

MEDICAL ESTABLISHMENTS ACT

Prom. SG. 62/9 Jul 1999, suppl. SG. 88/8 Oct 1999, amend. SG. 113/28 Dec 1999, corr. SG. 114/30 Dec 1999, amend. SG. 36/2 May 2000, amend. SG. 65/8 Aug 2000, amend. SG. 108/29 Dec 2000, amend. SG. 51/5 Jun 2001, amend. SG. 62/13 Jul 2001, amend. SG. 28/19 Mar 2002, amend. SG. 83/19 Sep 2003, amend. SG. 102/21 Nov 2003, amend. SG. 114/30 Dec 2003, amend. SG. 70/10 Aug 2004, amend. SG. 46/3 Jun 2005, amend. SG. 76/20 Sep 2005, amend. SG. 85/25 Oct 2005, amend. SG. 88/4 Nov 2005, amend. SG. 105/29 Dec 2005, amend. SG. 30/11 Apr 2006, amend. SG. 34/25 Apr 2006, amend. SG. 59/21 Jul 2006, amend. SG. 105/22 Dec 2006, amend. SG. 31/13 Apr 2007, amend. SG. 59/20 Jul 2007, amend. SG. 110/30 Dec 2008, amend. SG. 36/15 May 2009, amend. SG. 41/2 Jun 2009, amend. SG. 99/15 Dec 2009, amend. SG. 101/18 Dec 2009, amend. SG. 38/21 May 2010, amend. SG. 59/31 Jul 2010, amend. SG. 98/14 Dec 2010, amend. SG. 100/21 Dec 2010, amend. SG. 45/14 Jun 2011, amend. SG. 60/5 Aug 2011, amend. SG. 54/17 Jul 2012, amend. SG. 60/7 Aug 2012, amend. SG. 102/21 Dec 2012, amend. SG. 15/15 Feb 2013, amend. SG. 20/28 Feb 2013, amend. SG. 47/6 Jun 2014, amend. and suppl. SG. 72/18 Sep 2015, amend. SG. 95/8 Dec 2015, amend. SG. 81/14 Oct 2016, amend. and suppl. SG. 98/9 Dec 2016, amend. SG. 85/24 Oct 2017, suppl. SG. 99/12 Dec 2017, amend. and suppl. SG. 101/19 Dec 2017, amend. and suppl. SG. 103/28 Dec 2017, amend. and suppl. SG. 18/27 Feb 2018, suppl. SG. 77/18 Sep 2018, amend. and suppl. SG. 84/12 Oct 2018, amend. SG. 91/2 Nov 2018, amend. and suppl. SG. 102/11 Dec 2018

Part one. GENERAL PART

Chapter one. GENERAL PROVISIONS

Art. 1. This Act settles the structure and activity of the medical establishments in the Republic of Bulgaria.

Art. 2. (1) (amend. SG 76/05) Medical establishments, in the context of this Act, are organisationally separate structures on functional principle, in which doctors or dental practitioners, individually or with the assistance of other medical and non-medical specialists, carry out all or some of the following activities:

1. diagnostics, treatment and rehabilitation of patients;
2. care of pregnant women and provision of natal assistance;
3. care of chronically ill patients and persons threatened by disease;
4. prophylactics of diseases and early discovery of diseases;
5. measures for strengthening and protection of the health.
6. (new, SG 83/03) transplantation of organs, tissues and cells.

(2) Carried out in the medical establishments can be education of students and post graduate education of medical specialists by the order of this Act.

- (3) Scientific activity can be carried out in the medical establishments.

(4) (new – SG, 72/2015) The medical establishments may provide integrated medical-social services under Chapter Four, Section Ia of the Health Act.

Art. 2a. (new – SG 30/06) (1) (amend. - SG 59/10, in force from 31.07.2010, amend. – SG 72/2015) Medical and diagnostic activity may be carried out in the medical faculties and the faculties of dental medicine of the universities upon implementation of practical education of students and PhD students of medicine, dental medicine and pharmacy, post-graduate education of doctors and dental practitioners as well as upon implementation of scientific activity.

(2) The activity referred to in para 1 shall be carried out in compliance with the educational plans and programmes.

Art. 3. (1) (suppl. – SG 59.07, in force from 20.07.2007) The medical establishments, without those under Art. 5, para 1 shall be founded according to the Commerce Act or according to the Co-operatives Act, as well as companies under the legislation of European Union Member State or of a state which is a party under the European Economic Area Agreement subject to compliance with the requirements of this Act.

(2) (amend. SG 76/05; amend. - SG 59/10, in force from 31.07.2010) The medical establishments under Art. 8, para 1, item 1, letter "a" and item 2, letter "a" shall be established by:

1. natural persons – doctors and dental practitioners;

2. sole entrepreneurs or one-person companies, registered by doctors and dental practitioners; where the medical establishment is established in the form of one-person company, the single owner shall manage and represent the medical establishment.

(3) The medical establishments shall carry out their activity only upon obtaining permit or registration under the conditions and by the order of this Act.

(4) The medical establishments cannot carry out commercial transactions except for the needs of the medical activities carried out by them and for services to the patients.

(5) (new – SG 20/13) Medical establishments under Art. 5, para 1 and state medical establishments – trade companies shall make payments for transactions referred to in para 4 within 60 days from the date of receipt of an invoice or other payment reminder.

(6) (amend. – SG 59/07, in force from 20.07.2007; prev. text of para 5 - SG 20/13) As regards to medical establishments under par. 1, the provisions of the Commerce Act and of the Cooperatives Act shall apply, and as regards to foreign companies, the national legislation of the country of registration shall apply respectively, unless this Act stipulates otherwise.

Art. 4. (1) The medical establishments shall provide hospital and non-stationary care. They shall be founded by the state, by the municipalities and by other corporate bodies and individuals.

(2) The medical establishments shall be of equal status regardless of their ownership.

(3) The medical activity of each medical establishment shall be subject to control.

Art. 5. (1) (amend., SG 36/00, amend. SG 88/05; amend. - SG 59/10, in force from 31.07.2010; suppl. - SG 98/10, in force from 14.12.2010, suppl. – SG, 72/2015) The Centres for emergency medical care, the centres for transfusion haematology, the medical establishments for stationary psychiatric care, the homes for medical and social care, carrying out medical care and specific care for children, centres for complex service of disabled children and children with chronic diseases, as well as the medical establishments at the Council of Ministers, the Ministry of Defence, the Ministry of Interior, the

Ministry of Justice and the Ministry of Transport, Information Technologies and Communications shall be founded by the state.

(2) medical establishments for stationary psychiatric care can also be founded by other persons.

(3) Homes for medical and social care shall be founded by the municipalities and other corporate bodies.

(4) (new – SG 59/10, in force from 31.07.2010) The medical establishments for stationary psychiatric aid may provide social services under the order of the Social Support Act.

(5) (new - SG 98/10, in force from 14.12.2010, amend. and suppl. – SG, 72/2015) The directors of medical establishments under Para 1 shall submit to the Minister of Health information of the medical activities, resources of the medical establishments and analysis of their activity of the medical establishments according to a procedure determined by the competent minister of the Minister of Health.

Art. 6. (1) (amend. SG 62/02; amend. - SG 59/10, in force from 31.07.2010, amend. – SG, 72/2015, amend. – SG 102/18, in force from 01.01.2019) The activity of the medical establishments and of the medical and other specialists, working in them shall be carried out while observing the medical standards for good medical practice and ensuring the protection of the rights of the patient. The medical standards shall be approved with an ordinance of the Minister of Health.

(2) (amend. – SG, 72/2015) The medical establishments shall apply technologies and systems for gathering and exchange of information as well as health-information standards, confirmed by an ordinance of the Minister of Health.

(3) The medical establishments shall submit information about the medical activity carried out by them, as well as medical statistic information according to an ordinance of the Minister of health, in co-ordination with the National Institute of Statistics.

(4) (new – SG 54/12; amend. SG 15/13, in force from 01.01.2014) The medical establishments funded from the budget of the National Health Insurance Fund and/or from the state budget shall provide information of the expenses made by them for carrying out their activities as set out in the ordinance under Para 3.

(4a) (New – SG 102/18, in force from 01.01.2019) With the ordinance under Para. 3 shall also be determined the medical and statistical indicators and financial indicators for the hospitals and the complex oncology centers, which are financed by the budget of the National Health Insurance Fund and/or the state budget, and which the Ministry of Health publishes on its official [website](#) every three months. The National Health Insurance Fund shall provide the Ministry of Health with information on the relevant indicators of its competence.

(5) (prev. text of Para 04, amend. – SG 54/12, suppl. – SG, 72/2015) For fulfilment of the activities under para 2, 3 and 4 the medical establishments for hospital care shall establish information units. The structure and composition of the information units shall be defined by the ordinance under Para. 2.

(6) (New – SG 102/18, in force from 01.01.2019) The state and municipal health care establishments for hospital care and the complex oncology centers shall also apply standards for financial activities, approved by an ordinance of the Minister of healthcare.

(7) (Hew – SG 59/10, in force from 31.07.2010; prev. text of Para 05 – SG 54/12, suppl. – SG, 72/2015, previous Para. 6, amend. – SG 102/18, in force from 01.01.2019) The control of the medical establishment for compliance with the standards under Para 1, 2, and 6, and the requirements under Art. 19, Para 2 and 3 shall be carried out by the control authorities specified in this Act, the Health Act and the Health Insurance Act.

Art. 6a. (New – SG 102/18, in force from 01.01.2019) (1) The medical standards under Art. 6,

Para. 1 shall define the minimum obligatory requirements towards the structures carrying out the activities in certain medical specialties or the implementation of individual medical activities in order to provide quality prophylactics, diagnostics, treatment, rehabilitation and health care for patients.

(2) Medical standards shall contain:

1. main characteristic of the medical specialty / medical activity;
2. requirements for the persons pursuing professional activity in the medical specialty / medical activity;
3. requirements for carrying out the activities in the medical specialty / medical activity in structures of outpatient and hospital care and in the medical establishments under Art. 10;
4. quality criteria for the activities carried out in the medical specialty / medical activity.

(3) The requirements under Para. 2, items 2 to 4 shall be determined by levels of competence.

(4) The medical standards under Art. 6, Para. 1 shall be updated as necessary in the order of their validation.

Art. 7. No medical establishments can refuse medical care to persons who appear in status threatening their life, regardless of their place of living.

Chapter one "a".

CONTROL OF HEALTH CARE ESTABLISHMENTS AND OF MEDICAL ACTIVITIES (NEW - SG 102 OF 2018, IN FORCE FROM 01.01.2019)

Art. 7a. (New – SG 102/18, in force from 01.01.2019) (1) (In force from 01.04.2019) The control over the work of the medical establishments, the medical activities and the quality of the medical help shall be provided by the Executive Agency "Medical Supervision" to the Minister of Healthcare.

(2) (In force from 01.04.2019) The Executive Agency "Medical Supervision" shall be a legal entity on budget support with the Minister of Healthcare.

(3) (In force from 01.04.2019) The Executive Agency "Medical Supervision" shall be managed and represented by an Executive Director who is to be appointed by the order of the Administration Act.

(4) The activity, the structure and the organization of the work of the Executive Agency "Medical Supervision" shall be determined by a statute of regulations adopted by the Council of Ministers.

Art. 7b. (New – SG 102/18, in force from 01.01.2019) (1) The Executive Agency "Medical Supervision" shall:

1. register, refuse to register, change and delete the registration of outpatient care institutions and hospices;
2. register, refuse to register, change and delete registration for carrying out medical treatment under Art. 2a;
3. make motivated proposals to the Minister of Health for issuing, refusing to issue, for changing and revoking permits for for medical care to medical establishments for hospital care, mental health centers, centers for skin-venereal diseases, complex centers of oncology, homes for medical and social care, dialysis centers and tissue banks;
4. perform the functions of a competent body for management, coordination and control of the transplantation in the Republic of Bulgaria in accordance with the Act on the Transplantation of Organs, Tissues and Cells;
5. give an opinion on the rules of good medical practice sent out by the respective branch

organization, rules for good medical practice of dental practitioners, rules on good pharmaceutical practice and rules for good medical practice in healthcare in the relevant professional field, as well as perform control over their observance together with the professional organizations;

6. verify the conformity of the structure, management, operation and organization of the medical care in the medical establishments with the requirements of this Act, the Health Act, the Act on the Transplantation of Organs, Tissues and Cells, and the secondary legislation for their implementation;

7. verify the observance of patients' rights in the medical establishments;

8. verify the observance of the established medical standards in the medical establishments;

9. perform control over the quality of the medical care provided in compliance with the approved medical standards;

10. verify compliance with the approved standards for financial activity by the medical establishments under Art. 6, Para. 6;

11. verify compliance with the approved pharmaco-therapeutic manuals under Art. 259, Para. 1, item 4 of the Medicinal Products in Human Medicine Act, as well as the medical establishments in carrying out the activities under Art. 259, Para. 1, item 10 of the Medicinal Products in Human Medicine Act;

12. perform medical control under the provisions of Chapter Four of the Health Insurance Act;

13. carry out checks on requests of citizens and legal entities, related to the medical care provided;

14. exercise control over the work of the medical establishments in carrying out of medical expertise under the order of the Health Act;

15. perform inspections of the medical establishments for the spending of funds from the state budget under the procedure of Art. 82 of the Health Act and Art. 106a, Para. 6;

16. carry out checks on compliance of the medical establishments approved for carrying out training activities for students, postgraduates and / or graduate students, with the criteria and conditions of the ordinance under Art. 90 Para. 3;

17. make motivated proposals to the respective Minister for imposing disciplinary sanction on a director of a medical establishment under Art. 5, Para. 1;

18. make motivated proposals to the respective heads of medical establishments for imposing disciplinary sanctions;

19. make proposals to the Minister of Healthcare for imposing administrative penalties and implementing enforcement administrative measures;

20. apply enforcement administrative measures and impose administrative penalties in the cases specified by law;

21. submit to the Minister of Healthcare an annual report on the work of the Agency;

22. carry out other activities assigned by law.

(2) The Executive Agency "Medical Supervision" shall immediately notify the employer, the labour safety authorities, the state health control bodies, the Bulgarian Food Safety Agency and the environmental protection authorities to take the necessary measures in cases when it establishes labour conditions and other harmful environmental factors which threaten the health of citizens.

Art. 7c. (New – SG 102/18, in force from 01.01.2019) (1) The Executive Agency "Medical Supervision" shall carry out planned and occasional inspections of the medical establishments.

(2) Planned checks shall be carried out every two years of medical institutions for hospital care and the medical establishments under Art. 10 for compliance of their activity with the requirements of this law and of the approved medical standards.

(3) The Executive Agency "Medical Supervision" shall have the right to inspect the activity of all natural and legal persons, who have been reported to operate in violation of this Act, the Health Act

and the Act on Transplantation of Organs, Tissues and Cells.

(4) (In force from 01.04.2019) The conditions and procedure for carrying out the inspections under Para. 1 - 3 and for carrying out the medical control under Chapter Four of the Health Insurance Act shall be determined by an ordinance of the Minister of Healthcare.

(5) In exercising his powers, the Minister of Healthcare may entrust an inspection by the Executive Agency "Medical Supervision".

(6) The Executive Agency "Medical Supervision" shall carry out, jointly with the regional health inspections, checks under Para. 1 under conditions and by order, determined by the ordinance under Para. 4.

Art. 7d. (New – SG 102/18, in force from 01.01.2019) (1) The state authorities and the officials shall be obliged to assist the employees of the Executive Agency "Medical Supervision" in exercising their powers.

(2) In exercising their powers, the employees of the Executive Agency "Medical Supervision" shall be entitled to:

1. require from the inspected persons all necessary data, documents, information, references and written explanations related to the controlled activity, including the right of free access to the service premises of the medical establishments and the persons under Art. 7c, Para. 3;

2. access to the medical records kept by the medical establishments and by the persons under Art. 7c, Para. 3;

3. give mandatory prescriptions with a fixed term, and monitor their implementation.

Art. 7e. (New – SG 102/18, in force from 01.01.2019) (1) The employees of the Executive Agency "Medical Supervision" shall be obliged not to disclose any circumstances and facts that have become known to them during or in connection with the implementation of their official duties, except at the written request of a state authority, where this is provided for by law.

(2) In connection with their obligations under Para. 1, the persons shall sign a declaration in a form approved by the Executive Director of the Agency.

Art. 7f. (New - SG 102/18, in force from 01.01.2019) (1) The activity of the Executive Agency "Medical Supervision" shall be financed from budget funds and revenues from its own activity.

(2) The budget resources shall be provided by subsidies from the state budget through the budget of the Ministry of Health.

(3) The Executive Agency "Medical Supervision" shall be the administrator of the revenues from its own activities, which are formed by:

1. fines and pecuniary sanctions imposed by enforced penal decrees issued by the Executive Director of the Executive Agency "Medical Supervision", entered in its account;

2. other sources.

Art. 7g. (New - SG 102/18, in force from 01.01.2019) The financial resources under Art. 7e, Para. 3 shall be spent on the activities of the Executive Agency "Medical Supervision".

Part two.
MEDICAL ESTABLISHMENTS

Chapter two.

TYPES OF MEDICAL ESTABLISHMENTS

Art. 8. (1) Medical establishments for non-stationary care are:

1. ambulatory for primary medical care which can be:
 - a) individual practice for primary medical care;
 - b) group practice for primary medical care;
2. ambulatory for specialised medical care which can be:
 - a) individual practice for specialised medical care;
 - b) group practice for specialised medical care;
 - c) (amend. - SG 59/10, in force from 31.07.2010) medical centre and medical dental centre;
 - d) diagnostic and consultative centre;
3. independent medical diagnostic and medical technical laboratories;
4. (new – SG 59/10, in force from 31.07.2010) dental centres.

(2) (amend. SG 62/02; amend. - SG 59/10, in force from 31.07.2010, suppl. – SG, 72/2015)

Provided to the medical establishments under para 1, item 2, letters "c" and "d" and Item 4 can be up to 10 beds for observation and treatment up to 48 hours. The diagnostic-consultative centres may open additionally up to 5 beds for observation and treatment by 48 hours for the purposes of conducted by them clinical tests of medical products under the Act on Medical Products in Human Medicine.

(3) (new – SG 62/02) Upon occurring of need for longer stay in the cases of para 2 the medical establishment shall be obliged to organise the hospitalisation of the patient.

Art. 9. (1) Medical establishments for hospital care are:

1. hospital for active treatment;
2. (amend. – SG, 72/2015) hospital for continuous treatment;
3. rehabilitation hospital.
4. (new - SG 65/00, amend. – SG, 72/2015) hospital for continuous treatment and rehabilitation.

(2) The hospitals can be multi-profiled or specialised.

(3) (new – SG 62/02, suppl. – SG, 72/2015) University hospitals shall be multi-profiled or specialised hospitals, determined by the Council of Ministers, where are carried out activities for in every of the following areas:

1. (amend. – SG, 72/2015) clinical training of students and PhD students in medicine and/or stomatology and/or pharmacy;
2. (amend. – SG, 72/2015) clinical training for students in subjects of professional direction Health Care;
3. (amend. – SG, 72/2015) post graduate training of doctors, dentists, pharmacists , specialists in health care.

(4) (prev. (3) – SG 62/02; revoked – SG 598/10, in force from 31.07.2010)

(5) (prev. (4), amend. SG 62/02; revoked – SG 598/10, in force from 31.07.2010)

(6) (new - SG 98/10, in force from 14.12.2010) It shall be permissible that on the territory of a state or municipal medical establishment for hospital care another medical establishment for hospital care performs its activity, provided that the clinics, departments and laboratories in the two medical establishments for hospital care carry out different medical activities.

Art. 10. Medical establishments according to this Act are also:

1. centre for emergency medical care;
2. centre for transfusion haematology;
3. (amend. - SG 59/10, in force from 31.07.2010) mental health centre;
- 3a. (new - SG 59/10, in force from 31.07.2010) skin and venereal disease centre;
- 3b. (new - SG 59/10, in force from 31.07.2010) complex oncology centre;
4. home for medical and social care;
- 4a. (new – SG, 72/2015) centre for complex service of disables children and chronic diseases;
5. hospice;
6. (new – SG 62/02) dialysis centre.
7. (new, SG 83/03) tissue bank.

Chapter three.

MEDICAL ESTABLISHMENTS FOR NON-STATIONARY CARE

Art. 11. (1) (amend. SG 76/05) The ambulatories for primary or specialised non-stationary care are medical establishments in which doctors or dental practitioners:

1. carry out:
 - a) diagnostics, treatment, rehabilitation and care of patients;
 - b) consultations;
 - c) prophylactics;
 - d) (new – SG 46/05) dispensarization;
2. prescribe:
 - a) laboratory and other types of tests;
 - b) carrying out medical activities and manipulations under their supervision and responsibility;
 - c) the volume, the type of home care and aid to the patients;
 - d) medical supplies, dressing materials and medical instruments;
3. carry out expertise of temporary incapacity;
4. provide care and render medical aid for pregnancy and maternity;
5. observe, control and care for the physical and psychological development of persons under 18 years of age;
6. carry out activities on the health promotion and prophylactics, including prophylactic examinations and immunisations;
7. issue documents related to their activity;
8. direct patients for consultative and hospital care.

(2) (new – SG 60/11, in force from 05.08.11, suppl. - SG 84/18, in force from 12.10.2018) At a medical centre, a medical-dental centre and at a dental centre, as well as in individual and group practices for primary and specialized medical care, clinical testing of medicinal products may be carried out.

(3) (amend. SG 76/05; previous Para 2 – SG 60/11, in force from 05.08.2011) Doctor, respectively dental practitioner, practising in ambulatory for primary or specialised non-stationary care shall carry out treatment of a patient in his home when the condition of the patient so requires.

(4) (amend. SG 76/05; previous Para 3 – SG 60/11, in force from 05.08.2011) The doctors and dental practitioners from the medical establishments shall be obliged to hospitalise the patients in a hospital when the purposes of the treatment cannot be achieved in ambulatory conditions or in the home of the patients.

(5) (new – SG 41/09, in force from 02.06.2009; previous Para 4 – SG 60/11, in force from 05.08.2011) A dental practitioner, holding a certificate of respective qualification issued pursuant to the provisions of the Safe Use of Nuclear Energy Act, may carry out image diagnostic of patients' teeth and

jaws.

Art. 12. (amend. SG 76/05) The nature of the activity, the number and the qualification of the doctors, respectively of the dental practitioners, working in the medical establishment and the way of organisation shall determine the type of the ambulatory according to Art. 8, para 1, item 1 and 2.

Art. 13. (1) (amend. SG 76/05) Individual practice for primary medical care shall be organised and carried out by a doctor with recognized specialty in general medicine, respectively by doctor in dental medicine, who shall be registered by the order of Art. 40.

(2) (amend. SG 76/05) The individual practice for specialised medical care shall be organised and carried out by a doctor with recognized specialty out of this of para 1, respectively by a doctor in dental medicine, with acknowledged speciality, who shall be registered by the order of Art. 40.

(3) The persons under para 1 and 2 can also hire other persons according to the needs and the volume of the medical activity.

(4) (amend. SG 76/05; amend. - SG 98/10, in force from 01.01.2011) The persons under para 1 shall be obliged to appoint deputies in the cases of their absence, informing about that the respective regional health inspection and the regional health assurance fund. The person appointed as deputy must have the respective legal capacity and to be entered in the respective register according to the Act on Professional Organisations of Doctors and Dental Practitioners.

(5) In the cases of absence over 10 days the conditions and the order of the substitution shall be settled by the contract for providing medical care with the respective regional health assurance fund.

(6) The contract for providing medical care, concluded between the persons under para 1 and the health assurance fund, shall settle the conditions and the order of substitution both in cases of absence of the person - party to the contract and the substitution by other persons who have registered individual practice for non-stationary care in the same region.

