and leasing of assets shall comply with the law provisions on management and use of public assets, and the selection of lessees and lessors shall comply with the law provisions on bidding. The lease period must not exceed the amortization period of assets as specified by law or must not exceed the life cycle of assets.

2. The renting and leasing of clinical services, paraclinical services, non-medical services, pharmacy services, and management and operation of medical examination and treatment establishments shall comply with the law provisions on bidding, and management and use of public assets.

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Article 117. Purchase of medical equipment on deferred or installment payment, and borrowing of medical equipment

1. Purchase of medical equipment on deferred or installment payment:

a) State-run medical examination and treatment establishments shall, based on medical equipment norms and their funding sources, decide to purchase medical equipment in the form of deferred or installment payment;

b) Procurement shall comply with the law provisions on bidding, in which dossiers of bidding for medical equipment procurement must clearly state the form of deferred payment or installment payment.

2. Borrowing of medical equipment shall comply with the civil laws.

3. The use of medical equipment in the forms specified in Clauses 1 and 2 of this Article in medical examination and treatment shall be included in the costs of medical examination and treatment services that must be collected from patients or covered by the health insurance fund in accordance with the law provisions on health insurance.

Article 118. Donation or aid from domestic and foreign organizations and individuals

1. Medical examination and treatment establishments may receive monetary aid, technical support and in-kind support from international

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authorities, organizations or foreign individuals for medical examination and treatment activities in accordance with the law provisions on management and use of official development assistance (ODA) and concessional loans from foreign donors, and non-refundable aid other than the official development assistance of foreign authorities, organizations and individuals for Vietnam.

2. Medical examination and treatment establishments may receive grants or donations in money, assets, vehicles, or items from domestic and foreign authorities, organizations, and individuals for their activities in accordance with the Law on Prevention and Combat of Corruption, laws on management and use of public assets and relevant laws.

3. Medical examination and treatment establishments may receive donation and aid in assets for epidemic prevention and control from domestic and foreign organizations and individuals without applying usage standards and norms. After announcing the end of the epidemic, it shall be handled in accordance with the law provisions on management and use of public assets.

4. Assets, vehicles and items (hereinafter referred to as assets) that are donated but have not completed the procedures to establish ownership by the entire people may be used in medical examination and treatment. Costs of medical examination and treatment services using such assets shall be collected from patients or covered by the health insurance fund in accordance with the law provisions on health insurance. Medical examination and treatment establishments shall be responsible for the provided medical quality and services engaged in such assets and may use their funds to maintain and repair the assets during the course of use.

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Section 3

REGULATIONS ON CHARGES OF MEDICAL EXAMINATION AND TREATMENT SERVICES AND FUNDING FOR OTHER ACTIVITIES IN THE FIELD OF MEDICAL EXAMINATION AND TREATMENT

Article 119. Charges of medical examination and treatment services

1. Charges of medical examination and treatment services are the amount payable for each medical examination and treatment service, determined on the basis of each service, including:

a) Charge of medical examination;

b) Charge of hospital stay;

c) Charge of technical services used in medical examination and treatment. In the case where a patient is specified to use drugs, medical equipment, whole

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blood and standard blood products according to professional requirements when performing technical services, the medical examination and treatment establishment is entitled to collect from patients reasonable and valid expenses incurred in the performance of technical services (if any) as specified, and make payments to the social insurance authority.

2. Charges of medical examination and treatment services classified by service users include:

a) Charge of medical examination and treatment services covered by the health insurance fund;

b) Charge of medical examination and treatment services covered by the state budget;

c) Charge of medical examination and treatment services not included in the list of services covered by the health insurance fund that are not on-demand medical examination and treatment services;

d) Charge of on-demand medical examination and treatment services.

3. Total cost of medical examination and treatment services includes the constituents specified in Clause 2, Article 110 of the Law on Medical Examination and Treatment, specifically as follows:

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a) Labor cost:

- Labor cost for charges of medical examination and treatment services covered by the health insurance fund, charges of medical examination and treatment services covered by the state budget, charges of medical examination and treatment services not included in the list of services covered by the health insurance fund that are not on-demand medical examination and treatment services includes: salaries, wages, allowances and contributions as specified of officials, employees and outsourced workers (if any), including both direct and indirect workers; and specific costs to pay remuneration to experts and good doctors working at units, not exceeding 50% of their salaries and salary-based allowances;

- Labor cost for on-demand medical examination and treatment services is incorporated into the service charges according to the level of wages paid to employees. The head of units shall decide on the specific level of wages corresponding to the work performed in accordance with internal spending regulations or collective labor agreements or comparison methods to determine the level of wages.

b) Direct expenses:

Expenses incurred in the process of performing medical examination and treatment services and expenses incurred at departments or divisions in charge of performing such medical examination and treatment services shall be included in

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direct expenses (except for amortization expenses and labor costs), including:

- Expenses for drugs, chemicals, blood, blood products, and expenses for raw materials, materials, instruments, tools (including storage costs and losses according to regulations) used to perform technical services;

- Expenses for used fuel and energy, including electricity, water, fuel, waste treatment, environmental sanitation and infection control;

- Other direct expenses, including: maintenance, servicing, repair, inspection and calibration of medical equipment; maintenance, servicing and repair of fixed assets; purchase of replacement tools, instruments, and equipment directly used to perform technical services; expenses for application or rent of information technology services; and other direct expenses.

c) Expenses for amortization of medical equipment and fixed assets according to regulations. The amortization of medical equipment shall only apply to medical equipment that qualifies as fixed assets.

d) Administrative expenses are expenses of indirect management units to perform medical examination and treatment services and expenses for common activities of medical examination and treatment establishments, including:

- Expenses for maintenance, servicing and repair of medical equipment and fixed assets; expenses for inspection and calibration of assets, procurement of equipment, tools, instruments, supplies, vehicles, and stationery in service of management or indirect departments and general operations of the units;

- Expenses for environmental protection, infection control, and quality management; expenses for uniforms, clothing, labor protection, assurance of occupational safety and hygiene, health protection for employees, prevention of HIV infection, and vaccination for civil servants, public employees and workers;

- Expenses for training and scientific research; expenses for transfer of techniques and training to improve professional capacity;

- Expenses for electricity, water and fuel; charges for telecommunications and postal service; expenses for application or rent of information technology or services and management software; expenses for assurance of security and safety for patients; expenses for hygiene, environment protection and waste treatment; and other rental and purchasing expenses for medical examination and treatment;

- Expenses for hiring interpreters and translators; expenses for purchasing, printing, and photocopying documents and publications for professional use; expenses for communication, image and brand promotion as specified;

- Fees, charges, taxes (including land use levy), land rentals for business and service activities (if any); liability insurance in medical examination and treatment, and asset insurance; expenses for fire prevention and fighting; quality management expenses; expenses related to storage, loss, and destruction of drugs

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and supplies; risk provision expenses; expenses for liquidation and disposal of assets as specified;

- Loan interests (if any) and other administrative expenses.

4. Special allowances shall not be included in medical examination and treatment service charges, including allowances guaranteed by the state budget for medical staff in accordance with the law provisions.

5. The methods of determining medical examination and treatment service charges shall comply with regulations of the Ministry of Health. In cases of determining medical examination and treatment service charges by the cost method, the constituents of medical examination and treatment service charges shall be based on economic and technical norms (if any) and the cost levels shall be based on the criteria of classification suitable for medical examination and treatment activities.

6. The determination of medical examination and treatment service charges is based on the grounds in Clause 4, Article 110 of the Law on Medical Examination and Treatment:

a) The on-demand medical examination and treatment service charges are fully calculated with the constituents specified in Clause 3 of this Article;

b) For charges of medical examination and treatment services covered by the health insurance fund; charges of medical examination and treatment services covered by the state budget; charges of medical examination and treatment services not included in the list of services cover by the health insurance fund that are not on-demand medical examination and treatment services: The Ministry of Health shall assume the prime responsibility for, and coordinate with the Ministry of Finance, Ministry of Planning and Investment in, reporting to competent authorities for consideration and decision.

7. Upon payment of medical examination and treatment costs:

a) It is not required to list in detail the constituents incorporated into the charges for medical examination and treatment services;

b) Technical and economic norms and cost levels used in the process of establishing the charges for medical examination and treatment services shall not be used as a basis for payment for each specific medical examination and treatment service;

c) For on-demand medical examination and treatment services: The health insurance fund shall pay the medical examination and treatment charges within the scope of health insurance benefits (if any) in accordance with the law provisions on health insurance. Patients shall pay medical examination and treatment establishments the difference between the charges for on-demand medical examination and treatment services and the payment rates of the health

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insurance fund.

8. Private medical examination and treatment establishments that participate in medical examination and treatment covered by health insurance shall be paid the medical examination and treatment charges according to the charges for medical examination and treatment services on the list of services covered by the health insurance fund that has been approved by provincial-level People's Councils for state-run medical examination and treatment establishments in localities. Patients shall pay medical examination and treatment establishments the difference between the medical examination and treatment charges of private medical examination and treatment establishments and the charges for medical examination and treatment services on the list of services covered by the health insurance fund.

9. Provincial-level People's Councils shall prescribe the specific charges for medical examination and treatment services in accordance with Clause 6, Article 110 of the Law on Medical Examination and Treatment, and medical examination and treatment services in the following cases:

a) Services managed by local state-run medical examination and treatment establishments but the Ministry of Health has not specified the charges for such services;

b) Services that medical examination and treatment establishments under the Ministry of Health and other ministries and branches do not provide but local medical examination and treatment establishments provide.

Article 120. Funds for pre-hospital emergency care activities

1. Funds for pre-hospital emergency care activities are specified as follows:

a) The state budget shall allocate funds for investment in setting up facilities and equipment for the system of state-run pre-hospital emergency care establishments, and the medical emergency information and coordination system of state-run pre-hospital emergency care establishments in accordance with the Law on Public Investment;

b) The state budget shall cover expenses for transportation and use of medical examination and treatment services in the course of emergency transport in case of accidents, disasters, catastrophes, and group-A infectious diseases at the service charges specified by competent authorities;

c) The state budget shall cover expenses for management and operation of state-run pre-hospital emergency care establishments in accordance with the Government's regulations on financial sources of public non-business units.

2. Provincial-level People's Committees shall be responsible for:

a) Organizing the system of state-run pre-hospital emergency care establishments, and the medical emergency information and coordination system

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of state-run pre-hospital emergency care establishments in the localities under their management, ensuring compliance with the organizational model of local providers of such services;

b) Ensuring the budget according to state budget decentralization to implement regulations in Clause 1 of this Article;

c) Mobilizing social resources, and taking solutions to encourage organizations and individuals to invest and set up pre-hospital emergency care establishments.

3. The preparation, allocation, execution of estimates and finalization of payment funds from the state budget shall be carried out in accordance with the applicable provisions of the Law on Public Investment, the Law on State Budget, the Law on Accounting and other guiding documents.

Article 121. Expenses for nurturing, caring and providing medical examination and treatment for patients without relatives at medical examination and treatment establishments

1. Medical examination, treatment, caring and nurturing regimes for patients without relatives include:

a) Charges for medical examination and treatment in accordance with regulations on charges for medical examination and treatment services for medical examination and treatment establishments issued by competent authorities;

b) Monthly nurturing allowances for each subject during the period of treatment at medical examination and treatment establishments that are be equal to the allowance rates specified in Clause 1, Article 25 of the Government's Decree No. 20/2021/ND-CP dated March 15, 2021, providing social assistance policies for social protection beneficiaries (hereinafter referred to as Decree No. 20/2021/ND-CP);

c) Being equipped with items for daily activities: blankets, mosquito nets, mats, summer clothes, winter clothes, underwear, slippers, toothbrushes, personal sanitary napkins provided monthly for women of childbearing age and other expenses as specified;

d) Expenses for transporting patients from medical examination and treatment establishments to social assistance establishments. The basis for determining transportation expenses is the actual fuel consumption of vehicles used for transporting patients.

2. Funding sources shall be allocated in the following order of priority:

a) The health insurance fund shall cover the expenses eligible for health insurance and health insurance benefits in accordance with the Law on Health Insurance in the case where patients participate in health insurance;

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b) Funds for medical examination and treatment support specified in Clause 2, Article 111 of the Law on Medical Examination and Treatment;

c) Sources of donation, mobilization and other legal capital sources;

d) State budget sources in accordance with current state budget decentralization.

3. Preparation of estimates and payment methods from the state budget:

The preparation, allocation, execution of estimates and settlement of payment from the state budget shall be carried out in accordance with applicable regulations of the Law on State Budget, relevant legal regulations and the following regulations:

a) For state-run medical examination and treatment establishments:

- On an annual basis, the basis specified in Clause 1 of this Article of the previous year, after deducting the funding sources specified at Points a, b, and c, Clause 2 of this Article, shall be sent to direct superior management authorities;

- Superior management authorities shall review and incorporate such expenses into next year's budget estimate, send it to financial authorities at the same level for summing up, and submit to competent authorities to decide on reimbursement to medical examination and treatment establishments;

- Based on the state budget estimate assigned for reimbursement, state medical examination and treatment establishments shall withdraw the estimate at the state treasury to transfer it to non-business deposit accounts of medical examination and treatment establishments opened at the state treasury.

b) For private medical examination and treatment establishments:

- Private medical examination and treatment establishments participating in nurturing, caring, providing examination and treatment services for patients without relatives shall send a written request to specialized health authorities under provincial-level People’s Committees for supporting expenses according to the regime specified in Clause 1 of this Article in the previous year after deducting the funding sources at Points a, b, and c, Clause 2 of this Article;

- Specialized health authorities under provincial-level People’s Committees shall be responsible for making a report on reviewing and summing up expenses according to the regime of private medical examination and treatment establishments under their management, and sending it to financial authorities. The financial authorities shall be responsible for reviewing and submitting the report to People's Committees of provinces or centrally-run cities for consideration and resolution as specified.

c) Medical examination and treatment establishments shall be responsible for the accuracy of the amount of funds requested from the state budget,

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management, use, and settlement of funds in accordance with the law provisions.

