

THE GOVERNMENT

No. 87/2011/ND-CP

SOCIALIST REPUBLIC OF VIET NAM

Independence - Freedom – Happiness

Hanoi, September 27, 2011

DECREE

DETAILING AND GUIDING A NUMBER OF ARTICLES OF THE LAW ON MEDICAL EXAMINATION AND TREATMENT

THE GOVERNMENT

Pursuant to the December 25, 2001 Law on Organization of the Government;

Pursuant to the November 23, 2009 Law on Medical Examination and Treatment;

At the proposal of the Minister of Health,

DECREES:

Article 1. Scope of regulation

This Decree details Clause 6 of Article 25, Article 41, Clause 6 of Article 44, and Clause 3 of Article 51, of the Law on Medical Examination and Treatment regarding:

1. Organizational forms of medical examination and treatment establishments; organizational forms of army medical examination and treatment establishments.
2. Roadmap for licensing state medical examination and treatment establishments.
3. Roadmap for granting practice certificates for practitioners of state medical examination and treatment establishments.
4. National technical regulations, quality control standards and medical examination and treatment establishment quality accreditation organizations.

Article 2. Subjects of application

This Decree applies to domestic agencies, organizations and individuals, including medical examination and treatment establishments of the police and the army (below collectively referred to as organizations and individuals) and foreign organizations and individuals engaged in medical examination and treatment in Vietnam.

Chapter II

ORGANIZATIONAL FORMS OF MEDICAL EXAMINATION AND TREATMENT ESTABLISHMENTS

Article 3. Organizational forms of medical examination and treatment establishments

1. Organizations and individuals shall provide medical examination and treatment at:
 - a/ Hospitals, including general hospitals, specialized hospitals and traditional medicine hospitals;
 - b/ Medical assessment establishments;
 - c/ Clinics, including general clinics, specialized clinics, family-doctor clinics, traditional medicine clinics and infirmaries;

d/ Maternity hospitals;

e/ Diagnostic establishments, including imaging diagnosis departments and laboratories;

f/ Medical service establishments, including establishments providing such services as injection, change of dressing, and pulse, temperature and blood pressure measurement; establishments providing in-house healthcare services; Establishments providing first aid or transporting patients domestically or abroad; optical glasses establishments; and denture service establishments;

g/ Commune-level health centers; infirmaries of agencies, units and organizations.

2. The Minister of Health shall detail licensing conditions for each organizational form of medical examination and treatment establishments provided in Clause 1 of this Article.

Article 4. Organizational forms of army medical 'examination and treatment establishments

1. In the army, medical examination and treatment must be organized in one of the forms provided in Clause 1, Article 3 of this Decree. When necessary to meet wartime medical examination and treatment requirements, the Minister of National Defense may permit other appropriate forms of medical examination and treatment.

2. The Minister of National Defense shall detail licensing conditions for organizational forms of medical examination and treatment establishments provided in Clause 1 of this Article under his/her management.

Chapter III

ROADMAP FOR LICENSING STATE MEDICAL EXAMINATION AND TREATMENT ESTABLISHMENTS

Article 5. Roadmap for the licensing of state medical examination and treatment establishments by the Ministry of Health and provincial-level Health Departments

State medical examination and treatment establishments to be licensed by the Ministry of Health or Health Departments of provinces and centrally run cities (below referred to as provincial Health Departments) which are operating on the effective date of the Law on Medical Examination and Treatment and fully meet the conditions provided in Article 43 of the Law on Medical Examination and Treatment shall be licensed according to the following roadmap:

1. To complete the licensing of state medical examination and treatment establishments of the organization form provided at Point a, Clause 1, Article 3 of this Decree before December 31, 2013.

2. To complete the licensing of state medical examination and treatment establishments of the organization forms provided at Points b, c and d, Clause 1, Article 3 of this Decree before December 31, 2014.

3. To complete the licensing of state medical examination and treatment establishments of the organization forms provided at Points e, f and g. Clause 1, Article 3 of this Decree before December 31, 2015.

Article 6. Roadmap for the licensing of medical examination and treatment establishments by the Ministry of National Defense

Medical examination and treatment establishments to be licensed by the Ministry of National Defense which are operating on the effective date of the Law on Medical Examination and Treatment and fully meet the conditions provided in Article 43 of the Law on Medical Examination and Treatment shall be licensed according to the following roadmap:

1. To complete the licensing of medical examination and treatment establishments of the organization forms provided at Point a, b, c and d, Clause 1, Article 3 of this Decree before December 31, 2014.
2. To complete the licensing of medical examination and treatment establishments of the organization forms provided at Point e, f and g, Clause 1, Article 3 of this Decree before December 31, 2015.
3. The Minister of National Defense shall specify the licensing of medical examination and treatment establishments of the forms provided in Clause 1, Article 4 of this Decree.

