

# HEALTH ACT

*Prom. 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. 94/25 Nov 2005, amend. SG. 103/23 Dec 2005, amend. SG. 18/28 Feb 2006, amend. SG. 30/11 Apr 2006, amend. SG. 34/25 Apr 2006, amend. SG. 59/21 Jul 2006, amend. SG. 71/1 Sep 2006, amend. SG. 75/12 Sep 2006, amend. SG. 81/6 Oct 2006, amend. SG. 95/24 Nov 2006, amend. SG. 102/19 Dec 2006, amend. SG. 31/13 Apr 2007, amend. SG. 41/22 May 2007, amend. SG. 46/12 Jun 2007, amend. SG. 59/20 Jul 2007, amend. SG. 82/12 Oct 2007, amend. SG. 95/20 Nov 2007, amend. SG. 13/8 Feb 2008, amend. SG. 102/28 Nov 2008, amend. SG. 110/30 Dec 2008, amend. SG. 36/15 May 2009, amend. SG. 41/2 Jun 2009, amend. SG. 74/15 Sep 2009, amend. SG. 82/16 Oct 2009, amend. SG. 93/24 Nov 2009, amend. SG. 99/15 Dec 2009, amend. SG. 101/18 Dec 2009, amend. SG. 41/1 Jun 2010, amend. SG. 42/4 Jun 2010, amend. SG. 50/2 Jul 2010, amend. SG. 59/31 Jul 2010, amend. SG. 62/10 Aug 2010, amend. SG. 98/14 Dec 2010, amend. SG. 100/21 Dec 2010, amend. SG. 8/25 Jan 2011, amend. SG. 9/28 Jan 2011, amend. SG. 45/14 Jun 2011, amend. SG. 60/5 Aug 2011, amend. SG. 38/18 May 2012, amend. SG. 40/29 May 2012, amend. SG. 54/17 Jul 2012, amend. SG. 60/7 Aug 2012, amend. SG. 82/26 Oct 2012, amend. SG. 101/18 Dec 2012, amend. SG. 102/21 Dec 2012, amend. SG. 15/15 Feb 2013, amend. SG. 30/26 Mar 2013, amend. SG. 66/26 Jul 2013, amend. SG. 68/2 Aug 2013, suppl. SG. 99/15 Nov 2013, amend. SG. 104/3 Dec 2013, amend. SG. 106/10 Dec 2013, amend. SG. 1/3 Jan 2014, amend. SG. 98/28 Nov 2014, amend. SG. 107/24 Dec 2014, amend. SG. 9/3 Feb 2015, suppl. SG. 72/18 Sep 2015, suppl. SG. 80/16 Oct 2015, suppl. SG. 102/29 Dec 2015, amend. and suppl. SG. 27/5 Apr 2016, amend. and suppl. SG. 98/9 Dec 2016, amend. SG. 103/27 Dec 2016, amend. SG. 58/18 Jul 2017, amend. SG. 85/24 Oct 2017, amend. and suppl. SG. 102/22 Dec 2017, amend. and suppl. SG. 18/27 Feb 2018, suppl. SG. 77/18 Sep 2018, amend. and suppl. SG. 91/2 Nov 2018, amend. and suppl. SG. 98/27 Nov 2018, amend. and suppl. SG. 102/11 Dec 2018, amend. SG. 24/22 Mar 2019, amend. and suppl. SG. 58/23 Jul 2019, suppl. SG. 99/17 Dec 2019, amend. SG. 101/27 Dec 2019, amend. and suppl. SG. 23/14 Mar 2020, amend. and suppl. SG. 28/24 Mar 2020, amend. SG. 34/9 Apr 2020, amend. and suppl. SG. 44/13 May 2020, amend. SG. 67/28 Jul 2020, amend. and suppl. SG. 103/4 Dec 2020, amend. and suppl. SG. 105/11 Dec 2020, amend. and suppl. SG. 110/29 Dec 2020, suppl. SG. 21/12 Mar 2021, amend. SG. 8/28 Jan 2022, amend. SG. 17/1 Mar 2022, amend. and suppl. SG. 18/4 Mar 2022, amend. and suppl. SG. 32/26 Apr 2022, suppl. SG. 41/3 Jun 2022, amend. SG. 58/23 Jul 2022, amend. and suppl. SG. 62/5 Aug 2022*

In force from 1st of January 2005

## **Chapter one. NATIONAL SYSTEM OF HEALTH CARE**

### **Section I. General Provisions**

Art. 1. This Act settles the public relations in connection with the preservation of the health of the citizens.

Art. 2. The preservation of the health of the citizens as a state of a complete physical, psychic and social welfare is a national priority and shall be guaranteed by the state through applying the following principles:

1. equality in using health services;
2. providing accessible and qualitative health care, with priority for children, pregnant women and mothers of children up to one year;
3. priority of the health promotion and the integrated prophylactics of diseases;
4. prevention and reduction of the risk for the health of the citizens from the unfavourable effect of the factors of the living environment;
5. special health protection of children, pregnant women and mothers of children up to one year of age and disabled and mentally disordered persons;
6. state participation in financing activities aimed at preservation of the health of the citizens.

Art. 3. (1) The state health policy shall be managed and implemented by the Council of Ministers.

(2) The Council of Ministers, at a proposal of the Minister of Health shall approve National Health Strategy which shall be adopted by the National Assembly.

(3) (Suppl. - SG 32/22, in force from 26.04.2022) The Council of Ministers, at a proposal of the Minister of Health shall adopt national health programmes and national plans.

(4) (Amend. - SG 32/22, in force from 26.04.2022) The National Health Strategy, the national health programmes and the national plans shall be based on an assessment of the health status and health needs of the citizens, the health demographic tendencies and the resource capacity of the national system of health care.

(5) (Amend. - SG 15/13, in force from 01.01.2014, suppl. - SG 32/22, in force from 26.04.2022) The national health programmes and national plans shall be financed by the state budget as differentiated expenses of the budget of the Ministry of Health and may be supported through other financial resources.

Art. 4. (amend. - SG 31/07, in force from 13.04.2007) The national system of health care shall include the medical establishments under the Medical Establishments Act, the health establishments under this Act and the Medicinal Products in Human Medicine Act, as well as the state, municipal and public bodies and institutions for organisation, management and control of the activities related to preservation and strengthening of health.

## **Section II.**

### **Bodies of management of the national system of health care**

Art. 5. (1) The Minister of Health shall manage the national system of health care and shall exercise control over the activities of:

1. preservation of the health of the citizens and state health control;
2. implementation of emergency medical care, transfusion haematology, stationary psychiatric care, medical social care for children up to three years of age, transplantation and health information;
3. providing and sustainable development of the health activities in the medical and health establishments;
4. medical expertise.

(2) The Minister of health shall present to the National Assembly an annual report for the health state of the citizens and the fulfilment of the National Health Strategy within three months before the beginning of the budget year.

(3) (amend. â€“ SG 15/13, in force from 01.01.2014) The Minister of health shall approve the allocation of the subsidies of the state budget for the activities - subject of this Act, according to programmes, with exception of the activities under para 1, item 1 and 2.

(4) (amend., SG 88/05; amend. - SG 93/09, in force from 25.12.2009) The Minister of Health shall exercise methodological management and control of the medical activity of 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.

(5) The Minister of Health shall also exercise other legal capacities assigned to him by an Act or by a statutory instrument of the Council of Ministers.

Art. 6. (1) Established at the Minister of health shall be Supreme Medical Council.

(2) (suppl. SG 46/05, amend. SG 76/05; suppl. - SG 75/06, suppl. - SG 91/18) The Supreme Medical Council shall include five representatives appointed by the Minister of Health, five representatives of the Bulgarian Physicians Union, three representatives of the Union of the Dental doctors in Bulgaria, three representatives of the Bulgaria Pharmaceutical Association, three representatives of the National Health Insurance Fund (NHIF), one representative of the Bulgarian association of the professionals in health care, one representative of the Bulgarian Association of Dental Technicians and one representative each of the National Association of the Municipalities, of every higher medical school and of the Bulgarian Red Cross. The Minister of Health shall be chairman of the Council without a voting right.

(3) The Supreme Medical Council is a consultative body discussing and providing comments on:

1. the priorities of the National Health Strategy;
2. ethical problems of the medicine and biomedicine;
3. draft laws and draft normative acts of the Council of Ministers in the sphere of health care and of the competence of the Minister of Health;
4. the report of the Minister of Health under Art. 5, para 2;
5. the annual draft budget of the health care;
6. the scientific priorities in the sphere of medicine and stomatology;

7. the annual admission of students and specialists of professional sphere "health care" and the criteria for determining the educational centres for students and post-graduate studies under art. 91 and 92 of the Medical Establishments Act;

8. the kinds of specialties of professional sphere "health care".

(4) The organisation and the activity of the Supreme Medical Council shall be settled by regulations worked out by the Supreme Medical Council and approved by the Minister of Health.

Art. 6a. (new â€“ SG 41/09, in force from 02.06.2009) (1) (amend. - SG 102/18, in force from 01.01.2019) The Minister of Health by an order shall nominate:

1. expert councils on medical specialties or individual medical activities;

2. republic consultants on medical specialties.

(2) (amend. - SG 102/18, in force from 01.01.2019) The expert councils under par. 1, item 1 consist of medical specialists in the relevant fields of medicine and / or in the health care system and shall provide consultations and issue opinions on assigned by the Minister of Health matters.

(3) (amend. â€“ SG 98/10, in force from 14.12.2010) Republic consultants shall consult medical establishments for hospital care, the mental healthcare centres, the complex oncology centres and the centres for skin and venereal diseases for the provision of medical care.

(4) Financing of activities referred to in par. 2 shall be provided within the budget of the Ministry of Health for the respective calendar year, and of the activities referred to in par. 3 â€“ by the respective medical establishments.

(5) (amend. - SG 102/18, in force from 01.01.2019) The terms and conditions and the procedure of financing, organization and activity of the expert councils and the republic consultants shall be determined by an ordinance of the Minister of Health.

Art. 7. (1) (amend. â€“ SG 98/10, in force from 01.01.2011) The state health policy on the territory of the region shall be implemented and organised by a regional health inspection.

(2) (amend. â€“ SG 98/10, in force from 01.01.2011) For organising the health care in the municipalities the respective municipal council may establish a health care office within the municipal administration. The activity of the office shall be carried out under the methodological management of the regional health inspection.

Art. 8. (1) (amend. â€“ SG 98/10, in force from 01.01.2011; amend. â€“ SG 15/13, in force from 01.01.2014) The regional health inspections are corporate bodies at budget support with the Minister of Health, with a seat in the settlement - administrative centre of the region.

(2) (amend. â€“ SG 98/10, in force from 01.01.2011) The regional health inspections shall be established, transformed and closed down by the Council of Ministers.

Art. 9. (amend. â€“ SG 98/10, in force from 01.01.2011) (1) The regional health inspections shall be managed and represented by a director assisted by a deputy director.

(2) The director of a regional health inspection shall occupy the position following a competition organised by the Minister of Health as set out in the Labour Code.

(3) Director of a regional health inspection can be only a person with master of medicine educational and qualification degree, acknowledged medical specialisation, health management qualification and three years of service after completing the specialisation.

(4) The director of the regional health inspection shall be given testimonial every three years by a commission appointed by the Minister of Health. The order of carrying out the testimonial shall be determined by the regulation under Art. 10, para 3.

(5) The Minister of health may terminate the legal terms of employment of a director of a regional health inspection, having been given a negative testimonial, by notification under Art. 328, para 1, item 5 of the Labour Code.

(6) The deputy director of the regional health inspection shall be appointed following a competition organised by the director of the regional health inspection as set out in the Labour Code.

(7) Deputy director of a regional health inspection can be only a person with master of medicine educational and qualification degree, acknowledged medical specialisation, health management qualification.

Art. 10. (amend. â€“ SG 98/10, in force from 01.01.2011) (1) On the territory of the region the regional health inspections shall carry out activities of:

1. state health control;
2. control over the registration and the health activity carried out by the medical and health establishments;
3. checking the compliance with the requirements of Art. 40, Para 4 and Art. 47, Para 4 of the Medical Establishments Act;
4. planning, organising, management and control of the medical expertise;
5. health promotion and integrated prophylactics of the hospitals;
6. gathering, registration, processing, storing, analysis and submitting of health information for the needs of the national system of health care;
7. monitoring of the living environment factors and of the activities of importance for the health of the population;
8. analysis, assessment and prognosis for the health and demographic processes on regional level;
9. laboratory analysis and trials;
10. development and implementation of regional health programmes and projects;
11. coordination and implementation of national and international health programmes and projects;
12. methodological, consultation and expert aid;
13. postgraduate practical training in the field of public health protection;
14. checks following notifications by citizens related to the public health protection;
15. planning and organisation of the health care activities during calamities, accidents and catastrophes and drafting military plans for the territory of the region.

(2) The regional health inspections, jointly with the professional organisations, shall study the needs of medical and non-medical specialists with higher education, and propose to the Minister of Health the number of places for post-graduate studies on specialities.

(3) The names and number of directorates in the general and specialised administration of each regional health inspection, their functions and the number of personnel shall be determined in regulations issued by the Minister of Health.

(4) In the regulations referred to in Para 3 the Minister of Health may assign to certain regional health inspections activities to be carried out on the territory of several regions or on the territory of the entire country.

Art. 10a. (new â€“ SG 41/09, in force from 02.06.2009; amend. â€“ SG 98/10, in force from 01.01.2011) (1) Income of the regional health inspections shall be accrued from:

1. (amend. â€“ SG 15/12, in force from 01.01.2014) subsidy from the state budget;

2. own activity.

(2) Regional health inspections shall be administrators of income under par. 1, item 2, which shall be accrued from:

1. state fees;

2. fines and property sanctions, imposed by enforced penal decreed, issued by the directors of the regional health inspections, deposited to their account;

3. other sources.

(3) The funds under par. 1, item 2 shall be spent for:

1. carrying out of control activities;

2. prophylactics of the non-infectious diseases, prophylactics and monitoring of infectious diseases;

3. generation, maintenance and keeping of registers under this Act and under other laws, assigned to the regional health inspections;

4. laboratory analysis;

5. participation in national and international inter-laboratory trials;

6. accreditation and maintenance of the accreditation of the laboratories and the regional health inspections;

7. dissemination of information and research materials;

8. (revoked â€“ SG 38/12, in force from 01.07.2012)

9. (revoked â€“ SG 38/12, in force from 01.07.2012)

### **Section III. State Health Control**

Art. 11. (amend. â€“ SG 98/10, in force from 01.01.2011) Carried out, for the purpose of preservation of the health of the citizens on the territory of the Republic of Bulgaria, shall be state health control by performance of the activities referred to in Art. 15.

Art. 12. (1) (amend. â€“ SG 98/10, in force from 01.01.2011) Bodies of the state health control are the chief health inspector of the Republic of Bulgaria, the regional health inspections and the National Centre for radiobiology and radiation protection (NCRRP).

(2) (amend. - SG 59/06, in force from 01.01.2007; amend. â€“ SG 98/10, in force from 01.01.2011) The state health control shall be carried out by state health inspectors of the Ministry of Health, the regional health inspections and NCRRP. The state health inspectors of the Ministry of Health and the regional health inspections shall be civil servants.

(3) The state health inspectors may not carry out, in any form whatsoever, activity which is subject to state health control.

Art. 13. (1) The chief state health inspector shall be appointed by the Prime Minister at a proposal of the Minister of health.

(2) The legal capacities of the chief state health inspector in his absence from the country or when he is using his lawfully established leave, in each case, shall be carried out by a deputy who is an employee of the administration of the Ministry of Health, determined by the Minister of Health by a written order.

(3) The activity of the chief state health inspector shall be assisted by the administration of the Ministry of Health.

Art. 14. (1) The chief state health inspector shall organise and manage:

1. (suppl. â€“ SG 98/10, in force from 01.01.2011) the state health control under Art. 15;

2. the activities of health promotion and integrated prophylactics of diseases;

3. (revoked â€“ SG 98/10, in force from 01.01.2011)

4. (revoked â€“ SG 98/10, in force from 01.01.2011)

5. the prophylactic and anti-epidemic activities in time of calamities, accidents and catastrophes.

(2) (suppl. â€“ SG 98/10, in force from 01.01.2011) The chief state health inspector shall carry out methodological management and control of the units for departmental health control at the Ministry of Justice, the Ministry of Transport, Information Technologies and Communications, the Ministry of Defence and the Ministry of Interior.

Art. 15. (amend. â€“ SG 98/10, in force from 01.01.2011) (1) The regional health inspections shall carry out activities of:

1. control of the observance and performance of the medical requirements for the sites of public designation under § 1, Item 9 of the Additional Provision established in a normative act;

2. control of the observance and performance of the medical requirements for the products and the goods of importance for the human health under § 1, Item 10 of the Additional Provision established in a normative act;

3. control of the observance and performance of the medical requirements for the activities of importance for the human health under § 1, Item 11 of the Additional Provision established in a normative act;

4. control of the observance and performance of the medical requirements for the factors of the living environment under § 1, Item 12 of the Additional Provision established in a normative act;

5. monitoring of the infectious diseases;

6. control of the observance of the prohibitions and restrictions for advertisement and sale of spirits established in a normative act;

7. control of the observance of the prohibitions and restrictions for smoking established in a normative act;

(2) State health control for observance of the requirements for protection of people against the effect of ionising radiation shall be carried out by regional health inspections determined by the Minister of Health, as well as by NCRRP.

Art. 16. (revoked â€“ SG 98/10, in force from 01.01.2011)

Art. 17. (revoked â€“ SG 98/10, in force from 01.01.2011)

Art. 18. (amend â€“ SG 41/09, in force from 01.01.2009; revoked â€“ SG 98/10, in force from 01.01.2011)

Art. 18a. (new â€“ SG 41/09, in force from 01.01.2009; revoked â€“ SG 98/10, in force from 01.01.2011)

Art. 19. (1) The state health control shall be carried out systematically - without advance notice, and directed - upon received signal from citizens, state and municipal bodies and organisations, as well as in the presence of other data for occurred incidents.

(2) In carrying out the state health control the state health inspectors shall have the right:

1. to free access to the sites, products, goods, activities and persons subject to control;

2. to require information and documents and receive copies of them on paper and/or electronic carrier;

3. to take samples and patterns for laboratory analyses in quantities necessary for carrying out tests;

4. to order examinations and tests for assessment of the health status of the persons under Art. 34, para 3;

5. to prescribe removal from work of persons who a sick or infection carriers and pose danger for the health of the others;

6. to prescribe obligatory hygiene and anti-epidemic measures setting deadlines for their fulfilment;

7. (new â€“ SG 98/10, in force from 01.01.2011) to suspend the operation of sites with public designation, of parts thereof or of the particular activity in the cases of Art. 38, Para 3 by immediately notifying the director of the regional health inspection;

8. (new â€“ SG 98/10, in force from 01.01.2011) to stop placement on the market of products and goods of human health importance in the cases of Art. 39, Para 1, Item 1;

9. (prev. text of Item 07 â€“ SG 98/10, in force from 01.01.2011) to place certifying signs in the cases of Art. 38 and 39;

10. (prev. text of Item 08 â€“ SG 98/10, in force from 01.01.2011) to draw up acts for establishing administrative offences;

11. (new â€“ SG 41/09, in force from 02.06.2009; prev. text of Item 09 â€“ SG 98/10, in force from 01.01.2011) to propose to the authorities of the Directorate of National Construction Supervision in case of commissioning of constructions in the Republic of Bulgaria a decision for rejection of acceptance of projects of public purpose of use, when they identify essential violations of the standards and requirements, determined by a statutory act;

12. (new â€“ SG 41/09, in force from 02.06.2009; prev. text of Item 10 â€“ SG 98/10, in force from 01.01.2011) to issue hygiene conclusions on conformity of projects of public purpose of use, of products and activities being of importance for humansâ€™ health and of the maximum allowable levels of the factors of living environment with the health requirements;

13. (prev. item 9 â€“ SG 41/09, in force from 02.06.2009; prev. text of Item 11 â€“ SG 98/10, in force from 01.01.2011) to make proposals for compulsory administrative measures stipulated by a law.

(3) (amend. â€“ SG 98/10, in force from 01.01.2011) The compulsory administrative measures shall be imposed by an order of the directors of the regional health inspections.

(4) The terms and the order of exercising state health control shall be determined by an ordinance of the Minister of Health.

Art. 19a. (new â€“ SG 41/09, in force from 02.06.2009) (1) The analysis of samples of products and goods of importance for humansâ€™ health and of the factors of the living environment, taken for the purposes of the state health control, shall be carried out in laboratories, nominated by an order of the Minister of Health;

(2) The laboratories under par. 1 must be accredited in compliance with the requirements of BDS EN ISO/IEC 17025 and/or of BDS EN ISO/IEC 17020, whereas the scope of accreditation of the testing laboratories under BDS EN ISO/IEC 17025 shall refer to specific tests of groups of tests.

(3) The Minister of Health may nominate by an order analysis laboratories, which are not accredited pursuant to the provisions of par. 2 for a particular period where the following conditions are available:

1. the laboratories have initiated and are carrying out relevant accreditation procedures;

2. there are evidences, that for carrying out analyses for the purposes of the state control, laboratories are applying a system and procedures of control and testing, guaranteeing laboratory operations quality.

Art. 20. (amend. â€“ SG 41/09, in force from 01.01.2009; amend. â€“ SG 98/10, in force from 01.01.2011) Voluntary payment of fines and property sanctions, imposed by enforced penal decrees, issued by the authorities of the state health control, may be made in the Ministry of Health or in the respective regional health inspections.

#### **Section IV. Health Establishments**

Art. 21. (1) The health establishments are structures of the national system of health care in which medical and non-medical specialists carry out activities related to preservation and building-up of the health of citizens.

(2) Health establishments in the meaning of this Act are:

1. the national centres for the problems of the public health;
2. the National Expert Physicians Commission (NEPC);
3. the health consulting rooms under Art. 26.
4. (new â€“ SG 81/06) the optics referred to in Art. 26a.

(3) (amend. â€“ SG 31/07, in force from 13.04.2007) The pharmacies are health establishments with a status and activity determined by the Medicinal Products In The Human Medicine Act.

Art. 22. (1) (amend. â€“ SG 15/12, in force from 01.01.2014) The national centres for the problems of the public health are corporate bodies at budget support with the Minister of Health, which shall be opened, transformed and closed down by a decree of the Council of Ministers at a proposal of the Minister of Health.

(2) The national centres for the problems of the public health shall be managed by directors occupying their position on the grounds of a competition announced by the Minister of Health.

(3) The directors of the national centres for the problems of the public health shall be given testimonial every three years by a commission appointed by the Minister of Health. The order of carrying out the testimonial shall be determined by the regulations for the structure and activity of the respective national centre for the problems of the public health.

(4) The Minister of Health may terminate the legal terms of employment of a director of a national centre for the problems of the public health, having received negative testimonial, by a notification under art. 328, para 1, item 5 of the Labour Code.

Art. 23. (1) The national centres for the problems of the public health shall implement activities of:

1. studies, assessment, expertise, analyses and prognoses in the sphere of preservation of the public health;
2. prevention, restriction and liquidation of epidemics of infectious diseases;
3. organising, management and coordination of the medical care in times of calamities, accidents and catastrophes on the territory of the Republic of Bulgaria;

4. assessment of the risk and of the unfavourable impact of the factors of the living environment on the individual, family and public health;
5. laboratory tests and expertise;
6. (suppl. â€“ SG 98/10, in force from 01.01.2011) protection of the persons against the impact of the ionising and non-ionising radiation;
7. health promotion and integrated prophylactics of the diseases;
8. (amend. â€“ SG 98/10, in force from 01.01.2011) expert and consultative assistance to the regional health inspections;
10. planning and implementation of scientific and scientific applied activity;
11. state health control in the cases stipulated y a law;
12. studies;
13. (new â€“ SG 98/10, in force from 01.01.2011) collection, summary and analysis of the information from the activities of the regional health inspections.

(2) The structure and the activity of the individual national centres for the problems of the public health shall be settled by regulations of the Minister of Health.

Art. 24. (1) The income of the national centres for the problems of the public health shall be formed by:

1. (amend. â€“ SG 15/12, in force from 01.01.2014) subsidies from the state budget;
2. donations and legacies;
3. other budget receipts from:
  - a) (amend. â€“ SG 98/10, in force from 01.01.2011) state fees;
  - b) scientific research and expert activity;
  - c) fees for post-graduate studies.
- (2) (revoked â€“ SG 38/12, in force from 01.07.2012)

Art. 25. (1) (amend. â€“ SG 15/12, in force from 01.01.2014) The National Expert Physicians Commission is a corporate body at budget support with the Minister of health, with a seat in Sofia.

(2) The National Expert Physicians Commission shall be managed and represented by a director occupying the position o the grounds of a competition announced by the Minister of health.

(3) (new â€“ SG 41/09, in force from 02.06.2009) The Director of NEPC shall be appraised every three years by a commission, appointed by the Minister of health. The procedure of carrying out of the appraisal shall be determined by the regulation under Art. 109.

(4) (new â€“ SG 41/09, in force from 02.06.2009) Where negative appraisal has been issued, the Minister of Health may terminate the legal employment relationship of the Director of the NEPC by a notification under Art. 328, par. 1, item 5 of the Labour Code.

(5) (prev. par. 3 â€“ SG 41/09, in force from 02.06.2009) The National Expert Physicians Commission shall carry out expert, control methodological and consultative activities on the expertise of the working capacity.

Art. 26. (1) (amend. â€“ SG 41/09, in force from 02.06.2009) Health consultancy rooms shall be opened in:

1. the kindergartens and schools;

2. (revoked â€“ SG 95/07);

3. (amend. â€“ SG 95/07; amend. â€“ SG 41/09, in force from 02.06.2009, amend. - SG 24/19, in force from 01.07.2020, amend. on entry into force - SG 101/19) the social and integrated health and social services for residential care for more than 20 users and in social services for provision of shelter.

(2) (amend. - SG 76/05, in force from 01.01.2007; amend. - SG 103/05; suppl. â€“ SG 95/07; amend. â€“ SG 41/09, in force from 02.06.2009, amend. - SG 74/09, in force from 15.09.2009; amend. â€“ SG 50/10; amend. â€“ SG 68/13, in force from 02.08;2013) The requirements for the structure and activity of the health consultancy rooms, the procedure of their establishment, and also the documentation they keep, shall be determined by an ordinance issued by the Minister of health, coordinated with the Minister of Education and Science, the Minister of Finance, the Minister of Labour and Social Policy and the Minister of Youth and Sports.

(3) (amend. â€“ SG 95/07, in force from 01.01.2008; amend. â€“ SG 41/09, in force from 02.06.2009) By the Act on the state budget of the Republic of Bulgaria the financing by the state and by the municipalities shall be determined on an annual basis for health activities for children and school students and for equipment, consumables and for fulfillment of the activities in the respective year in the health consultancy rooms, established pursuant to the provisions of this Act.

(4) (new â€“ SG 95/07, in force from 01.01.2008; amend. â€“ SG 41/09, in force from 02.06.2009) By the ordinance of par. 2 the minimum number of children or school students shall also be determined, required for establishment of a health consultancy rooms of par. 1, as well as the requirements to equipment and consumables in them shall be set.

Art. 26a. (new â€“ SG 81/06) (1) The optics shall carry out the activities of:

1. (suppl. â€“ SG 98/10, in force from 14.12.2010) health consultation of the problems of the sight, carried out by a physician with acknowledged specialisation in eye diseases or by a physician with acknowledged professional qualification determined in the corresponding medical standard approved under Art. 6, Para 1 of the Medical Establishments Act;

2. undertaking measures of correction of the sight prescribed by a physician;

3. making and sale of eyeglasses and materials of eye optics.

(2) The optics shall be managed by persons with higher education in "master" educational qualification degree in professional direction "Medicine" with recognized speciality in eye diseases or by persons with professional qualification in the professions "eye optics technician" or "optician" â€“ optometrist" having at least one year service in the speciality.

(3) Making and sale of eyeglasses and materials for eye optics shall be carried out by persons with professional qualification in the professions "eye optics technician" or "optician-optometrist".

(4) (new â€“ SG 98/10, in force from 14.12.2010) The health consultations under Para 1, Item 1 may be carried out only in an optics establishment that has signed a contract with a physician with acknowledged specialisation in eye diseases.

Art. 26b. (new â€“ SG 81/06; amend. â€“ SG 98/10, in force from 01.01.2011)  
(1) The opening optics establishments under Art. 26a, Para 1 shall be carried out as set out in Art. 36.

(2) The requirements to the structure and activities of the optics establishments shall be determined in an ordinance, issued by the Minister of Health.

## **Section V. Health Information and Documentation**

Art. 27. (1) Health information are the personal data related to the health status, the physical and psychological development of the persons, as well as any other information contained in the medical prescriptions, recipes, records, certificates and other medical documentation.

(2) (amend. SG 76/05; amend. â€“ SG 98/10, in force from 01.01.2011) The medical and health establishments, the regional health inspections, the physicians, dental doctors, pharmacists and other medical specialists, as well as the non-medical specialists with higher non-medical education, working in the national system of health care, shall gather, process, use and store health information.

(3) The forms and the content, as well as the terms and the order of processing, using and storing of the medical documentation and for exchange of medical statistical information shall be determined by ordinances of the Minister of Health, coordinated with the National Institute of Statistics.

Art. 28. (1) Health information may be submitted to third persons where:

1. the therapy of the person continues in another medical establishment;
2. there is a danger for the health or life of other persons;
3. it is necessary for identification of a human corpse or establishing the reasons for the death;
4. it is necessary for the needs of the state health control for prevention of epidemics and spread of infectious diseases;
5. it is necessary for the needs of the medical expertise and public insurance;
6. it is necessary for the needs of the medical statistics or medical scientific research, after obliteration of the data identifying the patient;

7. (amend. â€“ SG 98/10, in force from 01.01.2011) it is necessary for the needs of the Ministry of health, the National Centre for Health Information, NHIF, the regional health inspections and the National Institute of Statistics;

8. (new â€“ SG 60/12, in force from 07.08.2012; suppl. - SG 102/15, in force from 01.01.2016) it is necessary for the needs of an insurer licensed under Section I of the Annex No 1 or the item 2 or item 1 and 2 of Section II, letter "A" of Annex no 1 of the Insurance Code.

(2) The submission of information in the cases of para 1 and 2 shall be made upon notification of the respective person.

(3) The persons under Art. 27, para 2 shall be obliged to provide protection of the health information kept by them against unauthorised access.

Art. 28a. (new " SG 41/09, in force from 02.06.2009; amend. " SG 98/10, in force from 14.12.2010; amend. " SG 15/13, in force from 01.01.2014) The Minister of Health, the administrators of budgets thereto and the medical establishments keeping a register of national significance pursuant to a normative act for and with regard to implementation of their functions, shall have the right to free access to information registers, created and maintained with budgetary funds.

Art. 28b. (new " SG 41/09, in force from 02.06.2009) The patient shall have the right to get from the medical establishment the health information, related to his/her health situation, including copies of the medical certificates.

(2) The patient shall have the right to authorize in writing another person to review his/her medical certificates, and also to make a copy thereof.

(3) In case of a patient passes away his/her heirs and relatives both direct and by-law up to the fourth degree inclusive shall have the right to review the medical file of the decedent and also to make copies of his/her medical certificates.

Art. 28c. (new " SG 41/09, in force from 02.06.2009) Medical specialists and employees in medical establishments shall not have the right to disclose information about the patient, having been obtained in the course of fulfillment of their official duties.

## **Section VI.**

### **National Health Information System (new - SG 102/18, in force from 01.01.2019)**

Art. 28d. (new - SG 102/18, in force from 01.01.2019) (1) A National Health Information System is established, which is administered and maintained by the Ministry of Health.

The establishment and maintenance of the National Health Information System is based on the following principles:

1. ensuring timeliness and accuracy of the data provided and stored;
2. providing a suitable data exchange environment;
3. ensuring regulated access to data in the electronic information system in compliance with the requirements of the law;
4. ensuring interoperability and information security.

(3) The National Health Information System gathers, processes and stores information on the health status of the population by creating and maintaining an electronic health record for every citizen.

(4) (Suppl. - SG 21/21, in force from 12.03.2021) The information system under para. 1 includes the electronic health records of citizens and all registers,

information databases and systems, for which it is stipulated in the ordinance under para. 6 or in another normative act that they are kept by the Ministry of Health and its secondary administrators with budget by medical and healthcare establishments, the National Health Insurance Fund and the insurance companies, licensed under item 2 or under items 1 and 2 of Section II, letter "A" of Annex 1 to the Insurance Code.

(5) For the needs of the information system under para. 1 data from the Population Register shall be provided free of charge from the Population Register - National Population Database, maintained by the Ministry of Regional Development and Public Works through the General Directorate "Civil Registration and Administrative Services", on the civil registration of the persons under the procedure of the Civil Registration Act.

(6) To create and maintain electronic health records of citizens the medical and healthcare establishments submit information to the Ministry of Health as the type of information, the manner of its provision and the conditions and procedure for its provision shall be determined by an ordinance of the Minister of Health.

(7) With the ordinance under para. 6 shall be determined the terms and procedure for keeping the registers, the information databases and the systems included in the National Health Information System.

Art. 28e. (new - SG 102/18, in force from 01.01.2019) (1) Right to free access to the National Health Information System shall have:

1. the citizen - to the information in his / her electronic health record;
2. medical and health establishments and the National Health Insurance Fund during and in connection with the fulfillment of its functions;
3. insurance companies licensed under item 2 or under items 1 and 2 of Section II, letter "A" of Annex 1 to the Insurance Code;
4. state bodies for which access to registers of national importance is provided by law.

(2) Providing access to the information in the electronic health record of the citizens and the persons under para. 1, items 2, 3 and 4 shall be allowed only after explicit written consent under conditions and by an order determined by the ordinance under Art. 28d, para. 6.

## **Chapter two. ACTIVITIES ON HEALTH PRESERVATION**

### **Section I. General Provisions**

Art. 29. (1) (Previous text of Art. 29, suppl. " SG 58/19)The state bodies and institutions shall plan, develop and conduct policy, directed to preservation of the health of citizens by ensuring healthy living environment, education in healthy way of life and health prophylactics.

(2) (New " SG 58/19) The activities of the municipalities in carrying out policies in the field of health prophylaxis among the population and the doctors in connection with the provided medical assistance may be assisted by health mediators.

(3) (New â€“ SG 58/19) The Minister of Health shall prescribe by ordinance the requirements for the activities of the health mediators.

(4) (New â€“ SG 58/19) The activity under Para. 2 may also be assisted by non-profit legal entities with proven experience in the relevant field under conditions, according to the order and criteria determined by the ordinance under ParĐ°. 3.

Art. 30. (1) The medical establishments shall systematically implement prophylactic examinations and dispensary treatment for preservation of the health and the ability to work of the citizens.

(2) The persons with increased health risk or with diseases shall be subject to dispensary treatment.

(3) The conditions, the order and the financing for implementing the prophylactic examinations and the dispensary treatment as well as the list of the diseases upon which dispensary treatment is implemented, shall be determined with an ordinance by the Minister of Health.

## **Section II. Ensuring of healthy living environment**

Art. 31. (1) The state, the municipalities, the corporate bodies and the individuals shall implement their activity ensuring the preservation of the living environment from the biological, chemical, physical and social factors, impacting harmfully on human health.

(2) The corporate bodies and the individuals shall be obliged to observe the established health requirements at implementing their activity.

Art. 32. (1) (amend. â€“ SG 08/11, in force from 25.01.2011) The Minister of Health shall manage the national system for analysis, assessment and control of the noise in the urbanised territories and the public buildings, the pollutants in the potable waters.

(2) The Minister of Health shall analyse and assess the factors of the living environment at national level in the annual report of art. 5, para 2 and propose measures for restricting of their harmful impact on the health of the citizens.

(3) (new â€“ SG 98/10, in force from 01.01.2011) The Minister of Health shall manage the national system for analysis, assessment and control of the non-ionising radiation in urbanized territories and public buildings.

(4) (prev. text of Para 03, amend. â€“ SG 98/10, in force from 01.01.2011) The regional health inspections shall monitor, analyse and assess the factors of the living environment on the territory of the region and propose measures for restricting of their harmful impact on the health of the citizens.

(5) (prev. text of Para 04 â€“ SG 98/10, in force from 01.01.2011) The state bodies, implementing analysis, assessment and control of the parameters of the environment, shall concede to the Minister of Health the data, necessary for implementing assessment of the health risk.

Art. 33. (amend. " SG 41/09, in force from 02.06.2009 ) (1) The Minister of Health shall organize holding or epidemiological studies for determination of relationships between the environmental pollution and health status of the population.

(2) The Council of Ministers and/or the municipalities shall approve and finance programmes for conducting of activities, connected with protection, strengthening and restoration of the health of the citizens in settlements, where a relationship between the environmental pollution and health status of the population has been identified.

Art. 34. (1) (revoked " SG 41/09, in force from 02.06.2009)

(2) The health requirements for the sites with public designation, the products and the goods of importance for human health and the activities of importance for human health as well as the maximum admissible levels of factors of the living environment shall be determined with ordinances by the Minister of Health as far as with another law other is not provided.

(3) (amend. - SG 24/19, in force from 01.07.2020, amend. on entry into force - SG 101/19) The health requirements to the persons, working in the children's establishments, the social and integrated health and social services for residential care, the water supply sites, the enterprises, producing or trading with foods, the barber's, the hairdresser's and the cosmetic parlours shall be determined with an ordinance by the Minister of Health.

Art. 35. (amend. " SG 82/12, in force from 26.11.2012) The bodies of the state health control shall participate in the expert councils for spatial planning, coordinate if necessary the development plans, participate in the assessment of the compliance of the investment designs when it is implemented with approval by expert council of the approving administration or upon request by individuals or corporate bodies, give statement on the readiness of the construction for entering into exploitation by the order of the Spatial Development Act.

Art. 36. (1) (amend. - SG 34/06, in force from 01.10.2006; amend. " SG 98/10, in force from 01.01.2011, regarding the second sentence " in force from 01.07.2011, amend. - SG 85/17) Anybody, who opens site with public designation, shall be obliged to notify about this the respective regional health inspection at the location not later than the day of starting the activity, pointing out the address of the site, the kinds of activity, implemented in it, as well as the name of and the permanent address of the person, who exercises the activity, and if he/she is a trader " indicate UIC. The notification may be carried out 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), referred to hereinafter "Regulation (EU) No 910/2014" and the Electronic Document and Electronic Trust Services Act and the Electronic Government Act.

(2) (amend. â€“ SG 98/10, in force from 01.01.2011) In one month term after the notification the territorial bodies of the state health control shall implement check for observing the health requirements in the site.

(3) (amend. â€“ SG 98/10, in force from 01.01.2011) The regional health inspections shall create and keep public register of the sites with public designation under conditions and by order, determined with an ordinance by the Minister of Health.

(4) (suppl. - SG 81/06; amend. â€“ SG 98/10, in force from 01.01.2011) Para 1 shall not be applied for medical establishments, enterprises for production and wholesale trade with medicines, pharmacies, drugstores, enterprises for production, preservation and trade with foods and for sites for public catering.

Art. 37. (1) (amend. â€“ SG 41/09, in force from 02.06.2009) Upon request by the interested persons the chief state health inspector shall issue health certificate for export of products and goods manufactured in the country of importance for human health, which certifies, that the products and goods have been launched on the market in conformity with the requirements of the national legislation and are freely distributed in the territory of the country.

(2) (new â€“ SG 1/14, in force from 03.01.2014) For the issuance of a health certificate for export of products and goods of importance for human health, the interested person shall submit an application to the Chief State Health Inspector, indicating:

1. the name, main office and registered address of the interested person;
2. the name of the state, for which the product or the good are being exported;
3. the justification of the necessity of issuance of health certificate;
4. for cosmetic products â€“ information about the reference number, under

which the product is notified in the Notified portal of cosmetic products of the European Commission according to Art. 13 of Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ, L 342/59 of 22 December 2009), herein after referred to as â€œRegulation (EC) No. 1223/2009â€“.

(3) (new â€“ SG 1/14, in force from 03.01.2014) To the application under par. 2 shall be attached:

1. information about the Unified Identification Code of sole traders and legal entities in the Trade Register, and for companies registered in a European Union Member State or in a state which is a party to the Agreement on the European Economic Area â€“ a document of valid registration under the national legislation issued by a competent body of the respective country.

2. list of products and goods intended for export, in Bulgarian language, with their correct designation, trade mark, type of packing and name and address of the manufacturer, and for cosmetic products â€“ also cosmetic product category and type;

3. assessment of cosmetic product safety, where the application is for issuance of a health certificate for export of cosmetic products;

4. a document of paid governmental fee.

(4) (new â€“ SG 1/14, in force from 03.01.2014) In case of identified incompleteness or irregularity of documents under par. 2 and 3, the applicant shall within 7 work days notify in writing thereof and the terms for the issuance of the health certificate shall stop elapsing.

(5) (new " SG 1/14, in force from 03.01.2014) The health certificate for export of products and goods of importance for human health shall be issued within 15 work days after the submission of the application under par. 2, respectively after the recovery of identified incompleteness or irregularity referred to in par. 4.

(6) (new " SG 1/14, in force from 03.01.2014, amend. - SG 85/17) The application under par. 2 may be submitted 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 and the Electronic Document and Electronic Trust Services Act and the Electronic Governance Act.