Article 122. Burial expenses for cases of death specified at Point b, Clause 1, Point b, Clause 2, Article 73 of the Law on Medical Examination and Treatment and Clause 2, Article 95 of this Decree

1. Authorities, organizations and individuals organizing burials for cases of death specified at Point b, Clause 1, Point b, Clause 2, Article 73 of the Law on Medical Examination and Treatment, and Clause 2, Article 95 of this Decree shall be considered and supported for burial expenses in accordance with the rates specified in Clause 3, Article 25 of the Decree No. 20/2021/ND-CP.

2. Burial expenses specified in Clause 1 of this Article and expenses for preserving or hiring for preservation of bodies while awaiting processing as specified at Point b Clause 1, Point b Clause 2 Article 73 of the Law on Medical Examination and Treatment and Clause 2, Article 95 of this Decree shall be covered by the local budget.

Section 4

LIABILITY INSURANCE IN MEDICAL EXAMINATION AND TREATMENT

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Article 123. Principles of implementing professional liability insurance in medical examination and treatment

1. Professional liability insurance in medical examination and treatment is a type of insurance used to pay damages for medical complications occurring in the course of medical examination and treatment within the insurance contract period, and costs for legal actions related to these medical complications, except the case specified at Point d, Clause 2, Article 100 of the Law on Medical Examination and Treatment.

2. Insurance enterprises, branches of foreign non-life insurance enterprises and medical examination and treatment establishments may proactively agree on insurance conditions, insurance liability limits, and above-mentioned insurance premiums on the basis of risk assessment of medical examination and treatment establishments and related factors in accordance with the law provisions.

Article 124. Funding sources for purchase of professional liability insurance in medical examination and treatment

1. For non-public establishments: Funding sources for purchase of professional liability insurance in medical examination and treatment shall be paid by medical examination and treatment establishments.

2. For public medical examination and treatment establishments: Funding

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sources for purchase of professional liability insurance in medical examination and treatment shall be allocated from the financial sources of public non-business units in accordance with the Government's regulations on the financial autonomy mechanism of public non-business units.

Chapter VIII

GUIDANCE ON EXECUTION OF REGULATIONS ON IMPLEMENTATION ROADMAP; TRANSITIONAL REGULATIONS REGARDING PRACTICING LICENSES AND OPERATION LICENSES

Section 1

GRANT OF PRACTICING LICENSES DURING THE TRANSITION PERIOD FOR DOSSIERS SUBMITTED FROM JANUARY 1, 2024 UNTIL THE TIME OF TESTING FOR EVALUATION OF PRACTICING CAPACITY FOR THE TITLES OF DOCTOR, ASSISTANT DOCTOR, NURSE, MIDWIFE, LABORATORY TECHNICIAN, CLINICAL NUTRITIONIST, PRE-HOSPITAL EMERGENCY CARE PROVIDER AND CLINICAL PSYCHOLOGIST

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Article 125. Procedure for grant of medical examination and treatment practicing licenses

1. After completing a training program, a person who possesses a degree in health may choose one of three options for grant of a medical examination and treatment practicing license as follows:

a) The applicant may carry out the procedures to request for granting a medical examination and treatment practicing license.

Before preparing a dossier of application for grant of a medical examination and treatment practicing license, the applicant must complete his/her medical examination and treatment internship as specified in Article 129 of this Decree.

b) The applicant may continue participating in a specialist training program; after completing such training program, he/she may carry out the procedures to request for granting a medical examination and treatment practicing license with the scope of specialist practice.

Before preparing a dossier of application for grant of a medical examination and treatment practicing license, the applicant is not required to complete his/her medical examination and treatment internship as specified in Article 129 of this Decree.

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c) The applicant may continue participating in a training program for a master's or doctorate degree in the field of medical examination and treatment at foreign training institutions; after completing such training program, he/she may carry out the procedures to request for granting a medical examination and treatment practicing license with the scope of specialist practice.

Before preparing a dossier of application for grant of a medical examination and treatment practicing license, the applicant must complete his/her medical examination and treatment internship as specified in Article 129 of this Decree.

2. In the case where after being granted a practicing license as specified at Point a, Clause 1 of this Article or having a practicing certificate granted before January 1, 2024, the applicant continues participating in a specialist training program:

a) If having been granted a specialist degree, the applicant may prepare a dossier of application for modification of the practicing license within the scope of specialist practice without having to complete his/her internship;

b) If having been granted a basic specialist certificate, the applicant must complete his/her specialist internship corresponding to his/her specialty recorded on the basic specialist certificate until the total duration of basic specialist training and internship is 18 months (determined by the time of starting basic specialist training program). After completing his/her internship, the applicant may prepare a dossier of application for modification of the practicing license within the scope of specialist practice;

c) The applicant may continue participating in a training program for a master's or doctorate degree in the field of medical examination and treatment at foreign training institutions; after completing such training program and his/her internship as specified in Article 129 of this Decree, he/she may carry out the procedures to request for modifying the practicing license within the scope of specialist practice.

3. In the case where a practitioner participates in training courses and has been granted a professional technical training certificate as specified in Clause 3, Article 128 of this Decree or a certificate or written certification (including certificate or written certification granted before January 1, 2024) beyond the scope of practice that has been granted, he/she is not required to carry out the procedure for modifying the scope of practice, but based on the professional technical training certificate issued by a legal training institution and his/her capacity to perform professional techniques, the person in charge of expertise of the medical examination and treatment establishment shall decide in writing to allow the practitioner to perform trained techniques.

In the case where a practitioner is entitled to receive a transfer of

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techniques beyond the scope of practice that has been granted, he/she is not required to carry out the procedure for modifying the scope of practice, but based on his/her written certification of eligibility for performing techniques as specified at Point c, Clause 4, Article 85 of this Decree, the person in charge of expertise of the medical examination and treatment establishment shall decide in writing to allow the practitioner to perform transferred techniques.

4. In the case where a person has completed a specialist training program as specified at Point b, Clause 1 of this Article but does not file a dossier of application for grant of a practicing license within 24 months from the date of issuance of a specialist degree, he/she must re-undertake internship for such specialty within a sufficient period as specified in Article 129 of this Decree before filing a dossier of application for grant of a practicing license.

5. In the case where a person has been granted a specialist degree as specified at Point a, Clause 2 of this Article but does not file a dossier of application for modification of the practicing license within 24 months from the date of granting the degree, he/she must re-undertake internship for such specialty within a sufficient period as specified in Article 129 of this Decree before filing a dossier of application for modification of the practicing license.

6. In the case where a person has been granted a basic specialist certificate as specified at Point b, Clause 2 of this Article but does not file a dossier of application for modification of the practicing license within 24 months from the date of completing his/her internship as specified at Point b, Clause 2 of this Article, he/she must re-undertake internship for such specialty within a sufficient period as specified in Article 129 of this Decree before filing a dossier of application for modification of the practicing license.

7. In the case where a person has been granted both a degree in health and one or more of the following certification: a written certification of a herb doctor, a written certification of an owner of traditional herbal remedy, or a written certification of an owner of traditional healing method, he/she may apply for a practicing license under one of the titles specified in Article 26 of the Law on Medical Examination and Treatment and must follow the procedures of grant as specified in Clause 1 or Clause 2 of this Article. The scope of practice stated in a practicing license granted under the provisions of this Clause includes:

a) In case of having been granted a practicing license under one of the following titles: doctor, nurse, laboratory technician, midwife, clinical nutritionist, clinical psychologist or pre-hospital emergency care provider, the scope of practice shall include: the scope of practice of the title stated in his/her practicing license and the scope of practice corresponding to one or more of the following certification: written certification of a herb doctor, written certification of an owner of traditional herbal remedy, or written certification of an owner of traditional healing method;

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b) In case of having been granted a practicing license under one of the following titles: herb doctor, owner of traditional herbal remedy, or owner of traditional healing method, the scope of practice shall include: the scope of practice of the title stated in his/her practicing license and the scope of practice corresponding to the results of the examination and assessment of practicing capacity.

8. In the case where the applicant for a practicing license who is practicing at medical examination and treatment establishments under the people's armed forces wishes to be granted a medical examination and treatment practicing license by the Ministry of Health or specialized health authorities under provincial-level People's Committees, the practice must satisfy the regulations in Section 1, Chapter II of this Decree.

Article 126. Cases and conditions for grant of practicing licenses

1. Grant of a practicing license applies to the following cases:

a) A person who applies for a practicing license for the first time as specified at Point a, Clause 1, Article 30 of the Law on Medical Examination and Treatment.

b) A practitioner whose professional title stated in his/her practicing license is changed as specified at Point b, Clause 1, Article 30 of the Law on Medical Examination and Treatment.

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c) A person who falls into any of the cases specified in:

- Point c, Clause 2, Article 137 of this Decree;
- Clause 3, Article 137 of this Decree;
- Point c, Clause 4, Article 137 of this Decree;
- Point b, Clause 5, Article 137 of this Decree;
- Point c, Clause 6, Article 137 of this Decree;
- Clause 7, Article 137 of this Decree;
- Clause 8, Article 137 of this Decree;
- Clause 9, Article 137 of this Decree;
- Point c, Clause 10, Article 137 of this Decree.

d) A practitioner who fails to carry out the renewal procedures as specified at Point a, Clause 2, Article 134 of this Decree.

dd) A practitioner who has been granted a practicing license by a licensing authority under the people's armed forces but he/she does not continue to work in the people's armed forces, no longer wants to use the granted practicing license, and wishes to practice at a medical examination and treatment establishment not under the people's armed forces, and the period from the time he/she terminates

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to practice at a medical examination and treatment establishment under the people's armed forces until the time of application for grant of a practicing license shall be more than 60 months.

2. Conditions for grant of a practicing license for the titles of doctor, assistant doctor, nurse, midwife, laboratory technician, clinical nutritionist, prehospital emergency care provider or clinical psychologist include:

a) Possessing a professional degree as specified in Article 127 of this Decree or possessing a practicing license recognized as specified in Article 37 of this Decree that is suitable with the to-be-applied title;

b) Being physically fit to practice;

c) Satisfying the requirement on Vietnamese language proficiency as specified in Article 138 of this Decree or having an interpreter who meets the provisions of Article 139 of this Decree in case of a foreigner who is not fluent in Vietnamese;

d) Not falling into one of the cases specified in Article 20 of the Law on Medical Examination and Treatment or being sanctioned for administrative violations for the act of medical examination and treatment without a practicing license but the sanctioning period has not yet expired to be considered as not having been sanctioned for an administrative violation;

dd) Having completed his/her internship as specified in Article 129 of this Decree, except for the cases specified at Point b, Clause 1, Article 125 of this Decree.

Article 127. Requirements on degrees eligible for grant of practicing licenses

1. For the titles of doctor, nurse, midwife, laboratory technician (except for the title of laboratory technician with the scope of medical testing practice), clinical nutritionist (except for the title of clinical nutritionist with the scope of basic practice), prehospital emergency care provider or clinical psychologist:

a) Degrees for consideration for granting a practicing license in accordance with Article 8 of this Decree;

b) Resident doctor degrees in accordance with Clause 1, Article 128 of this Decree;

c) Level-I specialist degrees in accordance with Clause 1, Article 128 of this Decree;

d) Level-II specialist degrees in accordance with Clause 1, Article 128 of this Decree;

dd) Master's degrees in the field of medical examination and treatment;

e) Doctorate degrees in the field of medical examination and treatment.

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2. For the title of assistant doctor:

a) The title of assistant doctor with the scope of general practice:

- Intermediate degrees of assistant doctor, including graduate degrees granted by foreign education institutions recognized by the Minister of Labor, Invalids and Social Affairs as equivalent to intermediate degrees of assistant doctor. Such degrees must be granted before January 1, 2027;

- Associate degrees of general assistant doctor, including graduate degrees granted by foreign education institutions recognized by the Minister of Labor, Invalids and Social Affairs as equivalent to associate degrees of general assistant doctor;

- Medical bachelor's degrees granted by foreign education institutions recognized by the Minister of Education and Training as university level.

b) The title of assistant doctor with the scope of traditional medicine practice:

- Intermediate degrees of traditional medicine assistant doctor, including graduate degrees granted by foreign education institutions recognized by the Minister of Labor, Invalids and Social Affairs as equivalent to intermediate degrees of traditional medicine assistant doctor. Such degrees must be granted before January 1, 2027;

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- Associate degrees of traditional medicine assistant doctor or associate degrees of traditional medicine, including graduate degrees granted by foreign education institutions recognized by the Minister of Labor, Invalids and Social Affairs as equivalent to associate degrees of traditional medicine assistant doctor or associate degrees of traditional medicine;

3. For the title of laboratory technician with the scope of medical testing practice:

a) Intermediate degrees of medical testing techniques, including graduate degrees granted by foreign education institutions recognized by the Minister of Labor, Invalids and Social Affairs as equivalent to intermediate degrees of medical testing techniques;

b) Associate degrees of medical testing techniques, including graduate degrees granted by foreign education institutions recognized by the Minister of Labor, Invalids and Social Affairs as equivalent to associate degrees of medical testing techniques;

c) Bachelor's degrees of medical testing techniques, including graduate degrees granted by foreign education institutions recognized by the Minister of Education and Training as equivalent to bachelor's degrees of medical testing techniques;

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d) Bachelor's degrees in chemistry, biology, and pharmacy at university level (including degrees granted by foreign education institutions recognized by the Minister of Education and Training as university level), accompanied by certificate or certification of specialized training in medical testing techniques with a minimum training period of 03 months granted by training institutions in medical testing techniques, or postgraduate training degrees about testing expertise.