Art. 14. (1) (amend. SG 76/05) Group practice for primary medical care shall be carried out by a trade company or co-operative, founded by doctors with recognized specialty in general medicine, respectively by doctors in dental medicine, which shall be registered by the order of Art. 40.

(2) (amend. SG 76/05) Group practice for specialised medical care shall be carried out by a trade company or co-operative founded by doctors with recognized one and the same speciality out of these of para 1, respectively doctors in dental medicine, with the same acknowledged speciality, which shall be registered by the order of Art. 40.

(3) The persons under para 1 and 2 can also hire other persons according to the needs and the volume of the medical activity.

Art. 14a. (1) (new - SG 47/14, in force from 03.06.2014) Doctors who have been admitted to training for specialization in general medicine shall also be entitled to organize and carry out an individual or group practice of primary medical care after registration under Art. 40, for a period not longer than the time limit for training for the specialty fixed in Art. 181 of the Health Act.

Art. 15. The persons under Art. 13, para 1 and Art. 14, para 1 can conclude contracts for carrying out medical activity with doctor's assistants and nurses (mid-wives) working in another populated area.

Art. 16. (1) (amend. SG 76/05; amend. - SG 59/10, in force from 31.07.2010) Medical centre or medical and dental centre is a medical establishment providing out non-stationary care, with not less than three doctors and/or three dental practitioners with different acknowledged specialities.

(2) (new - SG 59/10, in force from 31.07.2010) Dental centre means a medical establishment, in which at least three physicians in dental medicine of different acknowledged specialities provide primary and specialised non-stationary dental care.

(3) (amend. SG 76/05; prev. text of Para 02 – SG 598/10, in force from 31.07.2010) Medical centre, dental centre or medical and dental centre shall be managed by a doctor, respectively a dental practitioner with acknowledged speciality.

(4) (prev. text of Para 03, amend. – SG 598/10, in force from 31.07.2010) The structure, the activity and the internal order of the centre shall be settled by regulations approved by the manager under para 3.

Art. 17. (1) (amend., SG 65/00) The diagnostic and consultative centre is a medical institution carrying out specialised out-hospital care with no less than 10 physicians with various acknowledged specialities. The centre must be supplied with the necessary medical equipment, to have at least one medical diagnostic laboratory and a unit for image diagnostics.

(2) (amend. – SG, 72/2015) The diagnostic and consultative centre shall be managed by a doctor with acknowledged speciality and qualification on health management or master of economics and management with acquired educational and/or scientific degree, subject or passed education for raising the qualification under Art. 43 of the Act on Higher Education in the Area of the Health Management.

(3) The structure, the activity and the internal order of the centre shall be settled by regulations approved by the manager under para 2.

(4) (new – SG 31/07, in force from 13.04.2007) At the diagnostic and consultative centre may be carried out clinical trials of medicinal products following the procedure of the Medicinal Products in Human Medicine Act.

Art. 17a. (new – SG 59/07, in force from 20.07.2007) (1) (amend. and suppl. – SG, 72/2015) In the medical, medical dental and diagnostic consulting centre units may be established, in which medical assistants, medical nurses, midwives can provide obstetrical services health cares.

(2) (amend. - SG 92/18) The types of activities, being carried out in the units under par. 1 shall be determined in compliance with the Ordinance under Art. 7, par. 1 of the Act on the Professional Organizations of Nurses, Midwives and Associated Medical Specialists, Dental Technicians and Assistant-Pharmacists.

(3) (amend. – SG, 72/2015) The units of par. 1 shall be managed by persons having educational and qualification degree of "Bachelor" in the subjects medical assistant, nurse or "obstetrics" and a professional experience of not less than two years.

(4) The procedure of implementation of activities in the units under par. 1 shall be ruled in the Regulations for organization, operation and in-order of the respective medical establishment.

Art. 18. (1) (amend. SG 76/05, amend. – SG, 72/2015) The independent medical and diagnostic laboratory is a medical establishment in which doctor/s, with the assistance of other specialists carried out prescribed by another doctor or dental practitioner specialised medical tests in one or more medical

subjects. . Working in it shall be at least one doctor with acknowledged speciality in each of the directions of the laboratory activity.

(2) (amend. SG 76/05, amend. – SG, 72/2015) The independent medical technical laboratory is a medical establishment in which specialists with the respective education carry out prescribed by a doctor, respectively by a dental practitioner, specific technical activities and produce specialised medical products.

(3) (amend. – SG, 72/2015) The independent medical diagnostic laboratory is managed by a doctor with acknowledged speciality in one of the directions of the laboratory activity.

(4) (amend. SG 76/05) The independent medical technical laboratory is managed by a doctor, respectively by a dental practitioner or a specialist on the profile of the laboratory.

(5) (new – SG 41/09, in force from 02.06.2009, amend. – SG, 72/2015) The requirements for carrying out the activities of the laboratories under par. 1 and 2 shall be determined by the relevant medical standards under Art. 6, Para. 1.

(6) (prev. par. 5 – SG 41/09, in force from 02.06.2009, amend. – SG, 72/2015) The structure, activity and the internal rules of the laboratories under para 1 and 2 shall be provided by Rules, confirmed by the head of the laboratory.

Chapter four. MEDICAL ESTABLISHMENTS FOR HOSPITAL CARE

Art. 19. (1) (prev. text of Art. 19 - SG 59/10, in force from 31.07.2010) Medical establishment for hospital care is an establishment in which doctors with the assistance of other specialists and auxiliary personnel carry out all or some of the following activities:

1. diagnostics and treatment of diseases when the purpose of the treatment cannot be achieved in the conditions of non-stationary care;
2. natal care;
3. rehabilitation;
4. (amend. SG 76/05) diagnostics and consultations requested by a doctor or a dental practitioner or by other medical establishments;
 - 4a. (new, SG 83/03) transplantation of organs, tissues and cells;
 - 4b. (new, SG 102/03) taking, storing, supply of blood and blood components, transfusion supervision;
5. (revoked. – SG, 72/2015)
6. (amend. – SG, 72/2015) clinical tests of medicine products and medical products according to the legislation in force in the country;
7. educational and scientific activity.

(2) (new - SG 59/10, in force from 31.07.2010) The medical establishment for stationary care under Para 1 shall carry out its activity:

1. (suppl. - SG 102/18, in force from 01.01.2019) in compliance with the medical standards and the good medical practice rules approved under Art. 6, Para 1, the rules of good medical practice of dental practitioners and the rules of good medical practice for health care of nurses, midwives and associated medical specialists;
2. where the medical establishment for stationary care has employed medical specialists under primary employment contracts;
3. in case of availability of technically sound medical equipment and facilities on the territory of the medical establishment specified in the medical standards under Art. 6, Para 1.
4. (new - SG 102/18, in force from 01.01.2019) in accordance with the approved standards for financial activity - in the cases under Art. 6, Para. 6.

(3) (new - SG 59/10, in force from 31.07.2010) The medical establishment for stationary care under Para 1 shall ensure uninterrupted 24-hour performance of the medical activity in all medical specialities according to the permission under Art. 47, including emergency medical care.

(4) (new - SG 59/10, in force from 01.01.2011, repealed - SG 102/18, in force from 01.01.2019)

Art. 19a. (new – SG, 72/2015) In the consultative offices, medical-diagnostic and medical technical laboratories and wards without beds of the medical establishments for hospital aid under Art. 5, Para. 1 may also be carried out the activities under Art. 11, Para. 1.

Art. 20. (1) (prev. text of Art. 20 - SG 59/10, in force from 31.07.2010, amend. – SG, 72/2015, amend. – SG, 72/2015) Treated in the hospital for active treatment shall be patients with acute diseases, traumas, aggravated chronic diseases, conditions requiring operative treatment in hospital conditions, as well as natal care.

(2) (new - SG 59/10, in force from 31.07.2010, amend. – SG, 72/2015) In hospitals for active treatment may be opened structures for continuous treatment and rehabilitation.

(3) (new – SG, 72/2015) In a hospital for active treatments may be provided complex medical cares for sick persons with certain illnesses and for disabled children and chronic diseases.

(4) (new – SG, 72/2015) The complex cares under Para. 3 may be organized on a functional principle by the structural units of the hospital.

(5) (new – SG, 72/2015) In the cases under Para. 4, the complex cares for sick persons with psychotic, skin and venereal and oncologic sicknesses and for disabled children and chronic diseases shall include the activities under Art. 26, Para. 1 or Art. 26a, Para. 1, Art. 26b, Para. 1 and Art. 27, Para. 1 and for the sick persons with other sicknesses – the needed activity for their observation and treatment.

(6) (new – SG, 72/2015) The organization of the complex cares in the hospital shall be provided by the Rules of procedure, activity and internal order of the medical establishment.

(7) (new - SG 59/10, in force from 31.07.2010, former Para. 3, suppl. – SG, 72/2015) The activity under Para 2 and 3 may be carried out only after the grant of the permission under Art. 47.

Art. 21. (amend. - SG, 72/2015) The hospital for continuous treatment shall admit persons needing long recovery of health and persons with chronic diseases requiring care and sustenance of satisfactory corporal and psychological condition.

Art. 22. The hospital for rehabilitation shall admit persons needing physical therapy, motor and psychic rehabilitation, balneological, climatological and thalassotherapy.

Art. 22a. (new - SG 65/00, amend. – SG, 72/2015) Carried out in the hospital for continuous treatment and rehabilitation shall be the activities under art. 21 and 22.

Art. 23. (amend. - SG 59/10, in force from 31.07.2010) (1) Multi-profile hospital means a medical establishment containing departments and clinics for at least two medical specialities.

(2) Specialised hospital is a medical establishment containing departments or clinics for one medical or dental speciality.

(3) In the specialised hospital may be opened also structures of prevailing surgery, therapeutic, clinic and diagnostic or other direction and for anaesthesiology and intense treatment, providing for the performance in the speciality, in which the hospital has specialised,

(4) The specialities under Para 1 – 3 and their direction shall be determined under the procedure specified in Art. 181, Para 1 of the Health Act.

Chapter five. **OTHER MEDICAL ESTABLISHMENTS**

Art. 24. (suppl. – SG, 72/2015) Centre for emergency medical care is a medical establishment in which medical specialists with the assistance of other personnel render emergency medical care to sick and injured persons, including at home, at the place of the accident or during transportation to their eventual hospitalisation.

Art. 25. (amend., SG 102/03) (1) Centre for transfusion haematology is a medical establishment where doctors, with the assistance of other personnel:

1. take blood and blood components;
2. diagnose, process, store, provide blood and blood components;
3. produce, store and provide blood biological preparations.
4. carry out transfusion supervision.

(2) The centres under para 1 shall carry out their activity according to the requirements of this Act and the Blood, Blood Donation, and Blood Transfusion Act.

(3) The Minister of health may propose closing down of a centre for transfusion haematology which carries out activity in violation of para 2.

Art. 26. (amend. - SG 59/10, in force from 31.07.2010) (1) Mental health centre means a medical establishment where physicians, assisted by other personnel, carry out the following activities:

1. emergency psychiatry aid;
2. diagnosis and treatment of persons with mental disorders;
3. periodical monitoring and consultation of persons with mental disorders and home patronage;
4. psychotherapy and psycho-social rehabilitation;
5. psychiatric and psychological expert activity;
6. (new – SG 60/11, in force from 05.08.2011) clinical testing of medicinal products;
7. (previous item 6 – SG 60/11, in force from 05.08.2011) establishment and maintenance of regional information system of persons with mental disorders for the purposes of the register referred to in Art. 147a, Para 1 of the Health Act;
8. (previous item 7 – SG 60/11, in force from 05.08.2011) promotion, prevention and improvement of the mental health of the population;
9. (previous item 8 – SG 60/11, in force from 05.08.2011) public information in the sphere of the mental health;
10. (previous item 9 – SG 60/11, in force from 05.08.2011) research activities in the sphere of mental health.

(2) The medical activity in a mental health centre shall be headed by a physician holding an acknowledged specialisation in psychiatry and qualification in health management.

(3) (supple. - SG 98/10, in force from 14.12.2010) The mental health centre shall include the

following units and departments: reception-diagnostic; for emergency and mobile psychiatric aid; for active treatment of persons with severe mental disorders, which may be specialised according to sex, age, disease profile or other features; rehabilitation and resocialisation, including for labour therapy.

(4) Accommodation facilities for diagnosis and treatment stay may be opened within the mental health centre.

(5) The mental health centre may provide social services as set out in the Social Support Act.

(6) The structure, activity and internal order of the mental health centre shall be set out in regulations, approved by the head under Para 2.

Art. 26a. (new - SG 59/10, in force from 31.07.2010) (1) Skin and venereal disease centre means a medical establishment where physicians, assisted by other personnel, carry out the following activities:

1. diagnosis, treatment and rehabilitation of persons with acute and chronic dermatological diseases;

2. periodical monitoring and consultation of persons with skin and venereal diseases, including life-threatening bullous dermatological diseases (pemphigus forms);

3. diagnosis, treatment and prophylactics of persons with sexually transmissible diseases;

4. (new – SG 60/11, in force from 05.08.2011) clinical testing of medicinal products

5. (previous item 4 – SG 60/11, in force from 05.08.2011) periodical analysis of epidemiological indices for sexually transmissible infections and assessment of the quality and efficiency of the undertaken diagnostic, treatment, prophylactic and rehabilitation activities;

6. (previous item 5 – SG 60/11, in force from 05.08.2011) expert activities in the sphere of sexual health and skin and venereal diseases;

7. (previous item 6 – SG 60/11, in force from 05.08.2011) promotion, prevention and improvement of the sexual health of the population and of the skin and venereal diseases;

8. (previous item 7 – SG 60/11, in force from 05.08.2011) public information regarding the problems of the sexual health and the skin and venereal diseases;

9. (previous item 8 – SG 60/11, in force from 05.08.2011) research activities in the sphere of sexual health and skin and venereal diseases.

(2) The medical activity in a skin and venereal disease centre shall be headed by a physician holding an acknowledged specialisation in skin and venereal diseases and qualification in health management.

(3) (suppl. – SG, 72/2015) The skin and venereal disease centre shall include specialised diagnosis and consultation offices, wards and assistance units.

(4) Up to 10 accommodation places for diagnosis and treatment stay may be opened within the skin and venereal disease centre.

(5) The structure, activity and internal order of the skin and venereal disease centre shall be set out in regulations, approved by the head under Para 2.

Art. 26b. (new - SG 59/10, in force from 31.07.2010) (1) Complex oncology centre means a medical establishment where physicians, assisted by other personnel, carry out the following activities:

1. active search, diagnosis and treatment of persons with oncological diseases;

2. periodical monitoring, consultation and supervision of oncologically diseased and precanceroses;

3. registration and dispensation of oncologically diseased and precanceroses;

4. (amend. – SG, 72/2015) establishment and maintenance of information data base for persons, passed oncologic diseases for the needs of the National Cancer Registry and the national medical

registers;

5. promotion and prevention of the oncological diseases;
6. public information regarding the problems of the oncological diseases;
7. expert and consultation activities in the sphere of oncology and medical oncology;
8. research activities in the sphere of oncology;
9. performance of clinical and therapeutic trial in the sphere of medical oncology;
10. (new – SG 60/11, in force from 05.08.2011) clinical testing of medicinal products;
11. (previous item 10 – SG 60/11, in force from 05.08.2011) realisation of complex educational and specialisation programmes in oncology, medical oncology and ray treatment and healthcare;
12. (previous item 11 – SG 60/11, in force from 05.08.2011) consultation on the problems of oncology diseases within the serviced region;
13. (previous item 12 – SG 60/11, in force from 05.08.2011) prophylactics and screening programmes of the oncology diseases.

(2) The medical activity in a complex oncology centre shall be headed by a physician holding acknowledged specialisation in oncology or medical oncology and qualification in health management.

(3) The complex oncology centre shall have the following structure:

1. diagnosis and consultation block, including specialised diagnosis and consultation offices, laboratories and departments without beds in image diagnosis, pathoanatomy and nuclear medicine;
2. stationary block, including departments corresponding to the primary methods of the complex treatment – medical oncology, ray treatment, oncological surgery;
3. unit for registration and prophylactic of oncological diseases;
4. a pharmacy for internal purposes.

(4) (amend. – SG, 72/2015) Accommodation places for continuous treatment, rehabilitation and palliative care may be opened within the complex oncology centre.

(5) The complex oncology centre may provide social services as set out in the Social Support Act.

(6) The structure, activity and internal order of the complex oncology centre shall be set out in regulations, approved by the head under Para 2.

Art. 26c. (new – SG, 72/2015) The medical activities in the mental health centres, centres for skin and venereal diseases and complex oncologic centres shall be carried out in their structural units, which have levels of competence, defined in compliance with the established medical standards under Art. 6, Para. 1.

Art. 26d. (New - SG 18/18, in force from 27.02.2018) The territorial expert medical commissions shall also be structural units of the mental health centers, centers for skin-venereal diseases and complex oncology centers, having opened at these medical establishments under Art. 105 of the Health Act.

Art. 27. (1) (suppl. - SG 59/10, in force from 31.07.2010, suppl. – SG, 72/2015) Home for medical and social care is a medical establishment where medical and other specialists carry out continuous medical observation and specific care for persons, with the exception of the persons under Art. 27a of different age groups with chronic diseases, specific home care of persons with chronic disabling diseases and medical social problems.

(2) The medical activity in the home for medical and social care shall be headed by a medical specialist.

(3) The structure, activity and the internal order of the home for medical and social care shall be settled by regulations approved by the head under para 2.

(4) (new - SG 59/10, in force from 31.07.2010) The medico-social care homes may social services as set out in the Social Support Act.

Art. 27a. (new – SG, 72/2015) (1) Centre for complex service of disabled children and with chronic diseases shall be a medical establishment, in which medical and other subjects carry out at least one of the following activities:

1. support of the families with disabled children and with chronic diseases for appointment and conducting early diagnostics, diagnostics, treatment and medical and mental rehabilitation;
2. continuous treatment and rehabilitation of disabled children and severe chronic diseases and training of their parent for laying care in a family environment;
3. provision of visits by medical specialists for giving specific cares for disabled children and severe chronic diseases, raised in a family environment and in a special service - resident type;
4. provision of specialized palliative cared for children.

(2) For providing needs for children of consultative aid and active treatment in case of need, the centre for complex service of disabled children and with chronic diseases shall sign contracts with medical establishments for medical aid for outpatient care and with multy-profile hospitals for active treatment.

(3) direction of a child to a centre for complex service of disabled children and with chronic diseases shall be carried out by a physician after an assessment of the medical need of diagnostics, treatment, rehabilitation and/or palliative cares under a procedure, defined by the Rules under Para. 4.

(4) The organization, activity and internal order of the centre for complex service of disabled children and with chronic diseases shall be provided by Rules, issued by the Minister of Health.

(5) The centre for complex service of disabled children and with chronic diseases may provide social services under the Act on Social Support.

Art. 28. (amend. - SG 59/10, in force from 31.07.2010) (1) The hospice shall be a medical establishment, if medical and other specialists carry out palliative care for terminally ill patients.

(2) The treatment activity in the hospice registered under this Act shall be managed by a medical specialist.

(3) The structure, activity and the internal order of the hospice qualifying as medical establishment shall be settled by regulations approved by the head under para 2.

(4) The hospices qualifying as medical establishments may social services as set out in the Social Support Act.

Art. 28a. (new – SG 62/02) (1) (amend. – SG, 72/2015) Dialysis centre shall be a medical establishment, where doctors with the assistance of other specialists implement healing, rehabilitation and observation of diseased with chronic kidney insufficiency.

(2) (amend. - SG 98/10, in force from 14.12.2010, amend. – SG, 72/2015) The dialysis centre shall be managed by a doctor with recognised medical speciality and with at least two years of practice in a centre or ward or clinic for haemodialysis.

(3) (amend. – SG, 72/2015) The structure and the activity of the dialysis centre shall be provided with a regulation, approved by the head of the medical establishment.

(4) (new – SG 84/18, in force from 12.10.2018) Clinical trials of medicinal products can be conducted at the dialysis center under the Medicinal Products in Human Medicine Act.

Art. 28b. (new, SG 83/03) (1) (suppl. - SG 36/09) The tissue bank is a medical establishment where a physician, with the assistance of other specialists, takes, studies, labels, treats, transports,

stores and process organs, tissues and cells for medical purposes.

(2) The tissue banks may take only tissues and cells for implantation or processing, and organs – only for processing.

(3) The activity of the tissue bank shall be carried out according to a regulation for the structure, activity and internal order, approved by the head of the medical establishment.

Part three.

FOUNDING AND CLOSING DOWN MEDICAL ESTABLISHMENTS

Chapter six.

NATIONAL HEALTH CARD. REGIONAL HEALTH CARDS

Art. 29. (1) (amend. SG 62/02, amend. SG 76/05; amend. - SG 59/10, in force from 31.07.2010; suppl. – SG 54/12, amend. – SG, 72/2015) The needs of the population of accessible outpatient and hospital medical aid shall be defined and planned on a territorial principle through a National health map, through which the national health policy shall be carried out.

(2) (amend. – SG, 72/2015) The national health map shall be drawn up on the basis of the regional health maps.

(3) (new- SG 59/10, in force from 31.07.2010; amend. - SG 98/10, in force from 01.01.2011, amend. – SG. 72/2015) For the development of regional health maps the Minister of Health shall appoint a commission for every region, consisting of the regional governor, two representatives the regional health inspection, two representatives of the regional health insurance bank, two representatives of the regional college of the Bulgarian Physicians' Union, one representative of the regional association of the Bulgarian Dentists' Union and the regional association of the Bulgarian Association of the Healthcare Professionals, one representative of the representative organisations for patients' rights, recognized under Art. 86c of the Health Act and one representative of each municipality within the region. The regional Governor shall be chairperson of the commission.

(4) (new - SG 59/10, in force from 31.07.2010, amend. – SG, 72/2015) The representatives of the municipalities under Para 3 shall be determined as set out in the Local Government and Local Administration Act. The representative of the representative organisations for patients' rights protection in each of the regional commissions shall be elected and dismissed by generally by the representative organisations.

(5) (new - SG 59/10, in force from 31.07.2010) The map of each region shall comprise the municipalities in accordance with the list under Art. 6, Para 2 of the Health Insurance Act.

(6) (new – SG, 72/2015) The regional health map shall be drawn up according to a standard and procedure, defined by methods, approved by the Minister of Health.

(7) (new - SG 59/10, in force from 31.07.2010, former Para. 6 – SG, 72/2015) When drafting the regional health maps the commission under Para 3 shall be obliged to take into consideration the accessibility of the medical care by the population living in hardly accessible and remote regions.

(8) (new - SG 59/10, in force from 31.07.2010. former Para. 7 – SG, 72/2015) Each regional commission shall present to the Minister of Health the drafted regional health map and the entire primary information, used for its creation.

Art. 30. (new - SG 59/10, in force from 31.07.2010) (1) The regional health cards shall be created upon assessment of the needs of emergency, primary and specialised non-stationary and hospital care and the compliance of the medical establishments with the requirements under Art. 19, Para 2 and 3.

(2) (new – SG, 72/2015) While drawing up the regional health maps the regional commission under Art. 29 shall make an analysis of the relation between preliminary calculations under a procedure, defined by the methods under Art. 29, Para. 6, total number of beds for hospital treatment, including in types, which provide access of the population to hospital aid in the relevant region and the existing number of beds in types and levels of competence of the relevant structures in the area, as well as their distribution in medical establishments and on levels of competence of the relevant structures.