(7) (new " SG 1/14, in force from 03.01.2014) The refusal to issue a health certificate may be appealed according to the provisions of the Administrative Procedure Code.

(8) (prev. par. 2 " SG 1/14, in force from 03.01.2014) The Minister of Health shall determine with an ordinance the order for issuing of health certificate for export of products and the goods of importance for human health.

(9) (new " SG 41/09, in force from 02.06.2009; prev. par. 3 " SG 1/14, in force from 03.01.2014) The health certificate referred to in par. 1 shall be issued for a period of three years.

(10) (prev. par. 3, amend. " SG 41/09, in force from 02.06.2009; prev. par. 4 " SG 1/14, in force from 03.01.2014) The bodies of the state health control shall issue an opinion on safety and/or conformity with the statutory provisions concerning products and goods of importance for population health, in fulfillment of the provisions of Council Regulation (EEC) 339/93 of 8 February 1993 on checks for conformity with the rules on product safety in the case of products imported from third countries.

Art. 37a. (new " SG 1/14, in force from 03.01.2014) (1) A register of issued health certificates for export of products and goods of importance for human health shall be created and maintained. The register shall be public and shall contain:

1. reference number and date of the export certificate;
2. name of exporting company;
3. name of manufacturing company;
4. the state, to which the product is being exported;
5. list of products and goods included in the export certificate.

(2) In the register referred to in par. 1 a separate section shall be provided, where the persons having filed an application for granting of a health certificate for export shall be registered following the order of submission and the number and the type of the documents attached thereto shall be recorded. Progress of the file opened under the application shall be recorded in this Section.

(3) The Ordinance referred to in Art. 37, par. 8 shall determine the terms and conditions and the procedure of keeping of the register under par. 1.

Art. 38. (1) (amend. - SG 59/06, in force from 01.01.2007) Upon non observance of the health requirements for the sites of public designation, for the products, the goods and the activities of importance for human health and of the maximum

permissible levels of the factors of the living environment the state health inspectors shall give obligatory prescriptions and determine term for removal of the breaches.

(2) (amend. â€“ SG 98/10, in force from 01.01.2011) Upon not fulfilment of the obligatory prescriptions in the defined term the director of RIPCPH, respectively the director of the regional health inspection, shall issue order for stopping the exploitation of the site or parts of it or for stopping of the respective activity till removal of the breaches.

(3) (amend. â€“ SG 98/10, in force from 01.01.2011) In the cases when there is immediate danger to the life and the health of people, for dissemination of infectious diseases or for occurrence of poisoning, the state health inspectors shall stop immediately with a prescription the exploitation of the site or parts of it or the respective activity, determine measures for removal of the breaches and immediately notify the director of the regional health inspection.

(4) (amend. â€“ SG 41/09, in force from 02.06.2009; amend. â€“ SG 98/10, in force from 01.01.2011) The director of the regional health inspection, respectively the director of NCRRP, shall within 48 hours after the stopping of the site issue order, with which is confirmed or revoked the given prescription for stopping the exploitation of the site or the respective activity.

(5) At fulfilment of the obligatory prescriptions and the defined measures the body, issued the order, shall permit with an order the restoration of the activity or the exploitation of the site.

Art. 39. (1) At doubt of the safety of products and goods of importance for human health the state health inspector shall:

1. issue written prescription for stopping the realisation of goods of importance for human health, which shall be delivered against signature to the interested person or his representative;

2. (amend. â€“ SG 98/10, in force from 01.01.2011) take samples for laboratory analysis and expertise in the presence of the interested person or his representative and present them in the laboratory of the regional health inspection.

(2) The state health inspector shall notify the interested person about the results from the laboratory investigations and the expertise in three days term after receiving them.

(3) (amend. â€“ SG 98/10, in force from 01.01.2011) At contesting of the results from the laboratory analyses and the expertise second investigations shall be implemented upon written request by the interested person, made to the chief state health inspector through the director of the regional health inspection in three days term after the date of receiving the result from the initial investigation.

(4) (amend. â€“ SG 98/10, in force from 01.01.2011) In the cases of para 3 the second investigations shall be implemented by another regional health inspection, determined by the chief state health inspector.

(5) The results from the implemented investigations of para 4 shall not be subject to contestation.

Art. 40. In case the products and the goods are obviously unfit for use and the interested person has no written objections to this conclusion of the state health inspector, laboratory analyses and expertise shall not be implemented.

Art. 41. (1) In case the results from the laboratory investigations and the expertise confirm the compliance of the products and the goods with the health requirements, the state health inspector shall check them for occurred changes during the stopping and revoke the given prescription for stopping the realisation in three days term from the date of receiving the results.

(2) In case from the results from the laboratory investigations and the expertise it is established that the products and the goods do not comply with the health requirements, the state health inspector shall propose to be issued order for reprocessing, use for other purposes in reprocessed or not reprocessed form or destroying of the products and the goods of importance for human health.

Art. 42. (1) (amend. " SG 98/10, in force from 01.01.2011) Order for reprocessing, use for other purposes or destroying of products or goods of importance for human health shall be issued by the director of the regional health inspection or NCRRP - for products or goods with value up to 100 000 levs, and by the chief state health inspector - for products and goods with value over 100 000 levs.

(2) In 7 days term after the order of para 1 enters into force the products and the goods shall be delivered for reprocessing, use for other purposes or destroyed obligatory in the presence of state health inspector, about a which a record shall be compiled. The record shall be attached to the order of para 1.

Art. 43. (1) The conditions and the order for taking samples and conducting of laboratory investigations, analyses and expertises, necessary for the purposes of the state health control, shall be determined with an ordinance by the Minister of Health.

(2) (amend. " SG 98/10, in force from 01.01.2011) The laboratory investigations for the needs of the state health control shall be for the account of the regional health inspection.

(3) (new " SG 41/09, in force from 02.06.2009) In case of repeated laboratory tests in case of disputed results of laboratory tests and expert conclusion, the laboratory tests shall be at the expense of the person, disputing them, should the result of the first tests be confirmed.

Art. 44. The individuals and the corporate bodies shall be obliged to fulfil the obligatory prescriptions of the state health inspectors and the orders of the bodies for state health control.

Art. 45. (1) (amend. - SG 30/06, in force from 12.07.2006) The compulsory administrative measures, imposed by the order of this section, shall be appealed by the order of the Administrative Procedure Code. The compulsory administrative measures shall be subject to preliminary execution.

(2) The compulsory administrative measures, imposed by the order of this section, shall be appealed by administrative order as follows:

1. (amend. â€“ SG 98/10, in force from 01.01.2011) these, decreed by state health inspector - before the director of the regional health inspection and the director of NCRRP;

2. (amend. â€“ SG 98/10, in force from 01.01.2011) these, decreed by the director of the regional health inspection and NCRRP - before the chief state health inspector;

3. these, decreed by the chief state health inspector - before the Minister of Health.

Art. 46. (amend. â€“ SG 98/10, in force from 01.01.2011) For issuing of documents and rendering services under this Act by the bodies of state health control and the national centres on the public law issues state fees shall be paid, determined with tariff approved by the Council of Ministers.

Art. 47. The facts and the circumstances, which the officials, exercising state health control, learn at fulfilment of their obligations, shall be official secret except the cases when there is threat for the health and the life of the citizens.

Art. 48. (amend. â€“ SG 98/10, in force from 14.12.2010) The bodies of the Ministry of Interior, the other state and municipal bodies and the chiefs of the offices, organisations, natural and legal persons shall be obliged to render the necessary assistance and cooperation to the state health inspectors at exercising their authorities.

### **Section III. Health requirements to the cosmetic products**

Art. 49. (amend. â€“ SG 41/09, in force from 02.06.2009; amend. - SG 82/09, in force from 16.10.2009; amend. â€“ SG 1/14, in force from 03.01.2014) (1) Cosmetic products, available on the market, must be safe for the human health, when they are used under normal or reasonably foreseeable conditions, taking into account their presentation, labeling, application instructions and safe disposal after usage, and also any other instructions, issued by the manufacturer, the distributor or the importer.

(2) Cosmetic products launched on the market, are safe for human health, where:

1. the good manufacturing practice has been complied with according to Art. 8 of Regulation (EC) No. 1223/2009;

2. safety assessment has been carried out according to Art. 10 of Regulation (EC) No. 1223/2009;

3. the requirements to the file with the information about the cosmetic product has been complied with according to Art. 11 of Regulation (EC) No. 1223/2009; in cases where the file is being kept in the territory of the Republic of Bulgaria, the person in charge shall provide easy access thereto to the competent bodies in Bulgarian language; the file should be available in electronic or in a different format at the address of the person in charge, indicated on the label;

4. the provisions regarding sampling and analysis are complied with according to Art. 12 of Regulation (EC) No. 1223/2009;

5. the requirements regarding notification before launching of cosmetic products on the market are complied with according to Art. 13 and 16 of Regulation (EC) No. 1223/2009;

6. the restrictions regarding substances contained in the cosmetic products are complied with according to Art. 14, 15 and 17 of Regulation (EC) No. 1223/2009;

7. the requirements regarding testing on animals are complied with according to Art. 18 of Regulation (EC) No. 1223/2009;

8. labelling requirements have been complied with according to Art. 19, paragraphs 1, 2, 5 and 6 of Regulation (EC) No. 1223/2009; the information indicated in art. 19, paragraph 1, items "a", "b", "c" and "d" and paragraphs 2, 3 and 4 shall be displayed also in Bulgarian language;

9. the requirements regarding products claims are complied with according to Art. 20 of Regulation No. 1223/2009;

10. the requirements regarding access to information to the public are complied with according to Art. 21 of Regulation (EC) No. 1223/2009;

11. the requirements regarding reporting of serious adverse effects are complied with according to Art. 23 of Regulation (EC) No. 1223/2009;

12. the requirements regarding the information about substances contained in the cosmetic products are complied with according to Art. 24 of Regulation (EC) No. 1223/2009.

Art. 50. (amend. "SG 41/09, in force from 02.06.2009; amend. "SG 1/14, in force from 03.01.2014) (1) The Minister of Health and the state health monitoring authorities shall be the competent bodies within the meaning of Art. 34, paragraph 1 of Regulation (EC) No. 1223/2009.

(2) The toxicology clinic of the University General Hospital for Active Therapy "N. I. Pirogov" EAD is a toxicology center within the meaning of Art. 13, paragraph 6 of Regulation (EC) No. 1223/2009.

(3) The submitted to the European Commission information under Art. 13, paragraphs 1, 2 and 3 of Regulation (EC) No. 1223/2009 shall be used by the authority under par. 2 only for the purposes of implementation of therapeutic activity.

(4) The authority under par. 2 shall provide protection of confidentiality of the received information under par. 2.

Art. 51. (amend. - SG 1/14, in force from 03.01.2014) The Minister of Health from time to time shall review and assess the implementation of the activity carried out by the state health monitoring authorities regarding cosmetic products control.

(2) The reviews and the assessment referred to in par. 1 shall be carried out minimum once every 4 years and the results thereof shall be communicated to the other European Union Member States and to the European Commission and shall be publicized electronically and if appropriate through other means according to the provisions of Art. 22 of Regulation (EC) No. 1223/2009.

Art. 52. (amend. â€“ SG 1/14, in force from 03.01.2014) The Minister of Health shall determine by an Ordinance:

1. detailed rules for the provision of information referred to in Art. 19, paragraph 1 of Regulation (EC) No. 1223/2009 regarding cosmetic products which are not pre-packed or are being packed at the time of sale upon consumerâ€™s request, or are pre-packed for immediate sale;

2. the requirements to the efficiency of products intended for UV exposure protection and the claims placed thereof;

3. chemical methods for testing of cosmetic products composition.

## **Section IV.**

### **Activities for impact over factors risky for the health**

Art. 53. (1) (Amend. â€“ SG 58/19, amend. and suppl. - SG 62/22, in force from 05.08.2022) The Minister of Health and other competent state bodies shall together with the no government organisations create conditions for restricting the use of tobacco and related products, the abuse of alcohol, not admitting the use of narcotic substances as well as not allowing the use of nitrous oxide (paradise gas) by persons under 18 years of age by:

1. implementing promotional and prophylactic activities;

2. ensuring access to medical help and social protection of the affected persons.

(2) (Amend. â€“ SG 58/19, amend. and suppl. - SG 62/22, in force from 05.08.2022) The activities of para 1 shall be implemented through national programmes for restricting the use of tobacco and related products, the abuse of alcohol and not admitting the use of narcotic substances as well as not allowing the use of nitrous oxide (paradise gas) by persons under 18 years of age.

(3) (in force from 01.01.2006; amend. â€“ SG 15/12, in force from 01.01.2014, amend. â€“ SG 58/19, amend. and suppl. - SG 62/22, in force from 05.08.2022) One percent of the resources, received in the state budget from the excise duties on the tobacco products and the alcohol beverages, shall be used for financing of the national programmes for restricting the use of tobacco and related products, the abuse of alcohol, not admitting the use of narcotic substances as well as not allowing the use of nitrous oxide (paradise gas) by persons under 18 years of age.

(4) (Amend. â€“ SG 58/19, amend. and suppl. - SG 62/22, in force from 05.08.2022) The municipalities shall approve and implement regional programmes for restricting the use of tobacco and related products, the abuse of alcohol, not admitting the use of narcotic substances as well as not allowing the use of nitrous oxide (paradise gas) by persons under 18 years of age.

Art. 54. The sale of alcohol beverages shall be prohibited:

1. to persons below 18 years of age;

2. to persons in drunk state;

3. on the territory of the kindergartens, schools, hostels for students, medical establishments;

4. at sport events;

5. at public events, organised for children and students.

Art. 54a. (New - SG 62/22, in force from 05.08.2022) It is prohibited to sell nitrous oxide (paradise gas) and refills with it, including online:

1. to persons under 18 years of age;
2. on the territory of kindergartens, schools, dormitories for students, medical institutions;
3. of sports events organized for children and students;
4. at public events organized for children and students;
5. in closed public places, with the exception of sale for medical purposes and for the food industry.

Art. 55. (1) The direct advertising of spirit beverages shall be prohibited.

(2) The indirect advertisement of spirit beverages and the advertisement of wine and beer cannot:

1. be directed to persons below 18 years of age, as well as be transmitted in programmes or published in printed publications, designated for them;
2. use persons below 18 years of age as participants;
3. connect the use of alcohol beverages with sport or physical achievements or with driving of vehicles;
4. contain claims about usefulness for health, social or sexual well-being or present the abstention or the temperance in negative aspect.

(4) The indirect advertisement of spirit beverages cannot be transmitted in radio and television programmes before 22.00 hours.

Art. 56. (amend. â€“ SG 40/12, in force from 01.06.2012) (1) The smoking in indoor public places shall be prohibited.

(2) The smoking in premises with separate working places, where labour is rendered, and in the premises thereto with assistance and service purposes shall be also prohibited.

(3) As an exception, the smoking shall be allowed in separate independent premises located in the airport buildings.

(4) In the separate independent premises referred to in Para 3 shall not be allowed the presence of persons below 18 years of age.

(5) The separate independent premises referred to in Para 3 shall be separated by air-impenetrable walls, tightly closing doors, marked clearly and containing a ventilation installation.

(6) The Council of Ministers shall determine in an ordinance the requirements to be met by the separate independent premises referred to in Para 3.

Art. 56a. (1) (new â€“ SG 42/10, in force from 02.06.2010; amend. â€“ SG 40/12, in force from 01.06.2012, prev. text of Art. 56a - SG 62/22, in force from 05.08.2022) The smoking in the following open-air public places shall be prohibited:

1. adjacent terrains and sidewalks to baby care centres, kindergartens, schools, school campuses and places for providing social services for children;
2. sites for playing;

3. where child and school activities are organised;  
4. the sport sites, summer cinemas and theatres " during sport and culture activities.

(2) (New - SG 62/22, in force from 05.08.2022) It is prohibited to use nitrous oxide (paradise gas) in open public places according to para. 1, items 1 - 3.

(3) (New - SG 62/22, in force from 05.08.2022) The use of nitrous oxide (paradise gas) in closed public places is prohibited, with the exception of use for medical purposes and for the food industry.

Art. 56b. (new " SG 42/10, in force from 02.06.2010; revoked " SG 40/12, in force from 01.06.2012)

Art. 56c. (new " SG 42/10, in force from 02.06.2010; revoked " SG 40/12, in force from 01.06.2012)

### **Section V.**

#### **Supervision of the infectious diseases (Title amend. " SG 98/10, in force from 01.01.2011)**

Art. 57. (1) For protection of the country from dissemination of particularly dangerous infectious diseases if necessary border health control shall be implemented.

(2) The conditions and the order for conducting border health control shall be provided with an ordinance by the Council of Ministers.

Art. 58. (1) For protection of the citizens from infectious diseases obligatory immunisation shall be made.

(2) The Minister of Health shall determine with an ordinance the persons, who are subject to immunisations as well as the order, the way and the terms for implementing:

1. obligatory planned immunisations and re-immunisations, included in the immunisation calendar of the Republic of Bulgaria;

2. purposed immunisations and re-immunisations, which shall be implemented upon special indications;

3. recommended immunisations.

(3) With the ordinance of para 2 shall also be determined the specific requirements and the application of the separate serums, immune-globulins and other bio-products with prophylactic purpose.

Art. 59. (1) (prev. text of Art. 59 " SG 98/10, in force from 14.12.2010) Upon occurrence of extraordinary epidemic situation as well as upon registration of significant reduction of the immunisation coverage the Minister of Health can order:

1. obligatory immunisations and re-immunisations for defined groups of the population, which are not included in the immunisation calendar;

2. obligatory immunisations and re-immunisations with preparations, which are not included in the immunisation calendar;

3. immunisations and re-immunisations by order and way, different from these, pointed out in the immunisation calendar;

4. the organising of immunisation campaigns, the opening of temporary immunisation points, the formation of teams for immunisation at the place and other extraordinary measures.

(2) (new " SG 98/10, in force from 14.12.2010) The medical and health establishments irrespective of their ownership shall be obliged to implement the measures under Para 1 prescribed by the Minister of Health.

Art. 60. (1) The ill with infectious diseases, the persons, contacted with them and the infection carriers shall be subject to registration, obligatory announcement and account.

(2) The Minister of Health shall determine with an ordinance the diseases of para 1 and the order for registration, announcement and account.

(3) With the ordinance of para 2 the Minister of Health shall also determine the order and the way for supervision, early announcement and undertaking of measures in cases of bio-terrorism or occurrence of new, unknown infectious diseases.

(4) (amend. " SG 98/10, in force from 14.12.2010) The organisation of the prophylactics and the control of the infections related to the medical services shall be determined with an ordinance by the Minister of Health.

(5) (amend. - SG 59/06, in force from 01.01.2007) The Minister of Health shall determine with ordinances the order and the conditions for conducting diagnostics, prophylactics and control of separate infectious diseases.

(6) The conditions and the order for investigation, announcement and accounting of infection with the virus of the acquired immune deficiency syndrome shall be determined with an ordinance by the Minister of Health.

(7) (new " SG 98/10, in force from 14.12.2010) The order of notifying, researching and registering explosions of food diseases and the order of taking samples for the epidemiologic investigation shall be determined in an ordinance of the Minister of Health.

Art. 61. (Amend. " SG, 44/20, in force from 14.05.2020) (1) (Amend. - SG 105/20, in force from 11.12.2020) Persons suffering from and infected with anthrax, brucellosis, smallpox, viral haemorrhagic fevers, diphtheria, Ebola, yellow fever, typhoid fever, malaria, polio, severe acute respiratory syndrome, tuberculosis with bacillus secretion, cholera, plague and COVID-19 are subject to mandatory insulation.

(2) (Amend. - SG 105/20, in force from 11.12.2020) Contact persons of persons under Para 1 shall be subject to obligatory quarantine. In view to prevent the spread of infectious diseases under Para. 1, persons, who have entered the territory of the country from other countries may also be subject to obligatory quarantine.

(3) (Amend. - SG 105/20, in force from 11.12.2020) The Minister of Health, upon a proposal of the Chief State Health Inspector, may order mandatory isolation of sick persons and infectious disease carriers outside the ones indicated under para. 1, as well as

mandatory quarantine of the persons in contact with them, based on an assessment of the existing epidemic risk of the spread of the respective contagious disease.

(4) (Amend. - SG 105/20, in force from 11.12.2020) The obligatory isolation of a person under Para. 1 and 3 shall be carried out with a prescription of the director of the respective regional health inspection, upon proposal of the doctor, who has directed the person to hospitalization.

(5) (Revoked - SG 105/20, in force from 11.12.2020)

(6) (Amend. - SG 105/20, in force from 11.12.2020) The obligatory quarantine of a person under para. 2 or 3 shall be carried out with a prescription issued by the director or by a deputy director of the respective regional health inspection authorized by him.

(7) (Amend. - SG 105/20, in force from 11.12.2020) The Minister of Health, upon a proposal of the Chief State Health Inspector, shall determine by an order the term of the obligatory isolation under para. 1 or 3 and of the obligatory quarantine under par. 2 or 3 in accordance with the epidemic risk of the spread of the respective contagious disease under para. 1 or 3.

(8) (Amend. and suppl. - SG 105/20, in force from 11.12.2020) The contact persons under para. 2 or 3 may not refuse to perform an examination for the purpose of establishing the presence of a carrier of a contagious disease under para. 1 or 3 appointed by a prescription issued by the director or by a deputy director of the respective regional health inspectorate authorized by him.

(9) (Amend. - SG 105/20, in force from 11.12.2020) The Minister of Health shall approve a sample of the prescriptions under para. 4, 6 and 8.

(10) (New - SG 105/20, in force from 11.12.2020) About the issued prescription under para. 4, 6 or 8 the person under para. 1, 2 or 3 shall be notified by the order of Art. 18a, para. 1, 2, 3, para. 4, item 1 and para. 8 of the Administrative Procedure Code or in one of the following ways by:

1. verbal notification on a mobile or landline telephone number indicated by the person which is certified in writing by the signature of the official who performed it, and the written certification is attached to the file, which is certified in writing by the signature of the official who performed it, and the written certification is attached to the file;

2. sending an electronic or short text message to an e-mail address or mobile phone number specified by the person.

(11) (New - SG 105/20, in force from 11.12.2020) In the cases under para. 10, items 1 and 2 the person under para. 1, 2 or 3 is notified that he/she can receive the prescription in person after the expiration of the isolation period, respectively the quarantine. During the period of isolation, respectively of the quarantine, the prescription may be obtained only through a person authorized by a person under para. 1, 2 or 3.

(12) (New - SG 105/20, in force from 11.12.2020) The prescription under para. 10, item 1 shall be considered served from the date of the oral notification, and under para. 10, item 2 - when within 24 hours from the sending, the person confirms the receipt of the message by sending back an electronic or short text message to the e-mail address or mobile telephone number indicated by the respective regional health inspectorate.

(13) (New - SG 105/20, in force from 11.12.2020) When within the term under para. 12 the person does not send a confirmation for the receipt of the message under para. 10, item 2, the notification shall be made by the order of Art. 18a, para. 1, 2, 3, para. 4,

item 1 and para. 8 of the Administrative Procedure Code or by oral notification under para. 10, item 1.

(14) (Prev. para. 10, amend. - SG 105/20, in force from 11.12.2020) The prescriptions under para. 4, 6 and 8 are subject to preliminary execution.

(15) (Prev. para. 11, amend. - SG 105/20, in force from 11.12.2020) The orders under para. 3 and 7 and the prescriptions under para. 4, 6 and 8 are subject to appeal before the respective administrative court by the order of the Administrative Procedure Code.

(16) (Prev. para. 12, amend. - SG 105/20, in force from 11.12.2020) The orders under para. 3 and 7 are general administrative acts, which are issued by the order of Art. 73 of the Administrative Procedure Code, are published on the website of the Ministry of Health and are subject to preliminary execution.

(17) (New - SG 105/20, in force from 11.12.2020) The conditions and the order for carrying out the obligatory isolation of a person under para. 1 or 3, the obligatory quarantine of a person under para. 2 or 3 and of the assessment of the existing epidemic risk under para. 3 shall be determined by the ordinance under Art. 60, para. 5.

(18) (New - SG 105/20, in force from 11.12.2020, amend. - SG 32/22, in force from 26.04.2022) With the ordinance under para. 17 shall be defined also the criteria for determination of the contact persons under para. 2 and 3 in accordance with the specifics of spread of the respective contagious disease under Para. 1 or 3, including epidemic potential, infectivity and route of transmission of the pathogen, etc.

Art. 61a. (New - SG 105/20, in force from 11.12.2020) (1) In order to prevent the spread of infectious diseases under Art. 61, para. 1 or 3 the obligatory isolation of persons, diseased from or carriers of a contagious disease under Art. 61, para. 1 or 3, may be performed in a medical institution for hospital care.

(2) The obligatory isolation in a medical establishment for hospital care of a person under para. 1 shall be carried out with a prescription issued by the director or by a deputy director of the respective regional health inspection authorized by him at the proposal of the attending physician or the physician who directed the person under para. 1 for hospitalization on the basis of performed assessment of the existing epidemic risk from the spread of the respective contagious disease under Art. 61, para. 1 or 3.

(3) The Minister of Health shall approve a sample of the prescription under para. 2.

(4) About the issued prescription under para. 2 the person under para. 1 shall be notified by the order of Art. 61, para. 10.

(5) The prescription under para. 2 is subject to preliminary execution.

(6) The prescription under para. 2 shall be subject to appeal before the respective administrative court by the order of the Administrative Procedure Code.

(7) The conditions and the order for carrying out the obligatory isolation in a medical establishment for hospital care of a person under para. 1 and of the assessment of the existing epidemic risk under para. 2 shall be determined by the ordinance under Art. 61, para. 17.

Art. 62. (1) (amend. - SG 98/10, in force from 14.12.2010) The individuals and the corporate bodies, who implement activities for disinfection, disinsection and

deratisation, shall notify about this the Ministry of Health not later than the day of starting of the activity.

(2) (suppl. â€“ SG 99/13, amend. â€“ SG 58/17, in force from 18.07.2017) The conditions and the order for implementing the activities of para 1 shall be determined with an ordinance by the Minister of Health and the Minister of Agriculture, Foods and Forestry.

Art. 63. (Amend. â€“ SG, 44/20, in force from 14.05.2020) (1) In case of imminent danger to the life and health of the citizens from epidemic spread of a contagious disease under Art. 61, Para. 1, in view to protect and preserve the life and health of the citizens, an extraordinary epidemic situation shall be declared.

(2) Emergency epidemic situation under Para. 1 shall be declared for a certain period of time by a decision of the Council of Ministers, upon a proposal of the Minister of Health, on the basis of an assessment of the existing epidemic risk, performed by the Chief State Health Inspector.

(3) Immediate danger to the life and health of the citizens under Para. 1 is present, when while performing the assessment under Para. 2, it is established, that the contagious disease under Art. 61, Para. 1:

1. has been caused by a pathogen of high epidemic potential (infectious person, high mortality, multiple routes of transmission or healthy carrier) and / or the source, mechanism and route of transmission are unusual or unknown, or

2. poses a serious risk to public health, even when the number of human cases detected is low, or

3. may impede or delay public health control measures, including due to lack of treatment and / or vaccine and / or the presence of multiple outbreaks etc., or

4. has low immunization coverage of the population, or

5. is unusual for the region, season or population, or

6. is more severe, than expected, has a higher incidence and / or mortality, or has unusual symptoms, or

7. puts at risk vulnerable or at-risk groups of the population (children, the elderly, refugees, people with immune deficiencies and / or chronic diseases, etc.), or

8. there are registered cases among medical professionals.

(3a) (New - SG 32/22, in force from 26.04.2022) In case of declared emergency epidemic situation under Para. 1, as well as in the cases under Para. 10, the Minister of Health shall implement a National Plan for Preparedness and Action in the Event of an Epidemic or Pandemic adopted by the order of Art. 3, Para. 3, and if no such plan is adopted, the Council of Ministers upon proposal of the Minister of Health shall adopt a National Plan for Preparedness and Action in the Event of an Epidemic or Pandemic within one month from the declaration of the emergency epidemic situation under Para. 1.

(3b) (New - SG 32/22, in force from 26.04.2022) In the national plan under Para. 3a shall absolutely be defined the actions and types of measures in order to limit the spread of any contagious disease under Art. 61, Para. 1, including specific indicators, criteria and terms for introduction of temporary anti-epidemic measures under Para. 4 and 10, and for revocation of introduced temporary anti-epidemic measures under Para. 4 and

10 in accordance with the specifics of the spread of the respective contagious disease under Art. 61, Para. 1.

(4) (Suppl. - SG 32/22, in force from 26.04.2022) In case of declared emergency epidemic situation under Para. 1, the Minister of Health shall introduce - by an order - temporary anti-epidemic measures, upon proposal of the Chief State Health Inspector for the territory of the country or for a separate district in accordance with the measures defined in the national plan under Para. 3a.

(5) The measures under Para. 4 may also include a ban for entry on the territory of the country of citizens of other states, with the exception of the citizens with permanent, long-term or continuous residence on the territory of the Republic of Bulgaria, as well as the members of their families.

(6) The measures under Para. 4 may also include a temporary restriction of the movement on the territory of the country, as well as temporary suspension or restriction of the operation or the regime of operation of sites of public purpose and / or other sites, or services, provided to the citizens.

(7) Temporary anti-epidemic measures under Para. 4 may also be introduced by an order of the director of the respective regional health inspection, in coordination with the Chief State Health Inspector for the territory of a separate district, municipality or settlement.

(8) The medical and health establishments, regardless of their ownership, shall be obliged to implement the introduced measures under Para. 4 and 7.

(9) The state and municipal bodies shall create the necessary conditions for implementation of the measures under Para. 4 and 7, where the funds for their implementation shall be provided from the state budget, respectively from the municipal budgets.

(10) (New - SG 32/22, in force from 26.04.2022) In order to overcome the consequences after the cancelation of a declared emergency epidemic situation under Para. 1 and/or prevention of subsequent epidemic spread of a contagious disease under Art. 61, Para. 1, as well as for control of the epidemic risk, the Minister of Health upon proposal of the Chief State Health Inspector may, by order, introduce temporary anti-epidemic measures on the territory of the country or on a particular area therein for a certain period of time in accordance with the measures and terms defined in the national plan as per Para. 3a.

(11) (New - SG 32/22, in force from 26.04.2022) The temporary anti-epidemic measures under Para. 10 may be introduced by order of the Director of the respective regional health inspectorate in coordination with the Chief State Health Inspector for the territory of a particular district, municipality or settlement for a certain period of time in accordance with the measures and terms specified in the national plan under Para. 3a.

(12) (New - SG 32/22, in force from 26.04.2022) The temporary anti-epidemic measures under Para. 10 and 11 shall not include:

1. ban on entering the territory of the country;
2. restricting the movement on the territory of the country;
3. suspension of operation of public facilities and/or other facilities or services provided to citizens;
4. requesting a document to access the facilities and services under item 3.

(13) (Previous Para. 10, amend. - SG 32/22, in force from 26.04.2022) The orders under Para. 4, 7, 10 and 11 shall be subject to appeal before the respective Administrative Court under the Administrative Procedure Code.

(14) (Previous Para. 11, amend. - SG 32/22, in force from 26.04.2022) The orders under Para. 4, 7, 10 and 11 shall be general administrative acts, which are issued under Art. 73 of the Administrative Procedure Code, shall be published on the website of the Ministry of Health, respectively on the website of the regional health inspection and shall be subject to preliminary execution.

Art. 63a. (New " SG, 44/20, in force from 14.05.2020) (1) In case of epidemic spread of infectious diseases under Art. 61, Para. 3, the Minister of Health may introduce - by order - anti-epidemic measures, upon proposal of the Chief State Health Inspector for the territory of the country or for a separate district for a certain period of time.

(2) Anti-epidemic measures under Para. 1 may also be introduced by an order of the director of the respective regional health inspection, in coordination with the Chief State Health Inspector for the territory of a separate district, municipality or settlement for a certain period of time.

(3) In case of epidemic spread of infectious diseases under Art. 61, Para. 3, anti-epidemic measures shall not be introduced for prohibition for entry on the territory of the country of citizens of other states and temporary restriction of the movement on the territory of the country.

(4) The orders under Para. 1 and 2 shall be subject to appeal before the respective Administrative Court under the Administrative Procedure Code.

(5) The orders under Para. 1 and 2 shall be general administrative acts, which are issued under Art. 73 of the Administrative Procedure Code, shall be published on the website of the Ministry of Health, respectively on the website of the regional health inspection and shall be subject to preliminary execution.

Art. 63b. (new " SG 80/15, in force from 16.10.2015, former Art. 63a " SG, 44/20, in force from 14.05.2020) (1) In a crisis situation, including massive influx of foreigners seeking protection in the Republic of Bulgaria, and upon occurrence of a risk for the public health, the Minister of Health can mandate measures and activities for public health protection, others than the measures and activities under this section.

(2) Measures and activities under par. 1 shall be coordinated on a national level by the Chief State Health Inspector, shall be carried out by the regional health inspection offices in the territory of which accommodation facilities are opened, and shall be financed from the state budget.

Art. 63c. (New " SG, 44/20, in force from 14.05.2020, suppl. - SG 105/20, in force from 11.12.2020) In case of danger of, or in epidemic spread of infectious diseases under Art. 61, para. 1 or 3, the state and municipal bodies, natural and legal persons shall render full assistance to the bodies of the state health control.

Art. 63d. (New - SG 103/20, in force from 04.12.2020, amend. - SG 32/22, in force from 26.04.2022) The regional governors organize and coordinate the implementation and control of the introduced anti-epidemic measures under Art. 63, para. 4, 7, 10 and 11 and Art. 63a, para. 1 and 2, and the measures under Art. 63b, para. 1 on

the territory of the respective district, as they may order the performance of actions by the bodies of the local self-government and the local administration, the territorial units of the central administration, the natural and legal persons on the territory of the region.

## **Section VI. Protection from the impact of ionising radiations**

Art. 64. (1) (amend. - SG 102/17, in force from 01.01.2018) The protection of the persons from the impact of ionising radiations shall be implemented observing the principles of radiation protection.

(2) The protection of para 1 shall include:

1. control of the factors of the working and the living environment for determining and reduction of the radiation of persons from sources of ionising radiations;
2. (suppl. - SG 102/17, in force from 01.01.2018) medical observation of the persons, who work with sources of ionising radiations, including an assessment of their medical fitness to perform specific professional duties;
3. dosimetric control for determining the internal and the external radiation of the persons, who work with sources of ionising radiations;
4. assessment of the radiation and the radiation risk of the population as a whole and of groups from it;
5. medical monitoring of the persons, radiated with sources of ionising radiations at medical examinations or treatment;
6. medical ensuring of the public, of separate groups from it and of the persons, who work with sources of ionising radiations, in the cases of radiation accident.

(3) (new - SG 41/09, in force from 02.06.2009, suppl. - SG 102/17, in force from 01.01.2018) Medical monitoring of persons, working with ionizing radiation sources, including an assessment of their medical fitness to perform specific professional duties, shall be carried out by the NCRRP and by medical establishments, meeting the requirements set out in the ordinance under Art. 65, para. 1, item 4.

(4) (new - SG 102/17, in force from 01.01.2018) The medical fitness of the persons to perform specific professional duties shall be determined with the conclusion of a doctor under para. 3 with acquired specialty "Radiobiology" or "Radiation Hygiene". The conclusion can be appealed within 14 days of its receipt before the Medical Examination Commission at the NCRRP.

(5) (new - SG 102/17, in force from 01.01.2018) The commission under para. 4 shall be determined by the Director of the NCRRP and consists of at least three doctors with acquired specialty "Radiobiology" or "Radiation Hygiene".

(6) (new - SG 102/17, in force from 01.01.2018) The commission under para. 4 shall decide on appeals within 14 days from their receipt with a decision that is final. The decision determines the medical fitness of the persons to perform specific professional duties in an environment of ionising radiation.

Art. 65. (1) The Minister of Health shall determine with ordinances:

1. the conditions and the order for medical ensuring and health norms for protection of the persons in case of radiation accident;

2. the conditions and the order for ensuring of protection for the persons at medical radiation;

3. the conditions and the order for implementing individual dosimetric control of the persons, working with sources of ionising radiations;

4. the health norms and requirements at work in ambience of ionising radiations;

5. requirements for protection of the persons at chronic radiation as result of production, trade and use of raw materials, subjects and goods with increased content of radio-nuclides;

6. (new " SG 41/09, in force from 02.06.2009) general requirements for provision of radiological protection in case of operation with ionizing radiation sources for medical purposes.

(2) (revoked - SG 102/17, in force from 01.01.2018)

Art. 65a. (new - SG 102/17, in force from 01.01.2018) (1) Activities in testing the quality of medical radiological equipment shall be carried out by a corporate body or a sole trader, entered in the register under Art. 65c, para. 1.

(2) The corporate body or the sole trader shall employ on contract persons with acquired specialty "Medical radiological physics" and with at least 5 years of experience in radiotherapy, nuclear medicine or imaging to perform the testing activities. Employing of a person is required, when the sole trader possesses the necessary qualifications and experience and carries out the testing activities himself.

(3) For entry in the register under Art. 65c the persons under para. 1 shall submit to the Minister of Health an application enclosing:

1. unified identification code or BULSTAT code or a relevant document under the legislation of another Member State of the European Union, or under the legislation of another State - party to the Agreement on the European Economic Area;

2. current registration certificate for working with sources of ionizing radiation according to Art. 56, para. 3 of the Safe Use of Nuclear Power Act;

3. a list of the activities to be carried out;

4. list and identification data of the measuring instruments and current calibration or verification certificates, certifying the metrological characteristics of the measuring instrument;

5. the name of the person who will carry out the quality testing of medical radiological equipment and documents certifying his/her qualifications and experience.

(4) The application under par. 3 can also be submitted electronically under the terms and conditions of the Electronic Document and Electronic Trust Services Act and the Electronic Government Act.

(5) Within one month of receipt of an application under para. 3 the Minister of Health or an official authorized by him shall decide, as:

1. shall enter the person in the register under Art. 65c and issue a certificate of registration;

2. makes a motivated refusal to enter in the register under Art. 65c by notifying the applicant of this.

(6) If an irregularity is found or when additional information is required, the Minister of Health or the official authorized by him/her notifies the applicant in writing

and sets a term for removal the irregularity and/or to provide additional information, which can not be shorter than 10 days. Until the removal of the irregularity and/or the provision of the additional information, the term under para. 5 stops running.

(7) The registration certificate contains data on the entered person, the person who will perform the activities under para. 1, a list of registration activities, the name of the register and the registration number.

Art. 65b. (new - SG 102/17, in force from 01.01.2018) The Minister of Health or the official authorized by him/her refuses entry in the register under Art. 65c, when:

1. false data or fraudulent documents are provided;
2. the person who will perform the testing the quality of medical radiological equipment does not meet the requirements of Art. 65a, para. 2;
3. data or documents that do not meet the requirements of Art. 65a, para. 3, items 2 and 4 have been submitted.

Art. 65c. (new - SG 102/17, in force from 01.01.2018) (1) At the Ministry of Health shall be created register of persons who have received a registration certificate for carrying out activities for testing the quality of medical radiological equipment.

(2) The register is public and shall contain:

1. number and date of issue of the registration certificate;
2. name, seat and registered address of the corporate body or the sole trader, unified identification code or BULSTAT code or a relevant document under the legislation of another Member State of the European Union, or under the legislation of another State - party to the Agreement on the European Economic Area;
3. data under Art. 65a, para. 3, items 3 and 5.

(4) In the register in a separate section shall be entered persons, who applied for a registration certificate, the number and type of attached documents as well as the movement of the file shall be noted. The entry shall be made in the order in which the applications were received.

(4) The Minister of Health deletes from the register a person, having received a registration certificate for carrying out activities for testing the quality of medical radiological equipment at:

1. the request from the person with the original of the issued certificate attached;
2. termination of the corporate body or cancellation of the sole trader;
3. providing untrue data or documents with false content, which served as grounds for entering the person in the register;
4. termination or revocation of a registration certificate for activities under Art. 56, para. 3 of the Safe Use of Nuclear Power Act;
5. carrying out activities in violation of the requirements of Art. 65a, para. 2;
6. performing an activity without up-to-date certificates of calibration or verification, certifying the metrological characteristics of the measuring instrument.

(5) A person, entered in the register, is obliged to notify the Ministry of Health in case of change of circumstances under para. 2 within 7 days from occurrence or learning of change and for the circumstances subject to registration in the Commercial Register - within 7 days from their registration.

Art. 65d. (new - SG 102/17, in force from 01.01.2018, suppl. - SG 77/18, in force from 01.01.2019) The acts under Art. 65b and Art. 65c, para. 4 are subject to appeal before the relevant administrative court under the Administrative Procedure Code.

Art. 66. (1) Medical radiation with sources of ionising radiations shall be admitted at:

1. implementing diagnostics or treatment of patients;
2. conducting of health screening;
3. implementing of medical research programmes, in which volunteers participate.

(2) Medical radiation with sources of ionising radiations shall be admitted with regard to persons, who conscientiously and voluntarily render help to other persons in the process of medical radiation without this being their professional obligation.

(3) The medical radiation shall be prescribed and conducted by doctors or stomatologists.

(4) Radiation with ionising radiations of children as part of a programme for health screening as well as the radiation, connected with high doses for the patient shall be implemented only by specialists, passed additional specialised training.

