

Part I. LEGAL DOCUMENTS

THE GOVERNMENT

Decree No. 63/2012/ND-CP of August 31, 2012, defining the functions, tasks, powers and organizational structure of the Ministry of Health

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

Pursuant to the Government's Decree No. 36/2012/ND-CP of April 18, 2012, defining the functions, tasks, powers and organizational structures of ministries and ministerial-level agencies;

At the proposal of the Minister of Health,

The Government promulgates the Decree defining the functions, tasks, powers and organizational structure of the Ministry of Health.

Article 1. Position and functions

The Ministry of Health is a governmental agency, performing the state management of health, covering preventive health; medical examination and treatment, functional rehabilitation; medical expertise, forensic expertise and mental forensic expertise; traditional medicine and pharmacy; reproductive health; medical equipment and facilities; pharmacy; cosmetics; food safety;

health insurance; population and family planning; and state management of public services falling within the scope of its state management.

Article 2. Tasks and powers

The Ministry of Health shall perform the tasks and exercise the powers defined in the Government's Decree No. 36/2012/ND-CP of April 18, 2012, defining the functions, tasks, powers and organizational structures of ministries and ministerial-level agencies, and the following specific tasks and powers:

1. To submit to the Government draft laws and draft resolutions of the National Assembly, draft ordinances and resolutions of the National Assembly Standing Committee, draft resolutions and decrees of the Government under the Ministry's approved annual legislative programs and plans, and projects and schemes as assigned by the Government or the Prime Minister; development strategies, master plans, long-term, five-year and annual plans and national important projects and works falling within the scope of the Ministry's state management.

2. To submit to the Prime Minister draft decisions, directives and other documents related to the sectors falling within the scope of the Ministry's state management or as assigned.

3. To promulgate circulars, decisions, directives and other documents on the state management of the sectors falling within the

scope of the Ministry's state management.

4. To direct, guide and organize the implementation of legal documents, strategies, master plans, plans, national target programs, national important projects and works after they are approved; to conduct law information, dissemination and education and monitor the law enforcement in the fields falling within the scope of the Ministry's state management.

5. Regarding preventive medicine:

a/ To formulate and promulgate according to its competence or submit to competent authorities for promulgation legal documents, professional regulations, national standards and technical regulations regarding surveillance, prevention and control of contagious diseases, HIV/AIDS, non-contagious diseases, occupational diseases and injuries; border health quarantine; environmental sanitation and health, labor hygiene and health, school health and hygiene; drinking water and daily-life water hygiene and quality; community nutrition; and insecticides and germicides for domestic and medical use;

b/ To promulgate, amend and supplement lists of contagious diseases of different groups, a list of contagious diseases subject to use of vaccines or medical bio-products and organize vaccination and use of medical bio-products for compulsory subjects in accordance with law;

c/ To assume the prime responsibility for, and coordinate with related ministries and sectors in, promulgating a list of diseases of

which patients need long-term treatment and are entitled to sickness benefits, and a list of occupational diseases of which patients are entitled to occupational disease benefits in Vietnam;

d/ To organize surveillance of contagious diseases, non-contagious diseases, diseases with unidentified causes, the early detection of contagious diseases which can develop into epidemics and organize the announcement of occurrence and termination of epidemics in accordance with law; to assume the prime responsibility for, and coordinate with related agencies in, providing accurate and timely information on contagious diseases;

e/ To submit to competent authorities for decision or to decide according to its competence on the application of special anti-epidemic measures; to inspect, supervise and support units and localities in organizing the application of anti-epidemic measures;

f/ To conduct health quarantine at border gates; to promptly inform and report on extremely dangerous contagious diseases in the world for active prevention and control;

g/ To direct and guide the appraisal of assessment reports on the health impacts of investment projects to construct industrial parks, urban centers, residential areas and contagious disease examination and treatment establishments;

h/ To direct and guide the organization of primary healthcare for communities;

i/ To organize and decentralize the grant, suspension and withdrawal of certificates with respect to health establishments fully qualified for the use of vaccines and medical bio-products, and certificates of bio-safety standards with respect to laboratories according to its competence;

j/ To grant, suspend and withdraw certificates of circulation registration, appraisal of professional contents of dossiers of registration for advertisement of insecticides and germicides for domestic and medical use in accordance with law;

k/ To direct, guide, inspect and supervise the implementation of professional regulations and national technical regulations in preventive medicine nationwide;

l/ To direct and guide the organization, inspection, supervision and evaluation of HIV/AIDS control activities nationwide.