4. For the title of clinical nutritionist with the scope of clinical nutrition practice:

a) Associate degrees in nutrition, including graduate degrees granted by foreign education institutions recognized by the Minister of Labor, Invalids and Social Affairs as equivalent to associate degrees in nutrition;

b) Bachelor's degrees in nutrition, including degrees granted by foreign education institutions recognized by the Minister of Education and Training as bachelor's degrees in nutrition;

c) Degrees of doctor specified in Clause 1 of this Article and certificates of basic specialist training in nutrition.

Article 128. Requirements on specialist degrees, basic specialist training certificates, and specialized technical training certificates in medical examination, treatment, and clinical psychology

1. Requirements on specialist degrees, resident doctor degrees, level-I specialist degrees, level-II specialist degrees in the field of medical examination and treatment granted by training institutions:

a) Being granted by legal training institutions in accordance with the law provisions;

b) Having a minimum training period of 18 months.

2. Requirements on basic specialist training certificates granted by domestic training institutions:

a) Being granted by training institutions that have completed at least 01 training course to grant corresponding specialist degrees, or medical examination and treatment establishments that are practical training institutions meeting the provisions of Clause 2, Article 10 of the Government's Decree No. 111/2017/ND-CP dated October 5, 2017, prescribing the organization of practical training in the field of healthcare service (hereinafter referred to as Decree No. 111/2017/ND-CP), and such units are providing practical training in the discipline or specialty at the specialist level corresponding to the training programs for basic specialist training certificates;

b) Training institutions may develop, appraise and issue their own training programs and documents for basic specialist training certificates or use programs

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and documents of other training institutions when obtaining a written approval from such institutions; Program contents, learning load, and lecturers shall be consistent with the specialist degree training program of the corresponding discipline or specialty and be interconnected with the specialist training program;

c) Having a minimum training period of 09 months.

3. Requirements on certificates of specialized technical training in medical examination and treatment:

a) Being granted by education institutions with that have completed least 01 training course for grant of degrees according to the graduation discipline or level for granting medical examination and treatment practicing licenses with the corresponding titles, or being medical examination and treatment establishments authorized by competent authorities to implement corresponding specialized techniques for a minimum period of 06 months;

b) Training institutions may develop, appraise and issue their own training programs and documents for professional technical certificates or use programs and documents of other training institutions when obtaining a written approval from such institutions; Program contents, learning load, and lecturers shall be consistent with the list of professional techniques as specified by the Ministry of Health.

4. In the case where a specialist degree is used to modify the scope of practice in accordance with the provisions of Points a, b or c, Clause 1 Article 135 of this Decree, there must be the training start date after the date of granting the practicing license or practicing certificate or modifying the practicing license.

5. In the case where a practitioner possesses a basic specialist training certificate and wishes to modify the scope of practice in accordance with the provisions of Points a or b, Clause 1, Article 135 of this Decree, he/she must satisfy the following conditions:

a) The basic specialist training certificate must have the training start date after the date of granting the practicing license or practicing certificate, or modifying the practicing license;

b) He/she must complete the specialist internship corresponding to his/her specialty recorded on the basic specialist training certificate as a basis for modifying the practicing license. The total duration of training for the basic specialist training certificate and the internship shall be at least 18 months.

6. The training of degrees and certificates specified in Clauses 1, 2, 3 of this Article must be publicly announced by training institutions on their own websites.

Article 129. Requirements on medical examination and treatment internship for grant of practicing licenses

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1. The internship for interns from January 1, 2024 shall comply with the provisions of Section 1 Chapter II of this Decree, including internship for the titles of clinical nutritionist, pre-hospital emergency care provider or clinical psychologist as follows:

a) Internship period, location, and contents shall comply with the provisions of Section 1, Chapter II of this Decree.

b) An internship instructor must satisfy the following conditions:

- From January 1, 2024 to December 31, 2026: The internship instructor must be a practitioner whose scope of practice is consistent with the contents of internship instruction or a practitioner who has work experience consistent with the contents of internship instruction for 36 months or more;

- From January 1, 2027: The internship instructor must satisfy the conditions as specified in Clause 3, Article 7 of this Decree.

2. Regulations on certification of completion of internship for clinical nutritionist titles:

a) Certification of completion of internship as specified in Section 1, Chapter II of this Decree;

b) Documents certifying that applicants have worked in clinical nutrition for 9 months or more up to the date of application for grant of practicing licenses at medical examination and treatment establishments, in which the scope of professional practice includes clinical nutrition activities.

3. Regulations on certification of completion of internship for pre-hospital emergency care provider titles:

a) Certification of completion of internship as specified in Section 1, Chapter II of this Decree;

b) Documents certifying that applicants have worked on emergency duties for 9 months or more up to the date of application for grant of practicing licenses at one of the following establishments:

- Hospital emergency departments;

- Pre-hospital emergency care establishments;

- Emergency transport service providers established before January 1, 2024 with the scope of specialized emergency operations.

4. Regulations on certification of completion of internship for clinical psychologist titles:

a) Certification of completion of internship as specified in Section 1, Chapter II of this Decree;

b) Documents certifying that applicants have worked in clinical

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psychology for 9 months or more up to the date of application for grant of practicing licenses at one of the following establishments:

- Clinical psychology establishments;

- Hospitals that have specialized scope of operations in psychiatry or have a specialized department in clinical psychology.

5. The interns before January 1, 2024 in accordance with the Law No. 40/2009/QH12 on Medical Examination and Treatment are entitled to:

a) Apply the internship period as specified in Article 3 of this Decree;

b) Incorporate the internship period before January 1, 2024 into the total internship period but the applicants must ensure the internship period as specified in Article 3 of this Decree before December 31, 2024.

Article 130. Dossiers and procedures for grant of practicing licenses

1. For a person applying for a practicing license for the first time specified at Points a and b, Clause 1, Article 30 of the Law on Medical Examination and Treatment, a dossier shall comprise:

a) A written request, made using Form No. 08 provided in Appendix I to this Decree.

b) A valid copy of one of the following documents:

- Professional degree (not applicable to the cases where the professional degree has been connected and shared on the information system on management of medical examination and treatment activities or the national healthcare database);

- Practicing license that has been recognized in accordance with Article 37 of this Decree (not applicable to the cases where the results of recognition of the practicing license have been connected and shared on the information system on management of medical examination and treatment activities or the national healthcare database).

c) In cases of application for grant of a practicing license with the scope of specialist practice, in addition to the documents specified at Point b of this Clause, the applicant must submit a valid copy of one of the specialist degrees specified at Points b, c, d, dd or e, Clause 1, Article 127 of this Decree (not applicable to the cases where the specialist degrees have been connected or shared on the information system on management of medical examination and treatment activities or the national healthcare database).

d) The original or a valid copy of health examination certificate issued by a qualified medical examination and treatment establishment (not applicable to the cases where the health examination results have been connected or shared on the information system on management of medical examination and treatment

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activities or the national healthcare database) or a valid copy of the work permit in the case where a work permit is required in accordance with the Labor Code.

dd) A valid copy of one of the following documents:

- Certificate of Vietnamese proficiency as specified in Article 138 of this Decree (not applicable to the cases where the certificate has been connected or shared on the information system on management of medical examination and treatment activities or the national healthcare database);

- Certificate of interpreting qualifications of the interpreter as specified in Article 139 of this Decree in the cases where a foreigner is not fluent in Vietnamese (not applicable to the cases where the certificate has been connected or shared on the information system on management of medical examination and treatment activities or the national healthcare database), accompanied by the interpreter's labor contract with the medical examination and treatment establishment where the foreigner intends to work.

e) Practitioner's resume, made using Form No. 09 provided in Appendix I to this Decree (not applicable to the cases where the practitioner's resume has been connected or shared on the information system on management of medical examination and treatment activities or the national healthcare database).

g) The original or a valid copy of certificate of completion of internship, made using Form No. 07 provided in Appendix I to this Decree, for the cases specified at Points a and c, Clause 1, Clause 4, Article 125 of this Decree (not applicable to the cases where the internship results have been connected or shared on the information system on management of medical examination and treatment activities or the national healthcare database).

h) 02 portrait photos sized 04 cm x 06 cm, taken on a white background within a period of no more than 06 months up to the time of application for a practicing license (not applicable to the cases where the applicant has posted photos when carrying out the administrative procedures in the electronic environment).

2. For the cases specified at Points d and dd, Clause 1, Article 126 and the cases where their practicing licenses are revoked as specified at Point c Clause 2 Article 137, Point c Clause 3 Article 137, Point b Clause 4 Article 137, Clause 7 Article 137, Clause 8 Article 137, Clause 9 Article 137, Point c Clause 10 Article 137 of this Decree, a dossier shall comprise:

a) Documents specified in Clause 1 of this Article;

b) The original or a valid copy of the decision on revocation of the practicing license (not applicable to the cases where the decision on revocation of the practicing license has been connected or shared on the information system on management of medical examination and treatment activities or the national healthcare database).

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3. For the cases where an applicant has his/her practicing license revoked as specified at Point c, Clause 6, Article 137 of this Decree due to falling into one of the cases specified in Clauses 1, 2, 3, 4 or 6, Article 20 of the Law on Medical Examination and Treatment (Point dd, Clause 1, Article 35 of the Law on Medical Examination and Treatment), a dossier shall comprise:

a) Documents specified in Clause 1 of this Article.

b) The original or a valid copy of the decision on revocation of the practicing license (not applicable to the cases where the decision on revocation of the practicing license has been connected or shared on the information system on management of medical examination and treatment activities or the national healthcare database).

c) One of the following documents:

- The original or a valid copy of documents from competent authorities concluding that the practitioner is not guilty or not banned from practicing in cases of criminal prosecution but there has been a written conclusion that the practitioner is not guilty or not banned from practicing (Clause 1, Article 20 of the Law on Medical Examination and Treatment);

- The original or a valid copy of certificate of completion of probation period or certificate of completion of court judgment or decision (Clauses 2, 3 and 4, Article 20 of the Law on Medical Examination and Treatment);

- The original or a valid copy of documents from competent authorities determining that the practitioner has full civil act capacity or has no difficulty in cognition or behavior control or has no civil act capacity restricted (Clause 6, Article 20 of the Law on Medical Examination and Treatment).

4. A dossier of application for grant of a practicing license as specified at Point a, Clause 7, Article 125 of this Decree shall comprise:

a) Documents specified in Clause 1 of this Article.

b) A valid copy of one or more of the following documents (not applicable to the cases where these documents have been connected or shared on the information system on management of medical examination and treatment activities or the national healthcare database):

- Herb doctor certificate;

- Certificate of an owner of traditional herbal remedy;

- Certificate of an owner of traditional healing method.

5. Procedures for grant of a practicing license:

a) An applicant for a practicing license shall file 01 dossier of application for grant of a practicing license corresponding to each case specified in Clauses 1 thru 4 of this Article and pay fees in accordance with the law provisions on fees

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and charges to an authority competent to grant practicing licenses specified in Article 28 of the Law on Medical Examination and Treatment (hereinafter referred to as licensing authority);

b) A licensing authority shall grant a practicing license within 30 days from the date of receipt of a complete dossier. In the case where a practicing license is not granted, the licensing authority must issue a written response and clearly state the reasons.

In the case where it is necessary to verify documents containing foreign elements in the application for a practicing license, the time limit for granting a practicing license is 30 days from the date of verification results.

Article 131. Cases and conditions for re-grant of practicing licenses

1. Re-grant of a practicing license applies to the following cases:

a) The practicing certificate has been granted before January 1, 2024, and the practicing license is lost or damaged;

b) The practicing certificate has been granted before January 1, 2024, and the practicing license has a change in the information about full name, date of birth and personal identification number, for a Vietnamese practitioner; and passport number and citizenship, for a foreign practitioner;

c) The practitioner whose granted practicing certificate or license is revoked falls into the case of re-grant of practicing licenses in accordance with Article 137 of this Decree;

d) The practicing license is granted ultra vires as specified at Point d, Clause 1, Article 31 of the Law on Medical Examination and Treatment;

dd) A practitioner who has been granted a practicing license by a licensing authority under the people's armed forces but he/she does not continue to work in the people's armed forces, no longer wants to use the granted practicing license, and wishes to practice at a medical examination and treatment establishment not under the people's armed forces, and the period from the time he/she terminates to practice at a medical examination and treatment establishment under the people’s armed forces until the time of application for grant of a practicing license shall be more than 24 months.

e) A practitioner who has been granted a practicing license by a licensing authority under the people's armed forces but he/she does not continue to work in the people's armed forces, no longer wants to use the granted practicing license, and wishes to practice at a medical examination and treatment establishment not under the people's armed forces, and the period from the time he/she terminates to practice at a medical examination and treatment establishment under the people’s armed forces until the time of application for grant of a practicing license shall be more than 24 months to less than 60 months.

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2. Conditions for re-grant of a practicing license:

a) The applicant shall satisfy the conditions for re-grant of practicing licenses in accordance with Clause 2, Article 31 of the Law on Medical Examination and Treatment;

b) The practicing certificate that has been granted before January 1, 2024 in accordance with the Law No. 40/2009/QH12 on Medical Examination and Treatment and falls into the cases of re-grant specified at Points a, b, d, Clause 1 of this Article is entitled to be re-granted into a practicing license in accordance with the Law No. 15/2023/QH15 on Medical Examination and Treatment and this Decree.

Article 132. Dossiers and procedures for re-grant of practicing licenses

1. For the cases where the practicing license is lost or damaged as specified at Point a, Clause 1, Article 131 of this Decree, a dossier of application for re-grant of a practicing license shall comprise:

a) A written request, made using Form No. 08 provided in Appendix I to this Decree;

b) The original or a valid copy of the granted practicing license (if any) (not applicable to the cases where the practicing license has been connected or shared on the information system on management of medical examination and treatment activities or the national healthcare database);

c) 02 portrait photos sized 04 cm x 06 cm, taken on a white background within a period of no more than 06 months up to the time of application for a practicing license (not applicable to the cases where the applicant has posted photos when carrying out the administrative procedures in the electronic environment).