(5) In the cases of para 1 the persons, to whom is applied medical radiation, shall have right at any time to refuse diagnostics and treatment, connected with radiation with ionising radiations.

Art. 67. (amend. - SG 102/17, in force from 01.01.2018) (1) It is allowed to perform imaging studies with sources of ionizing radiation with non-medical purpose, subject to the principle of rationality of exposure.

(2) The cases in which is allowed to perform imaging studies under para. 1 as well as the conditions and procedure for their conduct shall be determined by an ordinance of the Minister of Health, the Minister of Finance and the Minister of Justice.

Art. 68. (1) Medical radiation with ionising radiations of pregnant women shall not be implemented except in the cases when there is serious danger for their life or health. At implementing of radiation with ionising radiations of women in reproductive age the medical specialists shall be obliged to be informed whether she is pregnant.

(2) At rendering medical help upon urgent statuses when the possibility of pregnancy cannot be excluded, measures shall be undertaken for protection of the health of the pregnant woman and the foetus.

(3) Medical radiation of suckling woman for diagnostics and/or treatment with the methods of nuclear medicine shall be admitted only in the cases when there is serious danger for her life or health.

Art. 69. (1) When at treatment or after diagnostics with radioactive substances the patient is in home conditions the specialist, responsible for the treatment or the diagnostics, shall be obliged to concede to the patient written instruction for restricting the radiation of the members of the family or the persons, who are immediately taking care of him.

(2) When the patient is young or under full interdict the instructions of para 1 shall be conceded to the parent or the guardian and when he is under age or under partial interdict - to the parent or the trustee.

Art. 70. (1) For saving of human life or preventing of bigger radiation at radiation accident the bodies of the state health control can permit as exception the implementation of activities by voluntaries at exceeding the established limits of radiation. The effective dose for one person must not be bigger than 50 milisieverts for one separate year and more than 200 milisieverts total for 10 years.

(2) The persons of para 1 shall be subject to immediate medical examination and monitoring.

Art. 71. (1) The Ministry of Health shall create and maintain register of the persons, who work or have worked in ambience of ionising radiations.

(2) The conditions and the order for registration, processing and preservation of the data of para 1 shall be determined with the ordinance of the Minister of Health.

Art. 72. (1) The individuals and the corporate bodies, implementing activities with sources of ionising radiations, shall be obliged:

1. to admit to work personnel from external organisations after presenting of medical conclusion for determining the fitness of the worker or the employee for work in ambience of ionising radiations;

2. to implement radiation monitoring and to ensure medical monitoring of these persons during the work at the site;

3. to present the results from the radiation monitoring to the employer of the external organisation.

(2) The persons of para 1 shall be obliged to notify the Ministry of Health about the deviations, occurred at normal exploitation of the facilities, which can lead to radiation of the citizens.

(3) The state bodies, implementing monitoring of the radiation parameters of the living environment, shall concede to the Minister of Health periodically data, necessary for implementing assessment of the health risk.

(4) (new "â€" SG 98/10, in force from 01.07.2011, amend. - SG 85/17) The provision of the results referred to in Para 1, Item 3 and the notification under Para 2 may be carried out 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 and the Electronic Document and Electronic Trust Services Act and the Electronic Government Act.

## **Section VII.**

### **Protection of the health of the citizens at implementing activities with asbestos and asbestos containing materials**

Art. 73. (1) (amend. - SG 59/06, in force from 21.07.2006; amend. " SG 98/10, in force from 01.01.2011) The activities for destroying or removal of asbestos and/or asbestos containing materials from buildings, constructions, enterprises, installations or ships shall be implemented after receiving permission from the director of the regional health inspection, on which territory they are implemented.

(2) (amend. - SG 59/06, in force from 21.07.2006) For receiving permission the interested person shall submit to RIPCPH:

1. application for issuing of permission;
2. plan of the work containing concrete measures for ensuring the health and the safety of the employees at the working place;
3. list of the engaged employees;
4. certificate for training of the employees.

(3) (amend. - SG 59/06, in force from 21.07.2006) In the plan for work shall be determined:

1. the type and expected duration of the activities;
2. the place of performance of the activities;
3. the methods which shall be applied with asbestos or asbestos containing materials;
4. the personal measures of protection that shall be provided where necessary;
5. the characteristics of the used equipment for protection of:
  - a) the employees and for elimination of the pollution with asbestos;
  - b) other persons located at the place of work or in proximity;
6. the activities determined for protection of the environment;
7. the order and the method of proving the lack of risk of explosion of asbestos at the working place after finishing the activities of destruction or elimination of asbestos or asbestos containing materials.

(4) (amend. - SG 59/06, in force from 21.07.2006) In the development of the plan for work shall be observed the requirement for elimination of the asbestos and/or the asbestos containing materials before application of techniques for destruction except in the cases where the works of elimination cause greater risk for the employees than the lack of elimination of the asbestos or the asbestos containing materials.

(5) (new - SG 59/06, in force from 21.07.2006) The training of the employees shall be carried out under conditions and order determined by the Ordinance referred to in Art. 36, Item 2 of the Healthy and Safe Working Conditions Act.

(6) (prev. text of para 05 - SG 59/06, in force from 21.07.2006) Permission shall not be required at implementing accident - rescue activities.

Art. 74. (1) (amend. - SG 59/06, in force from 21.07.2006; amend. " SG 98/10, in force from 01.01.2011) In three days term after submitting of the application the director of the regional health inspection shall send in official way the documents of Art. 73, para 2 for statement to the regional inspectorate for environment and waters, on which territory is located the site for destroying or elimination of asbestos or asbestos containing materials.

(2) (amend. " SG 98/10, in force from 01.01.2011) The regional inspectorate for environment and waters shall give statement in 14 days term from the date of receiving the documents. In case in the term, defined by the regional health inspection

statement is not received, it shall be considered that the regional inspectorate for environment and waters coordinates the presented documents without note.

(3) (amend. â€“ SG 98/10, in force from 01.01.2011) The director of the regional health inspection shall notify the applicant about the recommendations of the regional health inspection and/or the regional inspectorate for environment and waters about changes in the plan for work. In compliance with the recommendations in term not later than one month after the notification the applicant shall, be obliged to present the corrected plan for work in compliance with the recommendations.

(4) (amend. - SG 59/06, in force from 21.07.2006; amend. â€“ SG 98/10, in force from 01.01.2011) The permission for destroying or elimination of asbestos or asbestos containing materials shall be issued by the director of the regional health inspection in 5 days term after receiving positive statement by the regional inspectorate for environment and waters or receiving of the corrected plan for work.

(5) (amend. â€“ SG 98/10, in force from 01.01.2011) In the cases of non fulfilment of the recommendations the director of the regional health inspection shall make motivated refusal for issuing of permission.

### **Section VIII. Resort resources and resorts**

Art. 75. (amend. - SG 98/18, in force from 27.11.2018) (1) Resort resources shall be the mineral waters, the healing clays (healing mud), the coastal beaches and seawater and localities with prophylactic, treatment and rehabilitation bioclimatic conditions.

(2) Healing clays (healing mud) are firth-lagoon mud, wellspring mud, lake sediment, peat and bentonite clays.

(3) For the use of mineral waters for drinking, hygienic, medical, prophylactic, rehabilitation and sports-recreation purposes the Minister of Health or an official authorized by him / her shall issue a balneological assessment under the terms and procedures specified in the ordinance under Art. 77, item 1. The balneological assessment shall certify the composition and properties of the mineral water from a specific water abstraction facility of a mineral water deposit, its purpose and manner of application

(4) The balneological assessment under par. 3 is issued at the proposal of the director of the respective basin directorate or the mayor of the municipality managing / holding the mineral water from the respective mineral water deposit. A summary is provided for the proposal for the specific hydrogeological conditions and the performance of the abstraction facility.

(5) The balneological assessment under para. 3 is based on analyzes and conclusions of studies conducted on:

1. hydrogeological conditions and exploitation characteristics of the mineral water deposit;
2. the physical, physico-chemical, chemical, radiological and microbiological characteristics of mineral water;
3. pharmacological, physiological and clinical effects of mineral water.

(6) The balneological assessment under par. 3 is valid for a period of 10 years from the date of issue.

(7) The renewal of the balneological assessments after their expiry shall be carried out in accordance with para. 4, 5 and 6 as the renewal proposal shall be submitted not later than 6 months before the expiration of the term under para. 6.

(8) The issued balneological assessments shall be published on the website of the Ministry of Health.

Art. 76. (amend. - SG 98/18, in force from 27.11.2018) (1) Urbanized territories (settlements or parts thereof and settlement formations) with announced resort resources and opportunities for construction and exploitation of sites and facilities for prophylactics, healing, rehabilitation, recreation and tourism of the population shall be announced as resort.

(2) The announcement of the resorts shall be made on a proposal by the Minister of Health with decision of the Council of Ministers, which shall be promulgated in State Gazette.

Art. 77. (amend. SG 94/05; amend. - SG 82/09, in force from 16.10.2009; amend. - SG 66/13, in force from 26.07.2013; amend. " SG 98/14, in force from 28.11.2014; amend. - SG 9/15, in force from 03.02.2015) The Minister of Health shall together with the Minister of Regional Development and Public Works, the Minister of Environment and Waters and the Minister of Tourism shall determine with ordinances the conditions and the order for:

1. (amend. - SG 98/18, in force from 27.11.2018) announcement, use and protection of resort resources, resort areas and territories and resorts for the classification of resorts

2. (revoked - SG 98/18, in force from 27.11.2018)

3. the approval of exploitation reserves and the use of the healing mud deposits

4. (revoked - SG 98/18, in force from 27.11.2018)

Art. 78. (1) (suppl. - SG 98/18, in force from 27.11.2018) The medical establishments shall use with priority mineral waters and healing slime for implementing their healing activity, including in the cases when these resort resources are granted under the Concessions Act.

(2) (revoked " SG 41/09, in force from 02.06.2009)

Art. 78a. (new " SG 40/12) (1) For protection of the human life and health and prevention of water traumatism the water areas and the basins for public use shall be secured and water rescue activities shall be organised.

(2) The requirements to the water rescue activities and for the securing of the water areas and basins for public use shall be determined in an ordinance of the Council of Ministers.

## **Chapter three. MEDICAL SERVICING**

### **Section I. Accessibility and quality of the medical care**

Art. 79. (1) (prev. text of Art. - SG 102/18, in force from 01.01.2019) The medical care in the Republic of Bulgaria shall be implemented by applying methods and technologies, approved by the medical science and practice.

(2) (new - SG 102/18, in force from 01.01.2019) The requirement under para. 1 on the implementation of medical care shall also apply to medical activities carried out in respect of Bulgarian citizens abroad under Art. 82 para. 1a.

Art. 80. (amend. SG 76/05) The quality of the medical care shall be based on medical standards, approved by the order of art. 6, para 1 of the Medical Establishments Act and the Rules for good medical practice, approved and authorised by the order of art. 5, item 4 of the Act on Professional Organisations of Doctors and Dentists.

Art. 81. (1) Each Bulgarian citizen shall have right to accessible medical care under the terms and following the procedures of the Health Insurance Act.

(2) The right to accessible medical care shall be implemented applying the following principles:

1. timeliness, sufficiency and quality of the medical care;
2. equality at rendering medical care with priority for children, pregnant and mothers of children up to 1 year of age;
3. cooperation, consistency and coordination of the activities between the medical establishments;
4. respect to the rights of the patient.

(3) The conditions and the order for implementing the right to access to medical care of para 1 shall be determined with an ordinance by the Council of Ministers.

Art. 82. (1) Out of the scope of the compulsory health insurance of the Bulgarian citizens shall be conceded medical services, connected with:

1. medical aid at emergency status;
  - 1a. (new - SG 102/18, in force from 01.01.2019) intensive treatment of uninsured persons;
2. (new - SG 59/06, in force from 01.01.2007; suppl. â€“ SG 41/09, in force from 01.07.2009) prophylaxis examinations and tests and midwifery assistance for all health uninsured women regardless of the way of delivery in range and by order determined by an ordinance of the Minister of Health;
3. (prev. text of item 02 - SG 59/06, in force from 01.01.2007) stationary psychiatric care;
  - 3a. (new - SG 102/18, in force from 01.01.2019) complex dispensary (outpatient) care of uninsured persons with mental illness

- 3b. (new - SG 102/18, in force from 01.01.2019) treatment with substitution and maintenance programs with methadone and daily psychorehabilitation programs;
4. (prev. text of item 03 - SG 59/06, in force from 01.01.2007) ensuring blood and blood products;
5. (prev. text of item 04 - SG 59/06, in force from 01.01.2007) transplantation of organs, tissues and cells;
6. (prev. text of item 05 - SG 59/06, in force from 01.01.2007) compulsory treatment and/or compulsory isolation;
- 6a. (new - SG 102/18, in force from 01.01.2019) providing medical activities to patients with infectious diseases by a list established by an ordinance of the Minister of Health, including prevention of epidemiological risk;
- 6b. (new - SG 102/18, in force from 01.01.2019) complex dispensary (outpatient) care of uninsured persons with skin-venereal diseases;
- 6c. (new - SG 102/18, in force from 01.01.2019) provision of medical care for patients with non-specific lung diseases on a list established by an ordinance of the Minister of Health;
7. (prev. text of item 06 - SG 59/06, in force from 01.01.2007; suppl. â€“ SG 41/09, in force from 01.07.2009) expertises for the type and degree of damage and durable inability to work;
8. (prev. text of item 07 - SG 59/06, in force from 01.01.2007, amend. - SG 102/18, in force from 01.01.2019) payment for treatment of diseases by order and under conditions determined by the Minister of Health;
9. (prev. text of item 08 - SG 59/06, in force from 01.01.2007, amend. - SG 102/18, in force from 01.01.2019) ensuring the sustainability of medical activities and specialized care provided to certain persons in implementation of projects and programs funded by the European Structural and Investment Funds or by other international financial institutions and donors on a list established by an ordinance of the Minister of Health;
10. (new â€“ SG 106/13, in force from 01.01.2014) assisted reproduction.
- (1a) (new - SG 102/18, in force from 01.01.2019) Outside the medical services under para. 1 the Bulgarian citizens are entitled to payment for medical and other services related to their treatment in the country or abroad according to their illness for which no other financing mechanisms are envisaged with funds from the state budget, the municipal budgets and from the budget of the National Health Insurance Fund or which can not be insured in the country after preliminary approval.
- (2) Each Bulgarian citizen shall use:
1. (amend. â€“ SG 101/12, in force from 01.01.2013; amend. â€“ SG 106/13, in force from 01.01.2014) vaccines for obligatory immunizations and booster immunizations, vaccines at special indications and upon extraordinary circumstances, specific serums, immune-globulins and other bio-products, connected with the prophylactics of the infectious diseases as well as the technical means for their application;
2. full amount of anti-epidemic activities;
3. access to health activities, included in national, regional and municipal health programmes.
- (3) (amend. - SG 102/18, in force from 01.01.2019, suppl. - SG 99/19, in force from 01.01.2020) In the cases under para. 1a persons under the age of 18 are entitled to

medical care outside the scope of compulsory health insurance which also includes payment from the state budget of medical devices, highly specialized devices / appliances for individual use dietetic foods for special medical purposes, medicinal products not included in the list under Art. 262, para. 1 of the Medicinal Products in Human Medicine Act. Treatment of oncological and onco-hematologic diseases that started before the age of 18 years continue to be paid and after that age until the completion of treatment.

(4) The children, accommodated in medical establishments of Art. 5, para 1 of the Medical Establishments Act, shall have right to medical - social care free of charge.

(5) (amend. â€“ SG 15/12, in force from 01.01.2014, suppl. - SG 102/18, in force from 01.01.2019) The activities of para 1, 1a, 2, 3 and 4 shall be financed from the state budget and from the municipal budgets and they shall be used under conditions and by order, determined with an ordinance b the Minister of Health.

(6) (new - SG 102/18, in force from 01.01.2019, suppl. - SG 18/22, in force from 04.03.2022) The scope of medical and other services under par. 1a and 3, including their performance in the country or abroad and the use of medicinal products, dietetic foods for special medical purposes, medical devices and highly specialized devices / appliances for individual use the diseases of the persons for which they receive payment, as well as the conditions and the order under which they are approved and paid shall be determined by an ordinance of the Minister of Health. The term for issuing individual administrative acts for approval or refusal to pay for the specified medical and other services is up to one month.

(7) (new - SG 102/18, in force from 01.01.2019) Payment for the performance of medical and other activities under para. 1a and 3 in a country outside the European Union, the European Economic Area and the Swiss Confederation shall be permitted exceptionally where it is necessary to apply a method or technology not applicable in a country of the European Union, the European Economic Area or in the Swiss Confederation if confirmed by medical science and practice in the state and its application to patients is reported as beneficial to patients.

(8) (new - SG 102/18, in force from 01.01.2019) No medical and other activities are paid from the state budget which are within the scope of the medical assistance under Art. 45, para. 1, items 1 to 14 of the Health Insurance Act whether declared to be performed in a country outside the European Union, the European Economic Area and the Swiss Confederation.

Art. 82a. (new â€“ SG 98/10, in force from 01.01.2011) With the funds of own income the municipalities may support activities of prevention and treatment of low-income persons, unemployed and other persons that have a permanent address registered at the municipality.

Art. 82b. (new â€“ SG 54/12) (1) The medical establishments for hospital care shall be obliged to make available for their patients the necessary medical devices for their treatment.

(2) The medical devices under Para 1 shall be made available through the hospital pharmacies of the medical establishments for hospital care.

(3) (amend. â€“ SG 15/12, in force from 01.01.2014) Where the medical devices under Para 1 are not paid by the National Health Insurance Fund or by the state

budget, the patients shall pay them at the price they have been purchased by the medical establishment.

Art. 83. (amend. â€“ SG 95/06, in force from 24.11.2006) (1) (Suppl. â€“ SG 09/11, amend. and suppl. - SG 32/22, in force from 26.04.2022) Foreigners, to whom is permitted long-term or permanent residence in the Republic of Bulgaria, foreigners with granted refugee status, humanitarian status and right to asylum, shall enjoy medical assistance under Art. 81 and 82 under the terms and conditions for Bulgarian citizens.

(1a) (New - SG 32/22, in force from 26.04.2022) Foreigners with granted temporary protection shall have the right to medical care and medical services under Art. 81 and 82 under the terms and conditions for Bulgarian citizens with the exception of medical care provided in accordance with the rules for coordination of social security systems within the meaning of § 1, item 22 of the additional provisions of the Health Insurance Act.

(2) (Suppl. - SG 32/22, in force from 26.04.2022) The procedure for access to medical care of the persons referred to in Para. 1 and 1a shall be laid down in the ordinance as per Art. 81, para 3.

(3) (Amend. - SG 32/22, in force from 26.04.2022) The foreign students and doctorants, admitted for education in higher schools and scientific organizations in the country following the procedure of Decree No 103 of the Council of Ministers of 1993 for carrying out educational activity for the Bulgarians abroad (prom., SG 48/93; corr., SG 52/93; amend. and suppl., SG 54/95, SG 20/96, SG 38 and 73/99, SG 101/02, SG 89/04) and Decree No 228 of the Council of Ministers of 1997 for admission of citizens of the Republic of Macedonia for students in the state higher schools of the Republic of Bulgaria (prom. SG 42/97, amend. SG 72/99, SG 101/02), shall use medical care under Art. 81 and 82 under the terms and conditions for Bulgarian citizens.

(4) The foreigners, who stay continuously or for a short term in the Republic of Bulgaria or pass transit through its territory, shall pay the value of the medical care, rendered to them, at prices, determined by the medical establishment, under conditions and by order, regulated with an ordinance by the Minister of Health, the Minister of Foreign Affairs and Minister of Justice.

(5) The foreigners, who stay for a short term in the country or pass transit, shall be obliged to have concluded health insurance or insurance, covering the expenses for treatment and stay in a hospital for the time in the country as far as other is not provided in international agreement, to which the Republic of Bulgaria is a party.

(6) In the cases where the obligatory insurance under para 5 is concluded at entering the country the general conditions, the minimum insurance sum, the minimum insurance premium and the order shall be determined with an ordinance by the Council of Ministers.

(7) (Amend. - SG 32/22, in force from 26.04.2022) The provisions of para 4 through 6 shall not apply to foreigners who stay continuously or for a short term in the Republic of Bulgaria and with regards to whom are being applied the rules for coordination of the social security schemes within the meaning of § 1, item 22 of the additional provisions of the Health Insurance Act.

(8) The procedure of access to medical care in the Republic of Bulgaria of the persons referred to in para 7 shall be laid down in the ordinance as per Art. 81, para 3.

Art. 83a. (new â€“ SG 1/14, in force from 03.01.2014) (1) Regarding nationals of another European Union Member State to whom health care services are provided in Bulgaria according to the provisions of Chapter Two, Section XII of the Health Insurance Act, the established in the medicine science and practice methods and technologies shall be applied, and also medical standards, approved according to the provision of Art. 6, par. 1 of the Medical Establishments Act and the Rules of Good Medical Practice, adopted and approved according to the provision of Art. 5, item 4 of the Act on Professional Organisations of Physicians and Dental Practitioners, which apply also to Bulgarian nationals.

(2) The persons under par. 1 shall pay to the health care establishment the cost of provided health care services, for which the health care establishment shall issue an itemized financial accounting document for the spent financial resource.

(3) Health care establishments providing health care services to nationals of other European Union Member States may not fix prices of health care services different from the prices payable by Bulgarian nationals.

## **Section II. Rights and obligations of the patient**

Art. 84. (1) Patient shall be each person, who has required or to whom has been rendered medical care.

(2) The registration of a person as patient shall take place with his informed consent except in the cases, pointed out with a law.

Art. 85. (amend. â€“ SG 41/09, in force from 02.06.2009) The patient shall be provided with medical assistance regardless his/her age, sex, origin, language, race or political affiliation, education, ideas, culture level, sexual orientation, personal, public or material status, damage and type and cause of the disease.

Art. 86. (1) As patient anybody shall have right to:

1. respect of his civil, political, economic, social, cultural and religious rights'
2. care by the community he is living in;
3. accessible and high quality health care;
4. more than one medical statement about the diagnosis, the treatment and the prognosis of the disease;
5. protection of the data, referring to his health status;
6. remuneration for the work he implements, equal with the one he receives if he is not ill;
7. acquaintance in intelligible language with his rights and obligations;
8. clear and accessible information about his health status and the methods of his eventual treatment;
9. (new â€“ SG 41/09, in force from 02.06.2009) preventive health care and rehabilitation;

10. (new " SG 41/09, in force from 02.06.2009) reliability and safety of diagnostic and therapeutic procedures, carried out during his/her treatment;

11. (new " SG 41/09, in force from 02.06.2009) access to up-to-date therapeutic methods;

12. (new " SG 41/09, in force from 02.06.2009) prevention of pain and suffering during his/her treatment, as far as possible;

13. (new " SG 41/09, in force from 02.06.2009) access to medical files, related to his/her health status.

(2) At hospitalisation the patient shall have right:

1. to be visited by his personal doctor and by the specialist, issued direction for hospitalisation;

2. (new " SG 60/11, in force from 05.08.2011; amend. " SG 54/12; amend. " SG 15/13, in force from 01.01.2014) to be provided by the medical establishment for hospital care the medical devices necessary for their treatment, where the said devices are not paid by the National Health Insurance Fund or by the state budget;

3. (prev. text of item 2 " SG 60/11, in force from 05.08.2011) to receive or refuse visits;

4. (prev. text of item 3 " SG 60/11, in force from 05.08.2011) to use the services of psychotherapist, lawyer and clergyman;

5. (prev. text of item 4 " SG 60/11, in force from 05.08.2011) to education and access to activities, responding to his social, religious and cultural needs;

6. (amend. " SG 41/09, in force from 02.06.2009; prev. text of item 5 " SG 60/11, in force from 05.08.2011) to receive information about the price of each medical service, manipulation, treatment and the medical products in the outpatient and hospital care.

(3) (new " SG 60/11, in force from 05.08.2011; amend. " SG 54/12) In the cases referred to in para 2, item 2 the medical devices shall be made available and paid as set out in Art. 82b.

(4) (prev. text of para 3 " SG 60/11, in force from 05.08.2011) The rights of the patient shall be exercised observing the regulation for the structure, the activity and the internal order of the medical establishment.

Art. 86a. (new " SG 41/09, in force from 02.06.2009) (1) Public Council of Patient's Rights shall be set out to the Minister of Health.

(2) (amend. " SG 101/09, in force from 18.12.2009) The Public Council of Patient's Rights shall include seven representatives of representative organizations for protection of patients' rights in the meaning of Art. 86b, one representative of the organization of people with disability, who is a member of the National Council for Integration of People with Disability and one representative of the Ministry of Health, of the Ministry of Labour and Social Policy, of the NHIF, or the Bulgarian Union of Physicians, of the Bulgarian Union of Dentists, of the Bulgarian Union of Pharmacists, and of the Bulgarian Association of Health Care Professionals.

(3) The Public Council of Patient's Rights is a consulting body with the following functions:

1. to monitor and analyze all activities, related to patient's rights;

2. to prepare annual report on patients' rights issues and to present it to the Minister of Health;

3. to analyze the application of the statutory regulations related to patients' rights and to prepare proposals for their amendments and supplementation, which are to be presented to the Minister of Health;

4. to discuss and to issue comments on drafts of statutory acts, related to patients' rights.

(4) The organization and the activity of the Public Council of Patients' Rights shall be provided in Regulations, prepared by the Public Council of Patients' Rights and approved by the Minister of Health.

Art. 86b. (new " SG 101/09, in force from 18.12.2009) (1) Representative organizations for protection of patients' rights shall be organizations meeting the following requirements:

1. having the objective to protect the rights and interests of all patients regardless specific diseases, diagnoses and suffering;

2. to be registered as non-profit associations for public benefit in the Sense of the Non-Profit Legal Entities Act;

3. to be nationally representative and to have regional structures on the territory of the entire country.

(2) In the governing bodies of the associations under Para 1 may participate officials from state authorities, authorities of the local self-government and local administrations, officials from NHIF, performers of medical aid, members of governing and control bodies of manufacturers, importers and traders of medicinal products, medicinal devices and medicinal equipment.

(3) The Ministry of Health and the other state authorities, the local self-government authorities and the local administration and NHIF shall render assistance to the associations for protection of the patients' rights. The associations shall have the right to:

1. receive information about draft normative acts concerning the rights and interests of the patients;

2. inform the competent authorities of cases of infringement of the patients' rights, request information of the conducted checks, the results thereof and the implemented measures.

(4) Through their representatives the organizations under Para 1 may participate in the work of consultancy bodies, commissions and working groups at the authorities of the Ministry of Health and NHIF.

Art. 86c. (new " SG 101/09, in force from 18.12.2009) (1) The organizations for protection of the patients' rights shall be recognized as representative in the sense of Art. 86b, Para 1 at their request by the Minister of Health.

(2) The recognition of the organizations for protection of the patients' rights as representative under Para 1 shall be carried out according to a procedure and criteria, specified in an ordinance of the Minister of Health.

(3) (suppl. - SG 77/18, in force from 01.01.2019) The refusal of the Minister of Health to recognize an organization for protection of the patients' rights as

representative may be appealed before the relevant administrative court under the order of the Administrative Procedure Code.

(4) Every three years after their recognition under the order of Para 1 the organizations for protection of the patients'™ rights shall prove their representativeness under the procedure, specified in the ordinance under Para 2.

(5) The Minister of Health may carry out checks for compliance with the requirements of Art. 86b, Para 1 of each of the representative organizations for protection of the patients'™ rights and, depending on the results, shall approve or withdraw their representativeness. The checks shall be carried out according to a procedure, specified in the ordinance under Para 2.

(6) The order of the Minister of Health for withdrawal of the representativeness of an organization for protection of the patients'™ rights may be appealed according to the procedure of Para 3.

Art. 87. (1) The medical activities shall be implemented after expressed informed consent by the patient.

(2) When the patient is under age or under limited interdict for implementing of medical activities shall be necessary his informed consent and the consent of his parent or guardian.

(3) (new " SG 41/09, in force from 02.06.2009) The consent under par. 2 of the parent or guardian shall not be required for provision of health consultancy, preventive health care examinations and testing of persons under 16 years of age. The particular types of activities related to consultancy, preventive health care examinations and tests shall be determined by an ordinance of the Minister of Health.

(4) (prev. par. 3 " SG 41/09, in force from 02.06.2009) When the patient is young or judicially incapable the informed consent shall be expressed by his parent or guardian except in the cases provided with a law.

(5) (new " SG 41/09, in force from 02.06.2009) Where for a minor or under age person, accommodated under a court procedure outside the family, the consent of a parent, guardian or custodian under par. 2 and 4 cannot be obtained in due time, informed consent shall be expressed by a person, to whom the care for the child has been assigned following a positive opinion of the Directorate "Social support".

(6) (new " SG 41/09, in force from 02.06.2009) Where the minor or under age person has been accommodated temporarily following administrative procedure under Art. 27 of the Child Protection Act, the informed consent under par. 5 shall be expressed by the Directorate "Social support".

(7) (prev. par. 4 " SG 41/09, in force from 02.06.2009) For persons with psychic disorders and established inability to express informed consent it shall be expressed by the persons, determined by the order of Art. 162, para 3.

Art. 88. (1) (suppl. " SG 41/09, in force from 02.06.2009) For receiving informed consent the doctor (stomatologist) in charge shall notify the patient, respectively his parent, guardian or trustee, the person under Art. 87, par. 5, the Directorate under Art. 87, par. 6, as well as the persons of Art. 162, para 3, about:

1. the diagnosis and the character of the disease;

2. description of the purposes and the nature of the healing, the reasonable alternatives, the expected results and the prognosis;

3. the potential risks, connected with the proposed diagnostic - healing methods, including the side effects and the unwanted medical reactions, pain and other discomforts;

4. the probability of favourable influence, the risk for the health at applying of other methods of treatment or at refusal of treatment.

(2) (suppl. â€“ SG 41/09, in force from 02.06.2009) The medical information of para 1 shall be conceded to the patient, respectively to his parent, guardian or trustee, to the person under Art. 87, par. 5 and to the Directorate under Art. 87, para. 6, as well as to the persons of Art. 162, para 3 timely and in appropriate amount and form, giving opportunity for freedom of the choice of treatment.

Art. 89. (1) Upon surgery intervention, total anaesthesia, invasive and other diagnostic and therapeutic methods, leading to increased risk for the life and the health of the patient or to temporary change in his consciousness, the information of art. 88 and the informed consent shall be conceded in written form.

(2) The activities of para 1 can be implemented in favour of the health of the patient without written informed consent only when his life is immediately threatened and:

1. his physical or psychic status does not allow expressing of informed consent;

2. (suppl. â€“ SG 41/09, in force from 02.06.2009) it is impossible to be achieved informed consent by parent, guardian or trustee, by the person under Art. 87, par. 5, by the Directorate under Art. 87, par.6 or by the person of Art. 162, para 3 in the cases the law requires it.

(3) For persons with psychic disorders and established inability to express informed consent the activities of para 1 can be implemented only after permission by the commission for medical, ethics and after taking the consent of the lawful representatives or of the chief of the medical establishment when there is no created commission.

Art. 90. (1) (suppl. â€“ SG 41/09, in force from 02.06.2009) The patient, respectively his parent, guardian or trustee, the person under Art. 98, par. 5, the Directorate under Art. 87, par. 6 or the person of Art. 162, para 3, can refuse at any time the proposed medical care or the continuation of the started medical activity.

(2) The refusal of para 1 shall be certified in the medical documentation with signatures of the person.

(3) (suppl. â€“ SG 41/09, in force from 02.06.2009) If the person, respectively his parent, guardian or trustee, the person under Art. 87, par. 5, the Directorate under Art. 87, par. 6 or the person of Art. 162, para 2, is not in capacity or refuses to certify in writing the refusal of para 1, this shall be certified with signature by the healing doctor and a witness.

(4) (amend. â€“ SG 41/09, in force from 02.06.2009) In the cases when there is refusal under para 1 and the life of the patient is threatened, the chief of the medical establishment can take decision for implementing life saving treatment.

(5) (new â€“ SG 41/09, in force from 02.06.2009) The patient may withdraw his/her refusal under par. 2 at any time, and in this case the medical specialists shall not be held responsible for possible delay of the therapeutic and diagnostic processes.

Art. 91. Medical care against the will of the patient can be rendered only in cases, determined with a law.

Art. 92. (1) The healing doctor shall be obliged to inform the patient about:

1. his health and the need of treatment;
2. the disease, on the occasion of which he has looked for health care, and its prognosis;
3. the planned prophylactic, diagnostic, healing and rehabilitation activities as well as the risks, connected with them;
4. the diagnostic and the therapeutic alternatives;
5. the name, the position and the speciality of the persons, who participate in the diagnostic - healing process.

(2) (amend. â€“ SG 41/09, in force from 02.06.2009) The patient shall have the right to refuse to be informed under par. 1, item 2 and 3, unless in cases, where his/her health status endanger other personsâ€™ health.

access of the patient to the health information of para 1, items 2 and 3 can be restricted upon written refusal by him.

(3) The decision of para 2 shall be reflected in writing in the medical documentation of the patient.

(4) (new â€“ SG 41/09, in force from 02.06.2009) The patient shall have the right to authorize in writing a person to be informed for him.

Art. 93. (1) (suppl. â€“ SG 41/09, in force from 02.06.2009; amend. â€“ SG 98/10, in force from 01.01.2011) The patient, respectively his parent, guardian or trustee, the person under Art. 87, par. 5, the Directorate under Art. 87, par. 6, or person, authorised by them, shall have right to submit appeals and signals to regional health inspection upon breaching of his rights under this Act or at disputes, connected with the medical servicing.

(2) (amend. â€“ SG 98/10, in force from 01.01.2011) The regional health inspection shall in 7 days term make official check for the appeal or the signal.

(3) (amend. â€“ SG 98/10, in force from 01.01.2011) Upon establishing of administrative breach the checking employee of the regional health inspection shall compile act for establishing of the administrative breach and the director of the regional health inspection shall issue punitive decree by the order of the Administrative Violations and Penalties Act.

(4) (amend. SG 76/05; amend. â€“ SG 98/10, in force from 01.01.2011) Upon establishing of administrative breaches, punitive by the order of the Act on Professional Organisations of Physicians and Dental Practitioners and the Health Insurance Act, the regional health inspection shall notify and send the appeal to the regional colleges of the Bulgarian physicians' union and the Union of the stomatologists in Bulgaria and to the regional health insurance fund.

(5) (amend. " SG 98/10, in force from 01.01.2011) In three days term after finishing the check the regional health inspection shall notify the patient about the results from the check and the undertaken activities.

Art. 94. The patient shall be obliged:

1. to take care of his own health
2. not to damage the health of others;
3. to cooperate with the performers of medical care in implementing the activities, connected with improvement and restoration of his health;
4. to observe the established order in the medical and the health establishments.

Art. 95. (1) Upon incurable diseases with unfavourable prognosis the patient shall have right to palliative medical care.

(2) Objective of the palliative medical care shall be maintaining of the quality of life of by reduction or removal of some immediate performances of the disease as well as the unfavourable psychological and social effects, connected with it.

Art. 96. (1) The palliative medical care shall include:

1. medical observation;
2. health care, directed for care of the patient, removal of the pain and the psycho-emotional effects of the disease;
3. moral support of the patient and his relatives.

(2) (amend. " SG 59/10, in force from 31.07.2010) Palliative medical care shall be rendered by the personal physician, by medical establishments for off hospital and hospital care and by hospices.

(3) The requirements for rendering palliative medical care shall be determined with ordinance by the Minister of Health.

Art. 97. On the territory of the Republic of Bulgaria euthanasia shall not be applied.

Art. 98. (1) Pathological - anatomic autopsy shall be implemented for the persons, deceased in a medical establishment, after notifying of parent, full aged child, spouse, brother or sister.

(2) (new - SG 98/10, in force from 14.12.2010) Pathological-anatomic autopsy shall be carried out also in case of a death of a child accommodated outside the family as set out in the Child Protection Act.

(3) (prev. text of Para 02 - SG 98/10, in force from 14.12.2010) Pathological - anatomic autopsy of persons, deceased out of medical establishment, can be implemented upon request by the physician, who has established the death or upon request by the relatives of the deceased.

(4) (prev. text of Para 03, suppl. - SG 98/10, in force from 14.12.2010) Upon explicit request by the relatives of the deceased under Para 1 the chief of the medical establishment can issue order for exemption from pathological - anatomic autopsy.

(5) (new - SG 98/10, in force from 14.12.2010) Upon explicit written request of a parent, guardian or trustee the head of a medical establishment may issue an order for exemption from pathological-anatomy autopsy in the cases of Para 2, only where the child has died in a medical establishment for hospital care.

(6) (prev. text of Para 04 - SG 98/10, in force from 14.12.2010) The pathological - anatomic autopsy shall not be implemented when the corpse is subject to judicial medical expertise.

### **Section III. Medical care upon emergency status**

Art. 99. (1) The state shall organise and finance system for rendering medical care upon emergency status.

(2) Emergency status shall be acute or suddenly occurred change in the status of the man, requiring immediate medical care.

(3) The medical care at emergency status shall be directed to prevention of:

1. death;
2. grave or irreversible morphological and functional damages of vitally significant organs and systems;
3. complexities with women in child-birth, threatening the health and the life of the mother or the foetus.

Art. 100. Each person, being at the place of the incident, shall be obliged to inform the nearest located centre for emergency medical aid, another medical establishment or police department.

(2) Each medical establishment shall be obliged to implement the possible amount of medical activities with a patient in emergency status regardless of his citizenship, address or health insurance status.

(3) Upon impossibility to ensure the necessary amount of activities, if the status of the patient allows, he shall be accommodated at the closest medical establishment, disposing with the necessary conditions for this.

(4) In case of re-accommodation of a patient of one medical establishment into another one shall be attached all medical documents for implemented diagnostic, consultative and healing activities, summarised in epicrisis.

(5) Transport of patient shall not be admitted if the transport or the circumstances, connected with it, lead to unjustifiably high risk for his health and life.

### **Section IV. Medical expertise**

Art. 101. (1) (amend. â€“ SG 41/09, in force from 01.07.2009; suppl. â€“ SG 59/10, in force from 31.07.2010) Medical expertise shall be implemented for establishing temporary work inability, for establishing the type and the degree of disability of children of up to 16 years of age and of persons, having become eligible for pension for insured years of service and age under Art. 68 of the Code of Social Insurance and for the determination of the degree of permanently reduced ability to work of persons of active working age and also for confirmation of professional disease.

(2) (amend. - SG 98/10, in force from 01.01.2011) The medical expertise shall be organised and managed by the Minister of Health and the regional health inspection.

(3) (new â€“ SG 59/10, in force from 31.07.2010) During temporary work inability examinations an assessment shall be made if the health condition of the person permits him to appear before investigation or judicial authorities, if such appearance is necessary during the period of temporary work inability.

(4) (prev. text of Para 03 â€“ SG 59/10, in force from 31.07.2010) The type and the degree of disability and durably reduced ability to work shall be determined in percentage with regard to the abilities of the healthy person.

(5) (prev. text of Para 04 â€“ SG 59/10, in force from 31.07.2010) The type and the degree of disability of persons, having become eligible for pension for insured years of service and age under Art. 68 of the Code of Social Insurance shall be determined for life. The re-certification of these persons can be implemented upon their wish or upon request by the control bodies of the medical expertise.

(6) (prev. text of Para 05 â€“ SG 59/10, in force from 31.07.2010) For the persons under par. 4, exercising labour activity a degree of permanently reduced ability to work shall be determined unless a type and degree of disability have been determined.

(7) (prev. text of Para 06, amend. â€“ SG 59/10, in force from 31.07.2010) The principles and the criteria of the medical expertise, the order for establishing temporary work inability, the type and the degree of disability, the degree of permanently reduced ability to work, confirmation of professional disease, as well as the conditions and order of conducting medical examination under Art. 103, Para 3 shall be determined by an ordinance of the Council of Ministers.

Art. 101a. (new - SG 98/10, in force from 14.12.2010) (1) The term of the decision for the degree of permanently reduced work ability shall be determined in the ordinance under Art. 101, Para 7 in accordance with the characteristics of the damage, the dynamics of its development and the possibilities for recovery of the working ability.

(2) In cases of definitive conditions specified in the ordinance under Para 1, where there is no possibility for full or partial recovery of the working ability, the degree of permanently reduced working ability shall be determined for life.

(3) In cases of multiple damages, some of which do not qualify as definitive conditions, the term of the decision for the degree of permanently reduced working ability shall be determined as set out in Para 1.

Art. 102. (1) National council in medical expertise shall be created at the Council of Ministers with the following authorities:

1. develop and present to the Council of Ministers statements on the national health policy, related to the medical expertise;

2. implement coordination of the activities between the state bodies in connection with the medical expertise;
3. analyse information about the activity, the development and the status of the medical expertise in the country;
4. develop and present for approval to the Council of Ministers drafts of amendment and supplement of normative acts, related to the medical expertise;
5. develop methodology for financing and control over the activities of the bodies of the medical expertise, which shall be approved by the Council of Ministers.

(2) (amend. â€“ SG 41/09, in force from 02.06.2009; amend. - SG 62/10, in force from 10.08.2010) The members of the National council in medical expertise shall include: deputy Prime Minister, who is chairman of the council, the Minister of Health, the Minister of Labour and Social Policy, the Minister of Finance, the manager of the National Insurance Institute, the manager of the NHIF, the director of NEMC and the Executive Director of the Agency of People with Disabilities.