6. Regarding medical examination and treatment and functional rehabilitation:

a/ To formulate and promulgate according to its competence or submit to competent authorities for promulgation legal documents, professional regulations, national standards and technical regulations as well as economic-technical norms on medical examination and treatment, blood transfusion safety, convalescence, functional rehabilitation, clinical nutrition, plastic surgery, and medical expertise, forensic expertise and mental forensic expertise;

b/ To appraise and allow healthcare establishments to apply new techniques and new methods for the first time in Vietnam in accordance with law;

c/ To grant, re-grant and withdraw medicine practice certificates and grant, re-grant, modify and withdraw operation licenses with respect to healthcare establishments according to regulations;

d/ To appraise professional contents of dossiers of registration for advertisement of healthcare activities falling under its competence in accordance with law;

e/ To direct, guide, inspect and supervise the implementation of legal documents, professional regulations and national technical regulations on healthcare, functional rehabilitation, plastic surgery, medical expertise, forensic expertise and mental forensic expertise establishments.

7. Regarding traditional medicine and pharmacy:

a/ To formulate and submit to competent authorities for promulgation mechanisms and policies on inheritance, preservation, development and modernization of traditional medicine and pharmacy and the combination of traditional and modern medicine and pharmacy;

b/ To formulate and promulgate or submit to competent authorities for promulgation legal documents, professional regulations and national technical regulations on traditional

medicine and pharmacy;

c/ To grant and re-grant traditional medicine practice certificates; to grant, re-grant, modify and withdraw certificates of traditional remedies and operation licenses with respect to traditional-medicine establishments in accordance with law;

d/ To appraise professional contents of dossiers of registration for advertisement of traditional medicine practice in accordance with law;

e/ To direct, guide, inspect and supervise the implementation of mechanisms, policies, legal documents, professional regulations and national technical regulations on traditional medicine and pharmacy, and the combination of traditional and modern medicine and pharmacy.

8. Regarding medical equipment and works:

a/ To formulate and submit to competent authorities for promulgation national technical regulations on medical equipment; to promulgate professional regulations and national technical regulations on medical equipment;

b/ To promulgate a list of essential medical equipment for health units and establishments;

c/ To grant, suspend and withdraw registration certificates for circulation of home-made medical equipment, import permits for medical equipment on the Ministry of Health's list of those directly affecting people's health;

to appraise professional contents of dossiers of registration for advertisement of medical equipment in accordance with law;

d/ To direct, guide, inspect and supervise the implementation of legal provisions on the manufacture and trading of medical equipment;

e/ To assume the prime responsibility for, and coordinate with related agencies in, formulating and promulgating technical regulations and standards on designing and model designs of medical works.

9. Regarding pharmacy and cosmetics:

a/ To formulate and promulgate or submit to competent authorities for promulgation legal documents, professional regulations and national technical regulations on pharmacy and cosmetics, and sets of national standards on drugs; to issue Vietnam Pharmacopoeia and the National Pharmaceutical Bibliography;

b/ To grant and withdraw pharmaceutical practice certificates with respect to foreign-invested pharmaceutical practitioners; certificates of eligibility for medicine trading with respect to medicine manufacturers and providers of medicine preservation and medicine test services; medicine circulation licenses, medicine export and import permits; permits for registration of pharmaceutical activities in Vietnam of foreign suppliers of medicines into Vietnam; certificates of good manufacture practice (GMP), good laboratory practice (GLP), good storage practice (GSP), good clinical trial practice with respect to