(3) (new – SG, 72/2015) After carrying out the analysis under Para. 2 the regional commission shall attach to the regional health map also opinions about:

1. the concrete needs of doctors and dentists in specialties and specialists of professional direction Healthcare for provision of access of the population of the region to medical care in outpatient medical aid;

2. the need of restructuring of medical establishments or for undertaking other measures of creation, closure or optimization of the medical establishments in the area with the relevant proposals for restructuring of the medical establishments for hospital care as a result of the analysis made;

3. the need of creation of conditions for provision of concrete type of cares – palliative, etc., provided by a legislative act.

(4) (amend. SG 15/13, in force from 01.01.2014, former Para. 2, suppl. – SG, 72/2015) The medical establishments for hospital care shall be financed from the state budget funds or from the fund of the National Health Insurance Fund only in respect for the activity of clinics and departments compliant with the requirements under Para 1 and as set out in Art. 34, Para 4 and Art. 34a.

(5) (new – SG, 72/2015, in force from 1. 1. 2016) The medical establishments under Pra. 4 shall be funded by the state budget or from the budget of the National Health-insurance Fund and while observing the conditions of Art. 59, Para. 1a and 14 of the Act on Health Insurance.

(6) (amend. SG 15/13, in force from 01.01.2014, former Para. 3 – SG, 72/2015) The medical establishments for hospital care shall be financed from the state budget funds or from the fund of the National Health Insurance Fund only in respect for the activity of clinics and departments non-compliant with the requirement under Art. 19, Para 2, Item 2 under the conditions and order of Art. 59, Para 12 of the Health Insurance Act.

Art. 31. (amend. - SG 59/10, in force from 31.07.2010) (1) (amend. – SG, 72/2015) The regional health map shall contain:

1. data for the demographic structure, sickness in groups and in age and hospitalized sickness of the population on the territory of the region;

2. the type, the number, the activity and the distribution of the existing in the region medical establishments;

3. the necessary minimum number of the physicians and dental medicine physicians and of the specialists of professional direction Healthcare in the non-stationary care according to specialities;

4. the number of the practicing physicians, dentists in specialties and the number of the specialists of professional direction Healthcare in the non-stationary medical aid in the region;

5. the number of the existing beds for hospital treatment and the realized medical activities in types and their distribution in the medical establishments and on levels of competence of the relevant structures;

6. data about the type, number and distribution of the carried out in the area of highly technical methods of diagnostics and treatment and the available medical highly technological equipment for their application.

(2) (amend. – SG, 72/2015) To the regional health map under Para. 1, a proposal for distribution of the number of beds and medical activities in types under Para. 1, p. 5 shall be attached, as well as the number of the doctors and specialists under Para. 1, p. 3 determined according to the needs

of population in the relevant region under a procedure, defined by the methods under Art. 29, Para. 6.

(3) The Minister of Health shall be obliged to take into consideration the access to medical services by the population when drawing up the guidelines under Para 2.

Art. 32. (amend. - SG 59/10, in force from 31.07.2010) (1) (suppl. – SG, 72/2015, amend. - SG 102/18, in force from 01.04.2019) The National Health Map shall be drawn up by a national commission appointed by the Minister of Health, who shall chair the commission. The composition of the commission shall include the head of the National Health-insurance Fund, the director of the National Centre for Public Health and Analyses, the executive director of the Executive Agency "Medical Supervision", the chairperson of the National association of Municipalities in the Republic of Bulgaria, 2 representatives of the Bulgarian Doctors Union, one representative of the Bulgarian Dentists Union, one representative of the Bulgarian Association of Healthcare Professionals, one representative of the representing organizations for protection of patients' rights, acknowledged under Art. 86c of the Health Act and 3 representatives of the Ministry of Health.

(2) (amend. – SG, 72/2015) The national health map shall contain:

1. the regional health maps;
2. the concrete needs of doctors and dentists in specialties and specialists of professional direction Health cares for provision of access of the population to medical service in non-stationary medical aid for all areas;
3. concrete needs of beds for hospital treatments and medical activities in types and levels of competence of the relevant structures for all the areas;
4. the existing medical establishments for hospital aid, medical establishments under Art. 10 and medical establishments, carrying out highly technological methods of diagnostics and treatment on the map of the country;
5. analysis of the condition in the regions, including concerning the needed doctors and dentists in specialties and specialists of the professional direction healthcare of the non-stationary medical aid in the regions;
6. types of medical activities, which are planned at regional level, according to the provided regions under Art. 4, Para. 3 of the Act on Regional Development;
7. a map of the needed highly technological methods of diagnostics and treatment and the related highly technological medical equipment;
8. a map of the first aid, containing the number and location of the first aid centres.

(3) (new – SG, 72/2015) The National health map shall identify in regions the needs of doctors and dentists in specialties and specialists of professional direction Health cares in the non-stationary medical aid, as well as the number of beds for hospital treatments and medical activities in types and levels of competence of the relevant structures, by their planning, also planning of the medical establishments, carrying out highly technological methods of diagnostics and treatment.

Art. 33. (revoked - SG 59/10, in force from 31.07.2010)

Art. 34. (1) The national health map of the Republic of Bulgaria shall be approved by a decision of the Council of Ministers at the proposal of the Minister of Health.

(2) (amend. SG 62/02, suppl. – SG, 72/2015) The national health map shall be subject to complete updating every three years. Partial updating shall be made when necessary in the cases, defined by the methods of Art. 29, Para. 6.

(3) (new – SG 62/02; amend. - SG 59/10, in force from 31.07.2010, repealed – SG, 72/2015)

(4) (new - SG 59/10, in force from 31.07.2010, amend. – SG, 72/2015) The National Health Map under Para 1 shall be mandatory for the planning of the medical activities in types, carried out in the medical establishments, except for the medical establishments under Art. 8, Para 1 established by dental medicine physicians as set out in this Act.

Art. 34a. (new – SG, 72/2015) In the regions, where the number of beds for hospital treatment exceeds the concrete needs of the number of beds in types, defined by the National health map, the directors of RHIF shall sign contracts with medical establishments for hospital aid or their unifications, selected under criteria and procedure, defined by an ordinance of the Council of Ministers.

Chapter seven.

FOUNDING, REGISTRATION AND PERMITTING MEDICAL ESTABLISHMENTS

Section I.

Founding medical establishments

Art. 35. (1) (amend. – SG, 72/2015) The medical establishments under Art. 5, para 1 shall be founded and transformed by the Council of Ministers at the proposal of the Minister of Health. The proposal of the Minister of Health shall be coordinated with the respective minister when the medical institution belongs to the administrative bodies under Art. 5, para 1.

(2) The medical establishments under para 1 are corporate bodies at budget support for their specific functions.

(3) (amend. - SG 98/10, in force from 14.12.2010) The organisation, the activity and the structure of the medical establishments under Art. 5, para 1 shall be settled by regulations issued by:

1. (amend. and suppl. – SG, 72/2015) the Minister of Health - for the centres for emergency medical care, the centres for transfusion haematology, the medical establishments for stationary psychiatric care, the homes for medical social care where medical observation and specific care for children are carried out and the centres for complex service of disabled children and with chronic diseases;

2. (amend., SG 36/00, amend. SG 88/05; suppl. - SG 98/10, in force from 14.12.2010; amend. - SG 98/16) The Council of Ministers, at the proposal of the respective minister and the Minister of Health - for the medical establishments at the Council of Ministers, the Ministry of Interior, the Ministry of Justice and the Ministry of Transport, Information Technologies and Communications;

3. (new - SG 98/16) Minister of Defence coordinated with the Minister of Health - for medical institutions under the Ministry of Defense.

(4) (new - SG 59/10, in force from 31.07.2010; amend. - SG 98/10, in force from 01.01.2011) The regulations under Para 1 shall be issued after a check being made by the regional health inspection of the compliance with the medical standards and the health requirements, certified in the documents and according to the procedure under Art. 47, Para 4.

(5) (new - SG 59/10, in force from 31.07.2010; amend. – SG 54/12, amend. - SG 102/18, in force from 01.04.2019) Where the medical establishment is going to carry out activities under Art. 13, Para 1 of the Transplantation of Organs, Tissues, and Cells Act, the issue of the regulations under Para 3 shall be made following also a check by the Executive Agency "Medical Supervision" and issued certificate under Art. 13, Para 3 of the Transplantation of Organs, Tissues, and Cells Act.

(6) (New - SG 102/18, in force from 01.04.2019) In the cases where the medical establishment shall carry out activities under Art. 131, Para. 1 of the Health Act, the issuance of the regulations under Para. 3 shall also be carried out after a check by the Executive Agency "Medical Supervision" and a certificate issued under Art. 131, Para. 1, item 3 of the Health Act.

(7) (New – SG 54/12; amend. - SG 98/16, previous Para. 6 - SG 102/18, in force from 01.04.2019) The regulations of the medical establishment under Para 3, Item 2 and 3 shall indicate the medical specialities within the activity of the medical establishment, the structures of the medical establishment, the level of competence of the clinics, divisions and clinical diagnosis structures, in which the medical establishment renders hospital care.

Art. 36. (1) (suppl. – SG 59/07, in force from 20.07.2007) The medical establishments under Art. 10, item 5 and the medical establishments for non-stationary care, other than those under Art. 8, para 1, item 1, letter "a" and item 2, letter "a" shall be founded as trade companies or co-operatives, as well as companies under the legislation of an European Union Member State, or of a state which is a party under the European Economic Area Agreement upon which they shall be registered by the order of Art. 40. If necessary the state and the municipalities shall, independently or jointly with other person, can found such establishments as limited liability companies or joint-stock companies.

(2) (amend. - SG 59/10, in force from 31.07.2010) The medical establishments under Art. 8, Para 1, Item 1, Letter "a" and Item 2, Letter "a" shall be established as single person companies or sole entrepreneurs, followed by registration as set out in Art. 40. Where the medical establishments under Art. 8, para 1, item 1, letter "a" and Item 2, Letter "a" are established by natural persons – physicians or dental medicine physicians, they shall be registered only under Art. 40.

(3) In the cases under para 1 and 2 the subject of activity shall obligatorily contain carrying out of only non-stationary care or the activities under Art. 27 and 28.

(4) (amend. – SG 34/06, in force from 01.10.2006) The commercial registration of the company shall obligatorily contain the full indication of the respective type of medical establishment under Art. 8 and Art. 10, item 4 and 5.

Art. 36a. (new, SG 83/03) (1) (suppl. – SG 59/07, in force from 20.07.2007, amend. - SG 102/18, in force from 01.01.2019) The tissue bank shall be established as a limited liability company or as a joint-stock company, and also as a company under the legislation of an European Union Member State, or of a state which is a party under the European Economic Area Agreement, where this legislation allows this company to be a tissue bank and it shall carry out activity upon receipt of a permit by the order of this Act.

(2) Included in the subject of activity of the tissue bank shall obligatorily be only the activities under art. 28b.

(3) (amend. – SG 34/06, in force from 01.10.2006) The commercial registration of the company shall obligatorily contain the full name of the medical establishment.

Art. 37. (1) (amend. – SG 62/02; suppl. – SG 59/07, in force from 20.07.2007; amend. - SG 59/10, in force from 31.07.2010) Medical establishments for hospital care, medical and social care homes, mental health centres, centers for skin-venereal diseases, complex centres of oncology and dialysis centres shall be established by the state and the municipalities, by legal and natural persons, such as commercial companies or cooperatives, as well as companies under the legislation of a Member State of the European Union or of a state party to the Agreement on the European Economic Area, and shall operate after obtaining a permit under the order of Art. 46.

(2) (amend., SG 65/00; amend. - SG 59/10, in force from 31.07.2010) The subject of activity of the companies or co-operatives shall obligatorily contain carrying out of only hospital care and/or of the activities under Art. 26, para 1, Art. 26a, Para 1, Art. 26b, Para 1, Art 27, Para 1 and Art. 28a, Para 1.

(3) (amend. - SG 59/10, in force from 31.07.2010) The state and the municipalities shall found

medical establishments for hospital care, health centres, skin and venereal disease centres, complex oncology centres and dialysis centres as limited liability companies or as joint-stock companies.

(4) The state shall found medical establishments under para 3 by an act of the Council of Ministers at the proposal of the Minister of Health.

(5) The municipalities shall found by permit of the municipal councils medical establishments under para 3 upon the consent of the Minister of Health.

(6) (amend. – SG 34/06, in force from 01.10.2006) With the commercial registration the company shall obligatorily enter the full or abbreviated indication of the type of hospital medical establishment according to Art. 9, para 1 and 2.

Art. 37a. (new – SG, 72/2015, amend. - SG 102/18, in force from 01.04.2019) (1) The medical establishments for hospital care shall be formed after approval by the Council of Ministers on the basis of a complex assessment of:

1. the needs of the population from medical care according to the National Health Insurance Card;

2. the documents and the information under Para. 2.

(2) In order to carry out the assessment under Para. 1, an application shall be filed with the Minister of Health, to which shall be attached:

1. a project including information about the type of medical establishment, the structure and the envisaged number of beds for hospital treatment, and medical activities by types and levels of competence of the respective structures, also stages and term for realization of the project;

2. a three-year business plan for the development of the medical establishment, including financial justification and sources for financing the activity of the medical establishment;

3. a declaration of origin of the funds for realization of the project under item 1;

4. an opinion of the respective regional college of the Bulgarian Medical Association or of the Bulgarian Dental Union on the territory of the area, in which the medical establishment is established or transformed.

(3) Where in the documents under Para. 2 it is stated that the health care establishment shall be financed with funds from the budget of the National Health Insurance Fund, the Minister of Health or an official authorized by him shall ex officio request an opinion from the National Health Insurance Fund, including the options for financing by the National Health Insurance Fund concerned, the opinion being given within one month of the request.

(4) If in need of additional information and/or documents, the Minister of Health or an official authorized by him shall notify in writing the applicant to submit the relevant documents and/or information within 7 days. Until the inconsistencies have been remedied, the term under Para. 6 shall stop running.

(5) The assessment under Para. 1 shall be performed by the Executive Agency "Medical Supervision" within 45 days from the submission of the application under Para. 2.

(6) Within 2 months from the receipt of the application under Para. 2 and/or the additional information, and/or the documents under Para. 4, at the proposal of the Minister of Health the Council of Ministers shall adopt a decision approving, or refusing to approve, the establishment of a medical facility for hospital care.

(7) By the decision of the Council of Ministers under Para. 1, which approves the establishment of a medical institution for hospital care, it shall be determined:

1. the type of the establishment for hospital care;

2. the structure and the envisaged number of beds for hospital treatment and medical activities by types and levels of competence of the respective structures;

3. the period for realization of the project, for which an application for issuance of an

authorization under Art. 47.

(8) The refusal under Para. 6 shall be subject to appeal before the respective administrative court under the procedure of the Administrative-Procedure Code.

Art. 37b. (new – SG, 72/2015, amend. - SG 102/18, in force from 01.04.2019)

(1) The carrying out of new medical activities by medical institutions for hospital care shall be authorized by order of the Minister of Health on the basis of a complex assessment of:

1. the needs of the population from medical care according to the National Health Card;
2. the documents and the information under Para. 2.

(2) In order to carry out the assessment under Para. 1, an application shall be filed with the Minister of Health, to which shall be attached:

1. a project including information about the type of new medical activities, the structures in which they will be carried out, the envisaged number of beds for hospital treatment and the levels of competence of the respective structures, also stages and term for realization of the project;

2. a three-year business plan for the development of the medical establishment in connection with the implementation of the new medical activities, including financial justification and the sources for financing the new activities;

3. an opinion of the respective regional college of the Bulgarian Medical Association or of the Bulgarian Dental Union.

(3) Where in the documents under Para. 2 it is stated that the new medical activities will be financed with funds from the budget of the National Health Insurance Fund, the Minister of Health, or an official authorized by him, shall, of its own motion, request the opinion of the National Health Insurance Fund, including the options for financing by the National Health Insurance Fund of the relevant activities, the opinion being given within one month of the request.

(4) In case of additional information and/or documents needed, the Minister of Health or an official authorized by him shall notify in writing the applicant to submit within 7 days the relevant documents and information. Until the incompleteness has been remedied, the term under Para. 6 shall stop running.

(5) The assessment under Para. 1 shall be performed by the Executive Agency "Medical Supervision" within 45 days from the submission of the application under Para. 2.

(6) Within 2 months from the receipt of the application under Para. 2, or the additional information, and/or the documents under Para. 4, the Minister of Health shall issue an order authorizing, or refusing to authorize, the carrying out of new medical activities by a medical establishment for hospital care.

(7) In the order under Para. 1, which authorizes the carrying out of new medical activities by a medical establishment for hospital care, shall be determined:

1. the type of new medical activities, the structures in which they will be carried out, the envisaged number of beds for hospital treatment and the levels of competence of the respective structures;

2. the term for realization of the project, to which the medical establishment may submit an application for change of the permit under Art. 47.

(8) The refusal under Para. 6 shall be subject to appeal before the respective administrative court under the procedure of the Administrative-Procedure Code.

Art. 38. (1) Art. 72 and 73 of the Commerce Act shall not apply for the non-cash instalments of the state and the municipalities to state or municipal medical establishments.

(2) In the cases under para 1 entered in the capital of the company shall be the balance value of

all long-term assets of the property on which grounds it is founded.

Section II. Registration

Art. 39. (1) (prev. text of art. 39 – SG 30/06) Registered shall be the medical establishments for non-stationary care and the hospices.

(2) (new – SG 30/06) Subject to registration shall be also the medical activity referred to in art. 2a for the implementation of which 10 beds for supervision and treatment up to 48 hours may be provided.

(3) (new – SG 30/06; amend. – SG 59/10, in force from 31.07.2010, amend. – SG, 72/2015) Upon necessity for longer stay in the cases referred to in para 2 the medical faculty or the dental medicine faculty of the respective university shall be obliged to organize the hospitalization of the patient.

(4) (new - SG 98/10, in force from 14.12.2010) The basic requirements to be met by the structure, activity and the internal order of the medical establishments under Para 1 and the faculties carrying out medical activity under Art. 2a shall be determined in an ordinance of the Minister of Health.

Art. 40. (Amend. – SG 102/18, in force from 01.04.2019) (1) The registration shall be performed by the Executive Director of the Executive Agency "Medical Supervision" on the basis of an application stating the unified identification code of the company or cooperative from the Commercial Register, and to which are attached:

1. a document for current registration under the national legislation, issued by a competent authority of the respective state - for companies registered in a Member State of the European Union, or in a state party to the Agreement on the European Economic Area;

2. rules for the structure, activity and internal order of the medical establishment;

3. the names of the persons - partners or shareholders of the company, or members of the cooperative, establishing a group practice;

4. a diploma for the respective higher education of the persons who will manage, respectively work, in the medical establishment;

5. a document for a recognized specialty of the persons who will manage, respectively work, in the medical establishment, and in the cases under Art. 14a - a document certifying that the person has been admitted for training in general medicine;

6. a permit by the competent state body when medical equipment with a source of ionizing radiation will be used at the medical establishment;

7. documents for paid state fee under Art. 41, Para. 4, as well as under Art. 46 of the Health Act.

(2) The application under Para. 1 shall be submitted to the Regional Health Inspection.

(3) The Executive Agency "Medical Supervision" shall establish ex officio the circumstances regarding the criminal background of the persons - members of the management and control bodies of the medical establishment, when they are Bulgarian citizens. The persons who are members of management and control bodies and are not Bulgarian citizens shall present a criminal record or a similar document.

(4) Within 10 days from the receipt of the application under Para. 1, the Regional Health Inspectorate shall carry out a check on compliance with the health requirements and the approved medical standards by the medical establishment, and shall issue a certificate. Where it is established that

the healthcare establishment and/or the approved medical standards have not been met, the Regional Health Inspectorate shall prescribe and set a time limit for their removal, which may not be longer than three months.

(5) On the day of receipt of the application under Para. 1, the Regional Health Inspectorate shall send a request to the Bulgarian Medical Association, respectively to the Bulgarian Dental Association, and to the Bulgarian Association of Healthcare Professionals, for the issuance of certificates for entering in their registers the doctors, the doctors of dentistry, the medical assistants, the medical nurses or midwives who will manage and/or work in the medical establishment, respectively in the unit under Art. 17a. The professional organizations shall issue the certificates within 5 days of receipt of the request.

(6) The registration of the medical activity under Art. 2a shall be performed by the Executive Director of the Executive Agency "Medical Supervision" on the basis of an application by the Rector of the higher school, to which shall be attached:

1. data on the name, seat and address of management of the higher school;
2. diplomas for completed higher education and documents for a recognized specialty, if any, of the Heads of the relevant departments and of the doctors-lecturers and the doctors-lecturers dental practitioners who will carry out the practical training or carry out the scientific activity;
3. a permit by the competent state body when, in carrying out the activity under Art. 2a, medical equipment is used with a source of ionizing radiation;
4. a decision on the institutional accreditation of the higher school and a program accreditation document, issued by the order of the Higher Education Act;
5. information on the number of open beds under Art. 39, Para. 2;
6. a document for paid state fee under Art. 41, Para. 4.

(7) The application and the documents under Para. 6 shall be submitted to the Regional Health Inspectorate on the territory of which the higher school is situated.

(8) Within three days after the check under Para. 4 has been performed and obtaining the certificates under Para. 5, the Director of the Regional Health Inspectorate shall send to the Executive Agency "Medical Supervision" the documents under Para. 1, 4 and 5, respectively, under Para. 6.

(9) When the medical establishment is to carry out activities under Art. 13, Para. 2 of the Act on Transplantation of Organs, Tissues and Cells, within 10 days from the receipt of the documents under Para. 8 the Executive Agency "Medical Supervision" shall carry out a check on compliance with established medical standards in the field of organ, tissue and cell transplantation by the medical establishment. Where discrepancies are found, prescriptions shall be given and a time limit for their removal shall be set, which may not be longer than three months.

(10) When the medical establishment is to carry out activities under Art. 131, Para. 1 of the Health Act, within 10 days from the receipt of the documents under Para. 8 the Executive Agency "Medical Supervision" shall carry out a check on the observance of the approved medical standard of assisted reproduction by the medical establishment. Where non-compliances are found, prescriptions shall be given and a time limit for their removal set, which may not be longer than three months.

(11) In case of incompleteness of the submitted documents under Para. 8, the Executive Agency "Medical Supervision" shall notify the applicant in writing within 10 days, and shall set a deadline for their removal. Until the incompleteness is remedied, the term under Para. 13 shall stop running.

(12) If necessary and within the term under Para. 13, the Executive Agency "Medical Supervision" may carry out an independent verification of compliance with the requirements of Para. 4.

(13) Within one month from the receipt of the documents under Para. 8, the Executive Director of the Executive Agency "Medical Supervision" shall issue a certificate for registration of the medical establishment, or a certificate for carrying out medical activity under Art. 2a, or shall give a motivated refusal to register the medical establishment or the medical activity under Art. 2a.

Art. 41. (1) (amend. - SG 59/10, in force from 31.07.2010; amend. - SG 98/10, in force from 14.12.2010, amend. – SG 102/18, in force from 01.04.2019) The Executive Agency "Medical Supervision" shall keep a register for the medical establishments. The register shall be public and shall contain:

1. number;
2. date of issuance of the certificate for registration of the medical establishment;
3. (amend. – SG 34/06, in force from 01.10.2006; suppl. – SG 54/12) data about the medical establishment - name, headquarters, capital, unified identification code, address of carrying out the activity;
4. (amend. - SG 59/10, in force from 31.07.2010) data about the person representing the medical establishment – name from the identity document;
5. (amend. - SG 59/10, in force from 31.07.2010) data about the persons under Art. 40, para 1, item 3 in the medical establishment - name from the identity document;
6. types of activities for which the medical establishment is registered;
7. data about transformation, merging, incorporation, separation and termination of the medical establishment, change of the ownership;
8. date of deletion of the registration and grounds for that;
9. changes of the circumstances under item 1 - 8;
10. notes on the entered circumstances.