(3) The structure and the activity of the council of para 1 shall be provided with regulation of the Council of Ministers.

Art. 103. (1) (amend. â€“ SG 41/09, in force from 01.07.2009) The medical expertise shall include expertise of the temporary inability to work, expertise of the type and the degree of disability and expertise of the durably reduced ability to work.

(2) The expertise of the temporary inability to work shall be implemented by the doctor in charge, medical consultative commissions (MCC), territorial expert medical commissions (TEMC) and by NEMC.

(3) (new â€“ SG 59/10, in force from 31.07.2010) The physical examination regarding the personâ€™s capability of appearing before investigation and judicial authorities shall be made by MCC, by the emergency medical centres, by TEMC and by NEMC. The physical examination shall be documented in expert decision â€“ "Medical Certificate" in a form, approved by the Minister of Health and the Minister of Justice.

(4) (suppl. â€“ SG 41/09, in force from 01.07.2009; prev. text of Para 03 â€“ SG 59/10, in force from 31.07.2010) The expertise of the type and the degree of disability, the degree of durably reduced ability to work and the professional diseases shall be implemented by TEMC and NEMC.

(5) (amend. â€“ SG 41/09, in force from 01.07.2009; prev. text of Para 04 â€“ SG 59/10, in force from 31.07.2010; amend. â€“ SG 40/12) The expertise of the type and the degree of disability of children up to 16 years of age shall be done by LEMC and NEMC with the participation of a specialist in children's diseases.

Art. 103a. (new â€“ SG 106/13, in force from 01.12.2014) Medical expertise authorities shall submit to the National Social Insurance Institute data contained in the issued sick leave certificates and the decisions on their appeals following a procedure, determined by an act of the Council of Ministers.

Art. 104. (1) (amend. - SG 98/10, in force from 01.01.2011) The medical consultative commissions shall be opened and closed with an order by the directors of the

regional health inspections in medical establishments for off hospital and hospital care upon proposal by the chief of the respective medical establishment.

(2) In the medical establishments of art. 5, para 1 of the Medical Establishments Act and in the university hospitals the members of the MCC shall be determined with an order by the respective chief of the medical establishment.

(3) The medical consultative commissions shall be general and specialised. In the MCC shall be not less than two permanent members - doctors with recognised speciality, including one chairman.

Art. 104a. (new " SG 41/09, in force from 01.07.2009) (1) (amend. - SG 98/10, in force from 01.01.2011; revoked " SG 40/12)

Art. 105. (1) (amend. " SG 59/10, in force from 31.07.2010; amend. - SG 98/10, in force from 01.01.2011) The territorial expert medical commissions shall be opened and closed by the directors of regional health inspections in coordination with the Minister of Health at state and municipal medical establishments for hospital care, mental health centres, skin and venereal disease centres and complex oncological centres.

(2) The territorial expert medical commissions shall be structural units of the medical establishments, at which they have been opened.

(3) (amend. " SG 41/09, in force from 01.07.2009; revoked - SG 100/10, in force from 01.01.2012)

Art. 106. (1) (amend. " SG 41/09, in force from 01.07.2009) In the TEMC and NEMC shall work doctors with recognised speciality and not less than 5 years labour practice in medicine.

(2) (Repealed - SG 18/18, in force from 27.02.2018)

(3) (Amend. - SG 41/09, in force from 01.07.2009, amend. - SG 40/12, amend. - SG 18/18, in force from 27.02.2018) During a medical expertise no medical expert may participate in it who:

1. has participated in the preparation of the contested expert decision;
2. has participated in the consultation work related to the expertise of the temporary incapacity for work, of the type and degree of disability and the permanently reduced working capacity of the certified person;
3. is a husband/spouse, straight line relative without limit or collateral line up to the second degree to the certified person;
4. lives in an actual cohabitation with the certified person.

(4) (New - SG 18/18, in force from 27.02.2018) In the cases under Para. 3, the doctor from the membership of TEMC and NEMC shall be obliged to declare in writing that he wants to be removed from the meeting of the respective commission.

(5) (New - SG 18/18, in force from 27.02.2018) Removal of a doctor from a meeting in the cases under Para. 3 may also be requested by the certified person as well with a motivation.

(6) (New - SG 18/18, in force from 27.02.2018) The order of filing and the template of the request under Para. 4 and 5 shall be determined by the Regulations under Art. 109.

(7) (New - SG 18/18, in force from 27.02.2018) Upon request received for the removal of a doctor in the cases under Para. 4 and 5, the Head of the medical establishment or the Director of NEMC shall be obliged to rule on its merits within three days of its receipt.

(8) (New - SG 18/18, in force from 27.02.2018) In case the request for removal is justified, an alternate member of the TEMC shall be included in carrying out the medical examination, or a physician from the other specialized teams of NEMC appointed by the Head of the medical establishment or by the Director of NEMC.

(9) (New - SG 18/18, in force from 27.02.2018) A request under Para. 4 and 5 may also be made electronically under the terms and procedures of the Electronic Document and Electronic Trust Services Act and the Electronic Governance Act.

Art. 107. (1) (suppl. â€“ SG 41/09, in force from 01.07.2009; amend. â€“ SG 40/12) For implementing the activity of TEMC the director of the medical establishment shall conclude contract for financing with the Minister of Health.

(2) (suppl. â€“ SG 41/09, in force from 01.07.2009; amend. â€“ SG 40/12) The highly specialised and expensive medical - diagnostic investigations, connected with the process of the medical expertise of the ability to work, shall upon request by TEMC and NEMC be financed by NHIF within the framework of its annual budget.

Art. 108. (1) (suppl. â€“ SG 41/09, in force from 01.07.2009; amend. â€“ SG 40/12) The activity for registration, processing and preservation of health information about the persons, certified by TEMC and NEMC, shall be implemented by regional card-index of the medical expertises (RCME).

(2) (amend. â€“ SG 98/10, in force from 01.01.2011) The regional card-indexes of the medical expertises shall be structural units of the regional health inspections.

(3) (amend. â€“ SG 41/09, in force from 01.07.2009; amend. â€“ SG 40/12) The medical documentation of the persons, certified by TEMC and NEMC, to whom type and degree of disability and a percentage of durably reduced ability to work has been determined, shall be kept for 40 years after the last decision of TEMC and NEMC and of all other persons - 5 years.

(4) (amend. â€“ SG 41/09, in force from 01.07.2009; amend. â€“ SG 98/10, in force from 01.07.2011; amend. â€“ SG 40/12, amend. - SG 85/17) Copy of the decisions of TEMC and NEMC shall be sent electronically under the conditions and order set out in the Electronic Document and Electronic Trust Services Act and the Electronic Government Act to the National centre for health information and to the Agency of People with Disabilities.

Art. 108a. (new - SG 102/18, in force from 01.01.2019) (1) The National Expert Medical Commission establishes and maintains an information database for all persons who have gone through TEMC / NEMC to establish permanently reduced working capacity / type and degree of disability.

(2) The information database under para. 1 contains:

1. (new - SG 103/20, in force from 04.12.2020) application-declaration for certification / re-certification;
  2. (prev. item 1 - 103/20, in force from 04.12.2020) document directing to the assessment of permanently impaired work capacity / type and degree of disability (medical protocol / medical direction);
  3. (prev. item 2 - 103/20, in force from 04.12.2020) expert decision;
  4. (prev. item 3 - 103/20, in force from 04.12.2020) a diagnosis of the main disease;
  5. (prev. item 4 - 103/20, in force from 04.12.2020) diagnoses of concomitant diseases;
  6. (prev. item 5 - 103/20, in force from 04.12.2020) all medical-diagnostic activities performed relevant to the assessment of permanently reduced working capacity / type and degree of disability;
  7. (prev. item 6 - 103/20, in force from 04.12.2020) the examinations made by a physician relating to the assessment of permanently impaired work capacity / type and degree of disability;
  8. (prev. item 7 - 103/20, in force from 04.12.2020) other data relevant to permanently reduced working capacity / type and degree of disability.
- (2a) (New - SG 105/20, in force from 01.07.2022, amend. regarding entry into force - SG 8/22, in force from 01.01.2022, amend. regarding the entry into force - SG 18/22, in force from 01.04.2022) In the information database under para. 1 shall be entered also the medical documents, issued by the medical consultative commissions, TEMC or NEMC according to Art. 73, para. 1 of the People with Disabilities Act.
- (3) (Suppl. - 103/20, in force from 04.12.2020, suppl. - SG 41/22, in force from 03.06.2022) The information database under para. 1 aims at collecting, processing, storing and analyzing the data for the persons under para. 1 to be used for performing medical expertise, planning activities related to satisfy their needs for education, medical and social rehabilitation, employment as well as for assessing the health status of the population and controlling the activities of carrying out medical expertise.
- (4) (Amend. - SG 103/20, in force from 04.12.2020) The bodies of medical expertise, regional indexes of medical expertise, the National Health Insurance Fund, the National Social Security Institute and the persons wishing to be certified / re-certified shall provide the necessary information to create and maintain the database under para. 1.
- (5) (Amend. - SG 103/20, in force from 04.12.2020) The information in the database shall be entered and shall be used for the purposes of para. 3.
- (6) Right of access to the database has the Ministry of Health, the National Health Insurance Fund, the Ministry of Education and Science, The National Social Security Institute, the Agency for Social Assistance, the Agency for People with Disabilities, the State Agency for Child Protection, the Employment Agency, The National Revenue Agency, the National Statistical Institute, the National Center for Public Health and Analysis, the Directorate General for Civil Registration and Administrative Services and other bodies performing activities in the field of people with disabilities.
- (7) (New - SG 103/20, in force from 04.12.2020) Right of access to the health information of the certified person in the information database under para. 1 have the certified person and his legal representatives / proxies.

(8) (prev. para. 7, suppl. - 103/20, in force from 04.12.2020) The terms and the order for keeping and maintaining the database under para. 1, as well as the type of information and access to it, shall be determined by the regulation under Art. 109.

Art. 109. The structure and the organisation of work of the bodies of the medical expertise of art. 103 and of RCME shall be determined with regulation by the Council of Ministers.

Art. 110. (amend. â€“ SG 98/10, in force from 01.01.2011) Control over the medical expertise shall be implemented by the National centre for medical expertise, by the Minister of Health, the Minister of Labour and Social Policy, NHIF, NII the regional councils of Art. 111 and by the regional health inspections.

Art. 111. (1) (suppl. â€“ SG 59/10, in force from 31.07.2010; amend. â€“ SG 98/10, in force from 01.01.2011) For control over the acts, issued by the bodies for expertise of the temporary inability to work, with an order of the director of the respective regional health inspection shall be created regional council, including representatives of the regional health inspection, the territorial division of NII and RHIF. The regional council shall also implement checks of not less than 2 percent of the decisions, issued on the territory of the respective region, for temporary inability to work and expert decisions under Art. 103, Para 3, chosen by random principle.

(2) The regional council shall analyse and control the activities for expertise of the temporary inability to work, implemented by the doctors in charge, MCC and TEMC. The organisation of the activity of the council shall be determined with regulation, issued by the Minister of Health together with the manager of NII.

(3) Upon proposal by the interested persons and organisations (the certified, the insurers, the territorial divisions of NII and NHIF) the regional council shall implement checks for observing the requirements and the order at issuing decisions for temporary inability to work by the doctors in charge and TEMC.

(4) At establishing of breach at issuing the expert decisions for temporary inability to work the regional council shall notify in writing the higher body for expertise of ability to work and the interested persons and organisations (the certified, the insurers, the territorial divisions of NII and NHIF).

Art. 112. (1) (amend. â€“ SG 41/09, in force from 01.07.2009) The appeals and the objections on behalf of the interested persons and bodies (the certified, the insurers, NII, the Agency for social support, Agency of people with disabilities and the bodies of the medical expertise of the ability to work) shall be made:

1. against the decisions of the doctor in charge - in 14 days term after receiving them before the medical consultative commission;

2. (suppl. â€“ SG 59/10, in force from 31.07.2010) against the decisions of the MCC and the emergency medical centres - in 14 days term after receiving them before TEMC;

3. (amend. â€“ SG 41/09, in force from 01.07.2009; amend. â€“ SG 40/12) against the decisions of TEMC - in 14 days term after receiving them before NEMC;

4. (amend. - SG 30/06, in force from 12.07.2006 and for the replacement of the words "Sofia city court" by "Administrative court " city of Sofia", in force from 01.03.2007; amend. - SG 104/13, in force from 04.01.2014) against the decisions of NEMC - before the Administrative court " in the area of the permanent or present address or registered office of the applicant by the order of the Administrative Procedure Code.

(2) The interested persons and organisations (the certified, the insurers, the territorial divisions of NII and NHIF) can appeal in 14 days term decisions of MCC, with which are breached the requirements and the order at issuing expert decisions for temporary inability to work, also before the regional council of Art. 111.

(3) The regional council shall pronounce decision on the appeals in 10 days term after repeated expertise of the temporary inability to work, implemented by specialised MCC, determined by it, according to the kind of the disease.

(4) In the cases of established breach at issuing the regional council shall revoke the appealed expert decision, the ability to work being established with the decision of the repeated expertise.

(5) The decision of the regional council for revoking of the expert decision and the decision of the repeated expertise shall be sent to the persons, interested in the expertise (the certified, the insurers and NII), as well as to RHIF.

(6) The appealing of the decision of MCC by the order of para 2 shall be obstacle for its appealing by the order of para 1, item 2.

(7) the decision of the regional council for rejecting the appeal shall not be obstacle for appealing the decision of MCC before TEMC by the order of para 1, item 2. In this case the term shall start from the receiving of the decision of the regional council.

(8) The decision of the repeated expertise can be appealed by the order of para 1, item 2.

(9) (new " SG 41/09, in force from 01.07.2009) Appealing under the provisions of par. 1 " 8 of the expert decisions for permanently reduced ability to work/ type and degree of disability of the bodies of medical expertise shall not suspend their enforcement. In case of appealing, if NEMC pronounces a decision after the three-month period, which determines a reduced ability to work, type and degree of disability, resulting in a reduction of the initially determined compensation, the certified person shall not refund the received amount in excess.

(10) (new " SG 59/10, in force from 31.07.2010) The procedure under Para 1, Items 2, 3 and 4, Para 2-8 shall apply to appealing expert decisions under Art. 103, Para 3 by the interested persons and the investigation and judicial authorities.

(11) (new - SG 98/16, in force from 01.01.2017) For National Social Security Institute the term under para 1, item 1 shall start upon submission of the data, contained in the issued sick leave certificates according to the Ordinance of the order of presentation to the National Social Security Institute the data, contained in the issued sick leave certificates and the decisions on their appeal (SG 67/14), but not before the presentation of certificates under Art. 8, para. 1 and Art. 11, para. 1 of the Ordinance of reimbursement and support from state public insurance (prom. - SG 57/15; amend. " SG 17/16).

Art. 112a. (new " SG 98/10, in force from 01.01.2011; amend. " SG 40/12, amend. - SG 85/17, suppl. - 103/20, in force from 04.12.2020) The notification of

the decisions of TEMC and NEMC to the interested organisations – NII, NHIF, The Social Aid Agency, the Agency for the People with Disabilities and the working ability medical examination authorities shall be carried out electronically under the conditions and order set out in the Electronic Document and Electronic Trust Services Act and the Electronic Government Act, while the certified person and the insurers shall be notified by a letter with acknowledgement of receipt or electronically under the terms and conditions of the Electronic Document and Electronic Trust Services Act and the Electronic Government Act.

Art. 113. (1) The bodies of the medical expertise can also on their own initiative revoke or change incorrect decisions of lower bodies as well as to return their decisions for removal of mistakes or incompleteness in three months term after decreeing them.

(2) The chief of NEMM can order reconsidering of incorrect or contradictory decisions of its teams in three months term after issuing them.

(3) The decisions of the bodies of medical expertise, which are not appealed or the order for appealing them has been exhausted, shall be obligatory for all persons, bodies and organisations in the country.

## **Section V.**

### **Medical ensuring at disasters, accidents and catastrophes**

Art. 114. (1) (amend. – SG 98/10, in force from 01.01.2011) The management, the organisation and the resource ensuring of the health care at disasters, accidents and catastrophes shall be implemented by the Minister of Health, the chief state health inspector, the director of NCRRP, the directors of the regional health inspections, the medical and the health establishments.

(2) (amend. – SG 102/06; amend. – SG 102/08; amend. - SG 93/09, in force from 25.12.2009) The bodies of para 1 shall conduct the activity for the medical ensuring at disasters, accidents and catastrophes in close interaction with the bodies of the central and the local power, with Ministry of Interior, with the non-government organisations and with the Bulgarian Red Cross.

Art. 115. (1) The Minister of Health shall develop plans for medical ensuring at disasters, accidents and catastrophes, which shall be approved by the Council of Ministers.

(2) On the basis of the action plans at disasters, accidents and catastrophes, approved by the Council of Ministers, the bodies of Art. 114, para 1, shall:

1. create the necessary conditions for medical sorting, primary processing, treatment, rehabilitation and medical expertise of the damaged;
2. form and prepare bodies for management and teams for medical care;
3. ensure the protection of the stationary ill and the medical staff from external factors;

4. organise and implement anti-epidemic and hygienic activities and sanitary control on the affected territory;

5. form stocks for resource ensuring of the medical activities;

6. organise the continuing training of the medical specialists and the population in rendering medical care upon disasters, accidents and catastrophes.

(3) (amend. " SG 15/12, in force from 01.01.2014) The financial ensuring of the health care at disasters, accidents and catastrophes shall be implemented from the state budget.

Art. 116. (1) (amend. and suppl. " SG 98/10, in force from 01.01.2011) For implementing the medical ensuring at disasters, accidents and catastrophes at the director of the regional health inspection shall be created council for medical ensuring at disasters, accidents and catastrophes. The director of the regional health inspection shall be chairman of the council.

(2) (amend. " SG 98/10, in force from 01.01.2011) The council of para 1 shall include one representative of the regional health inspection, the directors of medical establishments for hospital care, of the centre for emergency medical care and representatives of the regional administration and of the municipalities in the respective region.

(3) The council of para 1 shall approve the action plans and the programmes for training of the medical teams, working in the conditions of disasters, accidents and catastrophes.

## **Section VI.**

### **Control over medical services (new " SG 41/09, in force from 02.06.2009, revoked - SG 102/18, in force from 01.04.2019)**

Art. 116a. (new " SG 41/09, in force from 02.06.2009, revoked - SG 102/18, in force from 01.04.2019)

Art. 116b. (1) (new " SG 41/09, in force from 02.06.2009; prev. text of Art. 116b, amend. " SG 101/09, in force from 01.01.2010, revoked - SG 102/18, in force from 01.04.2019)

Art. 116c. (new " SG 41/09, in force from 02.06.2009; amend. " SG 101/09, in force from 01.01.2010, revoked - SG 102/18, in force from 01.04.2019)

Art. 116d. (new " SG 41/09, in force from 02.06.2009, revoked - SG 102/18, in force from 01.04.2019)

Art. 116e. (new " SG 41/09, in force from 02.06.2009) (1) (amend. " SG 101/09, in force from 01.01.2010, revoked - SG 102/18, in force from 01.04.2019)

Art. 116f. (new " SG 41/09, in force from 02.06.2009, revoked - SG 102/18, in force from 01.04.2019)

**Chapter four.**  
**NATIONAL SYSTEM OF HEALTH CARE**

**Section I.**  
**Health protection of children**

Art. 117. The state and the municipalities, the corporate bodies and the individuals shall create conditions for healthy living environment and normal physical and psychic development of children.

Art. 118. (1) For supporting the family in bringing up children up to three years of age and for ensuring their normal physical and psychic development creches and children's kitchens shall be created.

(2) The creches shall be organisationally detached structures, in which there are medical and other specialists implement bringing up, training and education of children from three months to three years of age.

(3) The children's kitchens are organisationally detached structures, in which there are medical and other specialists prepare, preserve and concede food for children up to three years of age.

(4) The requirements to the structure and the activity of the creches and the children's kitchens as well as the norms for healthy feeding of the children up to three years of age shall be determined with an ordinance by the Minister of Health.

Art. 119. (1) The creches and the children's kitchens can be created by the municipalities, by individuals and corporate bodies.

(2) (new " SG 110/08, in force from 01.01.2009; amend. " SG 98/10, in force from 01.01.2011) Municipal creches and children's kitchens shall be created, transformed and closed according to order of the mayor of municipality upon decision of the municipal council and consent of the director of the corresponding regional health inspection.

(3) (prev. text of Para 02 " SG 110/08, in force from 01.01.2009) The maintenance of the children in the municipal creches and the activity of the municipal children's kitchens shall be supported by the respective municipal budget.

(4) (prev. text of Para 03 " SG 110/08, in force from 01.01.2009, amend. - SG 17/22, in force from 01.04.2022) For receiving children's food from the municipal children's kitchens the parents and the guardians shall pay fees in amounts, determined by the municipal council in compliance with the Local Taxes and Fees Act.

Art. 120. (amend. " SG 95/07, in force from 01.01.2008) (1) (amend. - SG 24/19, in force from 01.07.2020, amend. on entry into force - SG 101/19) The health offices in the kindergartens and the schools shall implement activities for:

1. medical services rendering first medical aid to children and school students and medical services until the arrival of a specialized team of emergency call service;

2. (new - SG 98/16, in force from 01.01.2017) support the monitoring and treatment of children with chronic diseases prescribed by a doctor from the hospital that

performs dispensary observation of relevant chronic disease, determined in the ordinance under Art. 30, Para. 3;

3. (prev. para 2 - SG 98/16, in force from 01.01.2017) promotion and prevention of children's and school students' health;

4. (prev. para 3 - SG 98/16, in force from 01.01.2017, amend. - SG 24/19, in force from 01.07.2020, amend. on entry into force - SG 101/19) organizing and carrying out activities for prevention of occurrence and for limitation of propagation of contagious and parasitic diseases in kindergartens and schools;

5. (prev. para 4 - SG 98/16, in force from 01.01.2017) participation in preparation, performance and control of various forms of recreation, tourism and sport for children and school students;

6. (prev. para 5 - SG 98/16, in force from 01.01.2017, amend. and suppl. "SG 58/19) organization and implementation of programs of health education of children and school students, of specialized programs of healthy feeding, of programs for prevention of abnormalities in food-related behaviour, for prevention from use of drugs and psychotropic substances, for prevention of the use of tobacco and related products and alcoholic drinks, and for development of sexual culture;

7. (prev. para 6 - SG 98/16, in force from 01.01.2017, amend. - SG 24/19, in force from 01.07.2020, amend. on entry into force - SG 101/19) coordination of the weekly schedule of lessons with the head of the kindergarten and school.

(2) (amend. "SG 98/10, in force from 01.01.2011) The activities of par. 1 shall be carried out with a frequency and shall be implemented by persons, having accomplished a higher education in "Medicine" and/or having obtained a qualification of a "medical doctor" and by other medical specialists having obtained educational and qualification degree of a "bachelor" pursuant to Art. 42, par. 1, item 1 of the Higher Education Act in compliance with standards, set by the ordinance referred to in Art. 26, par. 2. The ordinance sets also the rights, obligations and responsibilities of medical doctors and medical specialists, practicing in health offices of par. 1.

(3) (amend. "SG 41/09, in force from 02.06.2009; amend. "SG 98/10, in force from 01.01.2011, amend. - SG 24/19, in force from 01.07.2020, amend. on entry into force - SG 101/19) Medical doctors, respectively medical specialists shall keep forms of reports and records and shall systematize the information from the dental medicine doctor on the process of prophylaxis and treatment relating to the dental status of children and school students in kindergartens and schools.

(4) (amend. - SG 24/19, in force from 01.07.2020, amend. on entry into force - SG 101/19) Medical doctors and medical specialists of par. 2 work under an employment contract, concluded with the mayor of the respective municipality, in the territory of which kindergartens and schools are located, or with the person, having obtained a permit for establishing a private kindergarten or private school.

(5) (amend. "SG 99/09, in force from 01.01.2010, amend. - SG 24/19, in force from 01.07.2020, amend. on entry into force - SG 101/19) Financing of the activities of health offices in municipal and state schools and in municipal and state kindergartens shall be implemented with funds from the municipal budgets as delegated by the state activity. Financing of the activities of health offices in private kindergartens and schools shall be provided by their owner.

(6) (amend. â€“ SG 41/09, in force from 02.06.2009; amend. â€“ SG 98/10, in force from 01.01.2011) The control over the activity, carried out by the health offices shall be implemented by the respective regional health inspection.

Art. 121. Upon newly discovered disease or deviation in the development of the child the specialists from the health offices shall be obliged to notify the parents, the guardians or the trustees and the general practice doctor of the child.

Art. 122. (1) Within the framework of the approved study plans shall be ensured training of the students in:

1. personal hygiene;
2. healthy feeding;
3. healthy living environment;
4. healthy way of life;
5. protection from infectious diseases;
6. (amend. â€“ SG 58/19) health risks while using tobacco and related products, alcohol and narcotic substances;
7. sexual conduct, protection from sexually transferred diseases and AIDS and protection from unwanted pregnancy;
8. first aid for injured.

(2) (amend. - SG 74/09, in force from 15.09.2009; amend. â€“ SG 68/13, in force from 02.08;2013) The training of the lecturers in the issues of para 1 shall be organised by the Minister of Education and Science according to study programmes, coordinated with the Minister of Health.

(3) The school boards of trustees shall organise measures for acquainting the parents with the problems of children's health.

Art. 123. (1) (amend. - SG 24/19, in force from 01.07.2020, amend. on entry into force - SG 101/19) For ensuring prophylactic medical and stomatological aid to the children and the students in the creches, the kindergartens, the schools and social and integrated health and social services for residential care for children once in the year shall be required documents for carried out examinations or prophylactic medical and stomatological examinations shall be implemented.

(2) The conditions and the order for conducting the prophylactic examinations of para 1 shall be determined with an ordinance by the Minister of Health.

(3) The activities of para 1 shall be financed by NHIF.

Art. 124. (1) (Revoked - SG 24/19, in force from 31.12.2022, amend. regarding entry into force - SG 8/22, in force from 01.01.2022)

(2) (amend. - SG 74/09, in force from 15.09.2009; amend. â€“ SG 68/13, in force from 02.08;2013, amend. - SG 24/19, in force from 01.07.2020, amend. on entry into force - SG 101/19) The stomatological treatment, out of the scope of the National framework agreement, of the children from the institutions for children, opened by the Ministry of Education and Science, the Ministry of Interior and the Ministry of Justice, as

well as by the social and integrated health and social services for residential care for children, managed by the municipalities, shall be paid by the respective departments.

**Edition to SG, 110/29 Dec 2020**

*Art. 124. (1) (revoked - SG 24/19, in force from 31.12.2021)  
(2) (amend. - SG 74/09, in force from 15.09.2009; amend. " SG 68/13, in force from 02.08;2013, amend. - SG 24/19, in force from 01.07.2020, amend. on entry into force - SG 101/19) The stomatological treatment, out of the scope of the National framework agreement, of the children from the institutions for children, opened by the Ministry of Education and Science, the Ministry of Interior and the Ministry of Justice, as well as by the social and integrated health and social services for residential care for children, managed by the municipalities, shall be paid by the respective departments.*

Art. 125. For ensuring additional or specialised medical servicing of the children the establishments of art. 123, para 1 can conclude contract with medical establishment for off hospital care.

Art. 125a. (new " SG 41/09, in force from 02.06.2009) (1) Medical specialists shall be obliged to notify the Directorate "Social support" at the place of location of the medical establishment of every child, delivered in the medical establishment, for whom a risk of being left is existing, including where documents of mother's identity are missing at the time of delivery of the child, in case of a single mother, a mother of many children, a mother with serious or multiple diseases.

(2) Medical specialists, working in medical establishments or in health consulting rooms, shall be obliged to notify the bodies of the Ministry of Interior and the Directorate "Social support" of each child, admitted to the medical establishment or having visited the health consulting room, which a victim of harassment.

**Section I "a".**

**Integrated Health and Social Services (new - SG 72/15, revoked - SG 24/19, in force from 01.07.2020, amend. on entry into force - SG 101/19)**

Art. 125b. (new - SG 72/15, revoked - SG 24/19, in force from 01.07.2020, amend. on entry into force - SG 101/19)

Art. 125c. (new - SG 72/15, revoked - SG 24/19, in force from 01.07.2020, amend. on entry into force - SG 101/19)

Art. 125d. (new - SG 72/15, revoked - SG 24/19, in force from 01.07.2020, amend. on entry into force - SG 101/19)

**Section II.  
Reproductive health**

Art. 126. (1) The state shall ensure health protection of the reproductive health of the citizens through:

1. promotion and consultations for preservation of the reproductive health of children and persons in reproductive age;
2. ensuring of access to specialised consultative assistance on the issues of reproductive health and family planning;
3. prophylactics and treatment of sterility;
4. specialised information, consultations, prophylactics and treatment of the sexually transferred diseases and AIDS;
5. prophylactics, treatment and dispensary observation of persons with malignant diseases of the reproductive system.

(2) Anyone shall have right to information and freedom of decision about his reproductive health.

Art. 127. (1) For ensuring risk free motherhood each woman shall have right to access to health activities, directed to ensuring optimal health status of the woman and the foetus from occurrence of the pregnancy till rounding of 42 days age of the child.

(2) The health activities of para 1 shall include:

1. promotion, directed to preservation of the health of the woman and the foetus;
2. prophylactics of the danger from abortion and premature birth;
3. training in feeding and care of the newly born;
4. active medical observation of the pregnancy, implemented on dispensary principle by the medical establishments for primary and specialised off hospital care;
5. the prenatal diagnostics and prophylactics of genetic and other diseases under conditions and by order, determined with ordinance of the Minister of Health;
6. ensuring of optimal living environment for the women in childbed and the newly born;
7. dispensary observation and health cares for the woman in childbed and the child;
8. free access of the pregnant woman or the woman in childbed to medical establishments for specialised off hospital care;
9. free access of the pregnant woman to medical establishments for specialised off hospital and hospital care upon statuses, threatening the pregnancy;
10. right to choice for the pregnant woman of medical establishment for hospital care for childbirth.

Art. 128. (1) The conditions and the order for implementing artificial abortion and the criteria for viability of the foetus shall be determined with ordinance by the Minister of Health.

(2) With the ordinance of para 1 shall be determined also the obligations of the medical specialists upon doubt for abortion, made out of the conditions and the order of this Act.

(3) Permanent divesting of the ability for reproduction shall be implemented under conditions and by order, determined with ordinance by the Minister of Health.

### **Section III. Assisted reproduction**

Art. 129. The assisted reproduction shall be applied when the status of the man or the woman does not allow accomplishing of their reproductive functions in natural way.

Art. 130. (1) The assisted reproduction shall be implemented after receiving written informed consent by the persons, willing to create generation.

(2) The assisted reproduction shall be implemented after conducting medical investigations, guaranteeing the health of the generation.

(3) (amend. - SG 71/06, in force from 01.01.2007) The assisted reproduction shall be implemented according to the medical standard adopted by an Ordinance of the Minister of Health.

(4) (new - SG 71/06, in force from 01.01.2007) The assisted reproduction shall include the activities related to:

1. use of medical methods for fertilization of the ovum located inside or outside the body of the woman;

2. (suppl. " SG 36/09) procurement, expertise, processing, labelling, provision, transportation and storage of ova, spermatozoids and zygotes;

3. procurement of an ovum from a woman and placing it in the body of the same woman;

4. procurement of an ovum from a woman and placing it in the body of another woman.

(5) (new - SG 71/06, in force from 01.01.2007) Procurement of ova from a donor in the cases referred to in Para 4, Item 4 may be carried out if the following conditions are met:

1. (amend. - SG 67/20) the donor is of full legal age, is not placed under guardianship and meets the criteria set out in the medical standard under Para. 3 which guarantee the safety of the donor and the quality of the ova;

2. written consent of the donor was obtained, certified by a notary in whose area of activity is located the medical establishment which shall perform the procurement;

3. the donor was informed in intelligible language of the risks he undertakes;

4. the physical and psychical health of the donor was confirmed in a protocol signed by the members of a commission appointed by the Director of the medical establishment performing the procurement and consisting of at least three physicians who do not participate in the team of procurement.

(6) (new - SG 71/06, in force from 01.01.2007; amend. " SG 36/09, amend. - SG 102/18, in force from 01.04.2019)) The medical establishments shall be obliged annually to prepare a report on the performed activities referred to in Para 4 according to a sample approved with the Ordinance referred to in Art. 131, Para 7 and to present it before the Executive Agency for Medical Supervision.

(7) (new - SG 71/06, in force from 01.01.2007) It shall be prohibited to offer material profit to a donor of ova or spermatozoids as well as to receive material profit from the donor.

Art. 131. (amend. - SG 71/06, in force from 01.01.2007, amend. " SG 36/09, amend. - SG 102/18, in force from 01.04.2019) (1) The assisted reproduction as well as the provision, the use and the storage of human ova, spermatozoids and zygotes shall be performed by:

1. medical establishments for hospital care, which have been granted permission under Art. 48, para. 1 of the Medical Establishments Act, in which the respective activities are explicitly indicated;

2. medical establishments for outpatient care, registered under the procedure of Art. 40 of the Medical Establishments Act, in which certificate of registration the respective activities are indicated;

3. medical establishments at the Council of Ministers, the Ministry of Defense, the Ministry of Interior and the Ministry of Transport, Information Technology and Communications upon receipt of a certificate from the Minister of Health, upon a proposal of the Executive Director of the Executive Agency for Medical Supervision, that the medical establishment meets the requirements of the medical standard for assisted reproduction, which explicitly indicates the relevant activities.

(2) On the proposal of the Executive Director of the Executive Agency for Medical Supervision, the Minister of Health may, by order, stop an assisted reproduction activity for a period of up to 6 months, if the medical establishment fails to meet the requirements of the medical standard for assisted reproduction.

(3) Where, after the expiration of the term under para. 2 the medical establishment continued to fail to meet the requirements of the medical standard for assisted reproduction, the Minister of Health, on a proposal from the Executive Director of the Executive Agency for Medical Supervision, may by order:

1. withdraw the permit for medical activity, in the part regarding the implementation of assisted reproduction and provision, use and storage of human ova, sperm and zygote - for the medical establishments under par. 1, item 1;

2. delete from the registration of the medical establishments under para. 1, item 2 the activities of performing assisted reproduction and providing, using and storing human ova, sperm and zygotes;

3. withdraw the certificate of the medical establishments under par. 1, item 3, by informing the respective primary budget spending unit, to which the director of the establishment is a secondary budget spending unit.

(4) The Minister of Health may, by an order, apply the measures under para. 3 and when the medical establishment operates in violation of this Act and the secondary legislation for its implementation or performs assisted reproduction activities other than those for which the permit, respectively the certificate is issued.

(5) The orders under para. 2, 3 and 4 are subject to appeal before the relevant administrative court under the Administrative Procedure Code.

(6) The medical institutions carry out all medical activities related to the study, preparation and continuous monitoring of the persons undergoing assisted reproduction as well as controlling their health status until the birth of the fetus.

(7) The conditions and procedure for taking, placing, examining, processing, labeling and storing ova, sperm or zygotes for the purposes of assisted reproduction as well as the materials and products coming into contact with them and their tracking from

the donor to the recipient shall be determined by an ordinance of the Minister of Health and shall be controlled by the Executive Agency for Medical Supervision.

Art. 131a. (new " SG 36/09) (1) (amend. - SG 102/18, in force from 01.04.2019) In fulfillment of its powers under Art. 131, par. 7, the Executive Agency for Medical Supervision shall:

1. register, keep and analyze the information related to donor's data, recipient's health status, serious adverse reactions and serious incidents, related to the assisted reproduction

2. study and analyze medical, legal, ethical, religious, economic and social consequences of the assisted reproduction;

3. control the activities for provision of quality and safety when carrying out assisted reproduction;

4. every three year prepare a report to the European Commission on the accomplished in the Republic of Bulgaria activities for promotion and encouragement of the voluntary and free donorship of ova, spermatozoids and zygotes, the control and carried inspections.

(2) (amend. - SG 102/18, in force from 01.04.2019) The Executive Agency for Medical Supervision shall participate in the development of national strategies and programs, international projects, analyses and forecasts on the assisted reproduction.

(3) (amend. - SG 102/18, in force from 01.04.2019) The Executive Agency for Medical Supervision shall produce and maintain:

1. a public register;

2. an internal office register.

(4) The particulars and data, to be entered into the registers under par. 1, the procedure of entering and use of the information shall be set forth in an ordinance of the Minister of Health.

(5) The data contained in the public register shall be accessible for use by all persons under the terms and conditions and following the procedure of the Access to Public Information Act.

(6) The data contained in the internal office register shall be kept for a period of 30 years.

(7) Health related information contained in the internal office register shall be provided according to the provisions of Art. 28 of the Health Act.

Art. 132. (1) (amend. - SG 71/06, in force from 01.01.2007) The medical establishments referred to in Art. 131, Para 1 shall create and keep a register including:

1. data on each performed procurement, expertise, processing, fertilization, labelling and storage of ova, spermatozoids or zygotes;

2. the three names, unified civil number, permanent address and unique identification number of the persons from whom ova or spermatozoids are taken;

3. unique identification number of the taken ova, spermatozoids or zygotes related to the number referred to in Item 2;

4. the three names, unified civil number, permanent address and unique identification number of the woman to whom ova, spermatozoids or zygotes were placed related to the number referred to in Item 3.

(2) The dissemination of data, which can serve for identification of the donors or the recipients of ova or spermatozoids when the donor is a person, different from the man or the woman, willing to create generation, shall be prohibited except in the cases, provided with a law.

(3) The data from the register of para 1 shall be official information and they shall be preserved for 30 years.

(4) (amend. - SG 71/06, in force from 01.01.2007; amend. " SG 36/09, amend. - SG 102/18, in force from 01.04.2019) The order for registration, processing, storage and conceding of the information from the register of Para 1 shall be determined by the ordinance of art. 131, Para 7.

Art. 132a. (new - SG 71/06, in force from 01.01.2007) (1) (amend. - SG 102/18, in force from 01.04.2019) The medical establishments referred to in Art. 131, Para 1 shall be obliged to notify the Executive Agency for Medical Supervision within a term of 7 days from finding of all serious adverse reactions or serious incidents resulting from procurement, placement, expertise, processing, labelling and storage of ova, spermatozoids or zygotes and related to their quality and safety.

(2) The medical establishments referred to in Art. 131, Para 1 shall be obliged to create and implement a system of immediate blocking, extraction and destruction of all ova, spermatozoids or zygotes which may lead to a serious adverse reaction or a serious incident.

(3) The conditions and the order of notification, registration, reporting and conceding of information on the serious adverse reactions and the serious incidents and on blocking, extraction and destruction of ova, spermatozoids or zygotes shall be determined by an ordinance of the Minister of Health.

Art. 132b. (new - SG 71/06, in force from 01.01.2007) (1) The medical establishments shall be obliged to label the taken ova, spermatozoids and zygotes.

(2) (amend. " SG 36/09, amend. - SG 102/18, in force from 01.04.2019) The medical establishments referred to in Art. 131, Para 1 shall be obliged to provide conditions for tracing the ova, spermatozoids and zygotes as well as the products and materials coming into contact with them and related to their quality and safety under conditions and order determined by the Ordinance referred to in Art. 131, Para 7.

Art. 133. Artificial insemination of ovum with spermatozoids from a donor, who is in blood relation in direct line and in lateral line up to fourth degree with the woman, by whom is the ovum, shall not be admitted. The circumstance shall be established with written declaration by the persons, willing to create generation.

Art. 134. (1) (new - SG 71/06, in force from 01.01.2007; amend. " SG 36/09) Export and import of ova, spermatozoids and zygotes shall be carried out under the conditions and order referred to in Art. 37 and Art. 38 of the Transplantation of Organs, Tissues and Cells Act.

(2) (prev. text of Art. 134 - SG 71/06, in force from 01.01.2007) Ova, spermatozoids and fertile ova, which are not used for creating of generation, can be

conceded to scientific, educational and medical establishments in the country and abroad for medical, scientific and educational purposes after receiving written informed consent by the donor and upon fertile ovum - by both of the donors, by an order, determined with an ordinance by the Minister of Health.

Art. 135. (1) The use of techniques for assisted reproduction with purpose selection of the sex of the generation, except in the cases when inherited diseases, connected with the sex, must be prevented, shall be prohibited.

(2) The use of techniques for assisted reproduction, aiming transfer of genetic information only from one individual in his generation shall be prohibited.

(3) The reproductive cloning of people, including with purpose donation of organs, tissues and cells, shall be prohibited.

(4) Intervention, directed to modification of the human genome, can be undertaken only with prophylactic or healing purpose but not for introduction of modification in the genome of the generation.

Art. 136. each form of discrimination against a person, based on his genome, shall be prohibited.

#### **Section IV. Genetic health and genetic investigations**

Art. 137. The preservation of the genetic health shall be ensured by conducting health activities, directed to:

1. prophylactic and diagnostic investigations for proving and classification of genetic diseases;
2. dispensary system for the persons with increased risk of occurrence and development of genetic diseases;
3. healing of inherited diseases, innate anomalies and predisposition;
4. establishing of inherited characteristics and identification of parent;
5. preservation of genetic information.

Art. 138. Prophylactic genetic investigations shall be implemented for:

1. determining the risk of occurrence of genetic disease in the generation;
2. identification of clinically healthy carriers of genetic deviations;
3. diagnostics of inherited and other diseases in the periods before and during the pregnancy and after the childbirth.