medicine traders in accordance with law; to grant and cancel certificates of dossiers of announcement of enterprises organizing GPP drugstores;

c/ To grant and withdraw certificates of cosmetics good manufacture practice (CGMP); cosmetic product announcement card numbers; cards of receipt of dossiers of announcement of good practices in medicinal herb growing and harvest, and certificates of free sale of products with respect to medicine or cosmetics traders;

d/ To manage the quality of medicines and cosmetics; to suspend medicines or cosmetics from circulation or recall medicines or cosmetics in accordance with law; to coordinate with related agencies in preventing and fighting the manufacture and circulation of fake and poor-quality medicines and cosmetics, and the smuggling of medicines and cosmetics;

e/ To appraise professional contents of dossiers of registration for advertisement of medicines;

f/ To perform the state management of medicine prices and apply measures to stabilize market medicine prices in accordance with law;

g/ To direct, guide, inspect and supervise the reasonable, safe and effective use of medicines;

h/ To direct, guide, organize, inspect and supervise the implementation of legal provisions on pharmacy and cosmetics.

10. Regarding food safety:

a/ To assume the prime responsibility for formulating and promulgating or submitting to competent authorities for promulgation legal documents on food safety in the field under the Ministry's management;

b/ To assume the prime responsibility for formulating and promulgating national technical regulations or rules on safety and limits for all food products; to promulgate national technical standards on food additives, food processing aids, and packaging tools and containing materials in direct contact with food in accordance with law;

c/ To promulgate regulations on general conditions to ensure food safety, which are applicable to food producers and traders; to promulgate specific regulations on conditions to ensure food safety for collective kitchens, hotels, tourist resorts, restaurants, food catering establishments and street food vendors;

d/ To designate organizations to certify standard conformity of food products, food additives, food processing aids, packaging tools and containing materials in direct contact with food for which the technical regulations are available, after consulting ministries and sectors when necessary;

e/ To disseminate and educate in knowledge and law on food safety; to supervise, prevent, investigate and coordinate in preventing food poisoning and food safety incidents within the scope of the Ministry's management;

f/ To manage food safety throughout the

process of manufacturing, preliminarily processing, processing, preserving, transporting, exporting, importing and trading in food additives, food processing aids, bottled drinks, natural minerals, functional foods, nutrient-fortified foods, and packaging tools and containing materials in direct contact with food in accordance with law;

g/ To issue, suspend and withdraw written receipts of standard conformity announcement papers, certificates of announcement of conformity with food safety regulations with respect to pre-packed processed foods, food additives, food processing aids, and food-packaging tools and containing materials;

h/ To grant certificates of contents of advertisement for food additives, food processing aids, food-packaging tools and containing materials and food products falling within the scope of the Ministry's management;

i/ To grant and withdraw certificates of eligibility for food safety with respect to producers and traders of products falling within the scope of the Ministry's management;

j/ To grant certificates of free sale, medical certificates and origin certificates for food products falling within the scope of the Ministry's management; food additives; food processing aids, and packaging and containing tools and materials in direct contact with food at the request of organizations and individuals;

k/ To prescribe conditions on testing

establishments, designation of units to participate in food test to serve the state management within the scope of the Ministry's management; to designate units for arbitral testing and final conclusions when testing results of food testing units without and outside the health sector are different; to grant, suspend and withdraw registration certificates for circulation of quick test kits for food safety;

l/ To designate agencies to conduct state control of imported food safety for products under the Ministry's management;

m/ To direct, guide and organize the inspection and supervision of the implementation of the law on food safety within the scope of the Ministry's state management;

n/ To review and make statistics and periodical and extraordinary reports on food safety management based on the supervision and summarization of reports of line ministries.