Chapter IV

ROADMAP FOR GRANTING PRACTICE CERTIFICATES FOR PUBLIC MEDICAL PRACTITIONERS

Article 7. Roadmap for the grant of practice certificates for practitioners of state medical examination and treatment establishments by the Ministry of Health and provincial Health Departments

Practitioners of state medical examination and treatment establishments with practice certificates to be granted by the Ministry of Health or provincial Health Departments who are practicing on the effective date of the Law on Medical Examination and Treatment and fully meet the conditions provided in Articles 18 and 19 of the Law on Medical Examination and Treatment may obtain a practice certificate according to the following roadmap:

1. To complete the grant of practice certificates to practitioners of state medical examination and treatment establishments of the form provided at Point a, Clause 1, Article 3 of this Decree before December 31, 2013.
2. To complete the grant of practice certificates to practitioners of state medical examination and treatment establishments of the forms provided at Points b, c and d, Clause 1, Article 3 of this Decree before December 31, 2014.
3. To complete the grant of practice certificates to practitioners of state medical examination and treatment establishments of the forms provided at Points e, f and g, Clause 1, Article 3 of this Decree before December 31, 2015.

Article 8. Roadmap for the grant of practice certificates to practitioners of medical examination and treatment establishments managed by the Ministry of National Defense

Practitioners of medical examination and treatment establishments with practice certificates granted by the Ministry of National Defense who are practicing on the effective date of the Law on Medical Examination and Treatment and fully meet the conditions provided in Articles 18 and 19 of the Law on Medical Examination and Treatment may obtain a practice certificate according to the following roadmap:

1. To complete the grant of practice certificates to practitioners of medical examination and treatment establishments of the forms provided at Points a, b, c and d, Clause 1, Article 3 of this Decree before December 31, 2014.
2. To complete the grant of practice certificates to practitioners of medical examination and treatment establishments of the forms provided at Points e, f and g, Clause 1, Article 3 of this Decree before December 31, 2015.
3. The Minister of National Defense shall specify the grant of practice certificates for practitioners working at medical examination and treatment establishments of the organizational forms provided in Clause 1, Article 4 of this Decree.

Chapter V

NATIONAL TECHNICAL REGULATIONS, QUALITY CONTROL STANDARDS AND MEDICAL EXAMINATION AND TREATMENT ESTABLISHMENT QUALITY ACCREDITATION ORGANIZATIONS

Article 9. National technical regulations on medical examination and treatment establishments

1. National technical regulations on medical examination and treatment establishments are regulations on physical foundations and health equipment relevant to each organizational form of medical examination and treatment establishments.
2. Medical examination and treatment establishments may be licensed under Article 44 of the Law on Medical Examination and Treatment only when fully meeting the following conditions:
 - a/ Fully complying with national technical regulations on medical examination and treatment establishments under Clause 1 of this Article;
 - b/ Having sufficient medical practitioners relevant to their professional operations under the Ministry of Health's guidance;
 - c/ Meeting other conditions under Article 43 of the Law on Medical Examination and Treatment.
3. The Minister of Health shall promulgate national technical regulations on medical examination and treatment establishments under current regulations. Pending the promulgation of these regulations, the Minister of Health shall specify conditions on physical foundations and health equipment relevant to each organizational form of medical examination and treatment establishments.

Article 10. Quality control standards and recognition of quality control standards of medical examination and treatment establishments

1. Quality control standards for medical examination and treatment establishments comply with Clause 1, Article 50 of the Law on Medical Examination and Treatment.
2. The Minister of Health recognizes a number of international and foreign quality control standards for medical examination and treatment establishments for application in Vietnam.
3. The Minister of Health shall provide criteria, dossiers and procedures for recognition of other quality control standards for medical examination and treatment establishments apart from the standards recognized by the Ministry of Health under Clause 2 of this Article.

4. Licensed medical examination and treatment establishments are encouraged to apply the quality control standards provided in Clause 1 of this Article to raise medical examination and treatment quality.