Art. 139. (1) The genetic investigations in the period before the childbirth shall be implemented upon proven risk for transfer of genetic disease in the generation.

(2) The investigations of para 1 shall be implemented under the control of a doctor and they shall include:

1. proving of genetic deviations of clinically healthy and of ill parents;
2. establishing of predisposition for to genetic disease;

3. establishing of genetic deviations, occurred due to the way of life or the external environment;
4. proving of genetic diseases at their clinical manifestation.

Art. 140. For establishing the kind and the frequency of the genetic deviations and determining the genetic fund by national health programmes purposed investigations shall be carried out.

Art. 141. (1) Genetic investigations and taking of biological material for genetic investigations for medical or scientific purposes shall be conducted only after receiving of written informed consent by the investigated persons.

(2) Genetic investigations of children, persons with psychic disorders and persons under interdict, shall be implemented also after permission by the commission in medical ethics at the respective medical establishment.

(3) The results from conducted genetic investigations and screening cannot be basis for discrimination of the investigated persons.

(4) The data about the human genome of the persons shall be personal data and they cannot be conceded to employers, health insuring organisations and insurance companies.

Art. 142. (1) genetic investigations for medical or scientific purposes shall be implemented by accredited:

1. genetic laboratories at medical establishments for hospital care;
2. genetic laboratories at medical establishments for off hospital care;
3. independent laboratories.

(2) The Minister of Health shall determine with an order National genetic laboratory.

(3) The laboratory of para 2 shall implement methodical guidance and control over the activity of the genetic laboratories.

(4) The National genetic laboratory shall create and maintain national genetic register.

(5) The conditions and the order for work of the National genetic laboratory and the register of para 4 shall be determined with ordinance by the Minister of Health.

Art. 143. (1) The medical establishments of art. 142, para 1, shall inform every month the National genetic laboratory about the conducted genetic investigations and the results from them.

(2) The medical establishments of para 1 shall create and maintain official register of the investigations, implemented by them.

(3) The structure of the laboratories of para 1 shall be provided with regulation, issued by the Minister of Health and their activity as well as the order for registration, preservation, processing and access to information in the register shall be provided with the ordinance of art. 142, para 5.

Art. 144. (1) The genetic laboratories at the medical establishments can create DNA banks for taking and preservation of genetic material for scientific and medical purposes.

(2) The medical establishments of para 1 shall register in 7 days term the DNA banks, created by them, at the Ministry of Health under conditions and by order, determined with the ordinance of art. 142, para 5.

Art. 144a. (new " SG 1/14, in force from 03.01.2014) (1) For the determination of the type and the frequency of rare diseases and for the purposes of scheduling and provision of preventive, diagnostic and therapeutic activities, related to rare diseases, a national register of patients with rare diseases shall be produced.

(2) The terms and conditions and the procedure or registration of rare diseases shall be determined by an Ordinance of the Minister of Health.

(3) The terms and conditions and the criteria to health care establishments wishing to participate in the European reference networks shall be determined by the ordinance referred to in par. 2, as well as the procedure of establishment, indication and functioning of rare diseases expert centers and reference networks.

## **Chapter five. PSYCHIC HEALTH**

### **Section I. Protection of the psychic health**

Art. 145. (1) The state, the municipalities and the non government organisations shall organise activities for protection of the psychic health, connected with:

1. ensuring for the persons with psychic disorders accessible and high quality medical care, cares and support, necessary for their life in the family and in the community;
2. (amend. - SG 24/19, in force from 01.07.2020, amend. on entry into force - SG 101/19) protection of the psychic health in the risk groups: children, students, aged people, persons, accommodated in social and integrated health and social services for residential care, military servicemen, detained and deprived from liberty;
3. active prophylactics of the psychic disorders;
4. support of the public initiatives in the field of the psychic health care;
5. specialised continuing education of the persons, who implement activities for protection of the psychic health;
6. fulfilment of programmes for training in strengthening and protection of the psychic health of the persons, who teach, implement medical activity, social adaptation, organisation and management, protection of public order;
7. scientific applied studies, directed to strengthening of psychic health;
8. public awareness on the problems of psychic health.

(2) The municipalities shall ensure conditions for conducting of psychic - social rehabilitation and for support with financial and material means, including conceding abodes to the persons with psychic disorders.

Art. 146. (1) Persons with psychic disorders, in need of special health care, shall be:

1. mentally ill with established serious disorder of the psychic functions (psychosis or grave personality disorder) or with expressed durable psychic damage as result of psychic disease;

2. person with moderate, grave or deep mental retarding or vascular and senile dementia;

3. persons with other disorders of the psychic functions, difficulties in education and troubles in adaptation, requiring medical help, care and support, in order to live adequately in family and in social environment.

(2) Each person with psychic disorder shall enjoy treatment and care under conditions, equal with the conditions of the patients with other diseases.

Art. 147. (1) Nobody can be subject to medical activities for establishing or treatment of psychic disorder except under conditions and by order, determined with a law.

(2) The assessment of existence of psychic disorder cannot be based on family, professional or other conflicts as well as on data about psychic disorder, suffered in the past.

Art. 147a. (new " SG 41/09, in force from 02.06.2009) (1) The Ministry of Health shall generate and maintain a National Register of the persons with mental diseases. The procedure and the terms and conditions of maintenance and use of information from the register shall be determined by an ordinance of the Minister of Health.

(2) The procedure and the terms and conditions for official exchange of information on persons with mental disorders, applying for operating with general hazardous means, shall be determined by an ordinance of the Minister of Health in coordination with the Minister of Interior subject to compliance with the confidentiality requirements.

Art. 148. Basic principles at the treatment of persons with psychic disorders shall be:

1. minimum restriction of the personal freedom and respect of the rights of the patient;

2. reduction of the institutional dependence of the persons with psychic disorders on durable hospital treatment under the condition that this does not contradict with the approved medical standards;

3. creating of wide network of specialised establishments for off hospital psychiatric care and priority of the care in the family and in the social environment;

4. integration and equality of the psychiatric care with the other medical directions;

5. observing of the humanitarian principles and norms at implementing the healing process and social adaptation;

6. stimulation of self-help and mutual help and ensuring active public and professional support for the persons with psychic disorders;

7. specialised training, professional training and re-qualification of the persons with psychic disorders with objective their social adaptation;

8. participation of humanitarian non government organisations in the process of treatment and social adaptation.

Art. 149. (1) (amend. â€“ SG 59/10, in force from 31.07.2010) The treatment of the persons with psychic disorders shall be implemented by medical establishments for primary or specialised off hospital care, medical establishments for stationary psychiatric care, mental health centres, specialised divisions at the multi-profiled hospitals and homes for medical - social care.

(2) The medical activities, connected with the treatment of persons with psychic disorder, shall include diagnostic investigations, medicated and instrumental methods of treatment and psychotherapy. The conditions and the way for their conducting shall be determined with an ordinance by the Minister of Health.

(3) The use of surgery methods for change in the morphology of the central nervous system with objective achievement of defined psychic characteristics shall be prohibited.

Art. 150. (1) For patients with established psychic disorders, fallen into status, being direct and immediate danger for their own health or life or for the health and the life of other persons, can be applied measures for temporary physical restriction.

(2) The measures of para 1 shall be applied only as prerequisite for creating conditions for conducting the treatment and they do not substitute the active treatment.

(3) The undertaking of measures for physical restriction shall be ordered by a doctor, who defines the kind of the measure and the term for its application. This term cannot be longer than 6 hours.

(4) The measures of para 1 shall be implemented by staff, trained for this in advance.

(5) The kind of the undertaken measures for physical restriction, the reasons, imposed this, the term for their application, the name of the doctor, who has ordered them and the applied drug treatment shall be entered into special book of the medical establishment and in the history of the disease.

(6) The person, towards who have been undertaken measures for physical restriction, must be under constant observation by doctor or nurse.

(7) The kind and method of applying the measures for physical restriction shall be based on approved medical standards

(8) The order for applying measures for physical restriction shall be provided with ordinance by the Minister of Health together with the Minister of Justice.

Art. 151. (1) The labour therapy of the persons with psychic disorder shall be part of the psycho - social rehabilitation programmes.

(2) At conducting the labour therapy shall be inadmissible any for of exploitation and compulsory character of the labour.

(3) The activities for the organisation of the production, the conditions for exercising labour and the way for payment of remuneration for the work shall be provided

with ordinance by the Minister of Health in coordination with the Minister of Labour and Social Policy and the Minister of Finance.

Art. 152. (1) (amend. - SG 24/19, in force from 01.07.2020, amend. on entry into force - SG 101/19) In the social and integrated health and social services for residential care for more than 20 persons with psychic disorders shall be created health offices, in which shall work doctor, medical officer or nurse.

(2) The health offices shall implement activities for:

1. permanent medical observation;
2. rendering of first medical aid;
3. control over the hygiene status of the persons;
4. current control for observing the hygiene requirements;
5. preparing and maintenance of medical documentation for each person.

Art. 153. (1) The emergency psychiatric care shall be combination of medical rules and activities, which shall be applied towards persons with obvious characteristics of psychic disorder when their behaviour or status represents direct and immediate danger for their own health or life or for the health or the life of other persons.

(2) (amend. " SG 59/10, in force from 31.07.2010) Emergency psychiatric care shall be rendered by the mental health centres, the medical establishments for stationary medical care, the psychiatric divisions of clinics at the multi-profile hospitals and the centres for emergency medical care.

(3) Urgent psychiatric care shall be rendered according to the approved medical standards.

Art. 154. (1) When the status of a person of art. 146, para 1, items 1 and 2 imposes continuation of the treatment after coping with the emergency status the chief of the medical establishment shall take decision the person to be accommodated temporary for treatment for a term not longer than 24 hours, notifying immediately the relatives of the patient about this.

(2) As exception the term of para 1 may be extended one time with not more than 48 hours with permission by the district judge.

(3) At need decision to be taken for conducting of compulsory treatment the chief of the medical establishment shall immediately submit to the court motivated request for this, accompanied by statement about the psychic status of the person, prepared by a psychiatrist.

## **Section II.**

### **Compulsory accommodation and treatment**

Art. 155. The persons of art. 146, para 1, items 1 and 2, who due to their disease can commit a crime, which represents danger for their relatives, for the people around, for the society or threatens seriously their health, shall be subject to compulsory accommodation and treatment.

Art. 156. (1) The compulsory accommodation and treatment of the persons of art. 155 shall be decreed with decision by the district court at the present address of the person and in the cases of art. 154 - by the district court at the location of the medical establishment.

(2) (amend. " SG 59/10, in force from 31.07.2010) The compulsory accommodation and treatment shall be implemented in medical establishments for stationary psychiatric care and mental health centres, in psychiatric divisions or clinics of the multi-profile hospitals and in medical establishments for specialised psychiatric off hospital care.

Art. 157. The compulsory accommodation and treatment can be required by the prosecutor and in the cases of art. 154, para 3 - also by the chief of the medical establishment.

Art. 158. (1) The court shall send copies of the request for compulsory accommodation and treatment of the person, which accommodation will be considered. The person can in 7 days term make objection and point out evidences.

(2) The court shall consider the case in open session with the participation of the person in 14 days term after receiving of the request.

(3) When permission is given by the district judge by the order of art. 154, para 2, the court shall consider the case immediately and in this case para 1 shall not be applied. The copies shall be delivered at the court session and the chief of the medical establishment shall ensure the appearance of the person.

(4) The participation of psychiatrist, defender and prosecutor shall be obligatory.

(5) (Suppl. - SG 110/20, in force from 30.06.2021) The person, whose accommodation is required, must be interrogated personally and if need occurs, he shall be brought compulsory. When the health status of the person does not allow to appear at the court session the court shall be obliged to acquire immediate impression about his status. In such cases, as in the event of a state of emergency, martial law, disaster, epidemic, epidemic emergency situation or other force majeure circumstances, the person whose accommodation is sought and the expert appointed to give an expert opinion may take part in the case and by videoconference, and their identity is verified by the director of the hospital or by a person authorized by him.

Art. 159. (1) the court shall appoint judicial - psychiatric expertise when it establishes that some of the circumstances of art. 155 exists and after hearing to psychiatrist about the probable existence of psychic disorder of the person. The court shall determine the form of conducting of the expertise - ambulatory or stationary.

(2) The court shall determine the medical establishment and the expert for conducting the expertise as well as the term for implementing it, which cannot be longer than 14 days, and set the following session on the case, which shall be conducted not later than 48 hours after finishing of the expertise.

(3) If the term, defined for implementing the expertise, occurs insufficient, as exception the court may in an open session extend it one time but with no more than 10 days. In this case the court shall postpone with the same term also the set session of para 2.

(4) If the court establishes that the circumstances of art. 155 do not exist or after hearing to psychiatrist existence of psychic disorder of the person does not exist the court shall terminate the case.

Art. 160. (1) (Suppl., SG 45/11, in force from 14.06.2011) The judicial - psychiatric expertises according to the Art. 159, para 1 shall be conducted by an order, determined with ordinance by the Minister of Health and the Minister of Justice.

(2) During the conducting of the expertise treatment shall not be conducted except at emergency status or after expressed informed consent by the person.

(3) Simultaneously with the expertise the expert shall give statement about the ability of the person to express informed consent for treatment, propose treatment for the concrete disease and recommend medical establishments where it may be conducted.

Art. 161. (1) The definition of the court for termination of the case or for appointing of the expertise shall be subject to appeal with private appeal or protest in three days term. The appealing shall stop the conducting of the expertise unless the court decrees other.

(2) The regional court shall pronounce in an open session. Not appearing of the person without good reasons shall not be obstacle for considering the case.

Art. 162. (1) After hearing the person about the conclusion of the judicial - psychiatric expertise the court shall pronounce decision on the case on the basis of the collected evidences.

(2) With the decision the court shall pronounce on the need of compulsory accommodation, determine the medical establishment as well as the existence or the lack of ability of the person to express informed consent. The court shall determine the term of the accommodation and the treatment as well as the form of the treatment - ambulatory or stationary.

(3) When lack of ability of the person is accepted the court shall decree compulsory treatment and appoint a person from the relatives of the ill person, who is to express informed consent for the treatment. Upon conflict of interests or lack of relatives the court shall appoint representative of the municipal health service or a person, defined by the mayor of the municipality at the headquarters of the medical establishment, who is to express informed consent about the treatment of the person.

Art. 163. (1) The decision of the court can be appealed by the interested persons in 7 days term after it is decreed. The regional court shall pronounce in 7 days term decision, which shall not be subject to appeal.

(2) Appeal of the decision for compulsory accommodation and treatment shall stop its fulfilment unless the first or the appellate instance decrees other.

Art. 164. (1) The compulsory treatment shall be terminated with the elapse of the term, for which it has been decreed or with a decision of the district court at the location of the medical establishment.

(2) At each quarter on the basis of the judicial - psychiatric expertise, presented by the medical establishment, the district court at the location of the establishment shall officially pronounce decision about termination of the compulsory accommodation and treatment or for continuing of the compulsory accommodation and treatment by the order of art. 158, 159, 160 and 161.

(3) Upon falling away of the prerequisites for compulsory accommodation and treatment before the defined term to have elapsed the compulsory accommodation and treatment can be terminated by the court upon request by the person, the prosecutor or the chief of the medical establishment.

Art. 165. (1) As far as in this section special rules are not contained the provisions of the Penal Procedure Code shall be applied.

(2) The decision for compulsory accommodation and treatment, entered into force, as well as the definition of the court for appointing judicial - psychiatric expertise shall be brought to execution by the respective medical establishments if necessary with the cooperation by the bodies of the Ministry of Interior.

### **Chapter six.**

## **UNCONVENTIONAL METHODS FOR FAVOURABLE IMPACT ON THE INDIVIDUAL HEALTH**

Art. 166. (1) The Minister of Health shall control the applying of the unconventional methods for favourable impact on the individual health, which include:

1. using of non medicine products of organic origin;
2. using of non medicine products of mineral origin;
3. using of not traditional physical methods;
4. homeopathy;
5. acupuncture and acupressure;
6. iris, pulse and auricular methods of investigation;
7. diets and healing hunger.

(2) The use of unconventional methods for favourable impact on the individual health out of these, pointed out in para 1, shall be prohibited.

(3) The Minister of Health shall determine with an ordinance requirements to the activity of the persons, who exercise unconventional methods for favourable impact on the individual health.

Art. 167. (1) (suppl. - SG 59/06, in force from 01.01.2007) Right to practice unconventional methods of art. 166, para 1, except homeopathy, shall have Bulgarian citizens and citizens of Member States of the European Union, the other States of the European Economic Area and Switzerland, who are psychically healthy, have not been sentenced for unqualified crimes and meet one of the following conditions:

1. have educational - qualification degree "master" in professional directions "Medicine", "Stomatology" or "Pharmacy";

2. (amend. SG 85/05) have educational - qualification degree "specialist" or "bachelor" in professional direction "Health care";

3. (amend. - SG 74/09, in force from 15.09.2009; amend. â€“ SG 68/13, in force from 02.08;2013) have diploma for graduated high school and certificate for successfully conducted education not less than 4 semesters in a higher medical school under conditions and by order, determined with an ordinance by the Minister of Health and the Minister of Education and Science.

(2) (suppl. - SG 59/06, in force from 01.01.2007) Right to practice homeopathy shall have Bulgarian citizens and citizens of Member States of the European Union, the other States of the European Economic Area and Switzerland, who have educational - qualification degree "master" in professional directions "Medicine" or "Stomatology".

Art. 168. The persons, who practice unconventional methods, shall be obliged:

1. to exercise their activity in good faith;

2. not to admit damaging of the health of the persons, who have required their help;

3. to clarify to the persons, required their help, in details and in accessible language what unconventional method they will apply and the expected result from this;

4. to receive the explicit written consent of the persons, required their help, for applying of the respective methods;

5. not to lead into error the persons, who have required their help, including regarding to the possibilities for influence of their health status by the practiced unconventional method.

Art. 169. All forms of advertising of unconventional methods, including their connection with activities for prophylactics, diagnostics, treatment and rehabilitation, shall be prohibited.

Art. 170. (1) (amend. â€“ SG 98/10, in force from 01.01.2011) The persons, who practice unconventional methods, shall be registered at the regional health inspection in the region where they practice by submitting application, to which shall be attached documents, certifying the requirements of art. 167.

(2) In the application shall be pointed out comprehensively the unconventional methods and means, which the person will practice.

(3) (amend. â€“ SG 98/10, in force from 01.01.2011) Upon incompleteness of the presented documents or incompliance with the requirements for registration the director of the regional health inspection shall in 15 days term notify in writing the persons about this and determine 10 days term for removing them.

(4) (amend. â€“ SG 98/10, in force from 01.01.2011) In 15 days term after submitting of the application or removal of the incompleteness the director of the regional health inspection shall issue certificate for registration, in which shall be pointed out the

kinds of unconventional methods, which the person will apply, or make motivated refusal for issuing it.

(5) (amend. â€“ SG 98/10, in force from 01.01.2011) The director of the regional health inspection can refuse registration if the unconventional method, described in the application, is in violation of the normative requirements.

(6) (amend. - SG 30/06, in force from 12.07.2006) The refusal of registration shall be subject to appeal by the order of the Administrative procedure code.

(7) For implementing the registration fee shall be paid, determined with a tariff, approved by the Council of Ministers.

Art. 171. (1) (amend. â€“ SG 98/10, in force from 01.01.2011) The regional health inspection shall create and maintain register of the persons, who practice unconventional methods. The register shall be public and it shall contain:

1. consecutive number;
2. date of issuing of the certificate for registration of the unconventional practice;
3. data about the person, who practices unconventional methods - name, unified civil number and permanent address;
4. description of the unconventional method, which the person is practicing;
5. registration number of the book for visits of art. 173;
6. date of deleting of the registration and the ground for this;
7. changes in the circumstances of items 1 - 6;
8. notes of the entered circumstances.

(2) (amend. â€“ SG 98/10, in force from 01.01.2011) The registered persons shall be obliged to notify the respective regional health inspection about all changes in the implemented registration of the unconventional practice in 7 days term after their occurrence.

Art. 171a. (new â€“ SG 98/10, in force from 01.07.2011, amend. - SG 85/17) The application referred to in Art. 170, Para 1 and the notification referred to in Art. 171, Para 2 may be filed 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 and the Electronic Document and Electronic Trust Services Act and the Electronic Government Act.

Art. 172. (1) The registration shall be deleted:

1. upon request by the person, registered the unconventional practice;
2. upon death of the registered person or his placing under interdict;
3. at established presenting of incorrect data in the documents of art. 170, para 1;
4. at implementing activities in violation of the implemented registration;
5. at establishing unfavourable consequences for human health as result of the applied unconventional methods by the registered person.

(2) (amend. â€“ SG 98/10, in force from 01.01.2011) The deletion of the registration shall be implemented with order by the director of the regional health inspection.

(3) (amend. - SG 30/06, in force from 12.07.2006) The orders of para 1, items 3, 4 and 5 shall be subject to appeal by the order of the Administrative procedure code.

(4) The appealing of the order shall not stop its fulfilment.

Art. 173. (1) each person, who practices unconventional methods, shall be obliged to enter in the book for visits the data about each person, required his help as follows:

1. date of each visit;
2. consecutive number of each visit;
3. the three names, unified civil number and permanent address;
4. complaints, reported during the visit;
5. the implemented unconventional activities.

(2) (amend. â€“ SG 98/10, in force from 01.01.2011) The book for visits shall be threaded through, sealed and registered by the regional health inspection, issued the registration.

(3) The persons, who practice unconventional methods, shall be obliged to preserve the book for visits for 10 years after its finishing as well as to present it upon request by the control bodies.

## **Chapter seven.**

### **MEDICAL EDUCATION, MEDICAL PROFESSION, MEDICAL SCIENTIFIC INVESTIGATIONS OF PEOPLE. MEDICAL SCIENCE**

#### **Section I.**

#### **Medical education**

Art. 174. (1) The medical education shall ensure and guarantee the amount and the quality of preparation of the medical specialists, as well as of the non medical specialists, working in the national system for health care.

(2) Basic principles at conducting of the medical education shall be:

1. duration and high quality of teaching with learning of guaranteed amount of theoretic knowledge and practical skills;
2. staging and continuity of the training;
3. right to choice of speciality.

Art. 175. (1) The training and the acquisition of educational - qualification stage "master" in specialities from professional directions "Medicine", "Stomatology", "Pharmacy" and "Public health" shall be organised and conducted in faculties of higher schools, received accreditation by the order of the Higher Education Act.

(2) (amend. SG 85/05; suppl. â€“ SG 41/09, in force from 02.06.2009; amend. â€“ SG 98/10, in force from 01.01.2011) The training and the acquisition of educational -

qualification stage "bachelor" under Art. 42, par. 1, item 1, item "b" of the Higher Education Act in specialities from professional direction "Health care" and in the specialties "nurse", "midwife" and "medical assistant" of professional direction "Health care" shall be organised and conducted in faculties and/or branches of higher schools, received accreditation by the order of the Higher Education Act.

(3) (amend. SG 85/05; amend. â€“ SG 41/07) The training and the acquisition of educational - qualification degree "bachelor" under Art. 42, para 1, item 1, letter "a" of the Higher Education Act in specialities from professional directions "Health care" shall be organised and conducted in colleges, received accreditation by the order of the Higher Education Act.

(4) The training of persons for acquisition of educational and scientific degree "doctor" in scientific specialities in the field of health care shall be implemented in higher schools, the Bulgarian academy of science, the national centres on the problems of public health and other scientific organisations, received accreditation by the order of the Higher Education Act.

Art. 176. (1) At handing over the diplomas all doctors and stomatologists shall take Hippocratic oath. The text of the oath shall be approved by the Supreme medical council.

(2) (suppl. SG 85/05) For the persons, who are citizens of the European Union, the other states of the European economic space and Switzerland, shall be ensured oath appropriate in content and form.

Art. 177. (suppl. SG 85/05) The Council of Ministers shall approve unified state requirements for acquiring higher education in the specialities of the regulated professions from professional directions "Medicine", "Stomatology", "Pharmacy", "Public health" and "Health care" upon proposal by the Minister of Health.

Art. 178. (1) (amend. â€“ SG 41/07, amend. - SG 103/16) The post graduate education shall be conducted for persons with educational - qualification degree "doctor", "master" and "bachelor", who work in the national system for health care.

(2) The post graduate education shall include:

1. training for acquiring speciality in health care;

2. (suppl. SG 85/05) continuing medical training.

(3) The Minister of Health shall every year determine the number of the places for post graduate training in specialities, subsidies by the state in compliance with the objectives and the priorities of the national health strategy.

Art. 179. (1) (prev. text of Art. 179, amend. â€“ SG 98/10, in force from 01.01.2011) The Minister of Health shall plan, coordinate and control the activities for conducting post graduate training for acquiring speciality by the medical specialists with not medical education, working in the national system for health care.

(2) (new â€“ SG 98/10, in force from 01.01.2011) The Minister of Health shall exercise control of the activities related to the training for acquiring speciality in the healthcare system in the universities, the medical and health establishments, where for the

conducted inspections shall be drawn up protocols of findings within a term of one month containing propositions and specifying a time limit for correcting any infringements.

Art. 180. (1) The theoretic training of art. 178, para 2, item 1 shall be conducted by:

1. higher schools, received positive accreditation assessment under the Higher Education Act and the Military medical academy;
2. national centres on the problems of public health, received accreditation for the respective speciality by the order of the Higher Education Act.

(2) The practical education of art. 178, para 2, item 1 shall be conducted in:

1. the establishments of para 1;
2. (amend. - SG 102/18, in force from 01.04.2019) medical establishments, received approval by the Minister of Health for carrying out activities under Art. 90, para. 1 of the Medical Establishments Act

(3) Speciality shall be acquired after fulfilment of study programmes and successfully passed practical and theoretic examination before state examination commission, determined with an order by the Minister of Health.

(4) (new " SG 59/10, in force from 31.07.2010, revoked - SG 102/18, in force from 01.04.2019)

Art. 181. (1) (amend. " SG 41/09, in force from 02.06.2009; amend. " SG 68/13, in force from 02.08;2013) The nomenclature of the specialties in the system of health care, the conditions and the order for conducting of the training and acquiring of speciality in health care, as well as its financing, shall be determined with an ordinance by the Minister of Health, coordinated with the Minister of Education and Science and the Minister of Finance.

(2) The financing of the training for acquiring of speciality in health care shall be determined in compliance with the objectives and the priorities of the national health strategy.

Art. 182. (1) (amend. SG 85/05; amend. - SG 75/06, amend. - SG 103/16) The professional organisations of the physicians, of the doctors in dental medicine, the master-pharmacists and of the nurses, the midwives and the associated medical specialists shall organise, coordinate, conduct, register and monitor the continuing medical training of the physicians, the doctors in dental medicine, the master-pharmacists and the nurses, the midwives and the associated medical specialists under conditions and by order, determined in contracts with the higher schools, the Bulgarian Red Cross and the Military medical academy.

(2) (amend. SG 85/05) The higher schools, the Military medical academy, the medical colleges, the Bulgarian red Cross and other associations of working in health care shall conduct the continuing medical training of the specialists in the system of health care out of these, pointed out in para 1, under conditions and by order, determined in contracts with the bases for post graduate training.

(3) (amend. SG 85/05; amend. - SG 75/06) The Union of the scientific medical associations in Bulgaria, the Union of the scientists in Bulgaria and the medical

associations in specialities can participate in the conducting of the continuing medical training of doctors, doctors in dental medicine and master-pharmacists under conditions and by order, determined in contracts with the Bulgarian union of doctors, the Bulgarian Dental Association and the Bulgarian Pharmaceutical Association.

(4) (revoked - SG 103/16)

## **Section II. Medical profession**

Art. 183. (1) (amend. SG 85/05; amend. " SG 41/09, in force from 02.06.2009) The medical profession shall be exercised by persons having diploma for graduated higher education in specialties of professional directions "Medicine", "Dental medicine", "Pharmacy" and "Health care".

(2) (new " SG 85/05) The diploma of para 1 shall certify the acquired higher education in the respective specialty and educational " qualification degree as well as the acquired professional qualification determined in the state requirements of art. 177.

(3) (prev. (2) " SG 85/05) The doctors and the dentists shall exercise the medical profession under the conditions of para 1 and art. 3, para 1 of the Act on Professional Organisations of Physicians and Dental Practitioners.

(4) (new " SG 85/05, amend. - SG 91/18) The nurses, the midwives, the associated medical specialists, dental technicians and assistant pharmacists shall exercise the medical profession under the conditions of chapter two of the Act on the Professional Organizations of Nurses, Midwives and Associated Medical Specialists, Dental Technicians and Assistant-Pharmacists.

(5) (new " SG 75/06) The master-pharmacists shall exercise medical profession under the conditions referred to in Para 1 and Art. 3, Para 1 of the Act on the Professional Organization of Master-Pharmacists.

Art. 184. (revoked " SG 85/05)

Art. 185. (1) (amend. SG 85/05; amend. " SG 41/09, in force from 02.06.2009) The Ministry of Health shall officially create and maintain public list of the persons graduated higher education in specialties of professional directions "Medicine", "Dental medicine", "Pharmacy", "Public health" and "Health care".

(2) (revoked " SG 85/05, prev. para. 4, amend. - SG 85/05, in force from 25.10.2005) The data from the list shall be accessible for use by any person under the terms and conditions of the Access to Public Information Act.

(3) (revoked " SG 85/05; new " SG 98/10, in force from 01.01.2011, amend. - SG 91/18) The Bulgarian Physicians'™ Union, the Bulgarian Dentists'™ Union, the Bulgarian Pharmaceutics Union and the professional organizations under the Act on the Professional Organizations of Nurses, Midwives and Associated Medical Specialists, Dental Technicians and Assistant-Pharmacists shall submit on paper or electronically to the Ministry of Health information about:

1. entry and deletion of persons from the register of the concerned professional organisation within 30 days from making the changes in the register;

2. (amend. â€“ SG 27/16) imposed administrative penalties to members of the concerned professional organisation from the day after the entry into force of the penal decree.

(4) (new â€“ SG 98/10, in force from 01.01.2011) The professional organisations referred to in Para 3 shall submit to the Ministry of Health, where requested, information of the acquired speciality under Art. 178, Para 2 by members of the concerned professional organisation.

(5) (new â€“ SG 98/10, in force from 01.01.2011; amend. â€“ SG 68/13, in force from 02.08;2013) Every year, by 31 January, and also at request, the Ministry of Education and Science and the universities shall submit to the Ministry of Health information of the graduated students during the preceding year in the specialities of professional fields "Medicine", "Dental Medicine", "Pharmacy", "Public Health" and "Healthcare" and of persons that have met the requirements of Art. 186, Para 3.

(6) (new â€“ SG 98/10, in force from 01.01.2011) Every year, by 31 January, and also at request, the institutions within the system of the professional education and training shall submit to the Ministry of Health information of the persons that have acquired professional qualification in a medical speciality.

Art. 186. (amend. SG 85/05) (1) (amend. - SG 13/08, in force from 08.02.2008) The citizens of member state of the European Union, the other states of the European economic space and Switzerland shall exercise medical profession in the Republic of Bulgaria after recognition of their professional qualification under the order of the Recognition of Professional Qualifications Act.

(2) The Ministry of Health and the higher schools shall ensure to the persons of para 1 conditions for the acquisition of the necessary language knowledge and professional terminology in Bulgarian language for exercising their profession in the Republic of Bulgaria if necessary and when this is in their interest and in the interest of their patients.

(3) (amend. - SG 59/06, in force from 01.01.2007; amend. - SG 13/08, in force from 08.02.2008; amend. - SG 74/09, in force from 15.09.2009; amend. - SG 98/10, in force from 14.12.2010; amend. â€“ SG 68/13, in force from 02.08;2013) The foreigners out of these of para 1 shall exercise medical profession in the Republic of Bulgaria under the following conditions:

1. have command of Bulgarian language and the professional terminology in Bulgarian language established by order determined with ordinance of the Minister of Education, Youth and Science and the Minister of Health;

2. after recognition of their professional qualification under the order of the Recognition of Professional Qualification Act, where the professional qualification has been acquired in a Member State of the European Union, or

3. following a successful examination, where the professional qualification has been acquired in a third country:

a) including the state exams, determined in the unified state requirements under Art. 177 for the exercise of a regulated profession from the professional fields of "Medicine", "Dental Medicine", "Pharmacy" and "Healthcare";

b) under Art. 180, Para 3 for exercise of a speciality within the healthcare system.

(4) Out of the cases of para 1 - 3 medical profession may exercise also foreigners, invited for scientific exchange between medical establishments, under conditions and by order, determined with an ordinance by the Minister of Health.

(5) (revoked - SG 13/08, in force from 08.02.2008; new - SG 98/10, in force from 14.12.2010) The conditions and order for admission and sitting the examination referred to in Para 3, Item 3 shall be determined in an ordinance of the Minister of Health.

(6) (new - SG 98/10, in force from 14.12.2010) The payment procedure for sitting the examination referred to in Para 3, Item 3 shall be determined in the regulations on the activity of the respective university.

(7) (new - SG 98/10, in force from 14.12.2010) The university shall issue a certificate for successfully passed examination under Para 3, Item 3.

(8) (new - SG 27/16) Ordinance under par. 3 pt. 1 shall define the procedure for the Bulgarian language proficiency assessment of the persons under par. 1.

Art. 187. (revoked - SG 85/05)

Art. 188. (amend. SG 85/05) The Minister of Health shall issue ordinances for the professional competence of the persons, working in the national system for health care, graduated higher education in the specialities "psychology", "kinesitherapy", "biology", "biochemistry", "microbiology" and "molecular biology".

Art. 189. (prev. text of Art. 189 - SG 98/16, in force from 01.01.2017) The medical establishments shall obligatory insure the persons, who exercise medical profession in medical establishment, for the damages, which can occur due to guilty non fulfilment of their professional obligations.

(2) (new - SG 98/16, in force from 01.01.2017) Conditions, procedure, deadline and the amount of the minimal insurance sum at compulsory insurance under para 1 shall be determined with an Ordinance of the Council of Ministers.

Art. 190. (1) The persons, exercising medical profession, shall have right to free actions and decisions according to their professional qualification, the medical standards and the medical ethics.

(2) The medical specialists, as well as the medical establishments, cannot use for their activity commercial advertisement.

Art. 191. (1) (amend. SG 85/05; amend. - SG 59/06, in force from 01.01.2007; revoked - SG 41/09, in force from 02.06.2009)

Art. 192. (1) The medical specialists cannot exercise their profession if they suffer from diseases, endangering the health and the life of the patients.

(2) The list of the diseases of para 1 shall be determined by the Minister of Health.

(3) In the cases of para 1 the Minister of Health shall issue order, with which deletes the medical specialist from the register of art. 185.

(4) (amend. - SG 30/06, in force from 12.07.2006, suppl. - SG 77/18, in force from 01.01.2019) The order of the Minister of Health shall be subject to appeal before the relevant administrative court following the procedure of the Administrative Procedure Code.

(5) (new - SG 98/10, in force from 01.01.2011) The Ministry of Health shall send to the corresponding professional organisation and to the corresponding regional health inspection a certified copy of the order under Para 3 that has entered into force.

Art. 193. (1) The Minister of Health can with an order divest the right of a person to exercise medical profession in the Republic of Bulgaria for a term from six months to two years in case of:

1. repeated violation of the approved medical standards;
2. the repeated violation of the principles and the order for implementing the expertise of the ability to work;
3. (new " SG 59/10, in force from 31.07.2010) repeated infringement of the order for conducting medical examination under Art. 103, Para 3.

(2) (amend. - SG 30/06, in force from 12.07.2006, suppl. - SG 77/18, in force from 01.01.2019) The order of para 1 shall be subject to appeal before the relevant administrative court by the order of the Administrative procedure code.

(3) (new - SG 98/10, in force from 01.01.2011) The Ministry of Health shall send to the corresponding professional organisation and to the corresponding regional health inspection a certified copy of the order under Para 1 that has entered into force.

### **Section III.**

#### **Recognising professional qualification in medical profession (title amend. - SG 59/06, in force from 01.01.2007; revoked - SG 13/08, in force from 08.02.2008)**

Art. 194. (revoked - SG 13/08, in force from 08.02.2008)

Art. 195. (revoked - SG 13/08, in force from 08.02.2008)

Art. 196. (revoked - SG 59/06, in force from 01.01.2007)

### **Section IV.**

#### **Medical scientific studies of people. Medical science**

Art. 197. (1) The Ministry of Health shall organise and control the conducting of medical scientific studies of people.

(2) Medical scientific study in the sense of this Act shall be each experiment on people, which is implemented with objective increase of medical knowledge.

(3) The studied person shall have all rights of a patient.

(4) Medical scientific study shall be implemented upon ensuring of maximum safety for the health of the studied person and preserving the secret of his personal data.

(5) The interests of the studied person shall be more important than the scientific and the financial interests of the investigator at any stage of the medical study.

Art. 198. (1) Medical scientific studies of people shall not be implemented when:

1. they contradict with the law or medical ethics;
2. proofs about their safety have not been presented;
3. proofs about the expected scientific benefits have not been presented;
4. they do not comply with the set scientific objective and the plan for conducting the scientific study;
5. there is increased risk for the health and the life of the studied person.

(2) Medical scientific studies of people shall not be conducted with chemical substances and physical sources of radiation, which can cause changes of the human genome.

(3) Medical scientific studies of people shall not be conducted with products of gene engineering, which may lead to transmitting of new characteristics of the generation.

Art. 199. (1) Medical scientific studies shall be implemented only of persons, who have expressed in writing informed consent after written notification by the chief of the study about the essence, the significance, the scope and the eventual risks of the study.

(2) Consent for participation in medical scientific study shall be given only by legally capable person, who understands the essence, the significance, the scope and the eventual risks of the clinic trial.

(3) The consent shall be given personally in written form. It can be withdrawn at any time.

Art. 200. (1) Medical scientific studies of legally incapable persons shall not be implemented.

(2) When significant benefits for the health are not expected to medical scientific studies shall not be subject:

1. pregnant women and breast nursing women;
2. persons, deprived from liberty;
3. (revoked " SG 46/07, in force from 01.01.2008)

Art. 201. (amend. - SG 98/10, in force from 14.12.2010) (1) The head of the medical scientific research shall be jointly liable with the rest of the persons participating in the research team for the moral and economical damages caused by them to the participants in the medical scientific research resulting from effects suffered during the medical scientific research.

(2) The head of the medical scientific research shall be obliged to sign an insurance covering his liability and the liability of the persons, participating in the research

team, for the moral and economical damages caused to the participants in the medical scientific research resulting from effects suffered during the medical scientific research.

(3) The general conditions, the minimum insurance sum, the minimum insurance premium, the order and the term for making the insuring of para 2 shall be determined with an ordinance by the Council of Ministers.

Art. 202. (1) The chief of the medical study shall be doctor or dentist with recognised medical speciality and he shall be responsible for the planning and the conducting of the studies.

(2) Medical scientific studies of people shall be conducted only by qualified specialists with higher education in the field of medicine, stomatology, pharmacy, biology, biochemistry.

(3) Medical scientific studies can be conducted by foreign persons only on the basis of contract, coordinated with the Minister of Health.

Art. 203. (1) Medical scientific studies shall be conducted upon positive statement by local commission in ethics, established at the medical or the health establishment or in the scientific organisation, in which medical scientific studies are implemented.

(2) The members of the commission of para 1 shall be determined by the chief of the establishment or the organisation.

(3) Specialists, who participate in the preparation, the organisation and the conducting of the scientific study, cannot participate in the commission of para 1.

(4) The local commission in ethics shall give statement in 30 days term after receiving the request by the chief of the study.

(5) The local commission in ethics shall exercise control over the conducting of the medical scientific studies of people, for which it has expressed positive statement.

Art. 204. At finishing the medical scientific study of people the chief of the study shall in 30 days term inform about this the local commission in ethics.

Art. 205. (1) The medical scientific study can be terminated at any stage of its conducting:

1. upon withdrawal of the consent of the studied person;

2. (new " SG 41/09, in force from 02.06.2009) in case of detection of a harmful effect on the health of the tested person;

3. (prev. item 2 " SG 41/09, in force from 02.06.2009) upon proposal by the chief of the study;

4. (prev. item 3 " SG 41/09, in force from 02.06.2009) upon proposal by the chairman of the local commission in ethics in the medical or health establishment upon proven omissions and breaches in the process of its implementation.

(2) At terminating of the medical scientific study under para 1, items 1 and 2 the chief of the study shall inform in 15 days term the local commission in ethics.

(3) (new " SG 41/09, in force from 02.06.2009; amend. - SG 98/10, in force from 01.01.2011) In cases of par. 1, item 2 the medical research test shall be terminated

by an order of the Director of the regional health inspection under terms and conditions and following a procedure, determined by the ordinance under Art. 206.

Art. 206. (amend. - SG 74/09, in force from 15.09.2009; amend. â€“ SG 68/13, in force from 02.08;2013) The conditions and the order for conducting the medical scientific studies shall be determined with ordinance by the Minister of Health, coordinated with the Minister of Education and Science.

Art. 207. The Minister of Health shall determine scientific projects within the state scientific priorities in the field of medicine upon proposal by the rectors of the higher schools, the directors of the national centres on the problems of public health, chiefs of scientific organisations and other corporate bodies and upon statement by the Supreme medical council.