2. For the cases where the practicing license has a change in the information about full name, date of birth and personal identification number, for a Vietnamese practitioner; and passport number and citizenship, for a foreign practitioner as specified at Point b, Clause 1, Article 131 of this Decree, a dossier of application for re-grant of a practicing license shall comprise:

a) A written request, made using Form No. 08 provided in Appendix I to this Decree;

b) The original of the granted practicing license;

c) The original or a valid copy of documents proving the change (not applicable to the cases where information may be looked up and authenticated on the information system on management of medical examination and treatment activities or the national healthcare database);

d) 02 portrait photos sized 04 cm x 06 cm, taken on a white background

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within a period of no more than 06 months up to the time of application for a practicing license (not applicable to the cases where the applicant has posted photos when carrying out the administrative procedures in the electronic environment).

3. For the cases where the practicing license is revoked in accordance with Point a, Clause 2, Article 137 of this Decree because the dossier of application for the practicing license has been made in contravention of regulations (Point a, Clause 1, Article 35 of the Law on Medical Examination and Treatment), a dossier of application for re-grant of a practicing license shall comprise:

a) Documents specified in Clause 1, Article 14 of this Decree;

b) The original or a valid copy of the decision on revocation of the practicing license (not applicable to the cases where the decision on revocation of the practicing license has been connected or shared on the information system on management of medical examination and treatment activities or the national healthcare database);

c) 02 portrait photos sized 04 cm x 06 cm, taken on a white background within a period of no more than 06 months up to the time of application for a practicing license (not applicable to the cases where the applicant has posted photos when carrying out the administrative procedures in the electronic environment).

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4. For the cases where the practicing license is revoked in accordance with Point b, Clause 2, Article 137 of this Decree because the dossier of application for the practicing license has been made in contravention of regulations (Point a, Clause 1, Article 35 of the Law on Medical Examination and Treatment), a dossier of application for re-grant of a practicing license shall comprise:

a) Documents specified in Clause 1, Article 14 of this Decree;

b) The original or a valid copy of the decision on revocation of the practicing license (not applicable to the cases where the decision on revocation of the practicing license has been connected or shared on the information system on management of medical examination and treatment activities or the national healthcare database);

c) 02 portrait photos sized 04 cm x 06 cm, taken on a white background within a period of no more than 06 months up to the time of application for a practicing license (not applicable to the cases where the applicant has posted photos when carrying out the administrative procedures in the electronic environment).

5. For the cases where the practicing license is revoked in accordance with Point a, Clause 4, Article 137 of this Decree because the granted practicing license states the wrong professional title or scope of practice as compared to the dossier of application for the practicing license (Point c, Clause 1, Article 35 of

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the Law on Medical Examination and Treatment), a dossier of application for re-grant of a practicing license shall comprise:

a) A written request, made using Form No. 08 provided in Appendix I to this Decree;

b) The original or a valid copy of the decision on revocation of the practicing license (not applicable to the cases where the decision on revocation of the practicing license has been connected or shared on the information system on management of medical examination and treatment activities or the national healthcare database);

c) 02 portrait photos sized 04 cm x 06 cm, taken on a white background within a period of no more than 06 months up to the time of application for a practicing license (not applicable to the cases where the applicant has posted photos when carrying out the administrative procedures in the electronic environment).

6. For the cases where the practicing license is revoked in accordance with Point b, Clause 4, Article 137 of this Decree because the granted practicing license states the wrong professional title or scope of practice as compared to the dossier of application for the practicing license (Point c, Clause 1, Article 35 of the Law on Medical Examination and Treatment), a dossier of application for re-grant of a practicing license shall comprise:

a) A written request, made using Form No. 08 provided in Appendix I to this Decree;

b) A valid copy of the certificate of completion of internship, made using Form No. 07 provided in Appendix I to this Decree (not applicable to the cases where the internship results have been connected or shared on the information system on management of medical examination and treatment activities or the national healthcare database);

c) The original or a valid copy of the decision on revocation of the practicing license (not applicable to the cases where the decision on revocation of the practicing license has been connected or shared on the information system on management of medical examination and treatment activities or the national healthcare database);

d) 02 portrait photos sized 04 cm x 06 cm, taken on a white background within a period of no more than 06 months up to the time of application for a practicing license (not applicable to the cases where the applicant has posted photos when carrying out the administrative procedures in the electronic environment).

7. For the cases where the practicing license is revoked in accordance with Point a, Clause 5, Article 137 of this Decree because the practitioner has not practiced for 24 consecutive months (Point d, Clause 1, Article 35 of the Law on

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Medical Examination and Treatment), a dossier of application for re-grant of a practicing license shall comprise:

a) A written request, made using Form No. 08 provided in Appendix I to this Decree;

b) The original or a valid copy of the decision on revocation of the practicing license (not applicable to the cases where the decision on revocation of the practicing license has been connected or shared on the information system on management of medical examination and treatment activities or the national healthcare database);

c) The original or a valid copy of the certificate of completion of internship, made using Form No. 07 provided in Appendix I to this Decree (not applicable to the cases where the internship results have been connected or shared on the information system on management of medical examination and treatment activities or the national healthcare database);

d) 02 portrait photos sized 04 cm x 06 cm, taken on a white background within a period of no more than 06 months up to the time of application for a practicing license (not applicable to the cases where the applicant has posted photos when carrying out the administrative procedures in the electronic environment).

8. For the cases where the practicing license is revoked in accordance with Point a, Clause 6, Article 137 of this Decree because the practitioner falls into one of the cases banned from practice specified in Clauses 1, 2, 3, 4 and 6, Article 20 of the Law on Medical Examination and Treatment (Point dd, Clause 1, Article 35 of the Law on Medical Examination and Treatment), a dossier of application for re-grant of a practicing license shall comprise:

a) A written request, made using Form No. 08 provided in Appendix I to this Decree;

b) The original or a valid copy of the decision on revocation of the practicing license (not applicable to the cases where the decision on revocation of the practicing license has been connected or shared on the information system on management of medical examination and treatment activities or the national healthcare database);

c) One of the following documents:

- The original or a valid copy of documents from competent authorities concluding that the practitioner is not guilty or not banned from practicing in cases of criminal prosecution but there has been a written conclusion that the practitioner is not guilty or not banned from practicing (Clause 1, Article 20 of the Law on Medical Examination and Treatment);

- The original or a valid copy of certificate of completion of probation

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period or certificate of completion of court judgment or decision (Clauses 2, 3 and 4, Article 20 of the Law on Medical Examination and Treatment);

- The original or a valid copy of documents from competent authorities determining that the practitioner has full civil act capacity or has no difficulty in cognition or behavior control or has no civil act capacity restricted (Clause 6, Article 20 of the Law on Medical Examination and Treatment).

d) 02 portrait photos sized 04 cm x 06 cm, taken on a white background within a period of no more than 06 months up to the time of application for a practicing license (not applicable to the cases where the applicant has posted photos when carrying out the administrative procedures in the electronic environment).

9. For the cases where the practicing license is revoked in accordance with Point b, Clause 6, Article 137 of this Decree because the practitioner falls into one of the cases banned from practice specified in Clauses 1, 2, 3, 4 and 6, Article 20 of the Law on Medical Examination and Treatment (Point dd, Clause 1, Article 35 of the Law on Medical Examination and Treatment), a dossier of application for re-grant of a practicing license shall comprise:

a) A written request, made using Form No. 08 provided in Appendix I to this Decree;

b) The original or a valid copy of the decision on revocation of the practicing license (not applicable to the cases where the decision on revocation of the practicing license has been connected or shared on the information system on management of medical examination and treatment activities or the national healthcare database);

c) One of the following documents:

- The original or a valid copy of documents from competent authorities concluding that the practitioner is not guilty or not banned from practicing in cases of criminal prosecution but there has been a written conclusion that the practitioner is not guilty or not banned from practicing (Clause 1, Article 20 of the Law on Medical Examination and Treatment);

- The original or a valid copy of certificate of completion of probation period or certificate of completion of court judgment or decision (Clauses 2, 3 and 4, Article 20 of the Law on Medical Examination and Treatment);

- The original or a valid copy of documents from competent authorities determining that the practitioner has full civil act capacity or has no difficulty in cognition or behavior control or has no civil act capacity restricted (Clause 6, Article 20 of the Law on Medical Examination and Treatment).

d) A valid copy of the certificate of completion of internship, made using Form No. 07 provided in Appendix I to this Decree (not applicable to the cases

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where the internship results have been connected or shared on the information system on management of medical examination and treatment activities or the national healthcare database).

dd) 02 portrait photos sized 04 cm x 06 cm, taken on a white background within a period of no more than 06 months up to the time of application for a practicing license (not applicable to the cases where the applicant has posted photos when carrying out the administrative procedures in the electronic environment).

10. For the cases where the practicing license is revoked in accordance with Point a, Clause 10, Article 137 of this Decree because the practitioner himself/herself requests revocation of his/her practicing license (Point i, Clause 1, Article 35 of the Law on Medical Examination and Treatment), a dossier of application for re-grant of a practicing license shall comprise:

a) A written request, made using Form No. 08 provided in Appendix I to this Decree;

b) The original or a valid copy of the decision on revocation of the practicing license (not applicable to the cases where the decision on revocation of the practicing license has been connected or shared on the information system on management of medical examination and treatment activities or the national healthcare database);

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c) 02 portrait photos sized 04 cm x 06 cm, taken on a white background within a period of no more than 06 months up to the time of application for a practicing license (not applicable to the cases where the applicant has posted photos when carrying out the administrative procedures in the electronic environment).

11. For the cases where the practicing license is revoked in accordance with Point b, Clause 10, Article 137 of this Decree because the practitioner himself/herself requests revocation of his/her practicing license (Point i, Clause 1, Article 35 of the Law on Medical Examination and Treatment), a dossier of application for re-grant of a practicing license shall comprise:

a) A written request, made using Form No. 08 provided in Appendix I to this Decree;

b) The original or a valid copy of the decision on revocation of the practicing license (not applicable to the cases where the decision on revocation of the practicing license has been connected or shared on the information system on management of medical examination and treatment activities or the national healthcare database);

c) A valid copy of the certificate of completion of internship, made using Form No. 07 provided in Appendix I to this Decree (not applicable to the cases where the internship results have been connected or shared on the information

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system on management of medical examination and treatment activities or the national healthcare database).

d) 02 portrait photos sized 04 cm x 06 cm, taken on a white background within a period of no more than 06 months up to the time of application for a practicing license (not applicable to the cases where the applicant has posted photos when carrying out the administrative procedures in the electronic environment).

12. For the cases where the practicing license is granted ultra vires as specified in Point d, Clause 1, Article 31 of the Law on Medical Examination and Treatment, a dossier of application for re-grant of a practicing license shall comprise:

a) A written request, made using Form No. 08 provided in Appendix I to this Decree;

b) The granted practicing license;

d) 02 portrait photos sized 04 cm x 06 cm, taken on a white background within a period of no more than 06 months up to the time of application for a practicing license (not applicable to the cases where the applicant has posted photos when carrying out the administrative procedures in the electronic environment).

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13. For the cases specified at Point dd, Clause 1, Article 131 of this Decree, a dossier of application for re-grant of a practicing license shall comprise:

a) A written request, made using Form No. 08 provided in Appendix I to this Decree;

b) The original or a valid copy of documents certifying that the practicing license has been granted by a licensing authority under the people's armed forces, in which it clearly states the practicing license’s number, date of issue, place of issue, personal information, professional title and scope of practice;

c) The original or a valid copy of health examination certificate issued by a qualified medical examination and treatment establishment (not applicable to the cases where the health examination results have been connected or shared on the information system on management of medical examination and treatment activities or the national healthcare database) or a valid copy of the work permit in the case where a work permit is required in accordance with the Labor Code;

d) Practitioner's resume, made using Form No. 09 provided in Appendix I to this Decree (not applicable to the cases where the practitioner's resume has been connected or shared on the information system on management of medical examination and treatment activities or the national healthcare database).

dd) 02 portrait photos sized 04 cm x 06 cm, taken on a white background within a period of no more than 06 months up to the time of application for a

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practicing license (not applicable to the cases where the applicant has posted photos when carrying out the administrative procedures in the electronic environment).

14. For the cases specified at Point e, Clause 1, Article 131 of this Decree, a dossier of application for re-grant of a practicing license shall comprise:

a) A written request, made using Form No. 08 provided in Appendix I to this Decree;

b) The original or a valid copy of documents certifying that the practicing license has been granted by a licensing authority under the people's armed forces, in which it clearly states the practicing license's number, date of issue, place of issue, personal information, professional title and scope of practice;

c) The original or a valid copy of health examination certificate issued by a qualified medical examination and treatment establishment (not applicable to the cases where the health examination results have been connected or shared on the information system on management of medical examination and treatment activities or the national healthcare database) or a valid copy of the work permit in the case where a work permit is required in accordance with the Labor Code;

d) Practitioner's resume, made using Form No. 09 provided in Appendix I to this Decree (not applicable to the cases where the practitioner's resume has been connected or shared on the information system on management of medical examination and treatment activities or the national healthcare database);

dd) A valid copy of the certificate of completion of internship, made using Form No. 07 provided in Appendix I to this Decree (not applicable to the cases where the internship results have been connected or shared on the information system on management of medical examination and treatment activities or the national healthcare database);

e) 02 portrait photos sized 04 cm x 06 cm, taken on a white background within a period of no more than 06 months up to the time of application for a practicing license (not applicable to the cases where the applicant has posted photos when carrying out the administrative procedures in the electronic environment).