(2) (new – SG 30/06) The following data about the registered medical activity referred to in art. 2a shall be entered into the register referred to in para 1:

1. consecutive number;
2. issuing date of the certificate for implementation of the medical activity referred to in art. 2a;
3. (amend. – SG, 72/2015) data about the university – name, seat, management address and the period of the validity of the accreditation;
4. (amend. - SG 36/09; amend. – SG 59/10, in force from 31.07.2010, amend. – SG, 72/2015, amend. – SG 102/18, in force from 01.04.2019) the data referred to in art. 40, para 6, item 2;
5. date for removal of the registration and the grounds for that;
6. changes of the circumstances referred to in items 1 – 5;
7. notes on the entered circumstances.

(3) (new – SG 54/12, suppl. – SG, 72/2015) In the register under Para 1 shall be made a separate section, where, according to the order of filing, shall be entered the persons that have filed an application for registration and shall be described the number and type of the documents enclosed with the application. In this section shall be recorded the changes in the file of the application.

(4) (prev. text of para 02, suppl. – SG 30/06; amend. – SG 41/09, in force from 02.06.2009; prev. text of Para 03 – SG 54/12, amend. – SG 102/18, in force from 01.04.2019) For the issuance of a certificate of registration of the medical establishment, a certificate for carrying out therapeutic activity under Art. 2a and for using the register shall be paid fees in the amount determined with a tariff of the Council of Ministers.

(5) (new – SG, 72/2015, repealed – SG 102/18, in force from 01.04.2019)

Art. 42.(suppl. – SG 30/06, amend. – SG 102/18, in force from 01.04.2019) At the end of each six months the Executive Agency "Medical Supervision" shall send to the Ministry of Health and to the mayor of the respective municipality summarise data about the registrations of medical establishments and the medical activity referred to in art. 2a..

Art. 43. (suppl. – SG 30/06; amend. - SG 98/10, in force from 01.01.2011, amend. – SG 102/18, in force from 01.04.2019) The registered persons shall be obliged to inform the Executive Agency "Medical Supervision" about all changes on the registration of the medical establishment and the medical activity referred to in art. 2a within 7 days from their occurrence.

Art. 44. (Amend. – SG 102/18, in force from 01.04.2019) The Executive director of the Executive Agency "Medical Supervision" shall issue a motivated refusal of registration:

1. for omissions from the presented documents under Art. 40 and failure to rectify them within the term determined as set out in Art. 40, Para 11;

2. if a person representing the medical establishment was convicted for deliberate crime of general character, unless rehabilitated, or has been deprived of the right to exercise certain profession or activities;

3. when the regional health inspection finds non-compliance with the health requirements that has not been rectified within the time limit specified by it;

4. where non-compliances have been found with established medical standards in the field of organ, tissue and cell transplantation and/or with the approved medical standard of assisted reproduction which have not been corrected within the time specified;

5. when the physicians, the dental practitioners, the doctors assistants, nurses and midwives who are to head and/or work in a medical establishment, respectively in the unit referred to in Art. 17a, not entered in the register of the respective college of the Bulgarian Physicians' Union, respectively the Bulgarian Dentists' Union and of the Bulgarian Association of the Healthcare Professionals.

(2) The refusal under para 1 shall be subject to appeal before the respective administrative court by the order of the Administrative-procedure code.

Art. 45. (1) (amend. - SG 59/10, in force from 31.07.2010) The registration of a medical establishment shall be canceled:

1. when the regional college of the professional organisation has deleted from the register the doctor or the dental practitioner who has founded medical establishment under Art. 8, para 1, item 1, letter "a" and item 2, letter "a";

2. in case of established offence under Art. 3, para 4;

3. for performance of activities in violation of the registration;

4. (amend. – SG 102/18, in force from 01.04.2019) upon established violation of the approved medical standards and/or health requirements;

5. for suspension of the activity for more than 6 months;

6. under the circumstances referred to in Art. 44, Para 1, Item 2;

7. upon request of the medical establishment;

8. for termination of the corporate body, death of the registered person or his placing under guardianship;

9. (new - SG 47/14, in force from 03.06.2014) upon expiry of the term under Art. 14a, where the doctor has not acquired specialization in general medicine.

(2) (new – SG 30/06) The registration of the medical activity referred to in art. 2a shall be deleted:

1. (amend. – SG, 72/2015) upon request of the rector of the university;

2. (amend. - SG 59/10, in force from 31.07.2010, amend. – SG, 72/2015) upon closing of the medical faculty or the dental medicine faculty of the university;

3. upon expiration and not continuation of the period of validity of the programme accreditation;

4. upon implementation of activities in violation of the registration.

(3) (prev. text of para 02 – SG 30/06; amend. - SG 98/10, in force from 01.01.2011, amend. – SG 102/18, in force from 01.04.2019) The deletion of the registration shall be made by an order of the Executive Director of the Executive Agency "Medical Supervision".

(4) (prev. text of para 03 – SG 30/06; amend. - SG 59/10, in force from 31.07.2010; amend. - SG 98/10, in force from 01.01.2011, amend. – SG 102/18, in force from 01.04.2019) The orders under para 1, items 1 – 6 and Para 2, Item 4 shall be subject to appeal before the respective administrative court by the order of the Administrative-procedure code.

(5) (prev. text of para 04 – SG 30/06) The appeal of the order shall not stop its fulfilment.

Section III. Permit for carrying out activity

Art. 46. (1) (amend. SG 62/02; amend. - SG 59/10, in force from 31.07.2010, amend. – SG 102/18, in force from 01.04.2019) Subject to permit shall be the activity of the medical establishments for hospital care, the mental health centres, the skin venereal disease centres, the complex oncology centres and the homes for medical social care, dialysis centres and cell banks.

(2) (Amend. – SG 102/18, in force from 01.04.2019) Permits for carrying out medical treatment to medical establishments under Para. 1 shall be issued by the Minister of Health, upon proposal of the Executive Director of the Executive Agency "Medical Supervision".

(3) (suppl. - SG 59/10, in force from 31.07.2010, amend. – SG, 72/2015) The basic requirements to be met by the structure, the activity and the internal order of the medical establishments for hospital care and the homes for medical social care, as well as the conditions and order for opening structures and provision of activities under Art. 20, Para 2 and 3 shall be determined by an ordinance of the Minister of Health.

(4) (New – SG 102/18, in force from 01.04.2019) Permits for carrying out medical treatment to medical establishments for hospital care shall be granted after a decision of the Council of Ministers under the procedure of Art. 37a.

Art. 47. (Amend. - SG 59/10, in force from 31.07.2010, amend. – SG 102/18, in force from 01.04.2019) (1) For the issuance of a permit for carrying out of medicinal activity, the medical establishments under Art. 46, Para. 1 shall file an application with the Minister of Health indicating the unique identification code of the company or the co-operation from the Commercial Register, to which shall be attached:

1. a document for current registration under the national legislation issued by a competent authority of the respective state - for companies registered in a Member State of the European Union or in a state party to the Agreement on the European Economic Area;

2. rules for the structure, activity and internal order of the medical establishment;

3. a diploma for the respective higher education of the persons managing the medical establishment, and for the persons under Art. 63, Para. 1, respectively, a diploma, certificate or a letter-certificatory for qualification in health management, or a diploma or certificate for acquired educational and/or scientific degree, specialty or passed training for improvement of the qualification under Art. 43 of the Higher Education Act in the field of health management;

4. the data from the identity document - for the members of the management and control bodies of the medical establishment;

5. the permit of the competent state body, when medical equipment with a source of ionizing radiation will be used at the medical establishment;

6. standard operating procedures containing detailed written descriptions of the sequence and manner of transplantation activities for each specific process, the materials and methods to be used, and the expected outcome - for the tissue banks;

7. documents for paid state fee under Art. 49, Para. 5 and Art. 46 of the Health Act.

(2) The application under Para. 1 shall be submitted to the Regional Health Inspection.

(3) The Executive Agency "Medical Supervision" shall establish ex officio the circumstances regarding the criminal background of the persons - members of the management and control bodies of the medical establishment when they are Bulgarian citizens. The persons-members of the management and control bodies, who are not Bulgarian citizens, shall present a criminal record or a similar document.

(4) Within 20 days from the receipt of the application under Para. 1, the Regional Health Inspection shall check the compliance with the requirements of this Act, the ordinance under Art. 46, Para. 3 and the approved medical standards, and shall issue a certificate, and in the case of established inconsistencies - shall prescribe and fix a period for their removal, which may not be longer than three months.

(5) On the day of receipt of the application under Para. 2, the Regional Health Inspection shall send ex officio a request to the Bulgarian Medical Association, respectively to the Bulgarian Dental Association, for the issuance of certificates for entry into their registers of the members of the management and control bodies of the medical establishment who are doctors or doctors of dental medicine. The professional organizations shall issue the certificates within 5 days of receipt of the request.

(6) Within one week after the expiration of the term under Para. 4, the Regional Health Inspection shall send to the Executive Agency "Medical Supervision" the documents under Para. 1, 4 and 5.

(7) Where the medical establishment is to carry out activities under Art. 13, Para. 1 of the Transplantation of Organs, Tissues and Cells Act, as well as in the event of application for authorization for a tissue bank, the Executive Agency "Medical Supervision", within 20 days from the receipt of the documents under Para. 6, shall perform verification of the adherence by the medical establishment to the established medical standards in the field of organ, tissue and cell transplantation. Where discrepancies are found, prescriptions shall be given and a time limit for their removal set, which may not be longer than three months.

(8) Where the medical establishment is to carry out activities under Art. 131, Para. 1 of the Health Act, within 20 days from the receipt of the documents under Para. 6, the Executive Agency "Medical Supervision" shall verify the compliance with the established medical standard by the medical establishment in assisted reproduction. Where discrepancies are found, prescriptions shall be given and a time limit for their removal set, which may not be longer than three months.

(9) In case of incompleteness in the submitted documents under Para. 6, the Executive Agency "Medical Supervision" shall notify the person in writing within 20 days and shall set a deadline for their removal. Until the elimination of the incompleteness, the term under Art. 48, Para. 1 shall stop running.

(10) If necessary and within the term under Art. 48, Para. 1, the Executive Agency "Medical Supervision" may perform an independent verification of compliance with the requirements of Para. 4.

Art. 48. (Amend. – SG 102/18, in force from 01.04.2019) (1) Within three days from the receipt of the documents and performing the verifications under Art. 47, the Executive Agency "Medical Supervision" shall send to the Minister of Health the application for the issuing of a permit for medical treatment together with all the documents under Art. 47.

(2) In case of incompleteness or inaccuracies in the documents under Para. 1, the Minister of Health shall return them to the Executive Director of the Executive Agency "Medical Supervision" with specific instructions and a deadline for their updating. Until the incompleteness and inaccuracies have

been remedied, the term under Art. 48, Para. 3 shall stop running.

(3) Within 75 days from the filing of the documents under Art. 47, on the proposal of the Executive Director of the Executive Agency "Medical Supervision", the Minister of Health shall issue a permit for carrying out medical treatment of the medical establishment, or shall issue a motivated refusal to issue it. The permit for carrying out medical treatment shall include:

1. the full name of the medical establishment under its trade registration - for the commercial companies and the cooperatives;
2. the unified identification code of the medical establishment (for the companies and cooperatives) and a single registration number;
3. the activities under Art. 19, Art. 20, Para. 2 and 3, Art. 26, 26a, 26b, 27, 28a, 28b and Art. 131, Para. 1 of the Health Act;
4. the competence levels of the structures;
5. the medical specialities involved in the activity of the medical establishment;
6. the clinics and departments, where the activity is carried out, as well as the clinical and diagnostic structures with their competence levels;
7. the address of activity.

(4) On the proposal of the Executive Director of the Executive Agency "Medical Supervision", the Minister of Health shall issue a motivated refusal:

1. when a decision of the Council of Ministers has been adopted for refusal under Art. 37a respectively, an order has been issued for refusal by the Minister of Health under Art. 37b;
2. for omissions from the presented documents under Art. 47 and failure to rectify them within the term determined as set out in Art. 47, Para 9;
3. if a person representing the medical establishment was convicted for deliberate crime of general character, unless rehabilitated, or has been deprived of the right to exercise certain profession or activities;
4. if non-compliance with the requirements of this Act, the health requirements under Art. 6, Para 1 and the ordinance under Art. 46, Para 3 have been found that has not been rectified within the time limit specified in Art. 47, Para 4, 7 or 8;
5. when the physicians and the dental practitioners who are to head a medical establishment are not entered in the register of the respective college of the Bulgarian Physicians' Union, respectively the Bulgarian Dentists' Union.

(5) The refusal under Para. 4 shall be subject to appeal before the respective administrative court under the procedure of the Administrative-Procedure Code.

Art. 49. (1) (amend. - SG 59/10, in force from 31.07.2010) The Ministry of health shall keep register of the medical establishments having received permit for medical activity. The register shall be public and shall contain:

1. number and date of the permit for medical activity;
2. data about the medical establishment - name, headquarters, capital, unified identification code and unified registration number, address of the activity;
3. competence levels of the structures;
4. name from the identity documents – in respect of persons that are members of the management and control bodies of the medical establishment;
5. types of medical activity for which the permit is issued;
6. the data about revoking the permit and the grounds for that;
7. change in the circumstances under item 1 - 6.

(2) (New – SG, 72/2015, amend. – SG 102/18, in force from 01.04.2019) Stopping and Interruption of activities of assisted reproduction, provision, use and storage of human eggs, sperm and

zygotes, as well as termination of undertaken stopping shall be subject to entry in the register.

(3) (former Para. 2 – SG, 72/2015) For each medical establishment the register shall allocate a file with the necessary number of double pages on which its name shall be written.

(4) (new – SG 54/12, former Para. 3, suppl. – SG, 72/2015) In the register referred to in Para 1 shall be made a separate section, where in the order of filing shall be entered the persons who have filed an application for an authorisation and shall be entered the number and type of the documents enclosed with the application. In this section shall be recorded also the changes to the file of the application.

(5) (amend. – SG 41/09, in force from 02.06.2009; prev. text of Para 03 – SG 54/12, former Para. 4 – SG, 72/2015, amend. – SG 102/18, in force from 01.04.2019) For the issuance of the permit for carrying out medical activity and for use of the register, fees shall be paid in an amount determined by a tariff of the Council of Ministers.

(6) (new - SG 59/10, in force from 31.07.2010; prev. text of Para 04, amend. – SG 54/12, former Para. 5, amend. – SG, 72/2015, repealed – SG 102/18, in force from 01.04.2019)

Art. 50. (1) The registered persons shall be obliged to inform about all changes of the circumstances under the registration within 7 days from their occurrence.

(2) (amend. - SG 59/10, in force from 31.07.2010, suppl. – SG, 72/2015) Changes to the circumstances under Art. 48, Para 1 that are entered into the permit shall be made under the order of Art. 46, Para 2 and 3 and Art. 47. Only document about their change shall be produced, whose validity term has expired, accompanied by a declaration for a lack of change in all the other documents and circumstances.

(3) (New – SG 102/18, in force from 01.04.2019) Any changes in the permit for carrying out of medical activity by entering new medical activities shall be made only after an order issued by the Minister of Health pursuant to Art. 37b.

(4) (New – SG 54/12, repealed previous Para. 3 - SG 102/18, in force from 01.04.2019) The Minister of Health shall change the level of competence determined as set out in Art. 48, Para 1, Item 4 in cases of non-compliance with the approved medical standards under Art. 6, Para 1.

Art. 51. (1) (suppl. - SG 77/18, in force from 01.01.2019, amend. – SG 102/18, in force from 01.04.2019) On the proposal of the Executive Director of the Executive Agency "Medical Supervision", the Minister of Health may revoke the permit for medical activity when:

1. the permit is issued on the grounds of false data established by the respective order after its issuance;

2. medical activities other the those for which the permit is issued are carried out;

3. there is violation of Chapter Three, Sections I, II and III and Chapter Four, Sections III and IV if the Health Act;

4. a repeated violation of the requirements of this Act and/or a repeated violation of the approved medical standards under Art. 6, Para. 1 has been found;

5. the medical activity has not been started or has been suspended for 6 months;

6. a request has been filed by the medical establishment for termination of the medical activities, to which a decision of the new owner has been enclosed.

(2) (suppl. - SG 77/18, in force from 01.01.2019, amend. – SG 102/18, in force from 01.04.2019) The permit shall be revoked by a written motivated order of the Minister of Health which shall state the date from which the medical activity is terminated.

(3) (new - SG 59/10, in force from 31.07.2010, amend. and suppl. – SG, 72/2015, suppl. - SG 77/18, in force from 01.01.2019, amend. – SG 102/18, in force from 01.04.2019) In the cases under Para 1, Item 3 and 4 the permit shall be withdrawn pursuant to a reasoned order of the Minister of Health, on the proposal of the Executive Director of the Executive Agency "Medical Supervision", in the part concerning the performance of medical activity for the medical specialty concerned by the violation of

Chapter Three, Sections I – III and Chapter Four, Section iii and IV of the Health Act or of the approved medical standard.

(4) (amend. - SG 30/06, in force from 12.07.2006; prev. text of Para 03, suppl. - SG 59/10, in force from 31.07.2010, suppl. - SG 77/18, in force from 01.01.2019) The order under para 2 and 3 shall be subject to appeal by the order of the Administrative procedure code before the relevant administrative court.

(5) (prev. text of Para 04 - SG 59/10, in force from 31.07.2010) The appeal of the order shall not stop its fulfilment.

Art. 51a. (new, SG 83/03, repealed – SG 102/18, in force from 01.04.2019)

Section IV. Closing down medical establishments

Art. 52. (1) (amend. – SG, 72/2015) The medical establishments under Art. 5, para 1 shall be closed down by an act of the Council of Ministers at the proposal of the Minister of Health upon coordination with the respective minister.

(2) (amend. – SG, 72/2015) The act under para 1 shall indicate the respective minister who shall appoint the members of the liquidation commission, the term of its work, its tasks and the resources necessary for their fulfilment.

(3) The commission under para 2 shall consist of at least five persons and it shall include at least one representative of the administrative body, respectively the municipality, where the respective closed down has been registered, of the Ministry of Health, qualified lawyer and economist.

(4) The members of the commission shall conclude contract with the respective minister, which shall determine their concrete rights and obligations. The respective minister shall accept the concluding report and the report of the liquidation commission.

Art. 53. The conditions and the order for liquidation of the medical establishments under Art. 5, para 1 shall be determined by an ordinance of the Council of Ministers.

Art. 54. (1) (suppl. – SG 59/07, in force from 20.07.2007) The termination and the liquidation of a medical establishment - trade company or co-operative shall be carried out under the conditions and by the order stipulated by the Commerce Act, respectively for the foreign companies – of the national legislation of the state of registration, unless otherwise provided in this Act.

(2) In opening proceedings for bankruptcy shall not be admitted distraint on cash as security under Art. 630, para 1, item 4 and shall not apply the provision of Art. 630, para 2 of the Commerce Act.

(3) The termination of medical establishments founded by municipalities shall be carried out by consent of the Minister of Health.

Art. 55. (1) (repealed – SG, 72/2015)

(2) (amend. – SG 54/12) The decision for termination of the medical establishment shall determine the liquidator or liquidators as well as their remuneration.

(3) (revoked – SG 54/12)

Art. 56. (1) Liquidator can be a person who:

1. (amend. - SG 59/10, in force from 31.07.2010) has higher education and obtained "master" degree in medicine, dental medicine, economy or law;

2. has not be deprived of the right to occupy material accountancy post;

3. has not been member of executive or control body or unlimited liable partner in the company when it is terminated due to insolvency, if unsatisfied creditors are left.

(2) The liquidators shall be obliged to inform the public about the termination of the medical activity by publishing an announcement in at least one central and one local daily newspaper within seven days from their appointment and shall place it in public places and in the medical establishment.

(3) (amend. - SG 105/05, in force from 01.01.2006) The liquidators shall be obliged to inform the district health assurance fund and the territorial directorate of the National Revenue Agency about the started liquidation within fourteen days from their appointment.

(4) The liquidators shall create conditions for finishing the started medical activity observing the interests of the patients. They shall be obliged to provide the submission of the available documents to the patients regarding their diseases and their treatment by the medical establishment under liquidation.

Chapter eight.

STRUCTURE, MANAGEMENT AND PERSONNEL OF THE MEDICAL ESTABLISHMENT

Section I.

Structure of the medical establishments for hospital care

Art. 57. (1) (prev. text of Art. 57 – SG 59/10, in force from 31.07.2010) The medical establishment for hospital care shall consist of: clinic and/or departments with beds, medical diagnostic and medical technical laboratories, departments without beds, hospital pharmacy, consulting rooms, units for administrative, economic and servicing activities.

(2) (new – SG 59/10, in force from 31.07.2010) The level of competence of the clinics, departments and the medical diagnostic laboratories shall be determined in compliance with the approved medical standards referred to in Art. 6, Para 1. The level of competence shall be determined according to a procedure and criteria set out in the ordinance under Art. 46, Para 3.

Art. 58. (1) (amend. SG 76/05) The clinic is a hospital unit with definite medical or dental speciality, headed by a person with academic rank - doctor, respectively dental practitioner, which carries out diagnostic and treatment activity and education of students and/or education of specialists and/or long-term qualification.

(2) The clinic can open departments when it is stipulated by the regulations for the structure, activity and internal order of the medical establishment.

Art. 59. (1) (amend. SG 76/05; amend. – SG 59/10, in force from 31.07.2010) The department is a hospital unit for a definite medical or dental speciality, headed by a doctor, respectively dental practitioner, with acknowledged medical speciality in which diagnostic and treatment activity is carried out. Carried out in the department can be post-graduate education of specialists or long-term qualification.

(2) (revoked – SG 59/10, in force from 31.07.2010)

Art. 60. Medical diagnostic, medical technical laboratories and departments without beds are units where activities are carried out assisting directly the diagnostic and treatment process.

Art. 60a. (new – SG 59/10, in force from 31.07.2010) The consultancy cabinets shall carry out examination and reception of patients requiring hospitalisation or control examination following dehospitalisation.

Art. 61. (1) Administrative, economic and servicing units in a medical establishment for hospital care are all which do not participate directly in the diagnostic and treatment activity.

(2) The economic and servicing activities or a part of them, carried out in the medical establishments can be assigned to outside persons through a contract for order or production.

Art. 61a. (New - SG 18/18, in force from 27.02.2018) The territorial expert medical commissions shall also be structural units of state and municipal medical establishments for hospital care, having opened at these medical establishments by the order of Art. 105 of the Health Act.

Section II.

Management and control of the medical establishments

Art. 62. (1) The bodies of management and control of the medical establishments, other than those under Art. 5, para 1, shall be determined by the corporate form in which the medical establishment has been found.

(2) (amend. – SG, 72/2015, amend. – SG 102/18, in force from 01.01.2019) The Council of Ministers, at the proposal of the Minister of Health, shall submit to the respective higher school the rights of the sole owner of the capital for the management of the state medical establishments which are university hospitals by the order of Art. 90, para 4 for the period of the approval under Art. 91, Para. 10. The transformation and termination of these medical establishments, as well as the sale of parts thereof shall be carried out by the consent of the Minister of Health.

(3) The general meeting of the partners, stock holders or the member co-operators of the medical establishment shall appoint and release the members of the bodies of management and control and shall determine their remuneration.

(4) The rights and obligations of the persons under para 3 shall be settled by a contract. The contract for management and control shall also determine the remuneration of the managing and control bodies, the responsibility for non-fulfilment of the obligations of the parties and the grounds for termination.

(5) The time during which the persons have worked under the contract for management and control in the medical establishments and have been assured according to their contracts shall be considered time of service.