Art. 208. (1) The Minister of Health shall announce competition for choice of contractors of scientific projects within the defined scientific priorities.

(2) (amend. - SG 74/09, in force from 15.09.2009; amend. â€“ SG 68/13, in force from 02.08;2013) The conditions and the order for conducting the competition and the requirements to the candidates shall be determined with an ordinance by the Minister of Health, coordinated with the Minister of Education and Science.

(3) The scientific projects shall be financed from state subsidies and other sources.

Art. 208a. (new - SG 98/10, in force from 14.12.2010) The body of the deceased may be used for training and scientific research purposes in the higher medical schools after the dead has been established according to the medical criteria and the procedure set out in the ordinance under Art. 18, Para 1 of the Transplantation of Organs, Tissues and Cells Act.

Art. 208b. (new - SG 98/10, in force from 14.12.2010) (1) The body of the deceased may be used for training and scientific research purposes in the higher medical schools, if the person is a Bulgarian national and has expressed his written consent therefor before his death.

(2) In cases of lack of expressed consent under Para 1 the body of the deceased may be used for training purposes following a written consent within a reasonably short term given by one of the persons in the following order:

1. spouse or a cohabitant;
2. relative of direct lineage (descending or ascending);
3. collateral relatives up to third degree;
4. relatives-in-law up to second degree.

(3) The body of the deceased may be used for training and scientific research purposes also in cases of lack of consent under Para 1 and lack of consent under the legally specified procedure due to lack of known persons under Para 2.

(4) The order of using the bodies of the deceased referred to in Para 1 - 3 for training and scientific research purposes in the higher medical schools shall be determined in an ordinance of the Minister of Health coordinated with the Minister of Justice and the Minister of Interior.

Art. 208c. (new - SG 98/10, in force from 14.12.2010) (1) After the end of the training activity the higher schools shall notify the relatives of the deceased and shall cover the expenses for his burial.

(2) The higher medical schools shall organise and cover the expenses for the burial of the deceased person in the following cases:

1. in cases of expressed consent under Art. 208b, Para 1 and lack of known persons in the sense of Art. 208b, Para 2, or
2. under the conditions of Art. 208b, Para 3.

## **Chapter eight.**

### **ADMINISTRATIVE PUNITIVE PROVISIONS**

Art. 209. (1) Who does not appear to obligatory prophylactic medical examination, study or immunisation, shall be punished with fine from 50 to 100 levs and at second not appearing - from 100 to 200 levs.

(2) The penalties of para 1 shall be imposed also to the officials, who have impeded the appearing of the persons for implementing obligatory prophylactic medical examination, study and immunisation.

(3) Parents or guardians, who do not ensure the conducting of the obligatory immunisations of their children, shall be punished with fine from 50 to 100 levs. At second implementing of the breach the fine shall be from 100 to 200 levs.

Art. 209a. (New - SG 28/20, in force from 13.03.2020) (1) (Amend. - SG 34/20, in force from 09.04.2020, amend. " SG 44/20, in force from 14.05.2020, amend. - SG 32/22, in force from 26.04.2022) Who violates or fails to fulfil anti-epidemic measures, introduced by the Minister of Health or by a Director of Regional Health Inspectorate under Art. 63, Para. 4, 7, 10 or 11 and Art. 63a, Para. 1 or 2, unless the act constitutes a crime, shall be punished by a fine from BGN 300 to 1000, and in case of repeated violation from BGN 1000 to 2000.

(2) (Amend. - SG 34/20, in force from 09.04.2020) When the violation under para. 1 is made by a sole trader or legal entity, a pecuniary sanction from BGN 500 to 2000 shall be imposed and in the case of repeated violation from BGN 2000 to 5000.

(3) The violations under para. 1 and 2 shall be established by acts drawn up by state health inspectors or by officials designated by the director of the regional health inspection, officials appointed by the Directors of the Regional Directorates of the Ministry of the Interior or officials appointed by the mayors of municipalities.

(4) The penal decrees are issued respectively by the director of the respective regional health inspection, the director of the respective regional directorate of the Ministry of Interior and the mayor of the respective municipality.

Art. 210. (1) (amend. - SG 98/10, in force from 01.01.2011) Who implements activity in violation of the health requirements under this Act and the normative acts for its implementation shall be punished with fine from 100 to 1500 levs and at second breach - from 500 to 5000 levs.

(2) (amend. - SG 98/10, in force from 01.01.2011) When the breach of para 1 is implemented by sole entrepreneur, proprietary sanction shall be imposed in extent from 200 to 3000 levs, and at second breach - from 1000 to 8000 levs.

(3) (amend. - SG 98/10, in force from 01.01.2011) When the breach of para 1 is implemented by corporate body, proprietary sanction shall be imposed in extent from 1000 to 5000 levs, and at second breach - from 3000 to 12 000 levs.

Art. 211. (1) (amend. - SG 98/10, in force from 01.01.2011) Who implements activity in a site with public designation without having fulfilled his obligation to notify the regional health inspection shall be punished with fine from 200 to 3000 levs and at second breach - from 1000 to 10 000 levs.

(2) (amend. - SG 98/10, in force from 01.01.2011) When the breach of para 1 is implemented by sole entrepreneur, proprietary sanction shall be imposed in extent from 500 to 9000 levs, and at second breach - from 2000 to 15 000 levs.

(3) (amend. - SG 98/10, in force from 01.01.2011) When the breach of para 1 is implemented by corporate body, proprietary sanction shall be imposed in extent from 2000 to 15 000 levs, and at second breach - from 5000 to 20 000 levs.

Art. 212. (amend. - SG 98/10, in force from 01.01.2011) (1) Who fails to implement a prescription of by the state health control, if he is not subject to graver penalty, shall be punished with fine from 200 to 500 levs and at second breach - from 500 to 1000 levs.

(2) Where the breach under Para 1 was committed by a sole entrepreneur shall be imposed a property sanction from 500 to 2000 levs and at second breach - from 1000 to 3000 levs.

(3) When the breach of para 1 is implemented by corporate body, proprietary sanction shall be imposed in extent from 1000 to 3000 levs, and at second breach - from 2000 to 5000 levs.

Art. 212a. (new - SG 98/10, in force from 01.01.2011) (1) Who defies or impedes the performance of state health control or taking of samples by state health control authorities, unless subject to a more severe penalty, shall be imposed a fine from 200 to 1000 levs, and in cases of repeated breach - from 1000 to 2000 levs.

(2) Where the breach under Para 1 was committed by a sole entrepreneur shall be imposed a property sanction from 1000 to 3000 levs, and in cases of repeated breach - from 2000 to 5000 levs.

(3) When the breach under Para 1 was committed by a corporate body, a proprietary sanction shall be imposed from 2000 to 5000 levs, and in cases of repeated breach - from 5000 to 10 000 levs.

Art. 213. (1) (amend. - SG 98/10, in force from 01.01.2011) Who does not fulfil order for stopping of sites or parts of them or breaches prohibition for realisation of products and goods, ordered by the bodies of the state health control, if he is not subject to graver penalty, shall be punished with fine from 2000 to 6000 levs and at second breach - from 6000 to 12 000 levs.

(2) (amend. - SG 98/10, in force from 01.01.2011) When the breach of para 1 is implemented by sole entrepreneur, proprietary sanction shall be imposed in extent from 3000 to 9000 levs, and at second breach - from 10 000 to 30 000 levs.

(3) When the breach of para 1 is implemented by corporate body, proprietary sanction shall be imposed in extent from 5000 to 15 000 levs, and at second breach - from 15 000 to 30 000 levs.

Art. 213a. (new â€“ SG 1/14, in force from 03.01.2014) (1) Who launches on the market cosmetic products in violation of the provisions of Art. 49, par. 2, items 2, 3, 5, 6, 8, 9, 11 and 12 shall be penalized with a fine of BGN1500, and in case of repeated violation â€“ BGN3000.

(2) Where the violation under par. 1 is done by a sole trader, a proprietary sanction of BGN3000 shall be imposed, and in case of repeated violation â€“ BGN6000.

(3) Where the violation under par. 1 is done by a legal entity, a proprietary sanction of BGN6000 shall be imposed, and in case of repeated violation â€“ BGN12,000.

Art. 213b. (new â€“ SG 1/14, in force from 03.01.2014) (1) Who launches on the market cosmetic products in violation of the provisions of Art. 49, par. 1, items 1, 4, 7 and 10 shall be penalized with a fine of BGN1000, and in case of repeated violation â€“ BGN2000.

(2) Where the violation under par. 1 is done by a sole trader, a proprietary sanction of BGN2000 shall be imposed, and in case of repeated violation â€“ BGN4000.

(3) Where the violation under par. 1 is done by a legal entity, a proprietary sanction of BGN4000 shall be imposed, and in case of repeated violation â€“ BGN8000.

Art. 214. (1) (amend. - SG 59/06, in force from 21.07.2007) Who implements activities for destroying or elimination of asbestos and/or asbestos containing materials from buildings, constructions, enterprises, installations or ships without permission under Art. 73, shall be punished with fine up to 1500 levs and at second breach - from 1500 to 3000 levs.

(2) When the breach of para 1 is implemented by sole entrepreneur, proprietary sanction shall be imposed in extent from 500 to 1500 levs, and at second breach - from 1500 to 5000 levs.

(3) When the breach of para 1 is implemented by corporate body, proprietary sanction shall be imposed in extent from 1000 to 3000 levs, and at second breach - from 3000 to 6000 levs.

Art. 215. (supple. - SG 98/10, in force from 14.12.2010, amend. - SG 23/20, in force from 14.03.2020, amend. - SG 28/20, in force from 13.03.2020, amend. â€“ SG, 44/20, in force from 14.05.2020, amend. - SG 105/20, in force from 11.12.2020) (1) A

person, suffering from or is a carrier of a contagious disease under Art. 61, Para. 1 or 3, who refuses or interrupts the implementation of the obligatory isolation under Art. 61, Para. 4 or under Art. 61a, para. 2, shall be punished by a fine in the amount of BGN 5 000.

(2) Person under para. 1, refused to fulfill obligatory isolation under para. 1, as well as a person under para. 1, who interrupts the implementation of mandatory isolation under para. 1, shall be brought compulsorily with the assistance of the bodies of the Ministry of Interior at the request of the bodies of the state health control, of the head of the medical establishment for hospital care, of the attending physician or of the doctor, who directed the person for hospitalization.

Art. 215a. (New - SG 28/20, in force from 13.03.2020). (1) (Amend. " SG, 44/20, in force from 14.05.2020, amend. - SG 105/20, in force from 11.12.2020) A person who has been in contact with an infected person under the Art. 61, Para. 8, who refuses to be tested, in view of establishment if he/she is carrier of infectious disease shall be punished with a fine from BGN 50 to 500.

(2) Person under para. 1, who refuses to appear voluntarily for carrying out a test, shall be compulsorily brought with the assistance of the bodies of the Ministry of Interior at the request of the bodies of state health control.

Art. 215b. (New " SG, 44/20, in force from 14.05.2020) (1) A contact person with a person, suffering from a contagious disease under Art. 61, Para. 1 or 3, as well as a person, who has entered the territory of the country from other countries, who refuses or does not fulfill the obligatory quarantine under Art. 61, Para. 6, shall be punished by a fine in the amount of BGN 5,000.

(2) The persons under Para. 1, who do not fulfill the obligatory quarantine, shall be brought compulsorily with the assistance of the bodies of the Ministry of Interior at the request of the bodies of the state health control.

Art. 216. A medical specialist, who breaches the order for registration, announcement and account, as well as the order for isolation, investigation and dispensary system treatment of ill, former ill, infection carriers and contact persons, shall be punished with fine from 300 to 1000 levs and at second breach - with deprivation from the right to exercise medical profession for term from 6 months to one year.

Art. 217. (1) Who implements activities for disinfection, disinsection and deratisation in violation of the established requirements under this Act and the normative acts for its implementation, shall be punished with fine from 500 to 1500 levs and at second breach - from 1500 to 3000 levs.

(2) When the breach of para 1 is implemented by sole entrepreneur, proprietary sanction shall be imposed in extent from 300 to 1000 levs, and at second breach - from 1000 to 3000 levs.

(3) When the breach of para 1 is implemented by corporate body, proprietary sanction shall be imposed in extent from 500 to 1500 levs, and at second breach - from 1500 to 5000 levs.

Art. 218. (1) (amend. â€“ SG 40/12, in force from 01.06.2012) Who breaches art. 54, art. 56 or art. 56a shall be punished with fine from 300 to 500 levs and at second implementation of the same breach - from 500 to 1000 levs.

(2) (new â€“ SG 41/09, in force from 02.06.2009; amend. â€“ SG 40/12, in force from 01.06.2012, amend. â€“ SG 58/19) Whoever allows, in a facility managed by him, any violation of Art. 54, 56 or 56a, shall be liable to a fine of BGN 300 to BGN 500, and to a pecuniary sanction from BGN 1 000 to 1 500, where the violation is committed by a sole trader, and to a pecuniary sanction from BGN 3 000 to BGN 5 000, where the violation is committed by a legal person.

(2a) (New - SG 62/22, in force from 05.08.2022) Whoever violates Art. 54a, shall be punished with a fine of BGN 800 to BGN 1 500, and in case of repeated commission of the same violation - BGN 1 500 to BGN 3 000. When the violation under Art. 54a was committed by a sole trader or by a legal entity, a property sanction of BGN 3 000 to BGN 6 000 is imposed, and in the case of repeated commission of the same violation - from BGN 5 000 to BGN 12 000.

(3) (suppl. - SG 59/06, in force from 01.01.2007; prev. par. 2 â€“ SG 41/09, in force from 02.06.2009; amend. â€“ SG 40/12, in force from 01.06.2012, amend. â€“ SG 58/19) In the case of a repeated violation under Para. 2, a fine of BGN 500 to BGN 1 000 shall be imposed, respectively a proprietary sanction of BGN 1 500 to 3 000 for a sole trader, and between BGN 5 000 and 10 000 for a legal person.

(4) (prev. par. 3 â€“ SG 41/09, in force from 02.06.2009; amend. â€“ SG 40/12, in force from 01.06.2012) Who advertises alcohol beverages in breach of art. 55, para 1 and 2 shall be punished with fine from 1500 to 3000 levs, and at second breach - from 3000 to 5000 levs.

(5) (prev. par. 4 â€“ SG 41/09, in force from 02.06.2009; amend. â€“ SG 40/12, in force from 01.06.2012) When the breach of para 4 has been committed by a sole entrepreneur shall be imposed a proprietary sanction from 3000 to 10 000 levs, and at second breach - from 10 000 to 30 000 levs.

(6) (prev. par. 5 â€“ SG 41/09, in force from 02.06.2009; amend. â€“ SG 40/12, in force from 01.06.2012) When the breach of para 4 has been committed by a corporate body shall be imposed a proprietary sanction from 10 000 to 30 000 levs, and at second breach - from 30 000 to 50 000 levs.

(7) (prev. par. 6 â€“ SG 41/09, in force from 02.06.2009) The radio and television operators, who in breach of art. 55, para 1 and 3 transmit advertisement of spirit beverages, shall be punished with proprietary sanction in extent of 5000 levs and at second breach - 10 000 levs, imposed by the Council for electronic media by the order of the Radio and Television Act.

(8) (prev. par. 7 â€“ SG 41/09, in force from 02.06.2009) The radio and television operators, who in breach of art. 55, para 2 transmit advertisement of spirit beverages, shall be punished by the order of the Radio and Television Act

Art. 218a. (new â€“ SG 42/10, in force from 02.06.2010; revoked â€“ SG 40/12, in force from 01.06.2012)

Art. 219. (1) Who implements activities with sources of ionising radiations in breach of the requirements of this Act and the normative acts for its implementation shall

be punished with fine from 2000 to 5000 levs and at second breach - from 5000 to 15 000 levs.

(2) When the breach of para 1 is implemented by sole entrepreneur, proprietary sanction shall be imposed in extent from 1000 to 3000 levs, and at second breach - from 3000 to 10 000 levs.

(3) When the breach of para 1 is implemented by corporate body, the proprietary sanction shall be from 1500 to 5000 levs, and at second breach - from 5000 to 15 000 levs.

Art. 220. (1) An official, who does not inform the patient about the circumstances of art. 88, para 1, shall be punished with fine from 300 to 1000 levs and at second breach - with deprivation from the right to exercise medical profession for a term from 6 months to one year.

(2) Who renders medical care without informed consent of the patient or in violation of the requirements for giving informed consent by the patient, shall be punished with fine from 500 to 1500 levs and at second breach - with deprivation from the right to exercise medical profession for a term from 6 months to one year.

(3) An official, who concedes health information out of the conditions and the order of this Act and the normative acts for its implementation, if not subject to graver penalty, shall be punished with fine from 500 to 1500 levs and at second breach - from 2000 to 6000 levs.

Art. 221. (amend. â€“ SG 101/09, in force from 01.01.2010) (1) Medical establishment that violates rights of a patient, regulated with this Act and with the normative acts for its implementation, shall be punished with fine from 300 to 1000 levs and at second breach - from 500 to 1500 levs.

(2) When the violation under Para 1 is made by a medical establishment â€“ sole entrepreneur or legal person, a property sanction shall be imposed between BGN 500 to 1500, and in case of repeated violation â€“ between BGN 100 and 3000.

Art. 221a. (new â€“ SG 41/09, in force from 02.06.2009) A medical specialist, failing to fulfill and obligation under Art. 125a, shall be punished with a fine from 300 to 1000 Levs, and in case of repeated violation â€“ by depriving of the right to exercise medical profession for a period from 6 months to 1 year.

Art. 222. (1) (amend. SG 85/05; amend. - SG 59/06, in force from 01.01.2007) Who renders medical care or implements health activity without having the necessary professional qualification in medical profession, if he is not subject to a graver penalty, shall be punished with fine from 5000 to 10 000 levs and at second breach - from 10 000 t 20 000 levs.

(2) Medical specialist, who admits systematic breaches at exercising his profession due to negligence or ignorance, admits gross errors in his work or commits immoral acts by using his official status, if he is not subject to a graver penalty, shall be punished with deprivation from right to exercise his profession for a term from three months to two years.

(3) Doctor, dentist, nurse, midwife and medical officer, who refuses rendering of emergency medical aid to a person in status, critical for his life, shall be punished with fine from 1000 to 5000 levs, and at second breach - with deprivation from the right to exercise his profession for a term from three months to one year.

(4) (new " SG 41/09, in force from 02.06.2009) A national of republic consultant, refusing to fulfill or deliberately failing to fulfill an assigned obligation, shall be punished with a fine from 1000 to 3000 levs, and in case of repeated violation " from 3000 to 5000 levs.

Art. 223. (amend. - SG 71/06, in force from 01.01.2007) (1) Who implements assisted reproduction in violation of Art. 130, 131, 132a, 132b, 133, 135 and 136 if not subject to graver penalty, shall be punished by fine from 15 000 to 50 000 levs and at second breach - with deprivation from the right to exercise his profession for a term from three months to one year.

(2) Whoever violates the provision of Art. 132 shall be fined from 5000 to 10 000 BGN and where the violation was committed by a legal person proprietary sanction shall be imposed in amount from 20 000 to 50 000 BGN.

(3) Whoever violates the provision of Art. 134 shall be fined from 25 000 to 50 000 BGN and where the violation was committed by a legal person proprietary sanction shall be imposed in amount from 50 000 to 100 000 BGN.

Art. 224. An official, who imposes measures for physical restriction of a patient with established psychic disorder in violation of the requirements of this Act and the normative acts for its implementation, if not subject to graver penalty, shall be punished with fine from 500 to 1500 levs and at second breach - with deprivation from the right to exercise his profession for a term from three months to one year.

Art. 225. (1) Medical specialist, who issues patent's card in violation of the normatively established requirements, shall be punished with fine from 1000 to 3000 levs and at second breach - from 4000 to 10 000 levs.

(2) (amend. - SG 98/10, in force from 01.01.2011) An official, who does not fulfil the order of the director of the regional health inspection for establishing medical consultative commission, shall be punished with fine from 500 to 1500 levs and at second breach - from 1500 to 4500 levs.

Art. 226. Who implements medical scientific study in violation of this Act, if not subject to graver penalty, shall be punished with fine from 2000 to 6000 levs and at second breach - with deprivation from the right to exercise his profession for a term from three months to one year.

Art. 227. Who practices unconventional methods for impact on individual health in violation of this Act and the normative acts for its implementation shall be punished with fine from 500 to 1500 levs and at second breach - from 1500 to 5000 levs.

Art. 228. Medical specialist, who violates the requirements, established with this Act and with the normative act for its implementation, to the form, the content, the conditions and the order for use, processing, analysis, preservation and conceding of the medical documentation, shall be punished with fine from 500 to 1500 levs and at second breach - from 1500 to 3000 levs.

Art. 228a. (new " SG 41/09, in force from 02.06.2009) (1) (amend. " SG 15/12, in force from 01.01.2014) To a medical establishment, violating the procedure of spending of the funds, allocated to it from the state budget under the provisions of Art. 82, a proprietary sanction from 5000 to 15000 levs shall be imposed and in case of a repeated violation " from 15000 to 25000 levs.

(2) (amend. " SG 15/12, in force from 01.01.2014) To a medical establishment, violating the procedure of prescribing and releasing of medicinal products, purchased with funds from the state budget under the provisions of Art. 82, a proprietary sanction from 3000 to 10000 levs shall be imposed and in case of a repeated violation " from 10000 to 20000 levs

Art. 228b. (new " SG 41/09, in force from 02.06.2009; amend. " SG 101/09, in force from 01.01.2010, revoked - SG 102/18, in force from 01.04.2019)

Art. 228c. (new - SG 98/10, in force from 01.01.2011) (1) Any official breaching the conditions and order for conducting and financing the training for obtaining specialisation in the system of health care, determined in the ordinance referred to in Art. 181, Para 1, shall be imposed a fine from 500 to 1500 levs, and in cases of repeated breach - from 1500 to 3000 levs.

(2) Where the breach referred to in Para 1 was committed by a medical or health establishment or by a regional health inspection, a property sanction shall be imposed in amount from 2000 to 3000 levs, and in cases of repeated breach - from 3000 to 6000 levs.

Art. 229. (1) (amend. " SG 41/09, in force from 02.06.2009; amend. - SG 98/10, in force from 01.01.2011) Who violates the provisions of this Act or the normative act for its implementation out of the cases of art. 209 " 228c, shall be punished with fine from 100 to 600 levs and at second implementation of the same breach - from 500 to 3000 levs.

(2) When the breach of para 1 is implemented by sole entrepreneur, proprietary sanction shall be imposed in extent from 200 to 600 levs, and at second breach - from 600 to 2000 levs.

(3) When the breach of para 1 is implemented by corporate body, proprietary sanction shall be imposed in extent from 500 to 2000 levs, and at second breach - from 2000 to 5000 levs.

Art. 229a. (new - SG 71/06, in force from 01.01.2007; amend. - SG 98/10, in force from 14.12.2010, amend. - SG 102/18, in force from 01.04.2019) The violations

regarding Art. 223, Para 1 and 2 shall be found by acts compiled by officials designated by the Executive Director of the Executive Agency for Medical Supervision, and the penal decrees shall be issued by the Executive Director of the Executive Agency for Medical Supervision.

Art. 229b. (new - SG 71/06, in force from 01.01.2007; amend. - SG 98/10, in force from 14.12.2010, amend. - SG 102/18, in force from 01.04.2019) The violations regarding Art. 223, Para 3 shall be found by acts compiled by the customs bodies or by officials designated by the Executive Director of the Executive Agency for Medical Supervision, and the penal decrees shall be issued by the Director of the "Customs" Agency or official determined by him, respectively by the Executive Director of the Executive Agency for Medical Supervision.

Art. 230. (1) (amend. - SG 98/10, in force from 01.01.2011) The violations of art. 225 and 227 shall be established with acts, compiled by state health inspectors or by officials, determined by the director of the regional health inspection and the punitive decrees shall be issued by the director of the regional health inspection.

(2) Copy of the punitive decree, issued for breaches of para 1 shall be sent to the higher body for expertise of the ability to work, to the regional council for control over the acts, issued by the bodies for expertise of the temporary inability to work, to the persons, interested in the expertise (the certified, the insurers and the National Insurance Institute) and to RHIF.

Art. 231. (amend. - SG 41/09, in force from 02.06.2009; amend. - SG 98/10, in force from 01.01.2011; amend. - SG 40/12, in force from 01.06.2012) The violations of art. 209 - 217 shall be established with acts, compiled by state health inspectors or officials determined by the director of the regional health inspection, and the punitive decrees shall be issued by the director of the regional health inspection.

(2) The violations under Art. 218, Para 1 - 6 shall be established in acts drawn up by state health inspectors from the regional health inspectorates and/or by state health inspectors from the Ministry of Health, and the punitive decrees shall be issued by the director of the regional health inspection, respectively by the Minister of Health.

Art. 232. (revoked - SG 98/10, in force from 01.01.2011)

Art. 233. (amend. - SG 98/10, in force from 01.01.2011) The violations of art. 219 shall be established with acts, compiled by state health inspectors or by officials, determined by the director of the regional health inspection or by the director of NCRRP and the punitive decrees shall be issued by the director of the respective regional health inspection or by the director of NCRRP.

Art. 233a. (new - SG 98/10, in force from 01.01.2011, amend. - SG 102/18, in force from 01.04.2019) The breaches referred to in Art. 220, 221, 224, 226 and 228a shall be established in acts drawn up by officials determined by the executive director of

Executive Agency for Medical Supervision, and the penal decrees shall be issued by the Executive Director of Executive Agency for Medical Supervision.

Art. 234. (amend. â€“ SG 41/09, in force from 02.06.2009; amend. â€“ SG 101/09, in force from 01.01.2010; amend. - SG 98/10, in force from 01.01.2011) The violations of art. 221a and 222 shall be established with acts, compiled by state health inspectors or by officials, determined by the director of the regional health inspection, and the punitive decrees shall be issued by the director of the regional health inspection.

Art. 234a. (new - SG 98/10, in force from 01.01.2011, amend. - SG 102/18, in force from 01.04.2019) The breaches referred to in Art. 228 shall be established in acts, drawn up by state health inspectors or by officials, determined by the director of the regional health inspection or by the Executive Director of the Executive Agency for Medical Supervision, and the penal decrees shall be issued by the director of the regional health inspection or by the Executive Director of the Executive Agency for Medical Supervision.

Art. 234b. (new - SG 98/10, in force from 01.01.2011) The breaches referred to in Art. 228c shall be established in acts, drawn up by officials, authorised by the Minister of Health, and the penal decrees shall be issued by the Minister of Health.

Art. 235. (amend. â€“ SG 41/09, in force from 02.06.2009; amend. â€“ SG 101/09, in force from 01.01.2010; amend. - SG 98/10, in force from 01.01.2011, amend. - SG 102/18, in force from 01.04.2019) The breaches referred to in Art. 229 shall be established in acts, drawn up by state health inspectors or by officials, determined by the director of the regional health inspection or by the Executive Director of the Executive Agency for Medical Supervision, and the penal decrees shall be issued by the director of the regional health inspection or by the Executive Director of the Executive Agency for Medical Supervision.

Art. 235a. (new - SG 107/14, in force from 01.01.2015) (1) Whoever violates the provisions of the Council of Ministers act referred to in Art. 103a shall be imposed a fine between BGN 100 and 500 for each individual case. In case of repeating the same violation the fine shall be double the amount of the initially imposed.

(2) Manager of a health establishment violating his duties related to the organisation of the activities of supplying data to the register referred to in Art. 33, Para 5, Item 12 of the Social Insurance Code, specified in the ordinance referred to in Art. 101, Para 7 of the present Act, shall be imposed a fine between BGN 100 and 500 for each individual case. In case of repeating the same violation the fine shall be double the amount of the initially imposed.

(3) The violations referred to in Para 1 and 2 shall be established by acts of the control bodies of the National Insurance Institute, while the penal decrees shall be issued by the head of the territorial unit of the National Insurance Institute or an official authorised by him.

Art. 236. The compiling of the acts, the issuing, the appealing and the execution of the punitive decrees shall be implemented according to the provisions of the Administrative Violations and Penalties Act.

### **Additional provisions**

§ 1. In the sense of this Act:

1. "Health documentation" are all forms for registration and preservation of health information.

2. "Dispensary system" is method of active search, diagnostics, treatment and periodic observation of ill persons with defined diseases.

3. "Invasive methods" are diagnostic and treatment instrumental methods, at which through by invading the entity of the skin and the mucosa or through natural openings is penetrated into human body.

4. "Medical - legal procedures" are procedures, implemented with objective protection of the security of the country, the internal order or the health of the citizens without medical indication.

5. "Second breach" is breach, implemented in one year term after the entering into force of the punitive decree, with which the offender is punished for breach of the same kind.

6. "Screening" is purposed prophylactic study, implemented according to defined programme for establishing the dissemination of defined characteristic, symptom or disease among a group of individuals.

7. "Physical restriction" is applying of mechanical means for immobilisation, compulsory isolation in a special closed premises and use of medical products for reduction of the physical activity of the patient in cases when he is dangerous for himself or for those around.

8. "Promotion of health" is a process at which by ensuring social, economic, ecological and other conditions and adequate health education is given opportunity to the individuals to improve their health by strengthening the personal and the group responsibility.

9. "Sites of public designation" are:

a) (amend. â€“ SG 41/09, in force from 02.06.2009) water sources and mineral water sources, water supply sites and facilities for drinking - household water supply;

b) swimming pools, beaches and places for bathing;

c) (amend. SG 94/05; suppl. â€“ SG 41/09, in force from 02.06.2009; amend. â€“ SG 30/13, in force from 26.03.2013) ) means for shelter - hotels, motels, apartment tourist complexes, villa settlements, tourist complexes, villas, family hotels, hostels, boarding houses, recreation labour hotels, guest rooms and guest apartments, bungalows, camping places as well as tourist cottages, tourist training centers and tourist boarding houses;

d) sport sites - stadiums, sport halls, playgrounds, fitness centres and halls;

e) (suppl. â€“ SG 41/09, in force from 02.06.2009) theatres, cinemas, concert halls, public culture centers, computer and Internet halls, gambling halls;

f) (suppl. â€“ SG 41/09, in force from 02.06.2009; amend. â€“ SG 30/13, in force from 26.03.2013) barber's, hairdresser's and cosmetic parlours, solar studios, tattoo

studios and atelier for piercing of ears and of other body parts, balneotherapy (medical SPA) centres, SPA centres, wellness centers, and talasotherapy centres, public baths, laundries, saunas, public toilettes;

g) graveyard parks;

h) (suppl. - SG 81/06; amend. - SG 46/07, in force from 12.06.2007; amend. - SG 98/10, in force from 14.12.2010) sites for production and wholesale trade with medicinal products and medical goods, pharmacies, drugstores and optics;

i) (amend. â€“ SG 41/09, in force from 02.06.2009; amend. - SG 98/10, in force from 14.12.2010) sites for production, preservation and trade with cosmetic products;

j) railway stations, airports, ports, bus stations, metro-stations;

k) (amend. â€“ SG 41/09, in force from 02.06.2009) the assets under Art. 26, par. 1, item 3;

(2) (new â€“ SG 101/09, in force from 01.01.2010; amend. â€“ SG 08/11, in force from 25.01.2011) The Executive Agency "Medical audit" shall immediately notify the employer, the labour safety authorities, the state health control, the Bulgarian Food Safety Agency and the authorities on the protection of the environment to implement the necessary measures, when they establish labour conditions and other harmful environmental factors threatening the public health.

m) (suppl. SG 94/05; suppl. â€“ SG 41/09, in force from 02.06.2009; amend. - SG 98/10, in force from 14.12.2010; amend. â€“ SG 08/11, in force from 25.01.2011) sites for production of bottled natural mineral, spring and table water;

n) (suppl. â€“ SG 41/09, in force from 02.06.2009, amend. - SG 24/19, in force from 01.07.2020, amend. on entry into force - SG 101/19) nurseries and kindergartens, schools and higher schools, student hostels, schools for music, languages, sports, bases of childrenâ€™s and school studentsâ€™ recreation and tourism and centres for work with children;

o) (amend. - SG 59/06, in force from 01.01.2007; suppl. â€“ SG 41/09, in force from 02.06.2009) medical and health establishments, medical offices and facilities, where non-conventional methods of favourable effect on individual health are applied;

p) (revoked - SG 59/06, in force from 01.01.2007)

q) sites with sources of ionising radiations;

r) (revoked â€“ SG 82/07)

s) agricultural pharmacies;

t) (new - SG 98/10, in force from 14.12.2010) sites with transmission facilities, which are part of an electronic communication network such as: base and radio-relay stations, broadcasting transmitters and translators, radio-location and navigation stations, etc.

10. "Products and goods of importance for human health" are:

a) (amend. â€“ SG 08/11, in force from 25.01.2011) bottled natural mineral, spring and table water;

b) (amend. - SG 98/10, in force from 14.12.2010) medicinal products;

c) cosmetic products;

d) (amend. â€“ SG 41/09, in force from 02.06.2009) chemical substances and preparations;

e) second hand clothes;

f) (new â€“ SG 41/09, in force from 02.06.2009) sanitary and hygiene materials (ladies napkins, tampons, single use diapers for babies and for adults, wet tissues, etc.);

g) (new - SG 98/10, in force from 14.12.2010) medicinal products.

11. "Activities of importance for human health" are:

a) development of the urbanised territories;  
b) designing, construction, reconstruction, expansion, entering into exploitation of residential buildings and sites with public designation;  
c) maintaining of the hygiene of the settlements by the municipalities;  
d) fulfilment of the immunisation calendar of the Republic of Bulgaria;  
e) not admitting and restriction of inter-hospital infections in the medical establishments;

f) implementing disinfection, disinsection and deratisation;

g) preparing and observing of the weekly study schedules;

h) observing of the physiological norms for organised catering of groups of the population.

i) (new - SG 59/06, in force from 01.01.2007) the activities of the services of employment medicine;

j) (new - SG 59/06, in force from 01.01.2007; suppl. â€“ SG 41/10) the activities related to dangerous waste from medical and health establishments;

k) (new â€“ SG 41/09, in force from 02.06.2009) meeting the requirements for provision of healthy nutrition to groups of the population;

l) (new - SG 98/10, in force from 14.12.2010) activities with asbestos and/or materials containing asbestos;

m) (new â€“ SG 08/11, in force from 25.01.2011) compliance with the prohibitions and limitations for advertising and sale of alcoholic beverages provided for in a normative act;

n) (new â€“ SG 08/11, in force from 25.01.2011) compliance with the smoking prohibitions and limitations provided for in a normative act.

12. "The factors of the living environment" are:"

a) waters, designated for drinking - household needs;

b) waters, designated for bathing;

c) mineral waters, designated for drinking or for use for prophylactic, treatment or for hygiene needs;

d) noise and vibrations in residential, public buildings and urbanised territories;

e) ionising radiations in the residential, the production and the public buildings;

f) (amend. â€“ SG 41/09, in force from 02.06.2009) non ionising radiations in the residential, the production, public buildings and urbanized territories;

g) chemical factors and biological agents in the sites with public designation;

h) resort resources;

i) air.

13. "Urbanised territories" are the settlements and the settlement formations within construction boundaries, determined with a development plan.

14. (amend. â€“ SG 1/14, in force from 03.01.2014) "Cosmetic product" is every substance or compound, intended to get in contact with any exterior part of human body (epidermis, hair and haired parts, nails, lips and external sexual organs) or with the teeth and the mucosa (mucous membrane) of the oral cavity, exclusively or primarily with objective their cleaning, perfuming, change of their appearance, their protection, maintenance in proper condition or correction of the body odour.

15. "Informed consent" is consent, given voluntary after acquainting with defined information.

16. "Reproduction health" is the health of the persons, connected with their abilities to create generation.

17. "Alcohol beverages" are the spirit beverages, wine and beer.

18. "Spirit beverages" are liquids, designated for consumption, containing at least 15 volume percent ethyl alcohol.

19. "Direct advertisement" is each form of commercial message, note or recommendation, aiming promotion of alcohol beverages and/or their consumption by using the beverages themselves or activities, connected with their consumption, production and distribution.

20. (amend. - SG 98/10, in force from 14.12.2010) "Indirect advertisement" is each form of commercial message, note, recommendation or activity, using a name or trademark of alcohol beverage, as well as firm or trademark of producer of alcohol beverages on products and goods, which are not alcohol beverages.

21. "Assisted reproduction" is diagnostic and treatment methods, by which is aimed overcoming of sterility and which are implemented in specialised centres.

22. "Dietetics" is treatment method at which by prescribed nutrition regime, including only with fruits, vegetables or other products of organic origin, is achieved favourable impact on the individual health.

23. "Healing hunger" is treatment method at which by prescribed regime of taking in water, juices and other liquids is achieved favourable impact on the individual health.

24. (new - SG 71/06, in force from 01.01.2007) "Ovum" means the female reproductive cell.

25. (new - SG 71/06, in force from 01.01.2007) "Spermatozoids" means the male reproductive cells.

26. (new - SG 71/06, in force from 01.01.2007) "Zygote" means fertilized ovum in the stage of division.

27. (new - SG 71/06, in force from 01.01.2007) "Procurement" means extraction by medical methods of ova or collection of spermatozoids from a donor carried out with the objective of assisted reproduction or other scientific or educational needs of the medicine.

28. (new - SG 71/06, in force from 01.01.2007) "Placement" means putting by medical methods spermatozoids, ovum or zygote in the body of a female.

29. (new - SG 71/06, in force from 01.01.2007) "Expertise" means activity related to research for assessment the condition of an ovum, spermatozoids or zygote as well as for detection the presence of disease organisms, chemical or biological substances through which illness, infection or intoxication may be transferred.

30. (new - SG 71/06, in force from 01.01.2007) "Processing" means the activity of preparation of the ovum, spermatozoids or zygote for placement by implementation of physical, chemical or biological methods during procurement or immediately after this also including their packaging where no change in their integrity is implemented.

31. (new - SG 71/06, in force from 01.01.2007) "Storage" means the activity related to the use of physical or chemical processes or change of the environment in order to avoid or delay the biological or physical injury of the procured ova, spermatozoids or zygotes also including their packaging.

32. (new - SG 71/06, in force from 01.01.2007) "Donor" means any source of cells of human origin.

33. (new - SG 71/06, in force from 01.01.2007) "Labelling" means the activity of marking the package of organs, tissues and cells with the purpose of their identification.

34. (new " SG 41/09, in force from 02.06.2009, amend. - SG 58/22, in force from 01.01.2023) "Temporary inability to work" is a condition, under which the insured person is not able or is prevented from working due to: acute, sub-acute or aggravated chronic general disease; accident; occupational disease; therapy abroad; treatment in sanatorium or health resort center; urgent medical examination or testing; quarantine; suspension from work upon instruction of health care bodies; attendance of a sick person or of a family member under quarantine; due accompanying of a sick family member for medical examination; testing or treatment in the same or in a different settlement, in the country or abroad; pregnancy and delivery; and for taking care of a healthy child up to 12 years of age dismissed from a child-care facility or school because of quarantine imposed on that facility or on the school or on an individual group or class within it or due to quarantine on the child.

35. (new " SG 41/09, in force from 02.06.2009) "Permanently reduced inability to work" is a condition, under which because of chronic traumatic or non-traumatic injury (illness) the person has limited ability to work with regard to a permanent functional deficit of the respective affected organ or system.

36. (new " SG 41/09, in force from 02.06.2009) "Type and degree of disability" is a condition of chronic traumatic or non-traumatic injury (illness) under which the person of an age not eligible to work has a permanent functional deficit of a respective organ or system.

37. (new " SG 41/09, in force from 02.06.2009) "A person, assigned to take care for a child" is a close person, relative, foster parent, a manager of a child care institution, where they are permanently taken away from their family environment by a court resolution for accommodation of the child out of the family.

38. (new " SG 42/10, in force from 02.06.2010; revoked " SG 40/12, in force from 01.06.2012)

39. (new " SG 1/14, in force from 03.01.2014) "Distributor of cosmetic products" is natural person or a legal entity in a supply chain, other than a manufacturer or an importer, providing a cosmetic product in the territory of the European Union Member States.

40. (new " SG 1/14, in force from 03.01.2014) "Cosmetic products importer" is a natural person or a legal entity based in the territory of the European Union Member States launching on the market a cosmetic product from a third state.

41. (new " SG 1/14, in force from 03.01.2014) "Person in charge" is the manufacturer or their authorized representative, based in the territory of a European Union Member State, or the exporter or their authorized representative, based in the territory of a European Union Member State, and also the distributor, launching on the market a cosmetic product under their name or brand name or modifying a product which has already been launched on the market, in a way which may affect the compliance with the applicable requirements of Regulation (EC) No. 1223/2006.

42. (new " SG 1/14, in force from 03.01.2014) "Rare disease" is a disease with an infection rate of 5 per 10.000 persons of the population of the European Union.

43. (new " SG 58/19) "Tobacco products" shall be the products within the meaning of § 1, item 4 of the additional provisions of the Tobacco, Tobacco Products and Related Products Act.

44. (new " SG 58/19) "Articles related to tobacco products" shall be the products within the meaning of § 1, item 8 of the additional provisions of Tobacco, Tobacco Products and Related Products Act.

45. (new " SG, 44/20, in force from 14.05.2020) "Emergency epidemic situation under Article 63, Para. 1" is present in a disaster, caused by a contagious disease, which leads to an epidemic spread with immediate danger to life and health of citizens, the prevention and overcoming of which requires more than the usual activities for protection and preservation of the life and health of the citizens.