Article 11. Medical examination and treatment establishment quality accreditation organizations

1. Medical examination and treatment establishment quality accreditation organizations include:

a/ Non-business units;

b/ Enterprises;

c/ Vietnam-based branches of foreign accreditation organizations.

2. Establishment of medical examination and treatment establishment quality accreditation organizations complies with the following provisions:

a/ Medical examination and treatment establishment quality accreditation organizations being non-business units shall be established under the Government's Decree No. 83/2006/ND-CP of August 17, 2006, on order and procedures for establishment, re-organization and dissolution of state administrative organizations and non-business organizations;

b/ Medical examination and treatment establishment quality accreditation organizations being enterprises shall be established under the Enterprise Law;

c/ Medical examination and treatment establishment quality accreditation organizations being Vietnam-based foreign branches shall be established under the Investment Law.

Article 12. 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.

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.

Article 13. Operation conditions on medical examination and treatment establishment quality accreditation organizations

1. The document on establishment of a medical examination and treatment quality accreditation organizations is one of the following:

a/ Establishment decision of a competent state agency, for medical examination and treatment quality establishment accreditation organizations being state non-business units;

c/ Business registration certificate, for medical examination and treatment establishment quality accreditation organizations being enterprises;

c/ Investment certificate, for Vietnam-based branches of foreign medical examination and treatment establishment quality accreditation organizations.

2. A medical examination and treatment establishment quality accreditation organization shall be organizationally structured to suit its functions and tasks, comprising:

- a/ The technical section;
- b/ The information section;
- c/ The database management section;
- d/ Other sections.

3. Personnel of a medical examination and treatment establishment quality accreditation organization must match its functions, tasks and organizational structure, meeting the following conditions:

a/ The director or the deputy director in charge of professional issues has at least 3 years working at medical examination and treatment establishments or state management agencies in charge of health directly managing medical examination and treatment establishments and possesses a certificate of medical examination and treatment quality management granted by an institution licensed to provide training in medical examination and treatment establishment quality management;

b/ The medical examination and treatment establishment quality accreditation organization's technical section has at least 5 permanent evaluators being university-degree doctors, pharmacists or nurses, engineers or technicians specialized in health equipment, construction engineers or architects with at least 3 years working at medical examination and treatment establishments or state management agencies in charge of health directly managing medical examination and treatment establishments.

4. To register standard conformity certification operations at a competent state agency under law.

Article 14. Operation principles of medical examination and treatment establishment quality accreditation organizations

- 1. To operate only when fully meeting the conditions provided in Article 13 of this Decree.
- 2. To comply with Clauses 1 and 2, Article 51 of the Law on Medical Examination and Treatment.
- 3. To make quality accreditation in conformity with quality control standards recognized by the Ministry of Health.
- 4. To evaluate and accredit quality on a voluntary basis under service contracts with medical examination and treatment establishments.
- 5. To keep confidential information collected in the quality accreditation process.
- 6. To make regular or irregular reports at the request of competent health state agencies and submit to the examination and inspection of competent state agencies in charge of health.

Chapter VI

IMPLEMENTATION PROVISIONS

Article 15. Transitional provisions

1. Private medical examination and treatment establishments having obtained a certificate of eligibility for private medical practice under the Ordinance on Private Medical and Pharmaceutical Practice valid until or after December 31,2010, may continue their operations until they obtain an operation license under the Law on Medical Examination and Treatment before December 31, 2012.

2. Private medical practitioners having obtained a practice certificate to act as heads of private medical examination and treatment establishments under the Ordinance on Private Medical and Pharmaceutical Practice valid until or after December 31,2010, may continue their practice until they obtain a practice certificate under the Law on Medical Examination and Treatment before December 31, 2012.

3. Private medical practitioners currently operating under the Ordinance on Private Medical and Pharmaceutical Practice may continue their practice until they obtain a practice certificate under the Law on Medical Examination and Treatment before December 31,2012.

Article 16. Effect

1. This Decree takes effect on November 15, 2011.

2. The Government's Decree No. 103/2003/ND-CP of September 12, 2003, detailing a number of articles of the Ordinance on Private Medical and Pharmaceutical Practice, ceases its effect on November 15, 2011.

Article 17. Implementation responsibilities

1. The Minister of Health and the Minister of National Defense shall guide the implementation of this Decree.

2. Ministers, heads of ministerial-level agencies, heads of government-attached agencies and chairpersons of provincial-level People's Committees shall implement this Decree.-

**ON BEHALF OF THE GOVERNMENT
PRIME MINISTER**

Nguyen Tan Dung