Art. 63. (1) (amend. – SG, 72/2015) Manager, respectively executive director, of the medical establishment can only be a person with educational and qualification degree "master" of medicine, respectively Dental medicine and with qualification on health management or a person with educational

and qualification degree "master" of economy and management, acquired educational and/or scientific degree, specialty or passed education for raising the qualification under Art. 43 of the Act on Higher Education in the area of health management.

(2) (Suppl. – SG 102/18, in force from 01.01.2019) State and municipal medical establishments - sole owner joint-stock companies shall have single-instance system of management. The board of directors of state hospitals for hospital care shall consist of three people.

(3) (suppl., SG No 65/00, amend. and suppl. – SG, 72/2015) The managers, respectively the executive directors, of state and municipal medical establishments for hospital care and diagnostic consultative centres - sole owner trade companies and medical establishments under Art. 10 – sole trade companies shall be appointed by the owner upon a competition for a period of three years. The conditions and the order of holding the competition shall be determined by an ordinance of the Minister of Health.

(4) Upon expiration of the three-year period the contract for management or control can be renewed for another three-year period.

(5) (suppl., SG 108/00, amend. SG 62/02; amend., SG 83/03; suppl. – SG 59/10, in force from 31.07.2010; amend. – SG 54/12) The bodies of management and control of the medical establishments in the context of para 1 do not regard Art. 8, para 1, item 1, letter "a" and "b" and item 2, letter "a", "b" and "c", items 3 and 4 and Art. 10, items 3, 3a, 3b, 4, 5, 6 and 7.

Art. 64. (1) The contracts with the members of the managing and control bodies can be terminated before the expiration of the term of the contract:

1. at the request of the person by a prior notification of no longer than three months;
2. at transformation or termination of the medical establishment, as well as for change of its owner;
3. in case of death or placing under judicial disability of the individual, respectively in case of declaring bankruptcy or termination of corporate body;
4. due to actual inability of the person to fulfil its obligations, which continues for more than 60 days;
5. for occurrence of circumstances substantiating prohibition or restriction for the person for occupying such post according to the law or the statutes;
6. by mutual consent;
7. due to other conditions settled by the contract.

(2) The general meeting of the partners, the stock holders or member-co-operators of the medical establishments can terminate the contract for management and control before expiration of the term of the contract:

1. for violation of the law during or on occasion of the fulfilment of the contract;
2. (amend. – SG, 72/2015) for carrying out activities or lack of activities of the persons which have caused deterioration of the financial results or from which damages to the medical establishment have been caused;
3. for systematic non-fulfilment of the decisions and the written instructions of the owners of medical establishments.
4. (new – SG, 72/2015) in case of failure to fulfil the economic indicators, defined by the contracts for assigning management or control.

(3) Controller in the medical establishment can only be a person with higher education and at least five years time of service on the speciality.

Art. 65. (1) (amend. and suppl. - SG 98/10, in force from 14.12.2010, amend. - SG 81/16, in

force from 01.02.2017) The management of the medical establishments under Art. 5, para 1, without those of the Council of Ministers, the Ministry of Justice, the Ministry of Transport, Information Technologies and Communications and the Ministry of Defence shall be carried out by a director who shall have higher education on medicine and acknowledged medical speciality and qualification on health management, appointed by the respective minister upon a competition according to the Labour Code. The medical establishment shall supply to the applicants admitted to the competition information of the budget and the staff listing within a time limit determined in the publication about the competition.

(2) The director of the medical establishment shall be employer of all its employees.

(3) (new – SG 59/10, in force from 31.07.2010, amend. and suppl. – SG, 72/2015) The directors of emergency medical aid centres, transfusion haematology centres, of medical establishments for stationary psychiatric aid and of medico-social care homes that carry out medical monitoring and specialised care for children and of center for complex service of disabled children and with chronic sicknesses shall be attested annually by a commission appointed by the Minister of Health. The order of carrying out the attestation shall be determined as set out in regulations under Art. 35, Para 3.

(4) (new - SG 98/10, in force from 14.12.2010) The director of the medical establishment under Art. 5, Para 1 at the Council of Ministers, the Ministry of Defence, the Ministry of Interior, the Ministry of Justice and the Ministry of Transport, Information Technologies and Communications shall be assisted by the deputy director for the medical activity who shall be appointed in coordination with the Minister of Health.

Art. 66. Manager, executive director or director of state or municipal medical establishment cannot be also head of the units under Art. 58, 59 and 60.

Art. 67. There will be, in all medical establishments for hospital care, chief nurse (mid-wife, rehabilitator).

Art. 68. (1) The management of the structures carrying out medical activities in the medical establishments for hospital care shall be carried out by a head of a clinic, department, medical diagnostic and medical technical laboratory, senior nurse (mid-wife, laboratory assistant, rehabilitator).

(2) (amend. SG 76/05) Head of clinic can be a doctor, respectively dental practitioner - a person with academic rank, with acknowledged medical speciality on the profile of the clinic.

(3) (amend. SG 76/05) Head of department can be a doctor, respectively dental practitioner, with acknowledged medical speciality on the profile of the department.

(4) Head of laboratory can be a specialist on the profile of the laboratory.

(5) (new – SG 62/02, amend. – SG, 72/2015) The persons of para 2, 3 and 4 can also be chiefs of chairs in the medical faculties and dental medicine faculties of higher schools. The chiefs of chairs at the medical faculties and the dental medicine faculties of higher schools can take the positions of para 2, 3 and 4 with a contract, concluded with the manager or with the executive director of the hospital, made by the order of art. 111 of the Labour Code.

(6) (prev. (5), amend. SG 62/02; amend. – SG 59/07, in force from 20.07.2007) Senior nurse (mid-wife, laboratory assistant, rehabilitator) can be a person with educational and qualification degree "bachelor in health care" or "master in health care management"

(7) (prev. (6), amend. SG 62/02) The employment contracts with the head of clinic and with the chief nurse (mid-wife, rehabilitator) shall be concluded with the management of the medical establishment for a period of up to three years upon holding competition according to the Labour Code.

Art. 69. (1) The managing bodies of the medical establishment shall manage and be responsible for its entire activity.

(2) The managers, respectively the executive directors of the medical establishment shall:

1. manage the medical establishment;
2. represent the medical establishment before third persons;
3. (suppl. SG 62/02, amend. SG 76/05, amend. – SG, 72/2015) be employers of all employees in the medical establishment, the employment contracts with the doctors – lecturers and the dental practitioners – lecturers being concluded and terminated after co-ordination with the rector of the respective higher school;
4. (amend. – SG, 72/2015) control the financial situation of the medical establishment, are responsible for its financial stability;
5. carry out structural and organisational changes in the medical establishment;
6. (amend. – SG, 72/2015) assign to the heads of the clinics, departments and laboratories the control of the financial situation of their structures for a definite period;
7. convene the medical councils at the medical establishments;
8. (amend. – SG, 72/2015) submit, upon request, information about the medical activities, the resources for their provision and analysis of the efficiency of the medical establishment to the owner, to the financing body and to the Ministry of health;
9. discuss with representatives of the trade unions in the medical establishment issues related to the working time, the conditions and the protection of labour, the remuneration and the social protection in the legal terms of employment;
10. (new – SG 59/10, in force from 31.07.2010) provide for conditions for active cooperation of the medical establishment with the Social Support Agency and its territorial units on issues of prevention of children abandonment and violence against children.
11. (new – SG, 72/2015) fulfil also other activities, assigned by the management contracts.

Art. 70. (1) (suppl. SG 62/02; amend. – SG 59/07, in force from 20.07.2007) The chief nurse (mid-wife, rehabilitator) can be a person having educational and qualification degree "bachelor in health care" or "master in health care management".

(2) The chief nurse (mid-wife, rehabilitator) shall:

1. organise, coordinate and be responsible for the quality of the health care;
2. be responsible for the hygienic condition of the medical establishment, for the disinfecting, disinsecting and deratisation;
3. present to the director analysis and information about the condition of the health care in the medical establishment;
4. plan and organise the post-graduate education of the medical specialists in the medical establishment with educational degree lower than "master";
5. convene the council for health care.

Art. 71. The head of clinic, department and laboratory shall:

1. propose and give consent for the employment and release of the personnel in his unit;
2. plan, organise, control and be responsible for the entire medical activity in the structure he heads;
3. be responsible for the economic efficiency of the unit;
4. be responsible for the information activity of the unit;

5. (amend. SG 62/02, amend. – SG, 72/2015) plan, organise in co-ordination with the respective chairs of the medical faculties and faculties of dental medicine of the higher schools the activities on the academic process of students and the post-graduate education of the medical specialists in the unit he heads;

6. create conditions for fulfilment of scientific programmes of the medical establishment in the unit he heads;

7. (suppl. SG 62/02) report his activity to the executive director, and for the education process – before the chief of the chair.

Art. 72. The occupational characteristics of the head of clinic, department, laboratory, of the chief nurse, of the senior nurse (mid-wife, laboratory assistant, rehabilitator) shall be determined on the basis of the requirements of the Ministry of Health and shall be approved by the managing body of the medical establishment for hospital care.

Art. 73. (amend. SG 62/02, amend. – SG, 72/2015, amend. – SG 102/18, in force from 01.01.2019) The employees of the medical establishments which have acquired the quality of university hospital by the order of Art. 90, para. 4 can conclude additional employment contract for carrying out lecturing in the higher school for a definite period. Applied in these cases shall be the requirements of Art. 48, para 3.

Art. 74. (1) Created by an order of the head of the medical establishment shall be:

1. medical council;
2. treatment control commission;
3. commission for hospital infections;
4. council for the health care.

(2) The regulations for the structure, the activity and the internal order of the medical establishment can establish commissions and councils other than those under para 1: commissions for medical ethics, medicine policy, development of the information provision, as well as others according to the needs of the medical establishment.

Art. 75. (1) (amend. SG 76/05; amend. – SG 59/07, in force from 20.07.2007) The medical council is a consultative body in carrying out the management of the medical establishment and shall consist of the heads of clinics, department and medical diagnostic laboratories, the manager of the hospital pharmacy, the chairman of the association of the professional organisation of the Bulgarian Physician's Union, the Union of the dental practitioners in Bulgaria, the Bulgarian Association of health care professionals and the chief nurse.

(2) The medical council shall be chaired by the manager, the executive director or the director of the medical establishment who shall have the right to consultative voice.

Art. 76. The medical council shall consult:

1. the fulfilment of the plan for the activity of the medical establishment and its medical, social and economic efficiency;
2. the proposals of the heads of the clinics, departments and laboratories for improvement of the activities of their structures;

3. the information activity of the medical establishment and propose measures for its improvement;
4. introduction of new medical methods and technologies improving the efficiency and the quality of the medical services;
5. programmes for scientific activity of the medical establishment.

Art. 77. (1) The treatment control commission is a control body on the diagnostic and treatment process.

(2) The treatment control commission shall:

1. carry out inspections on the efficiency, the effect and the quality of the diagnostic and treatment activities in the hospital units;
2. take decisions on cases difficult for diagnostics and treatment;
3. control the observance of the rules of the good medical practice;
4. analyse the discrepancy between the clinical and the pathologoanatomic diagnosis of deceased patients in the establishment.

Art. 78. The commission for fighting hospital infections shall:

1. work out, discuss and adopt plans for prophylactics of hospital infections on the basis of carried out inspections and studies;
2. exercise systematic control over the condition of the hospital hygiene and the anti-epidemic regime;
3. analyse the morbidity of hospital infections and propose decisions to the management of the medical establishment;
4. work out the antibiotic policy of the hospital and control its fulfilment;
5. control the registration of the hospital infections and organise inspections for their active tracing;
6. work out programmes for improvement of the qualification of the personnel on the hospital infections.

Art. 79. (1) The council for health care is a consultative body of the chief nurse (mid-wife, rehabilitator) on:

1. the organisation, coordination, economic efficiency and quality of the nursing care;
2. (amend. – SG 59/10, in force from 31.07.2010) the planning and carrying out post-graduate education of the medical specialists in the medical establishment with "bachelor" and "professional bachelor" educational and qualification degrees.

(2) participating the council for health care shall be the senior nurses (mid-wives, laboratory assistants, rehabilitators) from the clinics and departments of the medical establishment.

(3) Chairwoman of the council for health care shall be the chief nurse (mid-wife, rehabilitator).

Section III. Personnel in the medical establishments

Art. 80. (1) (prev. art. 80, amend. SG 62/02) The personnel in the medical establishments shall consist of:

1. (amend. SG 62/02, amend. SG 76/05; suppl. – SG 38/10) doctors, dental practitioners,

pharmacists and other specialists with educational and qualification degree "master" or "doctor" participating in the diagnostic and treatment process, and in the university hospitals – also by doctors - lecturers; and dental practitioners – lecturers (assistants, senior assistants, chief assistants, associate professors, professors), specialists in the field of medicine, biology, chemistry and physics and the other non-medical fields;

2. (suppl. SG 62/02) medical specialists with educational and qualification degree "specialist" or "bachelor in medical care";

3. (new – SG, 72/2015) training specialists under the ordinance of Art. 181, Para. 1 of the Health Act;

4. (former p. 3 – SG, 72/2015) other persons carrying out administrative and auxiliary activities.

(2) (new – SG 62/02, amend. SG 76/05, amend. – SG, 72/2015) The doctors – lecturers and dental practitioners – lecturers shall be appointed under the conditions and by the order, provided in the Higher Education Act – for the lecturers with academic rank and with no academic rank in the higher schools. The competition shall be announced by the respective higher school upon a proposal, co-ordinated with the manager or with the executive director of the university hospital.

(3) (new – SG 59/10, in force from 31.07.2010, suppl. – SG, 72/2015) Medical establishments for hospital care shall be obliged to employ physicians with acknowledged qualification under primary employment contracts in the said qualification, as positions for training specialists..

Art. 80a. (new – SG 62/02) (1) (amend. – SG, 72/2015) The members of the scientific – lecturing staff of the clinics and the divisions of the university hospitals shall be members of the chair council of the respective chairs of the higher school.

(2) (amend. – SG, 72/2015) The educational and the research and development activity at the clinics and the divisions of the university hospitals shall be implemented according to plans and programmes, approved by the chairs medical faculties and the faculties of dental medicine of schools, in co-ordination with the manager or the executive director of the medical establishment.

Art. 81. (1) (prev. art. 81 - SG 65/00, amend. SG 76/05, suppl. - SG 59/06 r.) Doctors and with basic or profiled medical speciality who work in a medical establishment for hospital care under Art. 9 or medical establishments under Art. 10 can:

1. (amend. – SG 70/04, in force from 01.01.2005; amend. - SG 98/10, in force from 01.01.2011) register individual practice for non-stationary specialised care if in the same populated area there no such registered or the registered persons of the same basic or profile speciality are insufficient. The assessment of insufficiency shall be made by the director of the regional health inspection. In these cases the persons can conclude contract with the National Health Assurance Fund;

2. register individual practice for non-stationary specialised care, other than the cases under item 1. In these cases the persons cannot conclude contract with the National Health Assurance Fund;

3. (suppl. – SG 59/06) work under contract with a group practice for specialised non-stationary care with the centres under Art. 16 and 17, with independent medical diagnostic laboratories under Art. 18, par. 1 and with medical establishments for hospital care under Art. 9.

(2) (new - SG 65/00; amend. - SG 98/10, in force from 01.01.2011) The National Health Insurance Fund can conclude contracts with the medical establishments for out-hospital care under para 1, item 3 for the specialities occupied by specialists according to para 1, if the conditions of art. 62 of the Health Insurance Act have been met. The assessment of insufficiency shall be made by the director of the regional health inspection.

(3) (new – SG, 72/2015) The estimation for insufficiency under Para. 1, p. 1 and Para. 2 shall

be carried out depending on the needs of medical aid according to the National health map.

(4) (new – SG, 72/2015, amend. - SG 18/18, in force from 27.02.2018) In the cases under Para. 1, p. 1 and Para. 2 the director of the regional health inspection shall define the minimal number of hours, but not less than 5 hours per week, in which the doctors and dentists may work in the medical establishments under Para. 1, p. 1 and 3.

Art. 81a. (new – SG, 72/2015) The persons, working at medical establishments, for which decreased working time has been established under Art. 137 of the Labour Code may work in shifts, where the maximum length of the working shift in calculated working time may be up to 12 hours, notwithstanding of the length of the decreased working time.

Section IV. Hospital board of trustees

Art. 82. (amend. – SG 59/10, in force from 31.07.2010) Set up at the medical establishments for hospital care can be hospital board of trustees.

Art. 83. The hospital board of trustees shall have the purpose of assisting the hospital in its activity for better satisfaction of the public needs of medical services.

Art. 84. (1) The hospital board of trustees shall be set up by the owners of the medical establishment, as for the purpose they shall extend invitation in the mass media, as well as invite personally owners, donors of the medical establishment, representatives of non-governmental organisations and other persons.

(2) The persons under para 1 shall elect among themselves the number and the members of the hospital board of trustees.

Art. 85. (1) The hospital board of trustees shall gather at least once a year at the initiative of one third of its members, at the request of the managing body of the medical establishment or at the request of the owner.

(2) The hospital board of directors shall invite to its meetings the managing body of the medical establishment and shall receive from it information about the condition of the establishment.

(3) The hospital board of directors shall:

1. assist the creation and maintenance of the installations, equipment and real estate of the medical establishment;
2. propose to the owner measures for improvement of the activity of the medical establishment;
3. if necessary, carry out actions and information campaigns with the purpose of mobilisation of public forces and means of assisting the medical establishment.

Chapter nine.

ACCREDITATION (REPEALED – SG 102/18, IN FORCE FROM 01.01.2019)

Art. 86. (1) (Suppl. SG 62/02; amend., SG 83/03; suppl., SG 102/03; amend. – SG 59/10, in force from 31.07.2010, suppl. – SG, 72/2015, repealed – SG 102/18, in force from 01.01.2019)

Art. 87. (Repealed – SG 102/18, in force from 01.01.2019)

Art. 88. (Amend. – SG 59/10, in force from 31.07.2010, repealed – SG 102/18, in force from 01.01.2019)

Art. 88a. (New – SG 59/10, in force from 31.07.2010, repealed – SG 102/18, in force from 01.01.2019)

Art. 89. (amend. – SG 59/10, in force from 31.07.2010, repealed – SG 102/18, in force from 01.01.2019)

Art. 89a. (new - SG 59/10, in force from 31.07.2010, repealed – SG 102/18, in force from 01.01.2019)

Art. 89b. (new – SG, 72/2015, repealed – SG 102/18, in force from 01.01.2019)

Chapter ten.

PARTICIPATION OF THE MEDICAL ESTABLISHMENTS IN THE MEDICAL EDUCATION

Art. 90. (1) (Amend. – SG 102/18, in force from 01.01.2019) The medical establishments can also carry out activities on:

1. (suppl. SG 62/02) clinical education of students and PhD students of medicine, stomatology and pharmacy;

2. (amend. SG 62/02, amend. – SG, 72/2015) clinical education of students from subjects of professional direction Health Cares;

3. (amend. SG 62/02, amend. SG 76/05, amend. – SG, 72/2015) post-graduate education of doctors, dental practitioners, pharmacists, specialists on health care.

(2) (New – SG 102/18, in force from 01.01.2019) The activities under Para. 1 may be carried out by medical establishments which have received approval from the Minister of Health.

(3) (New – SG 102/18, in force from 01.01.2019) The criteria and conditions to be met by the structure and organization of the activity in the medical establishment, the necessary equipment and the qualification of the personnel, in order for the medical establishment to perform the activities under Para. 1, shall be determined by an ordinance of the Minister of Health.

(4) (Amend. SG 62/02; amend. – SG 59/10, in force from 31.07.2010, amend. – SG, 72/2015, previous Para. 2, amend. – SG 102/18, in force from 01.01.2019) The Council of Ministers, at the proposal of the Minister of Health shall determine which of the medical establishments, or their clinics or wards, having obtained the approval of the Minister of Health for the activities under para 1, item 1, shall acquire the rights of university hospitals for the period of the approval. The proposal of the Minister of Health shall be made on the basis of a grounded request by the respective rector of the higher school in coordination with the head of the medical establishment.

(5) (New – SG, 72/2015, previous Para. 3, amend. – SG 102/18, in force from 01.01.2019) Under Para. 2, the Council of Ministers may withdraw the rights of the university hospital/clinics or

ward before expiry of the term of the approval under Para. 2 of the medical establishment/clinics or ward.

(6) (New – SG 62/02, former Para. 4 – SG, 72/2015, previous Para. 4 – SG 102/18, in force from 01.01.2019) In the university hospitals/clinics or wards shall be admitted for treatment also persons with diseases, which are included in the programmes for student training and for training of post-graduate students and PhD students.

(7) (former Para. 4, amend. – SG, 72/2015, previous Para. 5 – SG 102/18, in force from 01.01.2019) The conditions and the order for carrying out of the education, as well as its financing, shall be provided with a contract between the medical establishment and the higher school.

(8) (New - SG 59/10, in force from 31.07.2010, former Para. 5, – SG, 72/2015, previous Para. 6 – SG 102/18, in force from 01.01.2019) The financing of the training of the students and doctoral students shall be funded from the part of the state budget intended for education and science, and the funds for training to obtain a speciality in the healthcare system at places financed by the state – from the part of the state budget intended for healthcare.

(9) (New – SG 102/18, in force from 01.01.2019) The criteria to be met by medical establishments or their clinics or wards under Para. 1 in order to acquire the rights of university hospitals / clinics or wards shall be determined by an ordinance of the Council of Ministers.

Art. 91. (amend. SG 62/02; amend., SG 70/04, amend. SG 85/05, amend. – SG 102/18, in force from 01.01.2019) (1) In order to obtain approval under Art. 90, Para. 2, the Head of the medical establishment shall submit to the Minister of Health an application to which is attached the following:

1. a justification for the compliance of the medical establishment with the criteria and conditions of the ordinance under Art. 90, Para. 3;

2. a document for a paid state fee in the amount determined by the tariff under Art. 41, Para. 4.

(2) The verification of compliance of the medical establishment with the criteria and conditions of the ordinance under Art. 90, Para. 3 shall be carried out by an expert commission appointed by the Minister of Health, or a Deputy Minister empowered by him, under conditions and by order determined by the ordinance under Art. 90, Para. 3.

(3) In case of incompleteness of the submitted documents under Para. 1, the Minister of Health, or a Deputy Minister empowered by him, shall notify the applicant in writing and set a 7-day period for their removal.

(4) The results of the verification under Para. 2 shall be considered by an advisory council, which is to give to the Minister of Health an opinion for approval or refusal to approve the medical establishment for carrying out the activities under Art. 90, Para. 1. The procedure for providing the opinion and the organization of the work of the council shall be determined by the ordinance under Art. 90, Para. 3.

(5) The advisory council under Para. 4 shall be established by an order of the Minister of Health and shall consist of representatives of the Ministry of Health, of the Executive Agency "Medical Supervision", of the National Health Insurance Fund, of the Bulgarian Medical Association, the Bulgarian Dental Association, the Bulgarian Pharmaceutical Union, the Bulgarian Association of Healthcare Professionals and of representative organizations for the protection of patients' rights.

(6) Within two months from the filing of the application under Para. 1, or by removing the incompleteness under Para. 3, the Minister of Health, or a Deputy Minister empowered by him, shall issue an order approving or refusing to approve, with motivation, the medical establishment to carry out the activities under Art. 90, Para. 1.

(7) The Minister of Health, or a Deputy Minister empowered by him, shall refuse to approve, with motivation, the medical establishment for carrying out the activities under Art. 90, Para. 1:

1. in case of incompleteness of the submitted documents and their non-removal within the term

under Para. 3;

2. when, during the verification under Para. 2, a non-compliance with the criteria and conditions of the ordinance under Art. 90, Para. 3 has been established.

(8) The refusal under Para. 7 shall be subject to appeal under the Administrative-Procedure Code before the respective administrative court.