15. For the cases where a practitioner has been granted a practicing certificate before January 1, 2024 but it is lost or damaged, a dossier of application for re-grant of a practicing license shall comprise:

a) A written request, made using Form No. 08 provided in Appendix I to this Decree;

b) The original or a valid copy of the granted practicing certificate (if any) (not applicable to the cases where the practicing certificate has been connected or shared on the information system on management of medical examination and

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treatment activities or the national healthcare database);

c) 02 portrait photos sized 04 cm x 06 cm, taken on a white background within a period of no more than 06 months up to the time of application for a practicing license (not applicable to the cases where the applicant has posted photos when carrying out the administrative procedures in the electronic environment).

16. For the cases where a practitioner has been granted a practicing certificate before January 1, 2024 but it has a change in the information about full name, date of birth and personal identification number, for a Vietnamese practitioner; and passport number and citizenship, for a foreign practitioner, a dossier of application for re-grant of a practicing license shall comprise:

a) A written request, made using Form No. 08 provided in Appendix I to this Decree;

b) The original of the granted practicing certificate;

c) The original or a valid copy of documents proving the change (not applicable to the cases where information may be looked up and authenticated on the information system on management of medical examination and treatment activities or the national healthcare database);

d) 02 portrait photos sized 04 cm x 06 cm, taken on a white background within a period of no more than 06 months up to the time of application for a practicing license (not applicable to the cases where the applicant has posted photos when carrying out the administrative procedures in the electronic environment).

17. For the cases where a practitioner has his/her practicing certificate revoked before January 1, 2024 under Points a and b, Clause 1, Article 29 of the Law on Medical Examination and Treatment No. 40/2009/QH12, and the time from the date of revocation to the date of application for a practicing license does not exceed 24 months, a dossier of application for re-grant of a practicing license shall comprise:

a) A written request, made using Form No. 08 provided in Appendix I to this Decree;

b) The original or a valid copy of the decision on revocation of the practicing license (not applicable to the cases where the decision on revocation of the practicing license has been connected or shared on the information system on management of medical examination and treatment activities or the national healthcare database);

c) 02 portrait photos sized 04 cm x 06 cm, taken on a white background within a period of no more than 06 months up to the time of application for a practicing license (not applicable to the cases where the applicant has posted

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photos when carrying out the administrative procedures in the electronic environment).

18. Procedures for re-grant of a practicing license or practicing certificate granted before January 1, 2024:

a) The applicant for re-grant of a practicing license or practicing certificate granted before January 1, 2024 shall file 01 dossier of application for grant or re-grant of a practicing license corresponding to each case specified in Clauses 1 thru 17 of this Article and pay fees in accordance with the law provisions on fees and charges to an authority competent to grant practicing licenses;

b) An authority competent to grant practicing licenses shall re-grant a practicing license within 15 days from the date of receipt of a complete dossier. In the case where a practicing license is not re-granted, the licensing authority must issue a written response and clearly state the reasons.

c) In the case where it is necessary to verify documents containing foreign elements in the dossier of application for a practicing license, the time limit for re-granting a practicing license is 15 days from the date of having verification results.

Article 133. Cases and conditions for renewal of practicing licenses

1. Renewal of practicing licenses applies to cases in which practicing licenses expire as specified in Clause 2, Article 27 of the Law on Medical Examination and Treatment.

2. Conditions for renewal of practicing licenses shall comply with the provisions of Clause 2, Article 32 of the Law on Medical Examination and Treatment.

Article 134. Dossiers and procedures for renewal of practicing licenses

1. For the professional titles of doctor, assistant doctor, nurse, midwife, laboratory technician, clinical nutritionist, prehospital emergency care provider or clinical psychologist, a dossier of application for renewal of a practicing license shall comprise:

a) A written request, made using Form No. 08 provided in Appendix I to this Decree;

b) A valid copy of the granted practicing license (not applicable to the cases where the practicing license has been connected or shared on the information system on management of medical examination and treatment activities or the national healthcare database);

c) Documents proving that medical knowledge has been continuously updated in medical examination and treatment in accordance with regulations of the Minister of Health (not applicable to the cases where the updating results have

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been connected or shared on the information system on management of medical examination and treatment activities or the national healthcare database);

d) Health examination certificate issued by a qualified medical examination and treatment establishment (not applicable to the cases where the capacity examination results have been connected or shared on the information system on management of medical examination and treatment activities or the national healthcare database) or a valid copy of the work permit in the case where a work permit is required in accordance with the Labor Code.

2. Procedures for renewal of practicing licenses:

a) An applicant for renewal of a practicing license shall file 01 dossier as specified in Clause 1 of this Article and pay fees in accordance with the law provisions on fees and charges to an authority competent to grant practicing licenses for at least 60 days before the date the practicing license expires.

In cases of illness, accidents or force majeure at the time of submitting the dossier, the applicant must send be a written notification to the authority competent to grant practicing licenses in order to delay the submission of dossier.

A practitioner may delay the date of renewal of a practicing license many times but the total delay period shall not exceed 22 months from the date the practicing license expires.

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b) During the period from receipt of a complete dossier to the expiration date stated on the practicing license, the licensing authority shall be responsible for renewing or must have a written response clearly stating the reasons of refusal; By the expiration date stated on the practicing license, if there is no written response, the practicing license shall remain valid in accordance with regulations;

c) In the case where it is necessary to verify the practitioner's continuous updating of medical knowledge according to a program implemented by a foreign authority or organization, the time limit for implementing the renewal procedure shall be 15 days from the date of having verification results.

Article 135. Cases and conditions for modification of practicing licenses

1. Modification of practicing licenses applies to the following cases:

a) An applicant has been granted a practicing license or practicing certificate before January 1, 2024 but there is no specialty stated in the scope of practice, and he/she requests to add a specialty to the scope of practice;

b) An applicant has been granted a practicing license or practicing certificate before January 1, 2024 and there is already a specialty stated in the scope of practice, but he/she requests to add another specialty other than the specialty already granted within the scope of practice;

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c) An applicant has been granted a practicing license or practicing certificate before January 1, 2024, and there is already a specialty stated in the scope of practice, but he/she requests to change the specialty granted into another specialty and no longer practices in the specialty granted within the scope of practice;

d) An applicant has been granted a practicing license or practicing certificate before January 1, 2024 and then a certificate of an owner of traditional herbal remedy, or an owner of traditional healing method.

2. Conditions for modification of practicing licenses:

a) In the case where an applicant has been granted a practicing license or practicing certificate before January 1, 2024 but there is no specialty stated in the scope of practice, and he/she requests to add a specialty to the scope of practice: The applicant shall satisfy the following conditions:

- Possessing one of the training degrees as specified at Points b, c, d, dd or e, Clause 1, Article 127 of this Decree or possessing a basic specialist training certificate as specified in Clause 2, Article 128 of the Decree equivalent to the title on the practicing license and the specialty proposed for addition;

- Having completed the internship for the cases specified at Points b and c, Clause 2, Article 125 of this Decree.

b) In the case where an applicant has been granted a practicing license or practicing certificate before January 1, 2024 and there is already a specialty stated in the scope of practice, but he/she requests to add another specialty other than the specialty already granted within the scope of practice, the applicant shall satisfy the following conditions:

- Possessing one of the training degrees as specified at Points b, c, d, dd or e, Clause 1, Article 127 of this Decree or possessing a basic specialist training certificate as specified in Clause 2, Article 128 of the Decree equivalent to the title on the practicing license and the specialty proposed for addition;

- Having completed the internship for the cases specified at Points b and c, Clause 2, Article 125 of this Decree.

c) In the case where an applicant has been granted a practicing license or practicing certificate before January 1, 2024, and there is already a specialty stated in the scope of practice, but he/she requests to change the specialty granted into another specialty, the applicant shall satisfy the following conditions:

- Possessing one of the training degrees as specified at Points b, c, d, dd or e, Clause 1, Article 127 of this Decree equivalent to the title on the practicing license and the specialty proposed for change;

- Having completed the internship for the cases specified at Point c, Clause 2, Article 125 of this Decree.

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Article 136. Dossiers and procedures for modification of practicing licenses

1. For the case of adding a specialty to the scope of practice as specified at Points a and b, Clause 1, Article 135 of this Decree, a dossier of application for modification of a practicing license shall comprise:

a) A written request, made using Form No. 08 provided in Appendix I to this Decree.

b) A valid copy of the granted practicing license (not applicable to the cases where the practicing license has been connected or shared on the information system on management of medical examination and treatment activities or the national healthcare database) or the practicing certificate granted before January 1, 2024.

c) A valid copy of one of the following documents (not applicable to the cases where these documents have been connected or shared on the information system on management of medical examination and treatment activities or the national healthcare database):

- Degrees as specified at Points b, c, d, dd or e, Clause 1, Article 127 of this Decree;

- Basic specialist training certificates as specified in Clause 2, Article 128 of this Decree.

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d) The original or a valid copy of certificate of completion of the internship, made using Form No. 07 Appendix I issued together with the Decree (not applicable to the case where the internship results have been connected or shared on the information system on management of medical examination and treatment activities or the national healthcare database) for one of the following cases:

- The practitioner falls into the cases specified at Points b and c, Clause 2, Article 125 of this Decree;

- The practitioner falls into the cases specified in Clauses 5 and 6, Article 125 of this Decree.

2. For the case where an applicant has been granted a practicing license that has already stated the specialty in the scope of practice but he/she requests to change the specialty granted into another specialty and no longer practices in the specialty granted within the scope of practice as specified at Point c, Clause 1, Article 135 of this Decree, a dossier of application for modification of a practicing license shall comprise:

a) A written request, made using Form No. 08 provided in Appendix I to this Decree.

b) A valid copy of the granted practicing license (not applicable to the cases

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where the practicing license has been connected or shared on the information system on management of medical examination and treatment activities or the national healthcare database) or the practicing certificate granted before January 1, 2024.

c) A valid copy of degrees as specified at Points b, c, d, dd or e, Clause 1, Article 127 of this Decree (not applicable to the cases where these documents have been connected or shared on the information system on management of medical examination and treatment activities or the national healthcare database).

d) The original or a valid copy of certificate of completion of the internship, made using Form No. 07 Appendix I issued together with the Decree (not applicable to the case where the internship results have been connected or shared on the information system on management of medical examination and treatment activities or the national healthcare database) for one of the following cases:

- The practitioner falls into the cases specified at Point c, Clause 2, Article 125 of this Decree;

- The practitioner falls into the cases specified in Clause 5, Article 125 of this Decree.

3. For the case where an applicant has been granted a practicing license and then a certificate of an owner of traditional herbal remedy, or an owner of traditional healing method as specified at Point d, Clause 1, Article 135 of this Decree, a dossier of application for modification of a practicing license shall comprise:

a) A written request, made using Form No. 08 provided in Appendix I to this Decree.

b) A valid copy of the granted practicing license (not applicable to the cases where the practicing license has been connected or shared on the information system on management of medical examination and treatment activities or the national healthcare database) or the practicing certificate granted before January 1, 2024.

c) A valid copy of the certificate of an owner of traditional herbal remedy, or the certificate of an owner of traditional healing method (not applicable to the cases where these certificates have been connected or shared on the information system on management of medical examination and treatment activities or the national healthcare database).

4. Procedures for modification of a practicing license for the cases as specified in Clause 1, Article 136 of this Decree:

a) An applicant for modification of a practicing license shall file 01 dossier corresponding to each case specified in Clauses 1 thru 4 of this Article and pay fees in accordance with the law provisions on fees and charges to the licensing

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authority;

b) The licensing authority must modify the practicing license within 15 days from the date of receipt of a complete dossier; In case of refusal, the licensing authority shall issue a written response clearly stating the reasons;

Forms of modification of a practicing license: A decision on modification of the scope of practice shall be made using Form No. 10 provided in Appendix I to this Decree. The decision on modification of the scope of practice shall be an integral part of the granted practicing license.

c) In the case where it is necessary to verify documents containing foreign elements in a dossier of application for modification of a practicing license, the modification period is 15 days from the date of having verification results.

Article 137. Procedures for suspension of practice, handling after suspension of practice, procedures for revocation of practicing licenses, and handling after revocation of practicing licenses

1. Procedures for suspension of practice, handling after suspension of practice, and procedures for revocation of practicing licenses shall comply with the provisions of Articles 30, 31 and 32 of this Decree.

2. In the case where a practicing license is revoked because the dossier of application for grant of the practicing license has been made in contravention of regulations as specified at Point a, Clause 1, Article 35 of the Law on Medical Examination and Treatment: the applicant whose practicing license is revoked shall complete the dossier and refile the dossier for grant of a practicing license.

a) In the case where the applicant whose practicing license is revoked files a dossier of application for grant of a practicing license within 24 months from the issuing date of the revocation decision, he/she may be re-granted a practicing license without having to complete the internship again;

b) In the case where the applicant whose practicing license is revoked files a dossier of application for grant of a practicing license within a period of between 24 months and 60 months from the issuing date of the revocation decision, he/she must complete the internship before carrying out the procedures for re-grant of a practicing license;

c) In the case where the applicant whose practicing license is revoked files a dossier of application for grant of a practicing license within a period exceeding 60 months from the issuing date of the revocation, he/she must complete the internship before carrying out the procedures for grant of a practicing license.

3. In the case where a practicing license is revoked due to forgery of documents in a dossier for grant of the practicing license as specified Point b, Clause 1, Article 35 of the Law on Medical Examination and Treatment: the applicant shall only file the dossier of application for grant of the practicing

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license after:

a) In case of forging degree or certificate of completion of the internship in the dossier of application for grant of a practicing license: at least 05 years from the issuing date of the revocation decision;

b) In case of forging other documents in the dossier of application for grant of a practicing license: 03 years from the issuing date of the revocation decision.