46. (new " SG, 44/20, in force from 14.05.2020) "Isolation" is an action for separation of persons, suffering from a contagious disease under Art. 61, Para. 1 or 3, and of infectious persons, in order, that the spread of the respective contagious disease is prevented.

47. (new " SG, 44/20, in force from 14.05.2020) "Quarantine" is an action for separation of contact persons from persons, suffering from a contagious disease under Art. 61, Para. 1 or 3, and to persons, who have entered the territory of the country from other countries, in order, that the spread of the respective contagious disease is prevented.

#### **Edition to SG, 44/13 May 2020**

*§ 1. In the sense of this Act:*

- 1. "Health documentation" are all forms for registration and preservation of health information.*
- 2. "Dispensary system" is method of active search, diagnostics, treatment and periodic observation of ill persons with defined diseases.*
- 3. "Invasive methods" are diagnostic and treatment instrumental methods, at which through by invading the entity of the skin and the mucosa or through natural openings is penetrated into human body.*
- 4. "Medical - legal procedures" are procedures, implemented with objective protection of the security of the country, the internal order or the health of the citizens without medical indication.*
- 5. "Second breach" is breach, implemented in one year term after the entering into force of the punitive decree, with which the offender is punished for breach of the same kind.*
- 6. "Screening" is purposed prophylactic study, implemented according to defined programme for establishing the dissemination of defined characteristic, symptom or disease among a group of individuals.*

7. "Physical restriction" is applying of mechanical means for immobilisation, compulsory isolation in a special closed premises and use of medical products for reduction of the physical activity of the patient in cases when he is dangerous for himself or for those around.
8. "Promotion of health" is a process at which by ensuring social, economic, ecological and other conditions and adequate health education is given opportunity to the individuals to improve their health by strengthening the personal and the group responsibility.
9. "Sites of public designation" are:
- a) (amend. â€“ SG 41/09, in force from 02.06.2009) water sources and mineral water sources, water supply sites and facilities for drinking - household water supply;
  - b) swimming pools, beaches and places for bathing;
  - c) (amend. SG 94/05; suppl. â€“ SG 41/09, in force from 02.06.2009; amend. â€“ SG 30/13, in force from 26.03.2013) means for shelter - hotels, motels, apartment tourist complexes, villa settlements, tourist complexes, villas, family hotels, hostels, boarding houses, recreation labour hotels, guest rooms and guest apartments, bungalows, camping places as well as tourist cottages, tourist training centers and tourist boarding houses;
  - d) sport sites - stadiums, sport halls, playgrounds, fitness centres and halls;
  - e) (suppl. â€“ SG 41/09, in force from 02.06.2009) theatres, cinemas, concert halls, public culture centers, computer and Internet halls, gambling halls;
  - f) (suppl. â€“ SG 41/09, in force from 02.06.2009; amend. â€“ SG 30/13, in force from 26.03.2013) barber's, hairdresser's and cosmetic parlours, solar studios, tattoo studios and atelier for piercing of ears and of other body parts, balneotherapy (medical SPA) centres, SPA centres, wellness centers, and talasotherapy centres, public baths, laundries, saunas, public toilettes;
  - g) graveyard parks;
  - h) (suppl. - SG 81/06; amend. - SG 46/07, in force from 12.06.2007; amend. - SG 98/10, in force from 14.12.2010) sites for production and wholesale trade with medicinal products and medical goods, pharmacies, drugstores and optics;
  - i) (amend. â€“ SG 41/09, in force from 02.06.2009; amend. - SG 98/10, in force from 14.12.2010) sites for production, preservation and trade with cosmetic products;
  - j) railway stations, airports, ports, bus stations, metro-stations;
  - k) (amend. â€“ SG 41/09, in force from 02.06.2009) the assets under Art. 26, par. 1, item 3;
  - (2) (new â€“ SG 101/09, in force from 01.01.2010; amend. â€“ SG 08/11, in force from 25.01.2011) The Executive Agency "Medical audit" shall immediately notify the employer, the labour safety authorities, the state health control, the Bulgarian Food Safety Agency and the authorities on the protection of the environment to implement the necessary measures, when they establish labour conditions and other harmful environmental factors threatening the public health.
  - m) (suppl. SG 94/05; suppl. â€“ SG 41/09, in force from 02.06.2009; amend. - SG 98/10, in force from 14.12.2010; amend. â€“ SG 08/11, in force from 25.01.2011) sites for production of bottled natural mineral, spring and table water;
  - n) (suppl. â€“ SG 41/09, in force from 02.06.2009, amend. - SG 24/19, in force from 01.07.2020, amend. on entry into force - SG 101/19) nurseries and kindergartens, schools and higher schools, student hostels, schools for music, languages, sports, bases of childrenâ€™s and school studentsâ€™ recreation and tourism and centres for work with children;
  - o) (amend. - SG 59/06, in force from 01.01.2007; suppl. â€“ SG 41/09, in force from 02.06.2009) medical and health establishments, medical offices and facilities, where non-conventional methods of favourable effect on individual health are applied;
  - p) (revoked - SG 59/06, in force from 01.01.2007)

- q) sites with sources of ionising radiations;
  - r) (revoked â€“ SG 82/07)
  - s) agricultural pharmacies;
  - t) (new - SG 98/10, in force from 14.12.2010) sites with transmission facilities, which are part of an electronic communication network such as: base and radio-relay stations, broadcasting transmitters and translators, radio-location and navigation stations, etc.
10. "Products and goods of importance for human health" are:
- a) (amend. â€“ SG 08/11, in force from 25.01.2011) bottled natural mineral, spring and table water;
  - b) (amend. - SG 98/10, in force from 14.12.2010) medicinal products;
  - c) cosmetic products;
  - d) (amend. â€“ SG 41/09, in force from 02.06.2009) chemical substances and preparations;
  - e) second hand clothes;
  - f) (new â€“ SG 41/09, in force from 02.06.2009) sanitary and hygiene materials (ladies napkins, tampons, single use diapers for babies and for adults, wet tissues, etc.);
  - g) (new - SG 98/10, in force from 14.12.2010) medicinal products.
11. "Activities of importance for human health" are:
- a) development of the urbanised territories;
  - b) designing, construction, reconstruction, expansion, entering into exploitation of residential buildings and sites with public designation;
  - c) maintaining of the hygiene of the settlements by the municipalities;
  - d) fulfilment of the immunisation calendar of the Republic of Bulgaria;
  - e) not admitting and restriction of inter-hospital infections in the medical establishments;
  - f) implementing disinfection, disinsection and deratisation;
  - g) preparing and observing of the weekly study schedules;
  - h) observing of the physiological norms for organised catering of groups of the population.
  - i) (new - SG 59/06, in force from 01.01.2007) the activities of the services of employment medicine;
  - j) (new - SG 59/06, in force from 01.01.2007; suppl. â€“ SG 41/10) the activities related to dangerous waste from medical and health establishments;
  - k) (new â€“ SG 41/09, in force from 02.06.2009) meeting the requirements for provision of healthy nutrition to groups of the population;
  - l) (new - SG 98/10, in force from 14.12.2010) activities with asbestos and/or materials containing asbestos;
  - m) (new â€“ SG 08/11, in force from 25.01.2011) compliance with the prohibitions and limitations for advertising and sale of alcoholic beverages provided for in a normative act;
  - n) (new â€“ SG 08/11, in force from 25.01.2011) compliance with the smoking prohibitions and limitations provided for in a normative act.
12. "The factors of the living environment" are:"
- a) waters, designated for drinking - household needs;
  - b) waters, designated for bathing;
  - c) mineral waters, designated for drinking or for use for prophylactic, treatment or for hygiene needs;
  - d) noise and vibrations in residential, public buildings and urbanised territories;
  - e) ionising radiations in the residential, the production and the public buildings;
  - f) (amend. â€“ SG 41/09, in force from 02.06.2009) non ionising radiations in the residential, the production, public buildings and urbanized territories;

g) chemical factors and biological agents in the sites with public designation;

h) resort resources;

i) air.

13. "Urbanised territories" are the settlements and the settlement formations within construction boundaries, determined with a development plan.

14. (amend. â€“ SG 1/14, in force from 03.01.2014) "Cosmetic product" is every substance or compound, intended to get in contact with any exterior part of human body (epidermis, hair and haired parts, nails, lips and external sexual organs) or with the teeth and the mucosa (mucous membrane) of the oral cavity, exclusively or primarily with objective their cleaning, perfuming, change of their appearance, their protection, maintenance in proper condition or correction of the body odour.

15. "Informed consent" is consent, given voluntary after acquainting with defined information.

16. "Reproduction health" is the health of the persons, connected with their abilities to create generation.

17. "Alcohol beverages" are the spirit beverages, wine and beer.

18. "Spirit beverages" are liquids, designated for consumption, containing at least 15 volume percent ethyl alcohol.

19. "Direct advertisement" is each form of commercial message, note or recommendation, aiming promotion of alcohol beverages and/or their consumption by using the beverages themselves or activities, connected with their consumption, production and distribution.

20. (amend. - SG 98/10, in force from 14.12.2010) "Indirect advertisement" is each form of commercial message, note, recommendation or activity, using a name or trademark of alcohol beverage, as well as firm or trademark of producer of alcohol beverages on products and goods, which are not alcohol beverages.

21. "Assisted reproduction" is diagnostic and treatment methods, by which is aimed overcoming of sterility and which are implemented in specialised centres.

22. "Dietetics" is treatment method at which by prescribed nutrition regime, including only with fruits, vegetables or other products of organic origin, is achieved favourable impact on the individual health.

23. "Healing hunger" is treatment method at which by prescribed regime of taking in water, juices and other liquids is achieved favourable impact on the individual health.

24. (new - SG 71/06, in force from 01.01.2007) "Ovum" means the female reproductive cell.

25. (new - SG 71/06, in force from 01.01.2007) "Spermatozoids" means the male reproductive cells.

26. (new - SG 71/06, in force from 01.01.2007) "Zygote" means fertilized ovum in the stage of division.

27. (new - SG 71/06, in force from 01.01.2007) "Procurement" means extraction by medical methods of ova or collection of spermatozoids from a donor carried out with the objective of assisted reproduction or other scientific or educational needs of the medicine.

28. (new - SG 71/06, in force from 01.01.2007) "Placement" means putting by medical methods spermatozoids, ovum or zygote in the body of a female.

29. (new - SG 71/06, in force from 01.01.2007) "Expertise" means activity related to research for assessment the condition of an ovum, spermatozoids or zygote as well as for detection the presence of disease organisms, chemical or biological substances through which illness, infection or intoxication may be transferred.

30. (new - SG 71/06, in force from 01.01.2007) "Processing" means the activity of preparation of the ovum, spermatozoids or zygote for placement by implementation of physical, chemical or biological methods during procurement or immediately after this also including their packaging where no change in their integrity is implemented.

31. (new - SG 71/06, in force from 01.01.2007) "Storage" means the activity related to the use of physical or chemical processes or change of the environment in order to avoid or delay the biological or physical injury of the procured ova, spermatozoids or zygotes also including their packaging.
32. (new - SG 71/06, in force from 01.01.2007) "Donor" means any source of cells of human origin.
33. (new - SG 71/06, in force from 01.01.2007) "Labelling" means the activity of marking the package of organs, tissues and cells with the purpose of their identification.
34. (new - SG 41/09, in force from 02.06.2009) "Temporary inability to work" is a condition, under which the insured person is not able or is prevented from working due to: acute, sub-acute or aggravated chronic general disease; accident; occupational disease; therapy abroad; treatment in sanatorium or health resort center; urgent medical examination or testing; quarantine; suspension from work upon instruction of health care bodies; attendance of a sick person or of a family member under quarantine; due accompanying of a sick family member for medical examination; testing or treatment in the same or in a different settlement, in the country or abroad; pregnancy and delivery; taking care of a healthy child, sent back home by a child care facility due to quarantine in the facility.
35. (new - SG 41/09, in force from 02.06.2009) "Permanently reduced inability to work" is a condition, under which because of chronic traumatic or non-traumatic injury (illness) the person has limited ability to work with regard to a permanent functional deficit of the respective affected organ or system.
36. (new - SG 41/09, in force from 02.06.2009) "Type and degree of disability" is a condition of chronic traumatic or non-traumatic injury (illness) under which the person of an age not eligible to work has a permanent functional deficit of a respective organ or system.
37. (new - SG 41/09, in force from 02.06.2009) "A person, assigned to take care for a child" is a close person, relative, foster parent, a manager of a child care institution, where they are permanently taken away from their family environment by a court resolution for accommodation of the child out of the family.
38. (new - SG 42/10, in force from 02.06.2010; revoked - SG 40/12, in force from 01.06.2012)
39. (new - SG 1/14, in force from 03.01.2014) "Distributor of cosmetic products" is natural person or a legal entity in a supply chain, other than a manufacturer or an importer, providing a cosmetic product in the territory of the European Union Member States.
40. (new - SG 1/14, in force from 03.01.2014) "Cosmetic products importer" is a natural person or a legal entity based in the territory of the European Union Member States launching on the market a cosmetic product from a third state.
41. (new - SG 1/14, in force from 03.01.2014) "Person in charge" is the manufacturer or their authorized representative, based in the territory of a European Union Member State, or the exporter or their authorized representative, based in the territory of a European Union Member State, and also the distributor, launching on the market a cosmetic product under their name or brand name or modifying a product which has already been launched on the market, in a way which may affect the compliance with the applicable requirements of Regulation (EC) No. 1223/2006.
42. (new - SG 1/14, in force from 03.01.2014) "Rare disease" is a disease with an infection rate of 5 per 10.000 persons of the population of the European Union.
43. (new - SG 58/19) "Tobacco products" shall be the products within the meaning of § 1, item 4 of the additional provisions of the Tobacco, Tobacco Products and Related Products Act.

44. (new â€“ SG 58/19) "Articles related to tobacco products" shall be the products within the meaning of § 1, item 8 of the additional provisions of Tobacco, Tobacco Products and Related Products Act.

45. (new â€“ SG, 44/20, in force from 14.05.2020) "Emergency epidemic situation under Article 63, Para. 1" is present in a disaster, caused by a contagious disease, which leads to an epidemic spread with immediate danger to life and health of citizens, the prevention and overcoming of which requires more than the usual activities for protection and preservation of the life and health of the citizens.

46. (new â€“ SG, 44/20, in force from 14.05.2020) "Isolation" is an action for separation of persons, suffering from a contagious disease under Art. 61, Para. 1 or 3, and of infectious persons, in order, that the spread of the respective contagious disease is prevented.

47. (new â€“ SG, 44/20, in force from 14.05.2020) "Quarantine" is an action for separation of contact persons from persons, suffering from a contagious disease under Art. 61, Para. 1 or 3, and to persons, who have entered the territory of the country from other countries, in order, that the spread of the respective contagious disease is prevented.

§ 1a. (new â€“ SG 42/10, in force from 02.06.2010) "Public places" within the meaning of Art. 56 shall be all places which are publicly accessible and / or intended for public use, with no prejudice to the ownership or the right to access, including the following:

- a) the sites referred to in § 1, item 9, letters "b", "d", "e", "f", "g", "k", "l", "o", "p" and "q";
- b) pharmacies, drugstores and opticians' shops;
- c) commercial sites within the meaning of § 1, item 41 of the additional provisions of the Value Added Tax Act;
- d) (amend. â€“ SG 30/13, in force from 26.03.2013) accommodation facilities, catering and entertainment establishments, catering facilities adjacent to tourist huts within the meaning of Art. 3, para 2, items 1, 2 and 3 of the Tourism Act;
- e) undertakings engaged in food manufacturing, storage and trading, catering and entertainment establishments, as well as catering facilities adjacent to tourist huts, including tourist self-service tourist canteens, tourist buffets and waiter-service tourist canteens;
- f) buildings accessible by any person, including administrative institutions and other buildings where citizens are serviced or to which they have access;
- g) elevators and staircases of all kinds of buildings, etc.;
- h) means of public transport â€“ trains, aircraft, ships, buses, trams, trolleybuses; underground trains, minibuses, fixed route taxi minibuses, taxis and means of transport for special purposes - sanitary service vehicles.
- i) (new â€“ SG 40/12) the playing sites.

§ 1b. (new â€“ SG 1/14, in force from 03.01.2014) Application of Regulation (EC) No. 1223/2009 of the European Parliament and of the Council on cosmetic products shall be provided by this Act.

§ 1c. (new " SG 1/14, in force from 03.01.2014) The requirements of Directive 2011/24/EC of the European Parliament and of the Council of 9 March 2011 on the application of patients'™ rights in cross-border healthcare (OJ, L 88/45 of 4 April 2011) shall be introduced by this Act.

### **Transitional and concluding provisions**

§ 2. (1) The persons, who have right to exercise medical profession by the order of the revoked Public Health Act, shall be legally capable medical specialists in the sense of art. 184.

(2) (revoked - SG 98/10, in force from 01.01.2011)

§ 2a. (new " SG 76/05) (1) The persons who have acquired educational " qualification degree "master" in professional direction "Stomatology" shall have the rights of persons acquired education " qualification degree "master" in "Dental medicine".

(2) The Minister of Health shall issue document with which he certifies the rights of the persons of para 1.

§ 2b. (new " SG 59/07, in force from 26.05.2007) (1) The persons who do not have rights under § 32, par. 2 and 3 of the Transitional and Conclusive Provisions of the Act Amending and supplementing the Higher Education Act (SG 41/07) shall exercise the right of people with education and qualification degree of "Bachelor" under Art. 42, par. 1, item 1, item "b" of the Higher Education Act for exercising of the profession, provided that they have exercised it for not less than three subsequent years over the last 5 years for a nurse and for not less than two subsequent years over the last 5 years for a midwife.

(2) The person, who do not meet the requirements for the length of service under par. 1, shall have the rights of persons with education and qualification degree of "Bachelor" under Art. 42, par. 1, item 1, item "b" of the Higher Education Act for exercising of the profession after accumulating of the required years of service.

§ 2c. (new - SG 98/10, in force from 01.01.2011) (1) The paramedic, entitled under § 32, Para 2 and 3 of the transitional and concluding provisions of the Act Amending and Supplementing the Higher Education Act (SG 41/07), shall have the rights of physician's assistants with "bachelor" education and qualification degree under Art. 42, Para 1, Item 1, Letter "b" of the Higher Education Act in exercising their profession, provided that they have exercised a medical profession at least two years during the last 10 years.

(2) (amend. - SG 91/18) The paramedic, entitled under § 3 of the transitional and concluding provisions of the Act on the Professional Organizations of Nurses, Midwives and Associated Medical Specialists, Dental Technicians and Assistant-Pharmacists, shall have the rights of physician's assistants with "bachelor" education and qualification degree under Art. 42, Para 1, Item 1, Letter "b" of the Higher Education Act

in exercising their profession, provided that they have exercised a medical profession at least three years during the last 10 years.

§ 2d. (new - SG 102/18, in force from 01.01.2019) The time during which the specialists were trained for acquiring a specialty on the basis of a training contract for the acquisition of a specialty, concluded in accordance with the repealed Ordinance No 34 of 2006 for acquiring a specialty in the healthcare system (promulgated, SG No. 7/2007, amended, SG No. 89/2007, No. 55 of 2008, No. 12 and 72 of 2010, pages 58 and 60 of 2011 Amended, SG No. 50/2012, No. 24 and 73 of 2013, amended by Decision No 15612 of 26.11.2013 of the SAC of the Republic of Bulgaria - issue 59 of 2014, revoked 7 of 2015) and have been insured under the procedure of the repealed Art. 4, para. 1, item 9 of the Social Insurance Code, shall be considered as length of service.

§ 3. The persons, to whom till December 31, 2004 is determined degree of durably reduced ability to work, at rounding 65 years of age shall be considered with determined degree of durably reduced ability to work for life.

§ 4. (1) In one month term after the law enters into force the Council of Ministers shall transform the existing district health centres into regional health centres and the existing hygiene - epidemiological inspectorates - into regional inspectorates for protection and control of public health.

(2) The Minister of Health shall in one month term after the decree of para 1 enters into force issue Regulation for the structure and the activity of the regional health centres and Regulation for the structure and the activity of the regional inspectorates for protection and control of public health.

(3) The persons, who exercise state sanitary control in the hygiene - epidemiological inspectorates by the entering of this Act in force, shall have the rights of § 3 of the transitional and concluding provisions of the Civil Servant Act.

(4) The regional inspectorates for preservation and control of public health can conclude contracts with the NHIF till December 1, 2005.

§ 5. This Act shall revoke the Public Health Act (Prom. SG 88/73, corr. SG 92/73, amend. SG 63/76, amend. SG 28/83, amend. SG 66/85, amend. SG 27/86, amend. SG 89/88, amend. SG 87/89, amend. SG 99/89, amend. SG 15/91, corr. SG 24/91, amend. SG 64/93, amend. SG 31/94, amend. SG 36/95, amend. SG 12/97, amend. SG 87/97, amend. SG 124/97, suppl. SG 21/98, amend. SG 7098, amend. SG 71/98, amend. SG 93/98, amend. SG 30/99, amend. SG 62/99, amend. SG 67/99, amend. SG 90/99, suppl. SG 113/99, amend. SG 10/00, amend. SG 36/00, amend. SG 63/02, amend. SG 83/03, suppl. SG 102/03).

§ 6. In art. 52, para of the Road Transport Act (prom. SG 82/99, amend. SG 11, 45/02, SG 99/03) the words "the sanitary" shall be substituted by "the bodies for state health control".

§ 7. In the Safe Use of Nuclear Energy Act (prom. SG 63/02, amend. SG 120/02) the following amendments and supplements shall be made:

1. In art. 15:

a) in para 3 item 6 shall be revoked;

b) in para 4 item 8 shall be revoked;

2. In art. 18, para 1, item 3 shall be changed to:

"3. of art. 15, para 3, items 2 - 5 in term up to one month".

3. In art. 29:

a) the previous text shall become para 1;

b) para 2 shall be created:

"(2) Fee shall not be due for issuing of permission for import or export of sources of ionising radiations or parts of them."

4. In art. 31:

a) new para 2 shall be created:

"(2) The initial license fee for issuing license for use of radioactive substances and other sources of ionising radiations for medical objectives and the annual license fees shall be in extent of 50 percent of the fees, determined under art. 28, para 1.";

b) the previous para 2 shall become para 3.

5. In art. 57 item 1 shall be revoked.

6. In art. 58:

a) in para 1 item 5 shall be revoked;

b) in para 3 after the words "for term" shall be added "of three".

7. Art. 59 shall be changed to:

"Art. 59. Permission for import of radioactive sources of ionising radiations shall be issued if:

1. the person, for whom they are designated, has the necessary license or permission, giving to him right to use and/or preserve them;

2. is ensured their transport by a person, who has license or permission for transport under this Act."

8. In art. 60:

a) in para 2 the words "and/or the national consultants in radiation therapy, nuclear medicine and radiology" shall be deleted;

b) para 3 shall be created:

"(3) The official coordination of para 2 shall be implemented with obligation that the sources of ionising radiations can be used for medical purposes."

9. Art. 61 shall be revoked.

10. In art. 63 after the words "The licensee" shall be added "or the titular of permission".

§ 8. In art. 47, para 1 of the Higher Education Act (Prom. SG 112/95, amend. SG 28/96, amend. SG 56/97, corr. SG 57/97, amend. SG 58/97, amend. SG 60/99, corr. SG 66/99, amend. SG 111/99, amend. SG 113/99, amend. SG 54/00, amend. SG 22/01, amend. SG 40/02, amend. SG 53/02, amend. SG 48/) after the words "agrarian sciences" shall be added "the national centres on the problems of public health".

§ 9. In the Water Act (Prom. SG 67/99, amend. SG 81/00, amend. SG 34/01, amend. SG 41/01, amend. SG 108/01, amend. SG 47/02, amend. SG 74/02, amend. SG 91/02, amend. SG 42/03, amend. SG 69/03, amend. SG 84/03, suppl. SG 107/03) the following amendments and supplements shall be made:

1. In art. 42, first sentence the word "sanitary" shall be substituted by "hygiene - epidemiological".

2. In art. 47, para 2 the words "the public health establishments" shall be substituted by "the medical establishments for hospital care".

3. In art. 48, para 1, item 7 the word "sanitary" shall be substituted by "hygiene - epidemiological".

4. In art. 151, item 1 f) the words "the public health establishments" shall be substituted by "the medical establishments for hospital care".

§ 10. Everywhere in the Civil Registration Act (prom. SG 67/99, amend. SG 28, 37/01, SG 54/02, SH 63/03) the words "health establishment" and "specialised health establishments" shall be substituted respectively by "medical establishment" and "medical establishments".

§ 11. In the Civil Aviation Act (Prom. SG 94/72, amend. SG 30/90, amend. SG 16/97, amend. SG 85/98, amend. SG 12/00, amend. SG 34/01, amend. SG 111/01, amend. SG 52/04) the following changes shall be made:

1. In art. 71, para 1 a) the words "health establishment" shall be substituted by "medical establishment".

2. In art. 85, para 2 the words "the sanitary" shall be substituted by "the medical".

§ 12. In art. 40, para 1 of the Value Added Tax Act (Prom. SG 153/98, corr. SG 1/99, suppl. SG 44/99, amend. SG 62/99, suppl. SG 64/99, amend. SG 103/99, amend. SG 111/99, suppl. SG 63/00, suppl. SG 78/00, amend. SG 102/00, amend. SG 109/01, amend. SG 28/02, amend. SG 45/02, amend. SG 117/02, suppl. SG 37/03, amend. SG 42/03, amend. SG 86/03, amend. SG 109/03, amend. SG 53/04) the words "health establishments under the Public Health Act" shall be substituted by "national centres on the problems of public health" and the words "medical specialists under the Public Health Act" shall be substituted by "medical specialists under the Health Act".

§ 13. In art. 123, para 1, item 2 d) of the Road Transport Act (prom. SG 20/99, amend. SG 1/00, SG 43, 45, 76/02, SG 16, 22/03, SG 6/04) the words "the health establishment" shall be substituted by "the medical establishment".

§ 14. In art. 83, para 4 of the Railway Transport Act (prom. SG 97/00, amend. SG 47, 96/02) the words "the sanitary" shall be substituted by "the bodies for state health control".

§ 15. In art. 32, item 8 of the Child Protection Act (prom. SG 48/00, amend. SG 75, 120/02, SG 36, 63/03) the words "from diseases of art. 36 and 36a of the Public Health Act" shall be substituted by "from AIDS and diseases of art. 61, para 1 and art. 146, para 1, items 1 and 2 of the Health Act".

§ 16. In art. 37, para 2, item 2 of the Exchange of Military Obligations with Alternative Service Act (prom. SG 131/98, amend. SG 69/99, SG 49/00, SG 50/03) the words "bodies of the state sanitary control" shall be substituted by "bodies for state health control".

§ 17. In the Health Insurance Act (Prom. SG 70/98, amend. SG 93/98, amend. SG 153/98, amend. SG 62/99, amend. SG 65/99, amend. SG 67/99, amend. SG 69/99, amend. SG 110/99, amend. SG 113/99, amend. SG 1/00, amend. SG 64/00, suppl. SG 41/01, amend. SG 1/02, amend. SG 54/02, amend. SG 74/02, amend. SG 107/02, amend. SG 112/02, amend. SG 119/02, amend. SG 120/02, amend. SG 8/03, suppl. SG 50/03, amend. SG 107/03, suppl. SG 114/03, amend. SG 28/04, suppl. SG 38/04, amend. SG 49/04) the following amendments and supplements shall be made:

1. In art. 49 the words "the state sanitary control" shall be substituted by "the state health control".

2. In art. 58 the words "and health establishments under the Public Health Act" shall be substituted by "national centres on the problems of public health under the Health Act".

§ 18. In the Health and Safety Working Conditions Act (prom. SG 124/97, amend. SG 86/99, SG 64, 92/00, SG 25, 111/01, SG 18, 114/03) the following amendments and supplements shall be made:

1. In art. 25 para 6 shall be created:

"(6) The activities of the services for labour medicine shall be subject to accreditation under the conditions and by the order, determined for accreditation of the medical establishments with the Medical Establishments Act."

2. In art. 37, item 6 the word "sanitary" shall be substituted by "health".

§ 19. In art. 9 of the Execution of Penalties Act (Prom. SG 30/69, amend. SG 34/74, amend. SG 84/77, amend. SG 36/79, amend. SG 28/82, amend. SG 27/86, amend. SG 89/86, amend. SG 26/88, amend. SG 21/90, amend. SG 109/93, amend. SG 50/95, amend. SG 12/97, suppl. SG 13/97, amend. SG 73/98, amend. SG 153/98, amend. SG 49/00, amend. SG 62/02, amend. SG 120/02, amend. SG 61/04, amend. SG 66/04) the words "the sanitary requirements" shall be substituted by "the health requirements".

§ 20. In the Blood, Blood Donation, and Blood Transfusion Act (SG 102/03) the following amendments and supplements shall be made:

1. Art. 34a shall be created:

"Art. 34a. (1) All medical establishments for hospital care and dispensaries with beds can take blood for auto-blood-transfusion observing the requirements of art. 12,

para 2 when they have no medical counter-indications for this and after receiving written informed consent.

(2) When the person is under age written informed consent shall be taken from the lawful representative or tutor of the under-aged."

2. In the additional provision item 13 shall be created:

"13. Auto-blood-transfusion" is method at which to a patient is transfused blood, which has been taken in advance from him."

§ 21. In the Medicines and Pharmacies in Humanitarian Medicine Act(Prom. SG 36/95, amend. SG 61/96, amend. SG 38/98, amend. SG 30/99, amend. SG 10/00, amend. SG 37/00, amend. SG 59/00, amend. SG 78/00, amend. SG 41/01, amend. SG 107/02, amend. SG 120/02, corr. SG 2/03, amend. SG 56/03, amend. SG 71/03, amend. SG 112/03) everywhere the words "the chief state sanitary inspector" shall be substituted by "the chief state health inspector" and the words "hygiene - epidemiological inspectorate" and "hygiene - epidemiological inspectorates" shall be substituted respectively by "the regional inspectorate for protection and control of public health" and "the regional inspectorates for protection and control of public health".

§ 22. In the Medical Establishments Act (Prom. SG 62/99, suppl. 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, amend. SG 62/01, amend. SG 28/02, amend. SG 83/03, amend. SG 102/03, amend. SG 114/03) the following amendments and supplements shall be made:

1. In art. 86:

a) new para 2 shall be created:

"(2) The medical establishments, out of these, pointed out in para 1, shall be subject to voluntary accreditation for assessment of their basic capabilities for training of students and specialising persons and doctors for the objectives of the continuing medical education.";

b) the previous para 2 shall become para 3.

2. Art. 91 shall be changed to:

"Art. 91. In the medical establishments for off hospital care can be conducted practical training of specialising persons in specialities, determined with the ordinances of art. 181 of the Health Act, and training for the objectives of the continuing medical education."

3. In art. 115 the following amendments shall be made:

a) in para 1 the words "100 to 300 levs" shall be substituted by "1000 to 3000 levs";

b) new para 2 shall be created:

"(2)" Who implements activity for off hospital medical care in violation of art. 39 shall be punished with fine in extent from 2000 to 5000 levs and at second breach - with deprivation from the right to exercise his profession for a term from three months to one year";

c) the previous para 2 shall become para 3 and in it the words "200 to 500 levs" shall be substituted by "2000 to 5000 levs".

4. I art. 116:

a) in para 1 the words "100 to 500 levs" shall be substituted by "1000 to 5000 levs".

b) in para 2 the words "750 to 2000 levs" shall be substituted by "8000 to 20 000 levs".

5. Everywhere in the Act the words "district health centre" and "district health centres" shall be substituted respectively by "regional health centre" and "regional health care centres" and the words "the hygiene - epidemiological inspectorate" shall be substituted by "the regional inspectorate for preservation and control of public health".

§ 23. In art. 6. para 1, item c) of the Local Taxes and Fees Act (Prom. SG 117/97, amend. SG 71/98, amend. SG 83/98, amend. SG 105/98, amend. SG 153/98, amend. SG 103/99, amend. SG 34/00, amend. SG 102/00, amend. SG 109/01, amend. SG 28/02, amend. SG 45/02, amend. SG 56/02, amend. SG 119/02, amend. SG 84/03, amend. SG 112/03, amend. SG 6/04, suppl. SG 18/04, amend. SG 36/04) after the word "creches" shall be added "children's kitchens".

§ 24. In art. 82 of the Ministry of Interior Act (Prom. SG 122/97, amend. SG 29/98, amend. SG 70/98, amend. SG 73/98, amend. SG 153/98, amend. SG 30/99, amend. SG 110/99, amend. SG 1/00, amend. SG 29/00, amend. SG 28/01, amend. SG 45/02, amend. SG 119/02, amend. SG 17/03, amend. SG 26/03, amend. SG 95/03, amend. SG 103/03, amend. SG 112/03, amend. SG 114/03, amend. SG 15/04) para 3 shall be changed to:

"(3) The establishments for sobering shall be established by the Ministry of Interior in coordination with the municipalities".

§ 25. In the Act on Maritime Spaces, Inland Waterways and Ports of the Republic of Bulgaria (Prom. SG 12/00, amend. SG 111/01, amend. SG 24/04) the following amendments shall be made:

1. In art. 23, para 1 the words "the sanitary" shall be substituted by "the health".

2. In art. 38 and in art. 66 the words "the sanitary requirements" shall be substituted by "the health requirements".

§ 26. In art. 19, para 2, item 1 of the Income Taxes on Natural Persons Act (Prom. SG 118/97, amend. SG 35/98, amend. SG 71/98, amend. SG 153/98, suppl. SG 50/99, amend. SG 103/99, amend. SG 111/99, amend. SG 105/00, amend. SG 110/01, suppl. SG 40/02, amend. SG 45/02, suppl. SG 61/02, amend. SG 118/02, amend. SG 42/03, amend. SG 67/03, suppl. SG 95/03, amend. SG 112/03, amend. SG 36/04, amend. SG 37/04, amend. SG 53/04) the words "and the health" shall be deleted.

§ 27. In art. 95 of the Waste Management Act (SG 86/03) the words "the director of the hygiene - epidemiological inspectorate" shall be substituted by "the director of RIPCPH" and the word "sanitary" shall be substituted by "health".

§ 28. In the Environmental Protection Act (prom. SG 91/02, corr. SG 98/02, amend. SG 86/03) in chapter three after art. 59 section VIII shall be created with names "Protection of environment against asbestos pollution" with art. 59a:

#### Section VIII.

#### Protection of the Environment Against Asbestos Pollution

Art. 59a. (new, SG 70/04) (1) The Minister of Environment and Waters, in coordination with the Minister of Health shall determine by an ordinance:

1. the requirements and the measures for prevention and reduction of the pollution of the air and water with asbestos;
2. the methods and procedures for establishing asbestos in dust emissions;
3. the methods and procedures for determining the concentration of insoluted substances in waste waters containing asbestos;
4. the cases admitting exceptions from the requirements and measures under item 1.

(2) The Minister of Environment and Waters may permit the using of methods and procedures, other than those determined by the ordinance under para 1, if they provide the obtaining of equivalent data and results."

§ 29. In art. 200k of the Judiciary System Act (Prom. SG 59/94, amend. SG 78/94, amend. SG 87/94, amend. SG 93/95, suppl. SG 64/96, amend. SG 96/96, amend. SG 104/96, amend. SG 110/96, amend. SG 58/297, amend. SG 122/97, amend. SG 124/97, amend. SG 11/98, amend. SG 133/98, amend. SG 6/99, amend. SG 34/00, amend. SG 38/00, suppl. SG 84/00, amend. SG 25/01, amend. SG 74/02, amend. SG 110/02, amend. SG 118/02, amend. SG 61/03, amend. SG 112/03, amend. SG 29/04, amend. SG 36/04) para 3 shall be created:

"(3) With the ordinance of para 2 shall also be determined the conditions and the order for determining and payment of the expenses of the medical establishments at implementing judicial expertises".

§ 30. (amend. SG 76/05) In the Professional Organisations of Doctors and Dentists (SG 83/98) the following amendments and supplements shall be made:

1. In art. 4 the words "art. 88 and 93 of the Public Health Act" shall be substituted by "chapter seven, section II of the Health Act".
2. In art. 5, item 4 the words "together with the National Health Insurance Fund" shall be deleted.
3. In art. 9 item 9 shall be deleted.
4. In art. 32, para 3:
  - a) item 2 shall be changed to:  
"2. certificate with regard to the Health Act;"
  - b) item 6 shall be changed to:  
"6. for foreigners - permission for long term stay and work in the country and certificate for legal capacity under the Health Act."

5. In art. 33, para 1 the words "of art. 88 and 93 of the Public Health Act" shall be substituted by "chapter seven, section II of the Health Act".

6. In the transitional and concluding provisions § 6a shall be created:

"§ 6a. The Bulgarian physician's union and the Union of the dentists in Bulgaria" shall prepare and approve Rules for good medical practice and propose them for approval to the Minister of Health till July 1, 2005."

§ 31. In art. 4, para 4 of the Gambling Act (Prom. SG 51/99, amend. SG 103/99, amend. SG 53/00, amend. SG 1/01, amend. SG 102/01, amend. SG 110/01, amend. SG 75/02, amend. SG 31/03) after the words "the education" shall be added "the medical establishments".

§ 32. In the Foodstuffs Act (Prom. SG 90/99, amend. SG 102/03) everywhere the words "the state sanitary commission control" shall be substituted by "the state health control", the words "the Public Health Act" shall be substituted by "the Health Act" and the words "chief state sanitary inspector" shall be substituted by "chief state health inspector".

§ 33. In art 24 of the Foreigners in the Republic of Bulgaria Act (Prom. SG 153/98, amend. SG 70/99, amend. SG 42/01, amend. SG 112/01, amend. SG 45/02, amend. SG 54/02, amend. SG 37/03, amend. SG 103/03, amend. SG 37/04) the words "health establishment" shall be substituted by "medical establishment".

§ 34. In art. 30. para 2 of the Tobacco and Tobacco Products Act (Prom. SG 101/93, amend. SG 19/94, amend. SG 110/96, amend. SG 153/98, amend. SG 113/99, amend. SG 33/00, amend. SG 102/00, suppl. SG 110/01, suppl. SG 20/03, amend. SG 57/04) the following amendments and supplements shall be made:

1. Item 1 shall be changed to:

"1. on the territory of creches and kindergartens, schools, hostels of students, medical and health establishments;"

2. item 5 shall be changed to:

"5. which do not correspond to the health requirements;"

3. In item 11 the words "in the sites, licensed for duty free trade" shall be deleted.

4. Item 16 shall be created:

"16. at sport events and public events, organised for children and students".

§ 35. In the Code for Social Insurance (Prom. SG 110/99, amend. SG 55/00, amend. SG 64/00, amend. SG 1/01, suppl. SG 35/01, amend. SG 41/01, amend. SG 1/02, amend. SG 10/02, amend. SG 45/02, amend. SG 74/02, amend. SG 112/02, amend. SG 119/02, amend. SG 120/02, amend. SG 8/03, suppl. SG 42/03, amend. SG 67/03, suppl. SG 95/03, amend. SG 112/03, amend. SG 114/03, amend. SG 12/04, amend. SG 21/04, suppl. SG 38/04, amend. SG 52/04, amend. SG 53/04, amend. SG 69/04) art. 14, 15, 16 and 17 shall be repealed.

§ 36. In the Protection from Discrimination Act (SG 86/03) the following supplements shall be made:

1. In art. 4, para 1 after the words "ethnic affiliation" shall be added "human genome".

2. In § 1 of the additional provisions item 14 shall be created:

"14. "Human genome" is combination of all genes in single (diploid) combination of chromosomes of given person."

§ 37. In the Protection of Personal Data Act (SG 1/02) the following supplements shall be made:

1. In art. 2, para 1 at the end shall be added "as well as the data of the human genome";

2. In § 1 of the additional provision item 10 shall be created:

"10. "Human genome" is the combination of all genes in a single (diploid) set of chromosomes of given person."

§ 38. In one year term after the Act enters into force the Council of Ministers shall approve and the Minister of Health shall issue the normative acts for its implementation.

§ 39. Till the entering into force of the acts of § 38 the issued normative acts for the implementing of the revoked Public Health Act shall be implemented as far as they do not contradict with this Act.

§ 40. The fulfilment of the Act shall be assigned to the Minister of Health.

§ 41. The Act shall enter into force from January 1, 2005 except art. 53, para 3, which shall enter in to force from January 1, 2006.

The Act is passed by the 39th National Assembly on July 29, 2004 and was affixed with the official seal of the National Assembly.

### **Transitional and concluding provisions (SG 85/05; amend. SG 59/07, in force from 26.05.2007)**

§ 17. (1) The higher schools shall ensure the training and the acquisition of educational "qualification degree "bachelor" in specialties of the professional direction "health care" by the order of the Higher Education Act till the beginning of the educational year 2006/2007.

(2) The persons who have started their training in the specialties "nurse" and "midwife" of professional direction "Public health" of the educational "qualification

degree "specialist" and till September 1, 2006 have not finished their education shall continue their training in faculty or branch of higher school during the following school year in the respective specialty of professional direction "Health care" for acquiring educational "qualification degree "bachelor" without competition examinations.