11. Regarding population and family planning and reproductive health:

a/ To formulate and submit to competent authorities for promulgation policies on reproductive health and population, covering population size, structure and quality;

b/ To formulate and promulgate or submit to competent authorities for promulgation legal documents and national standards on population and family planning and reproductive health; to formulate and promulgate systems of population and reproductive health indicators;

professional regulations and national technical regulations on reproductive healthcare and family planning services;

c/ To permit the provision of counseling services by population and family planning counseling service providers in accordance with law;

d/ To permit the re-assignment of gender and childbirth by scientific methods in accordance with law;

d/ To direct, guide, inspect and supervise the implementation of legal documents, national technical regulations, policies, programs and projects on population and family planning and reproductive healthcare.

12. Regarding health insurance:

a/ To formulate and promulgate or submit to competent authorities for promulgation legal documents, mechanisms and policies on health insurance;

b/ To promulgate lists of medicines, medical supplies and technical services which the insured are entitled to and professional and technical regulations related to healthcare covered by health insurance;

c/ To formulate and submit to competent authorities for promulgation solutions to ensure the balance of the health insurance fund;

d/ To direct, guide, organize and inspect the implementation of the law on health insurance by health establishments and other organizations and individuals.

13. Regarding environmental protection in healthcare activities:

a/ To assume the prime responsibility for, and coordinate with the Ministry of Natural Resources and Environment and the Ministry of Construction in, formulating and submitting to competent authorities for promulgation regulations, national technical regulations and standards on environmental protection in healthcare activities, environmental protection in burial and cremation activities and the quality of medical environment;

b/ To organize the appraisal of assessment reports on strategic environment and environmental impacts of projects to be decided by the Ministry of Health;

c/ To direct, guide and organize the observation of environmental impacts of healthcare activities; management and control of medical wastes; treatment of pollution and rehabilitation of medical environment; collection, archive and provision of information on the environment related to the fields under the Ministry's state management in accordance with law;

d/ To direct, guide and organize the application of measures to protect people's health in response to the impacts of climate change, environmental pollution and adverse environmental factors;

e/ To assume the prime responsibility for, guide, organize, inspect and supervise the implementation of legal documents and national

technical regulations on management and destruction of medical wastes and on environmental protection in healthcare activities.

14. Regarding management of public employees in the medical, pharmaceutical and population sector:

a/ To formulate and submit to competent agencies for promulgation professional title standards of public employees in the medical, pharmaceutical and population sector;

b/ To guide the identification of working positions, the quantity and structure of public employees based on professional titles in public non-business health units;

c/ To assume the prime responsibility for, and coordinate with related agencies in, specifying the standards, conditions, contents and forms of examination or consideration for promotion of public employees in the medical, pharmaceutical and population sector; to organize examinations and consideration for promotion of these public employees in accordance with law;

d/ To assume the prime responsibility for, and coordinate with related agencies in, developing regimes and policies applicable to public employees in the medical, pharmaceutical and population sector.

e/ To specify the contents, programs, forms and time of training public employees in the medical, pharmaceutical and population sector based on their professional title standards.

15. Regarding human resource training:

a/ To submit to competent authorities for approval master plans and plans on health personnel training, and specific mechanisms and policies applicable to health personnel training;

b/ To promulgate national technical regulations on conditions to ensure the quality of health personnel training, and guide and organize the implementation thereof;

c/ To promulgate professional qualification standards for training disciplines in health and guide and organize the implementation thereof;

d/ To coordinate with the Ministry of Education and Training in performing the state management of health-specialized postgraduate training, including grade-1 specialized physicians; grade-2 specialized physicians; hospital resident physicians, and training for continuous updating of medical knowledge for health workers and public employees;

e/ To formulate, and organize the implementation of, plans on professional and skill training and retraining for health personnel;

f/ To manage health personnel training institutions in accordance with law.

16. Regarding science and technology

a/ To formulate and submit to competent authorities for promulgation legal documents, policies, strategies, master plans, plans and national technical regulations on scientific

research and technology development in the health sector, and on clinical trial and bio-medical research ethics in the health sector;

b/ To guide and organize the implementation, supervision and evaluation of activities of popularization and application of scientific research and technological renovation results and the transfer of new health technologies;

c/ To manage the national technical regulations and standards in the health sector in accordance with law; to guide and monitor the popularization and application of national technical regulations and standards in the health sector;

d/ To organize the implementation of the agreements on technical barriers in trade (TBT) in the health sector.