4. In the case where a practicing license is revoked because the granted practicing license states the wrong professional title or scope of practice as compared to the dossier of application for grant of the practicing license as specified at Point c, Clause 1, Article 35 of the Law on Medical Examination and Treatment: the applicant whose practicing license is revoked must carry out the procedure for grant of a practicing license and shall not have to pay fees.

a) In the case where the applicant whose practicing license is revoked files a dossier of application for grant of a practicing license within 24 months from the issuing date of the revocation decision, he/she may be re-granted a practicing license without having to complete the internship again;

b) In the case where the applicant whose practicing license is revoked files a dossier of application for grant of a practicing license within a period of between 24 months and 60 months from the issuing date of the revocation decision, he/she must complete the internship before carrying out the procedures for re-grant of a practicing license;

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c) In the case where the applicant whose practicing license is revoked files a dossier of application for grant of a practicing license within a period exceeding 60 months from the issuing date of the revocation, he/she must complete the internship before carrying out the procedures for grant of a practicing license.

5. In the case where the practicing license is revoked because the practitioner has not practiced for 24 consecutive months as specified at Point d, Clause 1, Article 35 of the Law on Medical Examination and Treatment:

a) Within 36 months from the issuing date of the decision on revocation of the practicing license, if the applicant whose practicing license is revoked completes the internship, he/she shall comply with the procedure for re-grant of a practicing license;

b) Within 36 months from the issuing date of the decision on revocation of the practicing license, if the applicant whose practicing license is revoked fails to complete the internship, he/she shall comply with the procedure for grant of a practicing license.

6. In the case where a practicing license is revoked due to one of the cases specified in Clauses 1, 2, 3, 4 or 6, Article 20 of the Law on Medical Examination and Treatment:

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a) In the case where the applicant whose practicing license is revoked files the dossier of application for grant of a practicing license within 24 months from the date of the revocation decision, he/she may be re-granted a practicing license.

b) In the case where the applicant whose practicing license is revoked files the dossier of application for grant of a practicing license within a period of between 24 months and 60 months from the issuing date of the revocation decision, he/she must complete the internship before carrying out the procedures for re-grant of a practicing license;

c) In the case where the applicant whose practicing license is revoked files a dossier of application for grant of a practicing license within a period exceeding 60 months from the issuing date of the revocation, he/she must complete the internship before carrying out the procedures for grant of a practicing license.

7. In the case where a practicing license is revoked because the practitioner is concluded by the professional council specified in Article 101 of the Law on Medical Examination and Treatment, as committing professional and technical errors that are serious enough for revocation of practicing license (Point e, Clause 1, Article 35 of the Law on Medical Examination and Treatment): the applicant must complete the internship before carrying out the procedure for grant of a practicing license.

8. In the case where the practicing license is revoked because the practitioner has for the second time been concluded by the professional council specified in Article 101 of the Law on Medical Examination and Treatment as committing professional and technical errors that are serious enough for suspension from practice during the validity period of his/her practicing license (Point g, Clause 1, Article 35 of the Law on Medical Examination and Treatment): the applicant shall only file the dossier for grant of a practicing license after 12 months from the issuing date of the decision on revocation of the practicing license.

9. In the case where the practicing license is revoked because the practitioner has for the second time been concluded by a competent state authority as committing breaches of professional ethics that are serious enough for suspension from practice during the validity period of his/her practicing license (Point h, Clause 1, Article 35 of the Law on Medical Examination and Treatment): the applicant must complete the internship before carrying out the procedure for grant of a practicing license.

10. In the case where the practicing license is revoked because the practitioner himself/herself requests revocation of his/her practicing license in accordance with Point i, Clause 1, Article 35 of the Law on Medical Examination and Treatment but then requests for re-grant of a practicing license:

a) In the case where the applicant whose practicing license is revoked files

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a dossier of application for grant of a practicing license within 24 months from the issuing date of the revocation decision, he/she may be re-granted a practicing license without having to complete the internship again;

b) In the case where the applicant whose practicing license is revoked files a dossier of application for grant of a practicing license within a period of between 24 months and 60 months from the issuing date of the revocation decision, he/she must complete the internship before carrying out the procedures for re-grant of a practicing license;

c) In the case where the applicant whose practicing license is revoked files a dossier of application for grant of a practicing license within a period exceeding 60 months from the issuing date of the revocation, he/she must complete the internship before carrying out the procedures for grant of a practicing license.

Article 138. Criteria for recognition of practitioners who are proficient in Vietnamese or other languages in medical examination and treatment

1. A practitioner shall be recognized to be proficient in Vietnamese in medical examination and treatment when he/she is examined and recognized by an education institution specified in Article 140 of this Decree, except for the cases specified in Clause 3 of this Article.

2. In the case where a practitioner registers a language other than his/her mother tongue or Vietnamese for medical examination and treatment, he/she must be examined by an education institution specified in Article 140 of this Decree to recognize the practitioner as proficient in the language registered to use in medical examination and treatment, except for the cases specified in Clause 3 of this Article.

3. A practitioner may be recognized as proficient in Vietnamese or other languages in medical examination and treatment without having to undertake examination when he/she satisfies one of the following criteria:

a) Possessing a degree of intermediate level or higher in the medical field granted by a legal Vietnamese or foreign training institution and the language used during the training course is Vietnamese or the language registered to use in medical examination and treatment;

b) Possessing a certificate of completion of specialized medical training courses with a minimum training period of at least 12 months and the language used during the training course is Vietnamese or the language registered to use in medical examination and treatment;

c) Possessing a bachelor's degree in Vietnamese or the language registered to use in medical examination and treatment that is granted by a legal Vietnamese or foreign training institution.

Degrees and certificates specified at Points a and b of this Clause must be

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granted within a period of no more than 05 years, up to the date of submitting the dossier.

Article 139. Criteria for recognition of interpreters who are qualified for interpretation in medical examination and treatment

1. An interpreter shall be recognized as qualified for language interpretation in medical examination and treatment when he/she is examined for recognition by an education institution specified in Article 140 of this Decree, except for the cases specified in Clause 2 of this Article.

2. An interpreter may be recognized as qualified for language interpretation in medical examination and treatment without having to undertake examination when he/she satisfies one of the following criteria:

a) Possessing a degree of intermediate level or higher in the medical field that is granted by a legal Vietnamese or foreign training institution and the language used during the training course is the language that the interpreter registers for interpretation;

b) Possessing a certificate of completion of specialized medical training courses with a minimum training period of at least 12 months and the language used during the training course is the language that the interpreter registers for interpretation;

c) Possessing a degree of intermediate level or higher in the medical field or a degree of herb doctor, and a bachelor's degree in a foreign language appropriate to the language that the interpreter registers for interpretation.

Degrees and certificates specified at Points a and b, Clause 2 of this Article must be granted within a period of no more than 05 years, up to the date of submitting the dossier.

3. An interpreter may only act as an interpreter for a medical examination and treatment practitioner at the same time when the practitioner is examining and treating a patient.

Article 140. Conditions for education institutions eligible for conducting testing and recognition of persons who are proficient in Vietnamese or other languages or qualified for interpretation in medical examination and treatment

An education institution may test and recognize a person as proficient in Vietnamese or other languages or qualified for interpretation in medical examination and treatment when satisfying the following conditions:

1. Being a Vietnam-based higher education institution that provides training in the health specialty.

2. Having a foreign language department or faculty of the language

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registered for testing and recognition.

3. Having a test bank used for testing and recognizing a person as proficient in Vietnamese or other languages or qualified for interpretation in medical examination and treatment.

Article 141. Dossiers and procedures for grant of certificates of education institutions eligible for conducting testing and recognition of persons who are proficient in Vietnamese or other languages or qualified for interpretation in medical examination and treatment

1. A dossier shall comprise:

a) Valid copies of documents proving the establishment and operation of the education institution;

b) Documents proving the presence of a foreign language department or faculty as specified in Clause 2, Article 140 of this Decree and a list of full-time lecturers of such foreign language department or faculty;

c) The test bank test bank used for testing and recognizing a person as proficient in Vietnamese or other languages or qualified for interpretation in medical examination and treatment regarding the language registered for testing and recognition.

2. In the case where an education institution that has been granted a certificate of eligibility to test and recognize persons as proficient in Vietnamese or other languages, or qualified for interpretation in medical examination and treatment requests additional languages for testing and recognition, a dossier shall comply with the provisions of Points b and c, Clause 1 of this Article.

3. Procedures:

a) An education institution shall submit to the Ministry of Health 01 dossier of application for a certificate of eligibility to test and recognize persons as proficient in Vietnamese or other languages, or qualified for interpretation in medical examination and treatment (hereinafter referred to as language testing) in accordance with Clause 1 of this Article;

b) Upon receiving the dossier, the Ministry of Health shall send the education institution a written receipt, made using Form No. 02 provided in Appendix I to this Decree;

c) Within 15 days from the date of receipt of the dossier, if such dossier is valid, the Ministry of Health must grant a certificate of eligibility for language testing in medical examination and treatment to the education institution, made using Form No. 02 provided in Appendix III to this Decree. In case of refusal, it must issue a written response clearly stating the reasons;

d) If the dossier is not valid, within 5 working days from the date recorded

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on the written receipt of the dossier, the receiving authority must send to the education institution a written notice clearly stating the contents that the applicant must amend or supplement to complete the dossier;

dd) Within 15 days from the date of receipt of the amended and supplemented dossier, the Ministry of Health shall grant a certificate of eligibility for language testing to the education institution, made using Form No. 02 provided in Appendix III to this Decree. In case of refusal, it must issue a written response clearly stating the reasons;

e) Within 10 days from the date of grant of the certificate of eligibility for language testing to the education institution, the Ministry of Health shall publicly post the name of the institution that has been granted the certificate on its portal and the information system on management of medical examination and treatment activities.

Article 142. Dossiers and procedures of application for testing and recognition of persons who are proficient in Vietnamese or other languages or qualified for interpretation in medical examination and treatment

1. A dossier of application for testing and recognizing a person as proficient in languages in medical examination and treatment shall include:

a) A written request, made using Form No. 01 Appendix III to this Decree;

b) A valid copy of people's identity card, citizen's identity card or passport that still remains valid;

c) Two color photos sized 04 cm x 06 cm, taken on a white background within a period of no more than 06 months up to the date of submitting the dossier.

2. A dossier of application for recognizing a person as proficient in Vietnamese or other languages or qualified for interpretation in medical examination and treatment shall comprise:

a) A written request for recognizing a person as proficient in Vietnamese or other languages or qualified for interpretation in medical examination and treatment, made using Form No. 01 Appendix III to this Decree;

b) Documents specified at Points b and c, Clause 1 of this Article;

c) A valid copy of degrees and certificates specified in Clause 3, Article 138 of this Decree for cases of application for recognizing a person as proficient in Vietnamese or other languages in medical examination and treatment; degrees and certificates specified in Clause 2, Article 139 of this Decree for cases of application for recognizing a person as qualified for interpretation in medical examination and treatment.

3. Procedures for testing and recognition:

a) An applicant shall file 01 dossier as specified in Clause 1 of this Article

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to the education institution specified in Article 140 of this Decree;

b) Within 30 days from the date of receiving a complete and valid dossier, the education institution must check and grant a certificate, made using Form No. 03 provided in Appendix III to this Decree for the cases specified in Clauses 1 and 2, Article 138, and Clause 1, Article 139 of this Decree. The test results must be publicly listed.

4. Procedures for recognition:

a) An applicant shall file 01 dossier specified in Clause 2 of this Article to an education institution specified in Article 140 of this Decree;

b) Within 10 working days from the date of receiving a complete and valid dossier, the education institution must grant a certificate, made using Form No. 03 of Appendix III to this Decree, for the cases specified in Clause 3, Article 138, and Clause 2, Article 139 of this Decree. In case of refusal, the education institution must issue a written response clearly stating the reasons.

5. Education institutions shall post the list of persons who have been granted certificates as specified at Point b, Clause 3 and Point b, Clause 4 of this Article on their portal and the information system on management of medical examination and treatment activities.

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Section 2

THE ROADMAP FOR CONVERTING PRACTICING LICENSES AND TRANSITIONAL PROVISIONS FOR OPERATION LICENSES

Article 143. Transitional provisions for internship, practicing certificates and conversion of practicing certificates granted under the Law No. 40/2009/QH12 on Medical Examination and Treatment

1. A person who started his/her internship before January 1, 2024 but has not completed such internship may choose the internship according to one of the following regulations:

a) Continuing his/her internship in accordance with the Law No. 40/2009/QH12 on Medical Examination and Treatment and its guiding documents. The internship results shall be used to request for grant of a practicing license, in which the scope of practice complies with the Law No. 40/2009/QH12 on Medical Examination and Treatment;

b) Participating in the internship in accordance with this Decree.

2. From January 1, 2024, a practicing certificate granted in accordance with the Law No. 40/2009/QH12 on Medical Examination and Treatment and its guiding documents may be used as a practicing license until it is converted in

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accordance with Clause 3 of this Article, in which the scope of practice is carried out according to the scope of practice approved by a competent authority.

3. The conversion of a practicing certificate into a practicing license shall be carried out when performing the procedure for renewal as follows:

a) Regulations on the validity period of 05 years for practicing certificates granted in accordance with the Law No. 40/2009/QH12 on Medical Examination and Treatment and its guiding documents shall be applied from 2030;

b) Practicing certificates specified at Point a of this Clause shall expire in 2035. The expiration date is determined according to the date recorded on the granted practicing certificates;

c) If wishing to continue practicing, a practitioner shall carry out the renewal procedures as specified in Clause 2, Article 134 of this Decree. A practitioner possessing a practicing certificate granted by the Ministry of Health who no longer works at establishments under the Ministry of Health must carry out the renewal procedures at a specialized health authority under provincial-level People's Committees.