(9) In the order approving the medical establishment for carrying out the activities under Art. 90, Para. 1, shall be indicated the type of training and the specialties, in which the medical establishment is to provide training for students or post-graduate students.

(10) The approval for carrying out the activities under Art. 90, Para. 1 shall be for a period of 5 years.

(11) The Minister of Health, or an official authorized by him, may revoke the right of the medical establishment to carry out the activities under Art. 90, Para. 1 and before expiration of the term under Para. 10, if it is established that the medical establishment does not meet the criteria and conditions of the ordinance under Art. 90, Para. 3.

Art. 92. (Amend. – SG 102/18, in force from 01.01.2019) (1) The Ministry of Health shall keep a public register of the medical establishments approved for carrying out the activities under Art. 90, Para. 1. The following shall be entered in the Register:

1. the number and the date of the order for approval for carrying out the activities under Art. 90, Para. 1;

2. the name of the medical establishment;

3. the type of training and the specialties, in which the medical establishment is to provide training for students and/or post-graduate students.

(2) In the register under Para. 1 there shall be a separate section, in which the persons who have filed an application are to be entered in the order of filing, and the number and type of the documents attached to the application is to be described. This section shall also state the movement of the file formed following the application.

(3) The terms and procedure for keeping the register shall be determined by the ordinance under Art. 90, Para. 3.

Art. 93. (Amend., SG 65/00, amend. – SG, 72/2015, repealed – SG 102/18, in force from 01.01.2019)

Chapter eleven.

INTERCATION BETWEEN THE MEDICAL ESTABLISHMENTS

Art. 94. (1) When the interests of the society require joint activities at the time of natural calamities, epidemics and other extraordinary circumstances the medical establishments, regardless of the form of ownership, shall be obliged to interact with their available resources.

(2) The expenses of the medical establishments made in the cases under para 1 shall be reimbursed by the state by a decision of the Council of Ministers.

Art. 95. (1) The medical establishments can:

1. agree between themselves on providing medical specialists, medical services and other activities;

2. (amend. – SG 60/12, in force from 07.08.2012) sign contracts with an insurer licensed under Section II, letter A item 1 and item 1 and 2 from Appendix No 1 to the Insurance Code.

(2) State and municipal medical establishments for hospital care can treat patients against direct payment within the frames of not more than 10 percent of the available beds.

(3) Responsible for using the beds under para 2 shall be the respective heads of departments and clinics.

Art. 95a. (New – SG 102/18, in force from 01.01.2019) (1) The medical establishments may establish and participate in self-assessment systems and rating systems for assessment of the quality of the medical and organizational activities they perform, as well as of the financial and administrative management activities.

(2) For the purposes of Para. 1, medical establishments can interact with each other and with professional and patient organizations, as well as organize and associate without carrying out commercial transactions.

(3) Participation in the systems under Para. 1 shall be voluntary.

(4) The criteria for participation in the systems under Para. 1, the manner of their functioning, as well as the elements of the assessment provided by them, shall be determined by the persons under Para. 2.

(5) The medical establishments under Para. 2 shall be obliged to disclose the introduced systems under Para. 1 and keep up-to-date information on their functioning on the Internet with a view to informing patients and other stakeholders.

(6) The medical establishments - participants in the systems under Para. 1 shall publish information on the system's ratings on relevant indicators on their websites.

Chapter twelve.

FINANCING OF THE MEDICAL ESTABLISHMENTS

Art. 96. Sources of financing of the medical establishments can be:

1. The National Health Assurance Fund;
2. (amend. SG 15/13, in force from 01.01.2014) the state and the municipal budgets;
3. (amend. – SG 60/12, in force from 07.08.2012) insurers licensed under Section II, letter A item 1 and item 1 and 2 from Appendix No 1 to the Insurance Code;
4. local and foreign corporate bodies and individuals.

Art. 97. The revenue of the medical establishment shall be formed by receipts from:

1. contracts for provided medical care;
2. direct payments by individuals and corporate bodies, as well as under Art. 37, para 1 of the Health Insurance Act;
3. reimbursement of expenses made by a third party;
4. (amend. SG 15/13, in force from 01.01.2014) expedient subsidies from the state budget when stipulated by the State Budget Act;
5. expedient subsidies from the municipal budgets when provided by them;
6. rentals of equipment, premises and offices according to the acting legislation;
7. donations, wills and other sources.

Art. 98. (1) (prev. art. 98 - SG 65/00, suppl. – SG 102/18, in force from 01.01.2019) In cases where the medical services are provided without a contract with the National Health Insurance Fund and not by the order of Art. 82 of the Health Act, the medical establishments shall form a price.

(2) (New - SG 65/2000) The medical establishments under Art. 16 and 17 shall develop internal rules for the allocation of financial resources.

(3) (New – SG 102/18, in force from 01.01.2019) The medical establishments shall be obliged to place information on the type and the price of all provided medical and other services in publicly accessible places in their building and about the way they are paid. The information shall also be published on the websites of the medical establishments or shall be announced in another usual way, as well as on the [website](#) of the Ministry of Health.

(4) (New – SG 102/18, in force from 01.01.2019) The medical establishments shall be obliged to issue to the patients a financial document for all the amounts paid by them in connection with their servicing.

Art. 99. (1) The cost of the provided medical services shall not include expenses for education of students, specialists and doctorants, for long-term qualification, as well as for scientific research.

(2) The expenses under para 1 shall be subject to individual contracting between the assignor and the medical establishment.

Art. 99a. (new - SG 59/10, in force from 31.07.2010; revoked – SG 45/11, in force from 14.06.2011)

Art. 100. (1) (suppl., - SG 105/05, in force from 01.01.2006) The state and the municipalities may finance the state or municipal medical establishments through expedient subsidies approved by the State Budget Act and by the municipal budgets.

(2) Expedient subsidies under para 1 shall be granted for:

1. acquiring long-term material assets;

2. (amend. – SG, 72/2-15_ basic repair or renovation, related to a reorganisation of the medical establishment;

3. information technologies and systems;

4. (amend. - SG 105/05, in force from 01.01.2006) financial recovery of the medical establishments for hospital care.

5. (new., SG 108/00; revoked - SG 105/05, in force from 01.01.2006)

6. (new - SG 105/05, in force from 01.01.2006) medical establishments, located in regions of increased health risk.

(3) (new – SG 62/02) The financing of the activities, connected with the investment expenses, can be implemented according to the state or the municipal participation in the capital of the treatment establishments.

(4) (new - SG 102/12, in force from 01.01.2013, amend. and suppl. – SG, 72/2015) The funds provided from the state or municipal budget for settling obligations of state medical establishments - companies, and medical establishments - companies with mixed state and municipal share in the capital, shall be accounted as increase of their capital. The capital of the medical establishment shall be increased by the value of the funds provided from the budget for settling obligations of the said state medical establishment or medical establishment with mixed state and municipal share in the capital and the state and municipalities shall subscribe new quotas/shares.

(5) (new - SG 102/12, in force from 01.01.2013) Medical equipment and other long-term

tangible assets purchased through central supply shall be provided by the Ministry of Health according to their purpose to state and municipal medical establishments - companies, and medical establishments - companies with mixed state and municipal share in the capital.

(6) (new - SG 102/12, in force from 01.01.2013) In the cases under Para 5, if within three months from the delivery of the medical equipment, respectively of other long-term tangible assets, the medical establishment fails to pay their price, the capital of the medical establishment shall be increased with the value of the equipment or the long-term tangible assets at the price of their purchase and the state shall subscribe for itself all new quotas/shares.

(7) (new - SG 102/12, in force from 01.01.2013, amend. and suppl. – SG, 72/2015) The budget funds provided to state medical establishments - companies, and medical establishments - companies with mixed state and municipal share in the capital, intended for capital expenditures shall be accounted as increase of their capital. The capital of the medical establishment shall increase only with the value of the provided and used budget funds for capital expenditures of the state medical establishment or medical establishment with mixed state and municipal share in the capital in question and the state and the municipalities shall subscribe new quotas/shares. The non-used funds for capital expenditures shall be subject to refunding to the state budget in an order determined by the Minister of Health.

(8) (new - SG 102/12, in force from 01.01.2013) In the cases referred to in Para 4, 6 and 7 shall not apply the provisions of the Commerce Act and the statute/company contract in respect of the increase of the capital of the company and the amendment of the statute/company contract related thereto. The amendments shall be carried out only through filing an application with the commercial register by the Minister of Health of an official authorised by him.

(9) (new - SG 102/12, in force from 01.01.2013) The funding and increase of the capital referred to in Para 1 - 8 shall be carried out in compliance with the requirements of the State Aid Act.

Art. 100a. (new – SG 62/02) The dialysis centres can be financed by the National health insurance fund on the basis of contracts in compliance with the budget of the National health insurance fund.

Chapter thirteen.

TRANSFORMATION AND PRIVATISATION OF MEDICAL ESTABLISHMENTS

Section I.

Transformation of the public health establishments

Art. 101. (1) (amend. – SG, 72/2015) The existing public medical establishments for hospital care, dispensaries and hospital diagnostic and treatment structures to the higher schools shall be transformed into medical establishments - sole owner trade companies by an order of the Minister of Health by September 1, 2000.

(2) (amend., SG 65/00; amend. – SG 59/10, in force from 31.07.2010) The establishments transformed according to para 1 shall, within one month from their court registration, make a request for obtaining permit for carrying out medical activity by the order of Art. 46 as the kinds of medical establishments can only be those under Art. 9, para 1, item 1 and 2 or respectively Art. 10, item 3. Until the obtaining of the permit the transformed establishments can carry out medical activity.

(3) (amend. – SG 54/12, amend. – SG, 72/2015) The transformation under para 1 shall be carried out upon the enactment of the ordinances under Art. 46, para 3 and under Art. 49, para 5.

(4) (amend. – SG, 72/2015) With the transformation of the hospital diagnostic and treatment structures at the higher schools, the national centres carrying out medical activity, the state pulmonary

hospitals and the Scientific Institute for emergency medical care "Pirogov" into medical establishments - sole owner trade companies, the ownership of their capital shall be acquired by the state and the rights shall be exercised by the Minister of Health.

(5) (unconstitutional - SG 51/00 – Decision of the Constitutional Court No 11/01) With the transformation of the public health establishments into medical establishments - joint-stock companies the ownership of their capital shall be acquired by:

1. the state and shall be managed by the Minister of health - for 51 percent of the capital;
2. the municipalities of the region whose population is serviced by the medical establishment; the stock holding of the municipalities shall be proportional to the population living in the respective municipalities.

(6) With the transformation of the public health establishments, other than those under para 4 and 5, into medical establishments for hospital care or into medical establishments under Art. 10, item 3 the ownership of their capital shall be acquired by the municipality on whose territory is located the headquarters of the trade company and the rights shall be exercised by the respective municipal council.

Art. 102. (1) (amend. SG 113 1999; amend. - SG 98/10, in force from 01.01.2011) The existing public health establishments for non-stationary care shall be transformed by an order of the Minister of health into medical establishments - sole owner trade companies by March 1, 2000 and shall be registered in the regional health inspections by the order of Art. 40 as the kinds of medical establishments can only be those under Art. 8, para 1, item 2, letter "c" and "d" and item 3.

(2) (amend. SG 113 1999) The terms of employment with the medical specialists implementing non-stationary care provided by the health establishments under para 1 shall be provided by the order of art. 123 of the Labour Code.

(3) (amend. SG 113 1999; corr. SG 114 1999; amend., SG 65/00, amend. SG 76/05) The physicians and the dental practitioners working in the medical establishment carrying out out-hospital care, or medical establishments established by them shall conclude a rental contract for the premises, the equipment and the apparatuses with the managing bodies of the medical establishments.

(4) (amend. SG 113 1999; amend., SG 65/00; amend. – SG 105/06, in force from 01.01.2007; amend. - SG 95/15, in force from 01.01.2016) The managerial bodies of the medical establishments to which a proposal is made shall be obliged in 15 days after the requirement to conclude rental contracts at prices in extent 10 percent of the rental price determined by the corresponding municipality by the order of the Municipal Property Act, and for the equipment and apparatuses - at prices equal to their monthly amortisation deductions under the applicable accounting standards in accordance with Chapter Four of the Accountancy Act. The managing bodies cannot terminate unilaterally the contracts under para 3 in the presence of a contract with the National Health Insurance Fund, except in cases of failure to fulfil the basic obligations of the lessee. In case of refusal of the managing body to conclude the rental contract the persons under para 3 can lay a claim at the regional court for declaring the contract final.

(5) (new - SG 65/00) Rental contracts with medical establishments can be concluded with other medical establishments in the presence of free premises, equipment and apparatuses only after the conclusion of the contracts with the persons under para 3.

(6) (new - SG 65/00) The property of the not transformed public health establishments for out-hospital care shall be managed by the mayor of the municipality, a person authorised by him or by a trade company established by the municipal council for management and administering the property. The medical specialists who carry out out-hospital care on the premises of these establishments shall have the rights under para 3 and 4.

(7) (amend. - SG 30/06; amend. – SG 54/12) The transformation under para 1 into medical establishments for non-stationary care can be carried out upon the enactment of the ordinances under Art. 41, para 4 of this Act and Art. 26, para 3 of the National Health Act.

(8) (repealed SG 113 1999)

(9) (repealed SG 113 1999)

Art. 103. (1) The existing public sanatorium and medical recovery health establishments shall be transformed into sole owner trade companies with state property by an order of the Minister of health by September 1, 2000.

(2) The establishments transformed under para 1 shall, within 6 months, extend request for obtaining permit for carrying out the medical activity by the order of Art. 46 as hospital for rehabilitation. Until the obtaining of the permit the transformed health establishments can carry out medical activity.

Art. 104. (1) With the transformation of the public health establishments under Art. 101, 102 and 103 the real estate and chattel ceded for use and management - state or municipal property, including in the balances of the health establishments, on whose grounds they are transformed, shall be transferred to the property of the state.

(2) The trade companies established by the order of para 1 shall be legal successors of the health establishments on whose grounds they have been transformed.

(3) The legal terms of employment with the persons working in the transformed health establishments under Art. 101 and 103 shall be settled by the order of Art 123 of the Labour Code.

Art. 105. (1) (suppl., SG 65/00, suppl. - SG 99/17, in force from 01.01.2018) The renting and the administering of real estates and chattel of state or municipal medical establishment - sole owner trade company, as well as a medical establishment - a commercial company with mixed state and municipal participation in the capital, representing long-term material assets, shall be carried out only after approval of the sole owner of the capital, respectively of the Board of Directors, if the total value for the current year exceeds 5 percent of the balance value of the long-term assets of the company by December 31 of the previous year. This provision shall not apply for the rental contracts concluded by the order of art. 102, para 4.

(2) (Amend. – SG 102/18, in force from 01.01.2019) In the cases under Para. 1, cash proceeds shall be transferred to the account of the medical establishment, shall remain its property and may be used for investments directly related to the object of activity, and for the satisfaction of the interests of creditors after permission by the owner of the capital.

Art. 106. (amend – SG 105/05, in force from 01.01.2006) (1) The State and the municipalities may fund medical establishments for execution of national, regional and municipal health programmes and projects, as well as for performing of a certain types of medical activity beyond the range of obligatory health insurance, on the base of a contract.

(2) (Amend. – SG 102/18, in force from 01.01.2019) Funding by the state and the municipalities shall be executed by way of conclusion of a contract between the respective state or municipal body and the medical establishment.

(3) (new - SG 59/10, in force from 31.07.2010, amend. – SG 102/18, in force from 01.01.2019) The state may provide subsidies to hospital establishments established by municipalities and/or the state for their activity at addresses in settlements in hard-to-reach and/or remote areas, within the funds provided for in the budget of the Ministry of Health for the respective calendar year. Subsidization of medical establishments for hospital care established by municipalities shall be carried out at the suggestion of the National Association of Municipalities in the Republic of Bulgaria. The criteria and the order for determining the medical establishments and for granting the subsidies shall be determined

by the ordinance under Art. 106a, Para. 6.

Art. 106a. (new - SG 102/12, in force from 01.01.2013, amend. – SG 102/18, in force from 01.01.2019) (1) The Ministry of Health shall subsidize the converted state and municipal medical establishments for hospital care and the medical establishments for hospital care with state and/or municipal participation in the capital for the activities under Art. 82, Para. 1, item 6a, 6c and 9 of the Health Act.

(2) The Ministry of Health shall also subsidize the medical establishments under Para. 1 for activities on maintenance of medical records and activities under Art. 82, Para. 1, item 8 of the Health Act, determined by the Minister of Health with the ordinance under Para. 6.

(3) The Ministry of Health shall subsidize state and municipal medical establishments for hospital care and state and municipal centers for mental health for the activities under Art. 82, Para. 1, items 3 and 3b of the Health Act, as well as for medical expertise, carried out by LEMC.

(4) The Ministry of Health may subsidize for activities under Para. 1, 2 and 3 and the medical establishments of the Council of Ministers, the Ministry of Defense, the Ministry of Interior, the Ministry of Justice and the Ministry of Transport, Information Technology and Communications.

(5) Beyond the cases under Para. 1-4, the Ministry of Health shall subsidize:

1. medical establishments for hospital care for emergency medical care for patients with urgent conditions, who have passed through emergency rooms and who are not hospitalized in the same medical establishment;

2. state and municipal medical establishments for hospital care for the provision of consultative medical assistance to emergency patients at the request of the duty teams at emergency care centers.

(6) The subsidy under Para. 1-5 shall be carried out according to criteria and by an order determined by an ordinance of the Minister of Health on the basis of one-year contracts within the funds for these activities under the budget of the Ministry of Health for the respective calendar year and in compliance with the requirements of the State Aid Act.

(7) The ordinance under Para. 6 shall determine the criteria and the order of financing of state and municipal medical establishments in which veterans of wars, disabled ex-service men and injured military are to exercise their right to rest and treatment provided for in a normative act.

Art. 107. (amend., SG 65/00) The public health establishments which are not transformed shall be closed down by the Council of Ministers and shall be liquidated by the order of Art. 52.

Section II.

Section II. Privatisation of medical establishments with state and municipal participation (Revoked, SG 28/02)

Art. 108. - 114 Revoked SG 28/02)

Chapter fourteen.

ADMINISTRATIVE PENAL PROVISIONS

Art. 115. (1) (amend., SG 70/04) Who carries out activity on non-stationary medical care in violation of the provisions of this Act or of the normative acts related to its implementation shall be fined with 1000 to 3000 levs unless subject to a more severe sanction.

(2) (new, SG 70/04) Who carries out activity in off hospital medical care, in violation of art. 39,

shall be punished by a fine of 2000 to 5000 levs, and for a repeated violation – by deprivation from the right to practice the profession for a period of three months to one year.

(3) (prev. para 2 – amend., SG 70/04) When the offence under para 1 is committed by a corporate body a proprietary sanction shall be imposed amounting from 2000 to 5000 levs.

Art. 115a. (new – SG 101/09, in force from 01.01.2010) (1) Medical establishment, carrying out activity on non-stationary medical care in violation of the provisions of the established medical standards, shall be fined with 300 to 1000 levs.

(2) Where the violation under par. 1 has been done by a medical establishment – a single trader or a legal entity, a proprietary sanction from 300 to 1000 levs shall be imposed,

Art. 116. (1) (amend., SG 70/04) Who carries out activity on hospital medical care in violation of the provisions of this Act or of the normative acts for its implementation shall be fined with 1000 to 5000 levs.

(2) (amend., SG 70/04) When the offence under para 1 is committed by a corporate body proprietary sanction shall be imposed amounting from 8000 to 20 000 levs.

Art. 116a. (new – SG 101/09, in force from 01.01.2010, amend. – SG, 72/2015) Medical establishment carrying out activity on hospital medical care in violation of the provisions of the established medical standards shall be imposed a proprietary sanction from 2000 to 5000 levs.

Art. 116b. (new – SG, 72/2015) (1) Anyone, who violates the provision of this act or the legislative acts on its implementation while carrying out an activity in a medical establishment under Art. 10 shall be punished by a fine of BGN 1500 to 3000.

(2) A medical establishment under Art. 10, which carried out an activity in violation of this act or its legislative acts of its implementation shall be punished by a property sanction in the amount of BGN 2500 to 5000.

Art. 116c. (new – SG, 72/2015) (1) A medical establishment, which carried out an activity in violation of the provisions confirmed by health-information standards, shall be punished by fine of BGN 500 to 1000.

(2) Where the violation under Para. 1 has been committed by a medical establishment – sole trader or legal person, a property sanction of BGN 500 to 1000 shall be imposed.

Art. 116d. (New – SG 102/18, in force from 01.04.2019) Any manager, respectively Executive Director, of medical establishment under Art. 6, Para. 6, who acts in violation of the approved standards for financial activities, shall be punished with a fine in the amount from BGN 500 to 3000, and in case of repeating the same violation - by a fine in the amount from BGN 3 000 to 6 000.

Art. 116e. (New – SG 102/18, in force from 01.04.2019) Whoever performs any activities in violation of the approved rules for good medical practice, rules for good medical practice of dental practitioners, rules for good pharmaceutical practice or rules for good medical practice in health care in the respective professional fields, shall be sanctioned with a fine from BGN 200 to 1 000, and in case of repeat violation of the same nature - with a fine from BGN 1 000 to 3 000.

Art. 116f. (New – SG 102/18, in force from 01.04.2019) Any official who fails to cooperate with the employees of the Executive Agency "Medical Supervision" in exercising their powers shall be punished with a fine in the amount from BGN 1 000 to BGN 3 000, and in the case of repeating the same violation - by a fine from BGN 4 000 to BGN 8 000.

Art. 116g. (New - SG 102/18, in force from 01.04.2019) (1) Whoever fails to comply with any mandatory prescription under Art. 7d, Para. 2, item 3, unless subject to a more severe punishment, shall be liable to a fine of BGN 1 000 to 3 000, and in case of repeat offense of the same nature - by a fine of BGN 3 000 to 6 000.

(2) Where the violation under Para. 1 is committed by a legal person or a sole trader, a pecuniary sanction of BGN 3 000 to 6 000 shall be imposed and, in the case of repeat offense of the same kind - a pecuniary sanction of BGN 10 000 to BGN 15 000.

Art. 117. (amend. – SG 101/09, in force from 01.01.2010; amend. - SG 98/10, in force from 01.01.2011, amend. – SG, 72/2015, amend. - SG 102/18, in force from 01.04.2019) The violations under Art. 115 - 116g shall be established by acts drawn up by officials designated by the Executive Director of the Executive Agency "Medical Supervision", and the penal decrees shall be issued by the Executive Director of the Executive Agency "Medical Supervision".

Art. 118. The establishment of the offences, the issuance, the appeal and the fulfilment of the penalty decrees shall be carried out according to the provisions of the Administrative Violations and Penalties Act.

Additional provisions

§ 1. (amend. - SG 59/10, in force from 31.07.2010) In the sense of this Act:

1. "Single identification number" means a ten-digit code formed from the code of the region (the first two digits), the code of the municipality (the second two digits), the code of the type of the medical establishment (the following three digits) and the consecutive number of the medical establishment for the region (the last three digits) at the entry of the medical establishment into the register under Art. 49.

2. "State or municipal medical establishment" means also a medical establishment which capital over 50 percent belongs to the state or the municipality.

3. "Repeated offence" means offence committed within one year from entry into force of a penal decree punishing the offender for an offence of the same type.

4. "Terminally ill patients" means persons with progressing and incurable diseases, for whom the treatment does not change the negative medical prognosis for the length of life.

5. "Hardly accessible region" means a region with disadvantageous geographic terrain – mountain, semi-mountain and/or with disadvantageous road infrastructure requiring more than 60 minutes to access the closest medical establishment for hospital care by specialised medical automobile transport.