17. Regarding information technology:

a/ To formulate and implement strategies, master plans and plans on the information technology application and development in the health sector;

b/ To develop and promulgate technical standards on information technology application and development in the health sector;

c/ To formulate, promulgate and implement regulations on online medical activities;

d/ To direct, guide and organize the application of information technology in the health sector nationwide.

18. To direct, guide, organize, inspect and

supervise health communication and education activities.

19. To perform the state management of public services within the scope of the Ministry's state management in accordance with law; to issue specific criteria for classification of public non-business health units in conformity with the management requirements of the health sector.

20. To assume the prime responsibility for, and coordinate with related agencies in, natural disaster prevention and control and emergency treatment of disaster victims.

21. To draw up plans on and organize the national reserves of medicines, chemicals, medical equipment and means for epidemic and natural disaster prevention and control according to the lists of national reserves decided by the Government and prescribed by law.

22. To perform the state management of associations and non-governmental organizations operating in the fields within the scope of the Ministry's state management in accordance with law.

23. To draw up, and direct the implementation of, administrative reform plans of the health sector in line with the objectives and contents of the Government's mater plan on public administrative reform.

24. To manage the organizational apparatus, payroll, cadres, civil servants and public

employees; to apply the wage regime and preferential treatment, commendation and disciplining regime and policies to cadres, civil servants and public employees managed by the Ministry in accordance with law.

25. To implement international cooperation in the fields managed by the Ministry in accordance with law.

26. To manage its assigned finance and property and organize the implementation of the allocated budget in accordance with law.

27. To inspect and examine the implementation of legal provisions and settle complaints, denunciations and petitions related to the fields under the Ministry's state management; to prevent and fight corruption and handle violations in the fields under the Ministry's state management in accordance with law.

28. To formulate and promulgate systems of statistical indexes and reporting regime applicable in the health sector in accordance with law; to collect, synthesize, process, manage and archive statistical information on the health sector; to establish a database of the health sector.

29. To perform other tasks and exercise other powers assigned by the Government or the Prime Minister and as prescribed by law.

Article 3. Organizational structure

1. The Communication, Emulation and Commendation Department.

2. The Children's and Mothers' Health Department.

3. The Medical Equipment and Work Department.

4. The Health Insurance Department.

5. The Planning and Finance Department.

6. The Organization and Personnel Department.

7. The International Cooperation Department.

8. The Legal Affairs Department.

9. The Ministry's Office.

10. The Ministry Inspectorate.

11. The Preventive Medicine Department.

12. The Vietnam Administration of HIV/AIDS Control.

13. The Food Safety Department.

14. The Health Environmental Management Department.

15. The Science, Technology and Training Department.

16. The Healthcare Management Department.

17. The Traditional Medicine and Pharmacy Management Department.

18. The Drug Administration of Vietnam.

19. The Information Technology Department.

20. The General Office for Population and Family Planning.

21. The Health Strategy and Policy Institute.
22. The Health and Life newspaper.
23. The Applied Medicine magazine.
24. The Pharmacy review.

The following organizations may organize sections: The Planning and Finance Department (7 sections), the Organization and Personnel Department (3 sections), the Health Insurance Department (3 sections) and the Medical Equipment and Health Works Department (2 sections).

The organizations defined in Clause 1 thru Clause 20 of this Article shall assist the Minister in performing the state management; the organizations defined in Clause 21 thru Clause 24 of this Article are non-business units of the Ministry of Health.

Article 4. Effect

This Decree takes effect on October 20, 2012.

This Decree replaces the Government's Decree No. 188/2007/ND-CP of December 27, 2007, defining the functions, tasks, powers and organizational structure of the Ministry of Health, and Decree No. 22/2010/ND-CP of March 9, 2010, amending and supplementing Article 3 of the Government's Decree No. 188/2007/ND-CP of December 27, 2007; to annul all previous provisions which are contrary to this Decree.

Article 5. Implementation responsibility

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