4. Modification, re-grant, suspension, revocation and handling after suspension or revocation for persons granted practicing certificates in accordance with the Law No. 40/2009/QH12 on Medical Examination and Treatment shall comply with the Law No. 15/2023/QH15 on Medical Examination and Treatment and provisions in Section 1, Chapter VIII of this Decree. The duration of a practicing license shall be calculated from the time of re-grant of the practice license.

5. A written confirmation granted by commune-level People's Committees for dentists who have practiced since 1980 or earlier shall remain valid without requiring conversion into a practice license.

6. In the case where a person who is granted a practicing certificate in accordance with the Law No. 40/2009/QH12 on Medical Examination and Treatment wishes to convert such practicing certificate into a practicing license before the time specified in Clause 3 of this Article, the applicant shall prepare a dossier and carry out the procedures for grant of a practicing license in accordance with Article 130 of this Decree, and submit the granted practicing certificate.

7. In the case where a dossier of application for grant of a practicing certificate has been connected and shared on the information system on management of medical examination and treatment activities, the dossier of application for re-grant or modification of the practicing certificate shall be prepared in accordance with the Law No. 40/2009/QH12 on Medical Examination and Treatment, and submitted to the competent authorities specified in Article 28 of the Law No. 15/2023/QH15 on Medical Examination and Treatment.

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8. During the period when a dossier of application for grant of a practicing certificate has not been connected or shared on the information system on management of medical examination and treatment activities, the dossier of application for re-grant or modification of the practicing certificate shall be prepared in accordance with the Law No. 40/2009/QH12 on Medical Examination and Treatment and submitted to the authority that has granted the practicing certificate before.

Article 144. Transitional provisions for operation licenses

1. Medical examination and treatment establishments that are operating under operation licenses granted in accordance with the Law No. 40/2009/QH12 on Medical Examination and Treatment and its guiding documents may continue to operate under the granted licenses without requiring conversion into the organizational forms specified in the Law No. 15/2023/QH15 on Medical Examination and Treatment and Article 39 of this Decree.

In the case where a practitioner wishes to convert into the organizational forms specified in this Decree, he/she must carry out the procedures for modification of operation licenses specified in Articles 64, 65 and 66 of this Decree.

2. A medical examination and treatment establishment with the organizational form of a regional general clinic that has been granted an operation license before the effective date of this Decree may continue to provide inpatient treatment and must maintain the 24/7 organization of specialized departments.

3. A medical examination and treatment establishment with the organizational form of a patient emergency and transportation service provider that has been granted an operation license before the effective date of this Decree may continue to operate and must maintain the following conditions:

a) Physical foundations:

- Being at a fixed location, with adequate lighting, separate from family living areas;

- Having adequate electricity, water and other sanitary conditions to serve patient care.

b) Medical equipment and means of transportation:

- Having adequate emergency transport means with full medical equipment;

- Having an anti-shock medicine box and adequate emergency medicine to ensure safety and hygienic conditions for patients.

c) Human resources:

- If a person working at an establishment performs medical examination

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and treatment, he/she must possess a practicing certificate or practicing license and be assigned work appropriate to his/her scope of practice;

- The person in charge of an establishment's technical expertise must be a doctor granted a practicing certificate or a person granted a practicing license with the title of doctor, with a professional degree or certificate or certification that he/she has been trained in emergency resuscitation; have a minimum practice period of 36 months; and be a full-time practitioner at the establishment.

d) Having an emergency transport contract with an aviation service company if the establishment registers to transport patients abroad.

Article 145. Regulations on competence to grant, re-grant, or modify operation licenses in the period from January 1, 2024 to December 31, 2026

1. The Minister of Health:

a) Granting and re-granting operation licenses for medical examination and treatment establishments under the management competence and private hospitals.

b) Modifying operation licenses for medical examination and treatment establishments under the management competence and private hospitals when changing the scope of professional activities: supplementing or reducing techniques within the scope of professional activities.

c) Modifying operation licenses for medical examination and treatment establishments under the management competence and private hospitals when changing the scale of operation, including:

- Supplementing or reducing specialized departments and faculties, including the cases specified at Point dd, Clause 1, Article 54 of the Law on Medical Examination and Treatment;

- Changing the quantity of patient beds by 10% or more or changing the quantity of patient beds by less than 10% but the quantity of patient beds subject to modification exceeds 30 beds;

- Changing the quantity of patient beds in accordance with Clause 4 of this Article.

d) Modifying operation licenses for medical examination and treatment establishments under the management competence and private hospitals when changing working hours.

dd) Modifying operation licenses for medical examination and treatment establishments under the management competence and private hospitals when changing their names and addresses but not changing their locations.

2. Specialized health authorities under provincial-level People's Committees:

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a) Granting and re-granting operation licenses for medical examination and treatment establishments within the management area, except for medical examination and treatment establishments managed by the Ministry of Health, the Ministry of National Defense, and the Ministry of Public Security, and private hospitals.

b) Modifying operation licenses for medical examination and treatment establishments in the management area, except for medical examination and treatment establishments managed by the Ministry of Health, the Ministry of National Defense, and the Ministry of Public Security, and private hospitals when changing the scope of professional activities: supplementing or reducing techniques within the scope of professional activities.

c) Modifying operation licenses for medical examination and treatment establishments in the management area, except for medical examination and treatment establishments managed by the Ministry of Health, the Ministry of National Defense, and the Ministry of Public Security, and private hospitals when changing the scale of operation, including:

- Supplementing or reducing specialized departments and faculties, including the cases specified at Point dd, Clause 1, Article 54 of the Law on Medical Examination and Treatment;

- Changing the quantity of patient beds by 10% or more or changing the quantity of patient beds by less than 10% but the quantity of patient beds subject to modification exceeds 30 beds;

- Changing the quantity of patient beds in accordance with Clause 4 of this Article.

d) Modifying operation licenses for medical examination and treatment establishments in the management area, except for medical examination and treatment establishments managed by the Ministry of Health, the Ministry of National Defense, and the Ministry of Public Security, and private hospitals when changing working hours.

dd) Modifying operation licenses for medical examination and treatment establishments in the management area, except for medical examination and treatment establishments managed by the Ministry of Health, the Ministry of National Defense, and the Ministry of Public Security, and private hospitals when changing their names and addresses but not changing their locations.

3. A hospital may change the quantity of patient beds of departments and faculties if the change is less than 10% of the total quantity of patient beds recorded in the operation license, but the quantity of patient beds subject to modification must not exceed 30 beds and the hospital must submit to its direct managing authority a report which must clearly states:

a) The quantity of patient beds subject to modification in departments and

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faculties;

b) A declaration of facilities, medical equipment and personnel records proving that it satisfies the conditions for changing the quantity of patient beds.

4. In the case where a hospital has completed the change in quantity of patient beds to less than 10% and wishes to continue changing the quantity of patient beds, the hospital must carry out the procedures for modifying the operation license specified in Article 66 of this Decree. A dossier of application for modification of the operation license shall be sent to:

a) The Ministry of Health in cases of hospitals under the Ministry of Health and private hospitals;

b) Specialized health authorities under provincial-level People's Committees in cases of hospitals in the management area, except for hospitals under the Ministry of Health, Ministry of National Defense, Ministry of Public Security, and private hospitals.

5. After modifying an operation license in accordance with Clause 4 of this Article, if a hospital wishes to continue changing the quantity of patient beds, then at the next time of modifying the quantity of patient beds, the hospital shall comply with the provisions in Clauses 3 and 4 of this Article respectively.

6. A dossier of application for grant, re-grant or modification of an operation license submitted before December 31, 2026 shall comply with the competence specified in Clauses 1, 2 and 4 of this Article.

Article 146. Regulations on professional and technical levels

A hospital that has been granted an operation license before January 1, 2024 must carry out the procedure of application for professional and technical levels to be classified in terms of professional and technical levels before January 1, 2025. The classification of professional and technical levels shall be carried out as follows:

1. In the case where the time from the date of granting the operation license to the time of application to carry out the procedure is less than 02 years, the hospital may only submit a written request for classification as specified at Point a, Clause 1, Article 90 of the Decree. Within 15 working days from the date of receiving the hospital's written request, the licensing authority shall issue a temporary document on classifying such hospital into the basic level. The temporary classification period shall be 02 years from the date of submission stated on the temporary classification document. Within 60 days before the expiration of the temporary classification period, the hospital must file a dossier to carry out the procedures for classification of professional and technical levels as specified in Article 90 of this Decree.

2. In the case where the time from the date of granting the operation license

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to the time of application to carry out the procedure is 02 years or more, the submission of dossier and the procedure shall be carried out in accordance with Article 90 of this Decree. The classification results shall be applied from January 1, 2025.

Chapter IX
IMPLEMENTATION PROVISIONS

Article 147. Effect

1. This Decree takes effect from January 1, 2024.

2. Regulations on updating and posting information on the information system on management of medical examination and treatment activities in this Decree shall be implemented from January 1, 2027.

3. The Government's Decree No. 109/2016/ND-CP dated July 1, 2016, prescribing the grant of practice certificates to medical practitioners and of operation licenses for medical examination and treatment establishments, and Article 11 of the Government's Decree No. 155/2018/ND-CP dated November 12, 2018 amending and supplementing a number of regulations related to business investment conditions under the state management of the Ministry of Health cease to be effective from the effective date of this Decree.

4. Medical examination and treatment establishments may continue to pay medical examination and treatment charges according to regulations promulgated or approved by competent authorities until new regulations are issued but no later than December 31, 2024.

Medical examination and treatment establishments licensed to operate during the period specified in Clause 4 of this Article may apply regulations on classification to pay medical examination and treatment charges covered by the health insurance fund in accordance with the law provisions on medical examination and treatment.

5. The administrative procedures specified in this Decree shall be carried out directly or through postal services or online in accordance with the law provisions on carrying out administrative procedures in the electronic environment when meeting the set requirements.

6. Hospitals must complete the implementation of the provisions in Clause 4, Article 105 and the provisions in Article 106 of this Decree before January 1, 2026.

7. The phrase "medical equipment and devices" is replaced with the phrase "medical equipment" in legal documents issued before January 1, 2024.

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8. To amend the title of Chapter IV of the Government's Decree No. 98/2021/ND-CP dated November 8, 2021, on management of medical equipment and devices as follows:

"**Chapter IV. CLINICAL TRIALS ON MEDICAL EQUIPMENT".**

9. To amend and supplement Article 12 of the Government's Decree No. 98/2021/ND-CP dated November 8, 2021, on management of medical equipment and devices as follows:

"Article 12. Clinical trial stages for medical equipment

1. Clinical trial stages for medical equipment other than in vitro diagnostic medical equipment:

a) Stage 1: the first stage to conduct the preliminary research on the safety of medical equipment for humans and its usability for doctors and healthcare staff;

b) Stage 2: The confirmatory research to ascertain and establish evidence for the safety and efficacy of medical equipment.

c) Stage 3: The stage conducted after the medical equipment is placed on the market in order to collect more evidence for the safety and efficacy of the medical equipment during application upon request of competent state management authorities.

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2. Clinical trial stages for in vitro diagnostic medical equipment:

a) Stage 1: The stage of assessing the clinical performance of in vitro diagnostic medical equipment;

b) Stage 2: The stage conducted after in vitro diagnostic medical equipment is placed on the market in order to collect more evidence for the safety and efficacy of in vitro diagnostic medical equipment during application upon request of competent state management authorities.".

10. To amend Article 13 of the Government's Decree No. 98/2021/ND-CP dated November 8, 2021, on management of medical equipment and devices as follows:

"Article 13. Cases of exemption from clinical trials or from several stages of clinical trials for medical equipment before registration for circulation of medical equipment

1. Medical equipment may be exempt from clinical trials in the following cases:

a) Medical equipment of types A and B;

b) Medical equipment of types C and D that has been licensed for circulation by the Ministry of Health of Vietnam or a competent foreign authority.

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2. Domestically-manufactured medical equipment other than in vitro diagnostic medical equipment of types C and D shall be exempt from stage-1 clinical trial when they meet the following conditions:

a) Applying the transferred technology that already has medical equipment licensed for circulation by a competent authority, except in the case where the circulation license has been revoked;

b) Having the same indication for use as the medical equipment licensed for circulation by a competent authority specified at Point a of this Clause.

3. The Ministry of Health shall decide on exemption from clinical trials, and exemption from one or several stages of clinical trials for medical equipment serving urgent requirements for national defense, security, disease prevention and control, and remediation of consequences in case of disasters and catastrophes.".

11. To amend Article 14 of the Government's Decree No. 98/2021/ND-CP dated November 8, 2021, on management of medical equipment and devices as follows:

"Article 14. Requirements for medical equipment subject to clinical trials

1. Meeting the legal and technical requirements of dossiers of registration for circulation of medical equipment in accordance with regulations.

2. Labels of medical equipment used for clinical trial must contain the words "Medical equipment used for clinical trial, prohibited for other purposes". Labeling shall be carried out in accordance with the law on labeling of goods.".

12. To amend Article 15 of the Government's Decree No. 98/2021/ND-CP dated November 8, 2021, on management of medical equipment and devices as follows:

"Article 15. Requirements for clinical trial-hosting establishments for medical equipment

1. Meeting the requirements for good clinical practice of medical equipment trials in accordance with regulations of the Minister of Health.

2. Having the function of scientific research and the scope of professional activities appropriate to the medical equipment subject to clinical trials.

3. Being a legal entity that is independent in terms of organization, personnel, and finance from the organization or individual that has the medical equipment subject to clinical trials.".

13. To amend Article 16 of the Government's Decree No. 98/2021/ND-CP dated November 8, 2021, on management of medical equipment and devices as follows:

"Article 16. Clinical trial dossiers for medical equipment

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1. A clinical trial dossier for medical equipment shall include the following types: dossier of application for clinical trial approval; dossier of application for approval of clinical trial changes; dossier of application for approval of medical equipment clinical trial results. The composition of each type of dossier shall comply with the provisions of Article 17 of this Decree.