6. "Remote region" means a region on a distance requiring more than 60 minutes to access the closest medical establishment for hospital care by specialised medical automobile transport.

7. "Primary employment contract" shall be any employment contract signed for a specified or unspecified period of time that is full-time as determined for the respective position.

8. (amend. and suppl. – SG, 72/2015) "Level of competence" means the type and scope of the medical activity carried out by a structure of the medical establishment for hospital care, the mental health centre, the skin-venereal diseases centre and the complex oncologic centre and their capacity.

9. "Capacity" means the maximum volume of medical activities carried out by the clinics and departments in compliance with the requirements for sufficiency of medical specialists on a primary employment contract, availability of fit medical equipment and facilities as specified in the medical standards and in compliance with the medical standards approved by the Minister of Health.

10. (new – SG 54/12, amend. – SG, 72/2015)) "High-tech methods for diagnosis and treatment" means methods defined as highly technological in the methods under Art. 29, Para. 6.

11. (new – SG, 72/2015) "new medical activities" are medical activities in specialties in which the medical establishment has not performed activity, as well as medical activities in specialties, in which the medical establishment carried out activity but its volume is being changed (a new structure in the same specialty is formed or the level of competence is raised of the existing structure of the medical establishment) including highly technological methods of diagnostics and treatment, related to their application of highly technological medical equipment.

Transitional and concluding provisions

§ 2. The public health establishments, the private health establishments and the medical specialists carrying out private medical practice according to the National Health Act and the by-laws shall continue to carry out their activity by the previous order until bringing them in compliance with the requirements of this Act.

§ 3. (1) The found private health establishments at the time of enactment of this Act, carrying out hospital medical care, founded by the order of the National Health Act, shall bring their statute in compliance with its requirements and shall extend a request for permitting medical activity by the order of Art. 46 by September 1, 2000.

(2) (amend. SG 113 1999) The found persons at the time of enactment of this Act, carrying out private medical practice by the order of Art. 25a of the National Health Act, as well as the private health establishments carrying out non-stationary medical care, shall bring their statute and activity in compliance with its requirements and shall be registered till March 1, 2000 at the regional health centres on the basis of the issued certificates.

§ 4. (prev. § 4 - amend., SG 36/2000) Within six months from the enactment of the law the Council of Ministers, at the proposal of the Minister of health, in coordination with the respective minister, shall determine the existing centres for emergency care, centres for haematological transfusion, medical establishments for stationary psychiatric care, "Mother and child" homes, the health establishments at the Ministry of Defence, the Ministry of Interior, the Ministry of Justice and the Ministry of Transport and Communications as medical establishments according to Art. 5, para 1, as well as their specific functions.

(2) (New, SG 36/2000) The health establishments at the Ministry of Interior and the Ministry of Transport and Communications, other than those under para 1, shall be transformed by an order of the Council of Ministers at the proposal of the respective minister and the Minister of health into sole owner

companies under art. 3, para 1 by September 1, 2000. The order shall appoint the minister who shall exercise the rights of ownership of the capital of the medical establishment.

§ 5. (1) (prev. text of § 5 – SG 110/08, in force from 01.01.2009) The existing, by the moment of enactment of this Act, state health establishment Clinical Hospital "Lozenets" is a medical establishment at the Council of Ministers in the context of Art. 5, para 1 of the law.

(2) (new – SG 110/08, in force from 01.01.2009; amend. – SG 99/09, in force from 01.01.2010; amend. SG 15/13, in force from 01.01.2014) The Director of the "Lozenets" hospital shall be a second level administrator of budget credits to the first level administrator of budget under the budget of the Council of Ministers.

§ 6. (1) (suppl. SG 88/99, SG 62/02, amend. SG 76/05) Right to establish individual and group practice for primary medical care shall have:

1. doctors without specialty, doctors with basic medical care and profile specialty and doctors in process of acquiring of specialty who in 10 years after this Act enters into force must graduate course and acquire specialty of general medicine;

2. doctors in dental medicine.

(2) The Minister of Health shall determine with an ordinance the conditions and the order for specialisation and for long term qualification of the persons of para 1.

§ 7. Within ten years from the enactment of the law appointed at the positions nurse (mid-wife, laboratory assistant, rehabilitator) can be persons with educational and qualification degree lower than "bachelor" if a candidate meeting the requirements of this Act does not appear.

§ 8. (amend. - SG 30/06) Within six months from the enactment of the law the Council of Ministers and the Minister of Health shall issue by-law normative acts for its implementation, with exception of the ordinances under Art. 41, para 3 of this Act and according to Art. 26, para 3 of the National Health Act which shall be issued within three months from the enactment of the law.

§ 9. The following amendments and supplements are introduced to the National Health Act:

1. In Art. 1a:

a) para 2 is amended as follows:

"(2) The medical care for the population shall be organised by health establishments according to this Act and by medical establishments according to the Medical Establishments Act.";

b) in para 3 the words "and private" are deleted.

2. In Art. 2, para 2 is amended as follows:

"(2) Public health establishment shall be opened, transformed and closed down by the Council of Ministers at the proposal of the Minister of Health."

3. The following amendments and supplements are introduced to Art. 3:

a) in para 3, first sentence, after the words "the Ministry of Transport" a comma is added followed by "the Ministry of Justice and Legal European Integration" and the words "health establishments under Art. 2, para 2, item 2" are replaced by "medical establishments opened to them"; in the second sentence the word "health" is replaced by "medical";

b) para 5 is amended as follows:

"(5) The control over the health establishments shall be carried out by the Ministry of Health.";

c) in para 6 the words "ordinance for the requirements for the health establishments" are replaced by 'the regulations for the structure and activity of the health establishments'.

4. In Art. 3b, para 2, item 6 is revoked.

5. The following amendments are introduced to Art. 4a:

a) second sentence is created in para 1:

"The competition shall be announced by the Minister of health.";

b) para 2 is revoked.

c) in para 3 the words "and the heads of the territorial bodies of the Ministry of health" are deleted and the words "are given testimonial" are replaced by "is given testimonial";

d) para 4 is revoked.

6. In Art. 25, para 1, after the word "health" is added "and medical" and the words "offices of doctors and dentist at private medical practice" are deleted.

7. Art. 25a - 25j are revoked.

8. Art. 25k is amended as follows:

"Art. 25k. The medical specialists working in health medical establishments shall keep documentation and shall issue medical documents determined by an ordinance of the Minister of Health."

9. In Art. 26, para 1, 2, 3 and 4 are amended as follows:

"(1) Every Bulgarian citizen is entitled to accessible medical care under the conditions and by the order of the Health Insurance Act in medical establishments which have concluded contracts for providing medical care according to the obligatory health assurance, as well as free using of medical services related to the activities under Art. 3a, item 1, 2, 3, 4, 5, 13 and 15.

(2) The persons under para 1 who are obligatorily assured according to the Health Insurance Act shall be entitled to a free choice and treatment by a doctor and a dentist in medical establishments for primary and non-stationary care.

(3) The conditions and the order for exercising the right of choice under para 2, as well as the access to the specialised non-stationary and hospital care shall be settled by an ordinance of the Council of Ministers.

(4) The medical services related to the activities under Art. 3a, item 1, 2, 3, 4, 5, 6, 13 and 15 shall not be paid."

10. The following amendments are introduced to Art. 28:

a) in para 1 the word "first" is replaced by "emergency";

b) in para 2 the word "health" is replaced by "medical".

11. The following amendments are introduced to Art. 29:

a) in para 1 the word "first" is replaced by "emergency";

b) in para 2 the word "health" is replaced by "medical".

12. The following amendments are introduced to Art. 30:

a) in para 1 the words "public health" are replaced by "the health and medical".

b) in para 3 the words "health establishments" are replaced by "the establishments".

13. In Art. 31, para 4 the word "health" is replaced by "medical".

14. The following amendments and supplements are introduced to Art. 33:

a) in para 1, after the word "corpses" is added "of persons in condition of cerebral death";

b) in para 2 the words "public health" are replaced by "state or municipal medical";

c) in para 3 the words "public health" are replaced by "medical".

15. In Art. 34, para 2 is amended as follows:

"(2) Organs and tissues from corpses of persons who have dies in medical establishments can be taken without the consent of their heirs, as well as from persons in condition of cerebral death without the consent of their next of kin only if the persons were able Bulgarian citizens and have not

refused during their lifetime donation of organs and tissues after their death. The refusal shall be certified by indicating in the health assurance book of the person by an authorised employee of the district health assurance fund. In these cases the head of the medical establishment shall inform the next of kin about the taken organs and tissues."

16. In Art. 35, para 1 the words "the public health" are replaced by the "state medical".

17. The following amendments are introduced to Art. 36:

a) in para 1, 2, 3, and 4 the words "public health" are replaced by "state or municipal medical", and in para 5 the words "public health" are replaced by "state or municipal medical";

b) in para 6 and 8 the words "the health" are replaced by "the medical".

18. In Art. 36a, para 1 the words "public health" are replaced by "state or municipal medical" and in para 2 the words "public health" are replaced by "state or municipal medical".

19. The following amendments are introduced to Art. 37:

a) in para 1 the word "health" is replaced by "medical" and the words "the health" - by "the medical";

b) in para 2 the word "health" is replaced by "medical".

20. In Art. 38 the word "health" is replaced by "medical".

21. Art. 39 is revoked.

22. In Art. 40 the words "The health" are replaced by "The state and municipal medical".

23. The following amendments are introduced to Art. 42:

a) in para 2 the words "and establishments" are deleted;

b) in para 3 the word "public" is replaced by "medical".

24. In Art. 43 the words "The health" are replaced by "The medical".

25. Art. 44 is revoked.

26. In Art. 48, para 1 the words "Public health" are replaced by "The state and municipal medical".

27. Art. 50 is amended as follows:

"Art. 50. The Ministry of Health shall manage methodologically the rehabilitation treatment."

28. In Art. 56, item 2, after the word "health" is added "and medical".

29. The following amendments are introduced to Art. 61:

a) in para 1 the word the word "the health" are replaced by "the medical";

b) in para 3 the word "health" is replaces by "medical".

30. In Art. 62, para 2 the word "health" is replaced by "medical" and the word "the health" - by "the medical".

31. In Art. 87, para 2 the words "the public health" are replaced by "the medical".

32. The following amendments and supplements are introduced to Art. 93:

a) the previous text becomes para 1 and in it the words "Higher, college and high school medical employees" are replaced by the words "Medical specialists";

b) para 2 is created:

"(2) The time during which the medical specialists occupy elective position as representatives, ministers, mayors, deputy mayors and chairmen of municipal councils shall be considered professional time of service in the context of para 1."

33. In Art. 94 after the words "one health" is added "or medical" and after the words "the health" is added "or the medical".

34. In Art. 95, after the words "health establishment" is added "or state medical establishment".

35. The following amendments are introduced to Art. 97:

a) in para 1 the words "200 to 1000 levs" are replaced by "2000 to 10 000 levs" and the words "500 to 2000 levs" are replaced by "5000 to 20 000 levs";

b) in para 2 the words "500 to 1500 levs" are replaced by "5000 to 15 000 levs" and the words "1000 to 3000 levs" are replaced by "10 000 to 30 000 levs";

c) in para 4 the words "2000 to 10 000 levs" are replaced by "20 000 to 100 000 levs" and the words "20 000 levs" are replaced by "200 000 levs".

36. Art. 97a is revoked.

37. The following amendments are introduced to Art. 97b:

a) in para 1 the words "100 000 to 500 000 levs" are replaced by " 1 000 000 to 5 000 000 levs" and the words "500 000 to 1 000 000 levs" are replaced by " 5 000 000 to 10 000 000 levs";

b) in para 2 the words "500 000 to 1 000 000 levs" are replaced by "5 000 000 to 10 000 000 levs" and the words "1 000 000 to 5 000 000 levs" are replaced by "10 000 000 to 50 000 000 levs".

38. The following amendments are introduced to Art. 98:

a) in para 1 the words "100 to 10 000 levs" are replaced by "1000 to 100 000 levs" and the words "5000 to 20 000 levs" are replaced by "50 000 to 200 000 levs";

b) in para 2 the words "20 000 to 500 000 levs" are replaced by "200 000 to 5 000 000 levs" and the words "100 000 to 1 500 000" are replaced by "1 000 000 to 15 000 000 levs".

39. In Art. 98a the words "300 to 1500 levs" are replaced by "3000 to 15 000 levs" and the words "500 to 3000 levs" are replaced by "5000 to 30 000 levs".

40. In Art. 99, para 1 the words "2000 to 20 000 levs" are replaced by "20 000 to 200 000 levs" and the words "5000 to 40 000 levs" are replaced by "50 000 to 400 000 levs".

41. In Art. 100, para 1 the words "10 000 to 50 000 levs" are replaced by "100 000 to 500 000 levs".

42. In Art. 100a, para 1 the words "5000 to 50 000 levs" are replaced by "50 000 to 500 000 levs" and the words "10 000 to 100 000 levs" are replaced by "100 000 to 1 000 000 levs".

43. In Art. 101 the words "97a" are deleted and the words "500 to 15 000 levs" are replaced by "5000 to 150 000 levs" and the words "14 000 to 30 000 levs" are replaced by "140 000 to 300 000 levs".

44. The following amendments are introduced to Art. 102:

a) in para 1 the word "worker" is replaced by "specialist";

b) para 2 is revoked.

45. The following amendments and supplements are introduced to Art. 103:

a) in para 1 the words "97a" are deleted and after the words "100a" a comma is added followed by "101";

b) in para 5 the words "97a" are deleted;

c) in para 7 the word "health" is replaced by "medical".

46. The following amendments and supplements are introduced to the additional provisions:

a) paragraph 1 is amended as follows:

"§ 1. "health establishments" in the context of this Act are the hygienic and epidemiological inspections and the national centres for protection of the public health.";

b) In § 5 the words "knowledge and skills" are replaced by "theoretical knowledge and practical skills".

§ 10. The following amendments are introduced to the Health Insurance Act (prom., SG, No 70 of 1998; amend., No 93 and 153 of 1998):

1. Art. 58 is amended as follows:

"Art. 58. Providers of medical care in the context of this Act are medical establishments according to the Medical Establishments Act and health establishments according to the National Health Act."

2. In § 3, para 1 of the transitional and concluding provisions the words "the pre-hospital" are replaced by the words "non-stationary".

§ 11. In Art. 40 of the Value Added Tax Act (prom., SG, No 153 of 1998; corr., No 1 of 1999; amend., No 44 of 1999) para 1 is amended as follows:

"(1) Health services are the services provided by health establishments according to the National Health Act and by medical establishments according to the Medical Establishments Act in the homes for senior citizens and in other establishments by doctors, dentists and medical specialists according to the National Health Act and the Medical Establishments Act."

§ 12. The fulfilment of the Act is assigned on the Minister of Health.

§ 13. (amend. SG 113 1999) Paragraph 9, item 9 of the transitional and concluding provisions shall apply from July 1, 2000 for the non-stationary care and from July 1, 2001 for the hospital care.

The Act was passed by the 38th National Assembly on June 24, 1999 and was affixed with the official seal of the National Assembly.

§ 14. (new - SG 65/00) (1) The state institute hospitals and diagnostic medical structures at the higher medical schools shall retain their rights and obligations under the contracts with the higher medical schools for education of students, specialists and doctorants regardless of their transformation into medical establishments until the acquisition of the quality of university hospitals by the order stipulated by the law, but not later than July 1, 2001.

(2) (amend. SG 76/05) In transforming the establishments under para 1 the physicians and dental practitioners working also as teachers in them shall conclude a basic employment contract with the managing body of the medical establishment. Their legal terms of employment shall be settled under the conditions of art. 123 of the Labour Code.

§ 15. (new - SG 98/10, in force from 14.12.2010) The medical establishments for hospital care operating on the territory of a stare or municipal medical establishment for hospital care and failing to meet the requirements of Art. 9, Para 6 may continue their present activity until the expiration of the time limits specified in the rental or joint activity contracts signed before entry into force of this Act.

.....

This Act was adopted by XXXVIII Parliament on 24 June 1999 and was stamped with the official seal for the Parliament.

**Transitional and concluding provisions
TO THE ACT ON THE STATE BUDGET OF THE REPUBLIC OF BULGARIA FOR THE
YEAR 2006**

(PROM. – SG 105/05, IN FORCE FROM 01.01.2006)

§ 95. The Act shall enter in force from the 1st of January 2006.

**Transitional and concluding provisions
TO THE TAX-INSURANCE PROCEDURE CODE**

(PROM. – SG 105/05, IN FORCE FROM 01.01.2006)

§ 88. The code shall enter in force from the 1st of January 2006, except Art. 179, Para 3, Art. 183, Para 9, § 10, item 1, letter "e" and item 4, letter "c", § 11, item 1, letter "b" and § 14, item 12 of the transitional and concluding provisions which shall enter in force from the day of promulgation of the code in the State Gazette.

**Transitional and concluding provisions
TO THE ADMINISTRATIVE PROCEDURE CODE**

(PROM. – SG 30/06, IN FORCE FROM 12.07.2006)

§ 61. In the Medical Establishments Act (prom. SG 62/99, amend. SG 88/99, amend. SG 113/99, corr.. SG 114/99, amend. SG 36/00, amend. SG 65/00, amend. SG 108/00, amend. SG 51/01 - Decision No. 11 of the Constitutional Court from 2001, amend. SG 28/02, amend. SG 62/02, amend. SG 83/03, amend. SG 102/03, amend. SG 114/03, amend. SG 70/04, amend. SG 46/05, amend. SG 76/05, amend. SG 85/05, amend. SG 88/05, amend. SG 105/05) the words "Act of the administrative procedure" shall be replaced by "Administrative procedure code".

.....

§ 142. The code shall enter into force three months after its promulgation in State Gazette, with the exception of:

1. division three, § 2, item 1 and § 2, item 2 – with regards to the repeal of chapter third, section II "Appeal by court order", § 9, item 1 and 2, § 15 and § 44, item 1 and 2, § 51, item 1, § 53, item 1, § 61, item 1, § 66, item 3, § 76, items 1 – 3, § 78, § 79, § 83, item 1, § 84, item 1 and 2, § 89, items 1 - 4§ 101, item 1, § 102, item 1, § 107, § 117, items 1 and 2, § 125, § 128, items 1 and 2, § 132, item 2 and § 136, item 1, as well as § 34, § 35, item 2, § 43, item 2, § 62, item 1, § 66, items 2 and 4, § 97, item 2 and § 125, item 1 – with regard to the replacement of the word "the regional" with the "administrative" and the replacement of the word "the Sofia City Court" with "the Administrative court - Sofia", which shall enter into force from the 1st of May 2007;
2. paragraph 120, which shall enter into force from the 1st of January 2007;
3. paragraph 3, which shall enter into force from the day of the promulgation of the code in State Gazette.

**Transitional and concluding provisions
TO THE COMMERCIAL REGISTER ACT**

(PROM. – SG 34/06, IN FORCE FROM 01.10.2006)

§ 56. This Act enters in force from 1st of October 2006, except § 2 and § 3, which enter in force from the date of promulgation of the Act in the State Gazette.

**Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE ACCOUNTANCY ACT**

(PROM. – SG 105/06, IN FORCE FROM 01.01.2007)

§ 61. This Act shall enter in force from 1st of January 2007, except § 48, which shall enter in force from 1st July 2007.

**Transitional and concluding provisions
TO THE MEDICINAL PRODUCTS IN HUMAN MEDICINE ACT**

(PROM. – SG 31/07, IN FORCE FROM 13.04.2007)

§ 37. The Act shall enter in force from the day of its promulgation in State Gazette, except for § 22, which shall enter in force one year after entry into force of this Act.

**Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE MEDICAL ESTABLISHMENTS
ACT**

(PROM. – SG 59/07, IN FORCE FROM 20.07.2007)

§ 13. The persons occupying the position of a chief nurse (midwife, rehabilitator) and the position of a head nurse (midwife, laboratory operator, rehabilitator) prior to entering of this Act into force, having taken the position pursuant to the provisions of § 7 of the Transitional and Concluding provisions, shall keep their rights for the term, set up therein.

§ 15. This Act shall enter into force from the day of its promulgation in the State Gazette, except for § 14, which shall enter into force from 26 May 2007.

**Transitional and concluding provisions
TO THE ACT ON THE STATE BUDGET OF THE REPUBLIC OF BULGARIA FOR 2009**

(PROM. – SG 110/08, IN FORCE FROM 01.01.2009)

§ 104. This Act shall enter into force from 1 January 2009 except § 100, Item 7 which shall enter into force from 1 April 2009, if the conditions of § 102 have been fulfilled.

**Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE HEALTH ACT**

(PROM. – SG 41/09, IN FORCE FROM 02.06.2009)

§ 94 (1) Doctors, who within the term under § 6, par. 1, item 1 of the transitional and conclusive provisions of the Medical Establishments Act have not obtained a profession in general medicine, shall have the right to continue working as individual or group practice for initial medical assistance for a period of 5 years after entering of this Act into force.

(2) After the expiration of the term set in par. 1 the registration in the respective regional health care center of the doctors under par. 1, not having obtained a profession in general medicine, shall be

deleted.

§ 95. Doctors, who prior to entering of this Act into force, have registered a medical establishment under Art. 13, par. 1 or Art. 14, par. 1 of the Medical Establishments Act and who have got acknowledged profession in internal diseases, in paediatric or in emergency medicine, may carry out activity as individual or group practice for initial medical assistance without obtaining a profession in general medicine."

§ 96. The Act shall enter into force from the day of its promulgation in State Gazette, except for:

1. paragraphs 3, 5, 6 and 9, which shall enter into force from 1 January 2009;
2. paragraphs 26, 36, 38, 39, 40, 41, 42, 43, 44, 65, 66, 69, 70, 73, 77, 78, 79, 80, 81, 82, 83, 88, 89 and 90, which shall enter into force from 1 July 2009;
3. paragraph 21, which shall enter into force from 1 June 2010.

**Transitional and concluding provisions
TO THE ACT ON THE STATE BUDGET OF THE REPUBLIC OF BULGARIA IN 2010**

(PROM. – SG 99/09, IN FORCE FROM 01.01.2010)

§ 84. The Act shall enter into force from 1 January 2010, except for § 80, which shall enter into force from 15 December 2009.

**Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE HEALTH INSURANCE ACT**

(PROM. – SG 101/09, IN FORCE FROM 18.12.2009)

§ 77. The Act shall enter into force from the day of its promulgation in the State Gazette, except for:

1. paragraphs 4, 5, 10 (with reference to Art. 15, par. 1, item 2), 26, 27 (item 1, item "b", item 2, 4, 5 and 6), 28, 29, 30, 33, 34, 35, 37, 38, 40, 41, 42, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 56, 57, 58, 59, 60, 61, 62, 64 (item 2), 69, 72 (items 3, 4, 5, 6, 7 and 8), 73 and 75, which shall enter into force from 1 January 2010;
2. paragraphs 25 and 27, item 1, item "a", which shall enter into force from 2 January 2010;
3. paragraph 63, which shall enter into force from 1 February 2010;
4. paragraph 36 (with reference to Art. 55c), which shall enter into force from 1 January 2011;
5. paragraphs 31 and 43 (item 1), which shall enter into force from 1 January 2012;
6. paragraph 27, item 3, which shall enter into force from 1 January 2013;
7. paragraph 29, item 1, item "b", which shall enter into force from 1 January 2011.

**Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE MEDICAL ESTABLISHMENTS
ACT**

(PROM. - SG 59/10, IN FORCE FROM 31.07.2010; AMEND. - SG 98/10, IN FORCE FROM 01.01.2011; AMEND. - SG 100/10, IN FORCE FROM 01.01.2011; AMEND. SG 15/13, IN FORCE FROM 01.01.2014, AMEND. - SG 85/17)

§ 67. (1) The medical standards under Art. 6, Para 1 and the guidelines under Art. 31, Para 2 shall be approved within one month from entry into force of this Act.