(3) (revoked " SG 59/07, in force from 26.05.2007)

(4) The persons who have started their training in the specialties "rehabilitator", "medical laboratory technician", "X-ray lab technician", "sanitary inspector" and "masseur" of professional direction "Public health", in the specialty "dental mechanic" of professional direction "Stomatology" and in the specialty "assistant pharmacist" of professional direction "Pharmacy" of the educational "qualification degree "specialist" shall continue their training in the same specialties for acquiring the same educational degree in professional direction "Health care".

**Transitional and concluding provisions  
TO THE ACT AMENDING AND SUPPLEMENTING THE HEALTH ACT**

(PROM. " SG 18/06)

§ 6. The Act shall enter into force from the 1st of January 2007.

**Transitional and concluding provisions  
TO THE ADMINISTRATIVE PROCEDURE CODE**

(PROM. " SG 30/06, IN FORCE FROM 12.07.2006)

§ 61. The following changes shall be implemented in the Health Act (prom. " SG 70/04; amend. " SG 46/05, 76, 85, 88, 94 and 103/05, 18/06):

.....  
2. The words "Administrative Procedure Act" and "Supreme Administrative Court Act" 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. â€“ SG 34/06, IN FORCE FROM 01.10.2006)

§ 56. This Act shall enter into force from the 1st of October, with the exception of § 2 and § 3, which shall enter into force from the day of the promulgation of the law in State Gazette.

**Transitional and concluding provisions  
TO THE ACT AMENDING AND SUPPLEMENTING THE HEALTH ACT**

(PROM. - SG 59/06, IN FORCE FROM 01.01.2007)

§ 21. This Act shall enter into force from 1 January 2007 except § 4, 5 and 14 which shall enter into force from the day of promulgation of this Act in the State Gazette.

**Transitional and concluding provisions  
TO THE ACT AMENDING AND SUPPLEMENTING THE  
TRANSPLANTATION OF ORGANS, TISSUES AND CELLS ACT**

(PROM. - SG 71/06, IN FORCE FROM 01.01.2007)

§ 30. This Act shall enter into force from 1st of January 2007 except the provisions of § 4, Item 3, Letter "e" - regarding the creation of Items 15 and 16, and § 28 which shall enter into force from the date of entering into force of the Treaty of Accession of the Republic of Bulgaria to the European Union.

**Transitional and concluding provisions  
TO THE ACT AMENDING AND SUPPLEMENTING THE HEALTH ACT**

(PROM. - SG 81/06)

§ 5. (1) The existing to the date of entering into force of this Act craft enterprises providing services in the field of optics and optometry may continue their activities, provided that they register themselves under the order of Art. 26b in the respective RHCC.

(2) Within a term of 6 months from entering into force of this Act the owners of craft enterprises or heirs, or legal successors providing services in the field of optics

and optometry as well as the apprentices, the journeymen and the masters shall submit an application to the respective regional craft chamber for their deletion from the respective registers under Art. 21, 48, 54 and 63 of the Crafts Act.

(3) In the cases referred to in Para 2 the regional craft chambers shall delete the registration of the respective persons within a term of 14 days from submission of the application and shall issue a certificate of deletion of the journeymen and the masters on the basis of which the latter may exercise their rights referred to in Art. 26a.

§ 6. (1) The persons who have acquired professional qualification in the "Optometry" speciality may exercise their rights referred to in Art. 26a, Para 2 and 3 and may undertake measures for correction of the eyesight.

(2) The persons who have acquired professional qualification in the "assistant-pharmacist and optician" speciality shall exercise their rights under Art. 26a, Para 2 and 3 and the persons who have acquired professional qualification in the "optics, optico-mechanic and optico-electronic devices" speciality shall exercise the rights referred to in Art. 26a, Para 3.

**Transitional and concluding provisions  
TO THE ACT AMENDING AND SUPPLEMENTING THE HEALTH  
INSURANCE ACT**

(PROM. - SG 95/06, IN FORCE FROM 24.11.2006)

§ 15. The Act shall enter into force from the date of its promulgation in State Gazette, except for § 2, 3, 4, 5, 6, 7 and 10, which shall enter into force from the date of coming into effect of the Treaty of Accession of the Republic of Bulgaria to the European Union.

**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 into force from the day of its promulgation in State Gazette, except for § 22, which shall enter into force one year after the entry into force of this Act.

**Transitional and concluding provisions  
TO THE MEDICAL DEVICES ACT**

(PROM. - SG 46/07, IN FORCE FROM 12.06.2007)

§ 16. This Act shall enter into force from the day of its promulgation in the State Gazette except the provision of Art. 4, Para 2, which shall enter into force from 29 December 2009.

**Transitional and concluding provisions  
TO THE ACT AMENDING AND SUPPLEMENTING THE ACT ON  
DEFENCE AND ARMED FORCES OF THE REPUBLIC OF BULGARIA**

(PROM. - SG 46/07, IN FORCE FROM 01.01.2008)

§ 77. This Act shall enter into force from 1 January 2008 except:

1. Paragraph 1, § 2, Item 1, § 4, Item 1, Letter "a" and Item 2, § 5, 13, 15, 32, 33, 34, 35, 36, 37, § 38, Item 1, Letter "a" and Item 2, § 40, 43, 44, 46, 55, 59 and 75 which shall enter into force three days after its promulgation in the State Gazette.

2. Paragraph 2, Item 2, § 3, § 4, Item 1, Letter "b", § 6, 7, 60, 61 (regarding addition of the words "and 309b") and 63, which shall enter into force 6 months after its promulgation in the State Gazette.

**Transitional and concluding provisions  
TO THE CIVIL PROCEDURE CODE**

(PROM. - SG 59/07, IN FORCE FROM 01.03.2008)

§ 61. This Code shall enter into force from 1 March 2008, except for:

1. Part Seven "Special rules related to proceedings on civil cases subject to application of European Union legislation";

2. paragraph 2, par. 4;

3. paragraph 3 related to revoking of Chapter Thirty Two "a" "Special rules for recognition and admission of fulfillment of decisions of foreign courts and of other foreign bodies" with Art. 307a - 307e and Part Seven "Proceedings for returning a child or exercising the right of personal relations" with Art. 502 - 507;

4. paragraph 4, par. 2;

5. paragraph 24;

6. paragraph 60,

which shall enter into force three days after the promulgation of the Code in the State Gazette.

**Concluding provisions  
TO THE ACT AMENDING AND SUPPLEMENTING THE HEALTH ACT**

(PROM. - SG 95/07, IN FORCE FROM 01.01.2008)

§ 3. This Act shall enter into force from 1 January 2008.

**Transitional and concluding provisions  
TO THE RECOGNITION OF PROFESSIONAL QUALIFICATIONS ACT**

(PROM. â€“ SG 13/08, IN FORCE FROM 08.02.2008)

§ 15. (1) The subordinate and other normative acts on implementation of this Act shall be issued within one month from its entry into force.

(2) By entry into force of the acts referred to in Para 1 the acts issued on implementation of the provisions revoked by § 6, 7, 8, 9, 10, 11 and 12 shall apply as far as they do not contradict to it.

§ 16. 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 HEALTH ACT**

(PROM. â€“ SG 41/09, IN FORCE FROM 02.06.2009; AMEND. â€“ SG 40/12)

§ 65. (in force from 01.07.2009) The procedures before LEPC and NEPC for certification of children of up to 16-year of age and of persons, entitled to a pension for insured years of service and age under Art. 68 of the Code of Social Insurance, having started before 1 July 2009 and still pending, shall continue being considered following the existing procedure, but not later than 31 December 2009.

§ 65a. (new â€“ SG 40/12) In the cases where no children expert physician commissions have been established, the examination of the type and degree of damages for the applications for examination (re-examination) of children under 16 years of age filed after 1 July 2009 shall be carried out by LEPC with the participation of a specialist in child diseases.

§66. (in force from 01.07.2009) The persons for whom a degree of permanently reduced ability to work for life has been determined following the existing procedure, and the persons, having a degree of permanently reduced ability to work for life has been determined following the provisions of § 3 shall be deemed as having a determined type and degree of disability for life.

§ 67. Schools, kindergartens and specialized institutions for provision of social services under Art. 26, par. 1, item 3, where no health consulting rooms are set up as of the time of entering of this Act into force, shall open health consulting rooms by 1 July 2011.

§ 68. (1) Within two months after entering of this Act into force the Council of Ministers shall adopt Structural regulations of the Executive agency "Medical inspectorate".

(2) Within 6 months after entering of this Act into force the secondary legislative acts provided therein shall be issued.

â€¦

§ 96. The Act shall enter into force from the day of its promulgation in the 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.

**Concluding provisions**  
**TO A ACT AMENDING AND SUPPLEMENTING THE VOCATIONAL**  
**EDUCATION AND TRAINING ACT**

(PROM. - SG 74/09, IN FORCE FROM 15.09.2009)

â€¦

§ 29. Everywhere in the Act on Health (prom. - SG 70/04; amend. - SG 46, 76, 85, 88, 94 and 103/05, SG 18, 30, 34, 59, 71, 75, 80, 81, 95 and 102/06, SG 31, 41, 46, 53, 59, 82 and 95/07, SG 13, 102 and 110/08, SG 36 and 41/09) the words "the Minister of Education and Science" and "the Ministry of Education and Science" shall be replaced with respectively "the Minister of Education, Youth and Science" and "the Ministry of Education, Youth and Science".

**Transitional and concluding provisions**  
**TO THE ACT ON AMENDMENT OF THE TOURISM ACT**

(PROM. - SG 82/09, IN FORCE FROM 16.10.2009)

§ 59. 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 MINISTRY OF**  
**INTERIOR ACT**

(PROM. - SG 93/09, IN FORCE FROM 25.12.2009)



4. paragraph 36 (regarding Art. 55c), which shall enter into force from 01.01.2011;
5. paragraphs 31 and 43 (Item 1), which shall enter into force from 01.01.2012;
6. paragraph 27, Item 3, which shall enter into force from 01.01.2013;
7. paragraph 29, Item 1, Letter "b", which shall enter into force from 01.01.2011.

**Concluding provisions**  
**TO THE ACT ON AMENDMENT AND SUPPLEMENTATION OF THE**  
**HEALTH ACT**

(PROM. № SG 42/10, IN FORCE FROM 02.06.2010)

§ 6. Within three months from the entry into force of this Act the Council of Ministers shall adopt the ordinance as per Art. 56<sup>D</sup>, para. 3.

§ 7. This Act shall enter into force from June, 2 2010.

**Transitional and concluding provisions**  
**TO THE ACT AMENDING AND SUPPLEMENTING THE MEDICAL**  
**ESTABLISHMENTS ACT**

(PROM. № SG 59/10, IN FORCE FROM 31.07.2010)

§ 77. This Act shall enter into force from the date of its promulgation in the State Gazette, except for:

1. paragraphs 9 (regarding Art. 19, Para 4), 53, 60 and 66 (regarding Art. 98, Para 5 and 6), which shall enter into force from 1 January 2011;
2. paragraph 75, which shall enter into force from 30 September 2011.

**Transitional and concluding provisions**  
**TO THE ACT AMENDING AND SUPPLEMENTING THE HEALTH**  
**INSURANCE ACT**

(PROM. - SG 62/10, IN FORCE FROM 10.08.2010)

§ 18. This Act shall enter into force from the day of its promulgation in the State Gazette except for:

1. paragraph 6, which shall enter into force from 1 January 2011;
2. paragraph 8, which shall enter into force from 30 September 2011.



2. 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 CODE OF  
SOCIAL INSURANCE**

(PROM. - SG 100/10, IN FORCE FROM 01.01.2011; AMEND. â€“ SG 60/11, IN FORCE FROM 05.08.2011)

§ 65. (amend. â€“ SG 60/11, in force from 05.08.2011) The Act shall enter into force from January 1, 2011, except for:

1. paragraphs 32, 33 Ð, 36, which shall enter into force from January 1, 2013;
2. paragraphs 51, which shall enter into force from January 1, 2012.

**Transitional and concluding provisions  
TO THE BULGARIAN FOOD SAFETY AGENCY ACT**

(PROM. - SG 08/11, IN FORCE FROM 25.01.2011)

§ 65. This Act shall enter into force from the date of its promulgation in the State Gazette.

**Transitional and concluding provisions  
TO THE ACT AMENDING AND SUPPLEMENTING OF THE  
MEDICINAL PRODUCTS IN HUMAN MEDICINE ACT**

(PROM. â€“ SG 60/11, IN FORCE FROM 05.08.2011)

§ 84. This Act shall enter into force from the date of its promulgation in the State Gazette, except for § 65, which shall enter into force from September 30, 2011.

**Transitional and concluding provisions  
TO THE LAW ON AMENDMENT AND SUPPLEMENTATION OF THE  
LAW ON THE CIVIL SERVANT**

(PROM. - SG 38/12, IN FORCE FROM 01.07.2012)

§ 84. (In force from 18.05.2012) Within one month from the promulgation of this Law in the State Gazette:

1. the Council of Ministers shall make the Classification of Offices in the Administration compliant with this Law;

2. the competent authorities shall make the structural acts of the respective administration compliant with this Law.

§ 85. (1) The legal relationships with the persons of the administrations under the Law on the Radio and Television, the Law on the Independent Financial Audit, the Law on the Electronic Communications, the Law on the Financial Supervision Commission, the Law on the Access and Disclosure of Documents and Announcing Affiliation of Bulgarian Nationals to the State Security and Intelligence Services of the Bulgarian People's Army, the Law for Forfeiture of Property Acquired through Criminal Activity, the Law on Prevention and Discontinuance of Conflict of Interests, the Code of Social Insurance, the Law on the Health Insurance, the Law on the Support of Farmers and the Law on the Roads shall be settled under terms and conditions of § 36 of the Transitional and Concluding Provisions of the Law on the Amendment and Supplementation of the Law on the Civil Servants (SG 24/06).

(2) The act of appointment of the civil servant shall:

1. determine the lowest rank for the position specified in the Classification of Offices in the Administration, unless the officer holds a higher rank;

2. determine an individual basic monthly salary.

(3) The additional funds for insurance installments for the persons referred to in Para 2 shall be made available within the limits for expenses for salaries, remunerations and insurance installments in the budgets of the budget credit administrators.

(4) The Council of Ministers shall amend as required by this Law the non-budget account of State Fund "Agriculture".

(5) The governing bodies of the National Insurance Institute and the National Health Insurance Fund shall amend as required by this Law the respective budget credits.

(6) Any non-used days of leave under employment relations shall be preserved and shall not be subject to pecuniary compensation.

§ 86. (1) Within one month from entry into force of this Law the individual basic monthly salary of the officer shall be so calculated that the said salary, reduced by the due taxes and the mandatory insurance installments due by the insured person, if available, shall not be lower than gross monthly salary received before, reduced by the mandatory insurance installments due by the insured person, if available, and the due taxes.

(2) The gross salary referred to in Para 1 shall include:

1. the basic monthly salary or the basic monthly remuneration;

2. the additional remunerations paid on permanent basis together with the due basic monthly salary or the basic monthly remuneration and dependent only on the working time.

§ 87. This Law shall enter into force from 1 July 2012 except for § 84, which shall enter into force from the day of the promulgation of the Law in the State Gazette.

**Transitional and concluding provisions**  
**TO THE LAW ON AMENDMENT AND SUPPLEMENTATION OF THE**  
**LAW ON THE HEALTH**

(PROM. " SG 40/12)

§ 18. Within 7 days from entry into force of this Law the medical establishments having a LEMC, carrying out examination (re-examination) of the children under 16 years of age, shall ensure the participation of child disease specialist in the composition of LEMC.

" " " " " " " " " " " "

§ 22. The provisions of § 1, 2, 3, 12, 13, 14, 15 and 21 shall enter into force from 1 June 2012.

**Transitional and concluding provisions**  
**TO THE LAW ON AMENDMENT AND SUPPLEMENTATION OF THE**  
**LAW OF HEALTH INSURANCE**

§ 44. This Law shall enter into force from the day of its promulgation in the State Gazette.

**Transitional and concluding provisions**  
**TO THE ACT ON THE NATIONAL HEALTH INSURANCE FUND**  
**BUDGET FOR THE YEAR 2013**

(PROM. - SG 101/12, IN FORCE FROM 01.01.2013)

§ 1. Health insurance income over performance under Art. 1, para 1, line 1 shall be allocated among health insurance payments following a procedure set out by the Supervisory board of NHIF.

§ 2. By the end of each month, the Ministry of Health shall provide a transfer to the budget of NHIF under Art. 1, para 1, line 5 amounting to commitment to health institutions for the obstetric care provided pursuant to Art. 82, para 1, item 2 of the Health Act and for financing the costs for vaccines under national cervical cancer prevention programmes regarding specific population under Art. 82, para 2, item 3 of the Health Act. The funds shall be accounted pursuant to Art. 1, para 2, line 1.1.3.5.3 and line 1.1.3.7.1 of the NHIF budget.

§ 3. Target subsidies under Art. 23, para 1, item 11 of the Health Insurance Act, other than the ones under Art. 1, para 1 in relation to fulfilment of obligations, ensuing from the implementation of the rules on coordination of social security systems and referring to benefits in kind other than medical care under Art. 45 of the Health Insurance Act, shall be granted to the NHIF budget from the republican budget via the budget of the Ministry of Health. The amounts under Art. 1, para 2, lines 1, 1.1.3, 1.1.3.8 and 1.1.3.8.1 shall be increased by the costs incurred for the said compensations.

§ 4. The funds under hospital care agreements, concluded between budget credit administrators and NHIF shall be accounted as transfers under Art. 1, para 2, line 2.

§ 5. The estimates of the amounts due by the NHIF budget to the National Revenue Agency budget according to the requirements under Art. 24, item 6 of the Health Insurance Act, shall be carried out by the end of each calendar month and shall amount to 0,2 percent on instalments accumulated during the preceding month. The amounts shall be accounted as transfers between budget accounts under Art. 1, para 2, line 2.

§ 6. NHIF Supervisory board shall be entitled to carry out internal offset changes of credits between items of expenditures and transfers, in total, pursuant to Art. 1, para 2, which are within the framework of the approved budget, except for the staff costs under Art. 1, para 2, 1.1.1.

§ 7. On the grounds of Art. 26, para 2 of the Health Insurance Act NHIF Supervisory board shall be entitled to spend funds from the reserve, including unexpected and urgent expenditures under Art. 1, para 2, line 1.3.

§ 8. NHIF Supervisory board may decide proceeds from sale of tangible fixed assets to be used to acquire such assets over the approved cost of the art. 1, para 2, line 1.2.

§ 9. (1) NHIF Supervisory board shall, upon proposal by the manager of NHIF, approve by individual paragraphs the required changes in the costs incurred by NHIF and financed by funds from transfers of the Ministry of Health, that have not been covered by this Act, without unbalancing the NHIF budget.

(2) Transfers by Ministry of Health under para 1 shall refer to persons with no health insurance and shall include the following:

1. activities related to outpatient follow-up of patients with mental disorders;
2. activities related to outpatient follow-up of patients with skin and venereal diseases;
3. intensive treatment;
4. prophylactic examination and tests for all uninsured women regardless of the delivery method according to Art. 82, para 1, item 2 of the Health Act.

(3) The amount of the transfers under para 2 shall be fixed and provided by the Ministry of Health for uninsured persons under terms and following a procedure set out by the Minister of Health and the manager of NHIF.

§ 10. Vaccines for obligatory immunizations and reimmunizations provided by the Ministry of Health in 2012 shall be financed by the Ministry of Health in 2013 by the previous order till the NHIF covers them, however not later than April 1, 2013.

§ 11. (1) Healthcare establishments, financed by the Ministry of Health according to the Subsidisation Methodology for Healthcare Establishments in the year 2012, shall be subsidized by the Ministry of Health in 2013 according to the previous order, provided that by 31st of December 2012 the said establishments have provided their accounts in compliance with the concluded agreements for the operations that are transferred to NHIF funding in 2013.

(2) The activities under para 1 shall be financed by the Ministry of Health once the final amount of the grant is fixed for the fourth quarter of 2012.

§ 12. (1) The funds for medicinal products under Art. 4, item 1 of the War Veterans Act and those under Art. 15, para 1 and 2 of the War Invalids and Victims Act in the year 2013 shall be at the expense of the state budget and shall be paid up by the Social Support Agency via NHIF.

(2) The Social Support Agency shall transfer to NHIF the funds required to pay off the resources requested by pharmacies contracted with NHIF in order to provide medicinal products to war veterans, war invalids and victims.

.....

§ 16. The Act shall enter into force as of January 1, 2013.

### **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 from 1 January 2014 except for § 115, which shall enter into force from 1 January 2013, and § 18, § 114, § 120, § 121 and § 122, which shall enter into force from 1 February 2013.

### **Transitional and concluding provisions TO THE TOURISM ACT**

(PROM. - SG 30/2013, IN FORCE FROM 26.03.2013)

§ 20. This Act shall enter into force on the day of its promulgation in the State Gazette, except for provisions of Chapter Nine, Ten and Twelve which shall enter into force 6 months after the promulgation of the Act.

**Concluding provisions**  
**TO THE ACT AMENDING AND SUPPLEMENTING THE YOUTH ACT**

(PROM. " SG 68/13, IN FORCE FROM 02.08.2013)

§ 32. In the Health Act (prom. SG 70/04; amend. SG 46, 76, 85, 88, 94 and 103/05; SG 18. 30, 34, 59, 71, 75, 80, 81, 95 and 102/06; SG 31, 41, 46, 53, 59, 82 and 85/07; SG 13, 102 and 110/08; SG 36, 41, 74, 82, 93, 99 and 101/09; SG 41, 42, 50, 59, 62, 98 and 100/10; SG 8, 9, 45 and 60/11; SG 38, 40, 54, 60, 82, 101 and 102/12 and SG 15 and 30/13) the following amendments shall be made:

1.

2. In the remaining wording of the law the words "Minister of Education, Youth and Science" and "the Minister of Education, Youth and Science" shall be replaced respectively with "Minister of Education and Science" and "the Minister of Education and Science".

§ 55. The Act shall enter into force from the date of its promulgation in the State Gazette.

**Transitional and concluding provisions**  
**TO THE SPATIAL DEVELOPMENT ACT**

(PROM. " SG 66/13, IN FORCE FROM 26.07.2013)

§ 117. The Act shall enter into force from the date of its promulgation in the State Gazette.

**Concluding provisions**  
**TO THE VETERINARY PRACTICE ACT**

(PROM. " SG 99/13)

§ 14. Within 6 months from the entry into force of this Act the Minister of Health and the Minister of Agriculture and Food shall adopt the ordinance referred to in Art. 62, para 2 of the Health Act.

**Transitional and concluding provisions  
TO THE ACT AMENDING AND SUPPLEMENTING THE  
ADMINISTRATIVE PROCEDURE CODE**

(prom. â€“ SG 104/13, in force from 04.01.2014)

§ 3. Any pending cases, the jurisdiction of which is being amended by this Act, shall be heard by the courts where they have been initiated.

§ 5. The Act shall enter into force from the date of its promulgation in the State Gazette.

**Transitional and concluding provisions  
TO THE ACT OF NATIONAL HEALTH INSURANCE FUND BUDGET  
IN 2014**

(prom. â€“ SG 106/13, in force from 01.01.2014)

§ 19. The Act shall enter into force on 1 January 2014, except for § 15, which shall enter into force on the day of its promulgation in State Gazette.

**Transitional and concluding provisions  
TO THE ACT OF THE NATIONAL SOCIAL INSURANCE BUDGET IN  
2014**

(prom. â€“ SG 106/13, in force from 01.01.2014)

§ 9. The Act shall enter into force on 1 January 2014, except for § 6, which shall enter into force on the 1st December 2014.

**Transitional and concluding provisions  
TO THE ACT AMENDING AND SUPPLEMENTING THE HEALTH ACT**

(prom. â€“ SG 1/14, in force from 03.01.2014)

§ 13. The health certificates for export of products and goods of importance for human health issued according to the existing procedure prior to entering of this Act into force, shall remain valid until the expiration of the term indicated therein.

§ 14 The applications for issuance of health certificates for export of products and goods of importance for human health filed prior to entering of this Act into force,

shall be considered according to the existing procedure, whereby the information referred to in Art. 37, par. 2, item 4 shall be submitted for the applications for issuance of health certificates for export of cosmetic products.

§ 17. Within one month after entering of this Act into force the Minister of Health shall issue the ordinances referred to in:

1. Art. 37, par. 8, Art. 52 and Art. 114a, par. 2;
2. Art. 80f, par. 4 of the Health Insurance Act.

§ 19. Act shall enter into force from the day of its promulgation in the State Gazette.

### **Transitional and concluding provisions TO THE SPATIAL DEVELOPMENT ACT**

(PROM. " SG 98/14, IN FORCE FROM 28.11.2014)

§ 117. The Act shall enter into force from the date of its promulgation in the State Gazette.

### **Concluding provisions TO THE ACT AMENDING THE TOURISM ACT**

(PROM. - SG 9/15, IN FORCE FROM 03.02.2015)

§ 6. The Act shall enter into force from the date of its promulgation in the State Gazette.

### **Transitional and concluding provisions TO THE ACT AMENDING AND SUPPLEMENTING THE ASSYLUM AND REFUGEES ACT**

(PROM. - SG 80/15, IN FORCE FROM 16.10.2015)

§ 83. The Act shall enter into force from the date of its promulgation in the State Gazette, except for § 40, which shall enter into force on 1 January 2016.

### **Transitional and concluding provisions TO THE INSURANCE CODE**

(PROM. SG 102/15, IN FORCE FROM 01.01.2016)

§ 50. (1) This Code shall enter into force on 1 January 2016, with exception of Art. 574, para. 8, which shall come into force on July 1, 2016.

(2) Until 1 July 2016 the exchange of data under Art. 574, para. 3-7 shall be carried out weekly and at the each first working day of the week:

1. The Ministry of Interior and the Executive Agency "Automobile Administration" shall provide the actual data by the Art. 574, para. 3 and 4 to the Information Center;

2. The Information Center shall provide to the Ministry of Interior and the Executive Agency "Automobile Administration" actual data by the Art. 574, para. 5-7.

**Transitional and concluding provisions**  
**TO THE ACT ON THE BUDGET OF NATIONAL HEALTH INSURANCE**  
**FUND FOR 2017**

(PROM. â€“ SG 98/16, IN FORCE FROM 01.01.2017)

§ 14. This Act shall enter into force on 1 of January 2017.

**Transitional and concluding provisions**  
**TO THE ACT ON THE BUDGET OF STATE PUBLIC INSURANCE FOR**  
**2017**

(PROM. â€“ SG 98/16, IN FORCE FROM 01.01.2017)

§ 12. The Act shall enter into force on 1 of January 2017, except for:

1. Para 5, which shall enter into force on 9 of August 2016;

2. Para 3, items 13 â€“ 15 and § 8, which shall enter into force on 1 of June 2017;

3. Para 3, item 2, which shall enter into force on 1 of January 2018.

**Concluding provisions**  
**TO THE ACT AMENDING THE ACT ON BULGARIAN FOOD SAFETY**  
**AGENCY**

(PROM. - SG 58/17, IN FORCE FROM 18.07.2017)

§ 76. 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 SAFE USE OF**  
**NUCLEAR POWER ACT**

(PROM. - SG 102/17, IN FORCE FROM 01.01.2018)

§ 39. The Act shall enter into force on 1 January 2018 except for § 37 which shall enter into force on the day of promulgation of the Act in the State Gazette.

**Transitional and concluding provisions  
TO THE ACT AMENDING AND SUPPLEMENTING THE HEALTH ACT**

(PROM. " SG 18/18, IN FORCE FROM 27.02.2018)

§ 2. (1) Within two months after the entry into force of this act, the specialized units of the NEMC must be brought in alignment with the requirements of this Act.

(2) Procedures for carrying out medical expertise by specialized units of the NEMC, which were started before the entry into force of this Act, shall be completed according to the procedure established by this Act.

.....

§ 4. Within two months of the entry into force of this Act, the secondary legislation shall be brought into compliance with the requirements of this Act.

§ 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  
ENVIRONMENTAL PROTECTION ACT**

(PROM. - SG 98/18, IN FORCE FROM 27.11.2018)

§ 49. The Act shall enter into force on the day of its promulgation in the State Gazette with the exception of:

1. paragraph 3, items 1 and 3 concerning Art. 94 para. 1, item 9 and para. 4, § 4, item 2, § 5, 6, § 7, item 2, § 8, 10-12, § 15, item 2, § 16, 17, 21 - 26, 30 and 31, which shall enter into force nine months after its promulgation;

2. paragraph 40, item 24, which shall enter into force on 11 August 2006.

**Transitional and concluding provisions  
TO THE ACT ON 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.

**Transitional and concluding provisions  
TO THE ACT ON THE BUDGET OF STATE SOCIAL INSURANCE FOR  
2019**

(PROM. - SG 102/18, IN FORCE FROM 01.01.2019)

§ 5. The Act shall enter into force on 1 January 2019.

**Transitional and concluding provisions  
TO THE SOCIAL SERVICES ACT**



**Concluding provisions**  
**TO THE ACT AMENDING AND SUPPLEMENTING THE HEALTH ACT**

(PROM. â€“ SG 58/19)

§ 7. The Minister of Health shall issue the ordinance under Art. 29, Para. 3 within 4 months of the entry into force of this Act.

**Transitional and concluding provisions**  
**TO THE ACT ON THE NATIONAL HEALTH INSURANCE FUND**  
**BUDGET FOR 2020**

(PROM. - SG 99/19, IN FORCE FROM 01.01.2020)

§ 16. The Act shall enter into force on January 1, 2020, with the exception of § 14 and 15, which shall enter into force on the day of its promulgation in the State Gazette.

**Concluding provisions**  
**TO THE ACT AMENDING AND SUPPLEMENTING THE HEALTH ACT**

(PROM. - SG 23/20, IN FORCE FROM 14.03.2020)

§ 4. The Act shall enter into force on the day of its promulgation in the State Gazette.

**Transitional and concluding provisions**  
**TO THE STATE OF EMERGENCY MEASURES AND ACTIONS ACT,**  
**DECLARED BY A DECISION OF THE NATIONAL ASSEMBLY OF 13**  
**MARCH 2020 AND FOR OVERCOMING THE CONSEQUENCES**

(PROM. - SG 28/20, IN FORCE FROM 13.03.2020, AMEND. AND SUPPL. â€“ SG, 44/20, IN FORCE FROM 14.05.2020)

§ 52. (Amend. â€“ SG, 44/20, in force from 14.05.2020) The Act shall enter into force on March 13, 2020, with the exception of Art. 5, § 3, § 12, § 25 - 31, § 41, § 49 and § 51, which shall enter into force on the day of promulgation of the Act in the State Gazette.

**Concluding provisions**  
**TO THE ACT AMENDING AND SUPPLEMENTING THE ACT ON THE**  
**MEASURES AND ACTIONS DURING THE STATE OF EMERGENCY**  
**DECLARED WITH THE DECISION OF THE NATIONAL ASSEMBLY**  
**OF MARCH 13th, 2020**

(PROM. - SG 34/20, IN FORCE FROM 09.04.2020)

§ 18. The Act shall enter into force on the day of its promulgation in the State Gazette, with the exception of § 3, item 2 concerning Art. 4, para. 2, which shall enter into force within 7 days of its promulgation.

**Transitional and concluding provisions**  
**TO THE ACT AMENDING AND SUPPLEMENTING THE HEALTH ACT**

(PROM. - SG, 44/20, IN FORCE FROM 14.05.2020)

§ 44. The Act shall enter into force on 14 May 2020, with the exception of § 33, 34 and 35, which shall enter into force on the day of promulgation of the Act in the State Gazette.

**Transitional and concluding provisions**  
**TO THE ACT ON THE BUDGET OF THE NATIONAL HEALTH INSURANCE FUND FOR 2021**

(PROM. - SG 103/20, IN FORCE FROM 01.01.2021)

§ 24. The Act shall enter into force on January 1, 2021, with the exception of § 17, 22 and 23, which shall enter into force on the day of its promulgation in the State Gazette.

**Concluding provisions**  
**TO THE ACT AMENDING AND SUPPLEMENTING THE HEALTH ACT**

(PROM. - SG 105/20, IN FORCE FROM 11.12.2020)

§ 9. The 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 PEOPLE WITH DISABILITIES ACT**

(PROM. - SG 105/20, IN FORCE FROM 01.01.2021, AMEND. - SG 18/22, IN FORCE FROM 01.01.2022)

§ 26. (Amend. - SG 18/22, in force from 01.01.2022) The Act shall enter into force on 1 January 2021, with the exception of § 1, 2, 7, 9, 10, 13 - 17 and 25, which shall enter into force on July 1st, 2022.

**Transitional and concluding provisions**  
**TO THE ACT AMENDING AND SUPPLEMENTING THE CODE OF CIVIL PROCEDURE**

(PROM. - SG 110/20, IN FORCE FROM 30.06.2021)

§ 28. The Act enters into force on June 30, 2021, except for:

1. paragraphs 9 and 25, which shall enter into force on 30 June 2022;

2. paragraphs 26 and 27, which shall enter into force on 31 December 2020.

**Transitional and concluding provisions**  
**TO THE ACT AMENDING AND SUPPLEMENTING THE HEALTH**  
**INSURANCE ACT**

(PROM. - SG 21/21, IN FORCE FROM 12.03.2021)

§ 4. The Act shall enter into force on the day of its promulgation in the State Gazette.

**Transitional and concluding provisions**  
**TO THE ACT ON APPLICATION OF PROVISIONS OF THE STATE**  
**BUDGET ACT OF THE REPUBLIC OF BULGARIA FOR 2021, THE ACT**  
**ON THE BUDGET OF THE STATE SOCIAL INSURANCE FOR 2021**  
**AND THE ACT ON THE BUDGET OF THE NATIONAL HEALTH**  
**INSURANCE FUND FOR 2021**

(PROM. - SG 8/22, IN FORCE FROM 01.01.2022)

§ 14. This Act shall enter into force on January 1st, 2022.

**Transitional and concluding provisions**  
**TO THE ACT AMENDING THE CORPORATE INCOME TAXATION**  
**ACT**

(PROM. - SG 17/22, IN FORCE FROM 01.01.2022)

§ 9. The Act shall enter into force on 1 January 2022, with the exception of § 3, items 1, 2, 5 - 11 and § 5, 6 and 7, which shall enter into force on 1 April 2022.

**Transitional and concluding provisions**  
**TO THE ACT ON THE BUDGET OF THE NATIONAL HEALTH**  
**INSURANCE FUND FOR 2022**

(PROM. - SG 18/22, IN FORCE FROM 01.01.2022)

§ 20. The Act shall enter into force on January 1, 2022, with the exception of § 18 and 19, which shall enter into force on the day of promulgation of the Act in the State Gazette.

**Transitional and concluding provisions**  
**TO THE ACT ON THE STATE BUDGET OF THE REPUBLIC OF**  
**BULGARIA FOR 2022**

(PROM. - SG 18/22, IN FORCE FROM 01.01.2022)

§ 22. The Act enters into force on January 1, 2022, with the exception of:  
1. paragraphs 6 and 20, which shall enter into force on 1 April 2022;

2. paragraph 10, which shall enter into force on the academic year 2022 - 2023;
3. paragraphs 11, 12, 14, 15, 17, 18 and 19, which shall enter into force on the day of promulgation of the Act in the State Gazette.

**Concluding provisions**  
**TO THE ACT AMENDING AND SUPPLEMENTING THE HEALTH**  
**INSURANCE ACT**

(PROM. - SG 32/22, IN FORCE FROM 26.04.2022)

§ 12. The Act shall enter into force on the day of its promulgation in the State Gazette.

**Concluding provisions**  
**TO THE ACT AMENDING AND SUPPLEMENTING THE HEALTH ACT**

(PROM. - SG 32/22, IN FORCE FROM 26.04.2022)

§ 10. The Council of Ministers shall bring the National Plan for Pandemic Preparedness, adopted by Decision № 884 of the Council of Ministers of 2020, in accordance with the requirements of this act within one month from the entry into force of this act.

§ 11. This Act shall enter into force on the day of its promulgation in the State Gazette, with the exception of § 6 which shall enter into force on April 1, 2022.

**Concluding provisions**  
**TO THE ACT AMENDING AND SUPPLEMENTING THE**  
**EMPLOYMENT PROMOTION ACT**

(PROM. - SG 41/22, IN FORCE FROM 03.06.2022)

§ 24. The Act shall enter into force on the day of its promulgation in the State Gazette.

**Concluding provisions**  
**TO THE ACT AMENDING THE HEALTH ACT**

(PROM. - SG 58/22, IN FORCE FROM 01.01.2023)

§ 4. The Act shall enter into force on January 1, 2023.

**Concluding provisions**  
**TO THE ACT AMENDING AND SUPPLEMENTING THE HEALTH ACT**

(PROM. - SG 62/22, IN FORCE FROM 05.08.2022)

§ 6. The Act enters into force on the day of its promulgation in the State Gazette.

### **Relevant Acts from the European Legislation**

Commission Directive 1999/46/EC of 21 May 1999 amending Council Directive 93/16/EEC to facilitate the free movement of doctors and the mutual recognition of their diplomas, certificates and other evidence of formal qualifications

Commission Directive 98/63/EC of 3 September 1998 amending Council Directive 93/16/EEC to facilitate the free movement of doctors and the mutual recognition of their diplomas, certificates and other evidence of formal qualifications

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work

Commission Directive 98/21/EC of 8 April 1998 amending Council Directive 93/16/EEC to facilitate the free movement of doctors and the mutual recognition of their diplomas, certificates and other evidence of formal qualifications

Directive 97/50/EC of the European Parliament and of the Council of 6 October 1997 amending Directive 93/16/EEC to facilitate the free movement of doctors and the mutual recognition of their diplomas, certificates and other evidence of formal qualifications

Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom

Council Directive 93/16/EEC of 5 April 1993 to facilitate the free movement of doctors and the mutual recognition of their diplomas, certificates and other evidence of formal qualifications

Council Directive 91/382/EEC of 25 June 1991 amending Directive 83/477/EEC on the protection of workers from the risks related to exposure to asbestos at work

Council Directive 90/658/EEC of 4 December 1990 amending certain Directives on the recognition of professional qualifications consequent upon the unification of Germany

Council Directive 90/641/Euratom of 4 December 1990 on the operational protection of outside workers exposed to the risk of ionizing radiation during their activities in controlled areas

Council Directive 89/595/EEC of 10 October 1989 amending Directive 77/452/EEC concerning the mutual recognition of diplomas, certificates and other evidence of the formal qualifications of nurses responsible for general care, including measures to facilitate the effective exercise of the right of establishment and freedom to provide services, and amending Directive 77/453/EEC concerning the coordination of provisions laid down by law, regulation or administrative action in respect of the activities of nurses responsible for general care

Council Directive 89/594/EEC of 30 October 1989 amending Directives 75/362/EEC, 77/452/EEC, 78/686/EEC, 78/1026/EEC and 80/154/EEC relating to the mutual recognition of diplomas, certificates and other evidence of formal qualifications as doctors, nurses responsible for general care, dental practitioners, veterinary surgeons and midwives, together with Directives 75/363/EEC, 78/1027/EEC and 80/155/EEC

concerning the coordination of provisions laid down by Law, Regulation or Administrative Action relating to the activities of doctors, veterinary surgeons and midwives

Council Directive of 14 June 1989 on the official control of foodstuffs

Council Directive of 19 March 1987 on the prevention and reduction of environmental pollution by asbestos

Council Directive 85/433/EEC of 16 September 1985 concerning the mutual recognition of diplomas, certificates and other evidence of formal qualifications in pharmacy, including measures to facilitate the effective exercise of the right of establishment relating to certain activities in the field of pharmacy

Council Directive 85/432/EEC of 16 September 1985 concerning the coordination of provisions laid down by Law, Regulation or Administrative Action in respect of certain activities in the field of pharmacy

Council Directive 83/477/EEC of 19 September 1983 on the protection of workers from the risks related to exposure to asbestos at work

Council Directive 81/1057/EEC of 14 December 1981 supplementing Directives 75/362/EEC, 77/452/EEC, 78/686/EEC and 78/1026/EEC concerning the mutual recognition of diplomas, certificates and other evidence of the formal qualifications of doctors, nurses responsible for general care, dental practitioners and veterinary surgeons respectively, with regard to acquired rights

First Commission Directive of 22 December 1980 on the approximation of the laws of the Member States relating to methods of analysis necessary for checking the composition of cosmetic products

Council Directive of 22 December 1980 amending, by virtue of the accession of Greece, Directives 76/893/EEC, 79/693/EEC and 80/777/EEC with regard to the majority quorum of votes within the Standing Committee of Foodstuffs procedure

Council Directive 80/154/EEC of 21 January 1980 concerning the mutual recognition of diplomas, certificates and other evidence of formal qualifications in midwifery and including measures to facilitate the effective exercise of the right of establishment and freedom to provide services

Council Directive 78/686/EEC of 25 July 1978 concerning the mutual recognition of diplomas, certificates and other evidence of the formal qualifications of practitioners of dentistry, including measures to facilitate the effective exercise of the right of establishment and freedom to provide services

Council Directive 77/453/EEC of 27 June 1977 concerning the coordination of provisions laid down by Law, Regulation or Administrative Action in respect of the activities of nurses responsible for general care

Council Directive 77/452/EEC of 27 June 1977 concerning the mutual recognition of diplomas, certificates and other evidence of the formal qualifications of nurses responsible for general care, including measures to facilitate the effective exercise of this right of establishment and freedom to provide services