2. Requirements for dossiers:

a) A clinical trial dossier for medical equipment must be made in Vietnamese. If the dossier is not made in Vietnamese, there must be a certified translation of the dossier into Vietnamese.

b) Documents issued by foreign management authorities must be consularly legalized in accordance with the law provisions on consular legalization, unless exempted in accordance with the law provisions.".

14. To amend Article 17 of the Government's Decree No. 98/2021/ND-CP dated November 8, 2021, on management of medical equipment and devices as follows:

"Article 17. Composition of clinical trial dossiers for medical equipment

1. A dossier of application for medical equipment clinical trial approval shall comprise:

a) A written request for approval of clinical trials from organizations or individuals that have medical equipment subject to clinical trials.

b) A written request for approval of clinical trials from clinical trial-hosting establishments for medical equipment.

c) A written request from competent state management authorities for medical equipment subject to stage-3 clinical trial or for in vitro diagnostic medical equipment subject to stage-2 clinical trial.

d) A dossier of information about medical equipment subject to clinical trials shall comprise:

- Product information record (general information about medical equipment subject to clinical trials: name; characteristics; utilities; indications, contraindications; technical specifications and other related information);

- Pre-clinical research documents of medical equipment subject to clinical trials: research reports on safety, effectiveness, recommendations on usage and storage; research reports on stability and analytical performance (for in vitro diagnostic medical equipment) that are assessed as satisfactory by a clinical trial-hosting establishment or pre-clinical research establishment certified by the Ministry of Health;

- Research documents for clinical trials for medical equipment in the stages

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before the trial proposal stage.

dd) A legal dossier shall comprise:

- Information about the owner, manufacturer and manufacturing processes of medical equipment;

- Technical documents of medical equipment;

- Technical standards of medical equipment announced by the medical equipment owner;

- Satisfactory quality assessment results for technical standards of medical equipment issued by a qualified establishment in accordance with the law provisions on conformity assessment or a quality assessment certificate granted by a competent authority in Vietnam;

- User manual licensed for circulation for medical equipment requested for stage-3 clinical trials;

- A written confirmation of participation from the clinical trial participant;

- A clinical trial contract for medical equipment between the authority, organization or individual that has the medical equipment subject to clinical trials and the clinical trial-hosting establishment; Research support contract between the organization or individual that has medical equipment subject to clinical trials and the research support organization (if any).

e) A scientific dossier shall comprise:

- Explanation of clinical trials for medical equipment;

- Case report form;

- Summary of research information and volunteer forms of participation in research of medical equipment clinical trial participants.

g) An administrative dossier shall comprise:

- A scientific curriculum vitae and a copy of the principal researcher's certificate of completion of the Good Clinical Practice course granted by the Ministry of Health or by institutions providing training programs in good clinical practice;

- A minute of appraisal of science and ethics in research by the ethical committee in the grassroots biomedical research;

- Equipment labels as specified in Clause 2, Article 14 of this Decree and user manuals of research medical equipment.

2. A dossier of application for approval of changes in medical equipment clinical trials:

a) For administrative changes and changes in contact information of the

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clinical trial-hosting establishment: such establishment shall report to the Ministry of Health to summarize information.

b) For changes in the principal investigator or the clinical trial-hosting establishment, a dossier shall comprise:

- A written request for approval of changes in medical equipment clinical trials;

- Evidence documents for corresponding changes.

c) For changes not falling into the cases specified at Points a and b of this Clause, a dossier shall comprise:

- A written request for approval of changes in medical equipment clinical trials;

- The updated version of the corresponding documents specified in Clause 1 of this Article that has been changed.

3. A dossier of application for approval of medical equipment clinical trial results shall comprise:

a) A written request for approval of medical equipment clinical trial results;

b) A copy of the approved research outline;

c) A copy of the decision approving the clinical trial;

d) A minute of appraisal of medical equipment clinical trial results of the ethics committee in the grassroots biomedical research;

dd) A report on clinical trial results of medical equipment".

15. To amend Article 18 of the Government's Decree No. 98/2021/ND-CP dated November 8, 2021, on management of medical equipment and devices as follows:

"Article 18. Process and procedures for approval of clinical trials

1. A clinical trial-hosting establishment shall send directly, online or by post 01 dossier for approval of a clinical trial to the Ministry of Health.

2. The Ministry of Health shall examine the validity of the dossier within 05 working days from the date of receipt of the dossier. If the dossier is valid, within 02 working days, the Ministry of Health shall transfer the dossier to the National Ethics Council for appraisal and evaluation of the ethical aspects of the research. If the dossier is invalid, within 02 working days, there must be a written notification and specific instructions for the establishment to supplement the dossier.

The clinical trial-hosting establishment shall be responsible for completing the dossier within a maximum period of 60 days from the date of receipt of the written notification. After this time limit, the clinical trial approval procedures

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must be conducted again from the beginning.

3. The National Ethics Council shall conduct appraisal and evaluation of ethical aspects in research on a monthly basis.

4. Within 05 working days from the date of receiving the certificate of clinical trial approval from the National Ethics Council and accompanying dossiers, the Ministry of Health shall decide on approval for the clinical trial.".

16. To amend Article 19 of the Government's Decree No. 98/2021/ND-CP dated November 8, 2021, on management of medical equipment and devices as follows:

"Article 19. Process and procedures for approval of clinical trial changes

1. A clinical trial-hosting establishment shall send directly, online or by post 01 dossier for approval of clinical trial changes to the Ministry of Health.

2. The Ministry of Health shall examine the validity of the dossier within 05 working days from the date of receipt of the dossier. If the dossier is invalid, within 02 working days, the Ministry of Health shall issue a written notification and specific instructions for the establishment to supplement the dossier.

The clinical trial-hosting establishment shall be responsible for completing the dossier within a maximum period of 60 days from the date of receipt of the written notification. After this time limit, the procedure for approval of clinical trial changes must be conducted again from the beginning.

3. For the changes specified at Point b, Clause 2, Article 17 of this Decree: within 07 working days from the date of receiving a complete and valid dossier, the Ministry of Health shall decide on approval of clinical trial changes.

4. For the changes specified at Point c, Clause 2, Article 17 of this Decree:

a) If the dossier is valid, within 02 working days, the Ministry of Health shall transfer the dossier to the National Ethics Council for appraisal;

b) The National Ethics Council shall conduct appraisal and evaluation of ethical aspects in research on a monthly basis;

c) Within 05 working days from the date of receiving the certificate of approval of clinical trial changes from the National Ethics Council and accompanying dossiers, the Ministry of Health shall decide on approval of clinical trial changes.".

17. To amend Article 20 of the Government's Decree No. 98/2021/ND-CP dated November 8, 2021, on management of medical equipment and devices as follows:

"Article 20. Process and procedures for approval of clinical trial results

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1. A clinical trial-hosting establishment shall send directly, online or by post 01 dossier for approval of clinical trial results to the Ministry of Health.

2. The Ministry of Health shall examine the validity of the dossier within 05 working days from the date of receipt of the dossier. If the dossier is valid, within 02 working days, the Ministry of Health shall transfer the dossier to the National Ethics Council for appraisal. If the dossier is invalid, within 02 working days, the Ministry of Health must issue a written notification and specific instructions for the establishment to supplement the dossier.

The clinical trial-hosting establishment shall be responsible for completing the dossier within a maximum period of 60 days from the date of receipt of the written notification. After this time limit, the procedures for approval of clinical trial changes must be conducted again from the beginning.

3. The National Ethics Council shall conduct appraisal and evaluation of ethical aspects in research on a monthly basis.

4. Within 05 working days from the date of receiving the certificate of approval for clinical trial results from the National Ethics Council and accompanying dossiers, the Ministry of Health shall decide on approval for the clinical trial.".

18. Forms of documents and reports related to medical equipment clinical trials:

a) A written request for approval of clinical trial research of the organization or individual that has medical equipment subject to clinical trials in the dossier of application for approval of medical equipment clinical trials specified in Clause 14 of this Article shall be made using Form No. 10 provided in Appendix VI to this Decree;

b) A written request for approval of clinical trial research of the clinical trial-hosting establishment in the dossier of application for approval of medical equipment clinical trials specified in Clause 14 of this Article shall be made using Form No. 11 provided in Appendix VI to this Decree;

c) Explanation of research outline for medical equipment clinical trials in the dossier of application for approval of medical equipment clinical trials specified in Clause 14 of this Article shall be made using Form No. 12 provided in Appendix VI to this Decree;

d) A written request for approval of changes in medical equipment clinical trials in the dossier of application for approval of changes in clinical trials specified in Clause 14 of this Article shall be made using Form No. 13 provided in Appendix VI to this Decree;

dd) A written request for approval of medical equipment clinical trial results in the dossier of application for approval of medical equipment clinical

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trial results specified in Clause 14 of this Article shall be made using Form No. 14 provided in Appendix VI to this Decree;

e) A report on medical equipment clinical trial results in the dossier of application for approval of medical equipment clinical trial results specified in Clause 14 of this Article shall be made using Form No. 15 provided in Appendix VI to this Decree.

19. To amend and supplement Article 30 of the Government's Decree No. 98/2021/ND-CP dated November 8, 2021, on management of medical equipment and devices as follows:

a) Point h is added after Point g, Clause 1, Article 30 as follows:

"h) Certificate of medical equipment clinical trial results granted by a competent authority for medical equipment subject to clinical trials as specified in Clause 2, Article 94 of the Law on Medical Examination and Treatment.".

b) Point c, Clause 2, Article 30 is amended as follows:

"c) Documents as specified at Points b, c, d, dd, e and h, Clause 1 of this Article.".

c) Point h is added after Point g, Clause 4, Article 30 as follows:

"h) Certificate of medical equipment clinical trial results granted by a competent authority in the case where the clinical trial must be conducted in accordance with the law provisions.".

d) Point e is added after Point dd, Clause 5, Article 30 as follows:

"e) Certificate of medical equipment clinical trial results granted by a competent authority for medical equipment subject to clinical trials as specified in Clause 2, Article 94 of the Law on Medical Examination and Treatment.".

20. The provisions in Clause 5, Article 105 of this Decree and Clause 19 of this Article shall be applied from January 1, 2026.

21. To add Article 32a to the Government's Decree No. 98/2021/ND-CP dated November 8, 2021, on management of medical equipment and devices as follows:

"Article 32a. Priorities in processing of dossiers of registration for medical equipment circulation

1. A dossier of registration for medical equipment circulation may be given priority in the processing if it falls into one of the following cases:

a) Domestically-manufactured medical equipment;

b) Imported medical equipment for which a dossier of application for a medical equipment import license has been submitted to the Ministry of Health before January 1, 2022 but the medical equipment import license has not yet been

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granted, and a dossier of registration for grant of medical equipment circulation certificate has submitted;

c) Chemicals and preparations for only the purpose of sterilization of medical equipment;

d) Medical equipment to implement new techniques and new methods applied in medical examination and treatment that has been officially approved in writing by the Ministry of Health but has not yet been granted a circulation number in Vietnam;

dd) Medical equipment that has no change in information about types or product codes on the import license or decision to grant a circulation registration number or a valid circulation registration certificate but falls into one of the following:

- Changing the import establishment or circulation registration unit;

- Changing name of the manufacturer but not changing its address;

- Changing name of the medical equipment owner but not changing its address;

e) Medical equipment that has no change in information about types, but information about product codes has been changed because the old product codes have no longer been manufactured, in one of the following documents: valid import license or decision on grant of circulation registration number or circulation registration certificate;

g) A dossier of medical equipment circulation registration for which the Ministry of Health has previously requested in writing to supplement or issued a written refusal to grant a license, but the contents of documents are only related to the request to update the validity of one of the following documents: authorization letter of the owner of medical equipment circulation number, certificate of compliance with ISO 13485 quality management standards, and medical equipment circulation certificate;

h) A dossier of medical equipment circulation registration for which the Ministry of Health has previously requested in writing to supplement or issued a written refusal to grant a license, but the contents of documents are only required to modify or supplement the names of medical equipment.

2. Procedure for considering and giving priority in processing dossiers of registration for medical equipment circulation:

a) An applicant for priority in processing a dossier of registration for medical equipment circulation shall send to the Ministry of Health the following documents:

- A written request for priority in the processing, including sufficient

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information about the dossier code submitted on the portal of the Ministry of Health;

- Documents proving that it falls into the cases specified in Clause 1 of this Article;

b) The Ministry of Health shall consider and give priority in processing the dossier of registration for medical equipment circulation within 10 working days from the date of receiving a written request and enclosed documents from the applicant. In case of refusal, the Ministry of Health must issue a written response clearly stating the reasons.

3. Medical equipment in the cases specified at Point b, Clause 1 of this Article that has been granted a certificate of registration for medical equipment circulation shall not be considered for import license.".

22. The Government's Decree No. 102/2011/ND-CP dated November 14, 2011, on liability insurance in medical examination and treatment ceases to be effective from the effective date of this Decree.

23. Authorities competent to grant practicing licenses and operation licenses shall be responsible for:

a) Establishing a secretariat to evaluate dossiers for grant, re-grant and modification of practicing licenses under their management;

b) Establishing an advisory council to advise on cases of dispute during the process of granting, re-granting, modifying, and renewing practicing licenses under their management;

c) Establishing an appraisal team to grant, re-grant and modify operation licenses under their management.

Article 148. Responsibilities for implementation

Ministers, heads of ministerial-level authorities, heads of governmental authorities, chairpersons of People's Committees of provinces and centrally-run cities and relevant authorities, organizations and individuals shall implement this Decree.

On behalf of the Government

For the Prime Minister

The Deputy Prime Minister

TRAN HONG HA

** All Appendices are not translated herein.*

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