(2) The regional healthcare maps shall be drawn up and the national healthcare map – adopted, as set out in this Act within four months from approval of the medical standards under Art. 6, Para 1.

§ 68. (1) The multi-profile and specialised hospital failing to meet the requirements of Art. 9, Art. 19, Para 2 and 3 and Art. 23 shall make their activities compliant with the requirements of this Act and shall file documents for changing the issued permits for medical activity with the Minister of Health within three months from entry into force of this Act.

(2) By 1 December 2010 the control authorities of RHIF and of the Ministry of Health shall perform a check for compliance of the activities of the medical aid providers that are medical establishments for hospital care with the requirements under Art. 19, Para 2 and 3 and Art. 23.

(3) Where non-compliance with the requirements under Para 2 has been found, the changes to the funding of the activity of medical aid providers that are medical establishments for hospital care shall be effected by amendment and supplementation of the contract referred to in Art. 59, Para 1 of the Health Insurance Act.

(4) (amend. SG 15/13, in force from 01.01.2014) The medical establishments for hospital care shall be financed from funds from the state budget or from the budget of the National Health Insurance Fund only in respect of the activity of clinics and departments that are found to meet the requirements as set out in Para 2.

§ 69. (1) Medical establishments for hospital care that have failed to make their activities compliant with the requirements of this Act and have failed to file documents for changes to the issued permits for medical activity within the time limit specified in § 68, Para 1 may transform and/or re-register into medical establishments for non-stationary care.

(2) The transformation and/or re-registration of the medical establishments under Para 1 shall be done as set out in the Commerce Act and in Art. 40 pursuant to a decision of their owner. The director of the regional healthcare centre shall issue a registration certificate to the medical establishment for non-stationary care within the time limits under Art. 40.

(3) Following the issue of the registration certificate under Para 2 the Minister of Health shall issue an order for withdrawal of the issued permits for medical activity under Art. 47 granted to the transformed and/or re-registered medical establishments for hospital care.

(4) After expiration of the term under Para 1 the Minister of Health shall issue an order for withdrawal of the issued permits for medical activity under Art. 47 granted to medical establishments for hospital care that have failed to transform and/or re-registered as set out in Para 2.

§ 70. (1) The dispensaries existing at entry into force of this Act shall be transformed and/or re-registered following a decision of their owner and shall file documents for a medical activity permit with the Minister of Health within three months from entry into force of this Act as follows:

1. the dispensaries for mental diseases – into mental health centres;
2. the dispensaries for pneumo-phtsiatric diseases – into medical centres or into specialised hospitals for pneumo-phtsiatric diseases;

3. the dispensaries for skin and venereal diseases – into skin and venereal disease centres;
4. the dispensaries for oncology diseases – into complex oncology disease centres or into specialised hospitals for oncology diseases.

(2) If not transformed and/or re-registered, the dispensaries existing on entry into force of this Act shall continue performing their present activities under the Medical Establishments Act and the activities specified in other laws within the term under Para 1.

(3) The medical establishments – successors of the dispensaries referred to in Para 1 – shall continue performing their activities of active search, diagnostic, treatment and periodical monitoring of diseased.

(4) The dispensaries that have failed to transform and/or re-register within the term referred to in Para 1 shall be terminated and liquidated as set out in Art. 54, 55 and 56.

(5) On expiration of the term under Para 1 the Minister of Health shall issue an order for withdrawal of the permit for medical activity for dispensaries under Para 4.

§ 71. (1) In cases under § 70, Para 4 on decision of the owner of a dispensary and the owner of a medical establishment for hospital care the activity of the closed dispensary, without the immovable property, may be transferred to an existing or newly created clinic or department of a medical establishment for hospital care.

(2) Before the end of the liquidation proceedings referred to in § 70, Para 4 the liquidators and the persons representing the medical establishment for hospital care that is to accommodate the activity referred to in Para 1 shall organise its transfer and the transfer of the documentation related to the activity.

(3) The employment relations of physicians and medical specialists holding educational and qualification degree "bachelor" and "professional bachelor" in healthcare from the dispensaries referred to in Para 1 shall be arranged under the conditions and order of Art. 123, Para 1, Item 7 and Para 2 of the Labour Code, and the employment relations of the staff from the administrative, economic and service units of the dispensaries under Para 1 shall be terminated as set out in the Labour Code.

(4) The medical establishment for hospital care accommodating the said activity referred to in Para 1 shall file documents under Art. 50 for amendment of the permit for medical activity under Art. 47.

§ 72. (1) (amend. - SG 98/10, in force from 14.12.2010) The hospices failing to meet the requirements of Art. 28 shall make their activity compliant with its requirements and shall file documents for amendment of the issued certificates for registration with the corresponding regional healthcare centre within three months from entry into force of this Act.

(2) The patients in hospices under Para 1 that do not need the care referred to in Art. 28, Para 1 may continue their treatment in homes for medico-social care.

§ 73. (1) Medical establishments and structures operating for more than a year, respectively more than 6 months, before entry into force of this Act without accreditation shall be subject only to subsequent accreditation.

(2) The accreditation procedures opened before entry into force of this Act shall continue under the preceding order unless the medical establishment withdraws its accreditation application within 14 days. The accreditation application may not be withdrawn, if on entry into force of this Act the expert commission has filed with the Accreditation Council the report for the external assessment of the medical establishment and the draft accreditation decision.

§ 74. (1) The medical establishments shall not pay fees for issuing or amendments to the permits for medical activities by the Minister of Health or for issuing or amendments to the certificates for registration in the regional healthcare centre within the time limit under § 68, § 70 and § 72, related to making the activities of the medical establishments existing on entry into force of this Act compliant with its requirements.

(2) Medical establishments that have opened pharmacies and have filed documents for amendments to the permit for retail trade of medicinal products within the time limit under Para 1 related to changes to the name, merchant's type, seat and management address, shall not pay state fees.

§ 75. (In force from 30.09.2011) (1) (amend. - SG 98/10, in force from 30.09.2011, amend. - SG 85/17) The Ministry of Health, the regional health inspections and the Executive Agency for Transplantation shall make possible the reception of applications and documents related to the registration of medical establishments, issue of permits for medical activity and provision of information for the medical activity performed by the medical establishments electronically signed with an advanced electronic signature, an advanced electronic signature based on a qualified electronic signature certificate or qualified electronic signature, according to the Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC (OB, L 257/73 of 28 August 2014) and the Electronic Document and Electronic Trust Services Act and the Electronic Government Act.

(2) The electronic reception of applications and documents shall be performed after preparing the necessary technical and organisational conditions and the required software products.

§ 76. (1) The Minister of Health shall bring into compliance with this Act the ordinance under Art. 87, Para 1 within two months from its entry into force.

(2) The Council of Ministers shall approve the tariff under Art. 88, Para 5 within three months from entry into force of this Act.

§ 77. This Act shall enter into force from the day of its promulgation in the State Gazette, except for:

1. (amend. - SG 100/10, in force from 01.01.2011) paragraph 9 (regarding Art. 19, Para 4), 53, 60, which shall enter into force from 1 January 2011;
2. paragraph 75, which shall enter into force from 30 September 2011;
3. (new - SG 100/10, in force from 01.01.2011) paragraph 66 (regarding Art. 98, Para 5 and 6), which shall enter into force from 1 January 2012.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE HEALTH ACT

(PROM. - SG 98/10, IN FORCE FROM 01.01.2011)

§ 107. In the Medical Establishments Act (prom. - SG 62/99; amend. - SG 88, 113 and 114/99, SG 36, 65 and 108/00; Decision No 11 of the Constitutional Court of 2001 - SG 51/01; amend. - SG 28

and 62/02, SG 8, 102 and 114/03, SG 70/04, SG 46, 76, 85, 88 and 105/05, SG 30, 34, 59 and 105/06, SG 31, 53 and 59/07, SG 110/08, SG 36, 41, 99 and 101/09, SG 38 and 59/10) shall be made the following amendments and supplementations:

.....
14. In the remaining texts of the Act the words "regional healthcare centre", "regional healthcare centres" and "regional inspection for protection and control of the public health" shall be substituted by "regional health inspection" and "regional health inspections".
.....

§ 121. The Act shall enter into force from 01.01.2011, except for the following:

1. paragraphs 1, 16, 20, 29, 30, 32, 33, 34, 35, 42, 44, § 56, Item 1 and 2, § 65, 68, 70, 76, 80, 81, 90, 92, 96, § 102, Item 3, 4, 5, 7 and 8, § 105, т. 1, 3 and 5, § 107, т. 1, 2, 3, 4, 6, Letter "a", Item 7, 10, 11, 13 and 15, Letter "a", § 109, 110, 112, 113, § 115, Item 5, § 116, Item 4 and 6, § 117, Item 5 and 7 and § 118, Item 1, which shall enter into force from the date of its promulgation in the State Gazette;
2. paragraph 102, Items 1, 2 and 6, which shall enter into force from 1 March 2011;
3. paragraph 22, Item 1 (regarding Art. 36, Para 1, second sentence), § 37, § 48, Item 2, § 51 and 59, which shall enter into force from 1 July 2011;
4. paragraph 107, Item 15, Letter "b", which shall enter into force from 30 September 2011.

**Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE SOCIAL INSURANCE CODE**

(PROM. - SG 100/10, IN FORCE FROM 01.01.2011;AMEND. – SG 60/11, IN FORCE FROM 05.08.2011)

§ 65. This Act shall enter into force from 1 January 2011 except § 32, 33, 36 and 51, which shall enter into force from 1 January 2012.

**Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE MEDICAL ESTABLISHMENTS
ACT**

(PROMULGATED – SG 45/2011, IN FORCE FROM 14.06.2011)

§ 2. Executed and not reimbursed expenses for court medical expertises and for the connected with them medical transportation, which are due under the revoked Art. 99a, as well as the expenses for the remuneration of experts on those expertises, shall be paid to the medical establishments and to the experts by the appointing authority.
.....

§ 6. This Act shall enter into force from the day of its promulgation in the State Gazette.

**Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE MEDICIANL PRODUCTS IN THE**

HUMAN MEDICINE ACT

(PROMULG.- SG 60/11, IN FORCE FROM 05.08.2011)

§ 84. This Act shall enter into force from its promulgation in the State Gazette except for § 65, which shall enter in force from 30 September 2011.

Transitional and concluding provisions TO THE ACT AMENDING AND SUPPLEMENTING THE MEDICAL ESTABLISHMENTS ACT

(PROM. - SG 54/12)

§ 17. Within one month from entry into force of this Act the Minister of Health shall make the ordinance referred to in Art. 18, Para 1 of the Blood, Blood Donation, and Blood Transfusion Act compliant with this Act.

§ 18. The National Health Map shall be made compliant with the requirements of this Act within 6 months from its entry into force.

Transitional and concluding provisions TO THE ACT ON AMENDMENT AND SUPPLEMENTATION OF THE HEALTH INSURANCE ACT

§ 44. This Act shall enter into force from the day of its promulgation in the "State Gazette".

Transitional and concluding provisions TO THE ACT ON THE STATE BUDGET OF THE REPUBLIC OF BULGARIA FOR 2013

(PROM. - SG 102/12, IN FORCE FROM 01.01.2013)

§ 78. This Act shall enter into force on 1 January 2013 except for paragraphs 61, 68 and 73, which shall enter into force on the day of promulgation of the Law in the State Gazette.

Transitional and concluding provisions TO THE PUBLIC FINANCE ACT

(PROM. SG 15/13, IN FORCE FROM 01.01.2014)

§ 123. This Act shall enter into force on 1 January 2014 with the exception of § 115, which enters into force on January 1, 2013, and § 18, § 114, § 120, § 121 and § 122, which came into force on 1 February in 2013.

Transitional and concluding provisions

**TO THE ACT ON AMENDMENT AND SUPPLEMENTATION OF THE HEALTH
ESTABLISHMENTS ACT**

(PROM. - SG 47/14, IN FORCE FROM 03.06.2014)

§ 4. (1) Doctors under § 94 of the Transitional and Final Provisions to the Act Amending and Supplementing the Healthcare Act (SG 41/09), who have failed to acquire specialisation in general medicine by the 2 June 2014, but have enrolled for acquiring the said specialisation, may continue to operate as individual or group practitioners in primary medical care for a time period of 5 years from the date of the coming into force of this Act.

(2) After the time limit under Para 1 had expired, the registration with the Regional Health Inspectorates of the medical practitioners under Para 1, who had failed to acquire specialisation in general medicine, shall be deleted.

§ 5. (1) General practitioners, including the medical practitioners under the above § 94 of the Transitional and Final Provisions of the Act on Amending and Supplementing the Healthcare Act (SG No. 41/2009), who have not been enrolled for acquiring specialisation in general medicine by the 2 June 2014, may continue to operate as individual or group primary medical care practitioners for a time period of 5 years from the coming into force of this Act, provided that they have been enrolled for acquiring specialisation in general medicine within one year of the coming into effect of this Act.

(2) After the time period throughout which the medical practitioners had been allowed to operate as individual or group primary medical care practitioners, as stated under Para 1, had expired, the registration with the Regional Health Inspectorates of the medical practitioners under Para 1, who had failed to acquire specialisation in general medicine, shall be deleted.

§ 6. The provisions of § 4 and §5 shall not apply to medical practitioners who operate as individual or group primary medical care practitioners under the provisions laid down in the § 95 of the Transitional and Final Provisions of the Act Amending and Supplementing the HealthCare Act (SG No. 41/2009).

§ 7. This Act shall enter into force from June 3, 2014.

**Transitional and concluding provisions
TO THE ACT ON AMENDMENT AND SUPPLEMENTATION OF THE HEALTH
ESTABLISHMENTS ACT**

(PUBL. – SG, 72/2015)

§ 68 (1) Within 6 month term from the enforcement of this act, the commission under Art. 32, Para. 1 on the basis of the analysis under Art. 30, Para. 2 shall carry out an estimation and shall express opinion about the possibilities for provision of complex treatment (provision of a separate part of the whole process of treatment) of the patient in the existing canthers for mental health, skin-venereal diseases centres and complex oncologic centres.

(2) The commission under Para. 1 shall notify about its opinion the Minister of Health, as well as the relevant head of the canthers for mental health, skin-venereal diseases centres and complex

oncologic centres or the relevant owner of the centre, who may undertake the relevant actions under this act for carrying out a complex treatment of patients.

§ 69. (1) Medical establishments, which do not meet the requirements of Art. 9, Para. 1, Art. 19, Para. 1, Art. 20, Para. 1 and 2, Art. 21 and 22a shall be complied with the requirements, by entering the change in the trade register and shall submit documents for a change of the issued permits for medical activity to the Minister of health within the term of up to 3 months from the enforcement of this act.

(2) State fees for entry of the changes under Para. 1 shall be due.

§ 70. (1) The Minister of Health shall comply the relevant medical standards under Art. 6, Para. 1 with the requirements for levels of competence under Art. 26c within 1 month term from the enforcement of this act.

(2) Canters for mental health, skin-venereal diseases centres and complex oncologic centres shall comply their activity with the requirements of Art. 26c and shall submit documents for change of the issued permits for medical activity to the Minister of Health within 1 month from the enforcement of the relevant medical standard under Para. 1.

(3) State fees for entry of the changes under Para. 1 shall be due.

§ 71. (1) The methods under Art. 29, Para. 6 shall be confirmed within the term of up to 1 month from the enforcement of this act.

(2) The regional health maps shall be drawn up and the National health map shall be adopted under this act within the term of up to 2 months from confirmation of the methods under Para. 1.

(3) In case that with the appointment of the commission for drawing up the regional health maps no representatives of municipalities are determined under the Act on Local Self Government and Local Administration within 15 day term from receiving a request for their determination, as representatives of the municipalities shall be the relevant Mayors or officials, authorized by them.

§ 72. Para. 24, p. 3 and § 67, p. 2 shall come into force from 1 January 2016.

Transitional and concluding provisions TO THE ACCOUNTANCY ACT

(PROM. SG 95/15, IN FORCE FROM 01.01.2016)

§ 29. This Act shall enter into force from 1st of January 2016, with the exception of Art. 48 – 52, which shall enter into force from 1st of January 2017.

Transitional and concluding provisions TO THE ACT AMENDING AND SUPPLEMENTING THE MINISTRY OF INTERIOR ACT

(PROM. - SG 81/16, IN FORCE FROM 01.01.2017)

§ 70. (in force from 01.02.2017) (1) As from the date of entry into force of this Act, converted into Employment Relationships shall be the official relationships of the civil servants in the Ministry of Interior, to whom applies § 86 of the Act Amending and Supplementing the Ministry of Interior Act (SG 14 of 2015) and who, at the date of entry into force of this Act, hold offices for civil servants:

1. who are graduates of the Police Academy in the Ministry of Interior, carrying out teaching activities outside that of the vocational training of police authorities and of fire safety and protection of the population;

2. who are in the Medical Institute of the Ministry of Interior;

3. who hold secondary education;

4. with higher education and without higher education.

(2) Labour contracts for employment in the Ministry of Interior shall be concluded with the employees under par. 1, for positions for persons working under employment contracts specified in the

classification of Art. 143, para. 2 and on the staff of the respective structure, without probation period, except for those persons who are on a probationary period. In these cases, the probation period until the hiring shall be taken into account.

(3) The years of service under par. 1, acquired under the Ministry of Interior Act, shall count as service with one and the same employer within the meaning of the Labour Code, with the exception of Art. 222, para. 3 of the Labour Code.

(4) Upon conclusion of the employment contract with the Director of the Medical Institute of the Ministry of Interior, no contest shall be held in accordance with Art. 65, para. 1 of the Medical Establishments Act.

(5) Upon conclusion of employment contracts of employees of the Medical Institute of the Ministry of Interior under par. 1 for positions that require the holding of a competition under the Medical Establishments Act, no contest shall be held.

(6) Upon conclusion of employment contracts with the employees under par. 1, item 1 and 2 for hiring on academic positions at the Academy of the Ministry of Interior or at the Medical Institute of the Ministry of Interior, no competition or selection shall be held pursuant to the Development Of Academic Staff In The Republic Of Bulgaria Act.

(7) Upon refusal of an employee under par. 1 to conclude an employment contract to work at the Ministry of Interior, their employment relationship shall be terminated.

(8) Unused annual leave of employees under par. 1 proportionate to the date of entry into force of this Act shall be retained and may be used.

.....

§ 102. This Act shall enter into force on January 1, 2017, except for:

1. paragraphs 6-8, § 12, items 1, 2 and 4, § 13, § 14, § 18-20, § 23, § 26-31, § 32, items 1 and 4, § 33-39, § 41-48, § 49 on Art. 187, para. 3, first sentence, § 50-59, § 61-65, § 81-85, § 86, item 4 and 5, § 87, item 3, § 90, item 1, § 91, item 2 and 3, § 92, § 93 and § 97-101, which shall enter into force from the day of the Act's promulgation in the State Gazette.

2. paragraph 32, item 2 and 3, § 49 on Art. 187, para. 3, new second sentence, § 69-72, § 76 concerning persons under § 70, § 78 with respect to employees under § 69 and § 70, § 79 regarding employees under § 69 and § 70, § 91, item 1 and § 94, which shall enter into force on February 1, 2017.

Transitional and concluding provisions

TO THE ACT ON THE STATE BUDGET OF THE REPUBLIC OF BULGARIA FOR 2018

(PROM. - SG 99/17, in force from 01.01.2018)

§ 15. The Act shall enter into force on 1 January 2018.

Transitional and concluding provisions

TO THE ACT AMENDING AND SUPPLEMENTING THE MEDICAL ESTABLISHMENTS ACT

(PROM. - SG 101/17, IN FORCE FROM 01.01.2018)

§ 2. The Act shall enter into force on 01 January 2018.

Transitional and concluding provisions

TO THE ACT AMENDING AND SUPPLEMENTING THE ACT ON LIMITATION OF THE ADMINISTRATIVE REGULATION AND THE ADMINISTRATIVE CONTROL OVER THE BUSINESS ACTIVITY

(PROM. - SG 103/17, IN FORCE FROM 01.01.2018)

§ 68. The Act shall enter into force on 01 January 2018.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE HEALTH ACT

(PROM. – SG 18/18, IN FORCE FROM 27.02.2018)

§ 5. This Act shall enter into force on the day of its promulgation in the State Gazette.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE ADMINISTRATIVE PROCEDURE CODE

(PROM. - SG 77/18, IN FORCE FROM 01.01.2019)

§ 156. The Act shall enter into force on 1 January 2019, with the exception of:

1. paragraphs 4, 11, 14, 16, 20, 30, 31, 74 and § 105 item 1 on the first sentence, and item 2 which shall enter into force on 10 October 2019;
2. paragraphs 38 and 77, which shall enter into force two months after the promulgation of this Act in the State Gazette;
3. paragraph 79, items 1, 2, 3, 5, 6 and 7, § 150 and 153, which shall enter into force on the day of the promulgation of this Act in the State Gazette.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE MEDICINAL PRODUCTS IN HUMAN MEDICINE ACT

(PROM. - SG 84/18, IN FORCE FROM 12.10.2018)

§ 78. The law shall enter into force on the day of its promulgation in the State Gazette with the exception of § 5, § 7 - 12, § 14 - 21, § 27 - 30, § 31, items 2, § 32, § 39 - 41, § 56, § 60 and § 66, items 1-8, 10, 12, 15-17, 19-22, which shall enter into force 6 months after the publication of the notice under Art. 82 (3) of Regulation (EU) No 536/2014.

Transitional and concluding provisions
TO THE ACT ON THE BUDGET OF THE NATIONAL HEALTH INSURANCE FUND FOR 2019

(PROM. - SG 102/18, IN FORCE FROM 01.01.2019)

§ 43. The Act shall enter into force on 1 January 2019, with the exception of:

1. paragraph 29, item 13, letter "b", items 14 and 15, § 30 and § 42 item 2, which shall enter into force on the day of promulgation of the Act in the State Gazette;
2. paragraph 28, items 6 - 12 and items 14 - 19, § 35, item 3 with the exception of Art. 7a, Para. 4 and Art. 7c, Para. 4, item 5 and 6, item 8 - 22 and items 36 - 40, § 41, items 2 - 8, item 9, letters "a" and "c" and item 10 which shall enter into force on 1 April 2019;
3. paragraph 29, item 5, letter "a" on the words "through the budget of the Ministry of Health for the payment of medical devices, aids, devices and facilities for people with disabilities", item 9, letter "a" on the words "as well as medical devices, aids, devices and facilities for people with disabilities", item 9, letter "d" on the words "aids, devices and facilities for people with disabilities" and on the words "as well as with the persons carrying out activities related to delivery and repair of medical devices, aids, devices and facilities for people with disabilities, registered as traders and entered in the register of persons, performing activities related to delivery and repair of medical devices, aids, devices and facilities for people with disabilities", and item 9, letter "e" regarding Para. 15, item 3 and Para. 16

on the words "as well as persons carrying out activities related to delivery and repair of medical devices, aids, devices and facilities for people with disabilities, registered as traders and entered in the register of persons performing activities related to delivery and repair of medical devices, aids, devices and facilities for people with disabilities - for the payment of medical devices, aids, devices and facilities for people with disabilities", item 25, letter "a" - Para. 1, item 13 on the words "aids, devices and facilities for people with disabilities" and item 25 concerning Para. 4 on the words "persons carrying out activities related to delivery and repair of medical devices, aids, devices and facilities for people with disabilities, registered as traders and entered in the register of persons, performing activities related to delivery and repair of medical devices" and "and aids, devices and facilities for people with disabilities", § 36 and § 37 concerning Art. 14, Para. 8, item 2, letter "b", which shall enter into force from 1 January 2020.